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The Management of Antipsychotic-Induced Weight Gain

Improving the Equitable and Systematic Management of Antipsychotic-Induced Weight Gain Among Adults With Psychosis

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A thesis submitted to the National University of Ireland, Cork for the degree of Doctor of Philosophy in the School of Pharmacy

April 2025

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Declaration

"This is to certify that the work I am submitting is my own and has not been submitted for another degree, either at University College Cork or elsewhere. All external references and sources are clearly acknowledged and identified within the contents. I have read and understood the regulations of University College Cork concerning plagiarism and intellectual property."

Digital signature of the candidate: 

Ita Fitzgerald

Date: 25/03/2025

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List of Abbreviations

AIWG	Antipsychotic-induced weight gain
BMI	Body Mass Index
COREQ	Consolidated criteria for reporting qualitative health research checklist
CMOC	Context-mechanism-outcome configuration
CPG	Clinical Practice Guideline
CPGs	Clinical Practice Guidelines
CSWG	Clinically Significant Weight Gain
CVD	Cardiovascular Disease
DSM	Diagnostic and Statistical Manual of Mental Disorders
DST	Decision Support Tool
FEP	First Episode Psychosis
FGA	First-generation antipsychotic
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment Development and Evaluation
HCP	Healthcare Professional
ICD	International Classification of Diseases
IPT	Initial Programme Theories
MDD	Major Depressive Disorder
MHC	Mental Health Commission
NICE	National Institute for Health and Care Excellence
NRS	Non-randomised studies

OR	Odds ratio
PANSS	Positive and Negative Syndrome Scale
PICOTs	Population, Intervention, Comparator, Outcome, timing, setting
PPI	Patient and Public Involvement in Research
PT	Programme Theories
RCT	Randomised Controlled Trial
ROC	Recovery-oriented care
SDM	Shared Decision Making
SE	Standard Error
SGA	Second-generation antipsychotic
SMI	Severe Mental Illness
SPMHS	St Patrick's Mental Health Services
SU	Service User
SUAN	Service User Advisory Network
WHO	World Health Organisation

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Publications and Presentations

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3. ***Fitzgerald I****, Sahm LJ, Ní Dhubhlaing C, O'Dwyer S, O'Connell J, Torrens J, Crowley EK. Metformin in the management of antipsychotic-induced weight gain - why the 'weight'? Front Psychiatry. 2024; 15:1491417.*
4. ***Fitzgerald I,*** *Crowley EK, Ní Dhubhlaing C, O'Dwyer S, Sahm LJ. Informing the development of antipsychotic-induced weight gain management guidance: patient experiences and preferences - qualitative descriptive study. BJPsych Open. 2024;10(5):e136.*

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1. ***Fitzgerald I****, Sahm LJ, Byrne A, O'Connell J, Ensor J, Ní Dhubhlaing C, O'Dwyer S, Crowley EK. Predicting antipsychotic-induced weight gain in first episode psychosis – A field-wide systematic review and meta-analysis of non-genetic prognostic factors. European Psychiatry. 2023;66(1): e42.*

2. ***Fitzgerald I****, Sahm LJ, Howe J, Maidment I, Wallace E, Crowley EK. Shared decision-making interventions in the choice of antipsychotic prescription in people living with psychosis (SHAPE): Protocol for a realist review. PLoS One. 2024 Jul 25;19(7): e0304626.*

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1. ***Fitzgerald I,*** *Crowley EK, Byrne A, O'Connell J, Ensor J, Dhubhlaing CN, et al. Predicting antipsychotic-induced weight gain in first episode psychosis-a protocol for a field-wide systematic review of prognostic factor studies. Int J Clin Trials. 2022;9(4):300–13.*
2. ***Fitzgerald I****, O'Dwyer S, Brooks M, Sahm L, Crowley E, Ní Dhubhlaing C. Worth the Weight? Olanzapine Prescribing in Schizophrenia. A Review of Weight Gain and Other Cardiometabolic Side Effects of Olanzapine. Front Psychiatry. 2021 Sep 7;12:730769*

Peer-reviewed published abstracts

1. ***Fitzgerald I****, Crowley EK, Ní Dhubhlaing C, O'Dwyer S, Sahm LJ. Development of antipsychotic-induced weight gain management guidance: patient experiences and preferences - a qualitative descriptive study,* International Journal of Pharmacy Practice*, Volume 32, Issue Supplement_1, 2024, Pages i14–i15.*

Posters and oral presentations

Oral presentations

1. ***Fitzgerald I,*** *Crowley EK, Ní Dhubhlaing C, O'Dwyer S, Sahm LJ. "Development of antipsychotic-induced weight gain management guidance: patient experiences and preferences - a qualitative descriptive study", HSRPP (Health Services Research and Pharmacy) conference Cork, 2024. This presentation won Best Oral Presentation at the conference.*
2. ***Fitzgerald I.*** *"Metformin In the Management Of Antipsychotic-Induced Weight Gain: Development Of The First Evidence-Based Guideline Using*

Grade Methodology", PRIMM (Prescribing and Research and Medicines Management in the UK and Ireland) 33rd Annual Meeting, Manchester, June 2022.

3. ***Fitzgerald I**. "Metformin In the Management Of Antipsychotic-Induced Weight Gain: Development Of The First Evidence-Based Guideline Using Grade Methodology", European Association for the Study of Obesity Conference, May 2022.*
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Poster presentations

1. ***Fitzgerald I**, Sahm LJ, Byrne A, O'Connell J, Ensor J, Ní Dhubhlaing C, O'Dwyer S, Crowley EK. "Predicting antipsychotic-induced weight gain – are non-genetic prognostic factors (clinical, sociodemographic, biological) variables useful?" College of Mental Health Pharmacy Annual Conference, Northampton, October 2023.*
2. ***Fitzgerald I**, O'Dwyer S, Allen S, Moore S, Yoder R, Breen C. "The Role of Mental Health in Obesity Management - Adaptation of the Canadian Adult Obesity Clinical Practice Guidelines for Ireland", College of Mental Health Pharmacy Annual Conference, Northampton 2022.*
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Thesis Abstract

Introduction

Those living with a severe mental illness (SMI) have a life expectancy estimated as 15-20 years shorter than the general population, with those living with schizophrenia being the most adversely affected. Approximately 40-50% of this excess mortality has been estimated as attributable to death secondary to premature cardiovascular disease (CVD). High rates of obesity are a recognised significant contributor to the burden of CVD among SMI cohorts. Whilst antipsychotic medications are essential treatments in psychiatry, the prescription of any antipsychotic substantially increases the risk of developing obesity. Thus, effective management of antipsychotic-induced weight gain (AIWG) is paramount in addressing the burden of premature mortality among people living with a SMI.

Despite its prevalence and impact, international AIWG management practices continue to be suboptimal. This is in part due to deficits in the design of clinical practice guidelines addressing AIWG management. This includes the absence of recommendations considering prevention or early intervention and the absence of lived experience informing recommendation development. Precluding the development of evidence-based, patient-centred AIWG management guidelines are also significant gaps within available research. This includes: (i) whether those at highest risk of clinically significant AIWG can be identified prior to, or early in, treatment to facilitate early intervention, (ii) how application of shared decision-making (SDM) within antipsychotic prescribing can be increased to address the problem of excessive prescribing of antipsychotics associated with a high-risk of inducing AIWG, and (iii) how those with lived experience of AIWG conceptualise preferred management to ensure recommendations are acceptable, feasible, and transferable across cohorts.

The overarching aim of this thesis was to provide answers to these research questions. Thesis objectives were:

i. To ascertain whether routinely collected non-genetic prognostic factors can predict weight outcomes following antipsychotic initiation.
ii. To generate an in-depth understanding of how to implement SDM within antipsychotic prescribing decisions within psychosis management.
iii. To elicit the values and preferences of people with experience of AIWG regarding patient-centred AIWG management.

Methods

A systematic review and meta-analysis was undertaken to identify, synthesize, and appraise research evaluating non-genetic prognostic factors and their association with anthropometric outcomes following antipsychotic initiation. Subsequently, a realist review was undertaken addressing – from the perspective of prescribers – how interventions designed to improve SDM application within antipsychotic prescribing decision work and elicit the impact of structural and contextual factors on their successful implementation within real-world settings. Finally, a qualitative descriptive study was completed exploring the management experiences of varying individuals with experience of unwanted AIWG, alongside eliciting their values and preferences for preferred management.

Results

Systematic review results assessed seventy-eight prognostic factors across 29 studies (4,706 participants) and identified trend of early body mass index (BMI) increase as the most clinically significant prognostic factor influencing long-term AIWG prognosis. Previously thought prognostic factors were identified as non-significant following synthesis of primary research. This included age (b=-0.044, 95%CI -0.157-0.069), sex (b=0.236, 95%CI -0.086-0.558), and baseline BMI (b=-0.013 95%CI -0.225-0.200).

From the realist review, ten programme theories containing 23 context-mechanism-outcome configurations (CMOCs) were developed from 106 data sources. Programme theories 1-5 addressed implementing SDM within psychosis management and the impact of policy, governance, and system factors.

These five programme theories outlined relationships between (i) leadership and governance, (ii) workforce development and (iii) service delivery contexts and their impact on reducing prescriber engagement with behaviours required of SDM application. Key mechanisms reducing prescriber engagement in desired behaviours included: (i) a fear of individual blame for adverse outcomes and exposure to liability, (ii) pressure from service environments to prioritise decreasing risk of harm, (iii) inadvertent devaluing of experiential knowledge and (iv) existing beliefs that SDM conflicts with duties of beneficence and non-maleficence. Within programme theories 6-10, facilitative features within service delivery and workforce development contexts that can increase prescriber engagement with behaviours required of SDM were outlined. Key mechanisms included: (i) reducing prescriber fear of sole responsibility for harm, (ii) reducing the perceived burden of SDM within consultations, (iii) increasing prescriber confidence in their ability to productively negotiate treatment consultations and (iv) increasing prescriber confidence to safely increase patient autonomy within decision-making.

Finally, semi-structured qualitative interviews (n=17) highlighted significant changes required in current AIWG management guidance for such guidance to reflect the values and preferences of those with lived experience. Participants reported current guidance is oversimplified, lacks the specificity and scope required, and endorses a 'one-size-fits-all' management approach to an extensively heterogenous side-effect. Patient-centred AIWG management was outlined as collaborative, where guidance prioritises early intervention using the range of management interventions, tailored according to AIWG risk, participant ability, and participant preference.

Conclusion

This thesis addressed several key, previously unaddressed research questions within AIWG management, and thus, has significantly advanced knowledge in patient-centred, evidence-based AIWG management. The systematic review provided the first mapping and statistical synthesis of studies examining non-genetic prognostic factors within AIWG prognostication and produced practice, policy, and research implications. This included application of early BMI trend change to target

use of intensified management interventions to those at highest risk of the poorest long-term anthropometric outcomes. The realist review identified that, despite significant research in optimising the design of interventions for use within antipsychotic treatment consultations, e.g., decision aids, even empirically efficacious interventions will be difficult to implement at scale within real-world settings due to misalignment of the behaviours required of clinicians to engage in SDM with the complex social, cultural, legal, political, and professional realities common to mental health settings. Mechanisms identified as responsible for increasing or decreasing prescriber engagement with behaviours required for effective SDM application, and the contexts responsible for their activation, should be the focus of those responsible for implementing SDM at organisational and institutional level. Use of qualitative research results within future iterations of AIWG management guidelines will ensure recommendations are relevant and applicable, and thus, providing opportunities to maximise the impact of recommendations in practice for those funding, providing, and using services.

Chapter 1 - Background

1.1 Chapter description

This chapter provides an overview of the literature that informed the research questions addressed within this thesis. Firstly, the mortality gap between those living with a severe mental illness (SMI) and the general population is discussed. Those with schizophrenia are the focus as these individuals are most adversely affected by high rates of premature mortality. The contribution of high rates of cardiovascular disease (CVD) in explaining a major proportion of the premature mortality is discussed. The impact of high and increasing rates of obesity in contributing to the prevalence of CVD will then be outlined, in addition to the impact of antipsychotic treatment in explaining the prevalence of overweight and obesity. This is followed by a brief discussion on the pathophysiology of antipsychotic-induced weight gain (AIWG) and the varying risk profiles across individual antipsychotics.

The impact of the limited availability of AIWG management guidance for clinicians is discussed, alongside deficits in the development and scope of available guidance. Consequently, the limited clinical utility of current management guidance is highlighted, alongside specific knowledge that is urgently required to address these deficits. The chapter concludes by highlighting three important, unanswered research questions currently precluding the development of AIWG management guidelines to align with international standards of guideline development, whilst also aligning with new paradigms and practices within obesity management. These three research questions are:

1. Can weight outcomes following antipsychotic initiation be predicted using non-genetic prognostic factors, and be subsequently used to inform targeted use of AIWG management interventions?
2. How is patient-centred management of AIWG conceptualised by those with lived experience of AIWG and SMI, and how does this compare to currently available management guidance?

3. How can shared decision-making be implemented within antipsychotic prescribing decisions, such that the excess prescribing of antipsychotics with a high cardiometabolic burden can be reduced?

Work presented in this chapter within the following sections has been published elsewhere, as follows:

- Section 1.4 'Antipsychotic-induced weight gain – prevalence and pathophysiology' **and** Section 1.7.2 'Absence of recommendations addressing early intervention' has been published as: ***Fitzgerald I**, Sahm LJ, Ní Dhubhlaing C, O'Dwyer S, O'Connell J, Torrens J, Crowley EK. Metformin in the management of antipsychotic-induced weight gain - why the 'weight'? Front Psychiatry. 2024;15:1491417.*

- Section 1.6 'Guideline-directed overweight and obesity management' has been published as: *Breen C, O'Connell J, Geoghegan J, O'Shea D, Birney S, Tully L, Gaynor K, O'Kelly M, O'Malley G, O'Donovan C, Lyons O, Flynn M, Allen S, Arthurs N, Browne S, Byrne M, Callaghan S, Collins C, Courtney A, Crotty M, Donohue C, Donovan C, Dunlevy C, Duggan D, Fearon N, Finucane F, **Fitzgerald I**, Foy S, Garvey J, Gibson I, Glynn L, Gregg E, Griffin A, Harrington JM, Heary C, Heneghan H, Hogan A, Hynes M, Kearney C, Kelly D, Neff K, le Roux CW, Manning S, McAuliffe F, Moore S, Moran N, Murphy M, Murrin C, O'Brien SM, O'Donnell C, O'Dwyer S, O'Grada C, O'Malley E, O'Reilly O, O'Reilly S, Porter O, Roche HM, Rhynehart A, Ryan L, Seery S, Soare C, Shaamile F, Walsh A, Woods C, Woods C, Yoder R. Obesity in Adults: A 2022 Adapted Clinical Practice Guideline for Ireland. Obes Facts. 2022;15(6):736-752.*

1.2 Premature mortality in Severe Mental Illness

1.2.1 Rates of premature mortality among people with schizophrenia

People with a SMI (schizophrenia, bipolar affective disorder and major depressive disorder) have a life expectancy approximately 10-20 years shorter than individuals without a SMI.[1] People diagnosed with schizophrenia are the most adversely impacted; on average, individuals with schizophrenia die 14.5 years (95% Confidence Interval (CI) 11.2-17.8) earlier than their counterparts in the general population.[2,3] Recent analysis demonstrates this gap in longevity remains unchanged in the preceding 30 years.[4] Although suicide contributes to a significant proportion of premature deaths (with approximately 17% of mortality being estimated as attributable to unnatural causes),[5] the majority of life years lost relate to poor physical health outcomes, specifically due to comorbid non-communicable and infectious diseases.[6] Approximately 40-50% of the excess mortality among SMI cohorts has been estimated as attributable to death secondary to cardiovascular disease (CVD).[4,7]

1.2.2 Contribution of cardiovascular disease

Whilst the leading cause of death in the general population is also CVD, the risk of CVD and sudden cardiac death is up to five times higher among people with a SMI, across both sexes, all ages, and all ethnic groups.[1,8,9,10] Physical health disparities are also observed across the entire spectrum of mental illnesses in low-income, middle-income, and high-income countries.[6] Whilst the incidence of CVD and associated mortality rates have declined in the general population over recent decades,[1] those with a SMI have not benefitted similarly from interventions that can improve prognosis, such as lifestyle modification and guideline-directed medical and cardiovascular care.[10] The excess burden of CVD among people with a SMI is thought to be attributable to an interplay between biological factors (chronic systemic inflammation, immune system dysfunction), patient factors (high rates of overweight and obesity, low treatment adherence), and healthcare system factors (delayed access to diagnosis and physical health care treatments, fragmentation of care and stigma and discrimination).[1,10] In conclusion, much of the excess and

enduring CVD burden among individuals with a SMI, and the associated personal, social and economic costs, are explained by largely modifiable factors.[10]

1.2.3 Inequitable access to physical health care interventions

Despite the mortality gap, people with a SMI are more likely to receive a poorer standard of physical health care when compared to people without a SMI who have the same physical health problems. This includes access to appropriate monitoring and associated management interventions.[6] In 1937,[11] Malzberg first reported that psychiatric inpatients had a mortality rate six times greater than the rate of the general population in New York. At that time, Malzberg also reported that "*diseases of the heart*" constituted the leading cause of death, being responsible for almost 40 percent of all deaths.[11] Thus, in spite of longstanding knowledge of the mortality gap, inequalities in accessing physical health care interventions among people with a SMI is an ongoing concern internationally.[6] Indeed, disparities in timely access to adequate physical health care interventions and the consequent poor health outcomes among individuals with a SMI have been referred to as a human rights issue.[5,12]

Disparities in accessing adequate physical health care services have been documented at all levels of health services. In primary care settings, people with a SMI are less likely to have a physical examination (including assessment of weight or blood pressure), or to be assessed and treated for cardiometabolic risk factors than people without a SMI.[6,13] In secondary care settings, people with prior contact with mental health services have been demonstrated to be less likely to receive cardiac catheterisations and coronary artery bypass grafts than people with no prior contact.[14] People with mental illnesses are also less likely to receive appropriate medications, including beta blockers and statins, at discharge after myocardial infarction.[6] Those with a mental illness also have more emergency department visits and more avoidable admissions to hospital for physical conditions that - with appropriate primary care - should not require inpatient treatment.[6,15]

Explanations offered for the gaps in care those with mental illnesses receive outside of psychiatric settings include clinician's attributing somatic symptoms to mental illness, resulting in missed diagnoses (often referred to as 'diagnostic overshadowing').[16] Furthermore, clinicians may be reluctant to offer some medical procedures to people with a diagnosed mental illness due to a preoccupation with subsequent psychological stress and associated impacts on underlying mental illness, concerns about obtaining informed consent, or concerns about prescribing medications with potential contraindications or interactions with psychiatric medications.[6]

However, even among psychiatric clinicians, monitoring and management of physical health continues to fall well below international standards of best practice.[6] In the Republic of Ireland, the most recent audit of physical health care within mental health services was undertaken in 2018 by the independent regulator of mental health services, the Mental Health Commission (MHC).[17] Findings were such that a "*disregard for international best practice guidelines for monitoring the physical health of in-patients who are resident in mental health units and those who are on antipsychotic medication"* was identified. Among 100 residents in 10 mental health inpatient centres, only 25% of residents had a body mass index (BMI) recorded. Waist circumference was documented in 9% of cases. Measurement of lipids and blood glucose were documented in 66% and 72% of cases, respectively.[17] Whilst access to associated management interventions following identification of abnormal results was not reported, inequity regarding access to evidence-based physical health care interventions continues to be reported within mental health settings internationally.[10,18,19]

Suggested explanations for the disconnect between best practice guidance and real-world practice within psychiatric settings is - as would be expected among psychiatric clinicians - not a lack of awareness of the need for physical health monitoring and management; rather: (i) lack of adequate physical health care education and training, (ii) insufficiency of resources, (iii) fragmentation of care, and (iv) uncertainty regarding responsibility and duty of care between clinicians in

primary and secondary care settings.[20,21] To address the ongoing suboptimal standards of physical health care among SMI cohorts, changes are needed at within both healthcare and education systems. *The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness* recently recommended greater integration of physical and mental health care within psychiatric settings and emphasised the need for psychiatric clinicians to be able to access supports, including training, on the detection, management, and prevention of chronic medical conditions.[6]

1.3 Rates of obesity among people with schizophrenia

Among patient factors contributing to the burden of CVD among SMI cohorts is the high rate of obesity among those with a SMI.[22] The prevalence of obesity is considerably increased across most mental health disorders compared with the general population.[23] Specific to individuals with schizophrenia, prevalence estimates of obesity are approximately 25%, with prevalence of overweight and obesity being estimated as around 60%.[23] Whilst such a high prevalence of obesity is thought to be attributable to a range of factors, including increased rates of individuals living a sedentary lifestyle and social deprivation impacting dietary habits, weight gain induced by essential psychotropic treatment is a very common cause of overweight and obesity within SMI management.[24] Of all psychotropics, prescription of antipsychotic medications is associated with the highest risk of inducing clinically significant weight gain (CSWG), most commonly defined as a ≥5-7% increase in baseline weight.[25]

Antipsychotic medications are essential treatments in the management of psychotic illnesses. 'Psychosis' refers to a set of symptoms that includes distortions and impairments of thought, feeling and behaviour, leading to a loss of contact with consensual reality.[4,6] Psychotic symptoms typically include delusions, hallucinations, abnormal motor behaviours and distortions within the content, organisation and expression of thoughts. For chronic and enduring psychotic illnesses, including schizophrenia, antipsychotic treatment is often required for prolonged periods of time, and in many cases, requires life-long treatment.[4,6] Thus, within schizophrenia

management, antipsychotic-induced obesity often occurs early in the course of clinical treatment and can persist throughout the duration of treatment.[6,24,25]

1.4 Antipsychotic-induced weight gain – prevalence, presentation, and pathophysiology

1.4.1 Antipsychotic-induced weight gain – prevalence and presentation

Almost all antipsychotics have been associated with increasing risk of CSWG.[26] AIWG is commonly cited as one of the most distressing side effects of antipsychotic treatment and is a frequent cause of non-adherence.[27,28] Risk of experiencing AIWG and the associated clinical significance varies substantially across and within classes of antipsychotics.[24,29] For example, second-generation antipsychotics (SGA) are associated with a much higher risk of causing AIWG than first-generation antipsychotics (FGA). However, within each class there is also a significant difference in the risk of CSWG occurring. Table 1 provides an overview of the relative risk of weight gain across antipsychotics commonly prescribed within psychosis management.[30] Risk is typically defined according to the risk of inducing a 7% or greater increase in weight from baseline body weight following antipsychotic initiation. Estimates of risk provided are relevant over short- and long-term durations of antipsychotic treatment.[31,32]

Table 1 - An overview of the relative risk of weight gain specific to commonly prescribed antipsychotics.

Antipsychotic	Risk of AIWG
Clozapine (SGA)	High
Olanzapine (SGA)	
Quetiapine (SGA)	Medium
Risperidone/paliperidone* (SGA)	
Amisulpride (SGA)	Low
Aripiprazole (SGA)	
Haloperidol (FGA)	

** Risperidone and paliperidone are grouped together as paliperidone is the primary active metabolite of risperidone.*

Even among those prescribed the same antipsychotic, extensive interindividual variability in anthropometric outcomes following antipsychotic initiation is frequently observed.[24,33] Among those susceptible to AIWG, the largest proportion of total weight gained typically occurs within the first 12 months of antipsychotic treatment.[34] Whilst AIWG can continue after this time, it is usually at a much slower rate.[35,36] In this way, the relationship between duration of antipsychotic treatment and weight gain can be described as hyperbolic; weight increases steadily early in treatment until a plateau is reached. AIWG has also been shown to occur largely independently of the dose prescribed.[29]

1.4.2 Antipsychotic-induced weight gain – pathophysiology

Current understanding of mechanisms behind this hyperbolic relationship suggest that antipsychotics interfere with homeostatic mechanisms regulating weight and total body fat mass, culminating in the development of a new body weight set-point.[37] Mechanisms responsible for the orexigenic effects of antipsychotics are thought to be primarily attributable to their affinity to bind a broad range of neurotransmitter receptors in the central nervous system.[38] Through antagonism of specific subtypes of serotonergic, histaminergic, muscarinic, and dopaminergic receptors antipsychotics interfere with the regulation of metabolic signals that communicate energy status and suppress appetite when the body has met its energy requirements.[39,40]

As the primary regulator of food intake and body weight, the hypothalamus regulates energy intake and expenditure via signalling mediated by neuromodulators, including the anorexigenic neuropeptides proopiomelanocortin (POMC) and cocaine and amphetamine-regulated transcript (CART), and the orexigenic neuropeptides neuropeptide Y (NPY) and agouti-related peptide (AgRP). Antagonism of Histamine 1 (H1), 5HT (serotonin) 1A, 2A and 2C and Muscarinic 3 (M3) receptors by antipsychotics enhances appetite and reduces satiety through a final common pathway leading to up-regulation of the NPY-AgRP signals and downregulation of POMC. Antagonism of Dopamine 2 (D2) receptors in the mesolimbic pathway may lead to dysregulated eating by opposing the effects of

pre-synaptic dopamine release within neurons connecting the ventral tegmental area to the *nucleus accumbens* involved in mediating satiety following food intake.[38-40] The reward deficiency hypothesis posits that decreased dopaminergic signalling within the striatum may impair the reward response following food intake, resulting in compensatory increase in food cravings and excessive caloric intake.[38] However, antipsychotics with selective activity at D2 receptors through partial agonism (e.g., aripiprazole) or antagonism (e.g., amisulpride) are not commonly associated with clinically significant AIWG.[24] Additionally clozapine, often demonstrated as being the highest risk antipsychotic with regards to inducing AIWG,[24] possesses little affinity for the D2 receptor.[41] A high affinity for 5HT2A, 5HT2C and H1 appears important in mediating the most clinically significant presentations of AIWG.[38] Given the personal, social and healthcare costs, effectively managing AIWG is a priority in mental health.[42]

1.5 Managing AIWG within psychiatric settings

Effective management of both overweight and obesity necessitates a proactive approach with a focus on prevention and early intervention.[43] In the case of AIWG, to facilitate early intervention and address inadequate access to evidence-based physical health care interventions among individuals with a SMI, weight management must begin in settings where antipsychotics are initiated and where excess weight typically accumulates rapidly following treatment initiation.[36] Effectively managing AIWG is, however, challenging for clinicians as well as patients.[44] In addition to insufficient service resourcing and limited time already cited as barriers to proactive physical health management,[21] psychiatric clinicians report additional and unique barriers to providing obesity care. These include: (i) lack of knowledge and confidence regarding providing obesity care among psychiatric cohorts, (ii) concerns regarding the appropriateness and safety of prescribing anti-obesity medications outside of specialist settings, and (iii) pessimism regarding effectiveness of weight management interventions, given the prevalence and multifactorial causes of overweight and obesity within psychiatry.[44,45]

To address some of these concerns, clinical practice guideline (CPG) recommendations addressing AIWG management among people with a SMI have been developed.[46] There are, however, a number of shortcomings across current CPG recommendations – and the evidence informing their development – which limits their utility in clinical practice. Before discussing guideline deficiencies in detail, a brief overview of current best practice within obesity management in general medicine is provided. This serves as a foundation for outlining new paradigms within weight management and as a critique of approaches endorsed within available AIWG management algorithms.[46] New paradigms referred to include: (i) a focus on patient-centred management, (ii) accounting for the biological, including neurobiological, underpinnings of obesity within guideline recommendations, and (iii) a shift in conceptualisation of the benefits of weight management interventions from weight reversal alone to consideration of holistic health gains.[43]

1.6 The disease of obesity and guideline-directed care

1.6.1 Obesity as a chronic, relapsing, and progressive disease process.

The last decade has seen substantial advances in the understanding of the determinants, pathophysiology, assessment, and treatment of obesity across the lifespan.[43] The World Health Organisation (WHO),[47] the World Obesity Federation (WOF),[48] among others, [43] now define obesity as "*a complex, chronic disease in which excess or dysfunctional adiposity impairs health*". Excess or dysfunctional adiposity is associated with inflammation and an increased risk of metabolic, mechanical and mental health complications.[49] The updated definition of obesity has emerged based on an improved understanding of the biological underpinnings of the disease of obesity. The brain plays a central role in energy homeostasis by regulating food intake and energy expenditure. Appetite regulation is complex and involves integration of central neural circuits, including the hypothalamus (regulating homeostatic control), the mesolimbic pathway (regulating hedonic control) and the frontal lobe (regulating executive control). The neurobiology of appetite, body weight and energy regulation are mediated by a myriad of hormonal

signals from the gut, adipose tissue, and other organs. Many of these signalling pathways are altered by obesity.[50,51]

While in the short term, restricting energy intake and increasing physical activity leads to a negative energy balance and subsequent weight loss, this triggers a cascade of adaptive metabolic and neurohormonal mechanisms that increase hunger, reduce satiety and energy expenditure, attenuate weight loss and promote weight regain.[42] Obesity is also influenced by environmental factors. Increased availability and marketing of energy-dense, inexpensive foods and beverages, in parallel with economic growth, rapid urbanisation, health inequalities, changes to sleep, screen time, working patterns, and sedentary time, have resulted in a "*health disrupting*" environment, which promotes the development of obesity in susceptible populations.[42,52,53] For individuals with a genetic predisposition, small surpluses in energy intake can accumulate over years, leading to excessive weight gain.[43,52]

Historically, obesity has been defined based on an arbitrary cut-off of a BMI of >30 kg/m^2. At a population level, health complications increase as BMI increases.[54] Consequently, epidemiological studies continue to use this stratification for surveillance and as an indicator to screen for weight-related health risks.[52,55] However, BMI is not an accurate standalone tool for identifying adiposity-related complications in individuals.[56] At an individual level, health complications occur because of the mass, location, and distribution of adiposity, in addition to factors such as genetic predisposition and health inequalities. The threshold at which accumulation of adipose tissue impairs health in any individual varies.[54]

1.6.2 Guideline-directed obesity management

A guideline-directed approach to obesity management is now standard within general medicine.[57,58] Use of standardised and evidence-based management guidelines provides a method to account for the multifactorial aetiological causes of obesity, including genetics, environmental causes (including use of weight-increasing medications) and psychosocial factors, alongside the inherent

complexity of effective obesity management.[43] The latter includes the varying phenotypes associated with disease presentation and the associated differences in response to intervention – whether non-pharmacological, pharmacological or surgical.[59] A guideline-directed approach to obesity management also supports the management of obesity based on evidence-based principles of chronic disease management, as in other enduring illnesses. This includes care based on lived experience, movement beyond simplistic approaches of "*eat less, move more*" and in ensuring the root drivers of obesity are appropriately addressed.[58]

Development of obesity management guidelines can also inform resourcing of obesity management services across different healthcare settings by recognising the requirement for both interdisciplinary and cross-sectoral management in providing individualised care essential for effective weight management.[42,60] Alongside the prominence given to individualised care within management guidelines, prevention and harm reduction are emphasised within obesity management guidelines to align with the principles of chronic disease management.[58] Harm reduction includes providing the earliest possible interventions to reduce the consequences of living with excess weight or obesity.[43]

1.7 Clinical practice guidelines within psychiatry for managing AIWG

Within psychiatry only a limited number of guideline recommendations informing AIWG management exist, and only within subsections of larger guidelines.[43,46,58,61] A rigorously developed CPG solely dedicated to AIWG management is absent.[62] When reviewing available recommendations across guidelines, a number of issues arise impacting their clinical utility and conflicting with patient-centred paradigms of obesity management outlined in Section 1.6. Issues of primary importance include: (i) the absence of an individualised approach to AIWG management and replication of one-size-fits-all, hierarchical approaches to population-level weight management, (ii) limited scope of available recommendations, including a general absence of recommendations addressing early intervention and paucity of information contained in any recommendations addressing prevention, and (iii) the absence of

consideration of the perspective of lived experience within recommendation development.

Before each of these deficits in guideline development and their impact on patient care are discussed in detail, an overview of currently available recommendations is provided in Table 2. These specific limitations are highlighted as they serve as significant barriers to timely, systematic and equitable patient access to evidence-based AIWG management across cohorts and settings.[63,64,65] Only CPGs outlining AIWG management recommendations in adults published in the last 10 years (2014-present), and where guideline development was informed by a systematic review of available literature, are included. Whether early intervention is addressed and whether recommendation development was informed by patient and public (PPI) representation within guideline development groups (GDGs) are also highlighted.

Table 2 - Overview of AIWG management guidance contained within clinical practice guidelines published within the last 10 years (2014-present) and where recommendation development was informed by a systematic review process. Guideline recommendations are presented in reverse chronological order.

Guideline/year of publication	Recommendations addressing prevention or early intervention (Yes/No)	AIWG management recommendations	Patient and public involvement in GDG *
Obesity in Adults: A 2022 Adapted Clinical Practice Guideline for Ireland [43] *Chapter: The Role of Mental Health in Obesity Management*	Yes (recommendations only cover prevention)	Pharmacological treatment such as metformin and psychological treatment, such as cognitive behavioural therapy, should be considered for prevention of weight gain in people with severe mental illness who are treated with antipsychotic medications associated with weight gain.	Not specified in guideline development methodology, confirmed on contacting GDG representative.
Canadian Adult Clinical Practice Guidelines (2020) [58] *Chapter: The Role of Mental Health in Obesity Management*	Yes (recommendations only cover prevention)	Metformin and psychological treatment, such as cognitive behavioural therapy, should be considered for prevention of weight gain in people with severe mental illness who are treated with anti-psychotic medications associated with weight gain.	Not specified in guideline development methodology, confirmed on contacting GDG representative.

Guideline/year of publication	Recommendations addressing prevention or early intervention (Yes/No)	AIWG management recommendations	Patient and public involvement in GDG *
World Health Organisation (WHO) guideline on the management of physical health conditions in adults with severe mental disorders (2018) [46]	No	**Recommendation 1:** Behavioural lifestyle (healthy diet, physical activity) interventions should be considered in all people with severe mental disorders who are overweight or obese or at risk of becoming overweight or obese in accordance with WHO's Package of Essential Noncommunicable Disease Interventions (WHO PEN) for primary care in low-resource settings (2010). These interventions should be appropriate and tailored to the needs of this population. **Recommendation 2:** For people with severe mental disorders who are overweight or obese, and where lifestyle interventions and/or switching psychotropic medication do not appear successful, adjunctive metformin may be	Not specified in guideline development methodology. No response received from GDG representative.[46]

Guideline/year of publication	Recommendations addressing prevention or early intervention (Yes/No)	AIWG management recommendations	Patient and public involvement in GDG *
		considered. This should be considered under close clinical supervision and monitoring.	
National Institute for Health and Care Excellence (NICE) - Psychosis and schizophrenia in adults: prevention and management (2014) [61]	No	**Recommendation 1** If a person has rapid or excessive weight gain, abnormal lipid levels or problems with blood glucose management, offer interventions in line with relevant NICE guideline (NICE guideline on obesity) [65]	Not applicable as no recommendations specific for AIWG management are contained within either guideline.

* Identified on contacting guideline development group, or as documented within guideline development process (where publicly available).

1.7.1 A critique of hierarchical (stepwise) AIWG management algorithms

Given the international standing of the developing organisation and methodological rigour supporting guideline development,[66] the most influential guideline recommendations informing AIWG management in clinic practice is the WHO's 2018 guideline on the management of physical health conditions in adults with severe mental disorders.[46] The approach endorsed is similar to that recommended within population-level weight management i.e., a stepwise (or hierarchical) management approach. Such approaches comprise so-called 'lifestyle' or 'behavioural' interventions (typically interventions comprising mainly dietary and exercise measures, whilst also sometimes including psychological supports) as the standard management intervention offered universally.[63]

In the case of these supports being ineffective, the next step within hierarchical management algorithms is consideration of changing antipsychotic to a typically lower-risk medication with regard to risk of AIWG, followed finally by consideration of addition of metformin, as the pharmacological adjunct with the most consistent evidence base in reversing AIWG.[44,62,67] Aside from an apparent contraindication between homogenous management algorithms in managing an extensively heterogenous side effect,[24,33] specific to weight gain induced by antipsychotic treatment, empirical research has largely not demonstrated behavioural interventions to be more effective than relegated management options, including switching antipsychotic or addition of metformin.[68,69]

Within secondary analyses of studies indirectly assessing the comparative efficacy of various behavioural interventions versus addition of pharmacological adjuncts or changing antipsychotic, studies including individuals with AIWG are often considered collectively with individuals with a SMI who have experienced weight gain due to non-specific causes.[63] Such analyses therefore do not adequately account for the range of aetiological causes of overweight and obesity within SMI management. This may mean important differences in responsiveness to intervention, depending on the cause of overweight or obesity, are lost through collective assessment of average efficacy estimates. Accounting for the various

causes of weight gain within analyses is particularly important in the case of AIWG where interference with homeostatic appetite control mechanisms is primarily responsible for weight gain,[39,40] and where intervention through lifestyle or behavioural changes does not target the primary driver of excess caloric intake. Such an approach also does not reflect current understanding of the pathophysiology of obesity more generally, for example, expected heterogeneity in response to intervention and the requirement for individualised management to promote holistic health gains rather than weight loss alone.[43,52]

A recent systematic review and meta-analysis assessing the efficacy of behavioural interventions among a defined cohort of people with a SMI and AIWG did not find behavioural interventions to be significantly efficacious in preventing or treating AIWG.[70] Whilst limited in number, direct comparisons assessed within randomised controlled trials (RCTs) found that metformin in combination with lifestyle interventions was more effective than either intervention alone, and metformin was more effective in inducing weight loss and improving insulin sensitivity than lifestyle intervention alone.[68,71] An alternative explanation often given for delayed use of metformin by GDGs is its limited efficacy in reversing the typically significant burden of weight gain induced by antipsychotic treatment. A measure of 2-3kg weight reversal is often cited.[46] This "*modest*" weight reduction, alongside consideration of risk of side effects, increased tablet burden and concerns about adherence, are all arguments used to support delayed introduction of metformin.[72] Efficacy of metformin in reversing AIWG is, however, often presented with an implicit assumption that a plateau of weight gain has been reached. To draw accurate conclusions regarding the efficacy of any intervention in managing AIWG, the duration of antipsychotic treatment and associated prognosis of AIWG must be considered, specifically whether continued weight gain is likely.

Metformin treatment has been demonstrated to be more effective when prescribed in the context of first episode psychosis (FEP).[71] Compared to those with an established psychotic illness, those with FEP likely have minimal, or no, prior antipsychotic exposure. In one example, a subgroup analysis of a systematic review

tested the hypothesis of differential efficacy among those with varying illness chronicity. Metformin was more efficacious among those experiencing FEP compared to those with so-called 'chronic psychosis' i.e., extensive prior antipsychotic treatment. Among those treated with metformin, mean weight reduction was significantly higher among the FEP cohort, mean difference -3.24kg, 95% CI [-4.55 – (-1.92)], p <0.001. On closer inspection of individual studies included in the analysis, weight loss in both metformin-treated groups was similar, with median weight reductions of – 2.37kg in the FEP cohort, and – 1.56kg in the chronic psychosis groups. Rather, observed differences between the FEP and chronic psychosis groups are largely accounted for through dissimilarities in the weight gain trajectory of the placebo-treated groups of both cohorts. Corresponding median weight increases over an average of 16 weeks in the antipsychotic-placebo-treated groups were 2.5kg (FEP) and 0.16kg (chronic psychosis).[71] Median measurements are provided here as a more accurate representation of central tendency within the figures reported, given the interindividual variation in AIWG trajectory.

The primary benefit of metformin as a weight control agent in preventing further weight gain, or inducing modest weight reductions, can also be seen in more recent studies among those who are antipsychotic-naïve or initiating a new antipsychotic treatment. Given the typical short trial length (≤6 months),[71] and recommended duration of antipsychotic treatment extending far beyond this,[61] average weight change figures likely underestimate the impact of AIWG on final body weight, and thus, the benefits of early metformin initiation. Interpretations drawn from reviewing studies assessing the efficacy of metformin, without considering the timing of metformin initiation, and the typical prognosis of AIWG, substantially underestimate the benefit of metformin for most individuals in managing AIWG. Thus, an unintended consequence of current guideline recommendations is delayed use of a pharmacological intervention that is largely effective in preventing further weight gain, not significantly reversing established AIWG. This understanding of metformin's role in modifying the prognosis of AIWG when introduced early in treatment has been largely unaccounted for within discussions first addressing metformin's role in AIWG management published over 20 years ago.[73] For most, by

the time metformin is started following adherence to AIWG management guidelines,[46] the unique weight management benefits of this agent have been lost.

Thus, although perhaps justified as a pragmatic approach, current stepwise approaches to management do not reflect empirical evidence assessing the efficacy of interventions in managing AIWG, nor many of the recent developments in obesity management and associated best practice within guideline-directed care.

1.7.2 Absence of recommendations addressing early intervention

The next iteration of guideline recommendations within AIWG management also requires consideration of the need for specific recommendations addressing prevention and early intervention. As demonstrated in Table 2, most available guideline recommendations focus solely on treatment of established AIWG and so, detailed recommendations on prevention are not present within most guidelines.[46] Typically within discussions around AIWG management, there is a focus on either prevention *or* treatment.[25] Often missing from this conversation is the unique importance of early intervention specific to AIWG management i.e. acting promptly once objective evidence of weight gain is demonstrated. The extent of interindividual variability associated with AIWG and its long-term prognosis means that, in the case of recommending widespread use of preventative interventions, concerns exist regarding inefficient use of often resource-intensive behavioural and lifestyle interventions.[63] Specific to use of pharmacological adjuncts to prevent AIWG, concerns for polypharmacy and increased risk of side effects, have previously been identified as barriers to their prescription by psychiatric clinicians.[74]

Reorientation towards early intervention within AIWG management offers a novel alternative to the focus on prevention versus treatment, such that interventions are offered once objective evidence of a change in anthropometric measurements post antipsychotic initiation is established. However, either in the case of prevention or early intervention, identifying those at highest risk of poorer long-term prognosis, either before or early in antipsychotic treatment, would have many benefits to both patients and clinicians. Even without evidence of differential intervention efficacy

among groups at low- versus high-risk of experiencing CSWG, knowledge of a person's likely anthropometric prognosis following antipsychotic initiation represents one method of resource-efficient distribution of management interventions. With the availability of this knowledge, intervention use, particularly resource-intensive interventions, can be prioritised among groups most likely to benefit from associated average absolute weight reductions. Whether or not likely prognosis of AIWG can be predicted has been the subject of several retrospective and prospective cohort studies.[36,75,76]

In the case of biomarkers (defined as a naturally occurring molecule, gene, or characteristic by which a particular pathological or physiological process, disease etc; can be identified),[77] a systematic review of pharmacogenomic associations of AIWG concluded that effect sizes of individual gene variants were too small to fulfil the promise of personalized medicine.[78] However, no similar systematic assessment of the value of non-genetic prognostic factors in predicting anthropometric outcomes following antipsychotic initiation has been undertaken. Thus, their clinical utility within AIWG prognostication is currently unknown. Consequently, non-genetic prognostic factors represent a potentially underexploited resource within AIWG prognosis.

1.7.3 Absence of consideration of lived experience within development of guideline recommendations

Development of guideline recommendations should be underpinned by rigorous and transparent methodology to ensure decision-making processes are evidence-based and to improve the external generalisability of resultant recommendations. According to international best practice in guideline development,[66,79] for guideline recommendations to possess clinical utility among intended users, recommendation development requires consideration of a range of factors in addition to the likely risks and benefits of treatment interventions. For example, in considering GRADE's (**G**rading of **R**ecommendations, **A**ssessment, **D**evelopment, and **E**valuation) evidence-to-decision framework,[79] additional considerations include: (i) resources required to implement interventions, (ii) equity

considerations and (iii) the likely acceptability and feasibility among intended users of interventions. Qualitative evidence is typically required to inform these criteria.[80] However, specific to AIWG management, very little – if any – qualitative research has been undertaken regarding patient values and preferences for management. Whilst research has been undertaken assessing the physical and psychological impacts of AIWG,[6,81] an understanding of how people with experience of AIWG and a SMI conceptualise preferred management, and the impact of context on the feasibility of implementing management interventions, have yet to be systematically assessed. Given the extensive interindividual variability associated with AIWG and its prognosis,[24] it is likely patient preferences and priorities for management will be similarly variable.

As highlighted in Table 2, available recommendations have largely been informed by the expert opinion of GDGs with no or minimal patient input. Within overweight or obesity management, the absence of the voice(s) of lived experience within guideline development is of particular concern for several reasons. Despite improved understanding of the disease, people living with obesity continue to experience weight bias and stigma, which has been demonstrated to independently increase morbidity and mortality.[82] Some healthcare professionals endorse stereotypical assumptions and stigmatising attitudes about those living with obesity.[83,84] Obesity management amongst SMI cohorts may be particularly liable to such implicit biases, where the experience of a 'dual stigma' has been described by those living with both obesity and a mental illness.[85,86] Recommendations addressing weight management among those with a SMI may be distinctly susceptible to ideology and sociocultural values regarding the appropriateness of interventions, including use of anti-obesity medications and expectations of self-management,[87] reinforcing the need for co-produced AIWG management guidance. Lack of incorporation of lived experience within guideline development may go some way to explaining evidence of poor weight management experiences reported by patients within mental health services.[85]

1.8 High rates of prescribing of antipsychotics associated with high-risk of cardiometabolic side effects

As highlighted within the WHO's 2018 guideline,[46] one AIWG management strategy is rationalisation of antipsychotic prescribing, i.e., changing antipsychotic to one associated with a lower average risk of inducing CSWG.[30] Switching antipsychotic to ameliorate weight gain is supported by a recent systematic review and meta-analysis.[69] Antipsychotics are essential treatments within psychosis management.[30] Differences in average efficacy estimates between antipsychotics and across classes of FGA and SGA are small and, in most cases, lack clinical significance.[24] In comparison, the risk of side effects between antipsychotics does differ to a clinically significant extent.[24] This is particularly the case with regard to risk of AIWG.[24,36] Thus, in non-treatment-resistant psychosis, most major guidelines advocate that choice of antipsychotic should primarily be informed by an individual's preference regarding side effects, rather than informed by superiority of certain antipsychotics based on average efficacy estimates.[61,88]

As a consequence of adherence to guideline-informed antipsychotic prescribing, it is reasonable to assume antipsychotic prescribing trends within psychosis management would demonstrate significant variation, aligned to the natural variation in side effect preferences across the diverse range of people who present with psychosis.[89] The most commonly listed distressing side effects of antipsychotic treatments by patients include sedation, weight gain and cognitive impairment.[27,90] Despite the known impact of side effects on antipsychotic adherence,[91] and recommendations within CPGs, international trends in antipsychotic prescribing within psychosis management consistently demonstrate high prescribing rates of a small number of antipsychotics. These principally include those with a high burden of sedative, cognitive and cardiometabolic (weight gain, dyslipidaemia and hyperglycaemia) side effects, i.e., olanzapine, quetiapine and risperidone.[92,93,94]

In comparison to continued research focussing on identifying trends of antipsychotic prescribing, the development of knowledge addressing how to influence antipsychotic prescribing behaviours among clinicians receives

comparatively much less attention within international research. Developing knowledge of how to influence prescribing behaviours among clinicians and consequently, diversifying patterns of antipsychotic prescribing to align with patient preferences, is an urgent priority within psychiatry. Specific to AIWG management, this knowledge is essential to implement recommendations addressing optimised antipsychotic prescribing to improve anthropometric outcomes. To develop such knowledge an understanding of how to implement shared decision-making (SDM) is required. SDM is a process whereby clinicians and patients collaborate to make treatment decisions based on clinical evidence and patients' informed preferences.[95] SDM is considered a key component of person-centred care, and is advocated for as an exemplary model of decision-making within mental health policy internationally.[96] Despite SDM being increasingly featured in the rhetoric of government policy and best practice guidance, a disconnect exists between policy ideals and much of standard clinical practice.[97] This is particularly so among individuals experiencing psychosis and within antipsychotic treatment decisions, where evidence suggests even beyond acute treatment, clinician-led decision-making prevails.[98,99,100]

Whilst many interventions have been assessed for their efficacy in increasing SDM application within antipsychotic prescribing, results have proven variable and inconsistent.[101] Little consideration has been given to understanding causative processes responsible for effective interventions.[102] Despite prior evidence syntheses, questions of why some interventions work, and others do not, remain.[101,103] Even in the case of empirically efficacious interventions,[104,105] their widespread implementation in practice is limited - mirroring the 'know-do gap' prevalent within mental health research.[106] Thus, within SDM research in psychosis management, a need exists for evidence outlining how successful interventions work, for whom, and under what circumstances.

1.9 Chapter summary

AIWG is commonly cited as one of the most distressing treatment side effects of antipsychotic treatment and is a frequent cause of non-adherence.[27,28] CSWG has been linked to almost all antipsychotics [107] and contributes significantly to the 2-3-fold higher obesity rates seen amongst those with a SMI.[6] Consequently AIWG and its impact on the risk of cardiometabolic disease contributes appreciably to the poorer physical health,[6] reduced healthy years lived,[108] and the 10-20 year premature mortality seen amongst those with a SMI.[44,109] Given the personal, social, and healthcare costs, effectively managing AIWG is a key priority for patients, clinicians and policymakers. However, limited management guidance exists to inform clinical practice and to support psychiatric clinicians in managing AIWG.

There are also several significant issues associated with currently available management guidance limiting its clinical utility and thus, patient access to evidence-based management interventions in a timely, systematic and equitable fashion. This includes recommendations that largely focus on treating, rather than preventing AIWG, or intervening early to protect weight status in the case of significant weight gain following antipsychotic initiation. This shift in focus will be essential to protecting the physical health of those living with a SMI. To facilitate development of such recommendations, evidence is needed to support early identification of individuals at highest risk of experiencing the worse long-term prognosis, such that prevention and early intervention can be readily implemented in a resource-efficient and equitable manner. Equity includes targeting typically resource-intensive interventions to those most likely to glean the largest absolute benefits.

As part of facilitating a greater focus on prevention and early intervention, evidence is also needed to address the question of how to optimise antipsychotic prescribing practices within psychosis management. A shift away from excessive prescribing of antipsychotics associated with a high-risk of inducing AIWG would go a significant way towards both preventing and treating AIWG. This change in clinical practice would also facilitate more equitable management of AIWG by facilitating targeting

of interventions to a smaller absolute number of people prescribed high-risk antipsychotics. Redressing the balance between clinician-led prescribing and SDM within psychosis management is essential to facilitate this.[98] Finally, individuals with experience of managing AIWG have had no, or minimal input, into the development of available AIWG management recommendations. This calls into question the acceptability and feasibility of available recommendations among people living with a SMI and experiencing AIWG.[46]

Thus, whilst calls for improved and standardised guidance dedicated to AIWG management are increasing,[62,110] prior to the development of guidance that is both evidence-based and patient-centred, several gaps within available evidence require addressing. Addressing these gaps will be the focus of this thesis, whereby research questions will address: (i) whether non-genetic prognostic factors can be used to predict long-term weight outcomes following antipsychotic initiation, (ii) what patient values and preferences are for AIWG management and how this compares with available CPG guidance, and (iii) how SDM within antipsychotic prescribing can be effectively implemented among people experiencing psychosis.

Chapter 2 - Introduction to the thesis

2.1 Thesis aims and objectives

The overarching aim of this thesis is to address the following research questions to allow for the development of a patient-centred, evidence-based, and resource-efficient AIWG management guideline and its implementation within clinical practice:

1. Can weight outcomes following antipsychotic initiation be predicted using non-genetic prognostic factors, and subsequently be applied in informing risk-stratified use of AIWG management interventions?
2. How can shared decision-making be implemented within antipsychotic prescribing decisions, such that the excess prescribing of antipsychotics with a high cardiometabolic burden can be reduced?
3. How is patient-centred management of AIWG conceptualised by those with lived experience of AIWG and SMI and how does this compare to currently available management guidance?

To achieve this aim, the following objectives were developed:

1. Identify, synthesize, and critically appraise research examining clinical, sociodemographic, and biological non-genetic prognostic factors and their association with the prognosis of AIWG.
2. Explore the clinical utility of any significant and reliable prognostic factor-outcome associations in informing intervention prioritisation within AIWG management.
3. Describe how interventions designed to improve the application of shared decision-making among individuals with psychosis and within antipsychotic treatment choices work; elucidate the impact of contextual factors on successful implementation.

4. Develop recommendations on developing and implementing interventions to improve application of shared decision-making within the contexts outlined in (3).
5. Explore the experiences of a diverse patient group diagnosed with a SMI and with experience of unwanted AIWG; elicit their values and preferences regarding preferred management and identify areas of suggested change within AIWG management guidelines.
6. Explore the acceptability of current AIWG management algorithms and interventions among people with lived experience; identify areas of change required for AIWG management recommendations to better reflect patient preferences.

2.2 Thesis outline

To address each research question, and meet thesis aims and objectives, three work packages were designed, as outlined in Figure 1. The study design chosen to address each research question is also outlined in Figure 1. As this thesis uses a mixed methods design, a chapter (chapter 3) outlining research paradigms and associated methodologies chosen in addressing each research question is included initially. Each research question is answered within a separate chapter (chapters 4-6), followed by an overarching discussion chapter (chapter 7). Chapter 7 includes the implications of work conducted within this thesis for both clinical practice and future research.

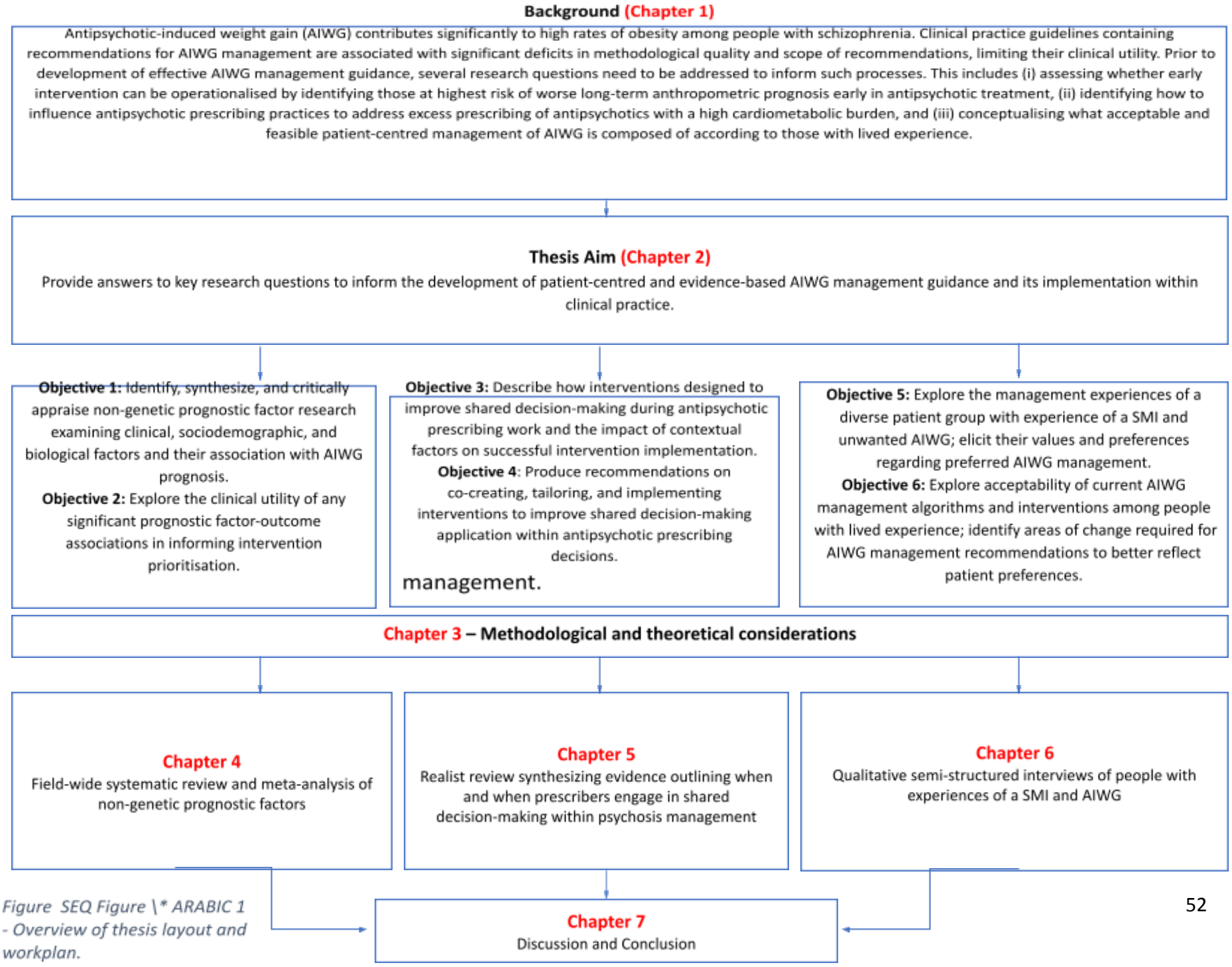


*Figure SEQ Figure * ARABIC 1 - Overview of thesis layout and workplan.*

Chapter 3 – Thesis methodological and theoretical considerations

3.1 Chapter description

This chapter discusses the research paradigms that informed work conducted within this thesis. The overarching research paradigm adhered to was pragmatism. Philosophical assumptions inherent within pragmatism and the rationale for its application are discussed within this chapter. Subsequently, the three different research paradigms informing methodologies applied in addressing each research question outlined in chapter 2 are presented. Considerations in deciding on the most appropriate research paradigm and associated methodologies in generating credible evidence question are outlined. An overview of philosophical assumptions underpinning each research paradigm is provided, alongside specific methodological considerations. Particular attention is given to the application of a realist philosophy of science and realist review methodology adopted in addressing the second research question (chapter 5), given its novelty within mental health research. Accordingly, explanations of key terminology within realist research are provided within this chapter. A more detailed discussion of methods specific to each research question is provided within the respective chapters.

Work presented in this chapter has been published elsewhere, as follows:

- Section 3.2.4 '*Research question 2 – rationale for application of a realist philosophy of science' as:* ***Fitzgerald I****, Sahm LJ, Howe J, Maidment I, Wallace E, Crowley EK. Shared decision-making interventions in the choice of antipsychotic prescription in people living with psychosis (SHAPE): Protocol for a realist review. PLoS One. 2024;19(7):e0304626.*

3.2 Research paradigms chosen for application within the thesis

3.2.1 Research paradigms in health and social sciences

A research paradigm has been defined as "*a shared worldview that represents the beliefs and values in a discipline which guides how problems are solved*".[111] A paradigm describes a worldview that is informed by philosophical assumptions about the nature of reality (also known as ontology – i.e. what do we believe about the nature of reality?), ways of knowing about that reality (also known as epistemology – i.e. how can we generate knowledge about that reality?) and ethics and value systems (also known as axiology – i.e. what do we believe is true?). Each distinct research paradigm also has associated methodologies aligning with the inherent philosophical assumptions (i.e., strategies that inform the choice and use of specific research methods used to develop knowledge). Thus, the chosen research paradigm assesses how knowledge is developed, interpreted and studied, whilst also clearly defining the purpose, motivation, and desired outcomes of a study.[111,112]

In health and social sciences, a range of different research paradigms are commonly applied, each with different philosophical assumptions.[111] Two dominant paradigms commonly used to address research questions within the field are that of positivism and constructivism, although other paradigms, particularly pragmatism, are becoming increasingly more common.[111] Figure 2 provides an overview of epistemological and ontological assumptions associated with commonly applied research paradigms in health and social sciences.[113]

Paradigm	Ontology *What is reality?*	Epistemology *How can I know reality?*	Theoretical Perspective *Which approach do you use to know something?*	Methodology *How do you go about finding out?*	Method *What techniques do you use to find out?*
Positivism	There is a single reality or truth (more realist).	Reality can be measured and hence the focus is on reliable and valid tools to obtain that.	Positivism Post-positivism	Experimental research Survey research	Usually quantitative, could include: Sampling Measurement and scaling Statistical analysis Questionnaire Focus group Interview
Constructivist / Interpretive	There is no single reality or truth. Reality is created by individuals in groups (less realist).	Therefore, reality needs to be interpreted. It is used to discover the underlying meaning of events and activities.	Interpretivism (reality needs to be interpreted) • Phenomenology • Symbolic interactionism • Hermeneutics Critical Inquiry Feminism	Ethnography Grounded Theory Phenomenological research Heuristic inquiry Action Research Discourse Analysis Femenist Standpoint research etc	Usually qualitative, could include: Qualitative interview Observation Participant Non participant Case study Life history Narrative Theme identification etc
Pragmatism	Reality is constantly renegotiated, debated, interpreted in light of its usefulness in new unpredictable situations.	The best method is one that solves problems. Finding out is the means, change is the underlying aim.	Deweyan pragmatism *Research through design*	Mixed methods Design-based research Action research	Combination of any of the above and more, such as data mining expert review, usability testing, physical prototype
Subjectivism	Reality is what we perceive to be real	All knowledge is purely a matter of perspective.	Postmodernism Structuralism Post-structralism	Discourse theory Archaeology Genealogy Deconstruction etc.	Autoethnography Semiotics Literary analysis Pastiche Intertextuality etc.
Critical	Realities are socially constructed entities that are under constant internal influence.	Reality and knowledge is both socially constructed and influenced by power relations from within society	Marxism Queer theory feminism	critical discourse analysis, critical ethnography action research ideology critique	Ideological review Civil actions open-ended interviews, focus groups, open-ended questionnaires, open-ended observations, and journals.

Figure 2 - An overview of epistemological and ontological assumptions associated with commonly applied research paradigms in health and social sciences from Patel.[113] Reproduced with permission.

3.2.2 Rationale for application of a mixed methods design

Across the research conducted within this thesis, the overarching research paradigm was that of pragmatism.[114] Researchers holding an interpretative framework based on pragmatism focus on the outcomes of the research – the actions, situations and consequences of enquiry – rather than on antecedent conditions. There is instead a

focus on application - the "*what works*?" - and developing solutions to problems. Thus, instead of a focus on methods, from the perspective of pragmatism, the important aspect of research is the problem being studied and the questions being asked about this problem. Pragmatism is not committed to any one system of philosophy and reality. Instead, researchers have the freedom to choose methods, techniques and procedures of research that best meet their needs and purposes. Pragmatists do not view the world as an absolute unity. Researchers look to many approaches of collecting and analysing data, rather than subscribing to only one way. Whilst pragmatists agree that research always occurs in social, historical, political and other contexts, truth is represented by what works at the time; it is not based in a dualism between reality independent of the mind or within the mind. Instead, pragmatists look to the "*what*" and "*how*" of research based on its intended use(s).[114]

Consequently, due to the diverse nature of research questions being addressed within this thesis, three different research paradigms and associated methodologies informed the development of evidence addressing each research question. The paradigm chosen was a function of:

1. The nature of the phenomena being studied within the research question.
2. Intended use of research outcomes.
3. Methodology considered best suited in producing valid and reliable results that would adequately address study aims.
4. Feasibility of any methodology under consideration.

The chosen research paradigm to address each research question and associated methodology will now be discussed.

3.2.3 Research question 1 - rationale for use of a positivist research paradigm

The first research question focussed on the predictability of AIWG via application of non-genetic prognostic factors. The specific question posed was:

Amongst antipsychotic-naïve adults with a first episode of psychosis, are there non-genetic prognostic factors that reliably influence weight and associated anthropometric outcomes following antipsychotic commencement?

In the absence of a prior evidence synthesis, it was agreed that undertaking a traditional systematic review and meta-analysis was the most appropriate methodology in addressing the research question. Application of traditional systematic review and meta-analysis methodology allowed for the production of quantifiable knowledge addressing the effect size and the associated reliability of each prognostic factor-outcome association.[115] By providing a methodology that established the clinical utility of each prognostic factor-outcome assessment, positive results could subsequently be used in directing AIWG management resources towards those at highest risk of worse long-term anthropometric outcomes post-antipsychotic initiation. Thus, the methodology chosen in addressing the first research question aligned with a positivist research paradigm.[116]

Positivists believe there is a single reality which can be measured and known.[116] A positivist research paradigm is characterised by its adherence to empirical observation, logical deduction in response to data collected based on pre-specified hypotheses, and the quest for objective and quantifiable knowledge through use of quantitative methods. Within positivism, an ontological assertion is made that only one true reality exists. Positivists contend that knowledge can and must be developed objectively, without the values of researchers or participants influencing its development. Knowledge, when appropriately developed, is truth – that is, it is certain, congruent with reality, and accurate. To appropriately develop truth, absolute separation must exist between research participants and the researcher. To achieve this separation, positivists operate in dualism and objectivity.[116,117]

3.2.4 Research question 2 – rationale for the application of a realist philosophy of science in informing evidence synthesis methodology

The second research question being addressed considered how to increase application of SDM within antipsychotic prescribing decisions. Development of this

knowledge is a prerequisite to diversifying antipsychotic prescribing trends, which is essential in addressing the high prescribing rates of antipsychotics with an increased risk of inducing clinically significant weight gain within psychosis management.[92,93,94] In comparison to the original research question outlined in chapter 2, the question addressed was focussed further to consider prescriber needs for engagement in behaviours required of SDM and associated interventions. This is described in detail in chapter 5. The final, focussed research question posed was divided into two parts, as follows:

1. *Within antipsychotic treatment decisions during psychosis management, what are the impacts of structural and contextual factors on prescriber engagement with SDM processes?*
2. *How do interventions designed to improve SDM application within antipsychotic treatment decisions work; what intervention strategies are likely responsible for effective interventions?*

In contrast to the first research question, prior evidence syntheses had been conducted assessing the efficacy of varying interventions in improving the application of SDM among individuals with a mental illness.[101,103] However, due to the nature of the phenomenon under assessment i.e. a behaviour change intervention, an approach suited to studying complex interventions was required. Such a distinction between simple and complex interventions was essential when considering the most appropriate methodology to inform evidence synthesis and produce reliable evidence addressing when SDM interventions are effective and within what contexts.[118]

As in all robust research, methods should be appropriate to the subject matter under investigation. The term 'intervention' is often used in capturing the totality of activities subsumed within healthcare, but in doing so conflates initiatives that are methodologically speaking, disparate. Thus, a clinical 'treatment' is not the same thing as a health care 'programme', which is not to be confused with health 'service delivery', which is a different from health 'policy'.[119] Whilst it is appropriate to use

traditional systematic review methodology to evaluate simple treatments, e.g., drug treatments, where a similar response is expected and desirable across individuals, application of this methodology in the case of studying complex interventions – typically defined by their numerous and interdependent components and outcomes [120] - can be uniquely disadvantageous.[119] Applying traditional systematic review methodology when studying complex and diverse behaviour change interventions almost guarantees the variable and inconclusive results seen within secondary analyses conducted thus far.[24,103,119]

For complex interventions, where outcomes following intervention implementation are expected to vary across people, use of average measures of effect size is unhelpful. Rather, it is important to identify the cohorts in whom this intervention works best. Furthermore, in the case of SDM research within psychosis management, the knowledge gap remaining unaddressed relates to **how** and **why** some interventions work (and others do not), and not whether – on average - these interventions are effective among target participants.[101] This knowledge of how and why complex interventions are effective, and within which groups, is uniquely beneficial to those invested in delivering evidence-based healthcare. Thus, it was agreed a novel approach to evidence synthesis was required.

For reasons of intervention complexity, and the need to understand the inner workings of interventions, a realist philosophy of science was chosen as the methodological orientation informing the approach to evidence synthesis.[119,121] Realist evidence syntheses (also known as realist reviews) are a theory-building, interpretative approach to evidence synthesis, which generate explanations as to how and why interventions work (or do not) within settings where they are implemented.[122] Realist reviews are a form of configurational (as opposed to aggregative) evidence synthesis, i.e. data are organised and interpreted to develop and substantiate explanations for why, how, when, for whom, and to what extent, outcomes have occurred.[123]

The benefits of using realist methodology when studying complex interventions and in addressing questions regarding effective design and implementation of SDM interventions within psychosis management will now be discussed in further detail. A brief overview of philosophical assumptions underpinning a realist philosophy of science will also be provided.

3.2.4.1 – Addressing questions of how and why interventions work and understanding the impact of context

The focus of the second research question was on understanding the effectiveness of efficacious SDM interventions and implementation contexts. Studies assessing interventions aimed at improving application of SDM in the choice of antipsychotic treatment within psychosis management have been undertaken.[101] Interventions have largely been modelled on the application of SDM models in somatic medicine, with additional design features to account for implementation within psychiatric settings.[124] Interventions typically assessed include a combination of decision aids,[125,126] educational interventions for patients and/or clinicians,[104] and digital support tools.[127,128,129] To date, the effect size of studied interventions has proven variable and inconsistent, and positive results generally smaller than in somatic medicine.[101,124,130] Reasons for varying results, including an understanding of which elements of efficacious interventions are hypothesized to be responsible for results and how they produced their effects, are largely missing from the literature. An understanding of these mechanisms is important to support increased and consistent application of SDM within antipsychotic prescribing decisions.

Thus, uncertainty exists about: (i) which intervention types to prioritise, (ii) characteristics of effective interventions, and (iii) the impact of different contexts on intervention effectiveness. Refinements and adaptations of traditional SDM models, in general and for local contexts, are likely needed to improve effectiveness. This includes consideration of the impact of contextual factors relating to patients, clinicians and the clinical encounter.[104] Although information exchange is an essential element in facilitating SDM,[131] the neglect of wider structural and/or contextual factors in the design and implementation of interventions for use within

psychosis management may be one reason for varying results and suboptimal implementation of even empirically efficacious interventions.[96,132]

As the focus within the research question was both on design and implementation of SDM interventions within real-world contexts, a methodology informed by implementation science was deemed most appropriate. Implementation science is the study of the components necessary to promote authentic adoption of evidence-based interventions, thereby increasing their effectiveness in clinical practice.[123] It uses a systematic and scientific approach to identify the range of facilitators and barriers which are likely to enhance adoption of an intervention. The underlying intent is to understand what, why, and how interventions work in real-world settings and to test approaches to improve them.[133] By providing a methodology to study causation and develop explanations of how outcomes of interest are generated, a realist philosophy of science was chosen as the specific methodological orientation to inform the evidence synthesis.[119,121]

Realist reviews, similar to other realist-informed approaches, are ontologically underpinned by tenets of critical realism and scientific realism, and are guided by the notions of ontological depth and mechanism-based theorising.[134] Ontologically, within a realist philosophy of science, a mind-independent reality does exist. However, epistemologically, using a realist philosophy of science is committing to the idea that theoretical claims constitute knowledge of the world and rejecting the objectivity of all knowledge forms.[116] This construction of knowledge, and our ability to know about reality, differentiates realism from positivism.[134,135] Within methodologies informed by a realist philosophy of science, the concept of ontological depth is applied, whereby reality is stratified into three layers; the empirical, actual and real.[122] The empirical is a realm that is observable, perceptible, experiential, describable and often measurable. The actual includes the empirical realm along with activated, but non-empirical, mechanisms. The real includes the actual and the empirical, but also latent (non-manifested, but still real) mechanisms.[122,123]

A fundamental tenet of realist analysis is that interventions are underpinned by hidden causal processes (or 'mechanisms') responsible for the manifestation of empirically measurable outcomes. Such mechanisms exist within the realm of the 'real' and are responsible for reality measurable at the empirical level.[136] In contrast to realism, positivist paradigms prioritise observable reality under the assumption that science must work with objects that scientists can observe and potentially manipulate. Consequently, approaches informed by positivism deprioritise aspects of reality not amenable to empirical testing. This is problematic when assessing how and why complex interventions work, as positivist approaches in isolation do not resolve apparent paradoxes well, as value is not placed on the idea of ontological depth. This depth is necessary for paradox resolution and scientific investigation into the invisible, but inherent, powers that produce the world at the empirical level. The result is missed opportunities for generating wisdom and insights, and possibly even radical departures from standard knowledge – which is needed to address and solve complex problems in science. The process of realist data analysis can reveal and resolve things that appear to be paradoxical through an understanding of the configuration and association among elements in the empirical and actual realms.[122,123]

Under realism, the basic evaluative question – "*what works*?" – changes to "*what is it about this intervention that works, for whom, in what circumstances*?". The hallmark of realist enquiry is its distinctive understanding of causality. The successionist model (which underpins intervention research) holds that causality is established when cause X is switched on (e.g., a randomised intervention) and effect Y follows. In contrast, the generative model of causality (which underpins realist enquiry) holds that to infer a causal outcome between two events (X and Y), one needs to understand the underlying mechanism that connects them and the context in which the relationship occurs.[119] Undertaking realist research reorients the researcher to ask questions about the interplay between contextual elements and mechanisms responsible for empirically measurable or observable outcomes. Realist reviews aim to move from empirical observation to developing causal explanations. This is to understand what it is, within the intervention, that

generates change (i.e., **mechanisms)** and in what **contexts,** are these mechanisms generating **outcomes** of interest. These three elements i.e., context, mechanism and outcome, are linked together as a context-mechanism-outcome configuration (CMOC) and are presented collectively within a realist programme theory.[102]

3.2.4.2 Studying and synthesizing evidence assessing complex interventions

Implementing SDM and translating results of efficacious SDM interventions relies on both prescribers and patients successfully engaging in required behaviours. This includes informing patients about the availability of different treatment options and sharing of decision-making responsibility.[100] Particularly in the case of prescribers and within psychosis management, this often requires a significant change in behaviour. SDM interventions are expected to be embedded within existing complex environments, including within systems which have traditionally used paternalistic, clinician-led decision making.[96,131] Interventions which rely on inducing desired behaviour change are grouped under the umbrella heading of complex interventions.[120] The complexity of these interventions stems from achieving their effects via active input of individuals and being embedded typically within multiple social systems. 'Active' interventions only work through stakeholders reasoning in response to intervention strategies. Knowledge of that reasoning is integral to understanding when and why these interventions achieve their desired outcomes.[120]

It can be expected in the case of complex interventions that the same intervention will be met with both success and failure when applied in different contexts. The success of active interventions is typically the product of its context, including the targeted individual(s) and contextual features within the implementation setting.[120] Differences in outcomes across settings require contextualisation in terms of policy, organisational culture and leadership, resource allocation, staffing level and capabilities, interpersonal relationships and competing local priorities. For complex intervention research to be most useful to decision-makers, it should consider the complexity that arises from both the intervention's components and from their interaction with the context(s) in which it is being implemented. Realist review

methodology is uniquely beneficial when studying complex interventions where outcomes are socially contingent,[120] i.e., there is some human reasoning or agency involved in the success of failure of interventions.[123] Realist data analysis involves interpreting data to make inferences about underlying generative causal mechanisms that explain how outcomes are generated and how context influences these.[122,123]

As outlined within Pawson and Tilly's original description of generative causation,[122] interventions do not bring about observed outcomes, but generate outcomes through individuals' responses to the resources, ideas and practices that interventions introduce, which are shaped by wider contexts.[134,135] Mechanisms produced via realist data analysis capture the way in which an intervention's resources impinge on the stakeholder's reasoning. By providing a methodology to explain causation, and the interaction between intervention implementation and context, realist methodology attends to the ways complex interventions, implemented within typically complex settings, may have different effects among different people, depending on the contexts in which they are introduced.[123,137]

3.2.5 Research question 3 - rationale for use of a constructivist research paradigm

The third and final research question relates to understanding the perspective of lived experience with regards to managing AIWG whilst concurrently living with a SMI. The specific research question posed was:

How do patients conceptualise preferred management of AIWG and how can this be realised in practice?

This research question aimed to develop an evidence base outlining the acceptability of current AIWG management algorithms - and included management interventions - among individuals with diverse experiences of AIWG and SMI, alongside understanding intervention feasibility and transferability across contexts. It was envisaged that the outputs of this research would be used by international guideline development groups to inform AIWG management guideline development

and implementation efforts. In acknowledging the subjective nature of lived experience, and the intended outputs and uses of this research, a constructivist research paradigm was chosen as the approach providing the most appropriate methodology to adequately address research aims.

Within a constructivist research paradigm, knowledge and meaningful reality are constructed in, and out of, interaction between humans and their world and are developed and transmitted in a social context. Ontologically, a constructivist research paradigm champions the idea of no single objective reality, and epistemologically, the need to interpret reality. The adoption of a constructivist research paradigm assumes an epistemological approach that many interpretations of reality exist, and that knowledge of reality is socially constructed, not only by the participants, but also by the researcher. It is therefore recognised that an objective reality cannot be discovered nor replicated by others.[138]

3.2.5.1 Adopting a qualitative descriptive approach

Qualitative descriptive methodology (or qualitative description) was chosen as the most appropriate qualitative methodology.[139] This methodology acknowledged that the aim and intended research outputs were not to provide an increasing theoretical, conceptual or highly abstract understanding of the phenomena under investigation, as in other qualitative approaches,[113] but rather to provide a descriptive summary of the informational content of the data organised in a way that best fits the data.[139] Qualitative descriptive methodology is used within studies where the goal is to discover and understand phenomena, processes or perspectives of participants, and provide a rich depiction of experiences from the perspective of research participants.[140] The desired outcome is to describe the phenomenon literally as a starting point, and then move beyond the literal description of the data, attempting to interpret findings without moving too far from the literal description.[141] As the output of qualitative descriptive research avoids high-level interpretation and theory development in data analysis, it's application results in data that can be more easily understood by participants and

non-researchers, making findings more readily implementable by relevant stakeholders.[142]

In health and social care research, meaningful descriptive responses to the 'what', 'why' and 'how' of participants' experiences or perception allows for development of knowledge informing policy development and evidence implementation.[142] The methodology has been applied in assessing how patients experience illness and associated healthcare interventions,[139,143] and in identifying critical information for refining existing guidelines and for programme development.[142,144] Qualitative descriptive methodology can provide rich subject information regarding concerns and issues that are grounded in both environmental and cultural contexts, and thus, is particularly useful when conducting research aimed at decreasing healthcare barriers for vulnerable groups, including SMI cohorts.[142]

3.3 Key realist terminology

Within this section, brief definitions of key terms within the application of realist review methodology are provided, with a focus on terminology employed within realist data analysis. These are provided here given that realist research remains in its infancy within mental health research.[106] These terms are referred to frequently within chapter 5, where additional explanation is not provided.

3.3.1 Context

Context refers to any condition that triggers and/or modifies the behaviour of a mechanism. Context refers to important features of the circumstance(s) in which an intervention 'works' (or a phenomenon of interest happens), which 'trigger' the mechanisms that generate outcomes. Context is always understood as functioning to activate the mechanism within a context-mechanism-outcome configuration (explained below). Alterations in context over time or in different settings will affect whether – and which – mechanisms are in operation. Realists understand interventions as attempts to manipulate contexts, with the aim of creating conditions in which certain mechanisms will be triggered and so, produce desired outcomes.[117]

3.3.2 Mechanism

The ultimate aim of a realist review is to generate new understandings of causal 'mechanisms' responsible for outcomes of interest.[123] Mechanisms represent the underlying processes by which outcomes of interest are generated and offer an explanation for why and how outcomes occur. Within realist research, mechanisms are causal processes that are hidden and context-sensitive. Thus, applying a realist logic of analysis within realist reviews involves interpreting data to make inferences about mechanisms. The realist philosophy of science underpinning realist analysis posits that mechanisms are inherent in social structures, objects and individuals and only take effect within certain 'activating' contexts.[117] This assumption provides a warrant for the transferability of realist causal explanations across settings. Thus, causal explanations interpreted using one set of data may have explanatory value in other situations where it may be reasonable to believe that the same mechanisms may be in operation.[123,134,135]

The 'hidden' nature of mechanisms refers to the fact that mechanisms are usually descriptions of the tendencies, reasoning and behaviour of an intervention's target participants and their response to the important contexts in which they operate (i.e., where interventions are implemented). This understanding allows for identification of solutions to complex problems, by developing theory-informed responses in the form of recommendations or new intervention designs.[123]

3.3.3 Outcome

Realists have a broad and flexible understanding of outcomes.[123] An outcome is anything caused by a mechanism. Outcomes can be interpreted as in other evidence syntheses, i.e., empirically measurable outcomes. However, realist reviews are not confined to considering only the final intended outcomes of an intervention or available, or measurable, proxies. Proximal outcomes i.e., process outcomes, are also of interest in generating an understanding of causation. Understanding how undesirable outcomes are generated can be of interest within realist data analysis.[123]

3.3.4 Context-mechanism-outcome configuration (CMOC)

Realist causal explanations are configurations representing the relationship between context, mechanism and outcome, usually presented as a context-mechanism-outcome configuration or a CMOC. A realist causal explanation for an outcome involves an understanding of the mechanism that produces it, and identification of what is functioning as context to activate or 'triggers' causative mechanism(s). Realist researchers use the heuristic: context + mechanism = outcome (C+M=O) as a way of demonstrating the relationship between the conceptual components demanded by a realist explanation of causation.[123]

3.3.5 Programme theory

The primary goal of undertaking realist data analysis is the production of programme theory i.e., theory explaining the composition of an intervention and how it is thought to work.[123] Programme theory can also be thought of as a theory explaining how outcomes of interest are generated.

Programme theory is typically expressed as a narrative description or diagrammatically. The unit of analysis or explanation is a CMOC. Programme theory usually contains multiple CMOCs and explains the relationship between them.[123] Within realist reviews, often multiple programme theories are produced, for example, explaining the effectiveness of interventions within different implementation contexts.[145]

3.3.6 Substantive theory

Substantive theory, also known as formal theory, refers to theories that operate in different domains or disciplines.[121] Realist programme theories informed by substantive theories are typically more effective than those that are not.[146] This is because substantive theories can provide a bridge to a wealth of existing research and knowledge about a topic and can inform several steps within development of programme theory. Most commonly, substantive theory informs the identification of mechanisms, important features of context, and in explaining how (often apparently disparate) sets of findings fit together.[121]

3.3.7 Realist data analysis – interpreting mechanisms and developing programme theory through induction, deduction, abduction and retroduction

To develop programme theory, data need to be identified as relevant, analysed, inferences made, and arguments constructed. Steps involved inference-making involve: (i) induction, (ii) abduction, (iii) deduction and (iv) retroduction.[134,147,148] Explanations of each can be found in Table 3.

Table 3 - Explanations of inductive, deductive, abductive and retroductive reasoning.[134,147,148]

Approach to inference-making	Conceptualisation
Induction	To generate theory from evidence. Inductive thinking involves projecting from what is known to what is not known and is applied to identify patterns across evidence sources to draw conclusions.
Deduction	To test a theory against evidence. Deductive thinking is applied to distil constructs from the sources of evidence towards construction of explanatory theories.
Abduction	To interpret and re-contextualise observed outcomes and events, identify mechanisms and contextual conditions to formulate the 'best explanation'.
Retroduction	To theorise and test for hidden causal mechanisms responsible for manifestation of the empirical, observable world.

Within realist data analysis, retroductive theorising is a key methodological process in understanding pheonmena.[147] Retroductive theories obtained from realist reviews are ontologically considered an approximation of the truth regarding the phenomenon under consideration.[134,135] Retroduction is closely associated with the concept of abductive theorising. Whereas retroduction is inference to theorise and test hidden mechanisms, abduction represents the inventive thinking required to imagine the existence of such mechanisms.[147] Abduction has been referred to as "*pragmatic theorising with a focus on creativity as a logic of inference"*.[149] Abduction is a gut feeling, hunch or informed imagination that leads to new ideas for generating theories and testing possible mechanisms.[147] Retroduction and abduction in the scientific realist process can be seen as a proverbial 'two sides of a coin'. Whilst abductive theorising is epistemological in the sense of directing attention to how we should think in terms of scientific innovation, retroduction is ontological in the sense of unearthing mechanisms part of manifested reality.[147,148]

3.4 Key steps involved in realist review methodology

Configurational and aggregative reviews have many overlapping steps.[136] However, there are several distinctive steps within realist review methodology.[121] Whilst methods applied are detailed in chapter 5, a broad overview of the four key steps involved in conducting a realist review is contained in Table 4, adapted from Pawson et al.[119]

Table 4 - Overview of steps involved in realist reviews.[119]

Step	Purpose	Considerations for researchers
1. Confirming the scope of the review	Defining the research question	- What is the content of the intervention? - What are the typical circumstances or contexts for its use? - What are the policy intentions or objectives with regards to the intended use of the intervention? - What outcomes are commonly assessed following use of the intervention?
	Clarifying the purpose (s) of the review	Within the final programme theory or theories, what is the intended explanatory lens? - Theory integrity – does the intervention work as predicted? - Theory adjudication – which theories addressing aspects of the intervention appear to fit best? - Comparison – how does the intervention work in different settings, for different groups? - Reality testing – how does the policy intent of the intervention translate into practice?
	Identifying and presenting initial programme theories to be further explored	- Conduct exploratory literature searches. - Formulate a list of programme theories. - Prioritisation of which theories to be tested (depending on project scope and resources).

2. Searching and selecting available evidence	Search for the evidence to test initial programme theories	- Decide search methods including sources (databases, supplementary search methods), index terms and key words to be used. - Decide and define purposive sampling strategies that could be used, if required, for example in the case of excess volume of data beyond the review team's capacity to analyse. - The realist researcher should not aim for an encyclopaedic coverage of all possible relevant literature. Rather than including all potentially relevant data sources, purposive sampling is a technique used where data sources are chosen for inclusion based on their characteristics. An example includes choosing data sources specifically based on their ability to contribute to some aspect of programme theory development.
	Appraise the quality of evidence	- Consider relevance, rigour and richness of each data source contributing to the review.
3. Data extraction and synthesis of findings	Extract relevant information from each data source	- Develop and pilot supportive data extraction forms or templates. - Extract relevant information to test, refine or refute new or emerging context-mechanism-outcome configurations and programme theories
	Synthesize findings	- Compare and contrast findings across data sources. - Seek both confirmatory and contradictory findings. - Refine programme theories considering emerging evidence.
4. Developing recommendations for practice and policy		- Disseminate review findings, conclusions, and recommendations.

For the purposes of further differentiating key distinctions between realist and systematic review methodology, further detail will now be provided on the following steps within realist review methodology: (i) developing the research question, (ii) searching for evidence to build programme theory, and (iii) assessing quality of data sources and programme theory.

3.4.1 Developing the research question

Within realist review methodology, defining and redefining the focus of the review, and thus, the question(s) the review will answer, is an iterative process and requires ongoing review considering emerging findings. This is based on the complexity of interventions typically studied within realist reviews and the different review questions, i.e., focus on providing explanatory statements, rather than final judgements about what works. In opening the 'black box' of understanding complex interventions, application of realist review methodology does not claim to provide an understanding of the full complexity of interventions. Instead, realist reviews take a particular 'cut' at key questions needed to understand how, when, why, for whom, and in what circumstances, such interventions are likely to work. Given the potential range of explanatory questions that can be addressed, as literature is searched and initial programme theories (IPTs) developed, in most cases it is necessary to refine what research questions should be addressed as a priority.[119]

3.4.2 Searching for evidence to build realist programme theory

Once an initial focus for the review question is agreed, the next step involves developing IPTs. IPTs represent initial statements attempting to explain how, when, why, for whom, and in what circumstances, interventions are likely to work. The purpose in developing IPTs is to surface and articulate available working theories that lie behind an intervention. Every intervention has a theoretical underpinning - whether made explicit or not.[146] IPTs are developed typically through exploratory literature searches, but also by consulting the project team's own knowledge and through liaison with key stakeholders.[150] Once formulated, IPTs are then 'tested' (confirmed, refuted or refined) using the best available evidence, and from which final programme theories are developed.[119,121] To build coherent arguments and

plausible programme theory, multiple sources of evidence beyond intervention studies are required.[136]

Realist reviews reject the hierarchy of evidence applied in systematic review methodology. In realist reviews, the range of eligible data sources goes far beyond RCTs.[151] A primary problem with testing complex interventions within an RCT is that such interventions are always implemented in the midst of (and therefore are influenced by) other contextual factors within implementation settings. Thus, implementation attempts are never alike in their different incarnations. Any other setting chosen as the comparator will also be in the midst of a maelstrom of change, making a clean comparison between implementation sites impossible. Whilst possible to perform an RCT on complex interventions, in many cases, such trials provide impoverished information because the RCT design is explicitly constructed to wash out vital explanatory ingredients.[122] Excluding all but a minority of studies on the basis of experimental rigour would reduce, rather than increase, the validity and generalisability of findings within realist reviews. Evidence sources are instead selected based on their ability to provide relevant information for individual contexts, mechanisms and outcomes.[119,152]

3.4.3 Assessing quality within realist reviews

3.4.3.1 Assessing quality of individual data sources

If evidence included in reviews is to inform practice and policy, then it should be free of bias and primary studies should have been carried out to the highest quality standards. Whilst realist reviews support this principle, realist researchers adopt a different position to how quality is appraised.[119,136] Appraisal of evidence of individual evidence sources depend less on the study's methodological quality and more on its contribution to our understanding of generative causation.[134] Whilst each data source must meet a set of minimum criteria highlighted in Table 5,[121] a study should not be excluded based on not meeting a single quality criterion. The exclusive use of checklists to establish quality of individual evidence sources is also not the solution, as realist reviews commonly rely on grey literature (e.g., impact

evaluations, process evaluations, surveys, legislative analysis), for which there is no standardised quality checklist. The realist solution to quality assessment is to cut directly to judgement, whereby relevance, rigour and richness of each data source are considered.[119,136] Brief definitions of each are outlined in Table 5.[118,134]

Table 5 - Assessing quality of data sources for inclusion in realist reviews: defining quality criteria for relevance, rigour and richness.[118,134]

Concept	Definition
Relevance	Whether evidence within the data source could contribute to some aspect of the testing and advancement of the programme theory.
Rigour	Whether methods used to generate the relevant data within the evidence source are credible and trustworthy to warrant changes to the programme theory. Assessment of quality should also be made at the level of PT by assessing plausibility of final theories, based on trustworthiness of available data and coherence of arguments made.[146]
Richness	Can be considered as conceptual richness and/or contextual thickness. Conceptual richness is the degree of theoretical and conceptual development that explains how an intervention is expected to work. Contextual thickness entails sufficient detail for the reader to (i) establish what is occurring in the intervention and in the wider context and (ii) infer whether findings can be transferred e.g., to other people, places, situations, and environments.

In considering 'quality' in realist reviews, assessment of the trustworthiness of data sources is just one narrow, but important, dimension of the judgements needed regarding quality. Wong has argued that assessment of rigour should be predominantly undertaken at the level of the programme theory.[146]

3.4.3.1 Assessing quality of realist programme theory

Realist programme theory should be underpinned by arguments made based on the most trustworthy data. However, this is often unachievable, and data of varying trustworthiness may be all that can be found to inform programme theory. Even data of limited trustworthiness can make some contribution to building arguments underpinning a realist programme theory that are plausible. To judge plausibility of final programme theory, coherence of arguments developed is necessary. Coherence in realist terms refers to how logical and consistent an argument is. The highest quality theory is plausible because it is supported by coherent arguments, based on trustworthy data.[146] In judging specifically the coherence of arguments made, one approach suggested by Wong is to apply the 'Inference to Best Explanation' model,[153] whereby coherence of arguments made is judged through consideration of the following criteria:[146]

1. Consilience (or explanatory breadth) – the ability of the theory to explain as much of the data as possible.
2. Simplicity – the theory that is simple and does not have to have special assumptions made to it, i.e., that final theory should be as parsimonious as possible.
3. Analogy – the theory fits with what we know and/or substantive theory.

Assessment of a theory using these criteria must consider all three principles together.[146]

3.5 Chapter summary

The rationale behind application of a positivist research paradigm, and use of systematic review and meta-analysis methodology in the case of addressing predictability of AIWG using non genetic prognostic-factors, was first discussed. This was followed by a discussion on the appropriateness of the application of a realist philosophy of science and associated realist review methodology in addressing how and why interventions aimed at increasing application of SDM work. Given the novelty of realist reviews within psychiatric research, considerable attention was given to explaining key concepts applied within a realist methodological orientation, including generative causation, context-mechanism-outcome configurations, the varying types of theorising required within inference-making, and the production of quality realist programme theory. In the case of the final research question, the rationale for use of a constructivist research paradigm, and specifically qualitative descriptive methodology, were provided.

Chapter 4 - Predicting antipsychotic-induced weight gain in first episode psychosis – A field-wide systematic review and meta-analysis of non-genetic prognostic factors

4.1 Chapter description

In chapter 1, the potential significance of targeting typically resource-intensive management interventions towards those at highest risk of clinically significant AIWG was discussed. One way of facilitating this may be through the application of prognostic factors. A prognostic factor is any measure that, among people with a given health condition is associated with a subsequent clinical outcome.[154] Prognostic factors thus distinguish groups of individuals with a different average prognosis. Genetic and non-genetic prognostic factors have been studied for their influence in predicting the prognosis of AIWG.[78,155,156] A systematic review of pharmacogenomic associations of AIWG concluded that effect sizes of individual gene variants were too small to fulfil the promise of personalised medicine, and that future studies should explore effects of combining genetic markers alongside clinical variables to improve prediction.[78] However, no similar evidence synthesis of non-genetic prognostic factors has been undertaken. In this chapter, results of a field-wide systematic review and meta-analysis of non-genetic prognostic factors in predicting anthropometric outcomes following antipsychotic initiation is discussed.

Work presented in this chapter has been published as: ***Fitzgerald I,*** *Sahm LJ, Byrne A, et al. Predicting antipsychotic-induced weight gain in first episode psychosis – A field-wide systematic review and meta-analysis of non-genetic prognostic factors. European Psychiatry. 2023;66(1):e42.*

4.2 Introduction

Managing AIWG is challenging for patients, clinicians, and policy makers alike. This is partly due to extensive interindividual variability in anthropometric outcomes following antipsychotic commencement.[24] Whilst antipsychotic choice is an established differentiator of risk,[107] genetic and non-genetic prognostic factors have been studied for their influence on AIWG prognosis.[78,155,156] A systematic review of pharmacogenomic associations of AIWG concluded that effect sizes of individual gene variants were too small to fulfil the promise of personalised medicine, and that future studies should explore effects of combining genetic markers with non-genetic variables within prognostic models to improve individual prediction.[78] However, no similar systematic review of non-genetic prognostic factors has been undertaken to inform such work. Though often ignored amidst the drive for more complex genetic measures, many simple, routinely collected patient characteristics have been shown to influence the prognosis of some side effects of medications.[157,158]

A range of biological (e.g., thyroid functioning, insulin resistance), clinical (e.g., positive and negative symptom burden) and sociodemographic (e.g., age, sex) variables have been evaluated for their influence on AIWG trajectory.[34,76,159,160,161] However, in the absence of a systematic appraisal of this research, the value of non-genetic prognostic factors in influencing AIWG prognosis is currently unknown, whereby non-genetic prognostic factors represent a potentially underexploited resource within AIWG prognostication. Whether current research supports the use of non-genetic prognostic factors in identifying those at highest risk of AIWG prior to, or early in, antipsychotic treatment, is a question of significant practical importance for both clinicians and patients. For example, by influencing stratified use of typically resource-intensive preventative AIWG interventions and targeting their use towards those most likely to derive the largest absolute benefits.[63,162] Thus, establishing the clinical utility of non-genetic prognostic factors is a priority within AIWG management research.

4.2.1 Aims and objectives

The aim of this review was to identify, synthesize and appraise research evaluating non-genetic prognostic factors and their association with anthropometric outcomes following antipsychotic initiation. Review objectives included:

(i) To identify the non-genetic prognostic factors that have been investigated for their role in AIWG prognosis.

(ii) To determine the direction, strength, and quality of all prognostic factor-outcome associations.

(iii) To determine the clinical utility of any significant and reliable prognostic factor-outcome associations.

For the purposes of this review, a non-genetic prognostic factor-outcome association was defined as any association that did not include the study of a gene variant and its relationship with AIWG prognosis. This includes, but was not limited to, measurement of clinical, sociodemographic, or biological variables and their potential role as prognostic factors.

4.3 Methods

The protocol was registered *a priori* on PROSPERO (CRD42021258148) and published separately.[67] Protocol deviations and a copy of the completed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for this review are contained in appendices 1 and 2, respectively.[163] Review methodology adhered to guidance produced by the Cochrane Prognosis Methods Group.[154]

4.3.1 Eligibility criteria

A summary of the modified PICOTS (Population, Index Prognostic Factors, Comparator Prognostic Factor, Outcomes, Timing and Setting) approach recommended for systematic reviews of prognostic factors applied to this review is outlined in Table 6.[154]

Table 6 - Modified PICOTS criteria applied to this review.[154]

Item	Definition
Population	Adult participants (16 years of age or older) diagnosed with a first episode of psychosis in the context of: - Brief psychotic disorder - Schizophrenia and associated phenotypes, including schizoaffective disorder - Delusional disorder Diagnosis is made in accordance with standardized clinical criteria (i.e., DSM-V/ICD-10)* Participants must be antipsychotic-naïve. For the purposes of this review, antipsychotic-naïve is defined as: - Six weeks or less lifetime antipsychotic exposure - 0-2 weeks exposure prior to trial/study enrollment - Never received a long-acting form of antipsychotic Studies where most participants (80% or more) met the above criteria were also included.
Index prognostic factors	Any non-genetic, including clinical (e.g., positive/negative symptomology), sociodemographic (age, sex, socioeconomic status), or biological (e.g., baseline weight, blood markers) prognostic factor measured upon or immediately prior to antipsychotic initiation and examined prospectively for an association with change in a subsequent anthropometric outcome(s). Studies that measured a prognostic factor with an initial baseline and subsequent repeat assessment post antipsychotic initiation but within the acute treatment phase i.e., change over time was assessed were also included, given the relevance of early change in such variables to the review question.
Comparator prognostic factors	Not applicable
Outcomes	**Primary outcomes**

	- Relationship between one or more non-genetic prognostic factor and mean change in weight (kg) following antipsychotic commencement. - Relationship between one or more non-genetic prognostic factor and mean change in BMI following antipsychotic commencement. - Relationship between one or more non-genetic prognostic factor and likelihood of experiencing clinically significant weight gain following antipsychotic commencement. Clinically significant weight gain is most commonly defined as a ≥7% increase in body weight,[67] but studies where this outcome was defined as a ≥5% increase were accepted. **Secondary outcomes:** - Relationship between one or more non-genetic prognostic factor and mean change in waist circumference (cm) following antipsychotic commencement.
Timing	No restrictions.
Setting	No restrictions.

*DSM-V = The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
*ICD 10 (International Classification of Diseases, Tenth Edition

Both randomised controlled trials (RCTs) and prospective non-randomised studies (NRS) with a clear inception point were eligible for inclusion. Retrospective or cross-sectional studies were excluded for reasons of increasing evidence certainty and strength of review conclusions. In establishing the prognostic value of potential prognostic factors, a prospective rather than retrospective design is preferable as it enables clear inclusion criteria, more complete baseline and follow-up data, greater standardisation of diagnostic and therapeutic procedures, and ensures primary prognostic factors and outcomes are specified in advance, reducing the potential for data dredging and type 1 errors.[164]

Studies where the prognostic factor's effect size was unadjusted or adjusted for other prognostic factors were eligible for inclusion. Studies that looked exclusively

at antipsychotic class/subclass or gut microbiome variants as potential prognostic factors were excluded. Scoping reviews completed during project planning identified gut microbiome variant research as remaining in its infancy and largely restricted to animal models, and with the direction of the relationship at the time of the review undertaking being unclear.[165,166] Studies solely assessing the impact of the type of antipsychotic prescribed were excluded as this is already an established differentiator of varying anthropometric outcomes.[24]

Studies that were classified as exploratory or confirmatory in design were included. Confirmatory studies (also referred to as Phase 2 studies) are designed to test the independence of a prognostic factor-outcome association and thus, provide more conclusive evidence compared to exploratory studies. Exploratory studies (also referred to as Phase 1 studies) aim to identify novel associations between prognostic factors and outcomes.[164] Studies were classified as exploratory or confirmatory according to author's objectives and approach to study design and analysis. Strict inclusion criteria were used to limit heterogeneity across studies and facilitate more meaningful interpretation of synthesized results.[154,167]

4.3.2 Search strategy

Focused and broad electronic database searches were conducted using index terms and free-text words and phrases relating to: (i) adults with psychosis, (ii) antipsychotic-induced weight gain and other anthropometric changes, e.g., BMI change, and (iii) prognosis and prognostic factors. PubMed, CENTRAL, PsycINFO and Embase were searched from inception until 30th of November 2021. Methods of searching each database are contained in appendix 3. Complementary searching methods were also undertaken in addition to database searches. This included forwards and backwards citation searching and contacting of two content experts. Content experts referred to researchers who have published significant work in AIWG management. CENTRAL database searching includes searching of trial registries, including ClinicalTrials.gov and the WHO's International Clinical Trials Registry Platform.[168] Forward citation searching was undertaken using the database Web of Science. All electronic database searches were repeated in February 2025 to

identify articles published between November 2021 and February 2025. Non-English language studies and grey literature were excluded.

4.3.3 Study selection

Rayyan (https://www.rayyan.ai) was used to screen title and abstracts of all database searches. Two reviewers independently screened all titles and abstracts (IF, LS, AB, EC). Disagreements were resolved via consensus and discussion with a third independent reviewer, where required. Study authors were contacted to clarify queries on study conduct or design. The same process was repeated for all full-text articles retrieved. Where multiple studies appearing to use the same or overlapping participant data were identified, the primary study was classified as the publication presenting the most relevant or comprehensive data for the review question.

4.3.4 Data extraction and management

Data extraction was undertaken using a modified version of the Checklist for Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies – Modified for Prognostic Factor Studies (CHARMS-PF).[154] The modified checklist used in the review can be found in appendix 4. All unadjusted and adjusted measures of association and variance estimates were extracted from each study. In the case of continuous outcome measures, regression coefficients and their standard errors (SE) were extracted. Regression coefficients could be expressed as an unstandardised regression coefficient (referred to as 'b') or a standardised regression coefficient (referred to as β or a beta weight). These can be interpreted as follows:[169]

1. **Unstandardised regression coefficient (b)** – describes the effect on the dependent variable by changing the explanatory variable by one unit. Hence, the impact on the dependent variable depends on the scale of the explanatory variable.
2. **Standardised regression coefficient (β) –** β is the estimate that results from an analysis carried out on variables that have been standardized, so that

their standard deviations are equal to one. Consequently, the standardised beta coefficient represents the number of standard deviations of change in the dependent variable for a one standard deviation unit change in the explanatory variable, while controlling for other variables. Standardised regression coefficients are used in meta-analyses when the exposure levels in the case of variables included in the analysis are measured in different units of measurement.

Where both standardised and unstandardized regression coefficients were reported, both were extracted. However, preference was given to synthesizing unstandardized regression coefficients within meta-analyses to facilitate result interpretation. In the case of binary outcome measures, i.e., risk of clinically significant weight gain (CSWG), odds ratios (OR) or risk ratios (RR), and their SE were extracted. If these estimates were unavailable, to avoid potential selection bias, attempts were made to recover them using alternative information provided and using available conversion formulae.[169] For example, via correlation coefficients or mean values of outcome variables reported between two exposure groups.[154] Before conversions were undertaken, study authors were contacted to request missing results. Where required, individual study associations and their measures of variance were appropriately transformed to their natural logarithms to normalise their distribution.

4.3.5 Risk of bias

Risk of bias was assessed independently by pairs of review authors (IF, EC, LS, JOC, CNiD) using the Quality in Prognosis Studies (QUIPS) tool.[170] Domains assessed within the QUIPS tool include: (i) study participation, (ii) study attrition, (iii) prognostic factor measurement, (iv) outcome measurement, (v) study confounding, and (vi) statistical analysis and reporting.[170] Each domain was judged as being at high, moderate, or low risk of bias, according to criteria outlined by Riley at al.[154] An overall rating of bias to a given study is not recommended when using QUIPS.[170] Ratings from QUIPS assessment of individual studies informed GRADE's (Grading of Recommendations, Assessment, Development, and Evaluation) quality assessment

of prognostic factor-outcome associations across studies. Disagreements between reviewers were resolved via consensus and recourse to a third author, where necessary. Attempts were made to contact study authors for information required to accurately complete assessments.

4.3.6 Data synthesis

Meta-analysis was conducted when usable data were available reporting the prognostic association between a factor and outcome in ≥3 studies deemed sufficiently homogenous. Separate meta-analysis was considered in the case of:

1. Adjusted and unadjusted associations.
2. Prognostic factor effects measured at different cut-offs.
3. Different methods of measurements (for prognostic factors and outcomes).
4. Different timepoints of outcome assessment.

In the case of adjusted prognostic associations, only adequately adjusted results were considered suitable for meta-analysis.[154] A minimum set of adjustment factors was decided upon based on existing evidence of their association with weight trajectory in the general population (age, sex, ethnicity) [171] and the known influence of antipsychotic prescription on AIWG prognosis.[107] All analyses were conducted via STATA (StataCorp version 17) and via application of a random-effects generic inverse variance meta-analysis model. Restricted maximum likelihood estimation (REML) was used to fit all analyses, with 95% confidence intervals (CI) derived using the Hartung-Knapp Sidik-Jonkman (HKSJ) approach to account for uncertainty in estimated variances.[172] Statistical heterogeneity was quantified using the I^2 statistic (which provides the proportion of total variability due to between-study heterogeneity) and the estimated between-study variance ('tau-squared').[173] In the case of significant heterogeneity identified, *a priori* planned subgroup analyses (provided there were at least three studies per subgroup) included: (i) antipsychotic subgroup prescribed (where varying) and (ii) country where the study was conducted.

To reveal the impact of heterogeneity more clearly, in the case of an individual prognostic factor being assessed in ≥5 studies, a 95% prediction interval for the prognostic effect was calculated. In the case ≥10 studies suitable for synthesizing via meta-analysis, it was planned that publication bias would be examined for by visually examining asymmetry using contour-enhanced funnel plots and appropriate statistical tests.[174] In the case of insufficient study numbers precluding combination via meta-analysis, or in the case of heterogeneity making combined results difficult to interpret meaningfully, results were presented qualitatively.

4.3.7 Certainty of evidence

Overall evidence quality of each prognostic factor-outcome association was assessed using a GRADE modified approach for prognostic factor research.[171] A quality rating in support of each prognostic factor-outcome association assessed across studies was assigned as high, moderate, low, or very low. Evidence quality was downgraded according to (i) early phase of investigation, (ii) study limitations, (iii) inconsistency, (iv) indirectness, (v) imprecision, and (vi) publication bias. As per guidance by Huguet et al,[174] publication bias was assumed in the case of all factors unless a similar association between the factor and outcome had been assessed repeatedly in independent studies. Evidence quality could be upgraded where evidence of a moderate-large effect size, or exposure-response gradient, was consistently demonstrated across studies.[171] GRADE assessments were initially conducted by IF and reviewed independently by a second author (EC, LS). Disagreements were resolved via discussion and recourse to a third reviewer, where necessary. Interpretation of each GRADE quality level can be found in Table 7.[171]

Table 7 - Interpretations of GRADE quality ratings.[171]

Quality level	Definition
	Interpretations of GRADE quality ratings for each rating
High	We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

4.4 Results

4.4.1 Study selection

Following repeat searches in February 2025 and duplicate removal, database searching yielded 4,750 articles for title and abstract screening. Of the 216 studies eligible for full-text review within database searches, 20 met inclusion criteria. Of 123 assessed, a further 9 eligible studies were identified through supplementary search methods. Studies involving apparent duplicate populations were identified in 10 cases. Twenty-nine studies were deemed eligible for final inclusion. Figure 3 contains the final PRISMA flow diagram of the study selection process i.e., an overview of all results from original (November 2021) and repeat (February 2025) searches.

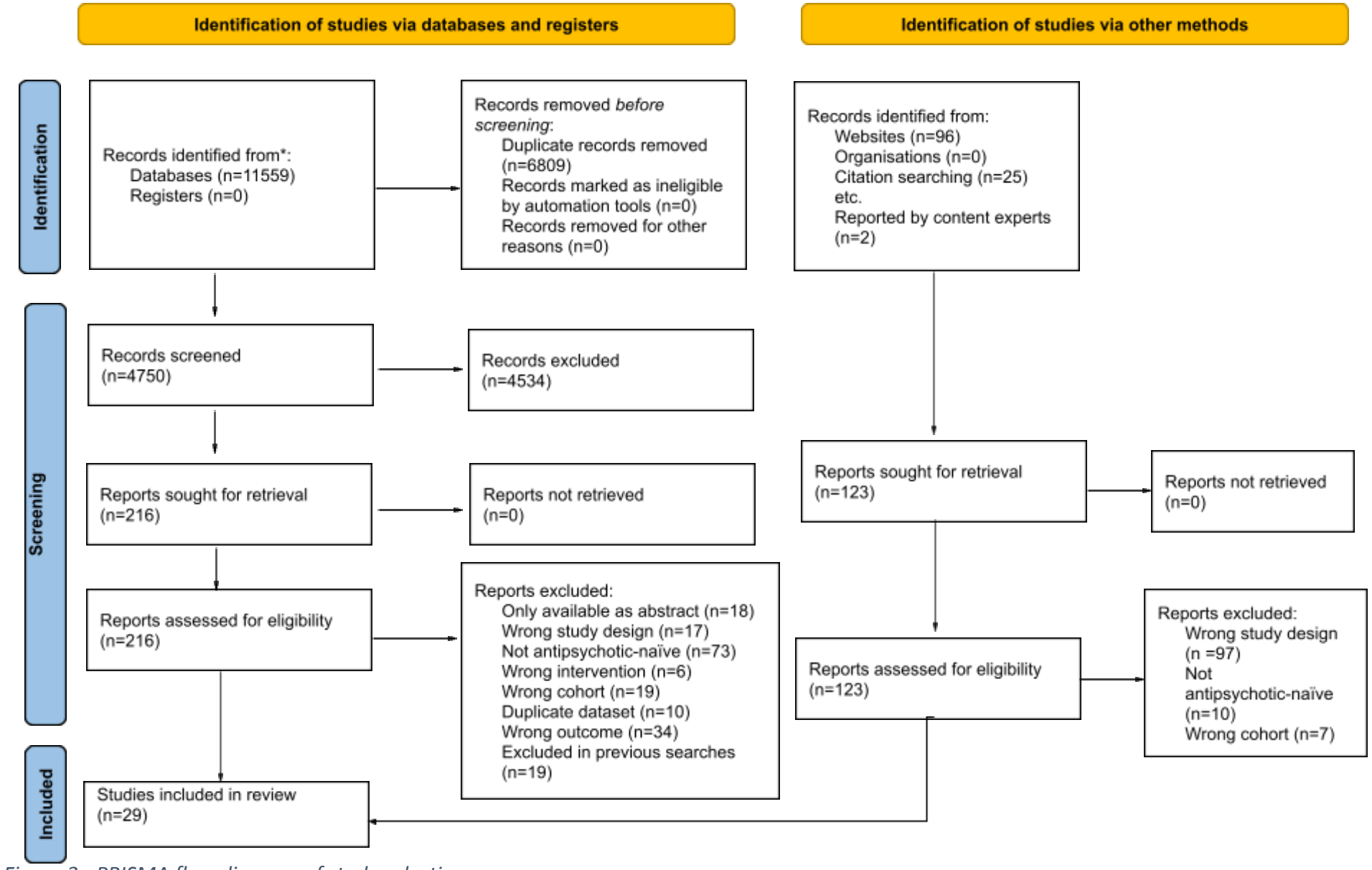


Figure 3 - PRISMA flow diagram of study selection process.

4.4.2 Study characteristics

Table 8 contains a detailed overview of study characteristics. Seventy-eight unique prognostic factors were assessed across studies involving 4,706 participants. Across studies, 83% were prospective cohort studies and the remaining were retrospective analyses of RCTs. Study populations comprised both inpatient and outpatient cohorts. 15/29 studies were classified as exploratory and 14/29 confirmatory in design. Confirmatory studies generally involved comparatively smaller participant numbers (n<100), with the exception of two studies.[175,176] Within these studies, 37% were conducted in exclusively Chinese populations, although these were primarily exploratory. Change in BMI was the most studied outcome, followed by change in weight, risk of CSWG, and change in waist circumference, respectively. Median follow-up time was 12 weeks (IQR 18) and ranged from 4 weeks to 6 years. In the case of adjusted analyses, 46% of analyses were considered adequately adjusted for covariates. Inadequately adjusted assignment was most commonly due to lack of adjustment for varying antipsychotic prescription.[177,178,179,180,181] Only one study evaluating birth weight as a prognostic factor assessed for the presence of a non-linear relationship.[182]

Table 8 - Overview of study characteristics of all studies included within the review, arranged chronologically with most recent first.

First author, year, country	Population characteristics	Number enrolled	Phase	Primary prognostic factor(s) assessed	Primary outcome(s) assessed
Zhang (2024), China [183]	Age (years) = 27.2 (7.19), 34% male, BMI* = 21.91 (3.83)	80	1 – Exploratory	**Range**: 1,913 lipid metabolites.	(1) % Weight change and (2) risk of clinically significant weight gain at 8 weeks
Qiu (2023), China [184]	Age = 40.47 (11.50), 50% males, BMI = 22.85 (3.22)	200	1 – Exploratory	**Range**: 54 differential metabolites	(1) BMI change and (2) change in waist circumference at 8 weeks
Vázquez-Bourgon (2022), Spain [178]	Age = 29.3 (8.8), 54.5% male, BMI = 23.77 (3.77)	307	1 – Exploratory	**Range:** (sex, age, duration of untreated psychosis, housing arrangement, ethnicity, smoking status, baseline BMI, baseline waist circumference, positive symptom burden, negative symptom burden)	(1) Weight change and (2) BMI change at 52 weeks
Kang (2022), China [185]	Age = 27.5 (9.73), 37.3% male, BMI = 20.86 (2.20)	51	2 – Confirmatory	Plasma antipsychotic concentration	(1) Weight change, (2) BMI change at 8 weeks
Muntane (2022), Spain [186]	Age = 30.63 (9.57), 58% male, BMI = 23.19 (3.81)	381	1 - Exploratory	**Range**: Age, sex, baseline BMI, antipsychotic prescribed, antipsychotic dose, primary diagnosis, concomitant antidepressant use, BMI increase	BMI change at 12 and 52 weeks

Chen (2021), China [175]	Age = 27.1 (9.1), 51% male, BMI = 21.4 (3.1)	526	2 – Confirmatory	Response to antipsychotic treatment (positive symptoms, negative symptoms, total psychopathology, general psychopathology)	Weight change at 8 weeks
Lin (2021), China [187]	Age = 27.60 (8.31), 59% male, BMI = 21.61 (3.91)	22	2 – Confirmatory	Illness severity – positive symptoms	BMI change at mean 6.04 years (2.16)
Liu (2021), China [176]	Age = 27.9 (9.3), 55% male, BMI = 21.4 (3.5)	225	2 – Confirmatory	**Range**: Antioxidant enzymes (Superoxide dismutase (SOD), Catalase (CAT), Glutathione peroxidase (GPx), Malondialdehyde (MDA)	Weight change at 12 weeks
Lago (2021), Spain [177]	Age = 29.4 (8.5), 62% male, BMI = 22.9 (5.1)	58	2 - Confirmatory	Metabolic markers expressed on peripheral blood mononuclear cells (glucose transporter 1, insulin receptor, fatty acid translocase on CD4+ T cells, CD8+ T cells, CD4-8- T cells, B cells and monocytes)	BMI change at 12 weeks
Canal-Rivero (2020), Spain [181]	Age = 31.12 (9.76), 55.5% male, BMI = 22.99 (3.88)	596	1 – Exploratory	**Range:** (age, dietary habits at 3-month follow up, baseline BMI)	Weight change at 1,2 and 3 years
Huang (2020), China [188]	Age = 23.5 (no estimate of variance provided), 36.4% male, BMI = 21.3 (1.7)	33	2 - Confirmatory	Early appetite increase	(1) Weight change and (2) BMI change at 12 weeks
Luckhoff (2020), South Africa [189]	Age = 25.8 (6.8), 73% male, BMI = 21.76 (4.04)	90	2 - Confirmatory	Hippocampal subfield volume – anterior + posterior	BMI change at 52 weeks

Pandit (2019), multisite [155]	Age = 26.2 (6.08), 71.3% male, BMI = 23.4 (5)	446	1 – Exploratory	**Range**: age, sex, ethnicity, employment status, primary diagnosis, comorbid MDD, illness severity, previous antipsychotic treatment, inpatient vs. outpatient care, baseline body weight	(1) Risk of clinically significant weight gain at 4 weeks (2) Weight change at 4 weeks
Homan (2019), multisite [190]	Age = 21.5 (5.5), 72% male, BMI = 23.6 (4.4)	81	2 – Confirmatory	Striatal volume, Striatal resting-state functional connectivity	Weight change at 12 weeks
Garriga (2019), Spain [182]	Age = 27.3, 61% male, BMI = 22 (3.1)	23	2 - Confirmatory	Birth weight	Weight change at 16 weeks
Zhou (2019), China [191]	Age = 26.16 (9.1), 51.2% male, BMI = 21.6 (3.9)	49	2 - Confirmatory	Sex	BMI change at 12 weeks
Li (2018), China [192]	Age = 39.6 (11.5), 44.7% male, BMI = 23.21 (3.84), Diagnosis = first episode schizophrenia (FES)	296	1 – Exploratory	**Range:** (age, sex, baseline BMI, systolic blood pressure, fasting triglycerides, fasting high density lipoprotein cholesterol (HDL-C), fasting LDL-C, total cholesterol, albumin, urea, C-Reactive Protein (CRP), Triiodothyronine (T3), Duration of illness, Waist-hip ratio, Diastolic blood pressure, total protein, fasting plasma glucose, Thyroid stimulating hormone (TSH), Thyroxine (T4)	Weight change at 12 weeks

Yuan (2018), China [193]	Age = 23.1 (8.0), 56% male, BMI = 20.54 (2.52)	80	1 – Exploratory	**Range**: Age, sex, smoking status, disease of illness	(1) Weight change and (2) BMI change at 24 weeks
Nielsen (2016), Denmark [194]	Age = 25 (6), 56% male, BMI = 25.5 (5.5)	69	2 – Confirmatory	**Range**: Striatal reward activity (right-sided putamen, Left-sided putamen, right ventral striatum, left ventral striatum)	Weight change at 6 weeks
Chiliza (2015), South Africa [161]	Age = 24 (6.5), 72% male, BMI = 21.6 (3.9)	133	1 – Exploratory	**Range:** (age, sex, substance abuse history, history of previous antipsychotic treatment, baseline BMI, baseline HDL-C, baseline LDL-C, fasting glucose, prolactin, baseline triglycerides, total cholesterol	BMI change at 52 weeks
Perez-Iglesias (2014), Spain [34]	Age = 27.3 (7.8), 61% male, BMI = 23.2 (3.5)	174	1 – Exploratory	**Range**: age, sex, ethnicity, employment status, primary diagnosis, comorbid Major Depressive Disorder (MDD), illness severity, previous antipsychotic treatment, inpatient vs. outpatient care, baseline body weight	Weight change at 3,12 and 36 months
Song (2014), China [195]	Age = 24.7 (7.5), 53% male, BMI = 20.14 (2.02)	78	2 – Confirmatory	Pro-inflammatory cytokines: Interleukin 1 beta (IL-1B), Interleukin 6 (IL-6), Tumour Necrosis Factor alpha (TNF-alpha)	Risk of clinically significant weight gain at 24 weeks
Rasmussen (2014), Denmark [196]	Age = 26.9 (5.5), 67% male, BMI = 24.2 (4.5)	30	2 – Confirmatory	Serotonin 2A (5HT2A) receptor binding capacity	Weight change at 24 weeks

Verma (2009), Singapore [180]	Age = 29.8 (6.2), 51.89% male, BMI = 21 (3.5)	56	1 – Exploratory	**Range:** (age, sex, baseline BMI, cumulative antipsychotic exposure, response to antipsychotic treatment – positive symptoms, fasting low density lipoprotein cholesterol (LDL-C), baseline triglycerides, baseline insulin secretion.	Risk of clinically significant weight gain* at 24 weeks
Medved (2009), Croatia [197]	Age = 31.07 (7.86), 0% male, BMI = 23.47 (4.43)	94	1 – Exploratory	**Range:** (antipsychotic prescribed, family history of diabetes mellitus, age, duration of illness, family history of cerebrovascular disorders, family history of obesity, smoking history, illness severity, primary diagnosis)	(1) Waist circumference and (2) BMI change at 12 weeks
Saddichha (2008), India [76]	Age = 26 (5.5), 52.5% male, BMI = 19.4 (3)	110	1 – Exploratory	**Range**: antipsychotic prescribed, baseline weight, baseline waist circumference, sex	(1) BMI change, (2) weight change, (3) Risk of clinically significant weight gain* at 6 weeks
Arranz (2007), Spain [198]	Age = 24.45 (7.04), 74% male, BMI = 21.75 (3)	38	2 – Confirmatory	Antipsychotic formulation – standard vs. disintegrating	(1) Weight change (2) BMI change at 6 weeks
Zipursky (2005), multisite [160]	Age = 23.8 (4.8), 82% male, BMI = 23.8 (4.6)	263	1 – Exploratory	**Range:** (age, sex, smoking status, primary diagnosis, premorbid functioning, age at illness onset, duration of untreated illness, history of previous antipsychotic treatment)	Risk of clinically significant weight gain at 104 weeks

Zhang (2003), China [179]	Age = 26 (8), 50% male, BMI = 22 (3)	117	1 – Exploratory	**Range:** (baseline BMI, illness severity, sex, age, response to antipsychotic treatment, duration of illness, antipsychotic dose, antipsychotic prescription)	BMI change at 10 weeks

* BMI in this column refers to body mass index at baseline.

4.4.3 Prognostic factor characteristics

A detailed overview of all seventy-eight prognostic factor-outcome assessments and reported effect sizes can be found in Table 9. Categories of factors assessed spanned clinical (e.g., psychopathology, comorbid psychiatric diagnoses), neurological (e.g., hippocampal volume, striatal functioning), biological (e.g., metabolites, antioxidant enzymes, pro-inflammatory cytokines), social (e.g., smoking status), medical (e.g., co-medications), sociodemographic (e.g., age, ethnicity), anthropometric (e.g., pre-antipsychotic weight), and cardiometabolic (e.g., fasting plasma glucose) groupings.

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
Zhang (2024) [183]	Lipid metabolites: (1)Ceramide Kinase P(d40:3) (CerP), (2)Phosphatidylcholine(20:1_22:6) (PC) (3) Triacylglycerol (12:1e_6:0_22:4)(TG)	(1) % change in weight at 8 weeks (2) Risk of clinically significant weight gain at 8 weeks	**Unadjusted estimates (r) =** CerP(d40:3) = r = 0.5, p = <0.001 PC (20:1_22:6) = r = 0.47, p = <0.001 TG(12:1e_6:0_22:4) = r = 0.46, p = <0.001 **Analysis (area under receiver operating characteristic curve (AUROC))** CerP(d40:3) = 0.76 (95% CI 0.63 – 0.90), cut-off = 0.23, sensitivity = 75%, specificity = 80.36% PC (20:1_22:6) = AUROC = 0.75 (95% CI = 0.62 – 0.88), cut-off = 0.66, sensitivity = 58.33%, specificity = 91.07% TG(12:1e_6:0_22:4) = 0.50 (95% CI 0.35 – 0.65) p = 0.983,

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			cut-off = 0.14, sensitivity = 29.71%, specificity = 85.71%
Qiu (2023) [184]	Metabolites: (1) Phosphatidylcholines (PC) aa C36:5 (2) Cholesteryl esters (CE) (20:5) (3) α-aminobutyric acid (ABAA)	Change in BMI at 8 weeks	**Partial correlation analysis results (r) =** PC aa C36:5 = r=0.392, p = 0.043 CE(20:5) = r = 0.417, p = 0.031 AABA = r = 0.416, p = 0.031
Chen (2021) [175]	Confirmatory study - Response to antipsychotic treatment ● Reduction in positive symptoms ● Reduction in negative symptoms ● Reduction in total psychopathology ● Reduction in general psychopathology	Change in weight at 8 weeks	**Unadjusted estimates (r) =** Decrease in PANSS (Positive and Negative Syndrome Scale) positive = 0.14, p = 0.004 Decrease in PANSS negative = 0.04, p = 0.47 Decrease in PANSS general psychopathology = 0.1 Decrease in PANSS total = 0.18, p <0.001 **Linear regression results (β) =**

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Age (years) = - 0.06 (95% CI -0.44 to 0.31), p = 0.73 Sex (F/M) = - 0.75 (95% CI -1.44 to -0.05), p = 0.035 Education (years) = 0.03 (95% CI -0.26 to 0.04), p = 0.45 Smoking (Y/N) = - 0.04 (95% CI -1.46 to 1.38), p = 0.96 Baseline BMI (kg/m^2) = - 0.29 (95% CI – 0.40 to – 0.18), p = <0.001 Age of illness onset (years) = 0.04 (95% CI -0.33 to 0.41), p 0.85 Atypical class of antipsychotic (Y/N) = 1.29 (95% CI -0.66 to 3.24), p = 0.19 Anticholinergic drug prescribed (Y/N) = - 0.08 (95% CI -1.51 to 1.35), p = 0.91

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Reduction in PANSS score total = 0.03 (95% CI 0.01 to 0.05), p = 0.002
Pandit (2019) [155]	Exploratory – range of candidate prognostic factors assessed	(1) Change in weight at 4 weeks (2) Risk of clinically significant weight gain at 4 weeks	**Linear regression results (β) =** Age (years) = - 0.07 (95% CI -0.13 to -0.01), p = 0.031 Sex (M/F) = 0.01 (95% CI -0.89 to 0.92), p = 0.982 Ethnicity (white vs. other) = 0.16 (95% CI -1.04 to 1.35), p = 0.798 Unemployed (Y/N) = 0.94 (95% CI 0.18 to 1.71), p = 0.016 Primary diagnosis (schizophreniform vs. schizophrenia) = 0.59 (95% CI -0.20 to 1.37) Comorbid MDD (Y/N) = 1.61 (95% CI -3.10 to -0.12), p = 0.034

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			PANSS total score = -0.01 (95% CI -0.03 to 0.01), p = 0.380 Antipsychotic-naïve (Y/N) = -0.50 (95% CI -1.32 to 0.33), p = 0.380 Inpatient versus outpatient care = -0.27 (95% CI -1.41 to 0.60), p = 0.537 Baseline body weight = -0.02 (95% CI -0.05 to 0.01), p=0.182 **Logistic regression results (OR) =** Age (years) = 0.96 (95% CI 0.91 – 1.01), p = 0.106 Sex (M/F) = 0.94 (95% CI 0.46 to 1.89), p = 0.852 Ethnicity (white vs. other) = 1.34 (95% CI 0.52 to 3.44), p = 0.545 Unemployed (Y/N) = 2.83 (1.50 to 5.36), p = 0.001

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Primary diagnosis (schizophreniform vs. schizophrenia) = 2.00 (95% CI 1.09 to 3.68), p = 0.025 Comorbid MDD = 0.39 (95% CI 0.08 to 1.79), p = 0.224 PANSS total score = 0.99 (95% CI 0.97 to 1.00), p = 0.085 Antipsychotic-naïve (Y/N) = 0.72 (95% CI 0.37 to 1.42), p = 0.345 Inpatient vs. outpatient care = 1.34 (95% CI 0.67 to 2.67), p = 0.407 Baseline body weight (kg) = 0.97 (95% CI 0.95 to 0.99), p = 0.032
Perez-Iglesias (2014) [34]	Exploratory – range of candidate prognostic factors assessed	Change in weight at 3,12 and 36 months	**Linear regression results (β) at 3 months =**

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Olanzapine treatment assignment = 0.185 (95% CI 0.04 to 0.33), p = 0.014 Sex (M/F) = 0.288 (95% CI 0.13 to 0.44), p = <0.001 Baseline BMI (kg/m^2) = -0.285 (95% CI -0.18 to -0.05), p = <0.001 **Linear regression results (β) at 12 months =** Poor social functioning (deficit vs. no deficit) = 0.159 (95% CI 0.00 to 0.32), p = 0.052 **Linear regression results (β) at 36 months =** Poor social functioning (deficit vs. no deficit) = 0.249 (95% CI 0.05 to 0.45)

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
Saddichha (2008) [76]	Exploratory – range of candidate prognostic factors assessed	(1) Weight change at 6 weeks (2) BMI change at 6 weeks (3) Waist circumferences change at 6 weeks	**Unadjusted analysis for change in BMI =** Baseline weight, r = 0.248 (no standard error or confidence interval provided), p = <0.01 **Unadjusted analysis for change in waist circumference =** Baseline waist circumference, r = -0.251 (no standard error or confidence interval provided), p<0.01 Baseline weight, r = -0.246 (no standard error or confidence interval provided), p<0.01 Sex (M/F), F test = 5.602 (no standard error or confidence interval provided), p<0.001 Linear regression results (β) for all outcomes only results of antipsychotic prescription

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			were described which were not under explicit investigation as part of study question due to established association.
Kang (2022) [185]	Confirmatory – Olanzapine plasma concentration	(1) Change in weight at 8 weeks (2) Change in BMI at 8 weeks	**Unadjusted results for change in weight (rho) =** Sex (M/F) = 0.086 (no standard error or confidence interval provided), p = >0.05 Smoking (Y/N) = 0.256 (no standard error or confidence interval provided), p = >0.05 Course of illness (years) = 0.021 (no standard error or confidence interval provided), p = >0.05 Olanzapine concentration (ng/ml) = 0.375 (no standard error or confidence interval provided), p = <0.01

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Baseline BMI (kg/m^2) = 0.987 (no standard error or confidence interval provided), p = <0.01 Fasting glucose (mmol/L) = 0.096 (no standard error or confidence interval provided), p = >0.05 Triglycerides (mmol/L) = -0.095 (no standard error or confidence interval provided), p = >0.05 Total cholesterol (mmol/L) = 0.114 (no standard error or confidence interval provided), p = >0.05 LDL-C (mmol/L) = 0.137 (no standard error or confidence interval provided), p = >0.05 HDL-C (mmol/L) = 0.377 (no standard error or confidence interval provided), p = <0.01

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Baseline PANSS measurement = 0.126 (no standard error or confidence interval provided), p = >0.05 BMI rate change = 0.977(no standard error or confidence interval provided), p = <0.01 **Unadjusted results for change in BMI (rho) =** Sex (M/F) = 0.148 (no standard error or confidence interval provided), p = >0.05 Smoking (Y/N = 0.275 (no standard error or confidence interval provided), p = >0.05 Course of illness (years) = 0.041 (no standard error or confidence interval provided), p = >0.05 Olanzapine concentration (ng/ml) = 0.365 (no standard

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			error or confidence interval provided), p = <0.01 Baseline weight (kg) = 0.987 (no standard error or confidence interval provided), p = <0.01 Fasting glucose (mmol/L) = 0.087 (no standard error or confidence interval provided), p = >0.05 Triglycerides (mmol/L) = -0.137 (no standard error or confidence interval provided), p = >0.05 Total cholesterol (mmol/L) = 0.104 (no standard error or confidence interval provided), p = >0.05 LDL-C (mmol/L) = 0.147 (no standard error or confidence interval provided), p = >0.05

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			HDL-C (mmol/L) = 0.388 (no standard error or confidence interval provided), p = <0.01 Baseline PANSS measurement = 0.112 (no standard error or confidence interval provided), p = >0.05 BMI rate change = 0.988 (no standard error or confidence interval provided), p = <0.01 **Linear regression results (β) for change in weight =** Olanzapine plasma concentration (ng/ml) = 0.376 (95% CI 0.08 to 0.67), p = 0.013 Smoking status (Y/N) = 0.130 (95% CI -0.15 to 0.41), p = 0.365

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Course of illness (years) = 0.067 (95% CI -0.21 to 0.34), p = 0.631 Sex (M/F) = 0.065 (95% CI -0.2 to 0.33), p = 0.63 **Linear regression results (β) for change in BMI =** Olanzapine plasma concentration (ng/ml) = 0.35 (95% CI 0.06 to 0.65), p = 0.019 Smoking status (Y/N) = 0.164 (95% CI -0.12 to 0.45), p = 0.254 Course of illness (years) = 0.096 (95% CI -0.18 to 0.37), p = 0.119 Sex (M/F) = 0.119 (95% CI -0.15 to 0.39), p = 0.387

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
Rasmussen (2014) [196]	Neocortical 5HT2A binding receptor profile	Change in weight over 24 weeks	**Unadjusted results for change in weight (rho) =** 5HT2A receptor binding capacity = 0.59 (no standard error or confidence interval provided), p =0.022
Muntane (2022) [186]	Exploratory – range of candidate prognostic factors assessed	(1) Change in BMI at 12 weeks (2) Change in BMI at 52 weeks	**Linear regression results (b) for change in BMI at 12 weeks =** Age (years) = -0.04 (95% CI -0.12 to 0.04), p = 0.37 Sex (F/M) = -2.08 (95% CI 0.47 to 3.69), p = 0.01 Baseline BMI (kg/m^2) = -0.60 (95% CI -0.80 to -0.40), p = <0.0001 Diagnosis (reference = schizophrenia diagnosis) Delusional disorder = -0.61 (95% CI -10.29 to 9.07), p = 0.90

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Schizoaffective disorder = -0.37 (95% CI -6.15 to 5.78), p = 0.91 Schizophreniform disorder = 0.91 (95% CI -0.81 to 2.63), p = 0.30 Brief psychotic disorder = -0.24 (95% CI -2.77 to 2.29), p = 0.85 Unspecified psychosis = 1.45 (95% CI -1.51 to 4.41), p = 0.34 Concomitant antidepressant use (Y/N) = 0.04 (95% CI -2.12 to 2.20), p = 0.97 **Linear regression (b) results for change in BMI at 52 weeks =** Age (years) = -0.17 (95% CI -0.29 to -0.05), p = 0.0046 Sex (F/M) = 1.43 (95% CI -3.68 to 0.82), p =0.21

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			BMI increase at 3 months = 0.89 (95% CI 0.73 to 1.05), p = <0.001 Baseline BMI (kg/m^2) = -0.13 (95% CI -0.40 to 0.14), p = 0.91
Nielsen (2016) [194]	Confirmatory - striatal reward activity ● Right-sided putamen ● Left-sided putamen ● Right ventral striatum ● Left ventral striatum	Change in weight at 6 weeks	**Linear regression results (β) for change in weight* =** Left putamen reward activity = -0.69 (95% CI -1.73 to 0.34), p = 0.196 Right ventral striatal reward activity = -0.546 (95% CI -1.72 to 0.62), p = 0.367 Left ventral striatal reward activity = 0.128 (95% CI -1.14 to 1.40), p = 0.845 * Additional dataset received from authors

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
Homan (2019) [190]	Confirmatory (1) Striatal volume (2) Striatal resting-state functional connectivity	Weight change over 12 weeks	**Striatal volume** **Linear regression results (β) for change in weight =** Average putamen volume = 0.31 (95% CI 0.02 to 0.60), p = 0.036
Liu (2022) [176]	Exploratory – range of candidate prognostic factors assessed	Change in weight over 12 weeks	**Linear regression results (β) for change in weight* =** Age (years) = -0.07 (95% CI -0.09 to 0.04), p = 0.50 Education (years) = -0.22 (95% CI -0.36 to -0.02), p = 0.03 Smoking status (Y/N) = -0.04 (95% CI -2.85 to 1.88), p = 0.69 Baseline BMI (kg/m^2) = -0.19 (95% CI -0.37 to 0.002), p = 0.05 Superoxide dismutase (U/ml) = -0.23 (95% -0.12 to -0.008), p = 0.025

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Glutathione peroxidase (U/ml) = -0.24 (95% CI -0.37 to 0.02), p = 0.014 *Results only reported for female participants in reporting. Not specified in statistical analysis plan.
Song (2014) [195]	Pro-inflammatory cytokines ● IL-1B ● IL-6 ● TNF-alpha	Risk of clinically significant weight gain* over 24 weeks	**Logistic regression results (OR) for risk of clinically significant weight gain** IL-1β = 0.91 (0.85-0.97), p = 0.005
Yuan (2018) [193]	Exploratory – range of candidate prognostic factors assessed	(1) Weight change over 24 weeks (2) BMI Change over 24 weeks	**Linear regression results for change in weight** R^2 for model including age, sex, smoking status, and disease duration = 8.3%, F = 0.631, P = 0.677

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Linear regression results for change in BMI R^2 for model including age, sex, smoking status, and disease duration = 9%, F = 0.695, p = 0.631
Lin (2021)[187]	Confirmatory – Illness severity (positive symptoms)	BMI change over mean 6.04 years	**Unadjusted results for change in BMI (r) =** Positive symptom severity = -0.23, (no standard error or confidence interval provided), p = 0.30 Negative symptom severity = 0.25, (no standard error or confidence interval provided), p = 0.25 **Linear regression results (b) for change in BMI* =** Positive symptom severity = 0.14 (95% CI 0.13 to 0.15), p <0.01

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			BMI at baseline (mg/k^2) = 0.04 (95% CI 0.02 to 0.06), p <0.01 Age (years) = -0.004 (95% CI -0.01 to 0.01), p = 0.4237 Sex (M/F) = -0.04 (95% CI -0.16 to 0.08), p = 0.50 Duration of illness (years) = -0.004 (95% CI -0.01 to 0.01), p = 0.4237
Medved (2009) [197]	Exploratory – range of candidate prognostic factors assessed	(1) Change in waist circumference over 12 weeks (2) Change in BMI over 12 weeks	No effects sizes reported for either outcome or not available from study author upon multiple requests.
Zhang (2003) [179]	Exploratory – range of candidate prognostic factors assessed	BMI over 10 weeks	No effects sizes reported and not available from study author upon multiple requests.

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
Verma (2009) [180]	Exploratory – range of candidate prognostic factors assessed	Risk of clinically significant weight gain * over 24 weeks	**Logistic regression results for risk of clinically significant weight gain (OR)** Age (years) = 0.6 (95% CI 0.6 to 0.9), p = 0.01 Sex (M/F) = 0.1 (95% CI 0 to 1.0), p = 0.05 Baseline BMI (kg/m^2) = 0.8 (95% CI 0.6 to 1.0), p = 0.03 Cumulative antipsychotic exposure = 1.0 (95% CI 1.0-1.0), p = 0.36 % Change in PANSS positive score = 1.0 (95% CI 0.9 to 1.2), p = 0.77 Baseline low density lipoprotein cholesterol (LDL-C) (mmol/L) = 2.0 (95% CI 0.7 – 5.9), p = 0.22 Baseline triglycerides (mmol/L) = 4.1 (95% CI 1.0 to 15.2), p = 0.05

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Baseline insulin (mmol/L) = 1.0 (95% CI 1.0 to 1.0), p = 0.87
Arranz (2007) [198]	Confirmatory - Antipsychotic formulation – standard vs. disintegrating	(1) Weight change over 6 weeks (2) BMI change over 6 weeks	**Results for change in weight =** Olanzapine standard tablets: mean difference = 6.4 (3.96) Olanzapine disintegrating tablets: mean difference = 3.3 (2.93) F = 7.7, p = 0.009 **Results for change in BMI =** Olanzapine standard tablets: mean difference = 2.1 (1.06) Olanzapine disintegrating tablets: mean difference = 1.1 (0.806) F = 4.7, p = 0.036
Li (2018) [192]	Exploratory – range of candidate prognostic factors assessed	Change in weight over 12 weeks	**Unadjusted results for change in weight (rho) =**

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Sex (M/F) = 0.042 (no standard error or confidence interval provided), p = 0.471 Age (years) = -0.205 (no standard error or confidence interval provided), p = 0.00001 Duration of illness (years) = -0.188 (no standard error or confidence interval provided), p = 0.001 Baseline BMI (kg/m^2) = -0.108 (no standard error or confidence interval provided), p = 0.065 Waist to hip ratio = -0.199 (no standard error or confidence interval provided), p = 0.008 Systolic blood pressure (mmHg) = -0.075 (no standard error or confidence interval provided), p = 0.206

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Diastolic blood pressure (mmHg) = -0.124 (no standard error or confidence interval provided), p = 0.036 Triglycerides (mmol/L) = 0.010, (no standard error or confidence interval provided), p = 0.873 High-density lipoprotein cholesterol (mmol/L) = - 0.014 (no standard error or confidence interval provided), p = 0.808 Low-density lipoprotein cholesterol (mmol/L) = - 0.068 (no standard error or confidence interval provided), p = 0.248 Total cholesterol (mmol/L) = -0.068 (no standard error or confidence interval provided), p = 0.460

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Total plasma protein (g/l) = -0.116 (no standard error or confidence interval provided), p = 0.050 Albumin (g/l) = -0.061 (no standard error or confidence interval provided), p = 0.304 Fasting plasma glucose (mmol/L) = - 0.144 (no standard error or confidence interval provided), p = 0.015 Urea (mmol/L) = -0.022 (no standard error or confidence interval provided), p = 0.714 C-reactive protein (CRP) (mg/L) = -0.087 (no standard error or confidence interval provided), p = 0.394 Thyroid Stimulating Hormone (TSH) (mIU/ml) = -0.138 (no standard error or confidence interval provided), p = 0.029

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Triiodothyronine (T3) (nmol/L) = - 0.120 (no standard error or confidence interval provided), p = 0.058 Thyroxine (T4) (nmol/L) = - 0.154 (no standard error or confidence interval provided), p= 0.014 **Linear regression results (b) for change in weight =** Age (years) = -0.02 (95% CI = -0.04 to 0.00), p = 0.107 Duration of illness (years) = 0.02 (95% CI = -0.01 to 0.05), p = 0.251 Waist to hip ratio = -2.45 (95% -4.83 to – 0.08), p = 0.044 Diastolic blood pressure (mmHg) = -0.002 (95% CI -0.03 to 0.02), p = 0.8146

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Total plasma protein (g/l) = -0.004 (95% CI -0.04 to 0.03), p = 0.83 Fasting plasma glucose (mmol/L) = - 0.112 (95% CI -0.31 to 0.08), p = 0.26 Thyroid Stimulating Hormone (TSH) (mIU/ml) = -0.075 (95% CI -0.19 to 0.04), p = 0.192 T4 (nmol/L) = - 0.01 (95% CI -0.02 to 0.00), p = 0.038
Chiliza (2015) [161]	Exploratory – range of candidate prognostic factors assessed	Change in BMI at 52 weeks	**Linear regression results (b) for change in BMI* =** Age (years) = -0.002 (SE = 0.06), p = 0.97 Sex (M/F) = 0.89 (SE = 0.78), p = 0.25 Substance misuse history (Y/N) = - 2.249 (SE = 0.71), p = 0.002 Previous treatment (Y/N) = 0.62 (SE = 0.669), = 0.35

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Baseline BMI (kg/m^2) = -0.088 (SE = 0.09), p = 0.334 Baseline high-density cholesterol (mmol/L) = 0.157 (SE = 0.63), p = 0.80 Baseline low-density cholesterol (mmol/L) = 0.508 (SE = 0.67), p = 0.45 Baseline fasting glucose (mmol/L) = -0.44 (SE = 0.48), p = 0.35 Baseline prolactin (mIU/L) = 0.07 (SE = 0.04), p = 0.12 Baseline triglycerides (mmol/L) = -0.80 (SE = 0.711), p = 0.26 Baseline cholesterol (mmol/L) = -0.59, (SE = 0.60), p = 0.33 ***Full dataset retrieved from author**

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
Canal-Rivero (2020) [181]	Exploratory – range of candidate prognostic factors assessed	Change in weight at 52 weeks	**Linear regression results (b) for change in weight =** Dietary habits at 3 months follow-up after FEP = 2.56 (95% CI 0.79 to 4.33), p = 0.0045 Baseline BMI (kg/m^2) = -0.46 (95% CI -0.74 to - 0.17), p <0.01 Emerging adulthood (18-30 vs 30-60 years of age) = -2.76 (95% CI -5.34 to – 0.18), p = 0.04
Huang (2020) [188]	Confirmatory - early appetite increase	(1) Weight change over 12 weeks (2) BMI change over 12 weeks	**Linear regression results (β) for change in weight** = 0.67 (95% CI 0.31 to 1.03), p = 0.0003 **Linear regression results (β) for change in BMI)** = 0.63 (95% CI 0.28 to 0.98), p = 0.004

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
			Prognostic factor = appetite increase (>10% increase in baseline appetite score vs. no)
Luckhoff (2020) [189]	Confirmatory - Hippocampal subfield volume – anterior + posterior	Change in BMI at 52 weeks	**Unadjusted estimates (r) =** Anterior hippocampal volume = -0.10, p = 0.327 Posterior hippocampal volume = -0.07, p = 0.506 **Linear regression results (b) for change in BMI =** Anterior hippocampal volume = 3.03 (95% CI = 0.11 - 5.95), p = 0.046 Posterior hippocampal volume = 2.18 (95% CI = -1.50 – 5.86), p = 0.250

Table 9 - Overview of prognostic factor-outcome associations studied and reported effect size. Listed in order data of extraction.

Study	Prognostic factor(s)	Outcome(s)	Study estimates + confidence intervals + P value (where available or could be estimated from study report)
Zipursky (2005) [160]	Exploratory – range of candidate prognostic factors assessed	Time to clinically significant weight gain assessed over 104 weeks	No numerical study results available in report or on request from study authors.
Garriga (2019) [182]	Confirmatory – birth weight	Change in weight at 16 weeks	**Linear regression results (β) for change in weight** = 0.219 (95% CI 0.04 to 0.40), p = 0.018* **Curvilinear regression quadratic correlation =** R^2 = 0.127, β = 4.328, p = 0.002* *Birth weight measured in kg
Lago (2021) [177]	Confirmatory – cellular markers of metabolic syndrome on peripheral blood mononuclear cells (glucose transporter 1, insulin receptor, fatty acid translocase on CD4+ T cells, CD8+ T cells, CD4-8- T cells, B cells and monocytes)	Change in BMI at 12 weeks	**Linear regression results (b) for change in BMI =** CD36 expression on T cells CD4+ = 0.0148, SE = 0.005, p = 0.005

The most frequently studied prognostic factor-outcome associations can be found in Figure 4, although in many cases results were not of practical significance, i.e., the reported effect size was not large enough to justify application of the prognostic factor in influencing the management of AIWG. Of the 78 assessed, 68% of prognostic factors were evaluated in a single study. In only two studies was antipsychotic adherence accounted for through study design or analysis.[161,189] One study assessed the impact of diet and lifestyle as a prognostic factor.[181] No analysis applied diet and lifestyle as a covariate.

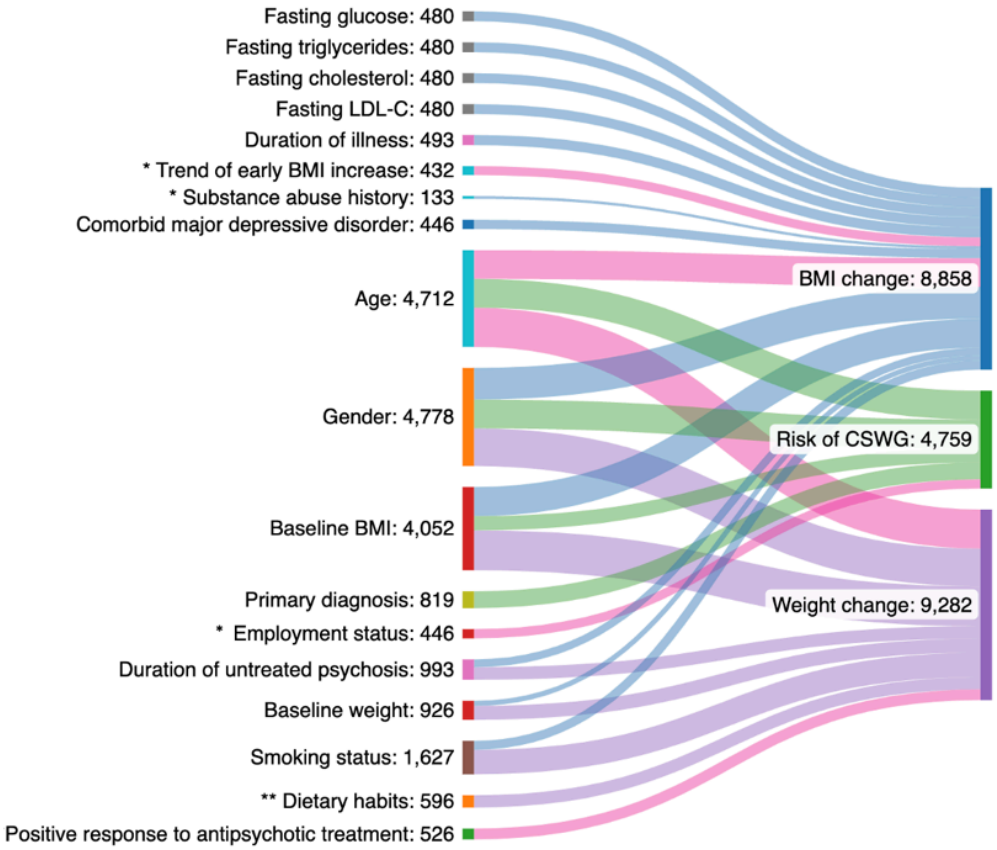


Figure 4 – Sankey chart outlining the most frequently studied prognostic factor-outcome associations.
Numbers indicate the number of participants included in studies assessing the prognostic factor. In the case of outcomes, the number indicates the total number of outcome measurements for that outcome across all prognostic factors. Thickness of each line connecting a prognostic factor with an outcome depends on the number of participants across studies examining the association. Each outcome studied is reflected in the diagram by a different colour. Lines highlighted in pink specifically indicate moderate quality supporting evidence as per GRADE assessment.
**Indicates moderate-large effect size demonstrated.*

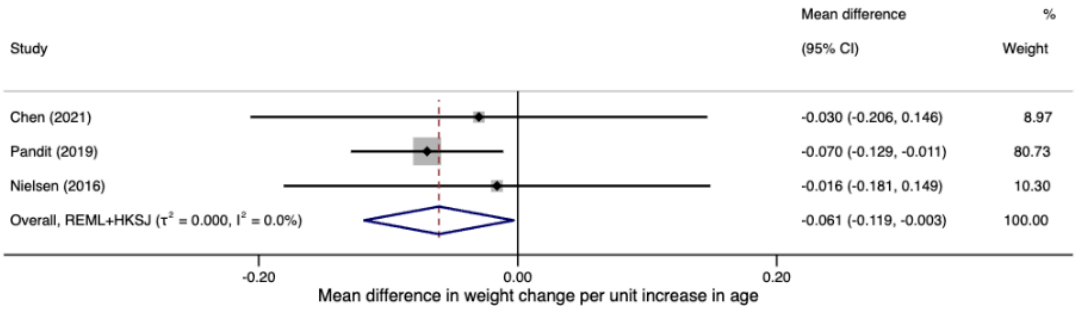
***Very low-quality supporting evidence for this prognostic factor-outcome association.*

4.4.4 Findings from meta-analyses

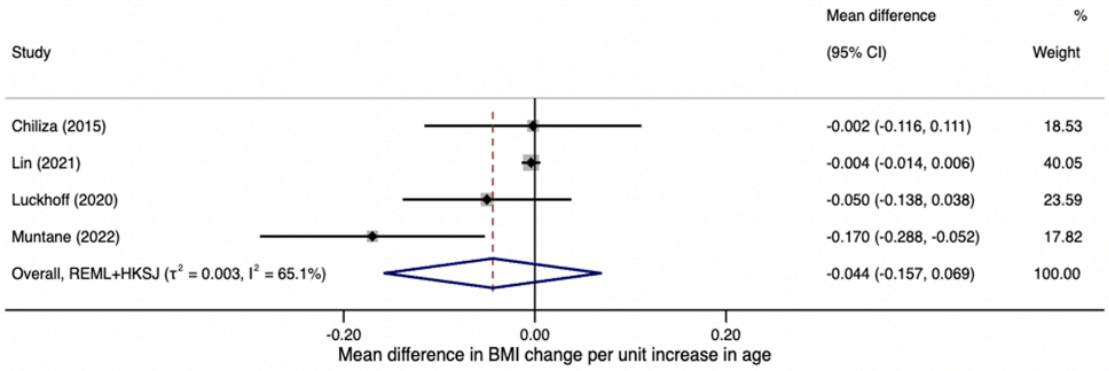
Prognostic factors eligible for meta-analysis were significantly limited by single study assessments, evaluation of different outcomes (e.g., BMI versus weight change) and at varying timepoints, and heterogeneity of adjusted covariates. Conduct of meta-analysis was also hampered by varying measurements of prognostic factors e.g., antipsychotic prescription being classified by grouping or by antipsychotic prescribed.[34,76,175,186] Incomplete reporting of results was an additional barrier to meta-analysis.[195] Adjusted estimates of age, sex and baseline BMI on change in weight and BMI were the only associations suitable for meta-analysis. Results of meta-analyses are displayed in Figure 5.

When assessed over the longest timepoint available, age (b= -0.044, 95%CI -0.157–0.069), sex (b=0.236, 95%CI -0.086–0.558), and baseline BMI (b= -0.013 95%CI -0.225–0.200) were associated with non-significant effects on AIWG prognosis. Confidence intervals were wide for all analyses, reflecting large uncertainty due to small numbers of available study estimates for synthesis. Limited study estimates also led to greater uncertainty in the estimated heterogeneity (tau-squared). Confidence intervals were inflated using the HKSJ method to better account for this uncertainty.[199] Insufficient numbers of primary studies prohibited both assessment of publication bias quantitatively and planned subgroup analyses.

Age (n=1041), change in weight up to 12 weeks



Age (n=626), change in BMI up to 52 weeks



Sex M/F (n=1197), change in weight up to 12 weeks

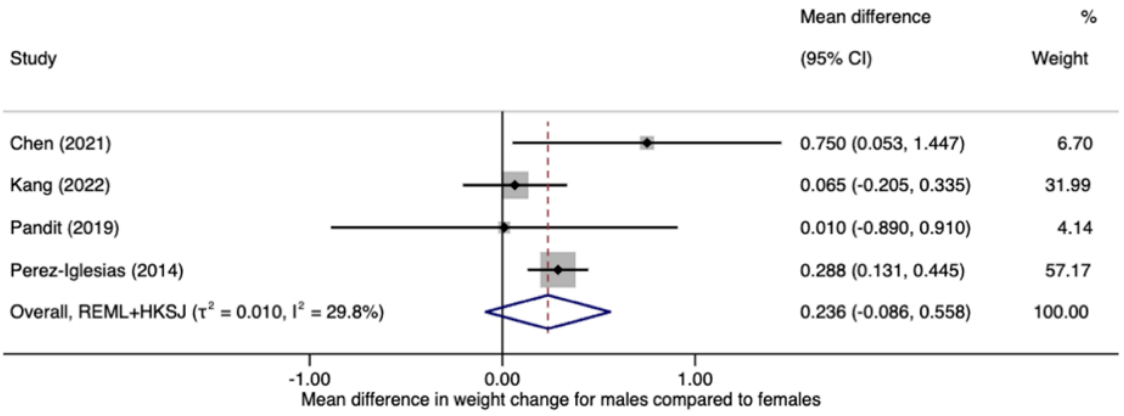
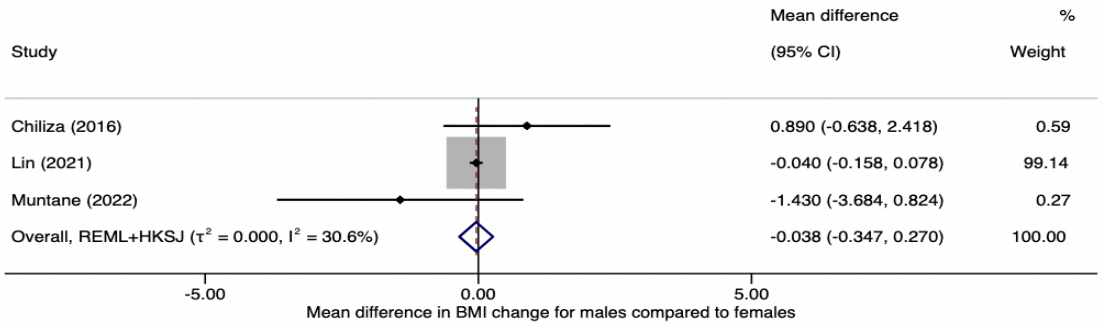


Figure 5 - Forest plot of adjusted estimates effects of age, sex, and pre-antipsychotic (baseline) BMI studied for their impact on change in BMI and weight at short- and long-term outcomes.

Sex M/F (n=536), change in BMI at 52 weeks



Baseline BMI (n=536), change in BMI at 52 weeks

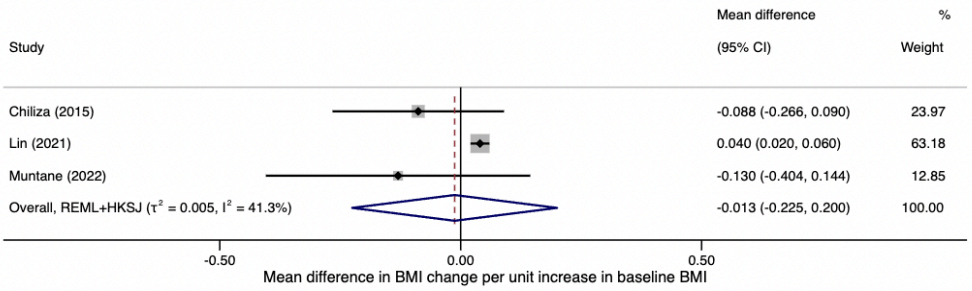


Figure 5 continued - Forest plot of adjusted estimates effects of age, sex, and pre-antipsychotic (baseline) BMI studied for their impact on change in BMI and weight at short- and long-term outcomes.

4.4.5 Risk of bias assessments

All studies presented with a moderate risk of bias in at least one domain, and 37% with a high risk in at least one domain. The most common section to receive a high risk of bias was statistical analysis and reporting, followed by study attrition and adjustment for other prognostic factors, respectively. Statistical pitfalls noted across studies included insufficient data presentation to assess adequacy of the analytical approach and inappropriate or misleading modelling strategies e.g., reliance on

univariable analyses.[192] No study reported an *a priori* sample size calculation. Incomplete or selective reporting of analyses based on presence or absence of statistically significant results was another potential source of bias noted.[176,179,181,182] Inadequate adjustment for covariates limited result interpretation and aggregation.[76,178,180,190,197] In the case of attrition, sources of potential bias included inappropriate handling of missing data e.g., complete case analysis.[155,176,177,182,186,193,196]

Reasons for a moderate risk of bias assignment included concerns of selection bias, where in all but one study,[76] inadequate description or inappropriate recruitment methods were identified.[164] Unclear measurement properties of prognostic factors was also highlighted in several studies, including how factors were measured and included in analyses.[181,188,194] Risk of bias assessments were often complicated by poor quality reporting of study design, conduct, and particularly analysis methods, and study results. Completed risk of bias assessments are contained in appendix 5.

4.4.6 GRADE assessment of quality for each prognostic factor-outcome association

Most prognostic factor-outcome associations presented with low-quality supporting evidence. Several had very low-quality evidence ratings. The highest quality rating assigned was moderate and in the case of the following prognostic factor-outcome assessments:

- Age and adjusted BMI change (at 52 weeks)
- Age and adjusted weight change (at 12 weeks)
- Employment status and weight change + risk of CSWG (at 12 weeks)
- Trend of early BMI increase and change in BMI (at 52 weeks)
- Response to antipsychotic treatment and weight change (at 12 weeks)
- Antipsychotic plasma concentration and change in weight + BMI (at 12 weeks)

Common reasons for downgrading evidence quality included assessment in primarily exploratory studies and concerns regarding internal validity of studies

following risk of bias assessments. Indirectness was identified in several studies where concerns of generalizability were identified.[160,171,182] Evidence quality was rated up in the case of employment status and trend of early BMI increase due to reported moderate-large effect sizes across studies.[174] Studies published in the last five years generally displayed a higher quality of design, analysis, and reporting.[32,155,175] Ninety three percent of confirmatory studies reported at least 1 statistically significant positive result, highly suggestive of publication bias. Detailed results of all GRADE assessments, including reasons for downgrading quality of evidence, can be found in appendix 6.

4.5 Discussion

This review is the first systematic collation and exhaustive methodological evaluation of non-genetic prognostic factors and their influence on AIWG prognosis. The review focused on clarifying the current stance of evidence in the area, including quantifying demonstrated associations between prognostic factors and weight outcomes and reporting on their reliability and associated clinical utility. Review methodology was designed in accordance with guidance produced by the Cochrane Prognosis Methods Group to produce a transparent evidence summary and increase strength of review recommendations for practice, policy and research.[167] This review also included several unpublished datasets by contacting authors of prior studies or studies which lacked complete reporting of study results.[161,178]

Prospective cohort studies that test a fully developed hypothesis without serious study limitations and confirmatory studies without serious limitations, constitute high-quality evidence on prognosis.[167] Whilst moderate quality evidence was found in support of a small number of prognostic factors, for many assessments, defects in study design, analysis and reporting led to reduced confidence in reported estimates. Certainty in reported prognostic factor-outcome associations was often limited by small sample sizes, brief evaluation periods, and concerns of bias, including publication bias, the latter being previously identified as prevalent within prognostic factor research.[200] Taken together, most prognostic factor-outcome

associations studied in this review require further independent study to confirm results. Whilst the rationale will be discussed further, review conclusions, including implications for policy, practice, and future research in the area, are summarised in Table 10. Prognostic factor-outcome associations that should be prioritised for assessment within future confirmatory studies are also highlighted.

Table 10 - Summary of systematic review conclusions.

Category	Conclusion	Practice and policy Implications	Research implications
1 – Measurement of prognostic factors evaluated *prior to* antipsychotic initiation and use of results to inform AIWG prognosis	Insufficient evidence exists to recommend routine measurement of any non-genetic prognostic factor *prior* to antipsychotic initiation.	Currently insufficient evidence exists to support use of non-genetic prognostic factors to inform AIWG management e.g., risk stratified use of interventions to prevent AIWG according to baseline risk.	Several prognostic factors that should be prioritis evaluation in future confirmatory studies with ex follow-up were identified. This includes employme antipsychotic plasma concentration and substance history. Only substance misuse history had a protect on AIWG prognosis.
2 – Clinical variables previously thought to be prognostic	Patient characteristics previously reported to influence AIWG prognosis including age and antipsychotic treatment response likely play a clinically insignificant role in long-term AIWG prognosis. The analysis conducted did not provide		The role of sex and baseline BMI on AIWG prognosis further study given low-quality evidence suppo conclusions. Effects of sex in studies with longer-term are required given increased risk found here in sho analyses. Adjustment for age in prognostic model dev clinical trial design, or in assessments of indepe associations of novel prognostic factors, are likely no

	conclusive evidence that sex or baseline BMI significantly impact AIWG prognosis at 1 year.		
3 - Prognostic value of the antipsychotic prescription	The antipsychotic prescribed remains the most significant baseline variable in influencing AIWG prognosis. This review did not find conclusive evidence to support antipsychotic dose in meaningfully impacting AIWG prognosis.	Significant differences in propensity to cause weight gain amongst antipsychotics should be accounted for within AIWG management guidelines given the strong prognostic information provided by use of low- versus high-risk agents. The absence of evidence demonstrating a protective effect of lower doses on AIWG prognosis should also be highlighted.	The results underscore the importance of evidenc antipsychotic prescribing in first episode psychosis. into methods to reduce indiscriminate use of olanza medium-risk antipsychotics in this context is need Research is also required as to whether a differer approach to management based on antipsychotic pr more effective in managing AIWG compared to the endorsed uniform approach, independent of the ant prescribed.
4 – Prognostic value of early BMI increases	Trend of BMI increase within the first 12 weeks of antipsychotic treatment likely provides strong prognostic information regarding extended AIWG prognosis.	Amongst those who experience significant BMI increases early in treatment, current stepwise management	Significant increases in BMI early in treatment likely r phenotypic expression of those at higher inherent ris and may be a more efficient way of measuring g correlates of AIWG and targeting management inter accordingly. Whether use of early BMI trend to info management leads to a sustained positive impact o

	Those who experience significant weight gain (most commonly defined as a ≥5% increase in baseline body weight) early in treatment have a worse long-term prognosis when compared to those who don't.[203]	algorithms should likely be accelerated and intensified.[46] Given the higher likelihood of experiencing absolute benefits and resources required to implement their use, use of intensive and individualised interventions would likely be used more efficiently amongst this group.[63] Pharmacological treatments, including those shown to be more effective at plateauing versus treating AIWG i.e., metformin,[64,71] may also be more beneficial amongst this group.	prognosis requires evaluation. Differential treatment to pharmacological and non-pharmacological inter amongst those whose trend of initial AIWG is more e also worthy of future research.
Additional research recommendations			
5 – Next steps	This review provides a blueprint for next steps in prognostic factor research in AIWG prognosis and has implicat both non-genetic and genetic prognostic research, for example, in developing individualized AIWG prediction m New studies should build on the results outlined here, including:		

	• Prognostic factors deserving of prioritization for further study, and methodological and reporting improv required to establish evidence-based prognostic assessments, have been highlighted here. Guidelines o reporting and methodological standards of prognostic factor research have been previously published a be adhered to in future studies.[115,204] • Results should be used by researchers to improve quality of future studies as well as ensuring evaluatio and outcomes similarly to facilitate meaningful comparison and meta-analysis of collective results. • Whether relationships between prognostic factors and outcomes assessed may have become apparent, become more clearly elucidated, through assessment for non-linear relationships is an important questi remains unaddressed. • A lack of study of prognostic factors operating at a broader contextual level was identified, including kn determinants of weight e.g., diet and lifestyle variables. Future research should consider this and the ne assessment of potential prognostic factors at an ecological level e.g., area-level social deprivation, healt access and physical environment given their relevance to the cohort under investigation.

4.5.1 Main findings

Prognostic factor-outcome associations with the greatest evidence certainty and results of highest practical importance, and from which conclusions in Table 10 were based, will now be discussed. Factors with very low-quality supporting evidence will not be discussed further due to very little confidence in the validity of reported findings, as per GRADE interpretation of evidence quality ratings.[171] The value of sociodemographic and clinical variables previously thought to be, and thus commonly reported within psychiatric resources as prognostic, including age, sex, baseline BMI, and response to antipsychotic treatment, will also be discussed.[155,156]

4.5.1.1 Impact of age on predicting AIWG prognosis

Most studies reported a small average negative effect of age on prognosis of weight increase, [175,176,194] BMI increase,[161,178,186,187,189,192] and risk of CSWG.[76,155] Results were similar in the case of varying follow-up durations,[32,155,178,180] antipsychotic prescribed,[32,155,161] and study setting.[155,161,180,186] A similarly small average negative effect estimate was also seen independent of study quality, including risk of bias rating,[155,180,205] although study precision in demonstrating a consistent negative effect was greater in better quality and larger studies.[32,178] Meta-analysis results for change in weight and BMI were similar, where reported effect sizes and the upper and lower limits of association confidence intervals, were compatible with no significant effect of age on AIWG prognosis. Evidence quality was moderate for adjusted estimates of BMI and weight change at all timepoints. Adjustment for age in prognostic model development, clinical trial design, or in assessments of independent associations of novel prognostic factors, are likely not essential.

4.5.1.2 Sex in predicting AIWG outcomes

Sex was assessed in 11 exploratory studies and one confirmatory study. Results reporting the prognostic effect of sex varied across studies, which may have been the result of heterogeneity in study design, particularly length of follow-up, and study quality.[155,161,180,191] In studies assessed qualitatively, non-significant differences between sex in influencing AIWG prognosis were largely seen across short-term,[76,179,180,193,192] and longer-term studies,[160,178] and in both unadjusted,[76,192]

and adjusted analyses.[160,193] Meta-analyses conducted also did not report a significant effect of sex on AIWG prognosis, although analysis was limited by small study numbers and weight largely being assigned to a single study. For all outcomes, GRADE assessment of quality was low. Given the low-quality evidence, conclusions regarding sex's role on AIWG prognosis are uncertain and require further confirmatory study.

4.5.1.3 Baseline BMI and early BMI increase as prognostic factors

Baseline BMI was the most studied anthropometric measurement assessed for its impact on AIWG prognosis. Meta-analysis of studies with a follow-up of 12 months found no significant effect of baseline BMI on AIWG prognosis. However, evidence quality for baseline BMI as a prognostic factor was low for all outcomes, except for change in waist circumference, where quality was very low. Thus, like sex, although a significant impact of baseline BMI was not seen here, results are inconclusive. Assessment of early anthropometric changes post antipsychotic initiation demonstrated significantly more prognostic promise.

Several studies assessed the impact of early anthropometric changes on weight and BMI up to 52 weeks. One study (n=381) assessed the value of 12-week BMI change on final BMI change at 12 months amongst participants prescribed varying antipsychotics and found that for every one-unit BMI increase at 12 weeks predicted an almost identical BMI increase at 1 year. Trend of early BMI increase explained approximately 30% variance in final BMI change - more than age, sex, baseline BMI, antipsychotic prescribed and dosage combined.[186] In another study (n=51), early BMI rate of change correlated almost perfectly with BMI and weight change at 8 weeks treatment, r=0.988 and r=0.992, P<0.001, respectively.[185] In a 10-year follow-up study, percentage weight increase at 12 months treatment had a significant prognostic effect on the odds of experiencing a 20% weight increase at 10 years (effect size not reported).[178]

Early BMI increase as a prognostic factor was judged to have moderate quality supporting evidence. Confirmatory evidence for the prognostic role of early

anthropometric changes was also provided indirectly through other included studies. One study assessed the role of early appetite increase on AIWG prognosis and found that increased appetite at 4 weeks was positively associated with increased weight gain at 12 weeks, b=0.67 (95% CI 0.31–1.03), p=0.0003.[188] At 12 weeks, participants with an earlier appetite increase (0-4 versus 4-8 weeks treatment) showed significantly greater weight gain, mean difference =2.67kg (95% CI 1.20–4.15), p<0.0001.[188] However, quality for early appetite increase as a prognostic factor was judged to be low. Previous research in non-antipsychotic-naïve cohorts (n=351) found that 5% weight increase at 1-month treatment predicted weight gain of 15% at 3 months (sensitivity 67%, specificity 88%, p=0.001). Amongst those who gained <5% at 1-month, average weight gain at 3 months was significantly lower when compared to the ≥5% group, 2.4% vs. 8.1% weight change, p=0.0005.[203]

Trend of BMI increase within the first 12 weeks of antipsychotic treatment likely provides strong prognostic information regarding extended AIWG prognosis. Those who experience significant weight gain early in treatment have a worse long-term prognosis when compared to those who do not.[203] Amongst those who experience significant BMI increases early in treatment, current stepwise management algorithms should be likely accelerated and intensified.[46]

4.5.1.4 Antipsychotic dose in informing AIWG prognosis

Several exploratory studies assessed the prognostic value of antipsychotic dose on weight and BMI changes.[32,179,185] In the only study with reported effect sizes,[186] adjusted analysis found insignificant effect sizes of <0.01 on BMI change at 3 (p=0.19) and 12 months (p = 0.24). Evidence quality was low and very low for impact on change in BMI and weight, respectively. However, plasma concentration is a more accurate reflection of bioavailable drug than dose. One confirmatory study (n=51) in China assessed the role of 4-week olanzapine plasma concentration in influencing weight and BMI change at 8 weeks and reported β=0.376 (95% CI 0.08-0.67), p=0.013 for weight change and β=0.354 (95% CI 0.06-0.65), p=0.019 for BMI change, suggesting a potential modest role of antipsychotic plasma

concentration as a prognostic factor.[185] Evidence quality was moderate in the case of antipsychotic plasma concentration as a prognostic factor.

A prior meta-analysis assessing the impact of antipsychotic dose on weight trajectory demonstrated hyperbolic dose curves for most antipsychotics, i.e., initial dose-related weight increases, with subsequent plateau at higher doses of antipsychotic. However, for most assessments, average weight differences between higher and lower doses did not differ to a clinically significant extent, although studies were of short duration.[29] In addition, a separate systematic review highlighting dose reduction as ineffective in significantly reversing AIWG supports the hypothesis of AIWG being somewhat dose-independent,[206] although absence of linear relationships may mean dose reductions are more effective within certain ranges.

Taken together, additional research is required to confirm whether antipsychotic dose meaningfully impacts AIWG prognosis. Future studies should be designed specifically to test this hypothesis and should assess the prognostic value of plasma concentration, rather than dose, to account for varying pharmacokinetics. Future studies should also account for potential trend differences between antipsychotics, evaluate the presence of non-linear relationships, and assess both dose ranges and timelines reflective of clinical practice.

4.5.1.5 Response to antipsychotic treatment as a prognostic factor

A positive response to antipsychotic treatment has previously been reported as negatively impacting AIWG prognosis, although the clinical significance of the relationship had been unclear.[207] A confirmatory study (n=529) in China assessed the association between AIWG and antipsychotic response measurements and reported weak correlations between weight gain and reduction in PANSS positive, negative, and total sub scores at 8 weeks. Adjusted analysis found a clinically insignificant positive association between total PANSS reduction and AIWG, β=0.03 (95% CI 0.01–0.05), p=0.007.[175] In a separate study (n=56), percentage change in PANSS positive subscale was not associated with substantial risk of CSWG at 6

months, OR=1.0 (95% CI 0.9-1.2), p=0.77.[180] Evidence quality was moderate for weight change and low for all other outcomes. Results here signify that treatment response is not a practically useful prognostic marker, although repeat assessments in additional ethnic groups is required to confirm generalizability of findings.

4.5.1.6 Moderate to large effect sizes observed within the review

A small number of prognostic factors with a reported moderate-large effect size were identified. In one study (n=446) without serious limitations, unemployment was associated with an increased risk of CSWG at four weeks treatment, OR = 2.83 (95% CI 1.50-5.36), p=0.001. Significant impact on weight change was also reported.[155] Evidence quality for unemployment as a prognostic factor was moderate. AIWG is mediated primarily through increased appetite and food cravings.[43] Unemployment may impact AIWG prognosis through increased consumption of higher calorie foods typically more readily consumed by those on lower incomes, as well as reduced access to lifestyle interventions shown to attenuate AIWG.[63] In another study,[161] a positive history of substance misuse was associated with protective effect on BMI increase at 52 weeks treatment, b=-2.25 (95% CI -3.66–(-0.84)), p = 0.002. Substance abuse history may be a proxy for other prognostic factors, for example, poor self-care, or may provide supporting evidence for the striatum's role in AIWG aetiology, as previously demonstrated.[190,194] However, evidence quality for this prognostic factor was low. Given the practical implications of the reported range of effect sizes for both patients and clinicians, valid mechanisms underlying potential associations, and rates of occurrence in the population of interest, their independent prognostic value deserves further experiment in confirmatory studies.

4.6 Limitations

Review limitations include the exclusion of non-English language papers. Although a previous evidence review has suggested otherwise,[208] there is potential that this decision may have introduced bias if statistically or clinically significant results were more likely to have been published in an English language journal. All attempts were made to avoid the inclusion of overlapping participant populations. However, in a

minority of cases where clarification was not received from study authors, review authors decided on the likelihood that overlapping populations were present. This may mean that some studies were included or excluded inappropriately. As highlighted within the results section, 37% of studies were conducted in exclusively Chinese populations. Prior systematic reviews in psychiatric cohorts have reported concerns regarding inclusion of Chinese trials due to suboptimal methodological and reporting standards.[209] The potential impact of including these studies on conclusions produced from this review was accounted for through extensive GRADE quality assessments in the case of each prognostic-factor outcome association. For example, the majority of these studies were exploratory rather than confirmatory in design, which is one reason to reduce evidence certainty according to GRADE. Recommendations produced from this review intended to inform clinical practice were made only in the case of moderate quality supporting evidence, according to assigned GRADE ratings. Accordingly, this step has minimized the potential impact of inclusion of a significant number of studies conducted in China on the resultant recommendations for clinical practice produced from this systematic review.

As in similar reviews of prognostic factor research,[46] primary studies may have been missed during searching due to a lack of standardized indexing of prognostic factor studies. Exclusion of cross-sectional and retrospective study designs assessing prognostic factor-outcome assessments may have excluded studies that identified candidate factors deserving of further confirmatory research. However, this decision was made to increase evidence certainty and thus, strength of review conclusions. Individual participant data meta-analysis may have addressed some of the limitations identified in this review e.g., publication bias or inappropriate statistical analyses,[154] but was beyond the scope of the review.

4.7 Conclusion

The prognosis of AIWG is associated with significant interindividual variability. Prior to this review, whether non-genetic prognostic factors influenced the prognosis of AIWG to a clinically significant extent, and whether reported associations were based on evidence of sufficient quality to inform clinical practice, had not been

systematically explored. This review represents the first overall mapping and statistical synthesis of studies examining non-genetic prognostic factors of AIWG and highlights practice, policy, and research implications. Insufficient evidence exists to recommend routine measurement of any non-genetic prognostic factor *prior* to antipsychotic initiation. After antipsychotic initiation, trend of early BMI increase was identified as currently the most significant factor influencing long-term AIWG prognosis. Significant BMI increases early in treatment likely represents phenotypic expression of those at higher inherent risk of AIWG. Age likely plays an insignificant role in longer-term AIWG prognosis. Effects of sex and baseline BMI are less certain.

The strong prognostic information provided by BMI trend change within 8-12 weeks of antipsychotic initiation should be included as part of novel, risk-stratified AIWG management guidance to highlight those at highest risk of poorer long-term prognosis and those for whom resource-intensive interventions should be prioritised. Review results confirmed that, at baseline, the strongest prognostic information is provided by the antipsychotic prescribed. Evidence is needed addressing how to diversify antipsychotic prescribing within psychosis management.

Chapter 5 - Designing and implementing **sh**ared decision-making interventions in the choice of **a**ntipsychotic prescription in **pe**ople living with psychosis (SHAPE): a realist review

5.1 Chapter description

Chapter 4 concluded that the antipsychotic prescribed remains the most significant, non-genetic, baseline variable influencing the prognosis of AIWG. Results of the evidence synthesis underscore the importance of evidence-based prescribing of antipsychotics within psychosis management. Despite CPGs recommending that antipsychotic choice should primarily be influenced by an individual's side effect preferences,[61] international trends in antipsychotic prescribing consistently demonstrate high prescribing rates of a small number of antipsychotics, namely those with a high burden of cardiometabolic side effects, including weight gain.[92,93,94] Knowledge of how to reduce indiscriminate use of high-risk antipsychotics within psychosis management is urgently needed within AIWG management.[202]

One way to develop knowledge of how to influence antipsychotic prescribing behaviours among clinicians is to study what interventions, and the environments in which they are implemented, are effective in increasing the application of shared decision-making (SDM) within psychosis management. However, results of prior systematic reviews have proven variable and inconsistent.[101] Little consideration has been given to understanding causative processes responsible for effective interventions.[102] Thus, questions of **why** some interventions work, and others do not, remain.[101,103]

Therefore, there is a need for evidence detailing how successful SDM interventions work, for whom, and under what circumstances. Evidence syntheses attempting to address these questions require a methodology that can provide answers about 'how' and 'why' interventions work and account for contextual factors within implementation settings.[102] This chapter describes the results of a realist review that aimed to understand how interventions designed to improve SDM application

within antipsychotic prescribing decisions work, and the impact of contextual factors on intervention success. Key realist terminology used in this chapter has been discussed in detail in section 3.3.

The work discussed within this chapter has been published as a protocol and a two-part series of papers:

1. **Protocol**: ***Fitzgerald I****, Sahm LJ, Howe J, Maidment I, Wallace E, Crowley EK. Shared decision-making interventions in the choice of antipsychotic prescription in people living with psychosis (SHAPE): Protocol for a realist review. PLoS One. 2024 Jul 25;19(7):e0304626.*
2. ***Review results (Part 1): Fitzgerald I,*** *Sahm LJ, Maidment I, Wallace E, Zisman-Ilani Y, Højlund M et al. From idealist to realist - designing and implementing shared decision-making interventions in the choice of antipsychotic prescription in people living with psychosis (SHAPE): a realist review (Part 1 - implementing shared decision-making: policy, governance, and system factors). Schizophrenia Bulletin. 2025. Online ahead of print. Available at: https://doi.org/10.1093/schbul/sbaf058*
3. ***Review results (Part 2): Fitzgerald I****, Howe J, Maidment I, Wallace E, Zisman-Ilani Y, Højlund M, et al. In press From idealist to realist - designing and implementing shared decision-making interventions in the choice of antipsychotic prescription in people living with psychosis (SHAPE): a realist review (Part 2 - designing SDM interventions: optimising design and local implementation). Schizophrenia Bulletin. 2025. Online ahead of print. Available at: https://doi.org/10.1093/schbul/sbaf059*

5.2 Introduction

SDM is a process whereby clinicians and patients collaborate to make treatment decisions based on clinical evidence and patients' informed preferences.[95] SDM is considered a key component of person-centred care, and is advocated for as an exemplary model of decision-making within mental health policy internationally.[96,210,211] Increased application of collaborative models of decision-making is also supported by people with a SMI and various mental health clinicians.[98,99,212,213] Despite SDM being increasingly featured in the rhetoric of government policy and best practice guidance, a disconnect exists between policy ideals and much of standard clinical practice.[97,214,215] This is particularly so among individuals experiencing psychosis and within antipsychotic treatment decisions, where evidence suggests clinician-led decision-making prevails, even beyond acute treatment.[98,99,100]

Whilst many interventions have been assessed for their efficacy in increasing SDM application within antipsychotic prescribing, results have proven variable.[101] Little consideration has been given to understanding the causative processes responsible for effective interventions.[102] Despite prior evidence syntheses, questions of why some interventions work, and others do not, remain.[101,103] Even in the case of empirically efficacious interventions,[104,105] their widespread implementation in practice is limited - mirroring the 'know-do gap' prevalent within mental health research.[106] Thus, within SDM research in psychosis management, a need exists for evidence outlining how successful interventions work, for whom and under what circumstances. Evidence syntheses that attempt to address such questions require a methodology that can (i) provide answers about 'how' and 'why' interventions work and (ii) account for contextual factors within implementation settings.[102]

Realist reviews are a theory-building, interpretative approach to evidence synthesis that identify how contexts and mechanisms combine to produce outcomes.[122] Unlike systematic reviews, realist reviews generate explanations as to how and why

interventions work (or not) within settings where they are implemented. Within this methodological orientation, interventions generate outcomes through individuals' responses to resources, ideas, and practices that interventions introduce, which are shaped by wider contexts. Realist reviews aim to move from empirical observation to developing causal explanations to understand what about interventions generate change (i.e., mechanisms) and under what circumstances these mechanisms are triggered (i.e., contexts), subsequently generating measurable outcomes. These three elements i.e., context, mechanism and outcome, are linked together as a context-mechanism-outcome configuration (CMOC) and are presented collectively within a programme theory.[121,122,123]

Realist methodology attends to the ways complex interventions may have different effects among different people, depending on the contexts in which they are introduced.[137] Realist programme theory produces explanations of how outcomes of interest are generated. Thus, they also provide a methodology to 'diagnose' problems. Within interventions aimed at generating behaviour change, realist reviews can be used to explain how and why both desirable and undesirable outcomes occur. Recommendations for policy, practice and intervention design are informed by the understanding within programme theories (PTs).[121,123]

5.2.1 Aims and objectives

This realist review aimed to address two research questions:

1. Within antipsychotic treatment decisions during psychosis management, what are the impacts of structural and contextual factors on prescriber engagement with SDM processes? Here, structural factors refers to broader political, cultural, economic, social, and environmental conditions at local, national, or international levels that influence individual prescriber behaviours.[216]
2. How do interventions designed to improve SDM application within antipsychotic treatment decisions work; what intervention strategies are likely responsible for effective interventions?

Review objectives included:

(i) Review the literature to identify data sources addressing when and why prescribers engage in behaviours required of SDM within psychosis management. This includes sharing of decisional responsibility and increasing patient autonomy within antipsychotic prescribing decisions.[101]

(ii) Apply a realist logic of analysis to data sources identified to develop explanations linking context to outcomes, whilst making explicit mechanisms responsible for affecting prescriber engagement with behaviours required of SDM.

(iii) Develop explanations of structural and contextual factors that serve to decrease prescriber engagement with behaviours required of SDM and as such, require systematic intervention.

(iv) Develop explanations of structural and contextual factors that increase prescriber engagement with behaviours required and as such, should be prioritised for scale-up.

(v) Review the literature to identify what interventions have been studied to increase application of SDM within the contexts outlined.

(vi) Apply a realist logic of analysis to data sources examining the efficacy or effectiveness of interventions identified in part (v) to develop explanations of what intervention strategies are likely responsible in the case of effective interventions and why, alongside facilitative implementation contexts.

(vii) Develop recommendations outlining how to design, tailor and implement SDM interventions to increase the likelihood of widespread prescriber engagement.

(viii) Engage with key stakeholders throughout the review process, including consultant psychiatrists and non-consultant psychiatric doctors, pharmacists, nurses, people with lived experience of psychosis and informal and formal carers.

5.3 Methods

5.3.1 PROSPERO registration

Methods outlined in section 5.4 were published on PROSPERO prior to review commencement on 13/10/23 (CRD42023443783). Any deviations from the protocol are outlined in Appendix 7. Realist and Meta-narrative Evidence Synthesis Evolving Standards (RAMESES) methodological guidance and publication standards were adhered to in preparing the review methodology and the review papers for publication.[121,217]

5.3.2 Ethical considerations

Given realist reviews are a form of evidence synthesis, no primary data was collected. Therefore, formal ethical approval from the research ethics committee was not required. In the case of involvement of participants in both stakeholder groups (clinician and lived experience), all participants were considered to represent Patient and Public Involvement in Research (PPI). To ensure this distinction was adhered to throughout the review process, guidance produced by the Health Service Executive Research & Development Guide to PPI in Research was consulted.[218] Involvement in the project stakeholder groups (discussed further in section 5.4.3.1) was voluntary and all PPI members were informed of their right to withdraw at any stage. Likely benefits and any potential risks of being involved were discussed with members of both stakeholder groups. All members were asked if they would like to be kept anonymous or have their details listed within any publications or sharing of results to explicitly acknowledge their contribution.

5.3.3 Pawson's five stage methodology

Review methodology adhered to Pawson's five stage methodology,[122] although, as recommended, movement through the steps proceeded in a non-linear fashion. Figure 6 provides a diagrammatic overview of the five stages that comprised the methodology applied within the review.[102]

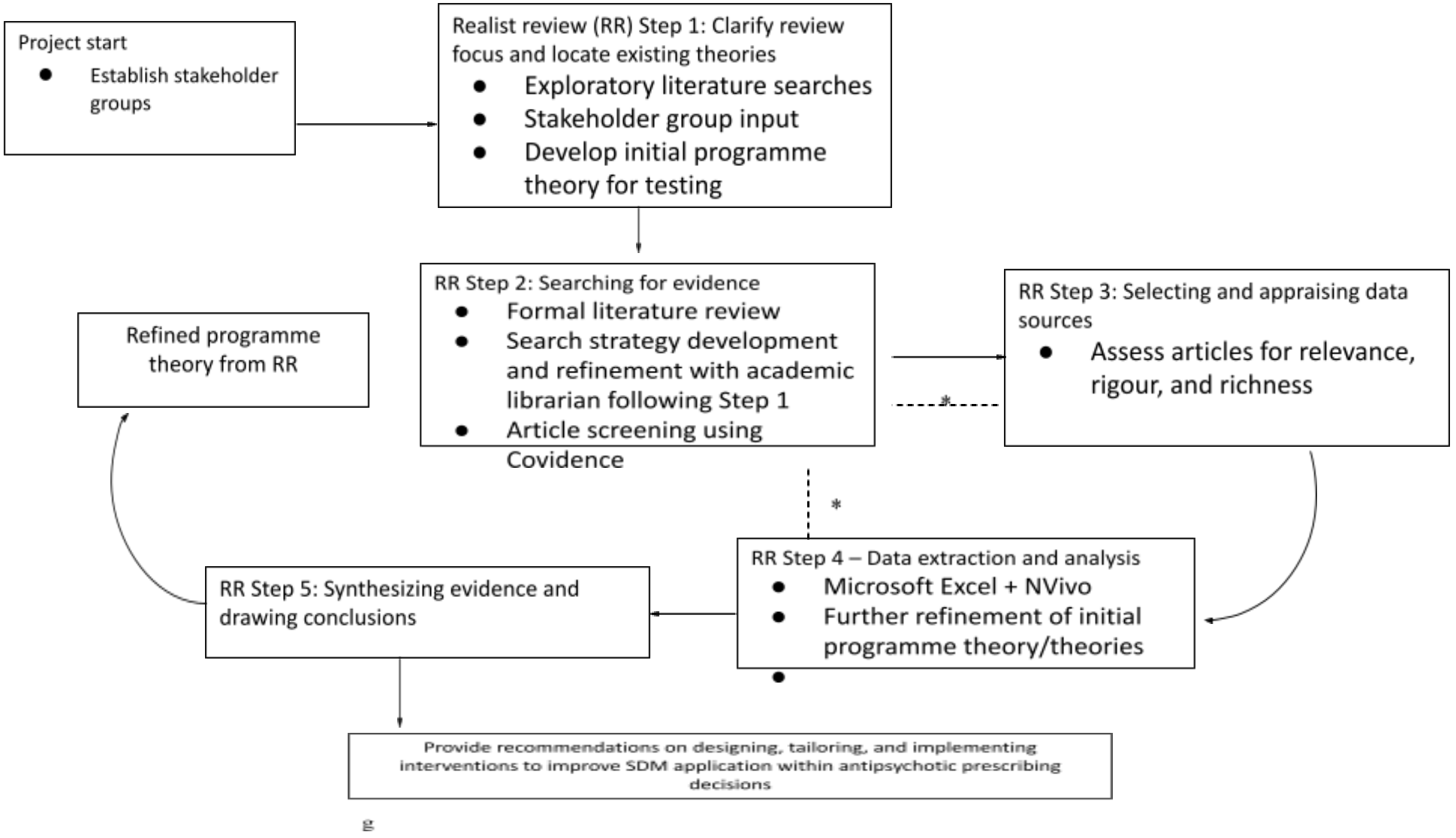


*Figure 6 - Project flow diagram. * Movement between steps if necessary to further refine programme theory.*

5.3.3.1 Project stakeholder groups

Work conducted within this review was informed by continuous engagement with clinician and lived experience stakeholder groups. The role of stakeholder groups included (i) advising on content within initial programme theories (IPTs), (ii) providing feedback on the credibility or completeness of emerging PTs and (iii) identification of additional data sources not previously identified. As such, involvement of stakeholder groups began during the initial stages of the review and continued until project completion. The clinician stakeholder group represented consultant psychiatrists, non-consultant psychiatric doctors, psychiatric nurses, and psychiatric pharmacists. Clinicians also represented those working in practice and within policy development. Peer support worker representation was also included within the clinician stakeholder group. Members of this group were recruited individually, for example, through contacts of the research team and places of work, and through general advertisement, for example, through partnership organisations or via advertisement at conferences. Groups members reflected clinicians practicing in many different settings, both nationally and internationally.

In the case of the lived experience stakeholder group, members included those with a history of psychosis and those who provided informal or formal care to them. Criteria for involvement in this group was limited to those with experience of psychosis management, or in the case of carers, experience with support provision. Members of the lived experience group were identified through the Service User Advisory Network and the Family Members, Carers and Supporters Advisory Network in St Patrick's Mental Health Services (SPMHS).[219,220] Flyers advertising for PPI collaborators were also distributed within outpatient pharmacy services of SPMHS. In the case of both groups, at the point of recruitment, information was provided on the background to the project, the roles of the stakeholder group, the voluntary nature of their involvement, the anticipated number of group meetings and their approximate duration. Further details of the primary investigator (IF) were also provided so that additional questions could be answered prior to any person agreeing to partake.

The primary investigator of the study (IF) chaired all meetings with the clinician and lived experience stakeholder groups. Within each meeting, another member of the research team attended and supported field note taking. A set of detailed notes was kept containing an overview of anonymised discussions to serve as an audit trail for decisions made within the review.

5.3.3.2 Step 1 - Clarifying review focus and locating existing theories

5.3.3.2.1 Locating existing theories

Prior to the initial meetings with stakeholder groups, the research group developed IPTs. Every intervention has a theoretical underpinning - whether explicit or not.[146] The purpose of IPTs is to articulate explanations and assumptions of how, when, why, for whom, and in what circumstances, interventions work.[221] IPTs developed by the research team represented a series of explanatory statements about how and why SDM interventions might work and what contextual factors may impact their successful implementation within practice. IPTs developed for subsequent testing were informed by (i) existing knowledge among researchers with experience of antipsychotic prescribing, psychosis management and application of SDM among individuals experiencing psychosis, and (ii) by exploratory reviews of the literature prior to formal literature searching. As a starting point for presenting IPTs for subsequent testing, individual components represented within SDM models were considered. The most widely agreed SDM model was originally formulated by Charles et al in 1997,[131] and encapsulates the following core features:

1. Involves at least two participants e.g., clinician and patient.
2. Both parties share information.
3. Both parties take steps to build a consensus about the preferred treatment (that is both sides participate in the decision-making process).
4. An agreement is reached on treatment to implement (that is a decision is made or is actively deferred).

In 2017, Montori and colleagues examined Charles et al's 1997 SDM model and modified the original core components to account for perceived differences in SDM application within long-term conditions.[222] They concluded that within such conditions, it was necessary to add another component: an ongoing partnership between the clinical team and the patient. Such a step also acknowledged that, within long-term conditions, the application of SDM rarely takes places within a single encounter. Rather, it's application is distributed over a range of people, times, and episodes. Application of SDM within the management of mental illness aligns with Montori et al's modified model and also requires an ongoing partnership between clinicians and patients.[101,222] Subsequent IPTs developed and presented to the stakeholder groups can be seen in Figure 7.

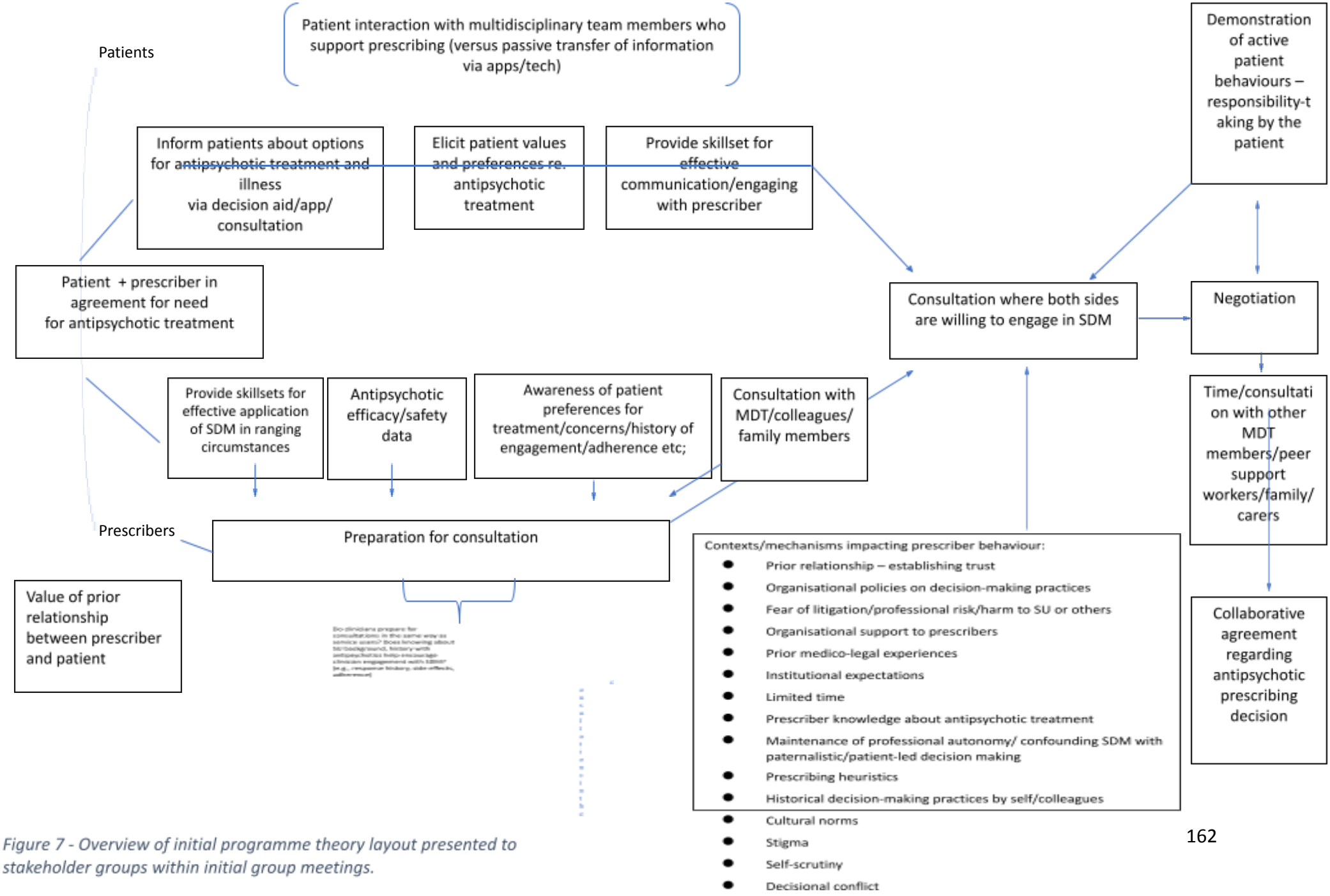


Figure 7 - Overview of initial programme theory layout presented to stakeholder groups within initial group meetings.

5.3.3.2.2 Clarifying the review focus

Following development of IPTs, the research team discussed the need to potentially focus the review further. Focusing the review, and thus, the research question(s) addressed, following IPT development is standard within realist review methodology, given the range of potential explanatory questions that could be addressed.[121] To ensure review results offered clear potential to inform SDM intervention design and implementation, and to direct practice and policy within psychiatry, experienced clinicians within the research team suggested narrowing the review scope to understanding prescriber *or* patient needs to engage in SDM within the contexts outlined. This suggestion was subsequently discussed in the initial stakeholder group meetings. Table 11 contains an overview of notes documented following these initial meetings.

Table 11 - Overview of notes taken from the first stakeholder group meetings where discussions were had about focussing the review.

Meeting 1	
Clinician stakeholder group notes (n=8)	Lived experience stakeholder group notes (n=5)
Professionals represented at the meeting: ● Medical (consultant and non-consultant psychiatric doctors) ● Psychiatric pharmacists ● Psychiatric nurses (managerial level and staff nurse) ● Policymaker in psychiatric settings ● Community pharmacist ● Researcher in shared decision-making ● Peer support worker **Topics discussed:** 1. Focussing the review initially – patient/prescriber needs ● Discussed merits of focussing the review on how SDM interventions work and how the environments in which they are offered impact prescriber ability and willingness to engage in SDM. ● Discussed neglect of prescriber needs in intervention design and delivery may explain small effect size of successful interventions to date and lack of implementation.	Experiences represented at the meeting: ● Family member/carer ● Individual with lived experience of psychosis **Topics discussed:** 1. Focussing the review initially – patient/prescriber needs ● Discussed power imbalance patients faced during antipsychotic treatment decisions. Participants discussed one person holding all the power to make decisions and that this may influence the burden of responsibility felt by prescribers. ● Agreed need to focus on prescriber and system-factors (inside and outside of mental

Meeting 1	
Clinician stakeholder group notes (n=8)	Lived experience stakeholder group notes (n=5)
● Discussed merits of focussing on interventions designed to motivate and prepare patients to engage in SDM. ● Agreed that focussing on highlighting intervention strategies that promote prescriber engagement in SDM and the impact of contextual factors on their success would provide a more impactful and novel explanatory lens given the focus on patient needs to date, without any associated meaningful change in practice. ● Agreed that focus on prescriber 'needs' within the review could include: ○ Interventions directly offered to prescribers through a targeted intervention strategy e.g., prescriber training. ○ Prescribers' response to patients responding to intervention strategies targeted towards them e.g., increased patient responsibility for decision-making during consultations. ○ Impact of wider contextual factors on prescriber willingness to engage with SDM interventions e.g., impact of organisational policy endorsing SDM as preferred model of decision-making.	health settings) impeding prescriber engagement in SDM as they hold greater power within the relationship to effectively apply SDM during antipsychotic treatment decisions. ● System factors may include: ● Inside organisation: Culture re. SDM/risk-taking, policies, resources (time, personnel) ● Outside organisation: Legislation, institutional norms.

Meeting 1	
Clinician stakeholder group notes (n=8)	Lived experience stakeholder group notes (n=5)
2. Areas of importance to focus on when looking at prescriber needs: ● Value of relationship amongst clinicians and the importance of trust between members of an MDT when engaging non-medics in antipsychotic prescribing. Responsibility for prescribing – does this fall to prescriber or teams? ● Value of relationship amongst patients and clinicians and mutual trust, who is engaging in SDM with the patient? ● Generating investment amongst prescribers that SDM leads to better longer-term outcomes. ● Peer support worker spoke about the value of education and training for prescribers from undergraduate level and beyond – not only in relation to training in SDM skillsets (what it is, why you should do it and how to do it), but also knowledge about antipsychotics in psychosis management, specifically similar efficacy estimates to challenge cognitive biases around some antipsychotics being significantly more effective than others.	2. Areas of importance to focus on during the review: ● Group reflected on general intervention strategies that they thought might be important to facilitating SDM - may provide insight into potential contexts or mechanisms. ● Need for tailored information about antipsychotic treatment options – one-size-fits all approach unlikely to meet diverse patient needs. ● Differences in mental versus physical health settings: ▪ Need to account for cognitive impairment, impact of delusional symptoms (particularly paranoia) ▪ Need for longitudinal application – application of SDM conceptualised as a continual process in mental health settings. Associated need for shared risk-taking approach

Meeting 1	
Clinician stakeholder group notes (n=8)	Lived experience stakeholder group notes (n=5)
• Prescriber reflections in meeting about prescribers often coming to consultation with a decision about antipsychotic treatment already in mind. How do we promote prescribers pausing to consider SDM rather than quick, 'system 1' thinking? • Addressing a cultural legacy of paternalistic decision-making. • Impact of SDM endorsement as the preferred model of SDM in organisational policy – would this help or hinder? • Flexibility provided to prescribers via longitudinal SDM application discussed, including interventions that are provided at multiple time points.	to changing antipsychotic during acute psychosis management if not well enough to engage in SDM during very acute illness. • Working with a longer-term and shared plan that is clearly communicated. • Multidisciplinary support facilitating SDM through tailored information and repeated interactions with patients – availability of longitudinal support. • Who is delivering the shared decision-making intervention – importance of trust and relationship in effectively achieving SDM beyond surface-level agreement. • Carer reflected that the system has to value SDM for it to happen. • Potential value of postgraduate training on effective communication and listening to patients. • SDM skillsets for prescribers:

Meeting 1	
Clinician stakeholder group notes (n=8)	Lived experience stakeholder group notes (n=5)
	▪ Training that includes feedback from patients following application to avoid tokenism. ▪ Supervision from trained peers. ● Involvement of personnel beyond prescriber-patient interaction in facilitating SDM ● Pharmacists ● Care co-ordinator (particularly where trust has been previously established).

A decision was subsequently made to focus on developing an in-depth understanding of when and why prescribers engage with behaviours required of SDM and associated interventions within antipsychotic prescribing. It was collaboratively agreed that a significant contributor to the SDM implementation gap is a lack of understanding regarding prescriber needs to support their engagement in SDM. This was supported by scoping searches prior to review commencement.[101,103] Of note, within this review, prescribers refers to medical prescribers and non-medical prescribers i.e., nurses and pharmacists.[223] This decision considered the design of psychiatric services internationally, where independent, non-medical prescribers may also prescribe antipsychotic medications. Where a specific prescriber group is being referred to, this was highlighted within the respective programme theory.

IPTs previously formulated addressing potential factors impacting prescriber engagement with SDM behaviours and interventions were then re-written to contain explanatory statements to be subsequently tested and refined through formal and grey literature searches. Explanatory statements within IPTs were further developed via additional scoping searches to identify (i) common SDM intervention strategies, (ii) existing theoretical perspectives underpinning the inclusion of selected intervention strategies, and (iii) impact of contextual factors on prescriber engagement with SDM interventions.

5.3.3.2 Step 2 – Searching for evidence

5.3.3.2.1 Inclusion and exclusion criteria

Following agreed review focus, inclusion and exclusion criteria informing formal literature searches were amended from the review protocol.[102] Finalised inclusion and exclusion criteria are outlined in Table 12.

Table 12 - Review inclusion and exclusion criteria.

Population	Include: ● Adult participants (aged 18-65 years) experiencing an episode of psychosis in the context of a psychotic illness where extended antipsychotic treatment is indicated. Exclude: ● Participants with treatment-resistant schizophrenia (due to clozapine being the preferred treatment choice among this cohort). ● Participants experiencing substance/medication-induced psychosis or psychosis in the context of an underlying medical condition where continued antipsychotic treatment is unlikely.
Intervention	Any intervention designed to increase application of SDM between prescribers and patients within decisions impacting antipsychotic treatment. Whilst within implementation research 'interventions' can broadly encompass individual-level, system-level and organisational-level programmes, government systems or organisational policies,[102] the majority of SDM research within psychosis management has focussed on developing individual-level strategies, and more recently, optimising local service delivery contexts.[103] Hence, the term 'intervention' here refers to its use within these contexts.
Comparator	Not applicable.
Outcome	In the case of studies assessing the efficacy of SDM interventions, eligible studies included those where outcomes related to evidence of SDM application. Assessing effective SDM application has been assessed using a variety of different outcome measures, typically measured via assessments of patient perceived involvement in decision-making.[101] For example, use of the Shared-Decision Making Questionnaire (SDM-Q-9), the CollaboRATE scale or the Perceived Involvement in Care Scale (PICS).[224] Studies

	where prescriber perceived involvement in SDM was the primary outcome measure were also included.
Timing	Use of interventions to inform choice of antipsychotic treatment (including initial treatment, change of treatment or continuation of treatment) as part of acute psychosis management i.e., when an individual is experiencing an episode of psychosis or in the initial recovery period.
Setting	Include ● Inpatient and outpatient settings, including community mental health teams and primary care settings, to account for differing models of care within mental health service delivery. Exclude: ● Forensic settings.

5.3.3.2.2 Formal literature searches

Literature searches, including databases searched and search terms used, were agreed in consultation with an academic librarian in University College Cork (UCC) and were piloted and reviewed accordingly. Literature searches combined terms in combinations across four categories: shared decision-making, intervention design/implementation, antipsychotic treatment and psychosis or psychotic illnesses. CINAHL Plus, Cochrane Library, Embase, PsycINFO, PubMed, Scopus, Sociological abstracts, and Web of Science were searched from 1990 to December 13th, 2023. To supplement database searches, a grey literature search was also undertaken via Google Scholar on June 24th, 2024. Guidance by Haddaway et al was adhered to in searching Google Scholar to optimise searching for grey literature,[225] whereby the first 200 results of each search string were reviewed and the advanced search function was applied to refine returned results. Title searching, rather than full text searches, was also undertaken. Despite expanding the number of results reviewed through application of Haddaway's guidance, limitations of searching for grey literature within Google Scholar remained, including lack of clarity by which the order of results is displayed, subsequently impacting reproducibility of searches,

and advanced searching reporting only allowing use of basic Boolean operation (even within advanced searching methods).[225] In the case of all searches, only English language data sources were included. Screening of all articles was undertaken using Covidence (http://www.covidence.org).

5.3.3.2.1 Supplemental literature searches

In line with the purposeful nature of searching for data within realist reviews,[146] following formal literature searches and in consultation with stakeholder groups, it was agreed that additional, specific searches were required. Within the second stakeholder group meeting, formalised risk management practices were identified as a prominent barrier to prescriber engagement in SDM, particularly positive risk-taking. Positive risk-taking is defined as risk management which improves patients' quality of life and plans for recovery, while remaining aware of the person's safety needs, their care and the public.[226] Positive risk-taking conceptually overlaps with much of the theory informing SDM models and a willingness to engage in positive risk-taking is a prerequisite for prescriber engagement in SDM.[227]

Adhering to Pawson's methodology,[122] it was agreed that additional IPTs to those formulated within Step 1 were required outlining the relationship between risk management practices and their impact on prescriber behaviours. Additional, purposeful searches within PubMed, Embase, PsycINFO, CINAHL and Google Scholar were undertaken from 1990 to June 24th, 2024, to identify data sources discussing factors influencing prescriber adoption of risk-averse prescribing behaviours or positive risk-taking within psychosis management. Results were used to test, refine or refute these specific IPTs.[102] In the case of both original and additional database searchers, alerts were established across all databases to identify data sources published until October 2024.

All searches were undertaken by one researcher (IF). A random 10% subsample of all studies were independently checked against inclusion and exclusion criteria by other members of the research team for evidence of any systematic errors.[122] Disagreements were resolved by discussion with recourse to an independent member of the project team until consensus was achieved. Details of all database searching are contained within appendix 10.

5.3.3.3 Step 3 – Selecting and appraising individual data sources

Inclusion of data sources within the review focussed on consideration of three criteria as follows:[122]

1. Relevance (i.e., whether data could contribute to testing, advancement, or development of initial programme theories).
2. Rigour (i.e., whether methods used to generate data were considered credible and trustworthy).
3. Richness (i.e., whether a data source can contribute meaningfully to PT development or refinement).

5.3.3.3.1 Assessing relevance

Data sources were initially screened according to their relevance to the topic area under investigation and initial programme theories that had been formulated. Rigour and richness were then subsequently considered in prioritising data sources to inform further programme theory refinement and advancement. A list of all data sources and criteria for exclusion based on reasons of low relevance was retained using Covidence. This was important given the iterative nature of programme theory development as it allowed for their reconsideration depending on programme theory advancement as the review progressed.

5.3.3.3.2 Assessing rigour

RAMESES quality standards for realist reviews define rigour as whether the method used to generate that particular piece of data is "*trustworthy*".[121] As detailed within chapter 3, given that eligible data sources were epistemologically complex and methodologically diverse, and the product of the review being theory, judgements of trustworthiness were not conducted using formal application of critical appraisal tools or scales, as applied within traditional systematic review methodology.[228] In the case of qualitative (e.g., semi-structured interview studies) or quantitative (e.g., results of RCTs) studies, whilst assessment of rigour considered robustness of methods applied, the research team also considered sample size, appropriateness

of data collection techniques, analysis methods applied and similarity of results to studies with similar designs, where relevant. Where it was unclear what methods were used, such data sources were treated with scepticism and viewed in the context of other data sources.[119] Assessments of rigour of individual data sources using criteria typically informed by positivist research paradigms were carefully balanced against the consideration that even methodologically weak studies can contain "*nuggets of wisdom*". Such data sources can be appropriate for consideration within realist reviews, when considered alongside the breadth of included data sources and relevant substantive theory.[152]

5.3.3.3.3 Assessing richness

Richness of the data source was considered according to criteria outlined by Booth et al,[118] where data sources could contribute 'conceptual richness' and/or 'contextual thickness'. Conceptual richness is the degree of theoretical and conceptual development that explains how an intervention is expected to work. Contextual thickness entails sufficient detail that enables the reader to establish (i) what is occurring in the intervention and in the wider context, and (ii) to infer whether findings can be transferred to other people, places, situations and environments.[118,134]

5.3.3.3.4 Operationalising assessments of relevance, rigour and richness.

A quality judgement was assigned to each individual data source based on a global assessment of relevance, rigour and richness, as outlined by Howe et al.[228] Application of this method involves assigning a star rating of one to five to full-text documents according to individual assessment of these three criteria. Documents assigned a one- or-two-star rating were deemed irrelevant to programme theory development, advancement or refinement and were not included. Three-star documents did not contribute to programme theory development, but were kept for use as background information. Four-star documents were those classified as relevant for programme development and refinement. Five-star documents were deemed the most conceptually rich, and/or contextually thick, and so, most relevant

to programme theory development. Thus, only four- and five-star documents contributed to programme theory development. All 1–3-star documents were re-reviewed before finalising each PT to confirm the classification was appropriate.[288]

Quality assessments were originally undertaken by one researcher (IF). A random subsample of 10% of data sources were assessed independently and assigned a quality rating according to the method outlined above by another member of the research team (JH) to identify any systematic errors and minimise subjectivity in assessments.[121,229] In the case of disagreement, a third member of the research team was involved (LS, EC), and discussions continued until consensus was agreed.

5.3.3.4 Step 4 – Data extraction and analysis

5.3.3.4.1 Data extraction

Data extraction and organisation was undertaken by one researcher (IF) using Microsoft Excel. Study characteristics extracted included:

- Study details (publication year, first author, location of study)
- Study setting
- Study design and methods
- Population included
- Study objectives
- Intervention description (where relevant)
- Any quality markers at study-level to inform assessments of rigour
- Outcomes assessed and measurement methods

5.3.3.4.2 Data analysis

Full texts of all included papers were uploaded to NVivo qualitative data analysis software (Release 1.7.1 for Mac). Relevant excerpts from data sources were extracted and mapped onto IPTs using a standardised data extraction form. All data were coded using NVivo. Sections of text were initially coded into broad conceptual

categories, e.g., developing therapeutic alliance, beginning with the richest data sources i.e., those deemed to have the greatest potential to further refine or refute IPTs. Subsequently, a realist logic of analysis was applied, as detailed in chapter 3, whereby data excerpts were coded as a CMOC, where applicable, and in other cases, as dyads (C-M, M-O, C-O).[137]

Data extraction was completed by one researcher (IF) and a 10% random subsample was reviewed independently by another member of the research team. Any disagreements were resolved via discussion until consensus was achieved. As PTs were refined and developed, four- and five-star studies were re-scrutinised for relevant data that may have been missed.[228] The application of a realist logic of analysis to all excerpts was completed by one researcher (IF) and subsequently completed independently by a second member of the research team (JH) with extensive methodological experience in realist methods.

5.3.3.4.3 Substantive theory – COM-B Model of Behaviour

Available substantive theory (formal theory) was also considered during data analysis, as outlined in chapter 3.[146] Specifically, substantive theory was used to identify, or further corroborate, mechanisms and features of activating contexts to facilitate development of CMOCs. To identify potentially relevant theories initially, the project team's own theoretical knowledge base was consulted.[146] Potentially suitable substantive theories were then assessed using criteria outlined by Shearn et al,[137,230] including:

1. The extent to which theories identified offer guidance for explaining phenomena at or between micro-, meso- or macro-levels.
2. Their potential alignment with the aims of the research, that is the extent to which they offer insights relevant to the two research questions being addressed.
3. Their simplicity i.e., how readily they can contribute to PT development.
4. Their compatibility with realist notions of causation i.e., the extent to which they offer guidance for articulating generative causation.

Given the focus on understanding influences on prescriber behaviours, the COM-B Model of Behaviour was selected as a framework to build and strengthen plausibility of CMOCs and resultant PTs. This theoretical model of understanding determinants of behaviour is often used in the context of designing effective behaviour change interventions.[231,232]

The COM-B model proposes that to engage in a behaviour (B), a person must feel both physically and psychologically capable of doing so (C) and have the social and physical opportunity (O) to exhibit the behaviour, and the want or the need to demonstrate the behaviour more than competing behaviours at that moment – motivation (M). Capability and opportunity are seen as influencing the relationship between motivation and behaviour, rather than motivation itself. This represents the idea that, at any individual and moment-to-moment basis, they act like 'logic gates' in that both of the 'gates' (capability and opportunity) need to be open for motivation to generate the behaviour. Aggregated over time and people, capability and opportunity can be thought of as more quantitatively: the greater the capability and opportunity, the more likely a behaviour is to occur because the more often the gates will be open when the motivation is present.[231,232] An overview of the relationship between components of the COM-B model is provided in Figure 8.[231,233]

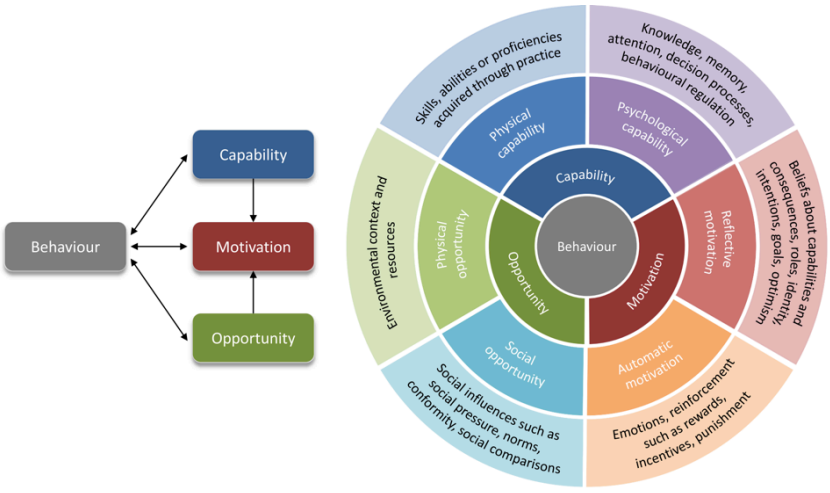


Figure 8 - The COM-B model of behaviour.[232]

Capability refers to whether the individual possesses the requisite knowledge, skills and abilities. Opportunity refers to external factors that make execution of a behaviour possible. Motivation refers to internal processes that influence decision-making and behaviour. The two main components within motivation are reflective motivation – the reflective processes involved in making plans – and automatic motivation – the automatic processes such as impulses and inhibition.[105,231]

5.3.3.5 Step 5 - Synthesizing evidence and drawing conclusions

In developing final PTs, members of the research team moved iteratively between data and interpretation to identify how mechanisms behaved in different contexts and why mechanisms may be triggered in specific circumstances and contexts. Following application of a realist logic of analysis to all relevant data sources by IF and JH, all researchers reviewed subsets of CMOCs and PTs (and supporting data excerpts) independently and applied a similar logic of analysis. This step provided the research team the opportunity to challenge theorising previously applied and question whether additional literature searches were needed to ensure final PTs were sufficiently evidence-based.[119]

Following this step, it was subsequently agreed in the case of a small number of CMOCs that adequate supporting data had not been identified. Whilst the choice to search for additional data was considered, it was agreed within the research team, and in consultation with stakeholder groups, that ten robust PTs had been developed that represented a meaningful advancement in understanding of how to effectively design interventions and supporting services to increase prescriber engagement in SDM.

Wording of final CMOCs and programme theories was refined iteratively such that all members of the research team agreed that programme theories accurately and adequately reflected supporting data. Final programme theories were also reviewed by members of the stakeholder groups to support assessment of coherence of argument and readability among target audiences.

5.4 Results

5.4.1 Results of data searches

Through initial and targeted searches, 3,927 data sources were identified for initial screening. A further 1,221 were identified through supplementary searching methods. Following title and abstract screening of 3,540 data sources, 295 full texts were assessed for eligibility. A total of 106 data sources were subsequently included for screening against IPTs and development of new programme theories. Searching and screening results are summarised in Figure 9.

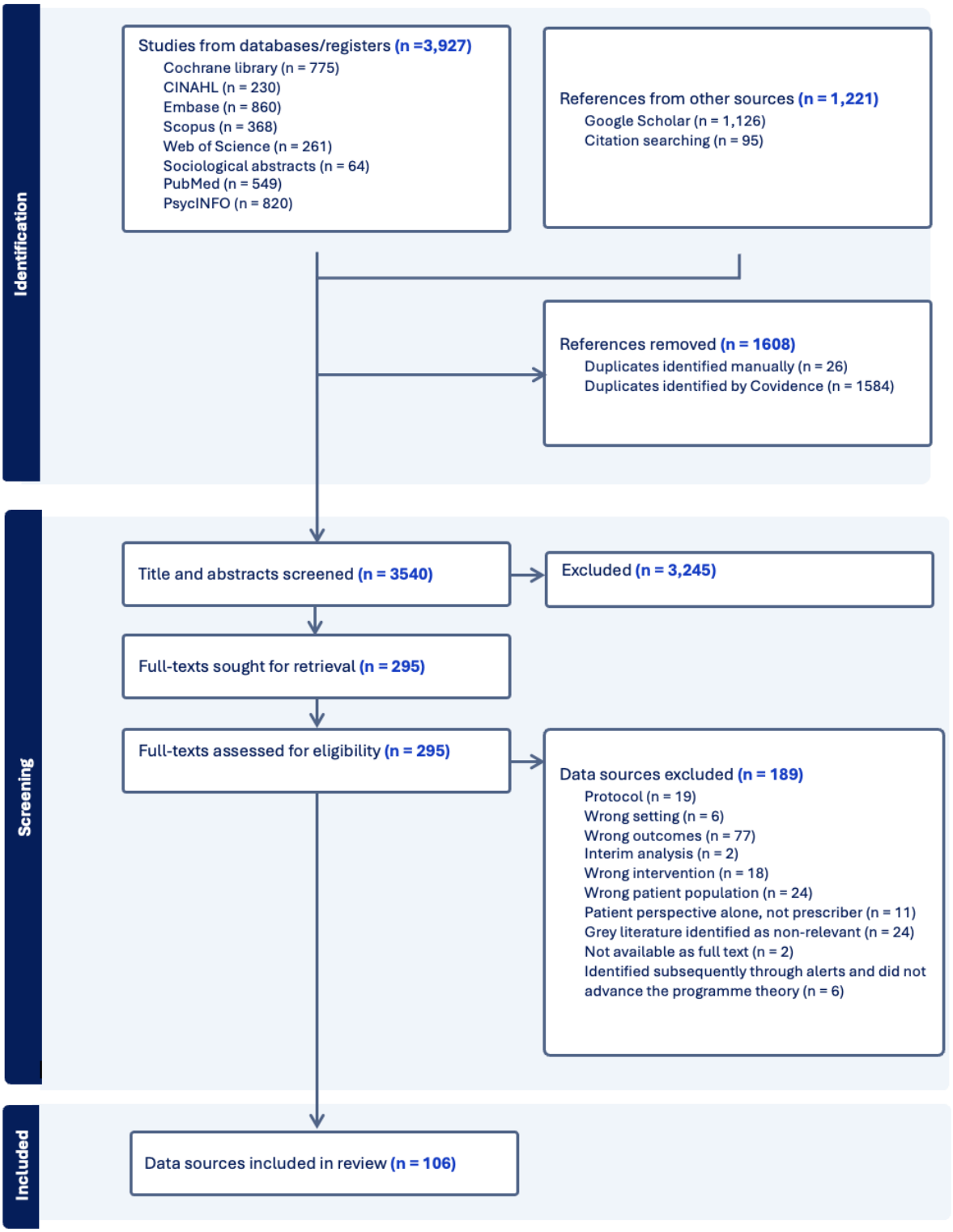


Figure 9 - PRISMA flow diagram of review searching and screening results.

5.4.2 Characteristics of included data sources

5.4.2.1 Results from initial literature searches

Primary characteristics of the 106 data sources are contained in Table 13, alongside global assessments of relevance, rigour and richness assigned to each data source.[228] Global quality assessment of individual data sources assigned 21 data sources a 5-star rating and 52 a 4-star rating. Thus, 73 data sources contributed to programme theory development.

Table 13 - Overview of data sources included in the review identified within initial planned searches. Quality ratings assigned to each data source from 1-5 are highlighted.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
	SDM intervention studies				
1	Zisman-Ilani et al (2024) [234] 4-star rating	Randomised controlled trial (pilot)	USA	18–25-year-old participants with a first episode of psychosis Co-ordinated speciality care setting providing early intervention to those with first episode psychosis	Evaluate the usability and feasibility of a decision aid for use during antipsychotic treatment consultations.
2	Perez-Revuelta et al (2023) [105] 5-star rating	Randomised controlled trial	Spain	≥18-year-old participants with a diagnosis of schizophrenia or schizoaffective disorder	Determine whether a traditional SDM model (information provision and deliberation) when

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				Inpatient	complimented with targeted timing pre-discharge and after very acute treatment + offering of booster sessions is more effective than treatment as usual on adherence and other variables, including participant satisfaction and confidence with the decision.
3	Vitger et al (2022) [127] 4-star rating	Randomised controlled trial	Denmark	18–35-year-old participants with a first episode of schizophrenia, schizotypal or delusional disorder Outpatient	Investigate the effect of a digital tool to support patient activation and shared decision making.
4	Hamann et al (2020) [104] 5-star rating	Randomised controlled trial	Germany	18–65-year-old participants with a diagnosis of schizophrenia or schizoaffective disorder Inpatient	Evaluate a complex intervention for the implementation of SDM (SDM-PLUS). SDM-PLUS aims to provide care providers and patients with skillsets required for engagement in SDM. SDM-PLUS teaches communication techniques derived from motivational

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					interviewing and negotiation approaches.
5	Hamann et al (2017) [235] 5-star rating	Randomised controlled trial	Germany	18–60-year-old participants with a diagnosis of schizophrenia or schizoaffective disorder Inpatient	Evaluate the impact of patient training in SDM skillsets (motivational and behavioural training) in preparation for consultations with prescribers.
6	Hamann et al (2011) [236] 4-star rating	Randomised controlled trial (pilot)	Germany	18–60-year-old participants with a diagnosis of schizophrenia or schizoaffective disorder Inpatient	Evaluate the impact of patient training in SDM skillsets (motivational and behavioural training) in preparation for consultations with prescribers.
7	Hamann et al (2006) [237] 4-star rating	Randomised controlled trial (pilot)	Germany	18–65-year-old participants with a diagnosis of schizophrenia or schizophreniform disorder Inpatient	Evaluate the impact of an SDM intervention (decision aid and 'planning talk') in facilitating SDM

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
	Mixed methods studies				
Data source no.	**First author (Year)**	**Study design/methods**	**Country**	**Participants/setting**	**Study objectives of relevance to this review**
8	Eliacin et al (2022) [238] 4-star rating	Psychometric testing of inpatient mental health settings for implementation of shared decision-making during medication management and qualitative interviews with key informants at each site assessed	USA	Inpatient mental health units	Examine the understanding and practice of shared decision- making (SDM) within the context of recovery- oriented care across Veterans Health Administration (VHA) inpatient mental healthcare units.
9	Finnerty et al (2019) [239] 3-star rating	Quantitative assessment of number of uses of SDM tool and qualitative assessment of associated implementation documents.	USA	Two mental health clinics Community treatment services	• Examine use of a web based SDM programme by individuals receiving speciality mental health services. • Identify factors influencing adoption during the first 18

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					months of implementation.
10	Schon et al (2018) [240] 4-star rating	Process evaluation of an implementation programme aimed at implementing use of decision support tool Qualitative focus group interviews with a subgroup of participating staff	Sweden	Six separate units across Sweden offering psychiatric services to people with severe mental illness Community treatment services	Describe and analyse the implementation process of an SDM intervention for users of psychiatric services in Sweden.
11	Ramon et al (2017) [241] 4-star rating	Quantitative assessment of SDM application within medication consultations Qualitative assessment of anonymous feedback of feedback provided	UK	Adult patients, care co-ordinators and psychiatrists providing care to adults with mental health conditions Community treatment services	Develop and evaluate a novel training programme to enhance SDM in psychiatric medication management for service users, psychiatrists, and care co-ordinators.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
		by participants at SDM training sessions Qualitative semi-structured interviews of sub-samples of service users, psychiatrists, and care co-ordinators at 12 months follow-up.			
12	Grim et al (2017) [242] 3-star rating	Cycles of development and usability testing via workshops, qualitative focus groups and semi-structured qualitative interviews	Sweden	Adults with psychiatric illnesses and psychiatric service providers Community treatment services	Use a participatory design to facilitate the development of a user-generated, web-based decision aid for individuals receiving psychiatric services.
13	Matthias et al (2014) [243]	Conversation analysis and correlation analysis	USA	Patients attending a psychiatric clinic with	Explore the association between shared decision making and consumers'

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
	4-star rating			varying mental health diagnoses Community treatment services	illness management skills and consumer-provider relationships.
	Qualitative studies				
Data source no.	**First author (Year)**	**Study design/methods**	**Country**	**Participants/setting**	**Study objectives of relevance to this review**
14	Muller et al (2023) [244] 4-star rating	Qualitative focus groups	Germany	Psychiatrists and patients with a diagnosis of schizophrenia spectrum disorder Inpatient	Explore the expectations and desires for an antipsychotic treatment decision aid to be developed among two main stakeholder groups: people treated for psychosis and psychiatrists.
15	Shue et al (2023) [245] 4-star rating	Qualitative analysis of development and implementation documents	USA	Subsample of extreme groups from a range of inpatient mental health units where the implementation of SDM during medication management was investigated. Inpatient setting	Systematically examine factors affecting the implementation of one aspect of recovery-oriented care in a large and diverse national sample of Veterans Health Administration (VHA) inpatient mental health units.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
16	Gurtner et al (2022) [246] 3-star rating	Qualitative ethnography	UK	Swiss psychiatric hospital offering services for people with mental health problems, from outpatient, intermediate and acute inpatient services, and rehabilitation. Mixed setting	Examine the nature of interactions and communication between health care professionals and patients during regular interprofessional psychiatric consultations.
17	Maples et al (2022) [247] 4-star rating	Qualitative semi-structured interviews	USA	Patients with a severe mental illness recently discharged or deferred from hospital and psychiatric clinicians (psychiatrists, nurses, and psychologists) Transitional care setting	Identify factors influencing the use of a shared decision-making model in a transitional care clinic providing treatment to people with serious mental illness after the occurrence of a psychiatric crisis or hospitalization.
18	Hilden et al (2021) [248] 2-star rating	Qualitative semi-structured interviews	Finland	Psychiatric clinicians working in outpatient, community healthcare and inpatient settings Mixed setting	Provide clinicians view on the possibilities of SDM in community mental health in Finland.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
19	Becher et al (2021) [249] 4-star rating	Qualitative semi-structured interviews	Germany	Participants from the intervention group of the SDM-PLUS trial. Participants included adults in the patient training group (aged 18-65 years of age with schizophrenia) and staff (psychiatrists, resident doctors, psychologists, and nurses) who participated in the staff training group Inpatient setting	Examine barriers and facilitators of SDM with acutely ill inpatients with schizophrenia.
20	Wesseldijk-Elferink et al (2021) [250] 2-star rating	Qualitative semi-structured interviews	The Netherlands	Mental health nurses and adult (≥18 years of age) patients with a diagnosis of schizophrenia or schizoaffective disorder Inpatient setting	Describe the experiences of patients with schizophrenia or schizoaffective disorder with SDM in a semi-secluded psychiatric facility, and the attitudes toward SDM by mental health nurses.
21	Just et al (2021) [226] 4-star rating	Qualitative semi-structured interviews	UK	Mental health nurses, social workers, occupational therapists, support workers or	Explore inpatient staff's understanding and implementation of positive risk management.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				healthcare assistants working in an adult acute psychiatric unit or psychiatric intensive care unit for at least 3 months Inpatient setting	
22	Kaminskiy et al (2021) [251] 4-star rating	Qualitative semi-structured interviews	UK	Patients, psychiatrists, and community psychiatric nurses, in a community mental health team in the United Kingdom. Community treatment setting	Examine the views of service users, community psychiatric nurses, and psychiatrists about enablers and barriers of SDM.
23	Martínez-Hernáez et al (2020) [252] 5-star rating	Qualitative semi-structured interviews and qualitative focus groups	Spain	Users of antipsychotics, family caregivers and psychiatric clinicians (psychiatrists, psychologists, nurses, and social workers) Mixed setting	Analyse the main obstacles to the collaborative management of antipsychotics.
24	Moleman et al (2021) [253]	Qualitative semi-structured interviews	The Netherlands	Patients with experience of psychiatric illness and healthcare professionals	Describe how healthcare professionals manoeuvre the

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
	4-star rating			(physicians, medical residents, nurses, and department managers) working in psychiatry. Inpatient setting	nuances of decision-making that shape SDM.
25	Haugom et al (2020) [99] 5-star rating	Qualitative focus groups	Norway	Healthcare professionals (psychiatrists, psychologists, psychiatric nurses, and social educators) with experience of caring for those with psychosis. Inpatient and community treatment settings	Describe and explore health professionals' SDM experiences with patients with psychotic disorders.
26	Henshall et al (2019) [254] 4-star rating	Qualitative focus groups	UK	Patients with a mental health diagnosis requiring treatment with an antipsychotic (currently or in the past), carers and psychiatrists Community treatment settings	Explore psychiatrist, patient and carers' views on the acceptability and usefulness of our newly developed decision support tool in relation to its use as a shared decision-making tool between clinicians and patients.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
27	Wood et al (2019) [255] 4-star rating	Qualitative semi-structured interviews	UK	Inpatients with psychosis and multidisciplinary staff members (psychiatrists, nurses, and occupational therapists) Inpatient	Examine patient and staff perspectives on the care priorities of psychiatric in-patients with psychosis.
28	Bauer et al (2019) [256] 3-star rating	Qualitative focus groups and semi-structured interviews	UK	Programme managers of five initiatives responsible for implementing recovery-orientated initiatives within community mental health services Community treatment setting	Understand the organisational characteristics of initiatives that implement recovery-oriented practice at the interface between mental health services and communities, as well as the mechanisms they employ to alter the conditions in which they operate.
29	Cooper et al (2019) [257] 4-star rating	Qualitative focus groups	UK	Mental health professionals (psychiatrists, mental health nurses, social workers, and clinical team managers) Secondary mental health care setting (providing inpatient and	Establish mental health professionals in secondary care attitudes towards, experiences of and the processes around antipsychotic reduction and discontinuation.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				community-based outpatient treatment)	
30	Zisman-Ilani et al (2018) [258] 3-star rating	Qualitative semi-structured interviews	USA	Patients with first-episode psychosis, patients with long-term psychosis, family members, psychiatrists, mental health counsellors, and administrators Community treatment setting	• Develop an electronic decision aid (EDA) for antipsychotic medications decision-making that formally addresses the three options (continue, adjust, or stop). • Revise the tool based on a qualitative user-testing study with potential users that was designed to evaluate the clarity, usability, and potential barriers to and facilitators of future implementation of the new EDA in psychiatric consultations.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
31	Forsberg et al (2018) [259] 4-star rating	Qualitative semi-structured interviews	UK	Psychiatric clinicians (psychiatrists, mental health nurses) Mixed setting	Examine clinicians' perspectives on supporting adults who wish to discontinue neuroleptic medication.
32	Giacco et al (2018) [260] 5-star rating	Qualitative focus groups and semi-structured interviews	UK	Healthcare professionals (psychiatrists, psychologists, psychiatric nurses), inpatients who Inpatient setting	Identifying barriers and facilitators to shared decision-making with involuntary patients.
33	Zisman-Ilani et al (2017) [261] 3-star rating	Qualitative semi-structured interviews	USA	People with psychosis, clinicians, caregivers, and health administrators Community treatment setting	Evaluate attitudes and readiness for digital decision aids among four stakeholder groups: people with psychosis, clinicians, caregivers, and health administrators.
34	Brooks et al (2017) [262] 5-star rating	Qualitative semi-structured interviews and focus groups	UK	Mental health care professionals (Psychiatrists, psychiatric nurses, pharmacist), patients aged over 18 with experience of antipsychotic prescribing	Explore the potential use of a tool designed to enhance collaborative antipsychotic prescribing from the perspectives of secondary care mental health service users, carers, and professionals.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				Secondary mental health care setting	
35	Stacey et al (2016) [263] 5-star rating	Qualitative focus groups	UK	Patients, carers, healthcare professionals (Psychiatrists, nurses, occupational therapists, social workers) and peer support workers Inpatient setting	Examine to what extent decisions about patients' care are perceived to be shared on adult acute mental health wards.
36	Hamann et al (2016) [264] 4-star rating	Qualitative focus groups	Germany	Psychiatrists and patients with a diagnosis of schizophrenia or schizoaffective psychosis, bipolar affective disorder, or depression with experience of both inpatient and outpatient treatment Inpatient and outpatient setting	Explore both patients' and psychiatrists' views on how patients can facilitate shared decision making in acute mental health settings.
37	Mikesell et al (2016) [265] 4-star rating	Qualitative semi-structured interviews and focus groups	USA	Healthcare providers (team leaders, administrators, psychiatric clinicians, patients, and family	Explore experiences with and perceptions about decision support strategies aimed to promote SDM around

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				members) with experience of serious mental illness Community treatment setting	psychotropic medication treatment.
38	Younas et al (2016) [266] 4-star rating	Qualitative semi-structured interviews	UK	Psychiatric pharmacists Secondary mental health care setting	To explore the views and experiences of UK mental health pharmacists regarding the use of SDM in antipsychotic prescribing in people diagnosed with SMI.
39	Coulter et al (2015) [267] 4-star rating	Qualitative assessment of policy climate in European countries for SDM implementation	UK	Academics with experience of researching, teaching, and writing about SDM with knowledge of SDM policy in each respective country Setting n/a	Assess the policy climate in respect of SDM in five European countries - France, Germany, the Netherlands, Spain, and the United Kingdom – with reference to ten factors considered necessary for successful implementation.
40	Shepherd et al (2014) [213] 5-star rating	Qualitative semi-structured interviews	UK	Psychiatrists practicing in inpatient general adult, community general adult, medical liaison psychiatry,	Explore the attitudes and experiences of consultant psychiatrists relating to shared decision making in

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				forensic psychiatry, and medical psychotherapy Mixed setting	the prescribing of antipsychotic medications.
41	Rodriguez del Barrio et al (2014) [268] 4-star rating	Qualitative analysis of semi-structured interviews, focus groups and reports of participant observation	Brazil and Canada	People living with mental health diagnoses and practitioners Mixed setting	Demonstrate how an approach GAM (Gaining Autonomy and Medication Management) highlights the issues surrounding the establishment of a culture of rights.
42	Chong et al (2013) [269] 4-star rating	Qualitative semi-structured interviews	Australia	Healthcare professionals representing range of professions (psychiatrists, general practitioners, pharmacists, psychiatrist nurses, occupational therapists, social workers, psychologists), speciality backgrounds (mental health, primary care) and healthcare settings (primary and secondary care settings) Mixed setting	Explore healthcare providers' perceptions of barriers and facilitators to both shared decisions making and interprofessional collaboration in mental healthcare.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
43	Mahone et al (2011) [270] 4-star rating	Qualitative focus groups	USA	Varying stakeholder groups including psychiatrists, psychiatric nurses, case managers, support staff and consumer groups. Community treatment setting	Explore SDM between provider and consumer in mental health treatment in public mental health.
44	Seale et al (2006) [271] 5-star rating	Qualitative semi-structured interviews	UK	Psychiatrists practicing in adult community psychiatric services	Explore the views of psychiatrists about their experiences of consultations involving discussion of antipsychotic medication.
	Quantitative studies				
Data source no.	**First author (Year)**	**Study design/methods**	**Country**	**Participants/setting**	**Study objectives of relevance to this review**
45	Cheung et al (2022) [272] 3-star rating	Survey	USA	Adult inpatients with a mental illness and multidisciplinary team members	• Understand how interdisciplinary teams conceptualize SDM. • Assess how adult inpatients and interdisciplinary clinician teams

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					compare in their rating of SDM. ● Explore the factors that may enhance or interfere with SDM.
46	Schuster et al (2020) [273] 3-star rating	Cross-sectional survey	Germany	Inpatients of a psychiatric hospital (excluding care of the elderly, or those receiving care for alcohol or drug dependency), their treating psychiatrist and an identified carer.	Gain deeper insight into triadic SDM patterns of service users, caregivers, and clinicians in inpatient mental health care and the three parties' expectations towards the prospects of triadic SDM.
47	Ali et al (2015) [274] 4-star rating	Cross-sectional survey	USA	Psychiatric care provider (psychiatrist, resident, and physician extender)	Determine psychiatric providers' willingness to engage in SDM and factors that influence willingness.
48	Hamann et al (2010) [275] 4-star rating	Prospective, longitudinal study	Germany	18–80-year-old participants diagnosed with schizophrenia in an inpatient setting across nine German psychiatric hospitals and psychiatrists responsible for their care	● Assess patient responses to three descriptions of physician-patient decision-making styles and to identify factors that determine increased

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					participation preferences. ● Assess how physicians believe drug decisions were shared/not shared with patients and which factors determined a more participatory behaviour. ● Assess the matching of the desire of patients for participation to their actual involvement in drug decisions.
49	Hamann et al (2009) [276] 4-star rating	Survey	Germany	Psychiatrists in attendance at German conference representing public and private hospital settings	Explored psychiatrists' views of shared decision making in schizophrenia treatment.
50	Mendel et al (2009) [277] 4-star rating	Case vignettes and assessment of response	Germany	Psychiatrists (sampling unclear)	Examine how psychiatrists inform themselves about the benefits and the risks of antipsychotic

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					treatment options when deciding on a therapy for a patient with schizophrenia. ● Investigate how psychiatrists inform a patient suffering from schizophrenia about the benefits and risks of a treatment.
51	Kaliniecka and Shawe-Taylor [278] 4-star rating	Survey	United Kingdom	Multidisciplinary team members recruited to a risk management panel	● Evaluate a local multidisciplinary model to support clinical practice and risk management.
	Evidence syntheses				
Data source no.	**First author (Year)**	**Study design/methods**	**Inclusion criteria**		**Study objectives of relevance to this review**
52	Cartwright et al (2024) [279] 5-star rating	Systematic review and qualitative analysis	● Studies published in peer reviewed journals between 2010 and 2022 ● Utilised qualitative methods ● Explicitly reported the experience of or attitudes towards SDM from the perspective of mental health staff from any professional background and/ or service users who had		● Understand the attitudes towards and experiences of shared decision-making in mental health services from first-hand perspectives of

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				accessed adult mental health care (classified as aged 16 or above). ● English language papers or those with an easily accessible reliable translation	- Staff working in mental health services - Service users with personal experience of SDM
53	Chmielowska et al (2023) [130] 3-star rating	Umbrella review		● Peer-reviewed articles ● Systematic reviews and/or meta-analyses of shared decision-making interventions for care and/or treatment of a mental illness. ● Published in English between 2010-2021 ● Study participants were men or women aged ≥18 years or older diagnosed with a mental illness facing a mental health care decision.	● Clarify what is considered an effective SDM approach in mental health. ● Identify the core targets and elements required for successful utilization and implementation of SDM.
54	Muller et al (2023) [280] 3-star rating	Scoping review		● Studies addressing decisions aids that presented medical evidence of antipsychotic drugs to patients with schizophrenia, irrespective of their design i.e., experimental, or observational	Identify current key concepts, research conduct and evidence gaps regarding the design of decision aids tools for presenting medical evidence of antipsychotics to patients with schizophrenia.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
55	Verwijmeren et al (2023) [281] 5-star rating	Systematic review and qualitative analysis	• English language full-text publications addressing challenges to SDM in mental health practice • Research studies, opinions, letters, and comments were all eligible for inclusion		Provide a systematic overview of all perceived challenges and reported barriers to SDM in mental health care.
56	Aoki et al (2022) [101] 3-star rating	Cochrane systematic review	• Randomised controlled trails assessing SDM interventions among people with mental health conditions		• Assess the effects of SDM interventions for people of all ages with mental health conditions. • Interventions could be targeted at people with a mental health condition, carers, or healthcare professionals.
57	Vitger et al (2021) [282] 3-star rating	Systematic review and meta-analysis	• Randomised controlled trials assessing digital SDM interventions for participants diagnosed with a mental health condition		Systematically examine the effectiveness of digital SDM interventions on patient outcomes as investigated in randomized trials.
58	Thomas et al (2021) [103] 3-star rating	Systematic review and qualitative analysis	• English language studies including qualitative or quantitative measures assessing the process or outcomes of interventions		Describe and evaluate participant, intervention, methodological, and outcome characteristics of

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				• Studies interventions aiming to improve the application of SDM between a provider and patient or caregiver • Assessing participants with a serious mental illness • Published since 1980	SDM intervention studies conducted within this population.
59	Gurtner et al (2021) [283] 4-star rating	Integrative review		• Studies (empirical, conceptual, theoretical) published in English or German studying adult participants in psychiatric care making a clinical or therapeutic decision with their healthcare provider	• Present an overview of how SDM in psychiatric care has been conceptualized in empirical and theoretical research. • Identify promoters of and barriers to the application of SDM in clinical practice, from the perspective of patients and of interprofessional care teams.
60	Ahmed et al (2021) [284] 4-star rating	Systematic review and qualitative analysis		• English language empirical studies assessing mental health professionals who work in adult mental health services (inpatient and outpatient) and their experiences and attitudes towards	Explore the perceived barriers and enablers to implementing shared decision-making in risk assessment and risk management from mental

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				SDM in risk assessment and risk management with people with mental health problems ● Studies that assess potential barriers and enablers to SDM in risk assessment and risk management as perceived by mental health professionals were also included.	health professionals' perspectives.
	61	Huang et al (2020)[285] 4-star rating	Integrative review	● English, peer-reviewed primary research studies published between January 2012 and June 2019 ● Study participants ≥18 years or older with a SMI ● Articles focus on stakeholder perceptions of SDM	Summarise extant knowledge about SDM and explore the perceived barriers and enablers to implementing shared decision-making in risk assessment and risk management from mental health professionals' perspectives and people diagnosed with SMI and identify gaps in the literature.
	62	Pedley et al (2018)[100] 4-star rating	Systematic review and qualitative analysis	● Peer-reviewed journal articles or conference papers reported in English that used qualitative methodology ● Study focusses on views of stakeholders	Systematically review published qualitative evidence on the barriers and facilitators to involving patients with SMI in antipsychotic prescribing decisions.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				• In the case of participants representing those with SMI, at least 75% must represent those with a SMI • In the case of participants representing healthcare professionals or carers, at least 75% provide care to those with a SMI • SMI definition adopted: SMI population meeting one of the following: (a) defined as 'SMI'; (b) diagnosed with psychosis, schizophrenia, or related disorders, chronic and/or recurrent major depression, personality disorder or bipolar disorder, or (c) patients in secondary care mental health services who are prescribed antipsychotics.	
	63	Kaminskiy et al (2017) [286] 4-star rating	Qualitative synthesis	• English language primary studies focusing on attitudes to SDM in mental health published between 1990 and 2016	Provide a synthesis of research in the following areas: • Research examining service user preferences and attitudes towards SDM, including

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					views of what facilitates and hinders the process. ● Research examining professional groups (e.g., psychiatrists', social workers', CPN's) preferences and attitudes towards SDM, including views of what facilitates and hinders the process. ● Provide a comparison of similarities and differences between professionals' and service users' attitudes and views about SDM.
64	Davidson et al (2017) [287] 2-star rating	Conceptual review	● Not specified within published paper		Consider the role of shared decision making (SDM) as one component of recovery-oriented care.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
65	Alguera-Lara et al (2017) [288] 3-star rating	Narrative review	• Published English language studies about SDM in mental health published between 2005 and 2016		Review the literature on shared decision making (regarding treatments in psychiatry), with a view to informing understanding of the decision-making process and the barriers that exist in clinical practice.
66	Zisman-Ilani et al (2017) [289] 3-star rating	Systematic review and qualitative analysis	• English language primary research studies published after 1990 (conceptual or empirical) that describe an SDM intervention in mental health		• Expand the review of SDM interventions in mental health by exploring diverse interventions that service to enhance patient engagement in care. • Identify additional components, other than information exchange, which may contribute to the SDM process in mental health.
67	Ramon et al (2017) [290] 5-star rating	Systematic review and qualitative analysis	• English language studies (peer reviewed or grey literature) published between 2000-2016 on the implementation of any type of		Provide an overview of process, degree, and outcomes of implementation; barriers and

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				SDM intervention within mental health settings ● Any mental health diagnosis could be included across participants of all ages	facilitators; perspectives on implementation by different stakeholders; analysis of the process of implementation of SDM in mental health services through the lenses of the normalisation process theory (NPT).
68	Stovell et al (2016) [291] 3-star rating	Systematic review and meta-analysis	● English language randomised controlled trials assessing a psychosocial intervention to enhance SDM in the planning of treatment for psychosis with usual care or a non-specific control treatment.		Examine the effects of shared decision-making on indices of treatment-related empowerment of people with psychosis.
69	Morant et al (2015) [97] 4-star rating	Conceptual review	● Not specified in published paper		Provide an argument that several aspects of mental health care that differ from other healthcare contexts (e.g., forms of coercion, questions about service users' insight and disempowerment) may impact on processes and possibilities for SDM and therefore it is problematic to uncritically import models

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					of SDM developed in other health-care contexts.
70	Hamann et al (2003) [292] 3-star rating	Literature review	• Not specified in published paper		• Sketch the model of shared decision making. • Present key literature of shared decision making in other medical fields. • Search the literature on shared decision making in psychiatry and to display empirical findings. • Discuss the feasibility of shared decision making in psychiatry, further research re-quired and the potential of this model.
	Opinions/perspectives/viewpoints/narrative reviews				
Data source no.	**First author (Year)**	**Country**	**Objectives**		
71	Leucht et al (2023) [293]	Germany	• Provide an argument for digital tools to facilitate SDM during antipsychotic prescribing decisions in schizophrenia management.		

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
	4-star rating				
72	El-Alti (2023) [294] 4-star rating	UK			• Address the 'responsibility problem' within person-centred care. • Argue for a functional approach to mental illness, a blameless responsibility ascription to the person with mental illness, and a nuanced understanding of SDM as part of an emancipation-oriented person-centred care model.
73	Treichler et al (2021) [295] 4-star rating	USA			• Highlight barriers to SDM among patients with SMI. • Propose a novel paradigm – collaborative decision making – and associated conceptual and practical solutions at the systemic and patient/clinician level.
74	Zisman-Ilani (2021) [296] 4-star rating	USA			• Offer a new conceptualization, shared risk taking, as a unique way to view SDM with people with serious mental illness.
75	Guidry-Grimes (2020) [297] 2-star rating	USA			• Explore what some clinicians see as obstacles to even attempting SDM with patients with psychiatric disabilities.
76	Simmons and Gooding (2017) [298] 4-star rating	USA			• Describe the defining features of both shared and supported decision-making. • Discuss the similarities and differences between the two and consider points where they may complement one another as strategies for strengthening the self-determination of consumers.
77	Slade et al (2017) [96] 3-star rating	UK			• Discuss three challenges to SDM implementation: creating widespread access to high-quality decision support tools; integrating SDM with other recovery-supporting interventions; and responding

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					to cultural changes as patients develop the normal expectations of citizenship. ● Discuss two approaches which may inform responses in the mental health system to these cultural changes: social marketing and the hospitality industry.
78	Coulter et al (2017) [299] 3-star rating		UK		● Provide response to Slade et al (2017) article. ● Discuss SDM implementation challenges further.
79	Kaminskiy et al (2014) [300] 4-star rating		UK		● Explore the theoretical concept of power in the context of SDM for psychiatric medication management practice.
80	Hamann et al (2014) [301] 4-star rating		Germany		● Describe barriers to shared decision making among mental health professionals and among patients. ● Propose an integrative approach-SDM-PLUS-that fosters shared decision making in mental health settings.
81	Roberts et al (2014) [302] 4-star rating		UK		● Overview of training resources created for working with risk and implementing positive risk-taking in psychiatry.
	Grey literature				
Data source no.	**First author (Year)**	**Country**	**Type of paper**	**Sample/setting**	**Objectives**
82	Perkins et al (2024) [303]	UK	Briefing paper	Co-produced by people with experience of	● Consider how relationships, culture

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
	2-star rating			admission to acute inpatient wards (family members and mental health practitioners from a variety of professional backgrounds (including nursing, psychiatry, psychology, and occupational therapy)	and practice might be changed to: 1. Improve the experience of acute inpatient support for people admitted to the ward, those who are close to them and the staff who provide their support. 2. Enhance the value of admission in fostering hope and promoting recovery among those who are admitted. 3. Support ward staff to remain hopeful and recovery-focused in their practice.
83	Gill (2024) [304] 2-star rating	Switzerland	Book chapter	n/a	Explore issues that arise during application of the Convention on the Rights of the Persons with Disabilities (CRPD) in mental health care through a discussion of case histories modelled on

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					real-life stories in clinical practice.
84	UK Parliament (2023) [305] 2-star rating	UK	Research briefing and results of stakeholder engagement	n/a	Summary of proposed reforms to the 1983 Mental Health Act to improve patient choice, highlighting relevance research evidence and stakeholder perspectives.
85	Coulter et al (2022) [306] 3-star rating	UK	Conference proceedings	2022 International SDM conference	Provide a brief outline of the current situation in the UK that follows a framework designed to encapsulate the full range of strategies that could be adopted to implement SDM across a health system.
86	Ramon and Yeung (2022) [307] 4-star rating	UK	Book chapter	n/a	Discuss development of SDM as a UK policy in the field of mental health.
87	Royal College of Psychiatrists (2017) [308] 5-star rating	UK	Report	n/a	Outline principles of best practice to be adopted as part of risk management in mental health services.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
88	Blood and Wardle (2018) [227] 5-star rating	UK	Report from an independent commissioning by Social Care Wales	Social care services in Wales	Understand existing evidence and practice in shared decision making and positive risk taking within social care.
89	O'Sullivan (date unknown) [309] 4-star rating	UK	Website article	Psychiatric teams working in community mental health settings	• Describe study promoting SDM for medicines management in mental health care. • Describe reaction from study participants and recommendations for practice. • Highlight facilitators of SDM
90	UK government (2018) [310] 5-star rating	UK	Report	Commissioning of an independent Review of the Mental Health Act. The review sought the views of service users, carers, relevant professionals, and affected organisations in	• Assess how the legislation in the Mental Health Act 1983 is used and how practice can improve. • The purpose of the review was to understand the reasons for:

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
				producing recommendations	1. Rising rates of detention under the Act. 2. The disproportionate number of people from black and minority ethnic groups detained under the Act. 3. Processes that are out of step with a modern mental health care system.
91	House of Lords, UK Parliament (2014) [311] 5-star rating	UK	Report	Post legislative scrutiny of the Mental Health Capacity Act 2005 as it functions and is implemented in relevant settings within the UK	• Consider and report on the Mental Health Capacity Act 2005. • Hold public evidence hearings. • Review written submissions from a wide range of individuals and organisations including those with direct and personal experience of the

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					Mental Health Capacity Act.
92	Kaminskiy et al (2014) [312] 4-star rating	UK	Thesis	Community mental health setting	Explore the views and experiences of shared decision making for psychiatric medication management amongst mental health service users and practitioners.
93	Gordon and Green (2013) [313] 4-star rating	USA	Medical trade online publication	n/a	Argument for the appropriateness of more collaborative styles of decision making in psychosis management.
94	Kaminskiy et al (2013) [314] 5-star rating	UK	Book chapter	n/a	Explore how SDM is conceptualised by both practitioners and service users for psychiatric medication management.
95	U.S. Department of Health and Human Services - Substance Abuse and Mental Health Services Administration (2011) [211]	USA	Report from expert stakeholder group meeting in SDM and mental health (researchers, SDM providers	n/a	• Exchange perspectives on SDM. • Inform one another of the state of the science and practice of SDM in general and mental health care.

Data source no.	First author (Year)	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
		4-star rating		in general and mental health care, policymakers, and mental health consumers	● Develop recommendations for advancing SDM within the U.S. mental health care field.
	96	Shepherd et al (2008) for the Sainsbury Centre for Mental Health [315] 3-star rating	UK	Policy paper	UK mental health services	Not specified in report.

5.4.2.2 Results from supplemental literature searches

In the case of additional searches required to future refine IPTs addressing the relationship between risk management practices and individual prescriber behaviours, an additional ten data sources were identified as eligible for inclusion. Characteristics of studies identified for potential inclusion are contained in Table 14. Five were judged to be of sufficient quality to justify making changes to IPTs and in developing final programme theories.

Table 14 - Overview of data sources included in the review identified within additional searches for data on risk management practices in psychiatry. Quality ratings assigned to each data source from 1-5 are highlighted.

Data source no.	First author (Year)	Type of paper	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
97	Just et al (2023) [316] 3-star rating	Research	Systematic review of policies	n/a	Adult mental health services	• Explore how positive risk management (PRM) was conceptualised and defined within policies and guidelines for adult mental health services using thematic synthesis. • Explore how, and in which contexts, policymakers justified PRM, and the existing guidance on implementation.
98	Conlan-Trant and Kelly (2022) [317]	Perspective	n/a	Ireland	n/a	Examines potential explanations for the difference in rates of

Data source no.	First author (Year)	Type of paper	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
	3-star rating					involuntary psychiatric admissions in the UK and Republic of Ireland.
99	Markham (2020) [318] 3-star rating	Perspective	n/a	UK	n/a	Set out the thesis that collaborative risk assessment and management practices in forensic and secure settings may be suboptimal and do not sufficiently implement SDM and mental health recovery principles.
100	Lady Hale (2019) [319] 2-star rating	Speech transcript	n/a	UK	Royal College of Psychiatrists Annual Conference	n/a
101	Crowe and Dean (2017) [320] 4-star rating	Research	Survey	Australia	Clinicians (unspecified) and managers	Assess clinicians' and managers' risk aversion and their self-reported learning experiences, commitment to using Collaborative Recovery Models (CRM), goal setting attitudes and

Data source no.	First author (Year)	Type of paper	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
						CRM implementation behaviour.
102	Holley et al (2016) [321] 4-star rating	Research	Qualitative semi-structured interviews	UK	Mental health clinicians (psychiatrists, social workers, occupational therapy, nursing) and patients (diagnosed with psychotic illness or bipolar affective disorder) Community treatment setting	Explore how risk management practice impacts upon the implementation of recovery-oriented care within community mental health services.
103	Boardman and Roberts (2014) [322] 5-star rating	Briefing paper	n/a	UK	People involved in risk assessment processes within mental health services Mixed setting	Examine current approaches to risk assessment and management and how these need to be changed to be more supportive of people's personal recovery.
104	Andersson and Liff (2012) [323]	Research	Mixed methods (qualitative interviews and	Sweden	Three inpatient psychiatric units	• Describe and analyze the results of efforts

Data source no.	First author (Year)	Type of paper	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
	5-star review		ethnographic observation)		Inpatient	to improve patient-centered care (PCC) in psychiatric healthcare. ● Apply concepts of uses theoretical concepts of risk trade-offs (risk substitution and risk transformation) to explain the unintended consequences of new public management reforms at the micro level.
105	Roberston and Collinson (2011) [324] 5-star rating	Research	Semi-structured qualitative interviews	UK	Clinicians (psychiatrists, community mental health nurses, occupational therapists, and a senior support worker) working in a	Explore outreach workers' experiences of positive risk-taking (PRT), including dimensions of risk staff face, and factors

Data source no.	First author (Year)	Type of paper	Study design/methods	Country	Participants/setting	Study objectives of relevance to this review
					community outreach MH team Community treatment setting	influencing their risk approaches.
106	Boardman and Shepherd (2011) [325] 3-star rating	Research	Descriptive summary of a recovery-focussed project. Two outputs from the project are considered; the challenges for mental health organisations in making the changes from their present state to that of a system which can deliver recovery principles and the role of commissioners in this process.	UK	Mental health services Mixed setting	Present the outline of a methodological approach to help address ten key challenges for the implementation of Recovery-orientated services.

5.4.3 Overview of programme theories 1-10

From the 106 data sources, ten final programme theories were developed. These programme theories contained 23 CMOCs in total, and explain the influence of macro-, meso- and micro-level influences on prescriber behaviour, and the modifying impact of intervention strategies, where relevant. Consequently, across ten programme theories, influences that serve to either increase or decrease prescriber engagement with behaviours required of SDM, were developed. Here, as elsewhere,[326,327] macro-level influences included structural and contextual factors that exist at an institutional or societal level and are beyond the influence of individual organisations or practitioners. 'Institution' refers to a broad concept that encompasses established systems, norms and practices that govern and influence the wider practice of mental health. Meso-level influences were considered local organisational influences that typically characterise or define parameters of service delivery. Thus, in contrast to institutional influences, organisation refers to a structured entity formed by individuals with a common purpose or goal. Micro-level influences encompassed attributes or characteristics of individual clinicians, and their practice environments, that shape prescribing behaviours.[326,327] An overview of the ten final programme theories and their spread across the three levels of influence are contained in Table 15.

Table 15 - Division of results across ten programme theories and further subdivided according to macro-, meso-, or micro-level of influence.

Macro-level

- PT 1 - Biomedical model informing clinician training and professional socialisation
- PT 2 – Legislative and regulatory frameworks prioritising harm reduction
- PT 3 – Absence of committed leadership
- PT 4 – Cultural and social norms within psychosis management
- PT 5 – Insufficient resourcing of mental health services

Meso-level

- PT 6 – Established trust in prescriber-patient relationships
- PT 7 - Multidisciplinary responsibility for facilitating SDM

Micro-level

- PT 8 – Workforce training in SDM skillsets
- PT 9 – Patient training in SDM skillsets
- PT 10 – Antipsychotic treatment decision aids

5.4.4 Macro-level factors influencing prescriber engagement with SDM processes within psychosis management (Programme theories 1-5)

Five programme theories outlining the impact of structural and contextual factors on reducing prescriber engagement with behaviours necessary for SDM application were developed. These were developed in response to the first research question posed. No facilitative influences at macro-level for systematically promoting prescriber engagement with SDM were identified. Structural factors reducing the likelihood of prescriber engagement with desired behaviours related to clinician training and socialisation (PT 1), leadership and governance structures common within mental health settings (PT 2 + 3), cultural and social norms common among clinicians within psychosis management (PT 4), and insufficient resourcing of mental health services (PT 5). An overview of the relationship between these contexts, their impact on prescriber behaviours, and causal mechanisms explaining the relationship between macro-level contexts and prescriber behaviours is outlined in Figure 10.

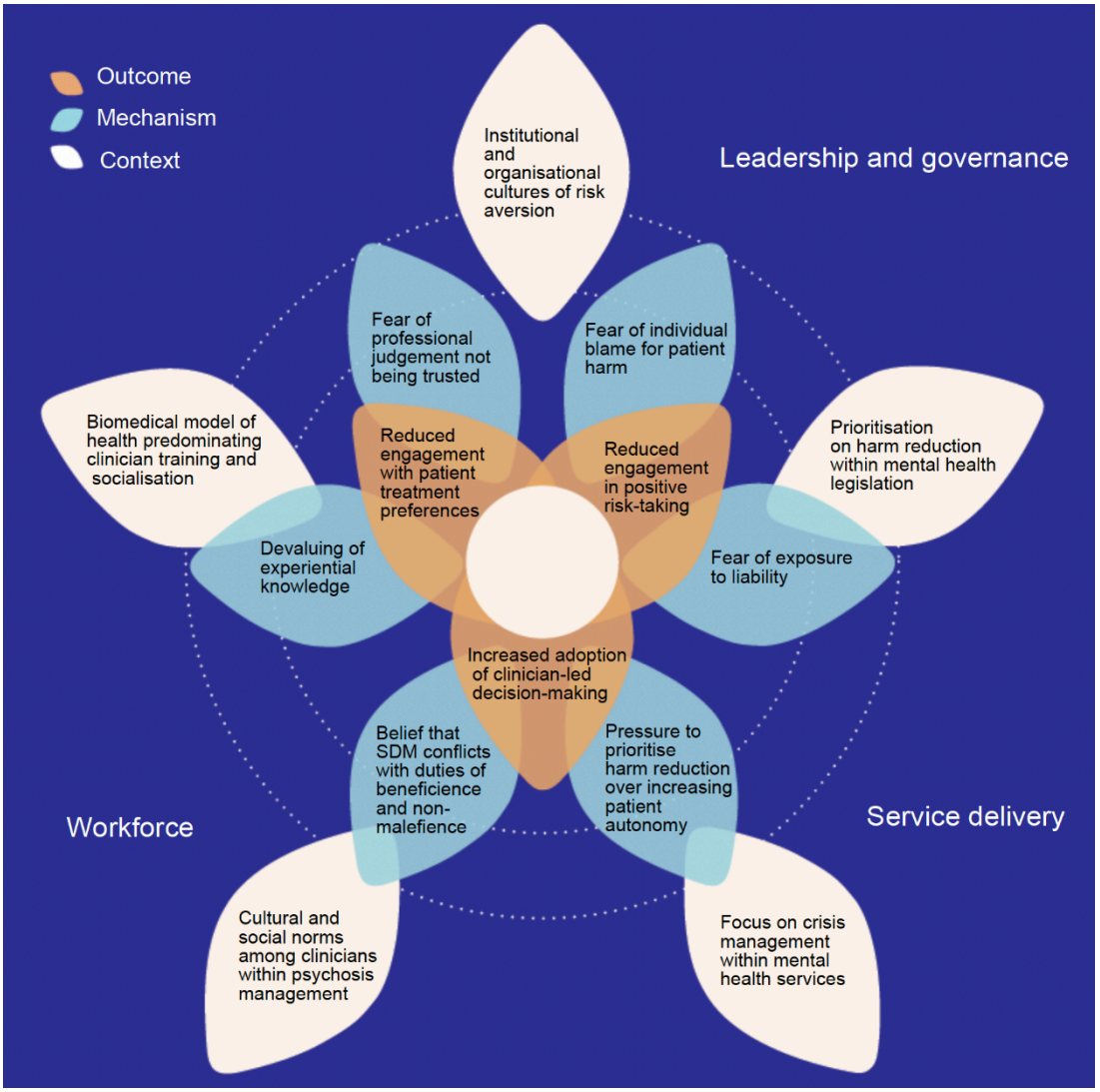


Figure 10 - Programme theories 1-5 outlining structural and contextual factors identified as reducing prescriber engagement with behaviours required of effective application of SDM and those that increase the likelihood of prescriber engagement with clinician-led decision-making. In the case of institutional and organisational cultures of risk aversion, two mechanisms and related outcomes are linked to this one context.

5.4.4.1 Programme theory 1 - Biomedical model informing clinician training and professional socialisation

The biomedical model of health is a medical model informing the training and socialisation of psychiatric clinicians within many countries internationally.[97,210,328] This model is based on the theory that a state of health is understood purely by the absence of illness and is defined by a focus on diagnosis, symptom management, and alleviation of illness.[329] Goals of pharmacological treatment reflected within the biomedical model can conflict with those of recovery-orientated practices, including

SDM. SDM is predicated on the assumption that each partner has unique knowledge to contribute to treatment decisions; neither clinical nor experiential knowledge is assigned greater value within decision-making.[131] Within the biomedical model, scientific knowledge and medical expertise primarily inform clinicians' prescribing behaviours; significant value is not assigned to a person's preferences or their experiential knowledge in informing decisions.[97,330] Prescribers whose education and professional experience have been largely informed by the biomedical model are less likely to engage with patient preferences for treatment due to an inadvertent devaluing of experiential knowledge reflected with their training.[97,300,307] This is particularly the case where patient preferences contrast with the prescriber's goal of minimising psychotic symptoms.[286,300,348] For example, changing antipsychotic to align with patient preferences, where an inherent risk is potential worsening or return of psychotic symptoms.

Table 16 provides an overview of the development of PT 1, including supporting CMOCs and excerpts from data sources that informed their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 16 - Programme theory 1, associated CMOCs, and excerpts used from specific data sources to develop this programme theory.

Programme theory 1 – Biomedical model informing clinician training and professional socialisation

The biomedical model dominates the training and subsequent practices of psychiatric clinicians within many countries. Within the biomedical model, a state of wellness is defined by the absence of illness. Associated goals of treatment are to alleviate psychotic symptoms as much as possible and restore health. Among clinicians where the biomedical model dominates their practice, including their prescribing behaviours (context), prescribers are less likely to engage with shared decision-making practices (outcome), where equal value is assigned to clinician and experiential knowledge in informing antipsychotic treatment decisions, as they question the validity of experiential knowledge compared to that of scientific knowledge and their own medical expertise (mechanism).

CMOC 1 (Biomedical model distancing the value of expertise from experience)

Mapping to COM-B model for behaviour categories: Motivation (reflective)

Where the biomedical model dominates the practice of prescribers (context), these prescribers are less likely to engage with patient preferences for antipsychotic treatment (outcome) as they doubt the validity of experiential knowledge in informing antipsychotic treatment decisions (mechanism)

Evidence sources:

1. Kaminsky (2015) – *The Elephant in the Room: A Theoretical Examination of Power for Shared Decision Making in Psychiatric Medication Management*
    a. In particular, for psychiatric medication management a dominating bio-medical model may distance the value of service users' experiential knowledge, thus hindering the recovery ideals of the service user taking back control and empowerment.
    b. A key challenge for SDM in psychiatric medication management is that practitioners (at times, at least) do not place equal value on service user expertise and knowledge.

c. According to Baker et al. (2013) there needs to be a rebalancing of the traditional focus on diagnosis and treatment with prioritisation on personal and self-determined perspectives. A key component of this shift would be the value and status that is ascribed to different forms of knowledge. Diagnosis, pathologizing, and the medicalization of mental illness are dominating structures, often associated with concerns over a depersonalization of experience and creating stigma. This has the potential to be a significant challenge to achieving the ideals of SDM and is therefore an important structural factor to consider for psychiatric medication management.

2. Mahone et al (2011) – *Shared Decision Making in Mental Health Treatment: Qualitative Findings from Stakeholder Focus Groups*
    a. Results: The question was asked: What practical barriers do you foresee in implementing shared decision making in mental health? Barriers identified by providers included the long tradition of basing treatment on the "doctor/diagnosis-driven medical, disease-focused model."
3. Ramon and Yeung (2022) – *The place of shared decision making in UK mental health services* (book chapter)
    a. Practitioners' voices concerning the usefulness of SDM focus on questioning whether people experiencing mental ill health have valid insight, and the validity of experiential knowledge versus that of scientific knowledge. On the whole, service users and most mental health practitioners such as nurses, occupational therapists, psychologists, and social workers tend to be supportive of SDM, while more dissenting voices come from psychiatrists.
    b. Unlike traditional psychiatry, SDM is based on accepting the value of experiential knowledge as a necessary component alongside scientific knowledge as the key assumption underlying SDM.
4. Wood et al (2019) - *The therapeutic needs of psychiatric in-patients with psychosis: a qualitative exploration of patient and staff perspectives*
    a. Discussion: The staff analysis outlined the importance of having an effective MDT to meet the care priorities of psychiatric in-patients. This was based on team cohesiveness, a biopsychosocial model - although acknowledged that the medical model was dominant - and strong therapeutic relationships with patients.
5. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (SDM) in mental health practice*
    a. Results:

i. The value placed on different types of knowledge within health services contributed to the perceived legitimation of involvement by service users in SDM. A conceptual review documented a gap in the significance placed on the experiential knowledge of service users and carers and the scientific knowledge attributed to professionals perpetuating the hierarchical nature of health services. This gap was most pronounced in the service user/psychiatrist dyad indicating a role for other types of workers such as care coordinators, peer workers and social workers which was supported by other studies.

6. Kaminsky et al (2017) – *Attitudes towards shared decision making in mental health: a qualitative synthesis*
    a. Results: SDM models were criticised for failing to capture the complicated nature and conflicting processes (e.g., risk agendas, biomedical models and professional pessimism) inherent within mental health contexts.
    b. Discussion: Practitioners report challenges surrounding the competing priorities of the role, and in particular, the challenges of being accountable and responsible for managing risk (e.g., Mahone et al., 2011). For some these challenges result in concerns regarding the clinical appropriateness of allowing service user choice. This potentially presents the greatest challenge for SDM in that it highlights the dominating role of a biomedical model for practitioners within mental health services, a system which is organised and underpinned by diagnostic classification systems. This, in turn, presents challenges for service users being able to present their expertise in a meaningful way in encounters.
7. Kaminsky et al (2014) - *A grounded construction of shared decision making for psychiatric medication management: findings from a community mental health team (thesis)*
    a. Chapter six: Interviewing psychiatrists: A subgroup of psychiatrists, however, referred to an overly medicalised or biological perspective as distancing experiential knowledge, and consequently, a problem in medication management practice
        i. I: *Do you see yourself as having any difference in style or approach to your colleagues?*
        ii. Dr. White.."*I think so, not to everybody, but I've got some colleagues who have got very specific views and I call it biological but I guess who come from a kind of view that um, symptoms can be targeted by medication and that when people keep representing with symptoms then all you need to do is increase the drug and it is about finding the right drug for the right person at the right dose or the combination. I think I see myself less as a, uh, I*

don't prescribe to that view in psychiatry, and I haven't seen it work. Um, so I think I am different from some of them, but I also have colleagues that have very similar views to what I have"

8. Pedley et al (2018) - *Qualitative systematic review of barriers and facilitators to patient-involved antipsychotic prescribing*
    a. Results: Findings within this theme indicated that for collaborative prescribing to be a success, patients and prescribers need to value both their own and their partner's contribution to the process. Additionally, both patients and prescribers need to understand that collaboration cannot be achieved without each partner being willing to value their own, as well as the other's expertise.
9. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
    a. The Practice of Shared Decision Making: Providers expressed reluctance to change or challenge their perceived role responsibilities to demonstrate authority and provide advice and cure.
    b. Barriers to SDM from the mental health care system
        i. Historically, the service delivery system has been organized around the provider's preference to control decision-making about pharmacotherapy and psychosocial interventions and supports. The role of the helping professional was defined by his or her ability to provide guidance and sound advice to consumers who did not have the same level of knowledge, training, and experience. Treatment plans were developed with the expectation that the consumer would be compliant with prescribed treatment.
10. Shue et al (2023) – *Exploring Factors Impacting the Implementation of Recovery-Oriented Treatment Planning on Acute Inpatient Mental Health Units*
    a. Results: Site reports noted that prescribers' interactions with veterans generally lacked rapport; many prescribers at low-scoring sites would tell the veteran what medication would be best for them, often based on symptoms and with little to no clinical interview. Site reports for several high-scoring sites indicated that veterans' input for medication decisions was valued. At site 211 it was noted that "patient preferences seemed to be weighed heavily. The following excerpt was in the site report for site 243:
        i. *"Both [prescribers] started by asking veterans what meds they had been on before, how those worked, any side effects, and what they would like to do now. They discussed treatment options (more than one med) and the*

pros and cons. Ultimately; the veteran made the decision. …Both prescribers took their time with veterans and worked to establish rapport and some alliance first".

11. Cooper at al (2019) - *Mental health professionals' views and experiences of antipsychotic reduction and discontinuation*
    a. Clinical and research implications: Previous research has found that over-reliance on a scientific model of treatment along with potentially coercive practices, can undermine the trust, choice and power service-users have in their mental health treatment. It has been suggested that coercion in mental health practice could be seen as a form of epistemic injustice, where clinicians do not see the service-users' knowledge and decision-making ability as legitimate due to the beliefs they hold about their diagnosis. For example, people with schizophrenia may be viewed as out of touch with reality, diminishing the legitimacy of their knowledge and requests, and increasing the possibility of more coercive or controlling treatment

5.4.4.2 Programme theory 2 – Legislative and regulatory frameworks prioritising harm reduction

The dominant emphasis within current approaches to risk management in psychiatry is concerned with reducing risk of harm.[308] This includes harm to individuals with mental illness and those around them. In many countries, formalisation of risk management is well-developed within mental health legislation. [308,322] A common risk management strategy is to assign the management of certain risks to a limited number of people, typically psychiatrists.[322,232] The perceived prioritisation on harm reduction or 'risk' within mental health legislative and regulatory frameworks has contributed to an increasing pressure among clinicians to control negative outcomes from occurring.[320] Among prescribers in many countries, the perception that legislative frameworks prioritise prescriber responsibility for harm reduction increases the likelihood of them adopting risk-averse prescribing behaviours, and subsequently engage in methods to promote patient agreement. For example, incomplete information sharing regarding the range of antipsychotic treatments or their side effects.[259,262,284,310,320,322,323]

Some prescribers believe these behaviours are encouraged within mental health legislation and, as such, their adoption of risk-averse prescribing practices is adhering to legislative requirements.[211,262,322] For prescribers who individually support positive risk-taking practices, they often feel personally unsafe when managing risk. They fear, should they not be risk-averse in their prescribing behaviours, they are exposing themselves to liability and associated repercussions in the event of subsequent adverse outcomes. These prescribers feel legislative pressure to weight decisions towards maximising harm reduction, even at the cost of increasing patient autonomy, and to intervene if an individual is making a decision which could be viewed as 'unwise'. Engagement in risk aversion decreases prescriber anxiety about exposure to liability.[259,290,310,316,320,322]

Initiatives promoting sharing of decision-making responsibility and positive risk-taking practices within settings where prescribers perceive mental health legislation prioritises prescriber responsibility for reducing harm are unlikely to

achieve widespread uptake. In the absence of targeted interventions to reduce fear of exposure to liability, prescribers do not feel confident that they would be legally protected in the event of harm following SDM application.[227,259,284,298] Table 17 provides an overview of the development of PT 2, including supporting CMOCs and excerpts used from specific data sources in their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 17 - Programme theory 2, associated CMOCs and excerpts used from specific data sources to develop this programme theory.

Programme theory 2 – Legislative and regulatory frameworks prioritising harm reduction
Where legislative and regulatory frameworks governing practice within acute mental health services are perceived to prioritise prescriber responsibility for reducing risk of harm to patients or others (context), prescribers are more likely to adopt risk-averse prescribing practices (outcome) as they perceive this meets the legislative requirements governing their practice (mechanism). Even among prescribers who otherwise support SDM practices (context), they are also more likely to adopt risk-averse prescribing practices (outcome), as they feel legislative pressure to weight decisions towards maximising patient safety, even at the cost of patient autonomy (mechanism). In both cases, prescribers fear, should they not adopt risk-averse prescribing practices, they are exposing themselves to legal and professional repercussions (mechanism). This fear among prescribers (context) increases the likelihood of them engaging in behaviours and practices to promote patient agreement with risk-averse treatment decisions (outcome), resulting in reduced prescriber anxiety about exposure to liability (mechanism) in the event of patient harm. For example, incomplete information sharing regarding the range of antipsychotic treatments and their side effects. In the presence of this fear, implementation of initiatives promoting shared responsibility for treatment decisions and positive risk-taking (context), are unlikely to be successfully adopted by prescribers (outcome) as they do not feel confident legislation would protect them (mechanism) in the event of adverse outcomes.
CMOC 1 (Legislative frameworks and regulatory processes promoting risk aversion among prescribers) **Mapping to COM-B model of behaviour categories (a, b ,c): Motivation (reflective)** a. Where legislative and regulatory frameworks governing practice within mental health services are perceived to prioritise prescriber responsibility for reducing risk of harm to patients or to others (context), prescribers are more likely to adopt

risk-averse prescribing practices (outcome) as they perceive legislation governing their practice expects them to weight decisions towards maximising reduction in risk of harm (mechanism).

b. Even among prescribers who otherwise support sharing of decision-making responsibility and positive risk-taking practices, the perception that legislative and regulatory frameworks prioritise prescriber responsibility for reducing risk of harm (context) increases the likelihood that they also will adopt risk-averse prescribing practices (outcome) due to fear of legal and professional repercussions if they don't (mechanism).

c. This perception among prescribers (context) increases the likelihood of them engaging in behaviours and practices to promote patient agreement with risk-averse treatment decisions (outcome), for example, incomplete information sharing regarding antipsychotic treatments. Prescribers adopt such practices to promote patient agreement with treatment decisions the prescriber perceives will maximise reductions in risk of patient harm, as this lessens prescriber anxiety about exposure to liability (mechanism) in the event of adverse outcomes.

Evidence sources

1. Becher et al (2021) - *Barriers and facilitators of shared decision making in acutely ill inpatients with schizophrenia—Qualitative findings from the intervention group of a randomised- controlled trial*
    a. Results: Barriers to SDM:
        i. Setting-related factors that impeded SDM included lack of resources (staff, hospital beds, availability of various therapy programmes on the wards), court orders, laws or regulations and the pending rotation of the treating clinician.
2. Brooks et al (2017): *Exploring the potential implementation of a tool to enhance shared decision making (SDM) in mental health services in the United Kingdom: a qualitative exploration of the views of service users, carers and professionals.*
    a. Results: Negative influences on potential implementation:
        i. Mental Health Act
        ii. Protocol driven practices

b. Results: There were no macro level facilitators to the use of the tool as reported by participants included in this study. It appeared that the reason for this was that the values enshrined in SDM and the tool itself assume the sharing of responsibility for decisions between the relevant parties, but these values are diametrically opposed to the coercive and legislative frameworks within wider mental health contexts.
c. Results: "*You'd get clients hiding medication in their mouth or under their tongue or even vomiting after medication to try and get rid of it so… quite problematic and, [it], often ended up in a depot medication or some other form of sort of enforced medication like tablets that melt on the tongue or things like that".* Professional, focus group 1
d. Results: These were compared to other settings, such as inpatient settings, which were considered to have cultures with a greater focus on risk, which would render it more difficult to have the type of dialogue advocated by the tool. It may be that these types of settings are also less constricted by the coercive and legislative frameworks to be discussed in the next section.

3. Royal College of Psychiatrists (2016) - *Rethinking risk to others in mental health services*
    a. Background: Issues of risk moved to the forefront of mental health policy in the subsequent decade, culminating in new legislation, changes in working practices and the introduction of tools for assessing risk. Although risk assessment in psychiatry aims at harm reduction, it is not uncommon for the outcome of a psychiatric risk assessment to cause harm to patients in terms of loss of liberty or freedoms.
    b. Psychiatrists and risk: The College views risk assessment and risk management as core duties of any doctor and does not accept that an emphasis on risk in psychiatry should be avoided. However, the College remains concerned over statistically problematic approaches to risk and a continued perception of a blame culture.
    c. Risk assessment as ethical processes: There is a human tendency to focus on negative consequences, not positive ones, so the possibility that good things will come from taking a chance is often given less weight, and patients' claims to positive strengths are ignored. Time course is also a factor: decision makers tend to focus on short-term risk that they can foresee but give less weight to long-term risks that are harder to assess. This is especially true if decision makers are also thinking about benefits and harm for themselves as opposed to for patients; this might be commonplace in blame cultures, in which professionals may be made a scapegoat if things go wrong. A preoccupation with risk remains

embedded in the UK, and contrasts with the international community. This is not to deny the relevance of risk in mental health services, nor to deny key professional responsibilities.

4. Conlan-Trant et al (2021) - *England's rate of involuntary psychiatric admission is double that of the Republic of Ireland: Why? A consideration of some possible causes*
    a. Revision of mental health legislation in England was driven, in significant part, by concerns about public safety, as opinions were substantially influenced by media coverage of homicides by mentally disordered people. Public safety remained a central consideration, even in an era of increased emphasis on human rights and was a key feature in the deliberations of the 1999 'Expert Committee', chaired by Professor Genevra Richardson. This process eventually resulted in the Mental Health Act, 2007.
5. Yaara Zisman-Ilani et al (2021) - *Shared Risk Taking: Shared Decision Making in Serious Mental Illness*
    a. Introduction: A greater barrier, though, may be clinicians' fear of liability and legal exposure. Clinicians may resist SDM with patients with serious mental illness because they fear being held liable for any potentially negative outcome that might result from SDM, such as symptom exacerbation, hospitalization, or death.
6. Crowe and Deane (2017) - *Characteristics of mental health recovery model implementation and managers' and clinicians' risk aversion*
    a. Introduction: Research suggests that clinicians predominantly perceive risk as negative, such as the consumer posing a risk to the community or the clinicians themselves. However, these risks are overshadowed by the additional risk that the clinician will be liable if any of these negative events occur. The fear of liability includes negative consequences to both personal and professional life, such as questioning in the coroner's court to ensure all necessary steps were taken, media portrayal of malpractice, or questions and judgement by the community and colleagues.
    b. Tickle et al. (2014) highlighted that clinicians' concerns regarding risk of harm to the consumer and personal liability for negative events were barriers to any potential benefits of recovery, such as learning from incidents. This concern exists specifically with regard to the use of the recovery model.
    c. Risk perception has been identified as impacting clinical decision making in health settings (Atwal et al., 2011), with risk assessments a core component of clinical work (Simpson et al., 2016). This focus on risk is a barrier to including clients in their own care (Bertram and Stickley, 2005; Simpson et al., 2016; Spandler and Vick, 2005). Tickle et al. (2014) identified

that despite clinicians reporting awareness of recovery-oriented principles they experienced difficulty including them in their practice, highlighting that positive risk-taking is likely to be deprioritised as risk aversion increases.

   b. The positive risk-taking literature highlights that positive and negative aspects of risk become fused in the context of mental health, resulting in calls for risks to be differentiated into those to be minimised as an unacceptable potential for harm and those that are to be encouraged as an individual right to be experienced. The perception that risk is negative and can be eliminated places pressure upon clinicians to control negative outcomes from occurring which is often at cross purposes to facilitating recovery practices.

7. Ramon and Yeung (2022) – *The place of shared decision making in UK mental health services* (book chapter)
   a. Yet the issue of the need for a positive risk-taking policy and practice, viewing SDM as an example of such a risk-taking position, is not raised by those who write about risk avoidance and lack of insight, though it has already been raised by those who promoted de-institutionalization and recovery. The existing UK legislation and policy concerning mental capacity in mental health provides a high level of safeguarding in case of lack of capacity (Mental Capacity Act, 2021 update), and too little recognition that in reality the lack of such capacity is often of very short duration.
8. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (DM) in mental health practice*
   a. Professionals sometimes withheld information about the potential adverse effects of medication and did not acknowledge that shared decision making also involved sharing responsibility and risk with the service users they were treating.
   b. SDM models were criticised for failing to capture the complicated nature and conflicting processes (e.g., risk agendas, biomedical models and professional pessimism) inherent within mental health contexts (Morant et al., 2015).
9. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
   a. SDM research (liability concerns): The doctor-patient relationship is defined to include legal and financial responsibilities and rights. The effect of employing SDM within a mental health care setting must be explored in light of these existing rights and responsibilities. Public perceptions of persons with mental illness as dangerous, and policy support for some degree of coercion, will influence efforts to minimize involuntary treatment.
10. Boardman and Roberts (2014) - *Risk, safety and recovery*

a. Risk and the law: Organisations and practitioners often feel unsafe when managing risk, fearing legal repercussions if anything should go wrong.
b. Risk and recovery – uncomfortable bed fellows?
    i. This emphasis on professional or institutional dominance in regulating risk can be seen as part of a wider societal trend towards risk-avoidance and associated calls for increased regulation which has resulted in a 'regulatory cycle' in which further harmful events are responded to by further regulation. The results of this are an increasing risk aversion, fear of litigation, a reduction of enterprise, and a separation of people from responsibility for their own risks which are then seen as belonging to experts and regulators.
    ii. Government policy in this area has often been contradictory: sometimes viewing service users as dangerous, whilst also asking for them to be involved in decision making. Thus, society appears to be ambivalent about risk and habitually operates with double standards, such that liberty, choice and support for independence and autonomy are promoted until something goes wrong. There is then a demand for control, custody, containment and blame. This means that the political imperative to manage risk to the public will invariably trump service users' preferences when the two conflict.
c. Professional perspective: Managing risks is a central concern in the day-to-day lives of clinicians. They may fear the consequences of taking risks because of the perceived legal and professional repercussions. They may feel the need to take action if a patient is seen to be making a 'bad decision'; or they may feel a pressure to remain in control. They may also work in organisational settings that give no clear guidance or assurances about risk practices and instead represent the double standards of open society. The response to these fears and uncertainties is often to increase surveillance, coercion and constrain. It is therefore not surprising that there is a broad professional concern that "a preoccupation with risk and a consequent tendency towards risk-averse practice is stifling creativity and innovation and represents an impediment to therapeutic relationships". There is also a concern that current risk management practice is overly focused on proximal concerns to reduce the occurrence of risky behaviours, rather than working with the person to identify what they need and value (Royal College of Psychiatrists, 2008; 2010a).

11. Ahmed et al (2021) – *Mental Health Professionals' perceived barriers and enablers to shared decision-making in risk assessment and risk management: a qualitative systematic review:*

a. Results – Knowledge: Professionals referred to policy and legislation in guiding them in supporting service users' influence in decision-making or risk-taking.
b. Results - Social influences: Findings suggest that the pressure of managing risk could lead to power imbalances that inhibit service users' involvement or influence in the decision-making process:
c. '… risk dominated the decision-making of professionals to such an extent that it defined how service users were understood and treated with limited evidence of power-sharing and involvement of service users in decisions.
d. Results: Beliefs about consequences: Professionals who encouraged risk-taking or supported a service user's wish to discontinue from medication were also fearful of being blamed if negative outcomes occurred as a result of their decision.
    i. "*Risk-taking and promoting an individual's freedom is encouraged but you're conscious of the fact that if someone gets hurt, it's not just them… criticism will be levelled at each level within the authority*"
e. Results: In other studies, fear of being blamed influenced the decision-making process and resulted in professionals adopting defensive or restrictive approaches. The possibility of a negative outcome from supporting a service user to discontinue from medication triggered anxiety in professionals.

12. Simmons and Goulding (2017) - *Spot the difference: shared decision-making and supported decision-making in mental health*
    a. Discussion: At present, many jurisdictions do not necessarily permit such an acceptance of risk (nor may professional and ethical guidelines and duties), and clinicians may raise concerns about where their duty to support risky decisions begins and ends.
13. Blood and Wardle (2018) – *Positive risk and shared decision making:*
    a. Section 2.3: Professionals views about risk: Recognising and tackling the institutional discrimination was felt to be the foundation for embedding positive risk practice. The Equality Act 2010 and the human rights legislation provide a framework and a lever for doing this. This should help counter the myth that the law promotes risk aversion and emphasise the point that positive risk taking is about fundamental rights, not a "nice-to-have" or something that only applies in innovative pilots. Regulation, audit and inspection were felt to place too much emphasis on throughput, and participants identified the importance of inspectors really understanding positive risk taking and finding more flexible ways to define and measure "success", including hearing the voices of people using services.

i. *"Asking providers to do innovative things but then that gets shut down by the inspectorate tomorrow because they don't understand."*

b. Section 3: Barriers to risk-taking in services/Lack of understanding of legal responsibilities: The published literature highlighted a generalised fear of litigation, which can lead to a "just in case" or defensive approach to professional decision-making (Department of Health, 2007; Andrews et al, 2015).

c. Section 3: Barriers to positive risk taking: Perhaps the fear of being sued for medical negligence creates a much more cautious definition of the duty of care, particularly in hospitals. This contributes to "territorial" and "defensive" practice of which we heard a number of examples, in which practitioners, managers, departments and organisations protect their boundaries and seem afraid of the consequences of taking or sharing responsibility.

14. Simon Wessely (on behalf of UK Government) (2018) – *Modernising the Mental Health Act: Increasing choice and reducing compulsion*

a. Risk aversion and its consequences:

i. More broadly, there are wider concerns about increased risk aversion amongst professionals following high profile judgments and inquiries.

ii. There is another issue, difficult to pin down in statistics, but which has played a substantial role in this rise and contributes to some of problems that we report in creating and sustaining a genuinely therapeutic atmosphere for those detained. It is the issue of risk and risk aversion. Some of this can be traced to the reasons which lay behind the introduction of the 2007 Act. Reading the newspapers, speeches, discussion papers and documents from the time, the risk posed to the public by those with mental illness, and the failings of the mental health care system to adequately manage those risks, was the major driver of the perceived need for reform. Sadly, looking back, we can see that some of the decisions taken by government leading up to the 2007 Act were an overreaction. So, whilst fear of the mentally ill has decreased in the public, parliament and media, a different kind of fear has increased - the fear of making a faulty risk assessment that influences many professionals. The importance of risk management and safety has steadily risen across society – as reflected in some key sociological texts. It is seen by many as a principal driver in modern society, so it is not surprising that it has become very influential in medicine as a whole, partly driven by scandal and perceived failings. But there are few places where

it has achieved the prominence or dominance that it has in mental health, and this happened over a relatively short period of time. As Szmukler writes “a pressure developed affecting all levels of staff, managerial through to clinical, to 'manage risk', which was the intended consequence of this shift in policy. But this soon slipped into 'managing risk to themselves'”. And Szmukler continues, this is understandable, since the consequences of a faulty risk assessment were and continue to be “quite horrendous... protracted investigations and scrutiny of the case, blame, negative publicity, formal inquiries, and scores of recommendations requiring implementation”. It is easy to see how this would have been reflected in a steadily rising number of detentions, as professionals of all kinds became increasingly risk averse, and more likely to make coercive interventions that at least in the short term were likely to reduce the risk of an early dreadful outcome – such as serious or fatal harm to a patient or a member of the public.

iii. But we cannot act on our own. If we are seriously to tackle the problem of risk aversion action must proceed across the board – there is little point in professionals deciding to accept more risk if the courts, regulators, media and others do the opposite. Intellectually everyone accepts that there is no such thing as zero risk – even if you detained every person with any mental disorder for prolonged periods of time, an absurd proposition, you would still not eliminate it. Any probability judgement must be wrong sometimes, and that should not automatically mean that this is a fault, let alone negligence. But the dynamics of the risk society seem to be running in the opposite direction, accelerated by legal judgements such as the one handed down by the Supreme Court in the tragic case of Melanie Rabone. As the President of the Supreme Court remarked recently, this judgement “where the hospital was held liable for the death of an informal patient who killed herself whilst on weekend leave of absence is bound to make practitioners less inclined to use informal care”. In other words, to increase, not decrease, the usage of the MHA.

15. Forsberg et al (2018) - *Clinician perspectives on supporting adults with psychosis who wish to discontinue neuroleptic medication: qualitative analysis*
    a. Harm prevention: Seeking advice from others, documenting decisions accurately and ensuring all relevant documentation was up to date were described by six clinicians as methods of protecting themselves if their decision were questioned:

i. *"Well, you can have professional conversations, and you can document it, defensively document your contact and communication with that person and that person's decision ... And also, you're worried about litigation ... you're worried about Coroner's Court. And you worry about getting ripped to bits, because everybody's scared about the coroner".*

i. Fears for discontinuation: Decisions supporting discontinuation triggered a range of anxieties for clinicians, including concerns for the service-user and the public, but also concerns for themselves. A common fear, mentioned by nine clinicians, was the service-user relapsing or experiencing withdrawal symptoms from discontinuation, potentially resulting in clinicians being blamed or formal investigations in the event of a serious negative outcome:

ii. *"You can almost hear someone saying to you 'you allowed this to happen, you were part of it, why did you do that? Why did you let them have that choice?' That kind of thing. So, I can always imagine like a relative saying it, or you know, someone in an SUI [Serious Untoward Incident], an investigation saying, 'Why would you do that?".* (P2)

b. Discussion (comparison with wider literature):

i. Yet, previous research also demonstrates that in practice clinicians rarely involve service-users in neuroleptic medication decisions, and service-users describe clinicians as being risk adverse and coercive where neuroleptic discontinuation is concerned (Hamann et al., 2009; Le Geyt et al., 2017). Our findings can explain this discrepancy. Our theory suggest that a clinician's desired collaborative approach often conflicts with other personal and professional influences, such as their professional obligations to manage risk and their fears that discontinuation may lead to a relapse; particularly for those perceived to be at higher risk during discontinuation. This conflict may lead clinicians to act with increased coercion and respond in a way they feel will prevent harm to themselves, the service-user and the public.

ii. Central to our theory is the focus on risk assessment and management. This is consistent with mental health law, which prioritises risk management over enhancing service-user's capacity and autonomy (Owen et al., 2009). Additionally, the existing risk-adverse mental health service culture has been found to make staff feel limited in their ability to implement recovery-oriented approaches and concerned about blame and litigation (Tickle, Brown,

& Hayward, 2014). Previous research has also confirmed that reducing neuroleptic medication can be anxiety provoking for clinicians (Thomas, Katsabouris, & Bouras, 1997). Our findings suggest that clinicians are acutely aware of their obligations to manage risk, and this drives a need to prevent harm and protect themselves if their decision were to be questioned.

16. Andersson et al (2011) – *Does patient-centred care mean risk aversion and risk ignoring?*
    a. Introduction: We respond to this call by arguing that theories on risk and regulation, such as risk transformation and risk substitution that are developed at the macro level, are also relevant at the micro level. However, the objective of our research is not to explore the societal effects of regulations; we are interested in how regulations influence individual actors in different ways, in different situations. Thus, we examine different risk management practices resulting from the same regulation in different contexts. These practices help us understand how managers and professionals deal with risk of legitimacy loss while dealing with larger risks (such as patient security) and coping with a regulatory context that is established to deal with these risks. In healthcare, formal risk management is well developed. Regulations dictate who is medically responsible for patients. However, this regulatory framework, created to increase accountability and transparency, has unintended consequences when individuals make risk trade-offs in responding to their responsibilities. Increased accountability means an increased risk for the institution and/or the individuals managing the risk.
    b. Accountability and risks in the Children and Adolescent Psychiatry (CAP): Although everyday practice in the CAP units has not changed significantly, there has been a movement towards identifying and formalizing management of various risks. These risks were hardly new in themselves; the novelty was the new approach to managing them. For example, a common risk strategy in healthcare is to assign the management of certain risks to a limited number of people (often particular professions). In CAP units, the psychiatrists, who are fewer in number than either the psychologists or the social welfare officers, nevertheless acquired a strong unit position because they had medical responsibility for the patients. With this responsibility, personal risk for the psychiatrists increased. A CAP unit psychiatrist describes the burden of this responsibility:
        i. *"Twenty-five colleagues have left over the years because they felt that the medical responsibility was too heavy".*

c. Risk aversion: the psychiatrists risk behaviour: The psychiatrist described here appears to look for “her” patients in the bigger patient group and wants the CAP unit to use its resources primarily for these patients. Consequently, her risk aversion stems from a concern for her personal risk rather than for the patients’ risk.
d. Analysis: patient-centered care generating risk aversion: The idea behind these reforms is that when healthcare professionals are held accountable, better, and safer patient care is possible. However, there are numerous examples of unintended consequences when new management ideas are introduced in professional groups (Freidson, 2001; Timmermans, 2008). In this study these unintended consequences appeared when risk strategies resulted in risk trade-offs. Professional or personal risk may then take priority over patient medical risk. Despite the lofty aspirations of individual actors to provide good patient healthcare, unintended consequences may result in less patient-centered care when there is transformation or substitution of target risk. The medical risk is the target risk (Graham and Wiener, 1995) that the CAP units are designed to deal with and reduce, especially for multi-patients who are the most challenging patients with their blurred, complex and multi-faceted symptoms. These patients, who may conceal suicidal tendencies, have the most urgent need of PCC. However, because of the very urgency of such patients’ diagnoses, when a psychiatrist admits such a patient, there may be a transformation (Rothstein et al., 2006) of patient medical risk to psychiatrist personal risk. If treatment fails in some way, the psychiatrist is at risk of losing his/her professional credibility or, at worst, losing his/her licensure.
e. Analysis: patient-centered care generating risk aversion: Thus, both psychiatrists and unit managers in the CAP units of this research were aligned in choosing self-preserving risk aversion strategies. Risk aversion thus takes priority over patient security and care.
f. Conclusion*:* This paper contributes to NPM research by applying concepts from the sociology of risk literature and thereby illustrates how NPM reforms intended to customize care and make it more patient-centered can result in unintended consequences. Furthermore, the paper contributes to risk theory by showing the relevancy of the macro level concepts of risk trade-off (risk transformation and risk substitution) and risk action (risk aversion and risk ignoring) to individual actors’ risk strategies. In particular, the paper shows how risk trade-offs function and influence each other when individual actors handle their personal risks through risk aversion or risk ignoring actions. Medical professionals

reduce their personal risk by using their knowledge base and skills to construct the patient instead of beginning with the needs of the patient

17. Holley et al (2015) - *The impact of risk management practice upon the implementation of recovery-oriented care in community mental health services: a qualitative investigation*
    a. Risk management in mental health services: In the UK, the assessment and management of risk is a key component in the delivery of mental health services. Concerns have been expressed that the formalization of risk management has resulted in service users becoming increasingly defined in terms of the risk they present ‘‘rather than in terms of their needs and rights’”. There are, however, concerns about implementing recovery-orientated care within a context of risk management practice. For example, Davidson and colleagues (2006, p. 642) invite the question, from the mental health professional’s perspective, ‘‘*If recovery is the persons’ responsibility, then how come I get the blame when things go wrong?*’’
    b. Competing frameworks of practice*:* When referring to real-life situations, our analysis suggested that mental health workers could experience ROC (recovery-orientated care) and RMP (risk management practices) as competing frameworks of practice, therefore elements of their role were in conflict.
    c. Discussion: In this hypothetical talk about recovery issues, risk could seem to be neglected. It has been acknowledged that the paradigms in which ROC and RMP are situated are seemingly opposite to one another (Roychowdhury, 2011). This is emphasized particularly in recovery-orientated care policies, which insist traditional risk management procedures are restrictive for ROC (Department of Health, 2008b). Our analysis suggests that idealistic thinking about recovery might inhibit proper consideration of how risk might be managed in the context of recovery orientated care. In the context of this, lack of explicit thinking about risk and recovery our analyses suggest that mental health workers’ aspirations to implement ROC could, in the real world, be contaminated by the responsibility they feel for managing and reducing service users’ exposure to risk.
18. Just et al (2020) – *Positive risk management: Staff perspectives in acute mental health inpatient settings*
    a. Emotional decision making: Practitioners anxieties and fears influenced their use of positive risk management. Staff were concerned about the prospect of accountability in the event of adverse outcomes. Practitioners were often preoccupied with the worst possible outcome, which was two-fold: harm to the service user and repercussions for staff. Therefore, risk management plans became driven by alleviating practitioners’ anxieties and emotional states.

CMOC 2 – (Prescriber prioritisation of legislation focusing on harm reduction)

Mapping to COM-B model of behaviour categories: Motivation (reflective)

Among prescribers in the United Kingdom, there is evidence of a lack of sufficient understanding of legislation that supports positive risk-taking and outlines prescriber responsibility to involve patients in treatment decisions, where capacity is present (context). Among this group of prescribers, prescribing behaviours reflect prioritisation of legislation outlining their responsibility to reduce risk of patient harm (outcome) due to insufficient awareness of wider legal frameworks (mechanism) or lack of confidence that such legislation would protect them in the event of harm resulting from prescriber engagement in positive risk-taking (mechanism).

Evidence sources:

1. Boardman and Roberts (2014) - *Risk, safety and recovery*
    a. Risk and the law: All those involved in responding to risk therefore need to be well informed concerning the legal frameworks that they are working within and where to turn to resolve uncertainties. This is not made easy by the number of overlapping legal considerations and frameworks for progressive practice scattered across multiple sources of policy and guidance. Box 1 shows the main areas to consider.
    b. Key legal and governance frameworks underpinning approaches to risk
        i. Duty of care – organisations must maintain an appropriate standard of care in their work and not be negligent. Individuals who have mental capacity to make a decision and choose voluntarily to live within a level of risk, are entitled to do so. In this case the law considers the person to have consented to the risk and there is thus no breach of duty of care and the organisation or individual cannot be considered negligent.
        ii. Human rights – all public authorities and bodies have a duty not to act incompatibly with the European Convention of Human Rights. A balance needs to be struck between risk and the preservation of rights, especially when the person has capacity.

iii. Health and safety – There are a legal duty on all employers to ensure, as far as reasonably practicable, the health, safety and welfare of their employees as well as the health and safety of those who use services. Health and Safety legislation should not block reasonable activity.

iv. Mental capacity – this is concerned with a person's ability to make decisions for themselves, and the principle enshrined in the Mental Capacity Act, 2005 is that they must be assumed to have capacity unless it is established that they do not. People with capacity may make unwise decisions. For those who lack capacity, decisions made on their behalf must be made in their best interests and with the least restriction.

v. Fluctuating mental states and dementia – The choices and wishes of people with fluctuating mental states and dementia must be respected and their risk agreements monitored and reviewed regularly. In these circumstances it is important to engage with families and carers.

vi. Safeguarding – For people who are considered to be vulnerable there is a need to consider the factors of empowerment and safety, choice and risk. Practitioners need to consider when the need for protection overrides decisions to promote choice and empowerment.

2. Blood and Wardle (2018) – *Positive risk and shared decision making*
    a. Section 3: Barriers to risk-taking in services/Lack of understanding of legal responsibilities: More specifically, there may be a lack of understanding of the Mental Capacity Act 2005. For example, the House of Lords (2014) concluded that the Act has "suffered from a lack of awareness and a lack of understanding... The empowering ethos has not been delivered". In the group discussions, participants highlighted the fact that much of the legal framework, including the Mental Capacity Act 2005 and the Social Services and Well-being (Wales) Act 2014, supported a positive risk-taking approach. They gave examples in which the Court of Protection had upheld positive risk-taking decisions made in a person's best interest, but against the family's wishes. However, there seemed to be a number of specific challenges here:
        i. Lack of awareness of the legislation that supports positive risk taking, by colleagues, the general public and, in particular, health professionals.
    b. Section 4: Enablers to positive risk taking in services: Morgan and Andrews (2016) argue that the rights and citizenship of people who may need care and support should be placed at the heart of a framework for positive risk-taking. At present: *"Practitioners do not often think in terms of rights, so they become more easily violated".* There was concern among a

number of focus group participants about a lack of skills, time and permission to support the effective use of values-led, rights-based and truly person-centred practice.

   c. Section 4 - Shared decision-making around risk: There also seemed to be a lack of confidence amongst frontline workers regarding the wider legal framework: exactly where their "duty of care" began and ended, and what (if any) the legal consequences might be if something "went wrong" following a properly made and recorded positive risk-taking decision. Wider dissemination of these key messages – perhaps reinforced by clear and specific feedback from a legal expert – might help allay this general sense that "legal action might follow" and reassure professionals of the distinction between negligence and positive risk-taking.

3. Ramon and Yeung (2022) – *The place of shared decision making in UK mental health services* (book chapter)
   a. However, feedback from psychiatrists involved in SDM training tended to focus on the management of risk avoidance, while omitting the need for calculated positive risk taking, and assuming a lack of insight by service users of their mental health conditions and needs.
4. Select Committee on the Mental Capacity Act 2005 (2014) - *Mental Capacity Act 2005: post-legislative scrutiny*
   a. The Mental Capacity Act placed the individual at the heart of decision-making. Capacity was to be presumed unless proven otherwise. Decision-making was to be supported to enable the individual as far as possible to take their own decisions. Our findings suggest that the Act, in the main, continues to be held in high regard. However, its implementation has not met the expectations that it rightly raised. The Act has suffered from a lack of awareness and a lack of understanding. For many who are expected to comply with the Act it appears to be an optional add-on, far from being central to their working lives. The evidence presented to us concerns the health and social care sectors principally. In those sectors the prevailing cultures of paternalism (in health) and risk-aversion (in social care) have prevented the Act from becoming widely known or embedded. The empowering ethos has not been delivered. The rights conferred by the Act have not been widely realised. The duties imposed by the Act are not widely followed.
   b. A consistent theme in the evidence was the tension between the empowerment which the Act was designed to deliver, and the tendency of professionals to use the Act for safeguarding purposes. Prevailing professional cultures of risk aversion and paternalism have inhibited the aspiration of empowerment from being realised.

c. Dr Ruth Allen, representing the College of Social Work, conceded that "*the MCA is not yet fully understood across any profession as an enabling piece of legislation … it is often seen as bolstering the desire to protect and, in some ways, control people's choice making"*
d. Dr Claud Regnard argued for the Royal Colleges and professional regulators to emphasise the central role of the Act in decision-making, including the importance of determining best interests as set out in the Act, as distinct from clinical best practice judgments. He also called for compliance with the Act to be a requirement of practice and continued employment as a health or care professional. Mencap expressed disappointment at "the failure of the General Medical Council to take to tribunal at least three cases that we have referred to them where doctors have … failed against the Mental Capacity Act", leaving the impression that professional regulators were not taking failures to adhere to the Act seriously enough.
e. The general lack of awareness of the provisions of the Act has allowed prevailing professional practices to continue unchallenged and allowed decision-making to be dominated by professionals.
f. A group of barristers and solicitors who jointly submitted evidence reported their shared experience that health professionals had a "much weaker knowledge and awareness" of the Act, which led to their capacity assessments being "less thorough and less compliant with the MCA and the Code of Practice, including on basic issues such as the need for an assessment of capacity to be decision-specific".

5.4.4.3 Programme theory 3 - Absence of committed leadership

Common to the operation of mental health services is a top-down, protocol-driven approach to organisational performance.[240,262,] Disciplinary forms of power are also prevalent within many mental health systems.[279] Staff behaviour within hierarchical models of service delivery is strongly influenced by the attitudes and actions of those in management and leadership positions.[227] Formalisation of risk management and perceived prioritisation of harm reduction within mental health legislation has contributed to organisational cultures of risk-aversion common within psychiatry.[308,310,315,316,323] Subsequent prioritisation of harm reduction within organisational policy, or reflected within actions of those in managerial and leadership positions, can create a perception among clinicians of a lack of organisational tolerance for positive risk-taking. This subsequently impacts their tolerance for risk.[226,296,320,322] Prescribers tasked individually with implementing positive risk-taking practices within perceived risk-averse organisational cultures fear their professional judgement will not be trusted by those to whom they are answerable. In the event of subsequent adverse outcomes following individual positive risk-taking, these prescribers fear singular blame, with associated professional and personal consequences.[226,227,259,268,284,308,322]

Fear of sole responsibility for adverse outcomes increases prescriber adoption of defensive prescribing practices and clinician-led decision-making in an attempt to reduce their perceived exposure to professional risk.[284,322] Attempts to increase prescriber engagement with SDM processes where there is a perceived lack of organisational tolerance for positive risk-taking are likely to be met by low rates of uptake as the fear of a punitive response in the event of harm remains unaddressed.[227,284,322] Even in cases of apparent organisational calls for increased application of SDM by individual prescribers, the absence of tangible workforce support, specifically practical supports that address the apparent tension between positive risk-taking and protecting patient safety, increases the likelihood that staff perceive such calls as spurious.[322,324,331] Table 18 provides an overview of the development of PT 3, including supporting CMOCs and excerpts used from specific

data sources in their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 18 - Programme theory 3, associated CMOCs and excerpts used from specific data sources to develop this programme theory.

Programme theory 3 – Absence of committed leadership
Where responsibility for implementing SDM practices is placed with individual prescribers within organisations where local governance structures (policies, guidelines) are developed with the implicit goal of maximising reduction in risk to patient harm (context), prescribers are less likely to engage with SDM processes (outcome) as they perceive there is a lack of organisational support for positive risk-taking practices (mechanism) inherent in engaging in SDM. Where prescribers perceive there is a lack of organisational tolerance for positive risk-taking, or where there is an absence of explicit organisational guidance to support prescribers in balancing their duty to both reduce risk of patient harm, whilst promoting positive risk-taking (context), prescribers are less likely to implement initiatives that rely on their engagement in positive risk-taking (outcome), as they fear their professional judgement about the appropriateness of engaging in such practices would not be trusted (mechanism) and they would be individually blamed by management (mechanism) in the event of an adverse outcome. This fear of individual blame and associated consequences (context) increases the likelihood of prescribers adopting decision-making styles that reflect a defensive position (outcome) as they perceive such actions reduce their exposure to professional risk (mechanism). Approaches to increase prescriber engagement with SDM processes within these organisational cultures, or offerings from management of training without enacted organisational support (including in policy, guidance and action taken following any adverse outcomes) (context) are likely to be met by low rates of prescriber uptake (outcome) as the fear of individual responsibility for adverse outcomes has not been addressed (mechanism).
CMOC 1 (**Promoting positive risk management practices in the absence of organisational support)** **Mapping to COM-B model of behaviour categories (a, b, c): Opportunity (social)** a. Where responsibility for implementing SDM is placed with individual prescribers and within organisations where policy and guidance documents for prescribers are developed with the implicit goal of maximising reduction in risk of harm to patient

safety (context), prescribers are less likely to engage in positive risk-taking practices (outcome) as they perceive a lack of organisational support for risk-taking (mechanism).

b. Where prescribers perceive there is a lack of organisational tolerance for positive risk-taking, or where there is an absence of explicit organisational guidance to support prescribers in balancing their duty to reduce risk of patient harm whilst promoting positive risk-taking (context), prescribers are less likely to engage with initiatives that rely on their individual engagement in positive risk-taking (outcome), as they fear that their professional judgement about the appropriateness of engaging in positive risk-taking with individual patients will not be trusted by those in management (mechanism) should an adverse event occur.

c. Where prescribers report not feeling confident that their professional judgement will be trusted by those in management and leadership positions (context), prescribers fear individual blame and associated professional consequences (mechanism) in the event of adverse outcomes resulting from their engagement in positive risk-taking. Fear of being singularly blamed by those to whom prescribers are accountable increases the likelihood of prescribers adopting decision-making styles that reflect a defensive position (outcome).

Evidence sources:

1. Verwijmeren et al (2023): *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
    a. Results: Mental health care delivery is defined by short-term interventions and aversion of risks, in which relapse prevention is deemed more important than the potential side effects of long-term medication use. Owing to this pragmatic and paternalistic organisational culture, having staff adopt new communication models and attend training courses can be challenging.
    b. Absence of a practical model: The ethics and moral imperatives of a shared decision approach are clear for most clinicians, but they often find its practical implementation challenging, requiring all kinds of organisational and cultural shifts (Brooks et al., 2019; Lovell et al., 2018). The absence of a universal implementation model may be one of the reasons why SDM is not readily adopted by mental health professionals

2. Boardman and Roberts (2014) - *Risk, safety and recovery*
    a. Risk and recovery: uncomfortable bed fellows? - Given this support for positive approaches to risk management, why has little changed? Clearly, many staff are concerned about adverse consequences and a lack of managerial and institutional support for changes in practice which are seen to increase risk. Inevitably, this leads to defensive practice. Thus, there needs to be clear local leadership for change. There also needs to be worked examples of how these principles can be applied in routine practice in ordinary settings.
    b. Professional perspective: Managing risks is a central concern in the day-to-day lives of clinicians. They may fear the consequences of taking risks because of the perceived legal and professional repercussions. They may feel the need to take action if a patient is seen to be making a 'bad decision'; or they may feel a pressure to remain in control. They may also work in organisational settings that give no clear guidance or assurances about risk practices and instead represent the double standards of open society. The response to these fears and uncertainties is often to increase surveillance, coercion and constraint. Staff are thus caught between the proverbial 'rock and a hard place' and simply blaming them for restrictive practices is not helpful. They need to feel safe and supported in making decisions and able to be constructive and creative in responding to risk.
    c. Key conditions: important elements in cultivating a supportive context for a recovery-orientated approach: Building an organisational culture supportive of a recovery-orientation that acknowledges the necessity of a degree of risk-tolerance in services if they are to support people in recovery and promotes a practical engagement in the inherent tensions between positive risk-taking and promoting safety.
    d. Organisational issues:
        i. Practitioners and managers are strongly influenced by concerns over the potential repercussions from within the organisation when things go wrong. To support cultural change for managing risk in organisations leaders, and those holding overarching responsibility and accountability, need to ensure that these revised principles are embedded in all relevant policy and procedures from incident reporting to serious untoward incident investigations and subsequent processing of recommendations and responses, including those involving appropriate disciplinary or remedial action. They will also need to ensure that there are no 'double standards'

operating where the value of learning from experience in a no or 'low blame' culture is espoused, but there are still apparent examples of staff being subject to scapegoating when things go wrong.

ii. Apparent resistance to implementing recovery-oriented care displayed by some mental health teams and individual workers may stem from this lack of explicit guidance at policy level, as well as a lack of support at practice level where mental health workers are embedded in a risk-averse organizational culture. Our findings suggests that only if a less risk-averse culture emerged in NHS Mental Health Trusts could a ROC approach be implemented more explicitly that reflected understandings of recovery as articulated within the service user movement.

3. Kaminsky et al (2017) – *Attitudes towards shared decision making in mental health: a qualitative synthesis*
    a. Results: Professionals saw obligations to society, legal liabilities related to responsible prescribing, a lack of system support, disconnect between inpatient and outpatient prescribing practice, and the need for commitment for "every part of the mental health clinic" as possible barriers and challenges to SDM. Prescribers focused primarily on their legal obligations and the responsibility they have always had for medication decisions.
4. Cartwright et al (2024) – *A meta-ethnography of shared decision-making in mental health care from the perspective of staff and service users*
    a. Results: Organisational and cultural constraints on mental health staff can mean they do not feel confident in involving service users in decisions about their care. Potential barriers cited in the research include limited time and resources to make reasonable adjustments, inadequate training in suicide prevention, fears about an adverse reaction from those considered to be a risk to others and fear of culpability and litigation.
    b. Discussion: Lastly, the review outlined the importance of considering organisational influences on the implementation of SDM. It is suggested that paternalistic practice and disciplinary forms of power are prevalent within the mental health system, and this presents significant challenges to achieving SDM in practice.
5. Morant et al (2015) - *Shared decision making for psychiatric medication management: beyond the micro-social*
    a. The psychiatric consultation: Treatment decisions that are weighted towards risk or safety concerns and based on more than simply the interests of the individual may place limitations on SDM, although services may be reluctant to

acknowledge this explicitly. Thus, the possibilities for SDM within a single psychiatric consultation relate to agendas in the broader organisational and social context of mental health care.

6. Robertson and Collinson (2011) - *Positive risk taking: Whose is it? An exploration in community outreach teams in adult mental health and learning disability services*
    a. Introduction: Langan and Lindow concluded that professionals should display a willingness to take appropriate risks, to talk about them, and to look holistically at all aspects of the service-user's life. They cautioned that organisational cultures can sometimes influence professionals into feeling constrained to practise defensively.
    b. Results: Organisational incoherence: Trusting the organisation to trust (in staff): A mixed picture emerged regarding the expected and perceived roles and responsibilities taken by the participants' employing organisation. Some participants felt trusted to undertake their duties as competent professionals and accepted that it was not reasonable to expect the organisation to anticipate all risks faced and provide appropriate advice for every eventuality. However, several participants expressed a concern at perceived organisational indifference to the risks that they were dealing with, that appeared to be based upon a narrow view of risk as something located just within the individual service-user. Where participants were more clearly critical of what they saw as the organisation's position they indicated frustration at its overcautiousness and concern with liability, and resultant failure to see the systemic aspects of risk work.
    c. This linked to an expressed frustration that the organisation had not underwritten any practical guidance on positive risk-taking leaving staff feeling insufficiently supported in some aspects of their work.
    d. Personal strain of risk liability: They identified cautious environments, including local communities and some inpatient settings, as challenging positive risk-taking decisions and sometimes undermining them: Participant 11*: "it's mainly to do with things that hinder it are far more universal than just being purely focused on the service user and usually are systematic sort of insecurities or systematic differences between acute psychiatric care and community psychiatric care*. Instead, they saw themselves as often advocating for the service-user against conservative elements within the wider service.
    e. Dangers of conservative approaches: The in-patient settings were seen as places of greater control over risks, where uncertainty was reduced, and safety was prioritised. Participants expressed respect for the tasks that such services had to carry out and recognised the greater constraints on staff working in those settings than in the community.

f. Discussion: They expressed concern that the absence of consistent practical guidance about positive risk taking could leave them more uncertain about their own liability when encouraging or tolerating service-users taking risks in their daily lives.

7. Crowe and Deane (2017) - Characteristics of mental health recovery model implementation and managers' and clinicians' risk aversion
    a. Introduction: The aggregate of risk-taking behaviours exhibited by employees and managers has been termed the "cultural risk value" of an organisation in business management literature. The individual is then influenced by the risk culture in a self-perpetuating loop. As such, external attributes of the organisational such as allocation of resources to recovery-orientated training and managerial support are likely to impact upon clinicians' tolerance of risk. Boardman and Roberts proposed that training and supervision provide support for clinicians to critically reflect on risk-aversive decision making. An increase in clinical confidence and expertise may influence the role risk aversion plays in clinical decision making. Effective leadership such as providing guidance and commitment to recovery is needed to establish and maintain any recovery-orientated culture change. Overconcern with risk-avoidance is one of the reasons that transformation to a recovery-orientation is needed within mental health services.
8. Ahmed et al (2021) – *Mental Health Professionals' perceived barriers and enablers to shared decision-making in risk assessment and risk management: a qualitative systematic review:*
    a. Results:
        i. *"Every encounter with a patient should be made therapeutic … but it isn't the primary purpose. The primary purpose is safety. I think the policy makes it very clear that safety trumps everything else"*
    b. Results: Beliefs about consequences: Professionals who encouraged risk-taking or supported a service user's wish to discontinue from medication were also fearful of being blamed if negative outcomes occurred as a result of their decision.
        i. "*Risk-taking and promoting an individual's freedom is encouraged but you're conscious of the fact that if someone gets hurt, it's not just them… criticism will be levelled at each level within the authority"*

c. In other studies, fear of being blamed influenced the decision-making process and resulted in professionals adopting defensive or restrictive approaches. The possibility of a negative outcome from supporting a service user to discontinue from medication triggered anxiety in professionals.
d. Results - Social influences: Findings suggest that the pressure of managing risk could lead to power imbalances that inhibit service users' involvement or influence in the decision-making process:
e. '… risk dominated the decision-making of professionals to such an extent that it defined how service users were understood and treated with limited evidence of power-sharing and involvement of service users in decisions.
f. Discussion: Managing risk and delivering recovery-orientated care were experienced as competing priorities that led to practice dilemma. The tension was believed to arise from organisational expectations, legal responsibilities, and contradictory frameworks of practice. Policy guidelines emphasise protection, harm minimisation, public safety, and duty of care. At the same time, they recommend recovery-orientated care based upon the components of SDM, positive risk-taking, therapeutic relationships, and empowerment.

9. Royal College of Psychiatrists (2016) - *Rethinking risk to others in mental health services*
    a. Key priorities in risk assessment: A robust risk assessment and a clear management plan that has a focus on recovery allows professionals to take risks to allow patients to demonstrate their progress and emphasise their strengths, rather than their risks and weaknesses, but requires organisational acceptance and support to take justifiable clinical risks. Approaches to risk assessment vary across the UK.
    b. Risk assessment in mental health services: Time course is also a factor: decision makers tend to focus on short term risk that they can foresee but give less weight to long-term risks that are harder to assess. This is especially true if decision makers are also thinking about benefits and harms for themselves as opposed to for patients; this might be commonplace within blame culture, in which professionals may be made scapegoat if things go wrong.
    c. Risk assessment in mental health services: Attention to public anxiety and professional anxiety about the professional's own well-being at work may mean that patients' claims to autonomy and freedom from interference are unjustifiably overwritten.
10. Blood and Wardle (2018) – *Positive risk and shared decision making:*
    a. Section 3: Barriers to risk-taking in services:

i. A key message from the focus groups was that risk averse practice, attitudes, systems and culture often restrict individuals' quality of life. Although we heard – and will present – many examples of good practice in relation to risk and decision-making, there was still a strong sense from participants that this was usually happening only when and where practitioners had the courage, time and support to "swim against the tide".

b. Section 3: Barriers to positive risk taking - A "blame culture": The underlying worry of being blamed or not supported by managers or higher levels of hierarchy was a major concern for all participants in the focus groups.

i. "*As professionals, can we be positive about taking risks ourselves? Is it okay for me to take a risk, if I might get into trouble for doing it next week?*

ii. There was a significant amount of discussion in the focus groups about the crucial role of leaders in supporting positive risk taking and a strong sense that this needs to "start at the top". Leaders need to model and actively support positive risk taking and will need development if they are to truly embed this transformation (rather than simply recycling the rhetoric).

c. Lack of professional judgement: The literature highlights the existence of a top-down approach to organisational performance management that does not allow for contextual decision-making at the front line. Practice is often geared towards protecting organisations from potential financial and reputational risks. This has led to a loss of confidence in professional judgement. There was a significant amount of discussion in the focus groups about the crucial role of leaders in supporting positive risk taking and a strong sense that this needs to "start at the top". Elected members needed to understand and be prepared to defend positive risk-taking decisions. Regulation, audit and inspection were felt to place too much emphasis on throughput, and participants identified the importance of inspectors really understanding positive risk taking and finding more flexible ways to define and measure "success", including hearing the voices of people using services.

d. Section 4: Enablers to positive risk taking in services: Participants in the focus groups felt very strongly that a move away from risk averse practices and systems could only be achieved by a systemic willingness across all agencies, partners, and levels of the workforce, to embrace and support positive risk-taking in practice. Many suggested that a new attitude to experimenting, innovating, and taking risks was required and that people should be allowed to learn from their mistakes rather than fear a punitive response. Leaders can be instrumental in helping create an asset-based approach, which demonstrates flexibility, and most importantly, trust in practitioners' professional judgement.

11. Brooks et al (2017): *Exploring the potential implementation of a tool to enhance shared decision making (SDM) in mental health services in the United Kingdom: a qualitative exploration of the views of service users, carers and professionals.*
    a. Results:
        i. Top-down protocol-driven practice (including the risk assessment process) was also considered a structural barrier to the nuanced negotiations required to successfully use the tool because they reduced flexibility in terms of the options available for professionals and service users.
        ii. These were compared to other settings, such as inpatient settings, which were considered to have cultures with a greater focus on risk, which would render it more difficult to have the type of dialogue advocated by the tool.
12. Yaara Zisman-Ilani et al (2021) - *Shared Risk Taking: Shared Decision Making in Serious Mental Illness*
    a. Introduction: Although promising, research and implementation of SDM in mental health care have overlooked the fact that SDM is sometimes at odds with clinicians' training to mitigate the risk of harm and with organizational policies that are inherently risk averse. In psychiatry, reducing risks to safety is the highest priority, because it is a key part of one aspect of clinicians' professional training and responsibility and is the common institutional policy among mental health services. Perceived risks to safety affect both clinicians and patients, but differently. For clinicians, safety risks, such as relapse, present high potential for legal liability, particularly if the risk is accompanied by symptoms potentially related to harm, such as suicidality or homicidality.
    b. Discussion: Practitioners report challenges surrounding the competing priorities of the role, and in particular, the challenges of being accountable and responsible for managing risk. For some these challenges result in concerns regarding the clinical appropriateness of allowing service user choice.
13. Schon et al (2018) - *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Results: An additional contextual barrier was the lack of a common organizational agenda supporting a commitment to concretely increasing user participation. User participation and SDM were considered voluntary activity in accordance with staff judgment, experience, and attitude.
    b. Organisational readiness and commitment: As in all implementations of new methods, manager's attitudes and level of commitment is crucial (Aarons et al., 2016; Gifford et al., 2013; Mooreetal., 2015). Managers need to provide sustainable

structures, with a clear vision of the new method as constituting a formal part of the ongoing activities. Although SDM is mentioned in key policy documents in Sweden and internationally, there are no incentives built into organisational structures and it is not promoted systematically at national, regional, or organisational levels (Stovell et al., 2016). A need to foster cultural change among managers, clinicians and users may be seen as well as a prerequisite for structural change, and this is described in the area of user involvement as a considerable challenge. Another important aspect of the organizational context was the structure for decision-making and planning in the particular organization. This included both an understanding of the decision hierarchy at the particular service, requirements and expectations for formal decision processes such as treatment planning, and even an understanding of documentation systems which were seen as both a current obstacle and a future possibility for integrating the interactive decision aid in the formal systems regarding user care planning.

14. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (DM) in mental health practice*
    a. Results: Reflective narratives on SDM implementation [anonymised] (qualified mental health nurse, advanced clinical lead).
        i. *This section reflects on my involvement in implementing SDM across the Trust.*
            1. *The importance of a policy and how to use it: Producing the Trust SDM policy was my first important implementation task. Being able to go to teams and tell them that senior managers, nurses and psychiatrists had signed up to SDM as a way of working gave authority to the training sessions we delivered.*
    b. Discussion: Pressures from the clinical environment and the informal norms within health services impeded the contextual integration of SDM. These pressures included limited flexibility, lack of management support, pressure to discharge and associated financial pressures, indicating the training alone was insufficient. Wider contextual support including support from the host organisation and high-level management were facilitators to implementing SDM.
15. Just et al (2020) – *Positive risk management: Staff perspectives in acute mental health inpatient settings*
    a. The impact of experience: Participants' experience and seniority affected the practice of positive risk management. They stated there was no training provided on risk management which required staff to learn on the job or from other people's approaches and being reliant on their own initiative.

b. Delivery in practice: All expressed intentions to implement positive risk management practices yet reported struggling to use positive risk management when they did not feel supported by colleagues and managers, or if they encountered competing systemic demands.
c. Emotional decision making: Practitioners anxieties and fears influenced their use of positive risk management. Staff were concerned about the prospect of accountability in the event of adverse outcomes. Practitioners were often preoccupied with the worst possible outcome, which was two-fold: harm to the service user and repercussions for staff. Therefore, risk management plans became driven by alleviating practitioners' anxieties and emotional states.
d. Discussion: Results indicate that across documents and practitioners, challenges are evident due to the need to balance challenging demand. Little guidance is provided on how practitioners can achieve the balances as this is likely person specific. However, only providing staff with awareness does not result in practical changes. Therefore, staff need experience of managing the complexities, as well as support from their peers, teams and organisations. Furthermore, staff do not routinely receive any formalised positive risk management training and subsequently find it challenging to navigate risk-based decisions. Their own experiences predominantly influence staff decision-making, and they commonly feel uncertain about engaging in positive risk management.
e. A key implication of the current research is the importance of support from colleagues and organisations. Training alone is unlikely to be sufficient in altering practices. Managing risk is a challenging and high stressful experience for staff, with the current results indicating that staff require senior support and verification if they are to feel more confident in their decision making.

16. Eliacin et al (2022) - *Implementation and staff understanding of shared decision- making in the context of recovery- oriented care across US Veterans Health Administration (VHA) inpatient mental healthcare units: a mixed- methods evaluation*
    a. Results: Moreover, sites that were guided by a culture of inclusion and autonomy of patients had a more consistent approach to SDM across providers. In comparison, observational notes indicated more variation across providers in low and medium sites in which one provider on the unit was more recovery- oriented in their approach, but other providers endorsed low power sharing views and practices. In addition, high power sharing sites had systematic approaches to solicit veterans' input and feedback about different aspects of care or life on the unit and used their feedback for quality improvement purposes.

17. Rodriguez del Barrio et al (2014) - *Human rights and the use of psychiatric medication*
    a. Results (obstacles within the healthcare system): In Brazil, structural problems in the public health system often led to failure to ensure the rights of users. Consequently, even when professionals understand the rights of users, many of them are reluctant to address the issue of rights with their patients. They feel responsible for promoting the exercise of those rights but, at the same time, feel unable to do so:
        i. "*Users' rights are hardly respected at all. Neither are the workers' rights. We are afraid to act, because we feel we don't have the necessary support to uphold those rights*" (PB5 – physician).
18. Forsberg et al (2018) - *Clinician perspectives on supporting adults with psychosis who wish to discontinue neuroleptic medication: qualitative analysis*
    a. Fears for discontinuation: Decisions supporting discontinuation triggered a range of anxieties for clinicians, including concerns for the service-user and the public, but also concerns for themselves. A common fear, mentioned by nine clinicians, was the service-user relapsing or experiencing withdrawal symptoms from discontinuation, potentially resulting in clinicians being blamed or formal investigations in the event of a serious negative outcome:
    b. "*You can almost hear someone saying to you 'you allowed this to happen, you were part of it, why did you do that? Why did you let them have that choice?' That kind of thing. So, I can always imagine like a relative saying it, or you know, someone in an SUI [Serious Untoward Incident], an investigation saying, 'Why would you do that?".* (P2)
    c. Discussion: Additionally, the existing risk-adverse mental health service culture has been found to make staff feel limited in their ability to implement recovery-oriented approaches and concerned about blame and litigation (Tickle, Brown, & Hayward, 2014). Previous research has also confirmed that reducing neuroleptic medication can be anxiety provoking for clinicians (Thomas, Katsabouris, & Bouras, 1997). Our findings suggest that clinicians are acutely aware of their obligations to manage risk, and this drives a need to prevent harm and protect themselves if their decision were to be questioned.
19. Roberts (2014) – *Risk Decision-Making: Working with Risk and Implementing Positive Risk-Taking*
    a. Concern for risk and safety are pivotal psychiatric preoccupations, but neither patients nor practitioners are happy with current practice. Morgan has previously observed that our unrewarding focus on risk aversion appears to be driven more by anxiety over organisational, political and public reactions than patient outcomes. Although it is recognised that the

most effective organisations are those with good systems in place to support positive approaches to risk rather than defensive ones, we have described in successive Royal College of Psychiatrists' reports the emphasis on risk-averse practice dominant in National Health Service settings. Despite this, the current Department of Health guidelines on best practice in risk management recommend positive risk management, conducted in a spirit of collaboration and trust, recognising service users' strengths and emphasising recovery. So, what is needed? Clearly, more than governmental policy and professional consensus. If we are to emerge from practices which stifle creativity and innovation, we will need the kind of local organisational endorsement that may come through adopting positive risk and safety policies underpinned by detailed, well-thought-out guidance on practice, as described in Morgan's training manual.

5.4.4.4 Programme theory 4 – Cultural and social norms within psychosis management

Cultural and social norms are unspoken rules or expectations of behaviour based on shared beliefs within specific groups.[332] Such norms offer social standards for behaviour, governing what is (and is not) acceptable in interactions among people, and are known to have a high degree of influence for individual behaviours.[332] The appropriateness of paternalism within healthcare decisions impacting individuals with psychosis remains dominant among clinicians and wider society.[214,227,253,311] Three norms among clinicians were identified as increasing the likelihood of their adoption of clinician-led decision-making and reducing their engagement with SDM behaviours within psychosis management. These norms reflect: (i) assumptions about decisional capacity, (ii) assumptions about insight and, (iii) the need to protect people with psychotic illnesses from responsibilities involved in SDM.

The appropriateness of clinician-led prescribing can be reinforced by prescriber assumptions about, and assessments of, decisional capacity.[100] Where prescribers assume capacity is absent, or consider capacity a binary concept, a decision-specific consideration of the appropriateness of SDM is not undertaken.[213,301,311] Instead, SDM application is rejected based on a belief of inappropriateness among individuals experiencing psychosis.[100,274,279,294] Many prescribers also believe insight into psychotic symptoms is a pre-requisite for SDM.[99,238,259,266,284,290,300,312,315] The presence of insight is necessary for these prescribers to view patients as capable of sharing decision-making responsibility with, and for their treatment preferences to be considered valuable within decision-making.[99,259,284] In its absence, attempts to initiate collaborative discussions about antipsychotic treatment are viewed as unproductive and a source of avoidable patient-prescriber conflict.[238,249,290,331] In either case, adoption of clinician-led decision-making is justified by prescribers as being appropriate to discharge their duty of care and ensure timely access to treatment.[99,253,259,313,315]

Even where decisional capacity is acknowledged, clinicians often lack confidence in the ability of people with SMI to cope with the responsibilities involved in

SDM.[99,211,227,240,253,279,284] Adoption of clinician-led decision-making, and use of methods to promote patient agreement, is viewed by these prescribers as a means of protecting patients from decision-making responsibility and the consequences of 'unwise' decisions.[240,245,253,259,265] Perceptions among wider society can also impact prescriber engagement in SDM. Societal beliefs about the dangers posed by those with mental illness and expectations of risk aversion can decrease prescriber perceived ability to increase patient autonomy within decision-making.[270,284,286,308] Where prescribers perceive society expects them to be risk-averse in their care of individuals with SMI, particularly within countries where investigations following serious incidents are publicised within mainstream media, fear of public shaming reduces the likelihood of prescribers engaging in SDM within psychosis management.[259,281,310,324]

Table 19 provides an overview of the development of programme theory 4, including supporting CMOCs and excerpts used from specific data sources in their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 19 - Programme theory 4, associated CMOCs and excerpts used from specific data sources to develop this programme theory.

Programme theory 4 - Cultural and social norms within psychosis management

The appropriateness of clinician-led prescribing can be reinforced by prescriber assumptions about and assessments of capacity. Where prescribers assume capacity is absent, or consider capacity as a binary concept (context), these prescribers do not believe SDM within psychosis management is applicable (mechanism), and so do not attempt to share decisions impacting any aspect of antipsychotic treatment with these patients (outcome). Viewing insight into illness as a pre-requisite to SDM (context) is another reason some prescribers do not consider SDM applicable among those with psychosis (mechanism) and again, do not attempt SDM in these circumstances (outcome). Attempts to initiate collaborative discussions about antipsychotic treatment, where patient preferences for treatment would be sought among those where illness reduces insight, is viewed as unproductive and a source of avoidable interpersonal patient-prescriber conflict (mechanism). Clinicians can also lack confidence in the ability of patients with a serious mental illness to cope with the responsibilities inherently involved in SDM. Where these beliefs exist among prescribers (context), prescribers are more likely to promote clinician-led decision-making (outcome), as this is viewed by them as a way of protecting patients from the responsibility of decision-making (mechanism) and the consequences of making an 'unwise' decision (mechanism). Societal perceptions of those with psychosis also influences the actions of prescribers. A perception exists among prescribers in some countries that the general public expects them to be risk-averse within treatment decisions among those with psychosis, due to public fear of the perceived risk those with a psychotic illness pose. This perception, coupled with their duty to protect the welfare of people other than their immediate patients (context), leads prescribers to be less willing to engage in SDM with this patient cohort (outcome) as they fear they will be publicly shamed (mechanism) should an adverse event occur following the non-adoption of the most risk-aversive approach to treatment.
CMOC 1 - (insight as a prerequisite for engaging in SDM)

Mapping to COM-B model of behaviour categories (a, b, c): Motivation (reflective)

a. Some prescribers view insight into psychotic symptoms as a pre-requisite for sharing responsibility for antipsychotic treatment decisions with patients with psychosis (context). Where this view exists, these prescribers do not attempt to engage patients in shared decision-making impacting any aspect of antipsychotic treatment decisions (outcome) as they don't consider SDM applicable among this cohort (mechanism). Attempts to initiate collaborative discussions about antipsychotic treatment, where patient treatment preferences would be sought among patients without insight, is viewed as unproductive and a source of avoidable conflict (mechanism).

b. Where insight is viewed as a pre-requisite to engaging patients with psychosis in collaborative antipsychotic treatment decisions (context), initiatives to increase prescriber engagement with patient treatment preferences are unlikely to receive sufficient engagement from prescribers (outcome), as these prescribers question the validity of the treatment preferences of those without insight in informing a critical treatment decision i.e., decisions impacting antipsychotic treatment (mechanism).

c. Assumptions by prescribers about lack of insight among those presenting with a psychotic illness (context) increases the likelihood of prescribers adopting clinician-led decision-making (outcome) due to the belief that this is uniformly necessary among those with psychosis (mechanism).

Evidence sources:

1. Mahone et al (2011) – *Shared Decision Making in Mental Health Treatment: Qualitative Findings from Stakeholder Focus Groups*
    a. Results – Consumer barriers: Prescribers agreed that consumer insight (or lack of it) was a significant factor in successfully practicing shared decision making.
2. Ramon et al (2017) - *Shared decision-making for psychiatric medication: a mixed-methods evaluation for a UK training programme for service users and clinicians*
    a. Results: Psychiatrists' evaluations of the content and level of teaching were more mixed:

i. *"Well, it would be good to set realistic expectations, because some people, especially people with schizophrenia they sometimes have a lack of insight…".* (PSY06).

b. Discussion*:* Existing research highlights psychiatrists' focus on an assumed lack of insight by service users of their mental ill-health as a key barrier to engaging in SDM.

3. O'Sullivan and Rae (unknown date) – *Shared Decision Making in Psychiatric Medicines Management*
   a. Lack of insight, or capacity or "the illness itself" were identified as potential barriers to SDM. Psychiatrists and service users acknowledged that sometimes when people are acutely unwell, they may be limits to how much shared decision making can take place. It was agreed that crisis plans could be used more widely and effectively. *"I've noticed a big difference between how the SDM happens – whether you're on a section or not." (Service User).*
4. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (DM) in mental health practice*
   a. Results: The themes of "we already practice SDM" and "*we can't engage certain services users in SDM (e.g., due to lack of insight)"* occurred in most sessions; teams varied in their capacity to challenge these assumptions.
   b. Results: Differences also existed in what constituted pre-requisites for SDM with professionals reporting that adherence and insight were necessary in order to undertake SDM. Deegan (2014) challenged this potentially circular argument (e.g., SDM being seen as a virtue until there was disagreement and then it reverting to an issue of insight and SDM then becoming a risk).
5. Ramon and Yeung (2022) – *The place of shared decision making in UK mental health services* (book chapter)
   a. However, feedback from psychiatrists involved in SDM training tended to focus on the management of risk avoidance, while omitting the need for calculated positive risk taking, and assuming a lack of insight by service users of their mental health conditions and needs.
6. Younas et al (2016) - *Mental health pharmacists views on shared decision-making for antipsychotics in serious mental illness*
   a. Results:
      i. Capacity and insight - A lack of service user insight was seen by the participants as an obstacle to SDM. *"If they don't have insight…it doesn't matter what decision you make or information you give (them)… (if they believe that) there's nothing wrong with them they don't need to take treatment".*

ii. *"They might be acutely unwell…they might not be in a position to make a decision they might be forced to have treatment against their wishes so in that scenario you're not going to be able to provide them with SDM".*

7. Kaminsky et al (2014) - *A grounded construction of shared decision making for psychiatric medication management: findings from a community mental health team (thesis)*
    a. Chapter Six. Thematic findings from interviews with psychiatrists:

        Looking for consensus in the data, one overarching theme was coded for all seven psychiatrists. This refers to the barrier of service users being ill as hindering involvement. Within this group, a majority (but not all) refer to 'lacking insight' as problematic for open dialogue.

        i. Many psychiatrists acknowledge that the amount and type of information about psychiatric medication changes according to the situation. In addition, a subgroup of participants confesses that, at times and during certain encounters, information about psychiatric medication is withheld. This was, in the most part related to circumstances where the service user is deemed by the psychiatrist as lacking insight into their illness.

        ii. Most participants referred to the problems of engaging in collaborative decision making if a service user was seen to lack insight into their illness. Formation of a joint dialogue and presenting information about psychiatric medication was seen as more difficult in these circumstances. Lack of insight was also related to changing the information that is presented and constructing a different argument to avoid conflict in the encounter. Thus, psychiatrists refer to a relatively sophisticated process of constructing conversations about psychiatric medication when someone is deemed to lack insight.

        iii. Dr White: ..."*they don't necessarily see as part of being ill, and then it becomes quite difficult to involve people um on the same level because you have to walk a fine line between giving information that is correct and factual um but also if you start talking about this is an antipsychotic drug ...People start saying, but I'm not psychotic and so it's often about a fine line. It's not about giving the wrong information but giving information that would lead people to consider perhaps the options more carefully".*

        iv. I: *What factors affect peoples' ability to be fully involved in the decision-making process about their psychiatric medication? Is there anything, and if so, what?*

v. Dr Bloggs: [laugh] *Yes there's factors. If you're very ill for instance uh somebody who is very agitated somebody who is so psychotic, they don't even understand the medication, makes it difficult for you either to discuss at length or for them to understand the information you are passing across...That is one. Even when they're not that ill, their insight is still very important, because there are those of them which see that they are ill, but they don't have any insight into the illness and so they don't want anything to do with you about medications sometimes [laughing]. So, insight is very important. The severity of the illness is also very important.*

8. Cartwright et al (2024) – *A meta-ethnography of shared decision-making in mental health care from the perspective of staff and service users*
    a. Discussion: It was suggested the characteristics of such mental health presentations would have a more significant impact on the service user's ability to engage in SDM. In fact, the construct of insight can simply become the frame through which professionals view, and therefore challenge, the service user's competence to participate based on the increased need for information and guidance when experiencing a crisis. Service users in the Kaminsky and colleagues' study [37] however don't refer directly to insight, but speak in more functional terms, describing poor concentration and memory problems – not excluding SDM but highlighting the increased need to support the person with information and guidance. Principle 2 of The Mental Capacity Act (2005) [49] requires practitioners to help a person to make their own decisions before deciding they're unable to decide. This means that practitioners should take an active role in supporting the service user with their memory or communication to reduce their distress and help them to understand and weigh up information relevant to their decision.
    b. Clinical implications: Consideration should be given to the issue of the mental capacity to engage in SDM in the context of service user's current difficulties, given its frequent indication by staff in the literature as a reason for not engaging in SDM. Lacking or fluctuating capacity will certainly be an issue in environments like inpatient wards, however, training and processes should emphasise that it does not preclude joint decision making. For those who are considered to lack capacity interventions such as advanced statements, the involvement of family and carers (ideally pre-agreed), and least restrictive human-rights based approaches could be introduced and made common practice. Processes should necessitate careful consideration of mental capacity and the implementation of associated legal frameworks.

9. Haugom et al (2020) - *Mental health professionals' experiences with shared decision-making for patients with psychotic disorders: a qualitative study:*
    a. Results: Almost all the participating psychiatrists and several other participants reported experiencing challenges with using SDM with patients with psychotic disorders whom they felt had a limited understanding of the consequences of the disorder for their lives. Some of the participants said early in the interview that they aimed to come to an agreement with the patient. Later in the interview, the same participants reported that, in many situations, they had to make the decision for the patient because of the patient's limited understanding. The findings suggest that health professionals often make the decision due to the patients' limited understanding of their own situation. Several participants found it particularly challenging if their patient was psychotic and said there are situations in which they, as therapists, must make the decisions. One participant also stated that SDM is not necessarily possible beginning at the patient's first contact with the therapist:
        i. *"You're psychotic, coming on strong with some paranoia. So, you're not capable of making decisions here and now, but later on we can talk about SDM"*. (P5, inpatient care)
        ii. "*I don't think SDM fits all types of patients and diagnoses. You have to be a bit realistic. (P3, in- and outpatient care)* This participant later continued: "*It's good that those who can decide are allowed to decide, but not everybody. The ones who are very sick, they can't decide".* (P3, in-and outpatient care)
10. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
    a. The practice of shared decision making: Participants at the SDM meeting stressed that, even in the case of involuntary commitment, opportunities for SDM exist and should be utilized.
        i. "We don't have to rule out SDM in emergency or crisis situations."
11. Shue et al (2023) – *Exploring Factors Impacting the Implementation of Recovery-Oriented Treatment Planning on Acute Inpatient Mental Health Units*
    a. Results: "*I think people can lack insight…somebody doesn't realize how much trouble they're having. But that's when I see a lot of the kind of authoritarian type exchanges happen. And I wish those conversations happened differently. And especially when it comes to like veterans being involuntarily hospitalized, you know. And sometimes veterans will get*

really angry or resentful in those treatment team meetings and I've even seen providers talk over the veteran in those instances"

12. Eliacin et al (2022) - *Implementation and staff understanding of shared decision- making in the context of recovery- oriented care across US Veterans Health Administration (VHA) inpatient mental healthcare units: a mixed- methods evaluation*
    a. Results: Whereas veterans who were new to the inpatient unit, unfamiliar with SDM process, or those with certain diagnoses, such as psychosis were not as supported in participating in SDM processes.
13. Becher et al (2021) - *Barriers and facilitators of shared decision making in acutely ill inpatients with schizophrenia—Qualitative findings from the intervention group of a randomised-controlled trial*
    a. Results*:* Patients' health belief model (n = 20) was a barrier predominantly named by clinicians. This included a lack of acceptance of the disease or insight, a lack of understanding thereof and the conviction that medication is not required for treatment.
14. El-Alti (2023) – *Shared Decision Making in Psychiatry: Dissolving the Responsibility Problem*
    a. One objection healthcare professional (HCPs) might put forth is that a person's limited insight into her illness is a contraindication for the whole SDM process. Lack of insight is a common symptom of psychotic illnesses. Some HCPs believe that the lack of insight is anathema to SDM.
15. Ahmed et al (2021) – *Mental Health Professionals' perceived barriers and enablers to shared decision-making in risk assessment and risk management: a qualitative systematic review:*
    a. Results: Social influences. Factors relating directly to the service user, such as insight or mental capacity impede on the SDM components.
        i. "*We can share the responsibility with the patient only when he has totally understood and accepted what is happening to himself, otherwise it is very difficult …"*
16. Shepherd et al (2014) – *Consultant psychiatrists' experiences of and attitudes towards shared decision making in antipsychotic prescribing: a qualitative study.*
    a. Results:
        i. In considering the process of deliberation, jointly between service-user and psychiatrist, most participants described the role of insight as a factor in psychosis that would limit, or completely prevent, shared decision

making. For some this was presented as a restriction that necessitated strategies to ensure the service-user was as involved as possible in the decision-making process, or that family members or other potential carers were involved. For six participants the impact on insight on the individual's capacity to consent was an absolute contraindication to shared decision making.

ii. *"Some patients are just too unwell to make that kind of decision, they can have no capacity at all to make that kind of decision at the time of admission, in which case we just have to go with what we feel is advisable at that time."*

iii. *"[I]f I was to see someone, who was acutely psychotic, very behaviourally disturbed, poor insight, it's obviously not going to be possible, at that particular point in time, to go through, all the side-effects of all the different antipsychotic medications, and expect a patient, at that point, to be able to, to engage in that process."*

iv. *"So, I think, at that stage you, well I attempt to, discuss the issues with the patient but, to be perfectly honest, if it's clear that they're insightless, or that they're not going to agree, and you get that, not only with the one-to-one conversation that you have, but also being aware of how they're being, from the time they're admitted to the unit. I don't think there is much point, at that, moment in time, to get into a conflict."*

v. *"I think giving patients choice is um is ideal if you can but at best um at worst, I should say it is rather idealistic you know I've got a patient in front of me who is floridly psychotic and totally insightless".*

vi. These participants presented insight in psychosis as a binary concept - present or absent.

vii. Reduced insight has been recognised as a barrier to seeking treatment and engagement with offered therapies and it has also been proposed that in such cases the adoption of more paternalistic approach to care is ethically appropriate; however qualitative research into the experiences of individuals suffering with psychotic disorders have also emphasised the importance of ensuring that autonomy be respected as far as possible throughout the clinical presentation.

b. Conclusion:

i. The biggest perceived intrinsic barrier to the shared decision-making model proposed by participants was the concept of insight, which was generally considered by participants as a binary concept; no additional description of domains of insight were presented.

ii. Insight, or competence, was recognised in both studies as being a significant barrier to the sharing of decision-making responsibility.

17. Brooks et al (2017): *Exploring the potential implementation of a tool to enhance shared decision making (SDM) in mental health services in the United Kingdom: a qualitative exploration of the views of service users, carers and professionals.*
    a. Results: Most micro level barriers to implementation were specific to severe mental illness, rather than arising from features general to all health care. There was a divergence in views about barriers to the implementation of the tool within health services. Professionals, in particular, focussed on the negative attributes of service user characteristics and how these might impact on potential implementation. The most prominent barrier reported by professionals was a 'lack of insight' on the part of service users to enable them to engage in discussions about medications and side effects. Insight' was considered a prerequisite to the use of the tool and SDM more generally and professionals acknowledged that insight fluctuated over time. At moments when professionals considered service users to be demonstrating florid symptoms, insight was considered to be lacking. In these situations, professionals felt that they needed to make decisions for service users and that use of the tool would not be appropriate.
    b. Results: In fact, a small number of service users went further. They pointed out that the threat of being detained against their will under the Mental Health Act was occasionally used as a coercive strategy to encourage compliance with medication and, as a result, implied that even when service users were not detained, meaningful collaborative choice through use of the tool might not be possible. Service users made the point that when their rationality was questioned, even if only indirectly by consideration of the use of the Mental Health Act, this indicated to them that clinicians did not consider their preferences valid. They implied that this validation was a prerequisite for meaningful involvement with the SDM tool.
    c. Discussion: Professionals thought the implementation of a SDM tool would fail because of negative attributes of service users' behaviour, and similarly service users were not confident that SDM discussions prompted by the tool would result in demonstrable accountable service-level decisions. The concept of 'insight' is a complex and highly subjective term often used to sustain the power imbalance within the mental health system. Despite these criticisms, professionals still cited service user 'insight' as the greatest barrier they perceived to the use of the tool, with no acknowledgement in the professional lexicon of a need to, or ways of addressing this.

18. Gordon and Green (2013) – Shared Decision Making in the Treatment of Psychosis
    a. Challenges in implementing shared decision-making: Some of the barriers to envisioning such a clinical pathway are conceptual, some practical. Some of these hurdles may be summarized as follows: A sense that many patients who are psychotic are ipso facto unable to engage in true shared decision making and that anosognosia blinds the patient to the true nature of the condition to be treated and to the dangers of nontreatment.
19. Morant et al (2015) - *Shared decision making for psychiatric medication management: beyond the micro-social*
    a. Whilst there may be moments of genuine lack of capacity, meaningful dialogue can also sometimes be compromised by practitioners' assumptions about lack of insight associated with mental health problems. This may exaggerate inequalities between service users' experiential knowledge and the scientific knowledge base of practitioners. These dynamics are most common when mental health problems are acute or severe (although they may not be explicitly acknowledged by service providers).
    b. One the other hand, if judged to lack capacity or insight, the validity of their views and subjective experiences can be questioned or devalued.

CMOC 2 (prescribers' assumptions about capacity among those experiencing psychosis)

Mapping to COM-B model of behaviour categories (a, b): Motivation (reflective)

a. Where prescribers conceptualise capacity among those with psychosis as universally absent or static, or assume capacity is lacking among those experiencing psychosis (context), prescribers do not believe application of SDM is applicable among this cohort (mechanism) and so don't attempt to share decisions regarding any aspect of antipsychotic treatment with these patients (outcome).

b. Where prescribers conceptualise capacity among patients with psychosis in this way (context), prescribers question the validity of the treatment preferences of those experiencing psychosis in informing a perceived critical treatment decision (mechanism), and so, are more likely to adopt clinician-led decision making (outcome).

Evidence sources:

1. Simon Wessely (on behalf of UK Government) (2018) – *Modernising the Mental Health Act: Increasing choice and reducing compulsion*
    a. Towards a right based Mental Health Act: I was surprised by the number of service users and former patients who have told me that their issues were not so much with being detained, although that is an issue, but the way in which having been deprived of their liberty, they were often deprived of much else. In other words, their wishes, preferences and choices were often not respected. This includes the rise of coercion and the continuing legacy of stigma, discrimination and racism in society. One of the Terms of Reference for the Review was to assess if we were up to date in recent developments regarding the rights of those with mental illness. We aren't.
2. Hamann and Heres (2014) - *Adapting Shared Decision Making for Individuals with Severe Mental Illness*
    a. Barriers among professionals: Many psychiatrists go even further, classifying specific situations and patients (such as those experiencing an acute psychotic episode) or distinct decisional steps (such as hospital admission) as generally unsuitable for shared decision making. Consequently, psychiatrists often act in a paternalistic way or apply pressure to patients.
3. Ali et al (2015) - *Psychiatric Providers' Willingness to Participate in Shared Decision Making When Prescribing Psychotropics*
    a. Results: A total of 26 (89.7%) respondents reported clinical situations in which they would not engage in SDM including psychosis, altered mental status, dementia, and patients that pose a danger to themselves or others. The most commonly reported perceived barriers were limited patient capacity (86.2%), limited time with patient (62.1%), and limited materials/staff (51.7%).
4. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*

a. The mental health field provides special challenges to implementation of SDM because of the history of interventions that assume limitations in mental health consumers' capacity to make decisions in their own best interests.

5. Haugom et al (2022) - *Mental health professionals' experiences with shared decision-making for patients with psychotic disorders: a qualitative study:*
    a. Results: *"I don't think SDM fits all types of patients and diagnoses. You have to be a bit realistic. (P3, in- and outpatient care) This participant later continued: It's good that those who can decide are allowed to decide, but not everybody. The ones who are very sick, they can't decide"*. (P3, in- and outpatient care).
6. Cartwright et al (2024) – *A meta-ethnography of shared decision-making in mental health care from the perspective of staff and service users*
    a. Results:
        i. Clinicians often highlighted limitations to service user engagement due to their symptoms. This was particularly highlighted in studies conducted in inpatient settings. For example, mental health nurses in inpatient wards stated that service users were 'too unwell' to have active involvement in SDM. Some clinicians reported trying to incorporate collaboration by using basic actions such as going for a walk or having conversations with a service user, rather than seeing this as a more formal process. Service users who had been diagnosed with serious mental illnesses expressed the most distrust and feelings of powerlessness in relation to the healthcare system. However, these participants still wished to be involved in decisions about their care.
        ii. Some staff members in the reviewed studies suggested that the service users they work with are too 'high risk' or 'vulnerable' to be considered appropriate for SDM. In such cases, it was recommended that SDM approaches could be adapted. It was argued that when people are most unwell, they are at the highest risk of feeling disempowered, therefore encouraging a service user to make even basic decisions is a way to provide a sense of control and increase motivation towards recovery. Participants reflected that this requires a high level of skill from the clinician in balancing safety and risk. The included papers make recommendations that mental capacity or 'insight' is not static and requires a dynamic dialogical approach, within which the goal should always be SDM.
        iii. Discussion: The second theme highlights the importance of fluctuating mental capacity of the service user and the impact this could have on SDM. This was particularly evident when staff considered the service user to have a

serious mental health difficulty such as a diagnosis of 'psychosis' or had been admitted to an inpatient service due to mental health crisis. Clinicians placed emphasis on considering service users fluctuating capacity to engage in SDM, however were less reflective on their own individual biases towards SDM or organisational barriers.

7. Morant et al (2015) - *Shared decision making for psychiatric medication management: beyond the micro-social*
    a. Whilst there may be moments of genuine lack of capacity, meaningful dialogue can also sometimes be compromised by practitioners' assumptions about lack of insight associated with mental health problems. This may exaggerate inequalities between service users' experiential knowledge and the scientific knowledge base of practitioners. These dynamics are most common when mental health problems are acute or severe (although they may not be explicitly acknowledged by service providers). One the other hand, if judged to lack capacity or insight, the validity of their views and subjective experiences can be questioned or devalued.
8. Simmons and Goulding (2017): *Spot the difference: shared decision-making and supported decision-making in mental health*
    a. Introduction: Morant et al. (2016) argue that shared decision-making models, largely devised within non-psychiatric settings, cannot be readily adapted for specialist mental healthcare settings. As they point out, decisions about mental healthcare are embedded in traditionally paternalistic systems of care with an ongoing history of coercion, presumption of lack of insight and decisional capacity and disempowerment.
9. Pedley et al (2018) - *Qualitative systematic review of barriers and facilitators to patient-involved antipsychotic prescribing*
    a. Results: In one study, individual differences in psychiatrists' attitudes to capacity were apparent, with some attempting to maximise involvement despite lack of capacity (including attempts to understand the patient's wishes prior to being unwell), and others regarding its lack as an 'absolute contraindication' to patient involvement. While there may be consensus between stakeholders that a degree of mental well-being and capacity are needed for involvement, precisely where that threshold lies appears to be more subjective and based on individual attitudes. When considering factors outside the consultation, there was evidence that involvement could be blocked by health professionals' attitudes, for example, a blanket view of patients' incapability.
10. Select Committee on the Mental Capacity Act 2005 (2014) - *Mental Capacity Act 2005: post-legislative scrutiny*
    a. The Mental Capacity Act placed the individual at the heart of decision-making. Capacity was to be presumed unless proven otherwise. Decision-making was to be supported to enable the individual as far as possible to take their own

decisions. Our findings suggest that the Act, in the main, continues to be held in high regard. However, its implementation has not met the expectations that it rightly raised. The Act has suffered from a lack of awareness and a lack of understanding. For many who are expected to comply with the Act it appears to be an optional add-on, far from being central to their working lives. The evidence presented to us concerns the health and social care sectors principally.

b. Our evidence suggests that capacity is not always assumed when it should be. Capacity assessments are not often carried out; when they are, the quality is often poor. Supported decision-making, and the adjustments required to enable it, are not well embedded.

c. This finding was supported by the Mental Health Foundation, whose research into best interests' decision-making had concluded that people were being found to lack capacity "for reasons which the Act does not allow, i.e., a blanket assumption based upon diagnosis or an unwise decision".

d. The quality of capacity assessments was also criticised. Serjeants' Inn Chambers told us: "A recurring feature of cases we see is low-quality capacity assessments, requiring the capacity assessment to be carried out afresh". A group of barristers and solicitors who jointly submitted evidence reported their shared experience that health professionals had a "much weaker knowledge and awareness" of the Act, which led to their capacity assessments being "less thorough and less compliant with the MCA and the Code of Practice, including on basic issues such as the need for an assessment of capacity to be decision-specific".

11. El-Alti (2023) – *Shared Decision Making in Psychiatry: Dissolving the Responsibility Problem*

a. SDM requires a reciprocal deliberative interaction to take place between the deciding parties, which seemingly assumes a set of capacities and executive abilities in each party. In a standard non-psychiatric medical setting, where adult patients are presumed to live with no mental illness, the responsibility problem of SDM is not expected to surface, as the patients' mental capacities are not usually under question. This means that the responsibility problem seems to come to light exclusively in contexts where a person's capacities are assumed to be atypical. Hence, the capacity question in the responsibility problem appears to be a rather intuitive concern for SDM practice, arising due to a tense marriage between high SDM demands and questionable patient capacities.

b. However, while this concern *seems* intuitive, it represents a misconstrual of the SDM process in two ways. First, it conflates the three SDM components with demands or requisite criteria for participation, such that if a person is unable

to fulfil (all of) them she risks being disqualified from the process. More importantly, it makes participation in SDM contingent on certain personal characteristics, viz. a person has to possess certain abilities in order to fit the process.

c. Another possible objection could be acute phases of illness during which a person becomes temporarily indisposed, and by virtue of the severity of the symptoms, unable to take part in any form of decision making or even less be ascribed responsibility. For the purpose of not further contributing to the perpetuation of stereotypical representation of mental illness through stressing incapacity rather than variability, worst case scenarios should not be generalized, as most persons, in fact, do not end up on the extreme end of the mental illness continuum which would also make said generalization fallacious.

d. The systematic psychiatric classification and description of mental illnesses and their symptoms also reinforces a stagnant quality to persons living under the label of their diagnoses. Persons with mental illness often face negative attitudes, unfounded stereotypical assumptions, fixed assessment of (in)capacities based on diagnosis, labelling and stigma by psychiatric and non-psychiatric HCPs.

12. Moleman et al (2020): *Shared decision-making and the nuances of clinical work: Concepts, barriers and opportunities for a dynamic model*

    a. Results: Similarly, a resident described how attitudes toward patient involvement in psychiatry could negatively affect SDM.

    "I think these people should get more rest and space so they can muster the courage to say what they want, and [that we don't think] that because they are psychiatric patients, they cannot choose anything."

CMOC 3 (Protection imperative)

Mapping to COM-B model of behaviour categories: Motivation (reflective)

Some clinicians lack confidence in the ability of patients with a serious mental illness to cope with the responsibilities involved in SDM and the potential risk of serious consequences associated with decision-making. Where these beliefs exist among prescribers (context), prescribers are more likely to adopt a clinician-led decision-making (outcome) and promote patient agreement with

prescriber-preferred treatment decisions (outcome). Adoption of clinician-led decision-making is viewed by prescribers as a way of protecting patients from the responsibility of decision-making (mechanism) and the consequences of making a 'bad' or 'wrong' decision (mechanism).

Evidence sources:

1. Brooks et al (2017): *Exploring the potential implementation of a tool to enhance shared decision making (SDM) in mental health services in the United Kingdom: a qualitative exploration of the views of service users, carers and professionals.*
    a. Results: Negative influences on potential implementation
        i. Culture (risk-focussed, paternalism).
2. Verwijmeren et al (2023): *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
    a. Cultural bias: The concept of SDM stems from a Western, liberal, individualistic view of human relations. Note that with a few exceptions the literature on SDM derives from Western countries. In other cultures, a more paternalistic approach to care—or even a culture of obedience to authority—is the norm, as are different traditions in care delivery or attitudes with respect to individual decisions (Huang et al., 2020b, 2021; Lin et al., 2020), which cultural differences become more notable with societies becoming increasingly more multicultural.
3. Haugom et al (2022) - *Mental health professionals' experiences with shared decision-making for patients with psychotic disorders: a qualitative study:*
    a. Results: Some participants said that patients with psychotic disorders must be fully respected. Health professionals must be willing to let these patients make a choice and live with the consequences of that choice, even if they disagree.
4. Moleman et al (2020): *Shared decision-making and the nuances of clinical work: Concepts, barriers and opportunities for a dynamic model*
    a. Perspectives on participation: Staff, who were very vocal in supporting user participation, nonetheless expressed concerns during the role play, that exposing users to various alternatives might lead to unnecessary stress and would therefore instead decide which alternatives were most appropriate "for them."
5. Blood and Wardle (2018) – *Positive risk and shared decision making:*

a. Section 2.3: Professionals views about risk: Morgan (2010b) reminds us that practitioners' own values and prejudices influence decision-making processes, especially around issues of "risk"; these may be built on (or in reaction to) dominant paternalistic views in services and in wider society.
b. Section 3: Barriers to positive risk-taking: This historical and institutional discrimination has led to a lack of trust in individuals to cope with the decision-making process, to make the "right" decisions or to handle the consequences. Focus group participants pointed out:
    i. *"There's a perceived risk of allowing people to work it out themselves."*
    ii. *Stress is part of life. As long as there is support for people to fall back on, then stress can be a learning experience… It's about supporting people to manage risk rather than doing it for them."*
    iii. *"People are allowed to make unwise decisions".*

6. Schon et al (2018) - *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Results: Staff at all six sites also expressed a lack of confidence in the willingness and ability of the users to participate in decision-making processes and this reservation affected their readiness to embrace the intervention. Their confidence in the users' ability to integrate information was low. One participant stated:
        i. "*Sometimes we have to decide ... Sometimes a patient has had the opportunity to make their own decision, but then it has not worked out the way they had hoped, and then you just have to take over some decisions"* (p. 2).
    b. Results: Another participant described the mistrust in the user's ability as "*Like, it's you (the provider) who are supposed to know about these things. You are best at this"*
7. Select Committee on the Mental Capacity Act 2005 (2014) - *Mental Capacity Act 2005: post-legislative scrutiny*
    a. A consistent theme in the evidence was the tension between the empowerment which the Act was designed to deliver, and the tendency of professionals to use the Act for safeguarding purposes. Prevailing professional cultures of risk aversion and paternalism have inhibited the aspiration of empowerment from being realised.
    b. The right to make an unwise decision, enshrined in section 1(4), underpins the empowering ethos of the Act: "A person is not to be treated as unable to make a decision merely because he makes an unwise decision." Across the evidence, the balance between empowerment and protection emerged as the key challenge to the implementation of the empowering

ethos of the Act, and this seems most clear in relation to unwise decision-making. The right to make an unwise decision runs counter to the prevailing cultures in health and social care, which present barriers to implementation.

c. Dr Ruth Allen, representing the College of Social Work, conceded that *"the MCA is not yet fully understood across any profession as an enabling piece of legislation … it is often seen as bolstering the desire to protect and, in some ways, control people's choice making".*

d. The concept of unwise decision-making faces institutional obstruction due to prevailing cultures of risk-aversion and paternalism. Instead, clinical judgments or resource-led decision-making predominate.

e. We were told that in health care "the paternalistic, medical model of care is still dominant". The British Psychological Society agreed that "*there is still a tendency to act in a paternalistic/authoritarian fashion and make decisions based on the staff's perception".* Gloucestershire MCA Governance Group found that a "protection imperative" often existed, especially in hospital settings, while Kent and Medway MCA Local Implementation Network suggested that many clinicians still find it difficult to "let go of their paternalistic ways".

8. Mikesell et al (2015) – *Integrating Client and Clinician Perspectives on Psychotropic Medication Decisions: Developing a Communication-Centered Epistemic Model of Shared Decision Making for Mental Health Contexts*

   a. Results: Clinicians equally voiced concerns about unfiltered information:

      i. *P1: I mean and a kid, going through puberty in high school?*
      ii. *Could you imagine? It's bad enough gaining weight as an adult.*
      iii. *P2: Of course, we're not going to say that to the parents of the children who are taking these medications.*
      iv. *P1: No!*
      v. *P3: No but we're in a focus group right here so it's—*
      vi. *P2: No but what I'm saying is that I would never say that to a parent or a child. "Oh my god you're sixteen, you're going to gain weight! You shouldn't take this medicine!"*
      vii. This exchange highlights clinicians' desire to provide clients with the information they believe will result in the best clinical outcome and vividly contrasts with comments discouraging deception or "game-playing."

9. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*

a. The Practice of Shared Decision Making: Despite their endorsement of the concept of SDM, health care providers also report holding several beliefs that serve as barriers to its implementation:
    i. Consumer reluctance to take decision-making responsibility and consumers' abilities to cope with the stress of decision-making. While SDM continues to grow in use, it remains difficult for clinicians, trained to give advice, to embrace shared decision-making in a way they feel is appropriate and responsible. Many feel that there is a basic conflict between their duties of beneficence and of supporting patient autonomy.

10. Ahmed et al (2021) – *Mental Health Professionals' perceived barriers and enablers to shared decision-making in risk assessment and risk management: a qualitative systematic review:*
    a. Results – beliefs about capabilities: Many were concerned that discussing risk with a service user or involving them in risk management would cause the individual distress or harm: "*Sometimes we avoid involving patients in order to preserve his saneness. In the psychiatric field is difficult to evaluate how much information the patient may tolerate*".
11. Shue et al (2023) – *Exploring Factors Impacting the Implementation of Recovery-Oriented Treatment Planning on Acute Inpatient Mental Health Units*
    a. Results: Prescribers at low-scoring sites generally did not conduct robust clinical interviews with patients and medication decisions were mostly unilateral.
        i. *"The final decision will be mine in directing the patient to choose the right medicine. Sometimes I give them two choices to choose from. For the people who do not have any previous experience with meds, many times we ask the nurses to bring them information about the medicines and give them to them to read and I think all the patients get that, but if the patients have experience with meds together and I choose the medication that works the best for them on behalf of them". (Psychiatrist, site 225)*
12. Forsberg et al (2018) - *Clinician perspectives on supporting adults with psychosis who wish to discontinue neuroleptic medication: qualitative analysis*
    a. Results: "*But it is within a framework of my being aware how I come across, of my broader duties, of how the service has different and conflicting incentives and ways of responding, the patient's autonomy and yet our duty of benevolence and non-maleficence utility and so on as well. So, I have those things in mind to some degree or not, I don't just say stuff randomly" (P10)*

b. Results: Five clinicians spoke of the change in service cultures in relation to neuroleptic discontinuation, with the "old" culture described as enforcing neuroleptics and offering little choice to service-users. Despite recognition of a changing culture towards increased choice, some felt that old traditions continued to dominate.
c. Adapting communication style: Communication styles with service-users appeared heavily influenced by a clinician's judgement of the risk factors and predicted outcome. Where discontinuation was considered acceptable, clinicians facilitated a collaborative discussion. In contrast, if discontinuation was deemed inappropriate, clinicians described increased persuasion and coercion in their communication with service users:
    i. *"If someone has had one previous episode of psychosis and they've taken antipsychotic medication for some time, and they no longer have any symptoms ... and they wish to stop the medication I think that might be a reasonable situation to try a period off antipsychotic medication. Conversely at the other end of things, someone that's often very unwell, who's continuing to have ongoing symptoms ... but has deteriorated when they've stopped their medication in the past, that would be a bit more a case to try and persuade them to continue on medication". (P8)*
d. Results: Clinicians used communication as a means of facilitating service-users' understanding of risks and benefits of discontinuation (indicated by 6/12 clinicians). Eight clinicians stated that where they held an increased perception of risk, they would increase their focus on explicitly stating the risks and using coercive techniques:
    i. *"There's a certain element of coercion as well within the field, it's not threat but it's that sort of 'if you become unwell, if you don't take them now, if you become detained again and end up in hospital you might end up on them anyway, so take them now'. It is slightly ... it is slightly threatening to a patient even though we try to certainly not make it that way" (P10)*
e. Results: Decisions facilitating discontinuation caused anxiety for clinicians, especially for service-users perceived to be at high risk of relapse during discontinuation. Clinicians' subsequent responses were aimed at protecting service-users and the public from harm, but also protecting themselves should their decisions be questioned.

13. Cartwright et al (2024) – *A meta-ethnography of shared decision-making in mental health care from the perspective of staff and service users*
    a. Results:
        i. Changing clinicians' behaviour and attitudes

1. Some clinicians expressed scepticism towards SDM approaches, particularly staff working in inpatient settings. It was found that some staff placed more value on safety, adherence and medication and felt this was conflicted with the values of SDM. Some staff also expressed a lack of trust in service user's abilities to be actively involved in their care and make wise decisions.

b. Discussion: Lastly, the review outlined the importance of considering organisational influences on the implementation of SDM. It is suggested that paternalistic practice and disciplinary forms of power are prevalent within the mental health system, and this presents significant challenges to achieving SDM in practice.

CMOC 4 (Societal attitudes towards people experiencing psychosis)

Mapping to COM-B model of behaviour categories: Motivation (reflective)

A perception exists among some prescribers that the general public expects them to be risk-averse in treatment decisions involving people with psychosis (context). Where this perception exists, these prescribers are less likely to engage in SDM (outcome) as they fear they will be publicly shamed (mechanism) should an adverse event occur resulting from them not adopting the most risk-aversive approach to treatment.

Evidence sources:

1. El-Alti (2023) – *Shared Decision Making in Psychiatry: Dissolving the Responsibility Problem*
    a. There is a ubiquitous image of the person with mental illness as unpredictable, untrustworthy, aggressive, or lacking control as often perceived by the general public and perpetuated by mainstream media, philosophers, or healthcare professionals.
2. Blood and Wardle (2018) – *Positive risk and shared decision making:*
    a. Section 2.3: Professionals views about risk: Morgan (2010b) reminds us that practitioners' own values and prejudices influence decision-making processes, especially around issues of "risk"; these may be built on (or in reaction to) dominant paternalistic views in services and in wider society.

3. Boardman and Roberts (2014) - *Risk, safety and recovery*
    a. Risk and recovery: uncomfortable bed fellows?
        i. Government policy in this area has often been contradictory: sometimes viewing service users as dangerous, whilst also asking for them to be involved in decision making (Langen & Lindow, 2004). Thus, society appears to be ambivalent about risk and habitually operates with double standards, such that liberty, choice and support for independence and autonomy are promoted until something goes wrong. There is then a demand for control, custody, containment and blame. This means that the political imperative to manage risk to the public will invariably trump service users' preferences when the two conflict. Practitioners necessarily work within this conflict, looking both ways, trying to balance both personal and public perspectives, but remaining significantly influenced by a fear of public blame and criticism (Morgan, 2007).
4. Royal College of Psychiatrists (2016) - *Rethinking risk to others in mental health services*
    a. Executive summary: Risk management remains a core role of psychiatrists, but is also a multidisciplinary, and indeed political, matter. Tensions remain, and psychiatrists' duty to protect the public needs to be integrated with their primary duty to assess and treat their patients. Thus 'risk to others' gets to the heart of our profession, and our ability to assess and manage risk is a key part of our professional identity.
    b. Background: Political focus and media commentary on the subject have increased. Society has become, in general, more risk averse. In the media, people with a mental disorder are often portrayed in a negative manner, and typically as dangerous. Turner & Salter (2008) have suggested that risk is overemphasised in psychiatry: 'Risk has become a central feature of modern life; a veritable industry has grown up around its detection, assessment and management. The risk posed by the fraction of people with mental illness who offend has always generated concern (BMJ, 1895), but as care for those with mental illness has moved out of institutions into the gaze of an increasingly risk-obsessed public, the intensity of the reaction that it provokes has grown out of all proportion to the actual risk involved.'
    c. Ethical duty of psychiatrists: Although the first duty of any doctor is towards the patient, it is also socially accepted that doctors have duties to protect and promote the welfare of people other than their immediate patients. In mental health, more frequently than in other specialities, we assess risks and benefits to persons other than the patient themselves, and sometimes prioritise third-party welfare over the patient's immediate interests. Attention to public anxiety and

professional anxiety about the professional's own well-being at work may mean that patients' claims to autonomy and freedom from interference are unjustifiably overridden.

   d. The need to educate the public was frequently stated in the survey responses collected for CR150.
      i. 'Risk cannot be completely eradicated but can be minimised; the government, press and public at large should be made aware of this.''
      ii. [There is a] need to address expectations of those outside mental health who seem to view risk assessment as some sort of precise science that leads to an ability to exactly predict and manage risk.

5. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
   a. SDM research (liability concerns): Mental health care providers are assigned some responsibility for protecting the safety of consumers and the public.
      i. "*We need to educate the public that mental illness is not a crime, and people with mental illness are more likely to be victims than perpetrators of crime.*" — SDM meeting participant
6. Mahone et al (2011) – *Shared Decision Making in Mental Health Treatment: Qualitative Findings from Stakeholder Focus Groups*
   a. Results: The question was asked: What practical barriers do you foresee in implementing shared decision making in mental health? Barriers identified by providers included the long tradition of basing treatment on the "doctor/diagnosis-driven medical, disease-focused model." Other related issues included the obligations of mental health professionals to society, the risks of harm to self or others, legal liabilities related to responsible prescribing and moral obligations.
7. Kaminsky et al (2017) – *Attitudes towards shared decision making in mental health: a qualitative synthesis*
   b. Results: Professionals saw obligations to society, legal liabilities related to responsible prescribing, a lack of system support, disconnect between inpatient and outpatient prescribing practice, and the need for commitment for "every part of the mental health clinic" as possible barriers and challenges to SDM.
8. Simon Wessely (on behalf of UK Government) (2018) – *Modernising the Mental Health Act: Increasing choice and reducing compulsion*

a. Foreword – review chair: In the various conversations that I have had with patients, service users, carers, and professionals of every description, one thing that was never far from the surface was fear. The public are often fearful of mental illness and of the consequences which they have been led to believe flow from it, specifically the danger posed by people living with mental illness. Professionals are fearful that unless they adopt a cautious, risk averse approach to their patients, they will find themselves being publicly shamed for those occasions when those same people cause serious harm to themselves or others.

9. Ahmed et al (2021) – *Mental Health Professionals' perceived barriers and enablers to shared decision-making in risk assessment and risk management: a qualitative systematic review:*
    a. Professionals' responsibility for reducing risk of harm to the individual and others conflicted with their intention to work collaboratively with the service user.
10. Robertson and Collinson (2011) - *Positive risk taking: Whose is it? An exploration in community outreach teams in adult mental health and learning disability services*
    a. Discussion: The public's perceptions of dangers posed by people with mental health problems are heavily influenced by high profile cases, not the everyday risk taking that may go awry. Participants in this study were acutely aware of potential public reactions. They reported trying to support service-users to live more positive lives enhanced by risk taking while anticipating outcomes of actions going wrong, particularly in terms of public backlash on the service-user and the service itself.
11. Forsberg et al (2018) - *Clinician perspectives on supporting adults with psychosis who wish to discontinue neuroleptic medication: qualitative analysis*
    a. Professional obligation to manage risk: Clinicians perceived themselves to have clear obligations to protect service-users and the public from harm, which were viewed as a priority (indicated by 11/12 clinicians). Professional obligations conflicted, at times, with clinicians' desire to work collaboratively and offer choice:
        i. "*You know they [meaning colleagues] have a duty to protect the populous from risk. Sometimes that may not chime with the personal interest of the patient .... but I think it's a key consideration. It's a perfect example of where people's interests diverge, and you shouldn't pretend that they're not going to*". (P10)

b. Fears for discontinuation: Decisions supporting discontinuation triggered a range of anxieties for clinicians, including concerns for the service-user and the public, but also concerns for themselves. A common fear, mentioned by nine clinicians, was the service-user relapsing or experiencing withdrawal symptoms from discontinuation, potentially resulting in clinicians being blamed or formal investigations in the event of a serious negative outcome:

   i. "*You can almost hear someone saying to you 'you allowed this to happen, you were part of it, why did you do that? Why did you let them have that choice?' That kind of thing. So, I can always imagine like a relative saying it, or you know, someone in an SUI [Serious Untoward Incident], an investigation saying, 'Why would you do that?".* (P2)

c. Discussion (comparison with wider literature): Yet previous research also demonstrates that in practice clinicians rarely involve service-users in neuroleptic medication decisions, and service-users describe clinicians as being risk adverse and coercive where neuroleptic discontinuation is concerned (Hamann et al., 2009; Le Geyt et al., 2017). Our findings can explain this discrepancy. Our theory suggest that a clinician's desired collaborative approach often conflicts with other personal and professional influences, such as their professional obligations to manage risk and their fears that discontinuation may lead to a relapse; particularly for those perceived to be at higher risk during discontinuation. This conflict may lead clinicians to act with increased coercion and respond in a way they feel will prevent harm to themselves, the service-user and the public.

12. Verwijmeren et al (2023): *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*

a. Obligations to offer/choose the right treatment: Both clients and health professionals mention (the feeling of) having obligations to society as an obstacle to SDM (Mahone et al., 2011a; Morant et al., 2016; Rogers et al., 1998), with clients specifying that this social control keeps them from being autonomous (Rogers et al., 1998). Psychiatrists may avoid involving patients in decisions out of fear of the negative consequences the choice of the patient may have or because of their legal and moral obligations to make responsible treatment decisions.

5.4.4.5 Programme theory 5 – Insufficient resourcing of mental health services

Insufficient resourcing of mental health services necessitates that staff focus on crisis management and contributes to common short-term, risk-averse service delivery cultures.[245,255,259] A resultant pressure is exerted on clinicians to treat symptoms quickly and discharge patients following sufficient symptom reduction, such that the person is deemed no longer in crisis.[240,245,252,255,259,279,295] Attempting to address the pressure to prescribe antipsychotics in a resource-efficient manner, prescriber adoption of methods to encourage patient concordance with clinician-led decision-making is increased.[251,259,262,264,281] Similarly, service prioritisation on reducing admission length also increases the likelihood of clinician-led decision-making within continued antipsychotic treatment decisions.[100,213] Where reduced decisional capacity initially precluded SDM, service prioritisation of reducing length of stay exerts pressure on prescribers to prioritise reducing risk of relapse over increasing patient autonomy within decision-making.[238,257,290] Thus, prescribers are less likely to initiate discussions about collaboratively reviewing initial treatment decisions.[100,213]

Attempts to increase SDM application by prescribers within settings where workforce behaviours are targeted towards crisis management are unlikely to achieve widespread uptake. Clinicians perceive the application of SDM to be time-consuming and antipsychotic prescribing complex.[213,240,281] SDM engagement by individual prescribers within services focussed on crisis management is viewed as onerous, inefficient use of limited consultation time, and conflicting with a priority to treat symptoms quickly to meet service demands.[240,262,266,290] Table 20 provides an overview of the development of PT 5, including supporting CMOCs and excerpts used from specific data sources in their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 20 - Programme theory 5, associated CMOCs and excerpts used from specific data sources to develop this programme theory.

Programme theory 5 – Insufficient resourcing of mental health services

Where insufficient resourcing within acute care services results in focus on crisis management, prescribers face competing priorities for their time (context). Prescribers are less willing to attempt engagement in SDM during initial antipsychotic treatment decisions (outcome), as they perceive use of their limited time to negotiate treatment options to be inefficient (mechanism) and conflicting with a service priority to start medication quickly (mechanism). Where resourcing is perceived as insufficient (context), prescribers are more likely to engage in strategies to encourage patient compliance with prescriber-led decision-making (outcome), for example, incomplete information sharing, as this is perceived as the quickest way of prescribing antipsychotics in a resource-efficient manner (mechanism). Similarly, service prioritisation on reducing length of inpatient stay (context) can lead prescribers to feel pressure from the service environment to prioritise reducing risk of relapse of psychosis at the cost of increasing patient autonomy within antipsychotic treatment decisions (mechanism). As such, prescribers within these settings are less likely to initiate discussions with patients about collaboratively reviewing initial treatment regimens (outcome).

CMOC 1 (SDM as burdensome and conflicting with priorities of service delivery)

Mapping to COM-B model of behaviour categories: Opportunity (physical)

Where insufficient resourcing within services necessitates focus on crisis management, prescribers face competing priorities for their time (context). Prescribers are less likely to engage with SDM processes within treatment consultations (outcome) as they perceive its application to be burdensome (mechanism) and conflicting with a service priority to start antipsychotic medication quickly (mechanism).

Evidence sources:

1. Brooks et al (2017): *Exploring the potential implementation of a tool to enhance shared decision making (SDM) in mental health services in the United Kingdom: a qualitative exploration of the views of service users, carers and professionals.*
    a. Results: Resource limitations at the macro level are likely to impact on the reports of limited resources at the meso healthcare organisation level, given the top-down structure of mental health services.
    b. Results: Time was considered critical to successfully implement and use the tool within health services and this was something that all stakeholders felt was missing from current healthcare climates due to increased work and caseloads. This also limited access to psychiatrists, alternative treatments and the availability of different types of medication within services. Without the required resources, participants felt there was a pressure to prescribe medication quickly within services, which was a significant barrier to the use of the proposed tool.
        i. *"I know that the Trust would probably want me to slam them on something straight away and let's get on with it".* Professional focus group 1.
    c. Results: The main barrier to the use of the tool described by participants at the meso-level was that of limited human resources within their healthcare organisation, which hindered the time professionals had to spend with service users and carers.
        i. *I've got half an hour per patient in the ward round, but that includes talking to the nursing staff, the junior doctor, the care coordinator, members of the family, any… anybody else and then the patient gets to come in as well at some point in that half an hour.* Professional focus group 1
2. Hamann et al (2016) - *What can patients do to facilitate shared decision making? A qualitative study of patients with depression or schizophrenia and psychiatrists:*
    Results: Time constraints were seen as an important barrier to SDM by both patients and physicians.
3. Martínez-Hernáez et al (2020) - *The collaborative management of antipsychotic medication and its obstacles: A qualitative study*
    a. Discussion: Many of the professionals also felt de-subjectivised by the healthcare burden caused by the scarcity of resources that turns them into mere dispensers of diagnoses and medical treatments.
4. Morant et al (2015) - *Shared decision making for psychiatric medication management: beyond the micro-social*
    a. Implications for research and clinical practice: Overstretched practitioners' concerns about SDM requiring additional time may be allayed by evidence that this is not the case, especially if accompanied by service reconfigurations.

5. Shue et al (2023) – *Exploring Factors Impacting the Implementation of Recovery-Oriented Treatment Planning on Acute Inpatient Mental Health Units*
    a. Results: Several sites (8 of the 13) directly stated their core function was acute stabilization of symptoms, primarily through maintaining safety during acute crisis and medication management.
6. Verwijmeren et al (2023): *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
    a. Time Constraints: As already alluded to above, a frequently mentioned obstacle to SDM is that the method costs too much time, what with health professionals already being under time pressure in their consultations, with the looming risk of unvoiced patient agendas.
7. Wood et al (2019) - *The therapeutic needs of psychiatric in-patients with psychosis: a qualitative exploration of patient and staff perspectives*
    a. Collaboration, meaningful treatment choice and control:
        i. Both patients and staff acknowledged the limitations of the in-patient ward, which restricted the ability for patients to have truly meaningful treatment choice.
            1. *'Sometimes we are too much in a haste, from diagnosis to the interventions, we are too much in a hurry, and on our acute ward, there is not time for analysis, we don't do critical analysis and I'm talking from the doctors to the nurses, we don't*.' (Participant 2)
8. Younas et al (2016) - *Mental health pharmacists views on shared decision-making for antipsychotics in serious mental illness*
    a. Results
        i. Time: Time was a key barrier to SDM. Pharmacists believed that clinicians often did not have the opportunity to speak to service users or time to fully implement techniques of SDM:
        ii. *"It takes a lot longer than just writing a prescription"*
        iii. Such time pressures were increasingly problematic with services experiencing high demand
9. Schon et al (2018) - *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Results: Staff suggested that a challenging aspect would be finding the time to introduce users to the decision support tool (DST) and to support them in using it. In their experience, it was always difficult to prioritize time for implementing

new methods, although once something is put into practice it tends to run smoothly. Their work situation was described as involving having to constantly deal with emergency situations which often become an obstacle for implementation. Even if the notion of encouraging users to write down their experiences and questions beforehand appealed to many of the staff, many felt that finding the time to read these comments would be difficult. One participant described the time challenge in the following manner "*When will I have time to read what the patients have written? It feels like that you don't really have time to sit with this before you see the patient*" Psychiatrist

b. Results: Applying SDM through the DST was perceived as something "over and above" their regular workload and something that required extra time in already stressful situations and in understaffed services. The following quote illustrates the participant's experience: *"There is so much, all of the time. There are a thousand things and constant crisis…We always have patients in acute crisis and that makes it very hard to focus".*
c. Results: Directly after the education, the staff was motivated and committed, but when it came time to implement the intervention in their daily work they fell back into everyday routines since routine work took up all their time. One participant stated *"Directly after the education you feel very inspired. Then you come back to your ordinary routine with loads of things you have to do. . . I think we need regular follow ups. What have you done? How is it going*?" [Psychiatrist]
d. Results: It also became clear from the results that the SDM process was perceived of as time-consuming by staff, a reaction which suggested that the method should be reserved for decisions which are considered priorities for both the organization and the user.
e. Discussion: Even if staff expressed a general commitment and a positive attitude towards the method, disruptive elements such as organizational changes, personnel turnover and a workflow characterized by constant interruptions related to acute demands, led to a gradual loss of focus on the process. As in all implementations of new methods, manager's attitudes and level of commitment is crucial. Managers need to provide sustainable structures, with a clear vision of the new method as constituting a formal part of the ongoing activities.

10. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
    a. Physicians and nurses expressed concerns about:
        i. Time limitations of consultations

11. Cartwright et al (2024) – *A meta-ethnography of shared decision-making in mental health care from the perspective of staff and service user*
    a. Results: Clinicians often reported being in dilemmas with competing demands between duty of care and promoting independence for service users. They felt challenged in trying to ensure that both were being always respected. In some cases, limited time and resources contributed to an inability to reflect on this, despite there being a wish to have this time to reflect. Staff participants reported that funding issues and organisational changes made it difficult to provide person centred care more broadly, which impacted their ability to engage in SDM with service users.
12. Treichler et al (2020) - *How Shared Is Shared Decision Making? Reaching the Full Potential of Patient-Clinician Collaboration in Mental Health*
    a. Implementation barriers to shared decision making at the systemic level: In the current U.S. health system and many others internationally, clinicians and institutions are generally not compensated for high quality of care, which could otherwise foster broad systemic investment in patient engagement in decision making, given its connection with improved treatment engagement, satisfaction, and outcomes. Instead, compensation is often based on the number of patients seen, which facilitates short appointments, clinician burnout, and patient disempowerment.
13. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (DM) in mental health practice*
    a. Results: [anonymised] service user trainer and researcher:
        i. *"In this write up I will reflect on my involvement in implementing SDM within an NHS (National Health Service, UK) mental health trust in the East of England during 2014-2015. Apart from the time constraints and the fact that each team only received one training session there were other challenges. The trust had been through an exceptionally difficult period and had been in "turn around" preceding the implementation phase. Staff were feeling stretched and undervalued as they were having to do more for less.* I imagine this is the reason why some staff were unreceptive and not open to new ways of working. *Another factor was the ongoing organisational change and pathway redesign, which had an unsettling effect. This may explain why we sensed that some of the staff felt we did not understand how hard their jobs were. During the training phase of the study there had been considerable resistance to using the forms, which had been developed to provide a clear framework for staff. The forms also enabled services users to express their preferences and priorities and identify any medication issues,*

which facilitated the decision-making process. This was because it was seen as extra paperwork and because clinicians felt that services users would always prioritise application forms and resist any additional form filling".

b. Reflective narratives on SDM implementation [anonymised] (qualified mental health nurse, advanced clinical lead).
    i. *This section reflects on my involvement in implementing SDM across the Trust. There was a tension between the desire to promote SDM via the use of SDM forms (which prompted service users to identify their preferences and priorities and give feedback on their experiences of medication, and for clinicians to summarise decisions taken jointly) vs a desire to win the "hearts and minds" of staff over to greater SDM without increasing the administrative burden. This tension remains unresolved.*
    ii. In addition, because this was a research project it was not perceived as mainstream or "business as usual", staff were reluctant to persevere with forms which they regarded as onerous. To try and reduce resistance, the forms were shortened and amended during the project to reflect the feedback we had received from the teams. However, despite making these changes the revised forms were not well received. Initial training sessions with clinicians became rather tense and slightly confrontational when additional paperwork was introduced. By the time the revisions were made the tide had already turned and psychiatrists had mostly made up their minds about not wanting to use the forms.

CMOC 2 (clinician led decision-making saving time)

Mapping to COM-B model of behaviour categories: Opportunity (physical)

Where prescribers report facing competing priorities for their time within services where insufficient resources necessitate focus on crisis management (context), prescribers are more likely to use strategies to encourage patient compliance with clinician-led

decision-making (outcome). Prescriber adoption of clinician-led decision-making is viewed as the quickest way of prescribing antipsychotics in a resource-efficient manner (mechanism).

Evidence sources:

1. Hamann et al (2016) - *What can patients do to facilitate shared decision making? A qualitative study of patients with depression or schizophrenia and psychiatrists:*
    a. Results: While patients acknowledge the high workload of physicians and often accept this as a limitation to more extensive discussions, many psychiatrists see a directive style of decision making as a possibility to save time. On the other hand, psychiatrists regret that time constraints hinder them from making more extensive attempts to foster active patient behaviour or more mutual decision making.
    b. Quotes from participants:
        i. *"Time just plays a decisive role". When having five new patients in night shift, I will not engage in discussions but then I am also directive, convincingly playing the role and seeing that as little questions as possible come up, because possibly I just feel certain. When having more time, I can arrange the conversation more freely" – Psychiatrist*
2. Kaminsky et al (2022): *Barriers and Enablers to Shared Decision Making in Psychiatric Medication Management: A Qualitative Investigation of Clinician and Service Users Views.*
    a. Results: Likewise, most psychiatrists, while stressing the importance of disclosing possible adverse effects, often referred to not doing so due to time constraints and limiting the conversation about what side effects might be important to them. Instead, psychiatrists preferred referring service users to other sources of information, such as leaflets. In addition, while psychiatrists did not think they would deliberately withhold information on adverse effects, some acknowledged that at times, limiting the discussion about adverse effects and possible benefits of the medication was used as a way (consciously or unconsciously) to encourage concordance and avoid possible conflict.
        i. Psychiatrist 1: *And I'm probably not great about telling people about possible longer term side effects about things and particularly anti psychotics I suppose. I guess there are slightly peculiar circumstances, so if someone's*

psychotic and has lots of delusions and is fairly wound up in them then a conversation about medication can go a slightly odd way and tend to focus on symptoms that might be otherwise quite secondary.

ii. Psychiatrist 2*: I think I'd usually say the commonest side effects that other people have mentioned to me about medication, but I usually tell them to look it up on the leaflet I provide, or the internet, because there's no way I can go through all the side effects, and I don't know which of the side effects might be important to them.*

3. Forsberg et al (2018) - *Clinician perspectives on supporting adults with psychosis who wish to discontinue neuroleptic medication: qualitative analysis*
    a. Results: The pressures of increased caseloads, administration requirements and service targets were described by four clinicians as barriers to supporting service-users to discontinue medication. Clinicians described attempting to avoid these pressures affecting service-users and their clinical decision making; however, the impact on their own well-being and that of service-users was evident.
4. Verwijmeren et al (2023) - *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
    a. Continuity of care: Shortage of staff can lead to rushed, more paternalistic consultations, and lack of time to rethink decisions at a later stage.

CMOC 3 (Pressure to discharge encouraging prescriber-led decision making in longitudinal antipsychotic treatment decisions)

Mapping to COM-B model of behaviour categories: Opportunity (physical)

Within longitudinal antipsychotic treatment decisions, service prioritisation on reducing length of inpatient admission (context) leads prescribers to feel pressure to prioritise reducing risk of relapse over increasing patient autonomy within treatment decisions (mechanism) and so, prescribers are less likely to initiate discussions about reviewing initial antipsychotic treatment regimens with patients (outcome).

Evidence sources:

1. Shepherd et al (2014) – *Consultant psychiatrists' experiences of and attitudes towards shared decision making in antipsychotic prescribing: a qualitative study*
    a. Results: Barriers to deliberation: Pressure to discharge, other clinical staff.
    b. Results: Pressures were also described as limiting the flexibility for decisions to be reviewed in the future, particularly if there was a need for people to move through hospital quickly and be discharged.
        i. "*The difficulty that we have in psychiatry, and I think in all medicine to be honest, about this sort of bed pressures and things like that, a lot of people get better on a medication that they were started on, and then people are very worried about rocking the boat. So, they might put them on something in the beginning and they might think, oh I'll later change it to another medication, but by that time the patient might be ready for discharge, or you feel oh well they're just better now I don't want to try anything different that's going to make them unwell again, they're back into hospital.*" Psychiatrist
    c. Results: The concept of revisiting treatment decisions was raised by participants and was presented as being particularly problematic when decisions had been taken without the service-users initial involvement. A pressure was then described between the need to meet the expectations of the individual, now with capacity to engage with treatment decisions, while also maintaining on-going treatment. Clinicians acknowledged that this subsequent discussion was a time when the interaction was likely to be at risk of coercion, with pressure being exerted by clinicians to encourage the service-user to remain compliant with a treatment already commenced.
2. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (DM) in mental health practice*
    a. Results: Pressures from the clinical environment and the informal norms within health services impeded the contextual integration of SDM. These pressures included limited flexibility, lack of management support, pressure to discharge and associated financial pressures.
3. Younas et al (2016) - *Mental health pharmacists views on shared decision-making for antipsychotics in serious mental illness*
    a. Results
        i. Time: Such time pressures were increasingly problematic with services experiencing high demand
            1. "There's always a demand for beds, it does have an impact on SDM"
4. Morant et al (2015) - *Shared decision making for psychiatric medication management: beyond the micro-social*

a. The mental health system as the context for SDM: Processes and possibilities of SDM specifically for psychiatric medication may be shaped by other systemic factors including: a short-term and risk-averse service culture that prioritizes relapse avoidance over the potential harm of long-term medication use.
b. Implications for research and clinical practice: Acceptability of SDM initiatives and implementation in clinical practice may be greater if practitioners' preconceptions about SDM are acknowledged. Resistance may stem from fears of relapse if users stop taking medication.

5. Verwijmeren et al (2023): *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
   a. Results: Mental health care delivery is defined by short-term interventions and aversion of risks, in which relapse prevention is deemed more important than the potential side effects of long-term medication use. Owing to this pragmatic and paternalistic organisational culture, having staff adopt new communication models and attend training courses can be challenging.

6. Pedley et al (2018) - *Qualitative systematic review of barriers and facilitators to patient-involved antipsychotic prescribing*
   a. Results: The wider organisational context was seen by health professionals as restricting their flexibility in prescribing. Resource limitations and restrictions imposed by funding bodies (statutory services or insurance companies) were regarded by health professionals as determining the choice of medication, in some cases restricting the opportunity to review decisions altogether. For example, health professionals in one study were unwilling to review medication decisions once a patient was sufficiently well to be discharged from in-patient settings owing to the pressure to free beds.

7. Cooper at al (2019) - *Mental health professionals' views and experiences of antipsychotic reduction and discontinuation*
   a. Results: 3.1 Organisational barriers:
      i. Some participants felt that services did not have enough resources to support the reduction process, making maintenance treatment more likely.
      ii. "*And I might worry slightly about putting extra pressure and demand on the service if we are going to have more people staying around, because they're relapsing.*" P20, Consultant Psychiatrist
   b. Results: Several groups also discussed how resource cuts over recent years in the UK service context mean there is increasing pressure to rapidly discharge people to primary care once they are stable. Relatedly, practitioners discussed how

rapid discharge may also mean that service users are not in contact with secondary mental health services for long enough to optimise medication regimes, or to attempt to find the 'minimum effective dose' of antipsychotics. Frustration was expressed over this issue:

i. *". . .people get put on high levels of medication often they are put on polypharmacy, and then as soon as they are not acute enough to need the home treatment team they are discharged, often straight back to the GP, so there is never the opportunity for stability and there is never the opportunity for de-escalation, and the GPs very reasonably do not reduce medication because they do not want to particularly when it is antipsychotic polypharmacy...I think seven or eight years ago...there was much more ability to continue to see people when they were not acutely unwell and to review things and to talk about reductions and plus/minus discontinuation, and actually to work out what was the minimum effective dose."* P9, Consultant Psychiatrist, Group 2.

5.4.5 Meso- and micro-levels factors influencing prescriber engagement with SDM processes and supportive interventions (Programme theories 6-10)

Programme theories 6-10 outline features of service delivery (PT 6+7) and intervention strategies targeting patient-prescriber interactions within consultations (PT 8-10) that can increase prescriber engagement in behaviours required for effective SDM application. Thus, programme theories 6-10 address the second research question. Relationships between these contexts - including the modifying influences of intervention strategies - their resultant impact on prescriber behaviours, and explanations of causal processes providing the link between context and impact on prescriber behaviours, are contained in Figure 11.

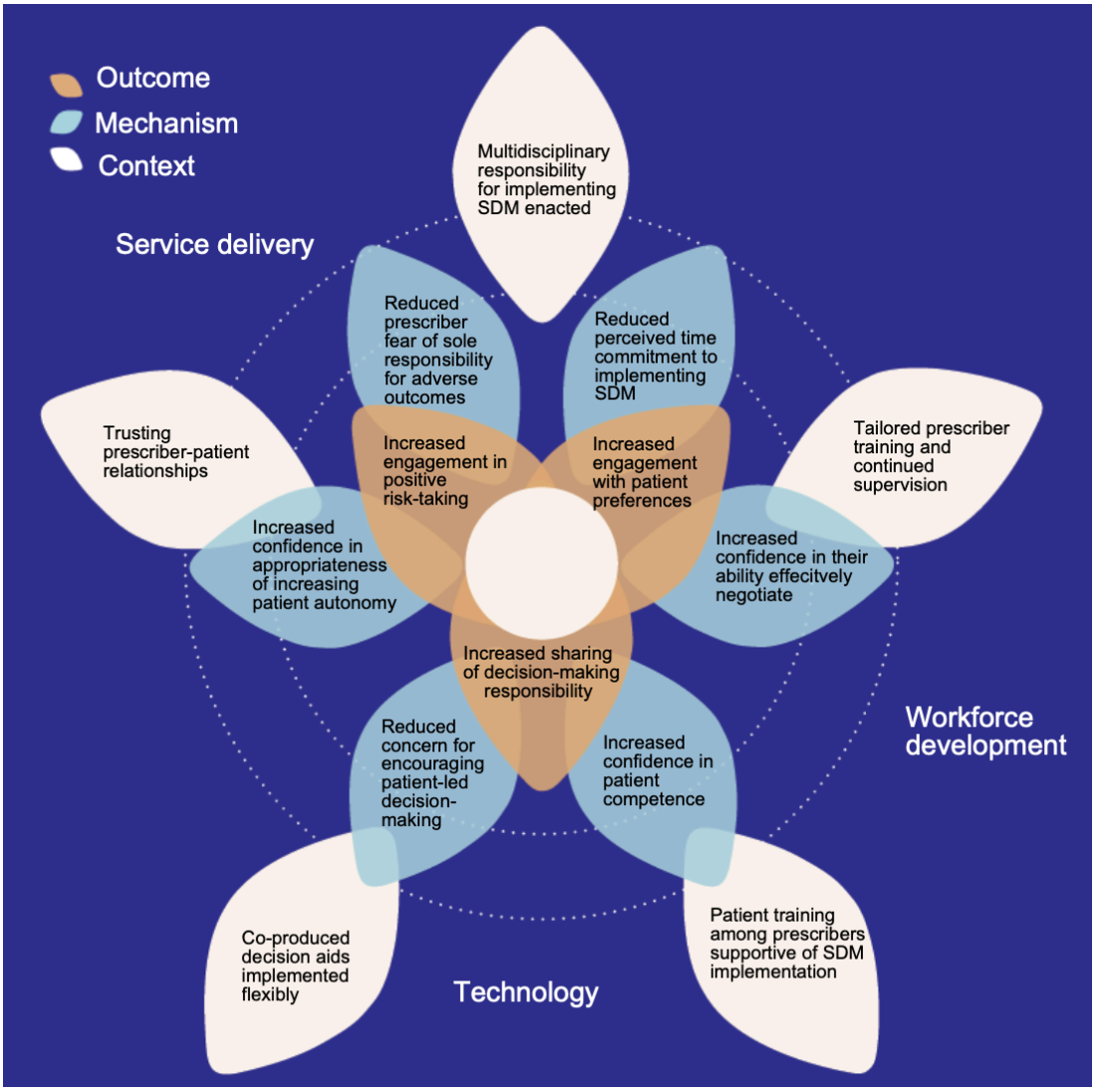


Figure 11 - Programme theories 6-10 outline features of service delivery, workforce development and antipsychotic treatment decision aids that function to increase the

likelihood of prescriber engagement in behaviours required of effective SDM application.

5.4.5.1 Programme theory 6 - Established trust in prescriber-patient relationships

Psychotic illnesses are heterogeneous in their presentation; the impact of psychosis on decision-making capacity will vary in severity across people and in the same person over time.[281] To increase prescriber engagement with SDM within psychosis management, prescribers require flexibility regarding timing of increasing patient autonomy within decision-making.[105,213,286] Affording flexibility to prescribers allows them to account for the individual's unique illness presentation and, in part, addresses the tension they experience between reducing risk of harm and increasing patient autonomy.[99,253,257] Standardised attempts at implementation of SDM interventions are likely to be met with resistance and low levels of prescriber engagement due to perceived restrictions on flexibility.[240,286,290]

Flexibility regarding SDM implementation also affords prescribers the time and opportunity to develop trust in patients. Within psychosis management, there is generally greater clinician concern regarding risk of harm to patients or others.[310] Prescriber trust in patients facilitates their engagement in positive risk-taking by increasing their confidence in the accuracy of their assessments of risk associated with specific decisions among individual patients and thus, their confidence in the appropriateness of increasing patient autonomy within decision-making.[99,227,244,249,251,259,262,284,316] Table 21 provides an overview of the development of programme theory 6, including supporting CMOCs and excerpts used from specific data sources in their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 21 - Programme theory 6, associated CMOCs and excerpts used from specific data sources to develop this programme theory.

Programme theory 6 – Established trust in patient-prescriber relationships

If prescribers have autonomy regarding timing of implementation (context), they are more likely to engage with SDM interventions (outcome), as they perceive their agreement to integrate these interventions into their practice does not place limits on the flexibility they require for deciding when sharing of responsibility for treatment decisions with individual patients is appropriate (mechanism). In longitudinal antipsychotic treatment decisions, for example, changing antipsychotic treatment to align with patient preferences, prescriber trust in patients (context) supports their engagement in positive risk-taking (outcome). Prescribers feel reassured about their ability to accurately predict the likely future actions of patients and their illness trajectory, and so, are more confident in the accuracy of their risk assessments (mechanism). Confidence in the accuracy of prescriber risk assessments (context) supports prescriber engagement in positive risk-taking (outcome) by providing prescribers with reassurance about the appropriateness of giving greater autonomy to patients within treatment decisions (mechanism). Prior prescriber knowledge of patient's illness history (context) can also build prescriber confidence in the appropriateness of increasing patient autonomy within treatment decisions (mechanism), facilitating their engagement in SDM (outcome).

CMOC 1 (Prescriber need for flexibility)

Mapping to COM-B model of behaviour categories: Motivation (reflective)

Where prescribers asked to engage with SDM interventions during antipsychotic treatment consultations are given autonomy about when applying shared responsibility for decisions is appropriate with individual patients (context), they are more likely to engage with interventions (outcome) as they perceive their agreement to engage does not place limits on the flexibility they require for deciding when prioritisation of patient safety over patient autonomy is appropriate (mechanism).

Evidence sources:

1. Perez-Revuelta et al (2023) - Shared decision making with schizophrenic patients: a randomized controlled clinical trial with booster sessions (DECIDE Study)
    a. Intervention strategy: The objective of the present single-centre study, conducted in schizophrenic patients hospitalized following an acute episode, was to determine whether a traditional two staged SDM model - information and deliberation, complemented with a reinforcement stage (with three booster sessions at follow up), and a strict control of SDM timing— sessions administered immediately prior to hospital discharge with regular booster sessions at 3, 6 and 12 months during the follow-up—would be more effective than treatment-as-usual (TAU) in adherence or other health related variables such as clinical status, days of hospitalization, insight, attitude to medication, satisfaction and confidence with the treatment decision and quality of therapeutic alliance. Satisfaction and confidence with the decision was measured by The Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness (COMRADE) was designed to evaluate the results of the shared decision-making process and was administered prior to hospital discharge and at months 3, 6, and 12 after discharge. The interventions were carried out by two different teams (one for SDM and one for TAU), each consisting of two psychiatrists and a nurse. The experimental intervention was a three-stage process, involving two initial stages (see below) and a third stage comprised of decision reinforcement and follow-up. Decision to be shared was the type of antipsychotic medication and the route of administration, including an alternative option in case first choice was considered not to be effective or caused important side effects. The intervention was initiated as soon as the treating physician determined that the patient was ready for discharge, starting from 5 to 7 days prior to discharge.
    b. Results: The experimental intervention had an early, stable, large, and significant positive effect on (COMRADE) patient confidence and satisfaction with the treatment decision (Cohen's D, range: 0.68–0.70).
2. Kaminsky et al (2017) – *Attitudes towards shared decision making in mental health: a qualitative synthesis*
    a. Results: Although most professionals support the model of SDM, they often report that flexibility depending on the clinical situation is important. Professionals highlight the need to tailor the style of decision making to the situation and the individual patient. In addition, in Hamann's randomized controlled trial, doctors recruited the SDM intervention

group patients a week later than patients in the control group, indicating that doctors wanted to treat the most severe symptoms first, before embarking on a trial of SDM.

2. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (DM) in mental health practice*
    a. Results: Pressures from the clinical environment and the informal norms within health services impeded the contextual integration of SDM. These pressures included limited flexibility, lack of management support, pressure to discharge and associated financial pressures.
3. Verwijmeren et al (2023): *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
    a. Results: One of the most prominent characteristics of severe psychiatric syndromes is their impact on decisional capacity, with the (temporary) impairment sometimes obliging clinicians to overrule the patient's wishes. In mental health and particularly in the context of SDM, monitoring cognitive and decisional control, and assessing risks are important aspects of a psychiatrist's tasks, where coercion to prevent self-harm or harm to others can be fundamental. SDM thus also means shared responsibility: not only the decision is shared but also the responsibility that comes with the decision. All members of the triad (patient, next of kin, and health professional) will face moral dilemmas in the decision process, sometimes having to decide which ethical principal should prevail (e.g., autonomy vs non-maleficence if tapering off of medication is being considered). We always need to be aware that every mental health issue has unique aspects that differ for every patient, making moral deliberation imperative in many cases to thus arrive at the best possible decision, be it consensual or coerced.
4. Shepherd et al (2014) – *Consultant psychiatrists' experiences of and attitudes towards shared decision making in antipsychotic prescribing: a qualitative study*
    a. Results:
        i. "*You need, I think, as a consultant psychiatrist to be able to fit into both roles, to be able to be a, sort of, educated supervisor and advisor for a family with an illness that they themselves can manage and you can support them with and then you need to be somebody who can take all the clinical decisions away from somebody when necessary when somebody is very, very acutely unwell.*" *Psychiatrist*

ii. Implications for future research: In summary participants in this study supported the principle of shared decision making in the prescribing of antipsychotics, with the caveat that the clinician would adopt a flexible position able to take more control as the situation required.

5. Schon et al (2018): *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Mechanisms of impact: The staff described the DST as facilitating their ability to work with SDM and as raising their awareness regarding their attitudes when attempting to increasingly involve users in decisions. Despite this positive report, only a minority of staff included in the study had in fact used the decision support tool in practice. They described their usual practice as demanding that they continuously need to adapt and develop options *"based on what the situation requires"* (p. 2)
6. Moleman et al (2020): *Shared decision-making and the nuances of clinical work: Concepts, barriers and opportunities for a dynamic model*
    a. Data collection: SDM may be perceived to require a difficult balance between patient safety and patient autonomy that could leave psychiatrists with little manoeuvring space for SDM.
    b. Discussion: Berg et al note that for every decision patient autonomy needs to be balanced against other ethical principles. This continuous balancing act shows how SDM is a process that may take on different shapes over the course of a treatment trajectory, rather than a one-off interaction. Our findings showed that individual and systemic barriers impose constraints on this ethical balancing act, limiting the manoeuvring space for SDM.
7. Haugom et al (2022) - *Mental health professionals' experiences with shared decision-making for patients with psychotic disorders: a qualitative study:*
    a. Results: According to several participants, as the patient's suspicions decrease and their confidence in the relationship increases, a firmer basis for co-operation on treatment options develops. One participant also stated that SDM is not necessarily possible beginning at the patient's first contact with the therapist: "*You're psychotic, coming on strong with some paranoia. So, you're not capable of making decisions here and now, but later on we can talk about SDM*". Psychiatrist

CMOC 2 (Prescriber trust in and knowledge of patients)

Mapping to COM-B model of behaviour categories (a, b): Motivation (automatic)

a. Prescriber trust in patients to communicate honestly about their illness experience and preferences for treatment (context) can facilitate prescriber engagement in positive risk-taking (outcome) and sharing of responsibility for antipsychotic treatment decisions (outcome). Prescriber trust in patients facilitates them feeling confident in the accuracy of their assessment of risk of patient harm (mechanism) should patient treatment preferences be associated with risk of worsening or return of psychotic symptoms.

b. Agreement to engage in positive risk taking within antipsychotic treatment decisions (outcome) can be also facilitated by prescribers having previous knowledge of patients and their illness history (context) as it facilitates prescribers feeling confident in the appropriateness of giving greater autonomy to individual patients within treatment decisions (mechanism).

Evidence sources:

1. Hamann et al (2016) - *What can patients do to facilitate shared decision making? A qualitative study of patients with depression or schizophrenia and psychiatrists:*
    a. Results*:* Patients and physicians emphasized that a detailed description of the patient's problem is an important first step in making decisions together.
2. Ahmed et al (2021) – *Mental Health Professionals' perceived barriers and enablers to shared decision-making in risk assessment and risk management: a qualitative systematic review:*
    a. Results: Others felt that knowing the service user enabled them to support positive risk-taking:
        i. *"If you're beginning to know a bit more about who they are, you might feel able to take greater therapeutic risks, in the hope of encouraging them to take responsibility".*
    b. Therapeutic trust and alliance were also viewed as critical strategies in engaging service users in risk management.

c. Staff acknowledged that they were more likely to err on the side of caution with risk management with service users that were less well known.

3. Muller et al (2023): *Informing the development of a decision aid: Expectations and wishes from service users and psychiatrists towards a decision aid for antipsychotics in the inpatient setting*
    a. Results: Both sides also mentioned the importance of a good physician-patient relationship as a prerequisite for joint decision-making.
4. Haugom et al (2022) - *Mental health professionals' experiences with shared decision-making for patients with psychotic disorders: a qualitative study:*
    a. Results: The participants describe using time to identify what is important for the patients suggesting that they follow-up decisions over time. The study also shows that health professionals feel it is more difficult to practice SDM as they need considerable time to build trust and a therapeutic alliance.
    b. Results: The participants said that they could spend months or even years learning what is important to some patients because it takes a long time for their patients to feel confident enough to share their wishes with a therapist:
        i. *"It's quite true what's been said here now, the time factor is very important, you spend time building an alliance and trust. And the quality of SDM, or the quality of the choices made, will increase when you trust the person who's suggesting something. So that's why I support this idea that the time factor is absolutely crucial"* Psychiatrist.
    c. Results: Some participants said that a good therapeutic alliance is important for building mutual trust between the patient and professional. Some participants said that dialogue is a useful tool for discovering what is most important to the patient.
    d. Discussion: Some studies show that SDM can be implemented in mental health without increasing the time involved. For example, Deegan showed that despite time constraints, technology and peer support can facilitate SDM. Despite this, decisions in mental health care can be more complex and take longer than in other fields of medicine. Decisions are thus not necessarily made in one consultation, but over several consultations. This underlines the importance of being patient and taking time to build an alliance based on trust, which can lead to a positive dialogue that elicits the patient's values and preferences.

5. Royal College of Psychiatrists (2016) - *Rethinking risk to others in mental health services*
    a. Risk formulation principles: good relationships make assessment easier and more accurate and may reduce risk. Risk may be increased if the doctor–patient relationship is poor.
    b. Communication and information sharing: 'An acknowledgement [is needed] that a risk assessment is only as good as the information available to complete it, and often essential information on risk is not available.
6. Becher et al (2021) - *Barriers and facilitators of shared decision making in acutely ill inpatients with schizophrenia—Qualitative findings from the intervention group of a randomised-controlled trial*
    a. Results: Barriers:
        i. Setting factors, including lack of resources, regulations/laws, unclear responsibilities, pending rotation of the treating clinician.
    b. Results: Facilitators:
        i. Good relationship with the patient, sufficient staff, atmosphere, nature of the decision, other involved parties.
    c. Discussion: Finally, setting-specific barriers (e.g., ward atmosphere or the fact that our interviews were mostly conducted on locked wards) have also been previously described. Within these studies, the facilitating functions of trust, communication and information provision had also been highlighted.
7. Forsberg et al (2018) - *Clinician perspectives on supporting adults with psychosis who wish to discontinue neuroleptic medication: qualitative analysis*
    a. Decision-making process: Consultations with service-users appeared heavily dependent on clinicians' assessment of risk factors and predictions of outcomes from discontinuation. These in turn determined the communication style and response to the service-user.
    b. Assessing risk from discontinuation: Clinicians considered various potential risk factors when determining the appropriateness of discontinuation. No clear process for assessment was evident, but key variables considered included the service-user's reason for discontinuation (mentioned by 8/12 clinicians), clinicians' perception of service-user insight (7/12), risk to self and others (11/12), stability of mental state (6/ 12), available social support (4/12) and relapse history (10/12). These factors affected clinicians' confidence in supporting discontinuation.
8. Just et al (2020) – *Positive risk management: Staff perspectives in acute mental health inpatient settings*

a. Trusting the untrusted: Staff talked about positive risk management being a matter of trust between practitioners and service users. However, they also reported how difficult it can be to trust service users, potentially creating an impossible prerequisite for positive risk management.
b. Discussion: Relationships are paramount: Services have become more concerned with relational security, illustrating the importance of a good therapeutic relationship between staff and service users. The current findings support the need to prioritise relational security and provide further impetus for services to focus on this aspect of risk management.

9. Hamann et al (2010) – Patient participation in antipsychotic drug choices
    a. Results:
        i. The model suggested that doctor–patient relationship (doctors' ratings) (P< 0.001) as well as drug attitudes (patients' ratings) (P = 0.008) significantly predicted actual participation in drug decisions.
    b. Discussion: It has been argued that physicians adapt different decision-making styles to different patients to address patients' needs. Thus, in our sample, psychiatrists might have adapted a more paternalistic approach for those patients showing poor insight, negative drug attitudes (indicating a higher risk for noncompliance) and poor therapeutic alliance. By this strategy, psychiatrists might wish to avoid patients refusing therapy if they were given the choice and decide in a paternalistic manner for their patients what they believe to be best.
10. Blood and Wardle (2018) – *Positive risk and shared decision making:*
    a. Section 4 - Shared decision-making around risk: shared decision-making can only happen where meaningful and trusting relationships have been built. As a result, Mitchell and Glendinning point out: "…supported personal risk-taking takes time, effort and resources".
11. Brooks et al (2017): *Exploring the potential implementation of a tool to enhance shared decision making (SDM) in mental health services in the United Kingdom: a qualitative exploration of the views of service users, carers and professionals.*
    a. Results: The successful implementation of the proposed SDM tool was considered dependent on adequate relationships between service users, carers and professionals that were underpinned by a number of service user and professional characteristics.
    b. Discussion: However, our study indicates that at the point of intervention, micro level factors might be most powerful, given that meso and macro level barriers to implementation may be overcome when a supportive dyadic relationship is

achieved whereby mutually beneficial decisions about medication can be made through the use of the tool, based on honest and open dialogue and mutual trust.

12. Kaminsky et al (2022): *Barriers and Enablers to Shared Decision Making in Psychiatric Medication Management: A Qualitative Investigation of Clinician and Service Users Views.*
    a. Results - The Therapeutic Relationship as an Enabler of SDM: Practitioners and service users alike emphasize the importance of achieving a constructive therapeutic alliance and see this as essential. Establishing trust and communicating honestly is seen as an integral aspect of SDM by all participant groups. When describing memorable positive meetings, psychiatrists referred to establishing rapport and service users feeling able to speak openly and honestly. Some psychiatrists acknowledge that there are potentially differing agendas in conversations concerning medication and that conflict may emerge when medication is deemed as the best course of action. In this context, service users feeling able to express their views honestly is seen as a particular success. Conversely, issues of false compliance, or service users withholding information about medication was often described as particularly concerning (but a common reality) for many psychiatrists and community psychiatric nurses (CPNs):
        i. Psychiatrist 3: *I thought it was really good that she was able to talk frankly about the pros and cons of the medication and she felt she could say she needed this stuff. Yeah, good rapport, trust, a sense that she could say what she really wanted… [Because] I cannot be absolutely sure that people are being absolutely honest with me and would say. "I don't want to take it." I mean some of them are going to say, "I got out of there . . . without losing face" and that's the problem, I don't want people to go away and not take the drug because they can't face me, but they will, some of them."*.
    b. Results - The Changing Role of the Psychiatrist: Psychiatrists often discussed the changing role of the psychiatrist toward that of being an expert advisor and performing a consultative role in the medication management process. Five psychiatrists referred to changing roles in recent years, with family doctors (GPs) providing ongoing continuity of care. This connected to the wider trend that longer term care for people occur in the context of primary care and that psychiatrists often only become involved as experts during crisis periods, or in complex cases.
        i. Psychiatrist 5: "*Compared to the past, where you would see a patient and would continue to see them for a good length of time, you'd build a relationship, and you are overseeing the treatment for a long period of time. From*

there to now it's moving towards the GP being the centre managing the patients and the consultant psychiatrist providing a sort of consultative model... and there are sort of pros and cons with either. But the current model is one of where you don't see the psychiatrist unless it's um, extremely complex, extremely risky".

c. Discussion: When discussing factors associated with the practitioner, the importance of the therapeutic relationship as a key facilitator to achieving SDM also receives differing attention among service users' and practitioners' perspectives. For medical practitioners, while being able to have open and honest dialogue is seen as very important, involvement, as a way of giving service users increased control or ownership over the decision, is more valued.

13. Verwijmeren et al (2023): *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
    a. Results: Discontinuity in the medical and nursing staff is a frequently described barrier to SDM as it negatively influences the doctor–patient relationship and may cause a lack of trust. Such discontinuity also necessarily leads to a loss of information: previous decision-making talks (reflecting the decision process) or (one-sided or joint) decisions may be unknown to the new staff.
14. Robertson and Collinson (2011) - *Positive risk taking: Whose is it? An exploration in community outreach teams in adult mental health and learning disability services*
    a. Discussion: As staff emphasised greater individual and team responsibility for managing risks, perceiving that their organisation could not guide them in specific actions, so the notion of gambling was introduced. This was used as a metaphor for working with significant amounts of unknown information when making judgements as to the wisdom of risk taking by service users and deciding on what actions to take. The anxiety is that all, or much, could be lost if a positive outcome does not ensue and that the service user's well-being could suffer. Staff undertaking good practice seek as much information as possible to inform their practice as suggested by Godin (2004); however, this study demonstrated that they can be acutely aware of the limits to their information searches in some cases and recognise that they are dealing with higher stakes (significance of potential negative outcomes).
15. Cooper at al (2019) - *Mental health professionals' views and experiences of antipsychotic reduction and discontinuation*
    a. Results: Psychiatrists in particular described the difficulty of reducing antipsychotics within a system in which service users frequently move between services at different stages of their illness. This was described as problematic when little or insufficient clinical information about medication decisions was transferred between services. This poor

	continuity of care may mean that psychiatrists may not have full understanding of the reasons behind medication prescriptions, and/or may not have the time or knowledge of their patient to reduce effectively.

5.4.5.2 Programme theory 7 - Multidisciplinary team (MDT) responsibility for facilitating SDM

Adoption of a multidisciplinary responsibility for facilitating SDM within antipsychotic prescribing was identified as one feature of effective SDM interventions.[104,105,245] The perceived time commitment required of SDM is a commonly cited barrier to increased prescriber engagement.[251] Where medical prescribers report inadequate time to discuss, or to become sufficiently knowledgeable about, comparative differences between antipsychotic treatments, particularly differences in risk profiles,[277] prescribers often resist initiating discussions about collaborative antipsychotic prescribing.[271,290] Whilst clinician-led decision-making is perceived as efficient use of limited consultation time,[271] prescribers also resist attempting SDM in these contexts due to lack of confidence in their ability to discharge their duty of care should patient preferences reflect antipsychotic treatments with which prescribers are less familiar.[255,262,271] In such circumstances, other, trusted MDT members completing the evaluative and informational work of SDM with patients can facilitate medical prescriber engagement with patient treatment preferences by reducing prescriber time commitment to SDM and increasing their confidence that patients have been appropriately counselled.[238,245,269,283,324]

In PT 2, perceived prioritisation on harm reduction within leadership and governance structures was identified as increasing prescriber adoption of clinician-led decision-making and reducing their willingness to engage in positive risk-taking. Adoption of a multidisciplinary responsibility for applying SDM within antipsychotic prescribing can facilitate development of psychological safety among medical prescribers.[226,227,263,278,290,313] In the case of implementing initiatives requiring positive risk-taking practices, a perceived collaborative responsibility for decision-making can decrease prescriber fear of sole responsibility for adverse outcomes and subsequent exposure to professional risk. [226,227,278,324] However, certain attributes of teams are required to facilitate mechanisms responsible for increasing prescriber engagement in positive risk-taking. Medical prescriber trust in the professionalism and competence of team members with the expertise to influence

their prescribing practices is necessary for prescribers to feel confident in the appropriateness of their engagement in positive risk-taking. Prescribers need to trust that team members will enact a shared responsibility for treatment decisions and associated sequalae.[255,324,278,313] Cultures of risk aversion among professional groups can damage this prescriber trust prerequisite for their engagement in positive risk-taking.[226,263,284,]

Table 22 provides an overview of the development of PT 7, including supporting CMOCs and excerpts used from specific data sources in their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 22 - Programme theory 7, associated CMOCs and excerpts used from specific data sources to develop this programme theory.

Programme theory 7 – Multidisciplinary responsibility for facilitating SDM

Adoption of a multidisciplinary responsibility for implementation of SDM during antipsychotic treatment consultations can facilitate medical prescriber engagement with SDM practices in certain circumstances. Where medical prescribers report inadequate comparative knowledge of antipsychotic medications, or insufficient time within consultations to discuss these in the detail required to adequately counsel patients (context), these prescribers resist initiating discussions about the availability of different treatment options (outcome) due to lack of confidence in their ability to discharge their duty of care specific to prescribing of medications (mechanism), should patients request prescribing of an antipsychotic with which the prescriber is less familiar.

Other multidisciplinary team members e.g., pharmacists, whom prescribers trust are sufficiently knowledgeable completing the informational and evaluative work of SDM prior to treatment consultations (context) can facilitate prescriber engagement with patient treatment preferences (outcome) by reducing their perceived time commitment to SDM engagement (mechanism) within consultations. These team members completing the work required to facilitate SDM (context) can also support prescribing of antipsychotic medications prescribers are less familiar with, but align with patient preferences (outcome), by increasing prescriber confidence that patients have been appropriately counselled, particularly regarding risks of antipsychotic medications (mechanism).

Specific to risk-averse organisational cultures, care provision to those experiencing psychosis via effective multidisciplinary teams (context), including where decision-making is collaborative, can support prescriber engagement in positive risk-taking (outcome). For example, changing an antipsychotic to align with patient treatment preferences. A perceived team responsibility for decision-making can decrease prescriber fear of sole responsibility for adverse outcomes (mechanism) that may result from them not adopting risk-averse prescribing practices. Prescriber trust in the professionalism and competence of team members who support their engagement in positive risk taking (context) is a prerequisite for prescriber engagement (outcome). Prescriber trust in team members who recommend their engagement in positive risk-taking practices enables prescribers to feel confident in the appropriateness of the recommendation and that they are appropriately discharging their duty of care to the patient (mechanism), and to feel reassured (mechanism) that team members will enact a shared responsibility for decisions and any potential adverse outcomes.

CMOC 1 – Multidisciplinary team members completing the work of SDM

Mapping to COM-B model of behaviour categories (a, b, c) = Opportunity (physical)

a. Where prescribers report having inadequate knowledge of the differences between antipsychotic medications, or insufficient time to discuss these in the detail required to appropriately counsel patients about comparative risks of different treatments (context), prescribers resist initiating discussions with patients about the availability of different antipsychotic treatment options (outcome), due to lack of confidence in their ability to discharge their duty of care specific to prescribing of medications (mechanism) if patient preference is to be prescribed an antipsychotic the prescriber is less familiar with.

b. Where prescribers of antipsychotics report competing priorities for their time within consultations, other multidisciplinary team members with whom prescribers have an established relationship with completing the informational and evaluative work of SDM with patients prior to treatment consultations (context) can facilitate prescriber engagement with patient preferences for treatment (outcome) by reducing prescriber perceived time commitment to their engagement in SDM (mechanism) within consultations.

c. Multidisciplinary team members that prescribers trust are knowledgeable about antipsychotic medications completing the evaluative work of SDM (context) can also support prescribing of antipsychotic medications that prescribers are less familiar with but align with patient preferences (outcome) by increasing prescriber confidence that patients have been appropriately counselled about risks and benefits of antipsychotic medications (mechanism).

Evidence sources:

1. Perez-Revuelta et al (2023) - Shared decision making with schizophrenic patients: a randomized controlled clinical trial with booster sessions (DECIDE Study)
    a. Intervention strategy: The interventions were carried out by two different teams (one for SDM and one for TAU), each consisting of two psychiatrists and a nurse. The SDM team (experimental intervention) was comprised of professionals selected for their greater predisposition to concordance treatment with patients (LatCon II scale). This team received specific training in SDM (theoretical-practical workshops based on a slides presentation and written case vignettes for role plays) according to published recommendations. The nurse on the SDM team was in charge of informing the patients about the procedures, providing help when necessary, exploring values, and clarifying any doubts. Weekly sessions of supervision of to what extent single elements of the intervention were implemented for patients were held with all personnel involved. The experimental intervention was a three-stage process, involving two initial stages (see below) and a third stage comprised of decision reinforcement and follow-up. Decision to be shared was the type of antipsychotic medication and the route of administration, including an alternative option in case first choice was considered not to be effective or caused important side effects. The intervention was initiated as soon as the treating physician determined that the patient was ready for discharge, starting from 5 to 7 days prior to discharge. The first stage consisted of three sessions (total duration = 150 min) carried out from 48 to 72 h before discharge. The treating nurse gave the patient an informational leaflet (adapted to the patient's cultural level) explaining the SDM model and briefly explained its purpose and stages. Then, the International Patient Decision Aid Standards for antipsychotic treatment was used to help the patient express his or her values and preferences using a treatment options worksheet. These patient decision aids included basic information of the treatment options, available antipsychotics, and side effects profiles. The second stage (deliberative) was carried out approximately 24–48 h before discharge and involved a single session in which the patient and treating psychiatrist agreed on an implementation plan after discharge based on the patients previously expressed options and preferences.
    b. Results: The experimental intervention had an early, stable, large, and significant positive effect on (COMRADE) patient confidence and satisfaction with the treatment decision (Cohen's D, range: 0.68–0.70).

2. Schon et al (2018) - *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Organisational commitment and readiness: It also became clear from the results that the SDM process was perceived of as time-consuming by staff, a reaction which suggested that the method should be reserved for decisions which are considered priorities for both the organization and the user.
3. Maples et al (2021) - *Perspectives of Patients and Providers in Using Shared Decision Making in Psychiatry*:
    a. Introduction: From the standpoint of efficiency, when SDM is used in prescriber–patient interactions, visits are perceived by prescribers to take more time than does a standard psychiatry appointment (Burton et al., 2010) and doctors cite this as one factor that limits their use of SDM.
4. Wood et al (2019) - *The therapeutic needs of psychiatric in-patients with psychosis: a qualitative exploration of patient and staff perspectives*
    a. Multidisciplinary facilitators of care: The first superordinate theme identified was the importance of effective MDT working to provide quality and diversity in care. Strong team relationships, where multiple perspectives towards patient care were respected, were described as essential. Participants spoke about the importance of communication and negotiating with one another to implement care. Having strong leadership was integral to a whole team approach.
        i. 1. 'We do apply a multidisciplinary model, but I think that there are enough distinctions within our respective roles to basically come at the same problem from different angles and I think that is the virtue of the team to be honest.' (Participant 12)
    b. Discussion: The staff analysis outlined the importance of having an effective MDT to meet the care priorities of psychiatric in-patients. This was based on team cohesiveness, a biopsychosocial model - although acknowledged that the medical model was dominant - and strong therapeutic relationships with patients.
5. Gurtner et al (2020) – *Conceptual understanding and applicability of shared decision-making in psychiatric care: An integrative review*
    a. Discussion:
        i. The original conceptual development of SDM has also changed in terms of the health professionals involved in the SDM process. While Charles et al. (1997) mainly focused on the physician–patient relationship, an

interprofessional treatment team is increasingly mentioned by other authors. The patient–health professional relationship and the involvement of multiple health professionals during the SDM process have been claimed to positively influence the implementation of SDM in psychiatric practice.

6. Kaminsky et al (2017) – *Attitudes towards shared decision making in mental health: a qualitative synthesis*
    a. Results: The aspect of interprofessional healthcare teams has been included into SDM in mental health recently. Healthcare providers perceive that interprofessional collaboration might facilitate SDM by addressing time barriers and providing more opportunities for consumers to discuss their medical-related concerns.
7. Eliacin et al (2022) - *Implementation and staff understanding of shared decision- making in the context of recovery- oriented care across US Veterans Health Administration (VHA) inpatient mental healthcare units: a mixed- methods evaluation*
    a. Results (patient education and advocacy): The use of clinical pharmacists and peer support specialists (peers) on the unit were useful in providing additional information to patients about their treatment options and to facilitate SDM. Several sites had pharmacists that led medication- education groups and met individually with veterans to provide information and answer questions.
8. Younas et al (2016) - *Mental health pharmacists views on shared decision-making for antipsychotics in serious mental illness*
    a. Results:
        i. Multi-disciplinary team (MDT) working: The level of input that mental health pharmacists have in SDM was dependent on the leadership of the MDT, with some clinical teams more collaborative than others, and resourcing within pharmacy services.
            1. *"Some of the clinical teams I'm in are very collaborative and very collegiate… I've also worked in teams where there's very little conversation apart from between nurses and doctors, me as the pharmacist has to almost fight to say something:*
9. Ali et al (2015) - *Psychiatric Providers' Willingness to Participate in Shared Decision Making When Prescribing Psychotropics*
    a. Results: The most commonly reported perceived barriers were limited patient capacity (86.2%), limited time with patient (62.1%), and limited materials/staff (51.7%).
10. Chong et al (2013): *Shared decision-making and interprofessional collaboration in mental healthcare: a qualitative study exploring perceptions of barriers and facilitators*

a. Results: Time constraint was cited as an important resource barrier for shared decision-making in both primary care and hospital settings. Some healthcare providers perceived that an interprofessional team approach facilitates consumers' involvement in decision-making by addressing time constraints and providing extra opportunities for consumers to engage in discussion with their various healthcare providers on treatment-related concerns.

11. Morant et al (2015) - *Shared decision making for psychiatric medication management: beyond the micro-social*
    a. Involvement of multiple stakeholders: non-medical practitioners can make various contributions to medication decisions, including exploring concerns, preferences, aspirations and perceived benefits and problems of medication; providing support to seek out or understand medication information; helping service users prepare for psychiatric consultations by clarifying what they want to discuss; or accompanying them to consultations.
12. Verwijmeren et al (2023) - *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
    a. Results: Because clinicians are generally pushed for time, and because of often limited access to research bases, they cannot always keep up with (recommendations on) the latest treatment options, while conveying information about the diagnosis and prognoses of different treatments can be complex, where clinicians sometimes resort to discussing less treatment options than actual possible.
13. Leucht et al (2023) - *Shared Decision-Making Assistant (SDMA) and other digital tools for choosing antipsychotics in schizophrenia treatment*
    a. In areas where there is a wide range of available medications with varied efficacy and side-effect profiles such as antipsychotics for schizophrenia, it is particularly difficult to choose the most suitable medication for a patient. It is almost impossible for the clinician to know all the specifics of each antipsychotic. Moreover, considering the individual preferences of patients within this vast amount of information is a formidable challenge.
14. Seale et al (2006): *Sharing decisions in consultations involving anti-psychotic medication: A qualitative study of psychiatrists' experiences:*
    a. Additionally, eight doctors mentioned difficulty in providing comprehensive or precise information about adverse effects, either because they found it hard to know these themselves or because it was impractical to discuss every single one, including those that might be extremely rare, in the time available. That this was a problem was indicated by

the fact that several linked this anxiety to the potential for later complaint or litigation from patients affected by harmful effects they had not been warned about.

b. Results: "*I am generally fearful that I don't give people enough information. And we live in a litigious world, and I don't know any doctor who is not worried about it. It is absolutely impossible to give them every bit of information".*

15. Mendel et al (2009) – *How psychiatrists inform themselves and their patients about risks and benefits of antipsychotic treatment*
    a. Results: (Balance of information search): The psychiatrists searched for significantly more information on the risks (mean = 3.5 items, SD = 1.8) than the benefits (mean = 2.9 items, SD = 2.0) of the two drugs overall (paired t-test: t =)3.4, df = 74, P = 0.001). This means that 45% of the requested information dealt with advantages and 55% with disadvantages (Fig. 2). The difference value benefits-risks, which results from the benefits minus the risks amounts to 0.6 (SD = 1.6). About half of the doctors studied (48%) exhibited a negative difference value (difference value benefits-risks < 0) in their search, i.e., these doctors searched for more risks than benefits. Approximately one third of the doctors (35%) made a balanced information search (difference value benefits-risks = 0), and 17% of the doctors searched for more benefits than risks (difference value benefits-risks > 0).
    b. Discussion: At first sight, the results of study 1 were surprising, since we did not expect an information search biased towards gathering more risks than benefits. From psychological research in related fields (e.g., confirmation bias, dissonance theory) one would rather have expected the bias to be more towards benefits (5, 6). However, there is also evidence that under special conditions (e.g., when the motivation to avoid making wrong decisions is very high) individuals prefer disapproving information. Taking more risks than benefits into account, as was done by the psychiatrists in our study, indicates that they might have followed the principle of primum nonnocere which has influenced physicians work for centuries. Given the potentially severe consequences of poor treatment decisions (e.g., severe side-effects) this principle makes sense, but an information search which is strongly risk dominated could possibly lead to an effective and appropriate treatment being withheld from a patient due to the physician's fear of its side-effects.

16. Brooks et al (2017): *Exploring the potential implementation of a tool to enhance shared decision making (SDM) in mental health services in the United Kingdom: a qualitative exploration of the views of service users, carers and professionals.*

a. Results: Service users, carers and professionals talked about successful use of the tool requiring professionals who displayed certain behavioural practices. These characteristics included taking the time get to know the service user, being compassionate, not focussing on psychosis alone, having adequate knowledge and being able to convey this successfully, as well as having conviction in the decisions that were made.

17. O'Sullivan and Rae (unknown date) – *Shared Decision Making in Psychiatric Medicines Management*
    a. Limited knowledge about medication made some staff reluctant to initiate discussions.
18. Mahone et al (2011) – *Shared Decision Making in Mental Health Treatment: Qualitative Findings from Stakeholder Focus Groups*
    a. Results:
        i. There were concerns expressed about adequate preparation and training of both sides - providers and consumers, prior to implementing shared decision making at the clinic. Consumers expressed the view that sometimes doctors do not have enough information prior to prescribing medications.
19. Shue et al (2023) – *Exploring Factors Impacting the Implementation of Recovery-Oriented Treatment Planning on Acute Inpatient Mental Health Units*
    a. Results: Overall, medication decisions were driven by the prescriber. Often, there was little to no input from other staff members or veterans. At sites with multiple prescribers, it was regularly observed that one prescriber was more engaged than the others and would collect some degree of personal information from the Veteran, such as asking about prior experience with medications:
        i. And one of our psychiatrists is a bit farther along than the other in that aspect. And she is very veteran centered, really helps them, helps empower them to make good decisions for themselves and really wants them involved in that. The other one is a little more old school I would say and struggles a little more with that. (Local recovery coordinator, site 219)
        ii. When prescribers did involve other disciplines, pharmacists and nurses were identified as the most involved.

CMOC 2 - Multidisciplinary responsibility facilitating positive risk-taking by prescribers

Mapping to COM-B model of behaviour categories (a, b): Motivation (reflexive)

a. Within risk averse organisational cultures, care provision to those experiencing psychosis via effective multidisciplinary teams (context), including where decision-making is collaborative, can support prescriber engagement in positive risk-taking (outcome). A perceived team responsibility for decision-making decreases prescriber fear of sole responsibility for adverse outcomes (mechanism) that could result from not them adopting risk averse prescribing practices.

b. Trust between prescribers and team members who support their prescribing practices (context) is an important facilitator of prescriber engagement in positive risk-taking (outcome). This includes trust in their competence and professionalism. Prescriber trust in those who challenge their engagement in risk-averse prescribing behaviours enables prescribers to feel confident in both the appropriateness of the recommendations (mechanism) influencing their prescribing behaviours and reassured that team members will enact a shared responsibility (mechanism) for decisions and any potential consequences.

Evidence sources:

1. Becher et al (2021) - *Barriers and facilitators of shared decision making in acutely ill inpatients with schizophrenia—Qualitative findings from the intervention group of a randomised-controlled trial*
    a. Results: Setting-related factors included sufficient resources in terms of staff, an enjoyable atmosphere in the ward, the presence of other involved parties (nurses, other patients or legal guardians) and the nature of the decision.
2. Gordon and Green (2013) – *Shared Decision Making in the Treatment of Psychosis*
    a. Questioning our assumptions about antipsychotics: Clearly, in the presence of substantial risk factors such as command hallucinations with impulses to self-injury or violence toward others, safety becomes the paramount concern and trumps most other considerations. However, for patients who do not pose such risks, watchful waiting and shared decision making can be used if some of the following elements are in place:
        i. A 24-hour crisis team that can enact a previously designed collaborative crisis plan that anticipates difficulties, with input and buy-in of the patient and his support system
        ii. With these tools and ideas in mind, psychiatrists-especially those who practice as part of an integrated team capable of offering wrap-around services to acutely psychotic patients-may be able to safely engage in a process of shared decision making with patients and families.

3. Boardman and Roberts (2014) - *Risk, safety and recovery*
    a. Professional perspective: Managing risks is a central concern in the day-to-day lives of clinicians. They may fear the consequences of taking risks because of the perceived legal and professional repercussions. They may feel the need to take action if a patient is seen to be making a 'bad decision'; or they may feel a pressure to remain in control. They may also work in organisational settings that give no clear guidance or assurances about risk practices and instead represent the double standards of open society. The response to these fears and uncertainties is often to increase surveillance, coercion and constraint. Staff are thus caught between the proverbial 'rock and a hard place' and simply blaming them for restrictive practices is not helpful. They need to feel safe and supported in making decisions and able to be constructive and creative in responding to risk.
4. Blood and Wardle (2018) – *Positive risk and shared decision making:*
    a. Section 4 - Shared decision-making around risk: Morgan and Williamson (2014) argue that we are more likely to be risk averse in our practice where we are making decisions on our own. In contrast, shared decision-making, which involves the person, their family, community supporters and a multi-agency group of professionals, may be more supportive of positive risk-taking. In this example, we hear how an open, collaborative approach to risk helped change risk averse attitudes and reduced the fear surrounding the legal consequences of something going wrong.
5. O'Sullivan and Rae (unknown date) – *Shared Decision Making in Psychiatric Medicines Management*
    a. Readiness to take a positive risk needs to be shared by all. Some care coordinators feared that initiating an open discussion about medication might set up the expectation in some service users that they could manage without medication; this was a subset of service users who had a history of relapsing whenever they stopped medication (usually against medical advice).
    b. It was agreed that the whole team needed to be signed to up taking positive risks. This was harder to address in the sessions where psychiatrists and care coordinators were trained separately. Where psychiatrists and care coordinators were trained together, these issues were aired more productively.
6. Robertson and Collinson (2011) - *Positive risk taking: Whose is it? An exploration in community outreach teams in adult mental health and learning disability services*
    a. Results:

i. Trusting the organisation to trust (in staff): Participants emphasised the central importance of the multi-disciplinary team for supporting positive risk-taking actions, and, in the absence of organisation directions, developing local guidance.

ii. Valuing good practice: The participants emphasised the importance of preserving their teams' engagement with the service-user as fundamental to effective risk-taking practice. In so doing, they highlighted a network of elements ranging from competence of the team and other agency staff, inter-staff relationships, honesty and trust between staff and service-users, to personal tolerance, durability and humility in relating to the service user. Most participants confirmed that where positive risk taking proved successful then colleagues were more likely to carry out further, similar risk activities in the future. They perceived that the team's approval underpinned such actions, providing a sense of security to that staff member in acting more boldly in support of the service-user's preferences. If such work proved difficult to resolve, then having access to other professional colleagues could make the difference between staff feeling confident enough to proceed with an uncertain decision or not.

b. Discussion: Where participants perceived an absence of clear organisational guidance on positive risk taking, they proposed placing greater emphasis on the importance of effective management of trust as it arose in several different contexts. Trust in colleagues and their support was just as fundamental as trust in the service-user, and the two clearly inter-related through team discussions and multi-disciplinary working. Support from colleagues and collective decision making were cited as vital in relation to actions with more complex trade-offs of anticipated benefits against likely adverse outcomes of errors.

In 'recovery-oriented' services there is a need to differentiate between risks that must be minimised, where personal harm might arise, and risks that people should be entitled to experience. Peter Bates of the National Development Team for Inclusion (NDTi) maintains that an extreme 'risk climate' (too reckless or too risk-averse) in any service has a negative impact. 'People using the service are unable to develop independence or establish a safe and satisfying life in the community. Resources are wasted and people become dependent or are recklessly neglected' (Bates 2010). Thus, the risk climate of a team can either promote opportunity and responsibility or not.

7. Stacey et al (2016) - *A critical analysis of shared decision-making in acute inpatient mental health care*

a. Results: Psychiatrists talked about having most responsibility for decisions. For them, responsibility meant making the decision as opposed to facilitating shared decision-making. This suggests that in this context 'responsibility' may be just another word for power. When it came to the process of shared decision-making, the psychiatrists spoke of their position with an air of resigned paternalism, suggesting that their perceived accountability left them feeling reluctant to share the responsibility of making decisions, which was an unavoidable professional strain:
    i. *'. . .because of the risks involved, the decision then gets escalated upwards to the person who they think is responsible.'* (Psychiatrists– Group 5)
    ii. *I still feel responsible if I hadn't overseen it, but then, you haven't the ability to oversee everything so you have to give them responsibility and the accountability but at the same time, something goes wrong, you still know you're going to get it in the neck at the end of the day, but I think you just have to accept that, and I think it's a matter of trust really. If you can trust the people you work with to do a good job, you know, or a reasonable job, then, I think your kind of halfway there really.'* (Psychiatrists Group 5).
b. Results:
    i. There was a consistent view of the need to guide others and to ensure that decisions were implemented. Members of this group (psychiatrists) spoke of how they attempted to include others but revealed that they were sceptical of other professional's willingness to take responsibility.
c. Discussion: Questioning this further however reveals how the findings of this study indicate how each group involved in decision-making absolved themselves of the capacity to take on the responsibility of making decisions. This functioned to enable participants to maintain a safe place in terms of professional accountability. Whilst they were critical of the hierarchical nature of decision-making processes, this functioned to maintain the current power relationships. Decisions made in mental healthcare can involve the restriction of liberty and enforced treatment. It was evident that most groups would rather distance themselves from decisions that meant personal freedom was revoked to avoid being viewed as at blame. This was revealed when groups, who had identified themselves as on the outside of decision-making, discussed their discomfort and rejection of opportunities to come in. This highlights the ambivalence amongst some when equity and influence are actually offered. These findings resonate with a wider theoretical analysis of shared decision-making models that have been criticised for neglecting to account for the dynamics of

interprofessional collaboration within their approach. This research supports the need for critical dialogue amongst those involved in decision-making processes. This dialogue should enable individuals to be open about these influential factors and pay attention to the implications of hierarchy and accountability. It is suggested that a model of interprofessional clinical supervision would facilitate this process as professionals are supported in a nonthreatening forum to explore their personal and professional motivations impacting their willingness to share power and influence. Very real power hierarchies exist and have powerful effects on actors within the hierarchy. This suggests that the current structures may at best obscure and at worst actively obstruct new ways of working. Until the role and identity of the professional groups are understood in the context of power, a practical implementation of shared decision-making, as advocated in policy and literature, will be illusory.

8. Just et al (2020) – *Positive risk management: Staff perspectives in acute mental health inpatient settings*
    a. The need for support and verification: Staff perceived successful implementation as reliant on a sense of shared responsibility and being able to verify their decisions with senior colleagues. Shared responsibility was closely linked to concerns over accountability. Practitioners felt anxious about risk and felt the need to discuss and consider alternative perspectives with colleagues. Staff were nearly unanimous, with 14 out of 16 participants stating that being supported by their colleagues had been essential to practicing positive risk management. They believed that positive risk management needed to be a team approach.
    b. Lone risk-based decisions felt too challenging and overwhelming, yet with the support of others, that uncertainty had become more manageable.
9. Ahmed et al (2021) – *Mental Health Professionals' perceived barriers and enablers to shared decision-making in risk assessment and risk management: a qualitative systematic review:*
    a. Results: A risk-averse team culture was highlighted as a barrier to positive risk-taking and the sharing of risk information with service users.
10. Kaliniecka and Shawe-Taylor (2008) – *Promoting positive risk management: evaluation of a risk management tool*
    a. Discussion: The participants felt supported, secure and relieved to be sharing responsibility and decision making for the cases and risks they were working with. These findings mirror the strengths identified by the CSIP (2007) in a risk management panel (RMP). The RMP encapsulates the BPMR (DoH 2007) philosophy of the organization's role alongside

the individual clinician ineffective risk management, with the involvement of senior colleagues to advise and support. Previous research demonstrates that such increased support eases feelings of isolation and stress in demanding environments.

b. Conclusions: Responses from mental health clinicians working with high-risk individuals indicate that the RMP is achieving its aims to alleviate anxieties and encourage fresh, reflective case discussion. This has been achieved through the multi-disciplinary risk management practices taking collective responsibility for the risks involved, offering support in order to promote positive risk management.

5.4.5.3 Programme theory 8 - Workforce training in SDM skillsets

Decisions impacting antipsychotic treatment are perceived by most prescribers as critical decisions within psychosis management.[263] Many misconceptions exist among prescribers about the level of autonomy provided to patients reflected within SDM models. It is not uncommon for prescribers to incorrectly conflate SDM with patient-led decision-making.[238,244,286,290,301] Where this conflation exists, initiation of conversations whereby treatment options – including the potential for patient preferences to be no treatment - can be perceived by prescribers as handing over decisional power to patients whose illness reduces insight and where the consequences of a 'wrong' decision could be serious.[96,211] Prescribers subsequently resist attempting SDM due to a fear their engagement within a critical treatment decision equates with the role of their clinical expertise being lost, or given lesser value, than that of patient preferences.[99,211,244,286] Additional misconceptions include prescribers believing their engagement in SDM involves informing patients about treatment options, but that decisional responsibility remains with prescribers. These prescribers subsequently discount the need for additional training in skillsets required of SDM application due to a belief they already sufficiently implement SDM.[240,290,295]

Even where an accurate understanding exists of assumptions inherent within SDM models, fear surrounding evoking conflict, or worsening distress based on a disagreement about need the for antipsychotic medication, also serve as barriers to prescribers attempting SDM within psychosis management.[241,251,260] Tailored training and continued supervision in effective communication and negotiation skills specific to psychosis management can facilitate prescriber engagement in SDM.[104,240,249,260] Development of such skillsets can increase prescriber confidence in their ability to engage in productive treatment discussions among people with psychosis, such that treatment decisions can reflect clinical expertise and patient preferences. Continued supervision after initial training is particularly important for the development of such confidence.[211,226,240,260,270,290] Formal training and ongoing supervision is also facilitative of improved prescriber awareness of their communication styles,

allowing for self-correction of behaviours not reflective of SDM principles.[240,241,268,270,277,320]

Collective training of cohesive multidisciplinary teams in skillsets relevant to SDM application can be uniquely beneficial where workforce implementation of SDM represents a significant technical and cultural change.[104,105,240,290] Team training facilitates necessary capacity building, including development and strengthening of skills and abilities among teams, and increases the perception of a shared sense of accountability in facilitating change. This can subsequently increase opportunities for interprofessional challenging of practices not reflective of SDM values and facilitate collaborative problem-solving of perceived implementation barriers.[286,290] Table 23 provides an overview of the development of programme theory 8, including supporting CMOCs and excerpts used from specific data sources in their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 23 - Programme theory 8, associated CMOCs and excerpts used from specific data sources to develop this programme theory.

Programme theory 8 – Workforce training in SDM skillsets

Among patients with psychosis, many prescribers resist application of SDM within antipsychotic treatment consultations (outcome) due to an incorrect conflation of shared decision-making with patient-led decision-making (context). Where this conflation exists, prescribers fear their engagement in SDM equates with the role of their clinical expertise being lost or given lesser value than patient preferences (mechanism) within what is typically perceived as a critical decision. Some prescribers also believe SDM involves providing information to patients, but that decisional processes remain clinician-led (context). These prescribers subsequently disregard the need for additional training in SDM skillsets (outcome) due to a belief that they already practice SDM (mechanism) by explaining to patients the rationale for their treatment decisions.

Even in the case of correct understanding of processes reflected within SDM models (context), prescribers often fear the creation of conflict (including around the need for antipsychotic medications) or worsening of patient distress should they attempt to engage in collaborative discussions about antipsychotic treatment among people with psychosis (mechanism). These prescribers revert to clinician-led decision-making to increase patient access to timely treatment (outcome). Where prescribers are provided with tailored training and supervision relevant to engaging people experiencing psychosis in SDM i.e., effective communication and negotiation skills (context), prescribers are more likely to attempt SDM with these patients (outcome) and engage with their treatment preferences (outcome). Tailored training and supervision facilitate prescribers to feel more confident in their ability to negotiate antipsychotic treatment consultations effectively (mechanism), such that treatment decisions will consider both clinical expertise and patient preferences. Continued supervision following training (context) can also facilitate improved prescriber awareness of their communication styles within consultations (mechanism), which can facilitate self-challenging of behaviours not reflective of SDM values (outcome).

Where workforce engagement with SDM models represents a significant change in practice, training existing multidisciplinary teams in the theory and skillsets required for the implementation of SDM facilitates capacity-building within teams (context), including development and strengthening of skills and abilities. This can increase team members, including prescriber's, adoption of SDM

practices (outcome), as team members feel a shared sense of accountability in facilitating change (mechanism). This shared sense of accountability can facilitate team members challenging practices that are not reflective of SDM and problem-solving perceived barriers to their engagement in SDM practices.

CMOC 1 – Absence of collective understanding about what SDM constitutes (and what it doesn't)

Mapping to COM-B model of behaviour change categories (a, b): Motivation (reflexive)

a. Due to an incorrect conflation of shared decision-making with patient-led decision making (context), many prescribers resist application of SDM during antipsychotic treatment discussions among patients with psychosis (outcome). Prescribers fear their engagement in SDM equates with the role of their clinical expertise being given lesser value than patient preferences in influencing what they perceive to be a critical decision (mechanism), where the absence of clinical expertise predominating treatment decisions could have serious adverse outcomes.

b. Prescriber misunderstanding about the level of autonomy in decision-making given to patients as part of SDM, including too much, such that decision-making is patient-led, or too-little, such that decision-making is prescriber-led (context) can lead to resistance among prescribers to engage in SDM (outcome) or disregarding of the need for training in SDM skillsets (outcome) based on a belief that SDM is inappropriate within psychosis management (mechanism) or that they already engage patients sufficiently in treatment consultations (mechanism).

Evidence sources:

1. Kaminsky et al (2017) – *Attitudes towards shared decision making in mental health: a qualitative synthesis*
    a. Results: Hereby professionals generally consider psychosocial matters (i.e., work therapy, future housing) to be more suitable for SDM than medical or legal decisions (Hamann et al., 2009).
    b. Results: During a survey among 352 psychiatrists in Germany in 2007, 44 per cent reported practicing paternalistic decision-making style, 5 per cent applied an informed choice model and the majority (51 per cent) were in favour of

SDM (Hamann et al., 2009). However, in other research, practitioners' perception of SDM bordered on the informed choice model (where the service user makes his own choice, based on the options presented).

   c. Results*:* Some authors see the need of modifying the process of SDM in challenging surroundings. Type of decision, economic and organisational limits, the degree of illness and the patient's wishes are possible challenges. One reason might be that in SDM, health care providers are not in control to the degree they were earlier.

2. Haugom et al (2022) - *Mental health professionals' experiences with shared decision-making for patients with psychotic disorders: a qualitative study:*
   a. Results: Another participant emphasized that the therapist cannot let patient involvement go so far that the therapist just gives in:
      i. *But by law, our patients have the right to user participation. Then I'm thinking about what you said, and I said something about it just now, if we were to go whole hog, and now I'm talking about the ones who are here voluntarily, then we'd be giving way too much if we didn't use our own expertise and kind of try to influence [the decision] in one direction or another. If it's too much, it's informal coercion, if it's too little, we're just giving way. You have to find the right balance. (Nurse, outpatient care)*
3. Hamman and Heres (2014) - *Adapting Shared Decision Making for Individuals with Severe Mental Illness*
   a. We believe that the most prominent hurdle is psychiatrists' fear of using shared decision making in critical situations (those in which making wrong decision might lead to poor outcomes) or with certain patients (those who lack insight, have poor health literacy, or have impaired decisional capacity). For example, the decision to start antipsychotic treatment of a psychotic patient who lacks insight may cause psychiatrists to fear that they will worsen the patient's outcome if they do not pressure the patient to take the medication. The psychiatrist may think, "if I leave it up to the patient, he will certainly choose not to initiate treatment. Symptoms would persist or even worsen, and thus I would harm the patient. If I apply pressure and he accept antipsychotics, he may respond to treatment and likely gain insight. Then he will later be thankful that I proceeded in the way that I did". Although most psychiatrists will be familiar with such deliberations and will have achieved some (short-term) success by taking this approach, it has several shortcomings. First, it mistakes the physician's role as a passive one – that is, it confuses shared decision-making with the informed choice model.

4. Verwijmeren et al (2023): *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
    a. Results: The shift in power SDM requires can challenge the authority and autonomy of the clinician, where it is not uncommon that the ultimate decision is still made by the doctor. Both clinician and patient have to develop skills to adapt to their new roles, while also changes at the organisational level may be necessary. Mutual misconceptions about the stakeholders' roles in SDM can lead to "unvoiced agendas" or unrealistic expectations.
5. Treichler et al (2020) - *How Shared Is Shared Decision Making? Reaching the Full Potential of Patient-Clinician Collaboration in Mental Health*
    a. Implementation barriers to shared decision making at the patient/clinician level: Clinicians tend to highly endorse shared decision making, and they commonly report that additional investment in it is unnecessary because they already use it. When asked to define shared decision making and their use of it, they report a list of relevant but incomplete activities such as asking patients if they have questions and providing them information about their medications or their diagnosis. A robust back-and-forth discussion about the decision itself is rare; for example, one study found that only 14% of appointments included interactions indicating patient-provider partnership in decision making. Additionally, treatment plans rarely reflect shared decisions. One study, for example, found that decisions explicitly incorporated the patient's preference only 22% of the time. Therefore, there are fundamental gaps in the communication that is essential for making accurate and shared treatment decisions, and these gaps limit the clinician's ability to identify patient preferences and act upon them.
6. Muller et al (2023): *Informing the development of a decision aid: Expectations and wishes from service users and psychiatrists towards a decision aid for antipsychotics in the inpatient setting*
    a. Results: Various fears were expressed by psychiatrists in the context of a clear drug recommendation, such as the concern that service users might become fixated on the outcome and that they as physicians might be deprived of control over the decision-making process; although the objection was also raised several times that this need not be a concern in the context of shared use.
7. Eliacin et al (2022): *Implementation and staff understanding of shared decision- making in the context of recovery- oriented care across US Veterans Health Administration (VHA) inpatient mental healthcare units: a mixed- methods evaluation*

a. Results: Also, the provider is viewed as having the responsibility to convince the veteran to take medication. This was the most frequently reported description of the medication decision- making process in participants' interviews. Participants also viewed this process as SDM because it involves patients' informed consent (knowledge of their medication and reason for taking it) and/or the option to decline or accept providers' recommended treatments.
    i. *Usually, the team and the resident will discuss it with the patient. They'll propose a medication change or a medication they think will be helpful. So, they'll discuss with the patient to get their consent*. – Psychiatrist
b. Discussion: Second, our findings indicate that there remains confusion about the various elements of SDM, including the role of patients in the treatment team and the meaning of collaborative care in the context of SDM and recovery-oriented care. Additional and ongoing education about SDM principles are needed to improve providers' understanding of SDM.

8. Slade (2017) – *Implementing shared decision making in routine mental health care*
    a. One reason for low implementation is represented by ethical tensions. A widely used biomedical ethical framework identifies four principles: respect for autonomy, justice, beneficence and nonmaleficence. Skilled clinicians attempt to integrate these principles, for example supporting patient participation not just for reasons of autonomy but also justified by beneficence (as well as other influences, such as avoiding legal liability). However, engagement remains challenging. The potential conflict between these principles has been characterized in relation to antipsychotic prescribing for a patient who lacks insight; the psychiatrist may think: "If I leave it up to the patient, he will certainly choose not to initiate treatment. Symptoms would persist or even worsen, and thus I would harm the patient. If I apply pressure and he accept antipsychotics, he may respond to treatment and likely gain insight. Then he will later be thankful that I proceeded in the way I did". This reflects the tension between deontological (duty-based) ethical frameworks emphasized in the training of many professional groups and teleological (rights-based) frameworks emphasized by citizens.
9. Schon et al (2018): *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Implementation issues: The modules making up the 1-day education of SDM were delivered to participating staff. Recorded observations following the seminar suggested that initially, several staff had a different conception of user

participation than that which is outlined in SDM models. Some staff felt that they already practiced SDM, using examples which might be described as either simply offering information to users or as noting users' presence in care planning situations.

b. Discussion: During these introductory seminars, staff agreed with the theories and reasoning related to participation, user influence and the recovery process. Others experienced this aspect of the training as too basic, suggesting that user involvement in decision-making and planning was an already integrated part of their practice. One barrier for implementation was therefore what might be referred to as the "we-already-do-that-syndrome," a somewhat common experience in implementing recovery-oriented interventions. Rather than exploring specific attitudes, assumptions and practice implications, the intervention is dismissed with this reasoning, prior to its implementation.

10. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
    a. Confronting Critical Challenges: The IOM Report:
        i. Hammond, Bandak, and Williams (1999), in studying perceptions of unilateral versus equalitarian role functions for nurses, physicians, and consumers in a psychiatric facility, found concern about retaining authority also contributed to the lack of implementation of collaborative decision-making, even though clinicians supported the general idea.
11. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (DM) in mental health practice*
    a. Results: Confusion between SDM and other concepts of patient centeredness along with the required shift in roles from more traditional, paternalistic ones were also barriers to SDM. The lack of a universal definition of SDM led to assumptions being made on the part of different stakeholders, which did not always reflect the values enshrined in SDM. There was some disagreement in terms of what constituted true SDM with stakeholders seeing a difference between being involved in the decision-making process itself and actively contributing to the final decision.

CMOC 2 (Developing and improving prescriber skillsets)

Mapping to COM-B model of behaviour change categories (a): Capability (psychological)

Mapping to COM-B model of behaviour change categories (b): Motivation (reflective)

a. Prescribers often fear creating conflict (including around need for antipsychotic medications) within conversations involving antipsychotic treatment or worsening the distress of those experiencing psychotic symptoms should they attempt to engage in collaborative discussions about antipsychotic treatment. Where prescribers are provided with training followed by dedicated supervision to develop skillsets (motivational interviewing, effective communication and negotiation) relevant to the implementation of SDM during consultations with patients with psychosis (context), prescribers are more likely to initiate conversations with patients about treatment options (outcome) and attempt to engage with their preferences for treatment (outcome). Where tailored training and supervision is provided specific to patients experiencing psychotic symptoms, prescribers feel more confident in their ability to effectively engage these patients in productive conversations relating to antipsychotic treatment (mechanism), including their ability to effectively negotiate treatment consultations.

b. Ongoing supervision/coaching in SDM (context) can also facilitate greater prescriber awareness of their communication styles within consultations (mechanism) and challenge compliance with prior practices not reflective of SDM values (outcome).

Evidence sources:

1. Hamann et al (2020) - *Implementing shared decision-making on acute psychiatric wards: a cluster-randomised trial with inpatients suffering from schizophrenia (SDM-PLUS).*
    a. Intervention strategy: The SDM-PLUS approach (Hamann and Heres, 2014) was developed by the authors and some parts of it (e.g., patient training) had been evaluated in earlier studies (Hamann et al., 2017b). SDM-PLUS aims to empower health care staff and patients alike with regard to SDM-specific communication techniques. For health care staff, the existing approaches to applying SDM (e.g., Elwyn et al., 2017) were expanded to include patients without insight or with reduced decisional capacity. Thus, SDM-PLUS teaches communication techniques derived from motivational interviewing and negotiation approaches (Hamann and Heres, 2014)

b. The two principal investigators provided interactive workshops on SDM-PLUS techniques to treatment teams (consultants, residents, nurses, psychologists and social workers) working on intervention wards. The two half-day workshops were based on a power point presentation and written case vignettes for role plays and took place in the respective psychiatric hospitals. It was mandatory that all physicians (residents and consultants) of intervention wards and as many members of the nursing team as possible participated in both workshops.
c. Results: The intervention yielded a significant (p = 0.002) effect on the primary outcome with a mean group difference of 16.5 points in the SDM-Q-9 sum score (95% confidence interval 9.0–24.0, T-statistics 4.3, ICC = 0.02), indicating that the intervention group felt more involved in decision-making (regarding antipsychotic medication) than the control group. In the sensitivity analyses, this result remained stable when accounting for baseline differences (β = 17.3, 95% confidence interval 10.8–23.8, T-statistics 5.2, p = 0.0004) and when using multiple imputation methods (β = 13.4, T-statistics 3.7, 95% confidence interval 6.2–20.6, p = 0.007).
d. Implications: These positive results were not continued during follow-up after discharge from the hospital. While improvements during inpatient treatment are positive achievements *per se*, the fact that the effects of the intervention diminished after discharge should be discussed. One major reason might be that health care staff in outpatient treatment (i.e., any psychiatrists practising in the region) was not trained in the SDM-PLUS approach. Further, patient training alone did not show effects on alliance and adherence (Hamann et al., 2017b).

2. Becher et al (2021) - *Barriers and facilitators of shared decision making in acutely ill inpatients with schizophrenia—Qualitative findings from the intervention group of a randomised-controlled trial*
    a. Results: Likewise, the barrier/facilitator of physician behaviour might have been of importance in our data due to the behavioural focus of our intervention on the staff side (i.e., SDM, motivational interviewing, etc). The importance of both patients' and clinicians' behaviour in the decision-making process as seen in our study is well in line with previous research findings, which emphasised that communication is a vital element for SDM in clinician–patient interactions.
3. Maples et al (2021) - *Perspectives of Patients and Providers in Using Shared Decision Making in Psychiatry*:
    a. Results:
        i. *"Learning SDM practices takes time and practice for those who were trained to be more paternalistic."* Provider

4. Cartwright et al (2024) – *A meta-ethnography of shared decision-making in mental health care from the perspective of staff and service users*
    a. Results:
        i. Some staff members in the reviewed studies suggested that the service users they work with are too 'high risk' or 'vulnerable' to be considered appropriate for SDM. In such cases, it was recommended that SDM approaches could be adapted. It was argued that when people are most unwell, they are at the highest risk of feeling disempowered, therefore encouraging a service user to make even basic decisions is a way to provide a sense of control and increase motivation towards recovery. Participants reflected that this requires a high level of skill from the clinician in balancing safety and risk. The included papers make recommendations that mental capacity or 'insight' is not static and requires a dynamic dialogical approach, within which the goal should always be SDM.
        ii. Results: Clinicians also emphasised the importance of mutual understanding to increase collaboration and goal setting.
5. Schon et al (2018): *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Intervention strategy: The 1-day education was offered to all staff in the units and included an introduction to the theory and evidence base for recovery-oriented practice and SDM (knowledge and attitudes to user participation in care meetings) as well as training in the use of the digital decision tool (skills). Following the education, two follow-up seminars were held with all participating staff to provide opportunities to share their experiences of working with and implementing SDM and to raise questions and issues regarding the digital decision tool.
    b. Implementation issues: Staff suggested that time and support needed to be allocated for group meetings, where they could discuss the method in relation to their ongoing practice. The important focus in the skills training in SDM consisted of thoroughly working through each item in the support tool. Direction and supervision from the trainers were therefore needed during the role play. Observations from all six units reinforced that staff were actively involved in the training and contributed to the discussion. The education was appreciated by the participants, with them actively asking questions related to their own work. The training was seen by staff as relevant and understandable and ended

with a discussion on the contextual barriers and facilitators for implementing SDM in the services. However, some staff expressed a need for additional implementation support, including one-on-one guidance and supervision at the unit *"It's about getting the hang of it. And we haven't had this hands-on, concrete on-site support and follow up. There has to be someone who is very engaged and has the overall responsibility, who is here, on-site"* (p. 16).

c. Mechanisms of impact: The staff described the DST as facilitating their ability to work with SDM and as raising their awareness regarding their attitudes when attempting to increasingly involve users in decisions.

d. Discussion: During these introductory seminars, staff agreed with the theories and reasoning related to participation, user influence and the recovery process. Others experienced this aspect of the training as too basic, suggesting that user involvement in decision-making and planning was an already integrated part of their practice. One barrier for implementation was therefore what might be referred to as the "we-already-do-that-syndrome," a somewhat common experience in implementing recovery-oriented interventions. Rather than exploring specific attitudes, assumptions and practice implications, the intervention is dismissed with this reasoning, prior to its implementation.

e. Discussion: In order for staff to grasp the difference between informing users and actually sharing power, it may be therefore that working more extensively in a "hands-on" situation with the DST would be required. In the staff training, decision support tool seemed to function as a concrete application for experiencing and learning participation values. The structure (web-based interactive design) and praxis (learning by doing) came to be seen as key elements of the learning process, and the actual mechanism by which staff could understand and apply the method.

f. The need for facilitation: The need to actively facilitate the implementation process was underestimated and therefore insufficient at all of the participating services. At the same time, staff clearly expressed a need for greater support during the implementation process, with regard to both guidance in the SDM model and support with the concrete use of the DST. The literature clearly reports that facilitators play a key role in supporting staff in understanding what and how they need to change in order to translate evidence into practice.

6. Martínez-Hernáez et al (2020) - *The collaborative management of antipsychotic medication and its obstacles: A qualitative study*

a. Results (The professionals' view): The professionals stated that providing complete information to patients about the adverse effects of medication could lead to a risk of discontinuation. According to one professional, "unconsciously, we

are all afraid that patients will abandon the treatment" (Professionals Focus Group 1). This perceived risk leads to the contradiction between their agreeing to give full clinical information and recognising patients' rights, and not informing, providing only partial information or adopting the logic of faits accomplis.

   b. Results: Assuming a role based on negotiation and dialogue was perceived as an improvement in clinical practice and, at the same time, as an additional personal burden, even among highly motivated professionals who observed that medical and psychotherapeutic treatments might require substantial efforts with no guarantee of clear clinical outcomes. Collaborative communication models were valued positively, even though they entailed more uncertainty and obliged them, as one nurse put it, "to be more fluid" and adaptable to changing situations (Professional Nurse 15).

7. Mahone et al (2011) – *Shared Decision Making in Mental Health Treatment: Qualitative Findings from Stakeholder Focus Groups*
   a. Results:
      i. Providers pointed to a need for ongoing coaching on person-centered, person-first language (emphasizing that they are people first and the disability second), and active listening ("listen to our consumers and hear their preferences"), including "changing expectations, setting the bar higher.
      ii. The need for negotiating and motivational-interviewing skills was mentioned, as well as the need to assess stage-of-readiness prior to engaging a client in shared decision making.
8. Coulter et al (2015) - *European Experience with Shared Decision Making*
   a. Introduction*:* Experience in various demonstration projects in the US: (http://www.informedmedicaldecisions.org/shareddecision-making-in-practice/demonstration-sites/) and Europe: (http://www.health.org.uk/areas-of-work/topics/personcentred-care/) leads us to believe that the following ten factors need to be in place to promote more widespread adoption:
      i. Training for clinical staff in SDM and risk communication skills, plus support and supervision for implementation.
   b. Results: Training and support: The picture in respect of SDM skills training is patchy. Various short courses and workshops have been developed and SDM is beginning to be included in basic communication skills training. However, it is not yet seen as a core component of European medical and nursing education, with the possible exception of Germany where it is now taught and examined in most medical schools.

9. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
    a. Engaging clinicians: One meeting participant pointed out that SDM could be utilized in even the most coercive settings and suggested that special efforts be made to promote SDM at facilities where consumers are involuntarily committed. These consumers, she suggested, are among the most vulnerable and might receive the greatest benefit from SDM. She also noted that staff at State mental hospitals are not often provided with opportunities to engage in new mental health initiatives.
    b. The Practice of Shared Decision Making: Despite their endorsement of the concept of SDM, health care providers also report holding several beliefs that serve as barriers to its implementation.
        i. Their own lack of skills in risk communication.
    c. Future directions and recommendations:
        i. Other Characteristics of Training
            1. Develop nondidactic training models (e.g., in vivo training in which participants put SDM quickly into use and receive continued supervision and feedback about SDM.
10. Kaminsky et al (2022): *Barriers and Enablers to Shared Decision Making in Psychiatric Medication Management: A Qualitative Investigation of Clinician and Service Users Views.*
    a. Results: In addition, while psychiatrists did not think they would deliberately withhold information on adverse effects, some acknowledged that at times, limiting the discussion about adverse effects and possible benefits of the medication was used as a way (consciously or unconsciously) to encourage concordance and avoid possible conflict.
        iii. Psychiatrist 1: *And I'm probably not great about telling people about possible longer term side effects about things and particularly anti psychotics I suppose. I guess there are slightly peculiar circumstances, so if someone's psychotic and has lots of delusions and is fairly wound up in them then a conversation about medication can go a slightly odd way and tend to focus on symptoms that might be otherwise quite secondary.*
11. Pedley et al (2018) - *Qualitative systematic review of barriers and facilitators to patient-involved antipsychotic prescribing*
    a. Results: Stakeholders perceived health professionals' communication as key to the success of collaborative prescribing. Professionals needed to take time in explaining relevant information about medication in non-technical, person-centred

language, and actively elicit preferences around medication. Health professionals recognised that their ability to demonstrate such skills may require additional training, for example, in motivational interviewing.

12. Giacco et al (2018) – *Shared decision-making with involuntary hospital patients: a qualitative study of barriers and facilitators*
    a. Results: Clinicians mentioned that some training in communication techniques aimed at facilitating patient involvement in decision-making and negotiation might help:
        i. *'Yeah, I mean. I think any sort of training in communication and helping with choices and that sort of thing is probably helpful. 'Cause as much as you do in psychiatry, in psychiatry you learn how to ask questions, I don't know if you really learn how to negotiate that much …'* – Clinician D04
    b. Discussion: Difficulties in clinician–patient communication may stand in the way of meaningful and therapeutic conversations. Hence, some attention should be given to equipping clinicians with the necessary communication skills to facilitate patient involvement in decisions. Such skills may involve active listening skills and the ability to elicit preferences and concerns from patients, no matter how distressed or agitated they are.
13. Ramon et al (2017) - *Shared decision-making for psychiatric medication: a mixed-methods evaluation for a UK training programme for service users and clinicians*
    a. Results: Some practitioners felt they had gained confidence to open dialogues about medication with service users, and had become more aware of the importance of helping service users in having a choice:
        i. *I think I am definitely much more open and … I don't feel so scared of having those medication conversations, because obviously there's always that fear, as soon as you start talking about medication, what's going to happen, there's always that fear of what's the next step. And I think having done the project I don't feel that fear, I feel quite comfortable, with service user, about what they would like, what they see would be the best for them and having that open discussion … and being able to come up with a mutual decision.* (Care co-ordinator)
        ii. *Yes. I think it has had impact in different ways; in my meetings with the patients, in my care plan reviews or medication reviews, I have been more focused in sharing more information, proposing different options, granting to the patient the final choice about medication.* (Psychiatrist)
14. Eliacin et al (2022): *Implementation and staff understanding of shared decision- making in the context of recovery- oriented care across US Veterans Health Administration (VHA) inpatient mental healthcare units: a mixed- methods evaluation*

a. Results: Third, although most participants were well informed about SDM, that knowledge did not always translate into practice. This finding further supports the need for increased implementation support. Decision coaching, for instance, has a been shown to be an effective strategy that helps providers build their SDM skills and prepares them to tailor and apply those skills in different situations.

15. Just et al (2020) – *Positive risk management: Staff perspectives in acute mental health inpatient settings*
    a. Discussion: Results indicate that across documents and practitioners, challenges are evident due to the need to balance challenging demand. Little guidance is provided on how practitioners can achieve the balances as this is likely person specific. However, only providing staff with awareness does not result in practical changes. Therefore, staff need experience of managing the complexities, as well as support from their peers, teams and organisations. Furthermore, staff do not routinely receive any formalised positive risk management training and subsequently find it challenging to navigate risk-based decisions. Their own experiences predominantly influence staff decision-making, and they commonly feel uncertain about engaging in positive risk management. Previous research indicates that lack of training to new members of staff to increase their practice knowledge and confidence.

CMOC 3 (Capacity building within teams providing support to prescribers)

Mapping to COM-B model of behaviour categories: Capability (psychological)

Training existing multidisciplinary teams in the theory and skillsets required for the implementation of SDM facilitates capacity building within teams where engagement with SDM models of practice represents a change in practice (context). Capacity building within teams can increase prescriber adoption of SDM practices (outcome), including sharing of responsibility for decisions with patients, as team members feel a shared sense of accountability in facilitating behaviour change (mechanism). This shared sense of accountability can facilitate team members challenging practices not reflective of SDM and problem-solving perceived barriers to their engagement in SDM within treatment consultations.

Evidence sources:

1. Hamann et al (2020) - *Implementing shared decision-making on acute psychiatric wards: a cluster-randomised trial with inpatients suffering from schizophrenia (SDM-PLUS).*
    a. Intervention strategy: The two principal investigators provided interactive workshops on SDM-PLUS techniques to treatment teams (consultants, residents, nurses, psychologists and social workers) working on intervention wards. The two half-day workshops were based on a power point presentation and written case vignettes for role plays and took place in the respective psychiatric hospitals.
    b. Results (Primary outcome) = The intervention yielded a significant (p = 0.002) effect on the primary outcome with a mean group difference of 16.5 points in the SDM-Q-9 sum score (95% confidence interval 9.0–24.0, T-statistics 4.3, ICC = 0.02), indicating that the intervention group felt more involved in decision-making (regarding antipsychotic medication) than the control group. In the sensitivity analyses, this result remained stable when accounting for baseline differences (β = 17.3, 95% confidence interval 10.8–23.8, T-statistics 5.2, p = 0.0004) and when using multiple imputation methods (β 13.4, T-statistics 3.7, 95% confidence interval 6.2–20.6, p = 0.007).
    c. Results (Secondary outcomes): The positive finding regarding the primary outcome (perceived involvement in decision-making) is also mirrored in group differences regarding therapeutic alliance, treatment satisfaction and self-reported adherence (drug attitudes).
2. Perez-Revuelta et al (2023) - Shared decision making with schizophrenic patients: a randomized controlled clinical trial with booster sessions (DECIDE Study)

    a. Intervention strategy: The interventions were carried out by two different teams (one for SDM and one for TAU), each consisting of two psychiatrists and a nurse. The SDM team (experimental intervention) was comprised of professionals selected for their greater predisposition to concordance treatment with patients (LatCon II scale). This team received specific training in SDM (theoretical-practical workshops based on a slides presentation and written case vignettes for role plays) according to published recommendations.
    b. Results: The experimental intervention had an early, stable, large, and significant positive effect on (COMRADE) patient confidence and satisfaction with the treatment decision (Cohen's D, range: 0.68–0.70).

3. Schon et al (2018) - *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Intervention strategy: The 1-day education was offered to all staff in the units and included an introduction to the theory and evidence base for recovery-oriented practice and SDM (knowledge and attitudes to user participation in care meetings) as well as training in the use of the digital decision tool (skills).
4. Gurtner et al (2020) – *Conceptual understanding and applicability of shared decision-making in psychiatric care: An integrative review*
    a. Results: Another reason for the reluctant implementation of SDM in psychiatric care, especially in inpatient settings, is the assumption that patients and the various groups of health professionals involved have fundamentally different ideas or a divergent understanding of the concept of SDM.
5. Schon et al (2018): *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Discussion: Others experienced this aspect of the training as too basic, suggesting that user involvement in decision-making and planning was an already integrated part of their practice. One barrier for implementation was therefore what might be referred to as the "we-already-do-that-syndrome," a somewhat common experience in implementing recovery-oriented interventions. Rather than exploring specific attitudes, assumptions and practice implications, the intervention is dismissed with this reasoning, prior to its implementation.
6. Kaminsky et al (2017) – *Attitudes towards shared decision making in mental health: a qualitative synthesis*
    a. Results: While an interprofessional team approach is seen positively in general, some providers point to confusing and contradictory recommendations between different practitioners (Chong et al., 2013b). Possible problems or gaps within a multi-disciplinary team need to be bridged by creating a common identity as a team.
7. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
    a. Engaging practitioners: Meeting participants spoke to the variety of professionals at work in the health care field and asserted the need that all be involved in SDM. Some suggested that SDM be promoted as the strategy for decision-making in all aspects and among all participants in mental health care, so that everyone would experience

SDM and become fluent in its use and support. Participants spoke to their interest in identifying and engaging the spectrum of mental health care providers—from clergy to social workers and case managers to psychologists and psychiatrists—in learning about and promoting SDM.

8. Verwijmeren et al (2023) - *Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care*
    a. Continuity of care: The implementation of newly trained communication strategies commonly fails because of a fragmented health care delivery and shortness of staff.
9. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (DM) in mental health practice*
    a. Results: Reflective narratives on SDM implementation (qualified mental health nurse, advanced clinical lead).
        a. The value of team training. *Four of the five teams that participated in the project had separate training for care coordinators and psychiatrists, with approximately half of care coordinators attending. The fifth team was trained as a whole team, doctors, care coordinators together, in a whole day session with nearly all team members attending. The follow up sessions with this team felt more constructive, with more discussion around how to implement SDM with particular service users and how to develop team practice. This team's leader challenged colleagues' statements that "we already do SDM" suggesting that they could do it better which led to fruitful discussion. In contrast, in the other four teams, staff appeared less able to challenge each other and discussions focussed on staff concerns about feeling overloaded with work. On reflection, the root of this may have been the difficulties the teams were experiencing at the time around staff turnover and reorganisation. One reason for my devoting time to visiting teams was the hope that training a team together could promote discussions among the team about SDM and enable team members to support each other in developing SDM. This hope partly arose from our experience of team training during the project.*
        b. Training team's vs disciplines - non-medical prescribers (NMPs), and peer workers received training separately as discipline-specific groups. NMPs and peer workers gave written feedback, which was generally positive. Although the positive commitment to SDM was evident during the training sessions with peer workers and NMPs, what has not been evaluated is the impact this had on their practice. The project team was concerned that peer workers may feel isolated in their teams if their team colleagues did not support their commitment to SDM.

b. Results: The work associated with implementing SDM is unlikely to simply be about individual commitment but also about building the relationships between stakeholders to enable SDM to be delivered successfully.

10. Martínez-Hernáez et al (2020) - *The collaborative management of antipsychotic medication and its obstacles: A qualitative study*
    a. Results: They criticised the lack of clinical positions in the public services as one of the structural impediments to dialogic communication in the clinical setting and identified potential solutions, such as coordinated teamwork, support for families and the strengthening of trust in the clinician-patient relationship.
11. O'Sullivan and Rae (unknown date) – *Shared Decision Making in Psychiatric Medicines Management*
    a. Readiness to take a positive risk needs to be shared by all.
    b. It was agreed that the whole team needed to be signed to up taking positive risks. This was harder to address in the sessions where psychiatrists and care coordinators were trained separately. Where psychiatrists and care coordinators were trained together, these issues were aired more productively.
12. Crowe and Deane (2017) - Characteristics of mental health recovery model implementation and managers' and clinicians' risk aversion
    a. Introduction: Boardman and Roberts proposed that training and supervision provide support for clinicians to critically reflect on risk-aversive decision making. An increase in clinical confidence and expertise may influence the role risk aversion plays in clinical decision making.

5.4.5.4 Programme theory 9 – Patient training in SDM skillsets

In the absence of accompanying prescriber training in the application of skillsets required of SDM, and in the context of SDM application typically representing a significant change in practice,[131] patient activation within treatment consultations is more likely to be incorrectly perceived by prescribers as challenging behaviour, confrontational, or as patients being "*difficult*".[127,235,236,240,243] Where prescribers are provided with complementary SDM training, as described in PT 8, patients with demonstrable knowledge and communicative competencies within consultations are more likely to be perceived as competent and committed to greater ownership within decision-making. Greater perceived commitment to decision-making responsibility among patients can provide prescribers with reassurance regarding about the appropriateness of sharing decision-making responsibility with patients.[100,238,249,251,264, 290] Table 24 provides an overview of the development of PT 9, including supporting CMOCs and excerpts used from specific data sources in their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 24 - Programme theory 9, associated CMOCs and excerpts used from specific data sources to develop this programme theory.

Programme theory 9 – Patient training in SDM skillsets

Where patients are prepared for, and active within, consultations (being informed about antipsychotic treatment options, their illness and asking questions) in settings where prescribers have also been trained in SDM skillsets (context), prescribers are more likely to engage with patient treatment preferences (outcome) as they perceive patients to be more competent (mechanism) and committed to greater ownership in decision-making (mechanism). Greater perceived ownership by patients within consultations (context) reassures these prescribers about the appropriateness of sharing responsibility for treatment decisions with patients (mechanism) and increases the likelihood of prescriber engagement in SDM processes (outcome). Where patient training is provided with the goal of facilitating patient activation within consultations, but without accompanying prescriber education and training in SDM skillsets (context) required to facilitate cultural changes supportive of increased patient empowerment, prescribers are less likely to engage with patient treatment preferences (outcome) as within these circumstances, patient activation is more likely to be incorrectly perceived as confrontational (mechanism).

CMOC 1 - Patient preparation for treatment consultations **Mapping to COM-B model of behaviour categories: Motivation (reflective)** Where patients are provided with knowledge and skillsets to enable them to be active within antipsychotic treatment consultations, and in settings where prescribers are also trained in SDM skillsets (context), prescribers are more likely to share responsibility for treatment decisions with patients (outcome) as they feel reassured about both patient competence and the appropriateness of sharing responsibility for decisions (mechanism) with them.
Evidence sources:

1. Hamann et al (2020) - *Implementing shared decision-making on acute psychiatric wards: a cluster-randomised trial with inpatients suffering from schizophrenia (SDM-PLUS).*
    a. *Intervention strategy:* The SDM-PLUS approach (Hamann and Heres, 2014) was developed by the authors and some parts of it (e.g., patient training) had been evaluated in earlier studies (Hamann et al., 2017b). SDM-PLUS aims to empower health care staff and patients alike with regard to SDM-specific communication techniques. For health care staff, the existing approaches to applying SDM were expanded to include patients without insight or with reduced decisional capacity. Thus, SDM-PLUS teaches communication techniques derived from motivational interviewing and negotiation approaches. In addition to these workshops, physicians were continuously supervised and supported by the study centre in the form of weekly meetings with the physicians in charge. In case of staff changes, one-to-one teaching sessions were offered to new staff members.
    b. Results: The intervention yielded a significant ($p = 0.002$) effect on the primary outcome with a mean group difference of 16.5 points in the SDM-Q-9 sum score (95% confidence interval 9.0–24.0, T-statistics 4.3, ICC = 0.02), indicating that the intervention group felt more involved in decision-making (regarding antipsychotic medication) than the control group. In the sensitivity analyses, this result remained stable when accounting for baseline differences ($\beta = 17.3$, 95% confidence interval 10.8–23.8, T-statistics 5.2, $p = 0.0004$) and when using multiple imputation methods ($\beta = 13.4$, T-statistics 3.7, 95% confidence interval 6.2–20.6, $p = 0.007$).
    c. Implications: These positive results were not continued during follow-up after discharge from the hospital. While improvements during inpatient treatment are positive achievements *per se*, the fact that the effects of the intervention diminished after discharge should be discussed. One major reason might be that health care staff in outpatient treatment (i.e., any psychiatrists practising in the region) was not trained in the SDM-PLUS approach. Further, patient training alone did not show effects on alliance and adherence (Hamann et al., 2017b).
2. Kaminsky et al (2017) – *Attitudes towards shared decision making in mental health: a qualitative synthesis*
    a. Results: Patient's characteristics like accepting medication, a high preference for participation, recovering from a first episode of illness, being dissatisfied with previous medication and being well informed were seen as speaking strongly in favour of SDM (Hamann et al., 2009). Information valued as enabling by practitioners could be described as professionally owned knowledge. For example, professionals found that patient's knowledge about their diagnosis and

related treatment options is important to participate in the SDM process and can be enhanced by information provision (e.g., psychoeducation).

3. Matthias et al (2014) - *Consumer and Relationship Factors Associated with Shared Decision Making in Mental Health Consultations*
    a. Results: Correlation between shared decision-making and PAM-MH (Patient Activation Measure, Mental Health), r = 0.03, p =>0.05
    b. Discussion: It is surprising that patient activation was not related to shared decision making. Consumers with higher levels of activation take greater "ownership" of their health care, which should translate to greater involvement in treatment decisions. However, a previous study also found no relationship between patient activation and observer-rated activation in mental health visits.
4. Hamann et al (2016) - *What can patients do to facilitate shared decision making? A qualitative study of patients with depression or schizophrenia and psychiatrists:*
    a. Results - Other behaviours in the consultation were deemed necessary to facilitate SDM by patients and psychiatrists. These include becoming an expert about one's own illness and being competent in the consultation. Being competent means expressing treatment preferences, suggesting treatment options, taking the time necessary to deliberate about treatment decisions, and asking for explanations required to make informed decisions. To take responsibility, to become and be competent, to take time for deliberation about therapeutic decisions, to have and express treatment preferences, to ask questions and to request explanations. Finally, some patients were reported – by psychiatrists - to induce a more participatory behaviour in their psychiatrists than others. This includes verbal and nonverbal patient behaviour, emotional stories or problems of particular interest.
    b. Results: Another important patient activity is becoming informed so that one is prepared for discussions with doctors. Many psychiatrists advocate this behaviour ''*that somebody arrives with a certain knowledge, that you are able to discuss and argue*'' (P6). This information was seen as an essential prerequisite for SDM by psychiatrists. However, many patients and physicians stated that this information is often not known by patients. Further, it was seen as helpful when patients prepare for consultations by either noting any thoughts, questions or requests they have or by organizing support (e.g., a relative who accompanies them.

c. Quotes from psychiatrists:
    i. *The feelings I arouse in patients are also aroused the other way round. What I always do at first contact is to evaluate the basic mental personality. How does he respond to the conversation? Is he rather stubborn or curious- bright? Then I also fancy telling him something - he is interested, it depends on whether he is a patient I can connect with at the same level, that is rather the patient that spontaneously attracts me".*
    ii. *"In private practice there are patients that are well suited to you, that differs between private practice and hospital".*

d. Discussion - In the more general literature on patient-clinician communication, aspects of patient activation tend to be emphasized. This includes active patient behaviours such as providing information, asking questions and preparing for consultations, which are consistent with our categories "informing the doctor and giving feedback" and "engagement and active participation during the consultation". Also, the category "openness and honesty" is close to these communicative.

5. O'Sullivan and Rae (unknown date) – *Shared Decision Making in Psychiatric Medicines Management*
    a. It was apparent that decisions are shared with some service users more readily than others; "*When the prescriber perceives that the service user is intelligent then they are more likely to give more information and there's more likely to be a shared decision"* (CPN)
6. Eliacin et al (2022) - *Implementation and staff understanding of shared decision- making in the context of recovery- oriented care across US Veterans Health Administration (VHA) inpatient mental healthcare units: a mixed- methods evaluation*
    a. Results (respect for veterans' autonomy): In contrast, observational notes for low power sharing sites indicated that veterans with prior admissions on the unit, veterans who were assertive, or able to express their needs during clinical encounters were more likely to be invited to participate in medication decision-making.
7. El-Alti (2023) – *Shared Decision Making in Psychiatry: Dissolving the Responsibility Problem*
    a. Since paternalism has traditionally been the dominant perspective within psychiatry, employing a person-centred care (PCC) framework in psychiatric contexts brings about a complex responsibility problem which has led to some reluctance within psychiatry to fully embrace PCC. This problem consists of a combination of three difficult and distinct challenges relating to patient responsibility: whether persons with mental illness are capable of taking responsibility,

how HCPs can share responsibility with them, and a responsibility/blame dilemma. Hence, what we are looking for is a practical way to ease the HCP's burden of how to share responsibility with patients in SDM.

8. Kaminsky et al (2022): *Barriers and Enablers to Shared Decision Making in Psychiatric Medication Management: A Qualitative Investigation of Clinician and Service Users Views.*
    a. Results: Service users, psychiatrists, and nurses viewed SDM in terms of encouraging service users to have increased say over decisions concerning medication and promoting ownership and self-determination in meetings concerning medication. All three groups strived toward the service user achieving greater self-management skills. Receiving a full explanation of options and gaining detailed information about adverse effects was related to feelings of increased control for service users and referred to specifically by clinicians when describing memorable examples of success.
        i. CPN 4: I *think she gained an understanding about how medication could be useful and, how, you know, it had its place. But she was... but she was taking control appropriately for when she took it. I felt, yeah, she's got it now, and that left me feeling reassured about her coming off it this time.*
    b. Psychiatrists also emphasized the importance of honesty, and, at times, disagreement was considered a success (and highlighted this during descriptions of successful meetings).
9. Mikesell et al (2015) – *Integrating Client and Clinician Perspectives on Psychotropic Medication Decisions: Developing a Communication-Centered Epistemic Model of Shared Decision Making for Mental Health Contexts*
    a. Results: Clinicians highlighted the need for clients to be open and reliable communicators—for clients to "do their part," "speak up," and keep clinicians well-informed. As one clinician remarked
        i. *"[Clients] need to be good communicators, and it's their responsibility to let the doctor know what their symptoms are, and then when they are prescribed medications, how are those medications working for them."* While clinicians most frequently highlighted client responsibility, they also acknowledged their own role in helping clients communicate clearly.
10. Becher et al (2021) - *Barriers and facilitators of shared decision making in acutely ill inpatients with schizophrenia—Qualitative findings from the intervention group of a randomised-controlled trial*
    a. Results: Active communication by the patient was also reported to be an important tool, since it involved the patient actively taking part in the decisional conversations (expressing wishes or fears, asking questions, giving feedback). By

communicating actively, patients were able to partly steer decisions themselves. One patient reported active communication to have been vital for participation, as it forced clinicians to engage more deeply in the decision-making process. Good preparation was largely achieved through the participation in patient groups in the context of the intervention but also through self-study, psychoeducation in group sessions and also individually by the clinicians.

b. Discussion: Additionally, qualitative studies that included mental health care providers have repeatedly highlighted consumers' lack of participation and communication problems as barriers to SDM. However, several other facilitators were identified in our data set. Among these were hints on the importance of patient behaviour during consultations as a barrier and moreover as a facilitator for SDM. This issue has been rather neglected in the existing literature. It might be especially pronounced in our study, as active patient behaviour was one major goal of the SDM-PLUS intervention.

c. Discussion: Within these studies, the facilitating functions of trust, communication and information provision had also been highlighted.

11. Schon et al (2018) - *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Results:
        i. They described “silent users”, who they considered as unable to express what they want or to take an active part in the decision-making process “*Some patients really do not want to make decisions but want someone else to do it for them”*
        ii. “*Before doctor’s appointments people are nervous, so it’s good to prepare yourself. Like, ‘what do you want to discuss?’ What is important to you?” What issues do you want to raise? Otherwise, it becomes a one-way communication, which it most often is. The person is really afraid and doesn’t dare to say anything. And that might be perceived as unwillingness to be involved.* [Consultant Psychiatrist].
12. Pedley et al (2018) - *Qualitative systematic review of barriers and facilitators to patient-involved antipsychotic prescribing*
    a. Results: Although most findings focused on the health professionals’ role in facilitating patient involvement, there was some recognition of the patient’s part in instigating change, by speaking out against decisions made without their involvement and by communicating side-effects to their prescriber. Health professionals validated these facilitators, emphasising the need for patients to ‘speak up’ and be ‘reliable communicators.

CMOC 2 - Active patients perceived as difficult without prescriber training

Mapping to COM-B model of behaviour categories: Motivation (reflective)

In settings where patients are trained in skillsets with the intention of facilitating activation within consultations without additional training among prescribers (context), prescribers are less likely to engage with patient preferences for treatment (outcome) as patient activation is more likely to be incorrectly perceived by prescribers as confrontational (mechanism).

Evidence sources:

1. Hamann et al (2017) – *Training patients with schizophrenia to share decisions with their psychiatrists: a randomised controlled-trial.*
    a. Intervention strategy: The intervention was a 5-session training (60 minute/session) addressing patient competencies for SDM. Group sessions took place twice a week and addressed the following topics:
        i. Patient rights
        ii. Prospects of SDM (better health)
        iii. Communication skills (asking questions, information provision, being assertive)
        iv. Preparing for ward rounds and consultations.
    b. Results:
        i. Patient rating of participant preferences at Time 1 (Autonomy Preference Index, API), Intervention = 11.6 (3.3) versus control 10.3 (3.8), T = 2.50, p = 0.013
        ii. Patient rating of responsibility for decision-making at Time 1, Intervention = 39.5 (6.2) versus control, 37.5 (6.5), T = 2.21, p = 0.029
        iii. Physician rating of who makes important decisions about the patient's medical treatment at Time 1, Intervention = 3.5 (0.6) versus control = 3.4 (0.6), T = 1.30, p = 0.20
    c. Interpretation:

i. The effects of only five sessions might have therefore dissolved over time. In addition, we did not implement an intervention addressing patients and professionals, which might have been a way to have yielded more powerful effects.
ii. Our intervention obviously affected patients' attitudes and behavior very specifically as neither patient satisfaction nor any other outcome (e.g., trust, drug attitudes) were touched. This is a very different pattern compared to other SDM-interventions (e.g., decision aids) that often positively influence drug attitudes or consumer satisfaction. One might speculate whether decision aids yielded these results because they increase professionals' devotion to patients which then results in better satisfaction. An intervention like ours, addressing only patients and not professionals seem to have only very limited effect on overall treatment parameters like adherence and treatment satisfaction.

2. Vitger et al (2022) - A Smartphone App to Promote Patient Activation and Support Shared Decision-making in People with a Diagnosis of Schizophrenia in Outpatient Treatment Settings (Momentum Trial): Randomized Controlled Assessor-Blinded Trial.
    a. Intervention strategy: This study aimed to provide new evidence on the effectiveness of a digital SDM intervention in mental health care and strengthen the evidence on how digital tools may promote patient activation. We evaluated the effectiveness of a digital solution to support SDM in an outpatient setting for people diagnosed with schizophrenia. We hypothesized that the intervention would support SDM, resulting in higher levels of self-perceived patient activation. Our primary outcome was the difference in self-perceived patient activation between the groups at the postintervention time point, as measured by the 10-item Consumer Health Activation Index for mental health (CHAI-MH).
    b. Results:
        i. Primary outcome: CHAI-MH: Mean difference = 4.39 (95% CI = 0.99-7.79, p = 0.01), Cohen's d = 0.33, favouring the intervention group
        ii. Secondary outcomes of relevance:
            1. Patient rated measure of feeling prepared to make a treatment decision by the 10-item Preparation for Decision-Making (PrepDM). PrepDM: Mean difference = 5.12 (95% CI 0.16-10.08, p = 0.04), Cohen's d = 0.27, favouring the intervention group

2. WAI-S-patient version: Mean difference = 2.43 (95% CI −0.25 to 5.12, p =0.08) Cohen d=0.22
3. Change in treatment alliance measured with the Working Alliance Inventory - short version (WAI-S) - patient version, WAI-S-patient version: Mean difference = 2.43 (95% CI −0.25 to 5.12, p =0.08) Cohen d=0.22
4. Change in treatment alliance measured with the Working Alliance Inventory - short version (WAI-S). Clinician version, WAI-S-clinician version: Mean difference = −0.81 (95% CI −2.5 - 0.87, p = 0.34), Cohen's d = -0.09
5. Patient engagement measured by the Service Engagement Scale (SES): Mean difference = =−0.10, (95% CI −0.48 to 0.28, p = 0.60), Cohen *d*=−0.06.

c. Discussion: Despite the difference in self-perceived patient activation, we found no difference in how providers perceived their patients' level of engagement via the SES. It may be intuitive to assume that increased levels of patient activation are associated with an increase in providers' perceptions of patients' level of engagement. However, studies have found that some providers find it challenging when patients become more active and ask questions that the provider might not always have an answer. This highlights that while promoting patient activation may be beneficial for the patient, it may also be important to consider how the provider responds to a suddenly more active and engaged patient and whether the provider needs support in adapting to this change. Another potential explanation for why providers seemingly did not report a difference in the group level of activation could be that the mean difference between the groups' CHAI-MH scores was too small for the providers to distinguish.

3. Hamann et al (2011) – "How to speak to your psychiatrist": Shared Decision-Making Training for Inpatients with Schizophrenia
   a. Intervention strategy: Many patients do not feel competent to participate in decision making, we developed an intervention that focuses on patients' communicative competencies. In somatic medicine similar programs have been shown to be effective in engaging patients in medical decisions and improving long-term compliance.
   b. Outcomes: After the intervention, psychiatrists provided ratings of their patients' decisional capacity (10-point rating scale) and the therapeutic alliance, and they filled out the Difficult Doctor-Patient Relationship Questionnaire.
   c. Results:

i. Decisional capacity: Intervention group = 62.7 (11.1) versus control group = 66.9 (13.2), t test for difference in means p=0.18, possible scores range from 16 to 96, with higher scores indicating better decisional capacity.
ii. Therapeutic Alliance: Intervention group = 23.8 (4.7) versus control group = 24.1 (4.8), t test for difference in means p = 0.83, possible scores range from 6 to 36, with higher scores indicating a better relationship.
iii. Difficult doctor-patient relationship questionnaire: Intervention group = 40.4 (7.6) versus control group = 44.6 (8.4), t test for difference in means, p =0.05.

d. Results: Psychiatrists perceived intervention group patients as more difficult than control group patients. Physicians did not rate intervention and control group patients differently with respect to their decisional capacity or therapeutic alliance.

e. Discussion: In addition, there was a trend for intervention patients to feel more involved in the decision-making process and to be more persistent about taking medication (self-rating) at follow-up. The latter finding, however, was not replicated by physicians' ratings. Alongside these encouraging findings, we also found a drop in patients' trust in physicians and more scepticism toward psychiatric treatment. On the one hand one could argue that the training brought unnecessary discord into the doctor-patient relationship by making patients sceptical and less cooperative. This fits the traditional model of compliance, in which patients are expected to follow their physician's advice without disagreeing. Accordingly, our intervention may have worsened some mediators of patients' compliance. Apparently, some psychiatrists might have felt this way and rated intervention patients as more difficult. Simultaneous shared decision-making training for physicians (including skills to deal with assertive patients) might have quelled some of the irritations shown in our study. Thus, our results might be interpreted as patients who no longer follow their doctors blindly but ask for explanations or challenge doctors' recommendations when they go against the patient's preferences. Therefore, our intervention might have boosted patients' behaviour in the direction of adherence, even if some psychiatrists were unhappy with the results.

5.4.5.5 Programme theory 10 – Antipsychotic treatment decision aids

Passive integration of antipsychotic treatment decision aids into consultations was not identified as a facilitator of systematic prescriber engagement in SDM based on current evidence.[127,234] Instead, mechanisms responsible for decreasing prescriber engagement, triggered by factors within the design and implementation of current decision aids, were identified. In the case of tools designed to produce recommendations for treatment, rather than a list of prompt questions to inform consultations, prescribers are more likely to engage with treatment recommendations where they consist of a potential range of antipsychotic treatment options for further collaborative discussion.[244] Where decision aids are used to inform discussions, rather than provide definitive treatment recommendations, prescribers are reassured that their integration into consultations is less likely to result in patient-led decision-making.[213,240,244,262,261,323]

For some prescribers, reassurance about the reliability of empirical research informing the output of decision aids is important to secure their engagement, particularly where patient preferences are different to that of clinicians' prescribing patterns. Prescribers are generally more concerned about patients being adequately informed about risks than benefits of antipsychotic treatment, driven by fear of exposure to professional risk in the absence of patients not being adequately counselled.[255,277] Thus, prescriber trust in the quality of tools intended to inform their prescribing needs to be established, rather than assumed.[244,262,267] In the context of competing priorities for time within consultations,[271] prescriber engagement with decision aids will be encouraged by their integration into existing healthcare delivery systems, such that prescriber engagement is not perceived to be an additional burden.[240,241,267,290] Table 25 provides an overview of the development of PT 10, including supporting CMOCs and excerpts used from specific data sources in their development. How theory outlined within the COM-B Model of behaviour informed data analysis is also outlined.[232]

Table 25 - Programme theory 10, associated CMOCs and excerpts used from specific data sources to develop this programme theory.

Programme theory 10 – Antipsychotic treatment decision aids

Where prescribers report competing demands for time as a significant barrier to their engagement in SDM during antipsychotic treatment consultations, patient engagement with decision aids that prescribers deem comprehensive in informing patients about benefits and risks of different treatment options (context) may support prescriber engagement with patient treatment preferences (outcome). Patient engagement with information sources prescribers judge to be reliable could facilitate the evaluative and informational work of SDM, and so, reduce prescriber perceived time commitment to prescriber engagement in SDM within consultations (mechanism). Patient knowledge of antipsychotic treatment options through their engagement with decision aids (context) may also increase the likelihood of prescribers engaging with their treatment preferences (outcome) and challenge prescriber passive compliance with previous prescribing practices (outcome), including prescribing antipsychotics with which prescribers are most familiar. Patient knowledge of antipsychotic treatments can encourage greater conscious awareness of prescribing behaviours among prescribers during consultations (mechanism).

Comprehensive decision aids may also facilitate prescriber education on antipsychotic treatment options (context) which can increase their engagement with patient treatment preferences (outcome) by increasing prescriber confidence in prescribing antipsychotics with which they are less familiar but that align with patient preferences (mechanism). Prescribers are more likely to engage with recommendations for treatment produced through patient interactions with decision aids (outcome) where the output consists of a potential range of treatment options for further collaborative discussion between patient and prescriber (context) as prescribers are reassured that patient use of decision aids, and their integration within treatment consultations, does not preclude the role of clinical expertise, including their knowledge of patients' illness history, in influencing antipsychotic treatment decisions (mechanism). Where prescribers report competing priorities for consultation time, integration of decision aids and resultant treatment recommendations into existing health delivery systems (context) will likely be required for prescriber engagement (outcome), such that their use within consultations is not a perceived additional burden for prescribers (mechanism).

CMOC 1 – Decision aids providing technical support and reducing prescriber time commitment to SDM

Mapping to COM-B model of behaviour change categories: Opportunity (physical)

Where prescribers report competing demands for their time, patient engagement with decision aids providing information that prescribers believe is comprehensive about benefits, and particularly risks, of different antipsychotic treatment choices (context), may increase prescriber likelihood of engagement with patient treatment preferences (outcome) by facilitating the evaluative and informational work of SDM, and reducing prescriber perceived time commitment to their engagement in SDM (mechanism).

Evidence sources:

1. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
    a. Shared Mental Health Decision Making: Physicians and nurses expressed concerns about:
        1. Lack of technical support (e.g., risk communication tools, decision aids) for SDM
    b. Future directions and recommendations:
        i. Decision Aids (DAs): Characteristics
            1. Develop DAs to support treatment planning and help consumers and clinicians identify and articulate life goals.
2. Leucht et al (2023) - *Shared Decision-Making Assistant (SDMA) and other digital tools for choosing antipsychotics in schizophrenia treatment*
    a. In areas where there is a wide range of available medications with varied efficacy and side-effect profiles such as antipsychotics for schizophrenia, it is particularly difficult to choose the most suitable medication for a patient. It is almost impossible for the clinician to know all the specifics of each antipsychotic. Moreover, considering the individual preferences of patients within this vast amount of information is a formidable challenge. In order to fill this gap, digital presentation is the way to go. For each drug, a brief text "in a nutshell" is displayed on the essential information such as

efficacy, side effects, dose, metabolism, interactions. This multi-layered and easily accessible information saves the medical user from having to look up the product information.

3. Ali et al (2015) - *Psychiatric Providers' Willingness to Participate in Shared Decision Making When Prescribing Psychotropics*
    a. Results: The most commonly reported perceived barriers [to SDM] were limited patient capacity (86.2%), limited time with patient (62.1%), and limited materials/staff (51.7%).
4. Seale et al (2006): *Sharing decisions in consultations involving anti-psychotic medication: A qualitative study of psychiatrists' experiences:*
    a. Results: Additionally, eight doctors mentioned difficulty in providing comprehensive or precise information about adverse effects, either because they found it hard to know these themselves or because it was impractical to discuss every single one, including those that might be extremely rare, in the time available. That this was a problem was indicated by the fact that several linked this anxiety to the potential for later complaint or litigation from patients affected by harmful effects they had not been warned about:
        i. "*I am generally fearful that I don't give people enough information. And we live in a litigious world, and I don't know any doctor who is not worried about it. It is absolutely impossible to give them every bit of information".*
5. Verwijmeren et al (2023) - Shifting Perspectives on the Challenges of Shared Decision Making in Mental Health Care
    a. Results: Because clinicians are generally pushed for time, and because of often limited access to research bases, they cannot always keep up with (recommendations on) the latest treatment options, while conveying information about the diagnosis and prognoses of different treatments can be complex, where clinicians sometimes resort to discussing less treatment options than actual possible.
6. Muller et al (2023): *Informing the development of a decision aid: Expectations and wishes from service users and psychiatrists towards a decision aid for antipsychotics in the inpatient setting*
    a. Results: Psychiatrists and service users mentioned the desire for a reliable, easy-to-understand source of information on antipsychotics so that they would no longer have to resort to the summary of product characteristics or internet search engines.
        i. Psychiatrist: *Well, what might also be nice is that sometimes we have suggested a medication and then they [service users] think a bit and they look at the package leaflet and google it and then they say 'yes, no way,*

because there is such a list, and it is all totally overwhelming and unorganised and there are the worst things on it'. It would be great to have an honest, realistic profile, so to speak.

b. Results: Hope was expressed by both sides that a decision aid (DA) could facilitate everyday work. Amongst others, the idea was mentioned to what extent a DA could outsource information from the doctor's consultation to be able to use the little time available effectively.

7. Forsberg et al (2018) - *Clinician perspectives on supporting adults with psychosis who wish to discontinue neuroleptic medication: qualitative analysis*
    a. Clinical and research recommendations: During interviews clinicians were asked what support they felt they required to support individuals with psychosis to discontinue neuroleptic medication:
        i. Difficulties identified and implications:
            1. Inadequate technology (difficulties in sharing information with service-users)
        ii. Recommendations:
            1. Reduced caseloads for clinicians to allow more time to discuss and support service-users to discontinue neuroleptics.
            2. Development of and access to technology allowing clinicians to share information with service-users.
8. Mendel et al (2009) – *How psychiatrists inform themselves and their patients about risks and benefits of antipsychotic treatment*
    a. Results: (Balance of information search): The psychiatrists searched for significantly more information on the risks (mean = 3.5 items, SD = 1.8) than the benefits (mean = 2.9 items, SD = 2.0) of the two drugs overall (paired t-test: t = 3.4, df = 74, P = 0.001). This means that 45% of the requested information dealt with advantages and 55% with disadvantages. The difference value benefits-risks, which results from the benefits minus the risks amounts to 0.6(SD = 1.6). About half of the doctors studied (48%) exhibited a negative difference value (difference value benefits-risks < 0) in their search, i.e., these doctors searched for more risks than benefits. Approximately one third of the doctors (35%) made a balanced information search (difference value benefits-risks = 0), and 17% of the doctors searched for more benefits than risks (difference value benefits-risks > 0).

b. Discussion: At first sight, the results of study 1 were surprising, since we did not expect an information search biased towards gathering more risks than benefits. From psychological research in related fields (e.g., confirmation bias, dissonance theory). one would rather have expected the bias to be more towards benefits (5, 6). However, there is also evidence that under special conditions (e.g., when the motivation to avoid making wrong decisions is very high) individuals prefer disapproving information. Taking more risks than benefits into account, as was done by the psychiatrists in our study, indicates that they might have followed the principle of *primum nonnocere* which has influenced physicians work for centuries. Given the potentially severe consequences of poor treatment decisions (e.g., severe side-effects) this principle makes sense, but an information search which is strongly risk dominated could possibly lead to an effective and appropriate treatment being withheld from a patient due to the physician's fear of its side-effects.

CMOC 2 (Challenging passive compliance with previous practices/educating prescribers)

Mapping to COM-B model of behaviour change categories (a, b): Capability (psychological)

a. Patient knowledge of antipsychotic treatment options within consultations, facilitated by their engagement with decision aids (context), may increase prescriber engagement with patient preferences for treatment (outcome) and reduce prescriber passive compliance with previous prescribing practices (outcome) by encouraging prescribers to be more conscious of their behaviours in treatment consultations (mechanism).

b. Prescriber education via antipsychotic treatment decision aids (context) may increase prescriber engagement with patient preferences for treatment (outcome) due to increased confidence in prescribing antipsychotics they are less familiar with but align with patient preferences (mechanism).

Evidence sources:

1. Simmons and Goulding (2017): *Spot the difference: shared decision-making and supported decision-making in mental health*

a. Introduction: According to Elwyn et al. (2012), improving knowledge for both the consumer and clinician is an important goal for shared decision-making interventions, as information about evidence and preferences is considered essential information necessary for the decision-making processes. In order to make an informed decision, both the clinician and consumer need access to readily understandable and evidence-based information about the potential harms and benefits of each option, and the likelihood of these potential outcomes.

2. Brooks et al (2017): *Exploring the potential implementation of a tool to enhance shared decision making (SDM) in mental health services in the United Kingdom: a qualitative exploration of the views of service users, carers and professionals.*
    a. Results: Service users, carers and professionals talked about successful use of the tool requiring professionals who displayed certain behavioural practices. These characteristics included taking the time get to know the service user, being compassionate, not focussing on psychosis alone, having adequate knowledge and being able to convey this successfully, as well as having conviction in the decisions that were made.
    b. Results: The main barrier to the use of the tool described by participants at the meso-level was that of limited human resources within their healthcare organisation, which hindered the time professionals had to spend with service users and carers.
        i. *"I've got half an hour per patient in the ward round, but that includes talking to the nursing staff, the junior doctor, the care coordinator, members of the family, any… anybody else and then the patient gets to come in as well at some point in that half an hour".* Professional focus group 1
3. Henshall et al (2019) - *Implementing a digital clinical decision support tool for side effects of antipsychotics: a focus group study*
    a. Results: All psychiatrists commented that the Decision Support Tool (DST) would help to increase their awareness and consideration of a wide scope of medications. They felt this was necessary as they admitted that they generally prescribed a limited selection of drugs, based on anecdotal evidence and simplistic cost-effectiveness considerations.
    b. Results: Psychiatrists felt that the comprehensive, up-to-date and evidence-based information on the DST would increase their prescribing confidence with new medications.
    c. Results: Some psychiatrists felt that there was a danger that the DST could increase paternalism if the drugs listed on it were not perceived as clinically relevant, as this could result in doctors overriding patient preferences if they felt that the patient's drug of choice was not credible. However, others commented that it could help to educate doctors about

the efficacy and side effect profile of relatively unknown medications, increasing the likelihood of them being integrated into practice.

i. "*Certainly, there's things there which I'm sure I'm going to learn that I will integrate into my practice as I go along. If there is a link for the evidence, that could be very helpful, actually, because every evidence needs to be looked at and can be discussed, debated, argued against".* Psychiatrist 2

4. Muller et al (2023): *Informing the development of a decision aid: Expectations and wishes from service users and psychiatrists towards a decision aid for antipsychotics in the inpatient setting*
    a. Results: In two of the three psychiatrists' focus groups, the idea was also expressed that the DA could broaden the professional horizon, for example by looking at other, less frequently used drugs.
5. Schon et al (2018) - *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Results: The staff stressed that DST [decision support tool] promotes the importance of being transparent, not selective and discriminative, when sharing information with the users. Although some information may be perceived as uncomfortable, it is still important that it is conveyed, and that staff present an accurate and fair view of options and possible consequences. These staff members appreciated how SDM challenges traditional practices where staff say, "how it is," and how SDM can support users in legitimizing their knowledge and increasing their decision-making ability.
    b. Results: The staff described the DST as facilitating their ability to work with SDM and as raising their awareness regarding their attitudes when attempting to increasingly involve users in decisions. They also felt that using the decision tool together with the users, contributed to their own ability to concretely and actively listen to and consider the users 'opinions and priorities rather than moving too quickly to solutions, something that they were often prone to in stressed situations, and in their eagerness to help. One participant described that: *"For me this is a confirmation (points at the DST) . . . To acknowledge the service user. That we, as staff, are reminded to really listen to our service users instead of just handing out a lot of good advice*" [Consultant psychiatrist].

CMOC 3 (Increasing prescriber engagement with decision aids):

Mapping to COM-B model of behaviour change categories (a, b): Motivation (reflective)

a. Prescribers are more likely to engage with decision aids outlining patient values and preferences for antipsychotic treatment (outcome) where the final output of patient engagement with the decision aid is a range of potentially suitable antipsychotic treatment options for further collaborative discussion (context) as prescribers are reassured that their clinical expertise in influencing antipsychotic treatment decisions is maintained (mechanism).

b. Within settings where prescribers report competing priorities for their time within treatment consultations, integration of decision aids containing information prescribers perceive as reliable sources of information into existing health delivery systems (context) will likely increase prescriber engagement with outputs from patient engagement with decision aids (outcome) as prescribers do not perceive their engagement is an additional burden (mechanism).

Evidence sources

1. Muller et al (2023): *Informing the development of a decision aid: Expectations and wishes from service users and psychiatrists towards a decision aid for antipsychotics in the inpatient setting*
    a. Results: With regard to the DA's data processing, psychiatrists suggested a decision tree or a filtering mechanism. The suggestion would lead to 'deselecting' antipsychotics that are unsuitable according to the service user profile. Above all, the transparency of the algorithm was repeatedly emphasized.
        i. Psychr: *Such a [decision] tree, so that the patient can retrace how we came to the decision. […] Also, the steps to get there could be explained. That you can also go back again if you come out where you don't want to come out, or you can have another look at what you can perhaps accept as a side effect.*
        ii. Psychiatrists were critical of any algorithm that is supposed to lead to a clear treatment recommendation in such complex decisions.
        iii. Psychr: *Maybe you could go through that by yourself in an app and choose. I think it's good to have some knockout criteria where you can say this side effect is not acceptable or that is omitted because of renal*

insufficiency and so on. You can then go through that with the patients themselves, like a tree. You just start and end up with a drug. Maybe with an alternative. (G3Psychr02, female, paragraph 43)

b. Results: Various fears were expressed by psychiatrists in the context of a clear drug recommendation, such as the concern that service users might become fixated on the outcome and that they as physicians might be deprived of control over the decision-making process; although the objection was also raised several times that this need not be a concern in the context of shared use. Occasionally, psychiatrists also suggested not making a recommendation but presenting the different antipsychotics on an equal footing.

c. Results*: Table 4 - Differences and common grounds in wishes and expectations towards the decision aid*

i. Psychiatrists:

1. *Physicians concern about loss of control due to app result*
2. *Concern about 'tunnel vision' due to outcome*

2. Henshall et al (2019) - *Implementing a digital clinical decision support tool for side effects of antipsychotics: a focus group study*
   a. Results: Contextual factors relating to patients' physical and social health were noted as also influencing psychiatrists' prescribing practices, something which was not factored for by the DST. Despite this, psychiatrists felt that it could be a useful base for considering medication options with patients.
      i. *You're much more constrained in the antipsychotic you could give each patient … But it could still be used as a launch pad for those types of discussions".* Psychiatrist 4
   b. Results: All participants acknowledged the complexity of the decision-making process and felt the DST was a small piece of the whole picture.
      i. *"The app … It's a good start … Sometimes decision-making is more complex. You as a clinician have to take more into consideration rather than just a few clicks, side effects*". Psychiatrist 1
3. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Substance Abuse and Mental Health Services Administration (2010) - *Shared Decision-Making in Mental Health Care: Practice, Research, and Future Directions*
   a. Future directions and recommendations:
      i. Decision Aids: Characteristics
         1. Develop DAs that focus on bilateral communication and collaboration between consumers and providers.

4. Coulter et al (2015): *European Experience with Shared Decision Making*
    a. Introduction: Experience in various demonstration projects in the US: (http://www.informedmedicaldecisions.org/shareddecision-making-in-practice/demonstration-sites/) and Europe: (http://www.health.org.uk/areas-of-work/topics/personcentred-care/) leads us to believe that the following ten factors need to be in place to promote more widespread adoption:
        i. Availability of good quality patient decision aids (PtDAs)
        ii. Integration of PtDAs into electronic medical record systems.
        iii. Institutional support for developing and updating PtDAs
        iv. Certification schemes to assure the quality of PtDAs
    b. Results: For patient decision aids to be widely used they must be readily accessible at appropriate decision points. One way to ensure this is to integrate them into electronic medical records (EMRs). Many PtDAs have been developed as part of individual projects, but development is only one part of the story. They need to be hosted in an accessible place or website, user-tested, promoted, distributed and kept up to date. Effective implementation of SDM depends on trust in the reliability of the information, which must also be well-designed, and user tested. The International Patient Decision Aids Standards (IPDAS) were developed by an international multi-stakeholder group and there is considerable interest in using these as the basis for certification schemes to assure the quality of PtDAs.
5. Schon et al (2018): *Psychiatric service staff perceptions of implementing a shared decision-making tool: a process evaluation study*
    a. Results: Staff suggested that a challenging aspect would be finding the time to introduce users to the DST and to support them in using it. In their experience, it was always difficult to prioritize time for implementing new methods, although once something is put into practice it tends to run smoothly. Their work situation was described as involving having to constantly deal with emergency situations which often become an obstacle for implementation. Even if the notion of encouraging users to write down their experiences and questions beforehand appealed to many of the staff, many felt that finding the time to read these comments would be difficult. One participant described the time challenge in the following manner "*When will I have time to read what the patients have written? It feels like that you don't really have time to sit with this before you see the patient*" Psychiatrist

b. Applying SDM through the DST was perceived as something "over and above" their regular workload and something that required extra time in already stressful situations and in understaffed services. The following quote illustrates the participant's experience:
    i. *"There is so much, all of the time. There are a thousand things and constant crisis…We always have patients in acute crisis and that makes it very hard to focus".*
c. Directly after the education, the staff was motivated and committed, but when it came time to implement the intervention in their daily work they fell back into everyday routines since routine work took up all their time. One participant stated *"Directly after the education you feel very inspired. Then you come back to your ordinary routine with loads of things you have to do. . . I think we need regular follow ups. What have you done? How is it going*?" [Psychiatrist]
    i. It also became clear from the results that the SDM process was perceived of as time-consuming by staff, a reaction which suggested that the method should be reserved for decisions which are considered priorities for both the organization and the user.
d. Discussion: Even if staff expressed a general commitment and a positive attitude towards the method, disruptive elements such as organizational changes, personnel turnover and a workflow characterized by constant interruptions related to acute demands, led to a gradual loss of focus on the process. As in all implementations of new methods, manager's attitudes and level of commitment is crucial. Managers need to provide sustainable structures, with a clear vision of the new method as constituting a formal part of the ongoing activities.
e. Discussion: In our particular intervention, it became evident that a certain degree of technical readiness in the services, such as access to computers for both staff and users is an aspect of implementation which should be focused on to a greater degree in the future. Accessibility to computers during the training session would have likely facilitated the interest in and readiness to utilize the tool together with users.

6. Forsberg et al (2018) - *Clinician perspectives on supporting adults with psychosis who wish to discontinue neuroleptic medication: qualitative analysis*
    a. Clinical and research recommendations: During interviews clinicians were asked what support they felt they required to support individuals with psychosis to discontinue neuroleptic medication:

i. Difficulties identified and implications:
    1. Lack of information on discontinuation for service users (conflicting advice, lack of understanding of discontinuation process)
ii. Recommendations: Development of nationally approved service-user information on discontinuation.

7. Treichler et al (2020) - *How Shared Is Shared Decision Making? Reaching the Full Potential of Patient-Clinician Collaboration in Mental Health*
    a. Implementation barriers to shared decision making at the systemic level: Perhaps the most important practical obstacle is that many of these interventions are currently difficult for patients and clinicians to access, usually requiring institutions to purchase tools, implement systems, or provide training. Since institutional buy-in and implementation are inconsistent, some stakeholders have no way of accessing any intervention.
8. Shepherd et al (2014) – *Consultant psychiatrists' experiences of and attitudes towards shared decision making in antipsychotic prescribing: a qualitative study.*
    a. Results: Three participants highlighted the importance of optimism and presenting the choice of antipsychotic prescription not as absolute, but as a trial that could be reviewed dependent on clinical response and side effects.
9. Brooks et al (2017): *Exploring the potential implementation of a tool to enhance shared decision making (SDM) in mental health services in the United Kingdom: a qualitative exploration of the views of service users, carers and professionals.*
    a. Results: For the SDM tool to be successfully implemented, participants felt it should not become another bureaucratic 'tick box' exercise or take away from face-to-face consultations, and instead represent a way to prompt SDM discussions and open up on-going discussions about choice with service users and carers.
    b. Discussion: It also highlighted the need for the use of such tools to support SDM to be an individualised and on-going process due to the floridity of illness as well as the use of different strategies to interact with service users and carers at different times of illness.
10. Ramon et al (2017) – *Key issues in the process of implementing shared decision making (DM) in mental health practice*
    a. Results: [anonymised] service user trainer and researcher:
        i. *"In this write up I will reflect on my involvement in implementing SDM within an NHS (National Health Service, UK) mental health trust in the East of England during 2014-2015. Apart from the time constraints and the fact*

that each team only received one training session there were other challenges. The trust had been through an exceptionally difficult period and had been in "turn around" preceding the implementation phase. Staff were feeling stretched and undervalued as they were having to do more for less. I imagine this is the reason why some staff were unreceptive and not open to new ways of working. *Another factor was the ongoing organisational change and pathway redesign, which had an unsettling effect. This may explain why we sensed that some of the staff felt we did not understand how hard their jobs were. During the training phase of the study there had been considerable resistance to using the forms, which had been developed to provide a clear framework for staff. The forms also enabled services users to express their preferences and priorities and identify any medication issues, which facilitated the decision-making process. This was because it was seen as extra paperwork and because clinicians felt that services users would always prioritise application forms and resist any additional form filling".*

ii. In addition, because this was a research project it was not perceived as mainstream or "business as usual", staff were reluctant to persevere with forms which they regarded as onerous.

5.5 Discussion

Similar to the division of programme theories across macro, meso-, and micro-level contexts, analysis of review findings will follow these subcategories.

5.5.1 Programme theories 1-5 (Macro-level factors influencing prescriber engagement with SDM processes)

The first five programme theories sought to understand structural and contextual influences on prescriber adoption of behaviours required of their engagement with SDM within psychosis management. Whilst interventions designed to increase SDM application within antipsychotic prescribing have largely focussed on optimising patient-prescriber interactions,[97] this evidence synthesis identified most barriers to prescriber engagement existing in realms beyond the influence of these intervention strategies.[100] Five programme theories were developed outlining the relationship between contexts within leadership and governance structures, workforce development and service delivery that can systematically reduce prescriber adoption of behaviours required of SDM within initial and continued antipsychotic prescribing decisions. Features of these contexts that, where present, reduce contextual integration of SDM into psychosis management have been made explicit to facilitate development of targeted solutions.

The prevalence of the biomedical model of health within clinician education and professional socialisation was identified as a significant structural challenge within workforce development to achieving the ideals of SDM in practice.[97] Although this review identified why, 'disease-focused' and 'overly medicalised' models of care have previously been identified as barriers to SDM implementation.[270,290] Value placed on different types of knowledge contributes to the perceived legitimisation of involvement by people with SMI in decision-making.[262,290] An unintended consequence of the predominance of the biomedical model in influencing clinician behaviour is the inadvertent devaluing of patient preferences and experiential knowledge within decision-making.[252,309] Within settings studied in this review, integration of patient preferences into prescribing decisions was increased where clinicians explicitly valued lived experience.[238,245] Whilst some SDM interventions studied provided prescriber training,[104,105] it is likely that preparation for

implementing recovery-orientated practices needs to be considered much earlier in clinical training, including within undergraduate curricula and continuing professional development.[334,335] Whether the systematic incorporation of lived experience into early education and training are effective in addressing the so-called epistemic injustice precluding widespread SDM implementation within antipsychotic prescribing is worthy of future research.

Several conceptual barriers contributing to a belief that SDM conflicts with the ethical principles of beneficence and non-maleficence within psychosis management were identified. More amenable to intervention are assumptions about the universal absence of decisional capacity and lack of insight into psychotic symptoms precluding decision-specific SDM application. Differences were identified in clinicians' attitudes to capacity impairment associated with psychosis and its impact on SDM application.[213,262,311] Whilst some clinicians view reduced capacity as a restriction on SDM and attempt to maximise patient involvement despite capacity impairments (e.g., ascertaining prior treatment preferences), others regard reduced capacity as an absolute contraindication to SDM.[100,213,266,279] Research has identified a spectrum of decision-making capacity for treatment decisions among individuals with psychosis.[336] One review identified around 50% of inpatients as demonstrating decision-making capacity, consistent with heterogeneity associated with psychotic illnesses.[337] Decisional capacity impairments are also temporal and identifiable, with some being responsive to intervention.[336] Such features, and the decision-specific nature of capacity impairment, are often not referred to by those who view 'lack of capacity' as a major barrier to SDM.[213]

Insight is relevant but not determinative of capacity.[338] A specific lack of insight into psychosis is not always relevant for an individual's ability to partake in treatment decisions, as treatment options can often be discussed in terms of symptoms of which the individual is aware.[294] Prior research has recognised the multidimensionality of insight and suggested the conceptualisation of insight is best considered as a continuous distribution across several domains.[213,339] Thus, whilst agreement exists that reduced decision-making capacity and insight into psychosis

impairs consistent SDM application, precisely where that threshold lies appears to be influenced by clinicians' individual attitudes.[100] Even where decisional capacity is acknowledged, clinicians' beliefs about the inability of people with a psychotic illness to cope with decision-making responsibility represents another cognitive obstacle reducing their likelihood of engagement in SDM.[210,240,253,311] Efforts to address subjectivity within capacity assessments and reduce stigmatising attitudes present among some clinicians will likely be required to support individualised, decision-specific implementation of SDM.

Mental health legislative and regulatory frameworks - far from their intended purposes of increasing accountability and transparency - were identified as decreasing prescriber engagement in positive risk-taking and increasing clinician-led decision-making.[284,310,320] Among clinicians in the UK,[308,310,311] Germany,[299] Sweden,[323] the USA,[296,320] and Australia,[320] a perception was identified that government policy and mental health legislation encourages their engagement in risk-aversion and paternalism to reduce risk of harm to patients or to others. This perception was generated through (i) a perceived dominant emphasis within legislation on prescriber responsibility for managing 'risk' without adequate or explicit consideration of patient autonomy and the changeable nature of capacity,[284,307,320,323] (ii) harmful events being responded to by increasing regulation,[308,321] (iii) experiences of harm reduction being prioritised during inspection processes,[324] and (iv) media representation of high profile judgements following harm to, or caused by, people with SMI.[259,310] The perception of harm reduction being prioritised within mental health legislation has contributed to decreased psychological safety among prescribers when attempting to increase patient autonomy within decision-making and reported difficulties distinguishing between defensible positive risk-taking practices and actions that could be viewed as negligent.[227,320,322]

Even in the case of supplementary legislation supporting clinician engagement in positive risk-taking, for example, the UK's Mental Capacity Act 2005,[311] clinicians are often unaware of these frameworks, or do not feel confident that they would protect them from exposure to professional risk in the event of harm.[311,322] This

suggests primary mental health legislation and associated regulatory practices are a more important influence on clinician behaviours. Although risk management in psychiatry centres around harm reduction, the preoccupation with reducing risk to safety inadvertently *increasing* risk to patients by restricting their autonomy within decision-making has previously been raised.[322] An established perception among clinicians that many jurisdictions do not permit acceptance of positive risk-taking within psychiatry, and a belief their implementation of recovery-orientated practices conflicts with prescriber legal obligations, serve as major barriers to SDM implementation.[227]

Contradictory frameworks of practice also contribute to the tension prescribers feel when managing risk, reducing harm and implementing SDM. This includes organisational policy and guidance emphasising protection, harm minimisation and duty of care, whilst also recommending delivery of recovery-orientated care.[283,322] To address the apparent tension between promoting patient autonomy and their primary duty of treating individuals, prescribers require tangible organisational supports.[240,322,331] In the context of harm reduction being prioritised within current practice,[310] organisational policy that promotes individual prescriber engagement in SDM is likely to be insufficient in promoting widespread engagement.[226] Effective prescriber supports should include adequate resourcing of services to create a perception of capacity among staff such that they can safely increase patient autonomy within decision-making.[170]

Processes inherent in SDM, including providing patients time to consider treatments, are also frequently deemed at odds with service delivery priorities within mental health.[290] Adequate staffing and reduced pressure to discharge patients are required to challenge informal norms among staff - contributed to by macro-level resource constraints - that core roles of acute care services are crisis management and reducing proximal risk of harm.[245,255,308,324] However, within cultures where fear of individual blame for adverse outcomes is prominent among clinicians, adequate resourcing alone is unlikely to sufficiently counter the perceived lack of organisational tolerance for positive risk-taking.[227,284,308] Effective leadership

needs to model and actively support positive risk-taking. Rather than fearing a punitive response, leadership committed to implementing SDM should invest in efforts to provide staff with reassurance that they have the professional autonomy and flexibility required to be constructive in responding to risk and providing individualised care.[227,320,322] Top-down, protocol-driven practices and disciplinary forms of power are direct barriers to achieving this.[170,340]

5.5.2 Programme theories 6-10 (Meso- and micro-levels factors influencing prescriber engagement with SDM processes and supportive interventions (programme theories 6-10)

Programme theories 6-10 outline key mechanisms responsible for promoting prescriber engagement with behaviours required for SDM application and facilitative features within service delivery contexts and workforce development. This included care provision via multidisciplinary teams, formalised prescriber training and ongoing supervision in SDM skillsets, and established relationships facilitating SDM engagement by prescribers. The insufficiency of sole patient training in SDM skillsets and the current design features popular within antipsychotic treatment decision aids in encouraging widespread prescriber engagement was also captured within two programme theories.

This synthesis identified prescriber trust in patients as a key context facilitating their engagement in positive risk-taking. Particularly within psychosis management where clinicians typically feel a heavy burden of responsibility,[308] prescriber trust in patients can provide prescribers with confidence in the safety of increasing patient autonomy within decision-making. Studies within this review identified reduced prescriber SDM engagement among patients new to services.[238] Better doctor-patient relationships were also found to predict improved SDM application within medication decisions.[275] Consequently, efforts should be dedicated to attempting SDM in the context of existing, trusting patient-prescriber relationships. However, increasingly common features of mental health service delivery internationally, including discontinuity and fragmentation of care between acute and community settings, alongside high caseloads reducing time and opportunity to develop therapeutic relationships,[6] can impair development of prescriber-patient

trust.[240,324] Thus, similar to the requirement for structural interventions outlined within programme theories 1-5, until features of service delivery contexts precluding development of therapeutic relationships are systematically addressed, they will continue to impede widespread implementation of SDM within psychosis management.

Care provision within effective multidisciplinary teams was also identified as a supportive context increasing prescriber engagement in positive risk-taking. Within increasingly common risk-averse organisational cultures,[271] a perceived collaborative responsibility for decision-making decreases prescriber fear of sole responsibility for potential adverse outcomes resulting from not adopting risk-averse prescribing practices. Even within cultures supportive of positive risk-taking, effective multidisciplinary working was identified as a context that can increase reflection of patient preferences within treatment decisions by addressing barriers of insufficient time or knowledge of antipsychotic treatments required to facilitate SDM.[99] Average consultation duration not being significantly increased by SDM application is often cited as a means of encouraging prescriber engagement.[289] However, an underappreciated aspect of medical prescriber engagement in SDM is the complexity associated with evidence-based antipsychotic prescribing.[213] Both the number and diversity of available antipsychotics is continually increasing.[341] It requires considerable clinician time outside of consultations to become familiar with antipsychotic treatments and develop confidence in their ability to integrate patient preferences with contemporary scientific knowledge.[293]

Standardising care delivery via multidisciplinary teams, including members with expertise in psychopharmacology, is likely to increase patient autonomy within antipsychotic prescribing decisions. However, for scale-up of this effective intervention strategy, understanding how to facilitate collaborative multidisciplinary working is required.[106] The facilitative function of an effective MDT in improving prescriber engagement in SDM processes requires prescriber trust in team members to enact a shared responsibility for decisions and associated consequences. Scepticism among psychiatrists regarding other professional's

willingness to share decision-making responsibility was identified within this review.[226,263] Conversely, difficulties team members encounter conceptually and practically when attempting to share power and influence with psychiatrists and cultures of risk aversion within non-medical professional groups were also identified.[263,266,284] Wider theoretical analysis of SDM models have been criticized for neglecting to account for the complex dynamics of interprofessional collaboration.[269,283,285] The importance of interprofessional trust in facilitating increased patient autonomy within decision-making also has important consequences for service delivery in the case of existing teams providing psychosis care, including the impact of staff rotations and turnover.

Psychiatrists have previously reported some patient behaviours as inducing more participatory behaviours within them.[264] However, this review did not identify sufficient evidence demonstrating improving patient's communicative competencies as systematically increasing prescriber engagement in SDM within psychosis management. This may be because patient 'activation' does not address primary prescriber implementation barriers related to tension between implementing SDM and protecting patient safety, and exposure to liability in the event of harm. In comparison, this synthesis identified that wider workforce training was effective in facilitating prescriber engagement in SDM processes. Fear of creating interpersonal conflict, and misconceptions about SDM depriving them of influence within prescribing decisions, were identified as common reasons for prescribers resisting SDM. Formal training and supervision specific to facilitating collaborative communication among people experiencing psychosis was identified as increasing prescriber confidence in their ability to productively negotiate treatment consultations. Furthermore, collective training of cohesive teams increases the perception of a shared sense of accountability in facilitating the extent of cultural and practical changes typically required of SDM implementation.[290] In contrast to a prior focus on prescriber education,[101] training and continued supervision should be expanded to multidisciplinary teams.

Hopes have previously been expressed that integration of antipsychotic treatment decision aids into consultations could outsource work required of prescribers within consultations and facilitate SDM.[254] However, prescriber concern regarding antipsychotic treatment decision aids as reductionist and encouraging patient-led decision-making were important conceptual barriers to prescriber engagement. Individualised antipsychotic treatment is essential to optimising clinical outcomes within psychosis management.[24] Patient use of decision aids when psychotic can create fear among prescribers that they will be deprived of the required influence within prescribing decisions to reflect the complexity inherent within effective psychosis management.[244] The importance of prescriber trust in information sources influencing their prescribing practices has also been overlooked within decision aid development. Both co-production and purposeful incorporation within decision aid design of mechanisms providing prescribers with the ability to confirm reliability of antipsychotic treatment information are required. When developing any tool for implementation into antipsychotic prescribing consultations, prescribers require flexibility regarding timing of implementation, such that they perceive the tool as supportive, rather than a restriction on their practice.

5.5.3 Implication of review findings

Even empirically efficacious SDM interventions will be difficult to implement at scale within real-world settings studied as part of this review due to misalignment with the complex social, cultural, legal, political, and professional realities common to these settings.[310] An overview of mechanisms identified across all ten programme theories responsible for increasing or decreasing prescriber engagement with behaviours required of SDM application is outlined in Figure 12. Such mechanisms, their resultant influence on prescriber behaviour and the contexts responsible for their activation, should be the focus of those interested in implementing SDM within antipsychotic prescribing at organisational-, institutional- and policy-level.

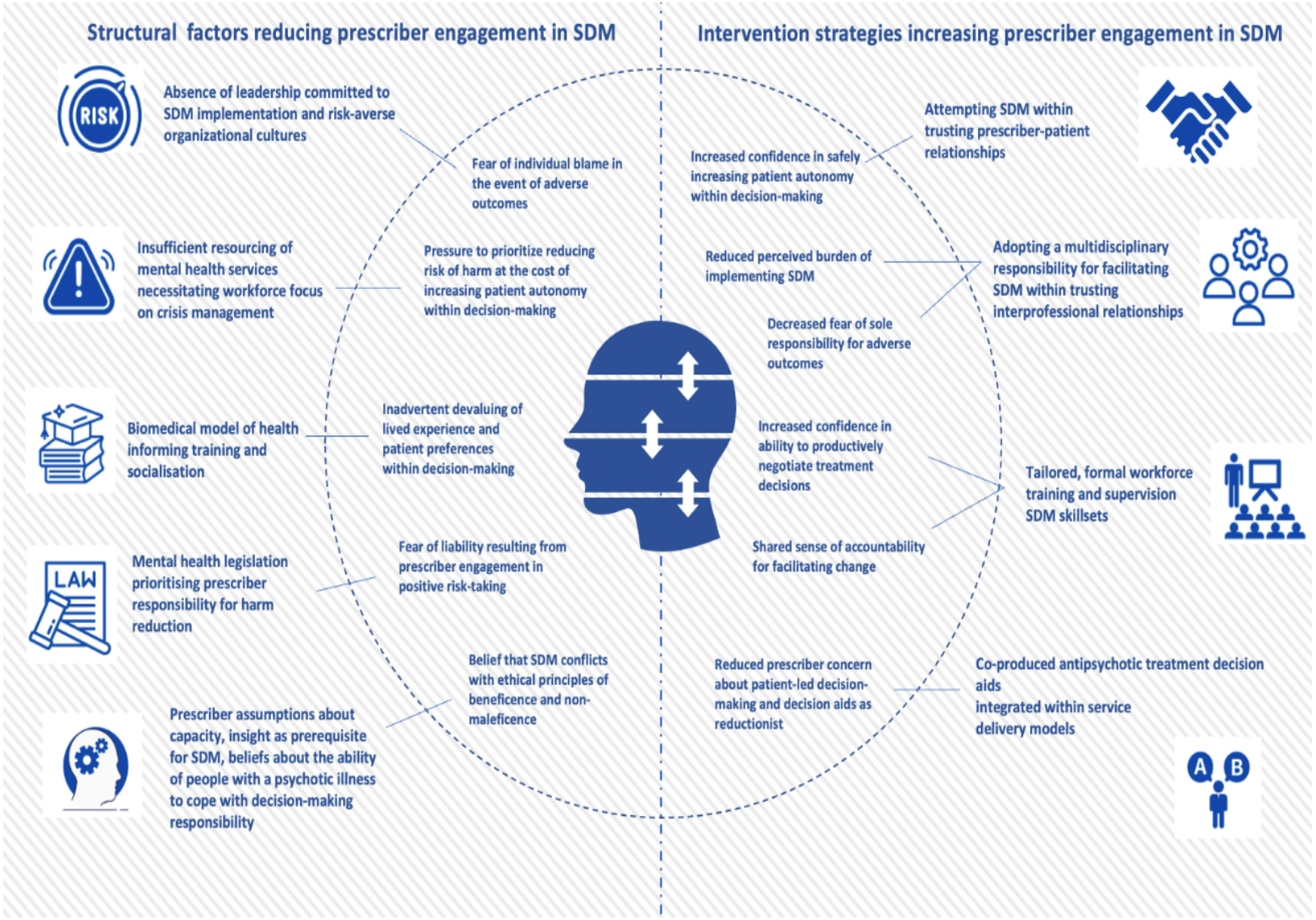

Structural factors reducing prescriber engagement in SDM
Intervention strategies increasing prescriber engagement in SDM
RISK
Absence of leadership committed to SDM implementation and risk-averse organizational cultures
Fear of individual blame in the event of adverse outcomes
Attempting SDM within trusting prescriber-patient relationships
Increased confidence in safely increasing patient autonomy within decision-making
Insufficient resourcing of mental health services necessitating workforce focus on crisis management
Pressure to prioritize reducing risk of harm at the cost of increasing patient autonomy within decision-making
Reduced perceived burden of implementing SDM
Decreased fear of sole responsibility for adverse outcomes
Adopting a multidisciplinary responsibility for facilitating SDM within trusting interprofessional relationships
Biomedical model of health informing training and socialisation
Inadvertent devaluing of lived experience and patient preferences within decision-making
Increased confidence in ability to productively negotiate treatment decisions
Shared sense of accountability for facilitating change
Tailored, formal workforce training and supervision SDM skillsets
LAW
Mental health legislation prioritising prescriber responsibility for harm reduction
Fear of liability resulting from prescriber engagement in positive risk-taking
Belief that SDM conflicts with ethical principles of beneficence and non-maleficence
Reduced prescriber concern about patient-led decision-making and decision aids as reductionist
Co-produced antipsychotic treatment decision aids integrated within service delivery models
Prescriber assumptions about capacity, insight as prerequisite for SDM, beliefs about the ability of people with a psychotic illness to cope with decision-making responsibility
A
B

Figure 12 - An overview of mechanisms identified in Part 1 and Part 2 as responsible for increasing or decreasing prescriber engagement with behaviours required of SDM application.

5.6 Limitations

The results of this review should be interpreted in the context of limitations specific to this review and application of realist review methodology more generally. SDM as a concept stems from a Western, liberal, and individualistic view of human relations.[281] Most evidence assessing SDM within SMI also originates from high-income countries.[13] Within cultures where a more paternalistic approach to care is the norm, or within low- or middle-income countries, structural and contextual impacts on prescriber behaviours identified here may differ. Realism emphasizes the chasm between actually manifested reality and our ideas about that reality. An epistemological assumption with a realist methodological orientation is that knowledge is always partial and accruing. Outputs of scientific realist inquiry may not embody mechanisms in the truest ontological sense, but by striving towards that direction, and committing to cycles of theory development and testing, intelligence increases within our knowledge systems.[147] Thus, despite its comprehensiveness, this review does not claim to represent a definitive statement of the universal practices of clinicians. Rather, it explains factors which influence prescriber behaviours, as supported by currently available empirical and grey literature, with the intention of highlighting factors beyond the influence of individual clinicians and services requiring purposeful intervention for SDM implementation.

As discussed originally in Chapter 3, the research paradigm informing realist review methodology differs from traditional positivist paradigms and the application of realist methodology, particularly within psychiatry, remains in its infancy. The conduct of realist reviews requires researchers to align with a realist ontology and epistemology, maintain methodological rigour and produce relatable and practical results.[342] The complexity of conducting realist reviews, and the need to balance methodological purity and practical applicability likely, contributes to the variation previously noted in the conduct of evidence syntheses informed by a realist philosophy of science.[342] Whilst methodological standards exist and were adhered to in the conduct of this review, realist review methodology affords researchers

more flexibility in the application of the methodology than in a traditional systematic or 'Cochrane' review.[343] This can increase subjectivity within application of the methodology. Within this review, involvement of two experienced realist researchers within the research team was planned with the intention of reducing subjectivity in application of the methodology.

Due to the ability of realist reviews to address a range of potential research questions beyond 'what works', this necessitates focussing of the research question.[343] The process for how the research question was focussed within this review has been clearly outlined. However, a consequence of the need to focus the research questions the review addressed was that some areas of application of SDM within psychosis management were prioritised at the cost of others. The most important of these was that the review does not directly address patient needs for engagement in SDM within the contexts studied. This includes the role of caregivers in patient advocacy and is an obvious area for complementary realist research.

The review produced ten programme theories judged to be coherent, plausible and supported by sufficiently rigorous and rich data sources. As in all quality appraisal attempts, a value judgement must be made. Whilst multiple team members were involved to address potential for subjectivity and all judgements were reviewed independently and at several occasions by various research team members, this does not eliminate the potential for subjectivity. Furthermore, due to the volume of review results, in the case of programme theories judged not to meet pre-specified quality criteria, a decision was made not to pursue further literature searches due to ten robust programme theories already being formed.

Finally, when originally developed by Pawson et al in 2005,[119] realist review methodology was proposed as a way of addressing the practical realities and challenges of translating evidence into policy-making by offering explicit, empirically testable explanations of how context is linked to outcomes through mechanisms. However, given the complexity of attempting to represent all possible causal mechanisms to explain behaviour and effective mechanisms underlying intervention

strategies, the output of realist reviews, including in this review, tend to be complex theories.[342] This can limit the practical value of review findings for policymakers and practitioners. This was of particular concern within this review due to the volume of review results and the complexity of the topic area under investigation. Efforts to improve accessibility among key stakeholders included involvement of the lived experience group in presenting results and in planning dissemination activities and use of figures and graphic design. It is likely that dissemination efforts will need to be updated following sharing of review results with various stakeholders and upon seeking feedback as to how to improve their practical applicability, particularly among those responsible for the design and delivery of mental health services.

5.7 Conclusion

This realist review aimed to addresses when and why prescribers engage with behaviours required of SDM within antipsychotic prescribing decisions as part of psychosis management. Programme theories 1-5 identified contexts within (i) leadership and governance (mental health legislation and regulatory frameworks prioritising harm reduction), (ii) service delivery (absence of committed leadership, insufficient resourcing of mental health services), and (iii) workforce development (the biomedical model informing clinician training and professional socialisation, cultural and social norms within psychosis management) that reduce prescriber engagement with behaviours required of SDM application. Key mechanisms identified as responsible for reducing prescriber engagement included fear of individual blame and exposure to liability in the event of patient harm, pressure from service environments to prioritise decreasing risk of harm, devaluing of lived experience and beliefs that SDM conflicts with duties of beneficence and non-maleficence within psychosis management.

Thus, even empirically supported SDM interventions will be difficult to implement at scale within real-world settings common to psychiatry due to misalignment with the complex cultural, legal, political, and professional realities prominent within mental health settings internationally. For widespread prescriber uptake of

behaviours required of SDM, structural interventions that focus on altering contexts in which health services operate will be essential. Although the target of SDM interventions is typically individual prescribers, much greater responsibility for implementing SDM within psychosis management is required at organisational-, institutional- and policy-level.

In contrast, programme theories 6-10 outlines features of service delivery contexts and workforce development that can increase prescriber engagement in behaviours required for SDM. This included care provision via multidisciplinary teams, formalised prescriber training and ongoing supervision in SDM skillsets, and established relationships facilitating SDM engagement by prescribers. Such contexts should be prioritised for scale-up within standardised psychosis management to increase prescriber engagement. Key mechanisms identified as responsible for promoting prescriber engagement with desired behaviours included reducing prescriber fear of sole responsibility for harm, reducing the perceived burden of SDM within consultations, increasing prescriber confidence in their ability to productively negotiate treatment consultations and their confidence in the safety of increasing patient autonomy within decision-making. These mechanisms should be the focus of those interested in designing novel SDM interventions to increase their likelihood of successful prescriber engagement, and those responsible for translating results of empirically efficacious interventions into real-world settings to ensure evidence-based, facilitative contexts are maintained.

Chapter 6 - Informing the development of antipsychotic-induced weight gain management guidance: patient experiences and preferences - a qualitative descriptive study

6.1 Chapter description

One significant challenge in the development of AIWG management guidance is the lack of empirical research outlining how those with lived experience of AIWG and a SMI conceptualize preferred AIWG management. This chapter outlines findings of a qualitative descriptive study conducted via semi-structured interviews with a diverse range of participants with varying experiences of AIWG and mental illness. Participants were asked about their experiences of managing AIWG across different contexts, and how they would conceptualize preferred management and its implementation with clinical practice. Participant values and preferences were sought regarding the acceptability, feasibility, and transferability of current AIWG management algorithms and the range of non-pharmacological and pharmacological interventions recommended therein.

Work presented in this chapter has been published as: ***Fitzgerald I**, Crowley EK, Ní Dhubhlaing C, O'Dwyer S, Sahm LJ. Informing the development of antipsychotic-induced weight gain management guidance: patient experiences and preferences - qualitative descriptive study. BJPsych Open [Internet]. 2024 [cited 2025 Jan 13];10(5): e136.*

6.2 Introduction

AIWG is commonly cited as one of the most distressing treatment side effects and a frequent cause of non-adherence.[28] Clinically significant weight gain has been linked to almost all antipsychotics, and contributes significantly to the 2-3-fold higher obesity rates seen amongst those with a SMI.[6,107] Consequently AIWG and its impact on the risk of cardiometabolic disease contributes appreciably to the poorer physical health,[6] reduced healthy years lived,[108] and the 10-20 year premature mortality seen amongst those with a SMI.[44,109] Given the associated personal, social, and healthcare costs, effectively managing AIWG is a key priority for patients, clinicians, and policy makers.

Successfully managing AIWG is, however, challenging. Whilst interindividual variability in the prognosis of AIWG is an important factor, limited guidance for clinicians invariably increases management complexity.[44] Although a limited number of recommendations exist within larger guidelines,[43,46] a rigorously developed clinical practice guideline (CPG) solely dedicated to AIWG management is notably absent.[62] This includes guidance informed by consultation with varying stakeholder groups and recommendation development to align with international standards of guideline development.[66,79] The absence of a quality guideline is an important barrier to timely, systematic and equitable patient access to evidence-based AIWG management across cohorts and settings.

Calls for standardised and evidence-based guidance dedicated to AIWG management are increasing.[62,110] Guideline development, however, requires evidence addressing criteria beyond intervention effectiveness. This includes knowledge of patient values and preferences for management interventions, and patient views regarding the acceptability, feasibility, and transferability of ensuing recommendations.[80] One challenge in developing relevant and applicable AIWG management guidance is the lack of empirical research assessing these criteria. To date, the scope and endorsement of AIWG management recommendations have largely been informed by the expert opinion of guideline development groups with

minimal or no patient input.[43,46,58] The prognosis of AIWG is extensively variable.[34,36] Thus, patient preferences and priorities for management are likely similarly variable.

Clinicians can (often unconsciously) endorse stereotypical assumptions and stigmatising attitudes about those living with obesity.[83,84] Obesity management amongst those with a SMI may be particularly liable to such implicit biases, where the experience of a "*dual stigma*" has been described by those living with both obesity and a mental illness.[86,87] Recommendations addressing weight management in those with a SMI may be distinctly susceptible to ideology and sociocultural values regarding the appropriateness of interventions, including use of anti-obesity medications and expectations of self-management.[84] These concerns reinforce the need for explicit patient engagement during guideline development.

This study is the first to ask; how do patients conceptualise preferred management of AIWG and how can this be realised in practice? Qualitative research methods are particularly helpful in ascertaining patient values and preferences for treatment interventions, whilst also acquiring evidence addressing other key guideline decision-making criteria.[80] The WHO recently reinforced the importance of considering qualitative evidence during guideline development to ensure the views, needs and preferences of people with lived experience are considered during recommendation development and in designing implementation processes.[80]

6.2.1 Aims and objectives

Figure 13 outlines study aims and objectives. Exploring prior AIWG management experiences can inform assessments of feasibility of varying management interventions and implementation processes within real-world contexts. This includes the impact of wider social, contextual, and personal factors on effective implementation of recommended AIWG management interventions.

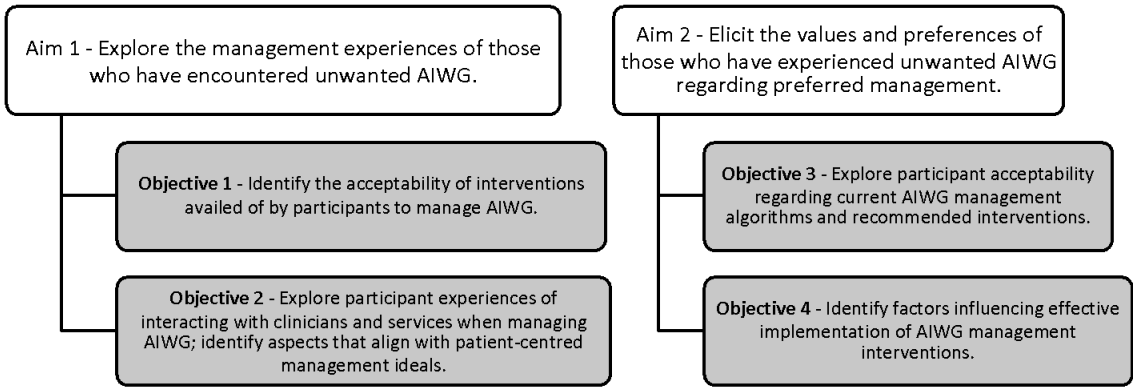


Figure 13 - Overview of study aims and objectives.

6.3 Methods

The consolidated criteria for reporting qualitative health research checklist (COREQ) informed research reporting.[344] A completed copy is contained within appendix 11.

6.3.1 Study design and setting

Qualitative descriptive methodology was chosen as the preferred approach to conducting qualitative research.[141] In qualitative descriptive research, the goal of applying the methodology is to provide a rich description of the experience of the phenomenon under investigation in an easily understood language, rather than to develop a more theoretical or abstract understanding of an experience, as in other considered qualitative approaches, e.g., phenomenology.[139] Within the qualitative descriptive design, the desired outcome is to describe the phenomenon literally as a starting point, and then move beyond the literal description of the data and attempt to interpret findings without moving too far from the literal description. The

approach, therefore, offers the opportunity to gather rich descriptions regarding a phenomenon about which little is known. In healthcare research, a qualitative descriptive study design is typically used for the purposes of learning from participants and using this knowledge to influence policy and practice.[143] Given study aims were not to provide an increasing theoretical, conceptual or highly abstract understanding of the topic, but rather to provide a descriptive summary of the informational content of the data that could be easily understood and implemented by stakeholders, qualitative descriptive methodology was chosen as the most suitable methodology. Philosophical assumptions underpinning the methodology have been discussed within Chapter 3.

All procedures involving patients were approved by St Patrick's Mental Health Services (SPMHS) Research Ethics Committee (Protocol 02/22). A copy of the approval letter is contained in appendix 12. Written informed consent was obtained from each participant prior to study enrolment.

6.3.2 Participant recruitment and sampling

Individuals attending outpatient services of a psychiatric secondary care setting in the Republic of Ireland were eligible for inclusion. Participants were primarily recruited via advertisement, where interested parties were asked to respond to advertisements placed within outpatient clinics. Clinicians within the recruiting centre could also highlight the study to potentially relevant individuals for further discussion with the research team. Purposive sampling guided the sampling strategy, whereby participants with a diversity of experiences of AIWG management and severity of mental illness were recruited to increase credibility and transferability of results. Although recruited through one centre, participants were explicitly asked to reflect on all experiences of managing AIWG to capture varying experiences over time and across settings. Table 26 outlines study inclusion and exclusion criteria.

Table 26 - Study inclusion and exclusion criteria.

Inclusion criteria
- Adults ≥ 18 years of age. - Those with a diagnosis of a severe mental illness (SMI) including bipolar affective disorder, schizophrenia (or other enduring psychotic illness), or major depression and who were prescribed an antipsychotic for any period of time. - Those with experience of unwanted AIWG.
Exclusion criteria
- Those receiving inpatient care. - Cases where weight gain was not primarily due to antipsychotic treatment. - Those prescribed an antipsychotic for an illness other than a SMI.

Concepts arising from data analysis following early interviews drove subsequent participant recruitment to test emerging concepts. Thus, participant sample size was not determined *a priori.* Recruitment cessation was based on the concept of 'data sufficiency' i.e., sufficient data was available to address study aims.[345,346] Data sufficiency was conceptualised as consensus amongst researchers that a sufficiently detailed and rich aggregate account of AIWG management experiences and preferences for management was reached.

6.3.3 Data collection

Data was collected via individual semi-structured interviews. Interviews took place primarily online due to COVID-19 restrictions in place during research planning. Following lifting of restrictions, two interviews took place in person. All interviews were conducted by one researcher (IF), a female senior psychiatric pharmacist working within the recruiting centre. Interviews were audio-recorded only and supplemented with field notes taken during interviews. An interview guide was drafted with reference to existing literature and study aims. The guide was reviewed by individuals within the Service User Advisory Network (SUAN) group in SPMHS who possessed requisite experience of a SMI and AIWG (who were not study

participants). SUAN represents an established network of service users with experience of mental illness who represent the views and opinions of those with lived experience. One role of this group is to provide the perspective of lived experience to local researchers when designing research studies. The interview guide was amended based on the feedback of SUAN members before study commencement and thus, was not piloted. Changes made based on their involvement primarily involve re-wording of questions to enhance clarity among research participants. For example, suggestions from this group involved removing the word 'interventions', and replacing with 'choices' or 'options'. Members of SUAN had no additional role within this study.

The interview guide was also updated iteratively throughout data collection to incorporate questions addressing emerging concepts. The final version of the interview guide is contained in appendix 13. Verbatim transcription of interview audiotapes and redaction of identifying information was undertaken by one researcher (IF). Transcript verification was offered to all participants. Participant sociodemographic data collected included: age, sex, diagnosis, duration of mental illness, living arrangements, employment status, and BMI.

6.3.4 Data analysis

Thematic analysis was conducted according to the principles of Braun and Clarke, specifically their reflexive approach.[347,348] Reflexive thematic analysis involves six phases: (1) familiarisation with data, (2) generating initial codes, (3) generating themes, (4) reviewing potential themes, (5) defining and naming themes, and (6) producing the report. Initially three researchers (IF, EC, LS) double-coded anonymised transcripts independently using NVivo for Mac (Release 1.7.1). Both semantic and latent codes were developed, largely inductively.[348] Subsequently, a codebook was developed and used amongst all members of the research team to discuss emerging findings, develop themes, and discuss additional recruitment needs. Themes were developed separately for each aim for greater clarity in result presentation.

6.3.5 Reflexivity

In keeping with quality standards for rigour in qualitative research, members of the research team engaged consistently with reflexivity throughout the research process, from question development and throughout data analysis. Members of the research team considered their views and opinions on managing AIWG in psychiatry, and obesity more generally, as possible influences on the decisions made in designing and conducting the study and on how the emerging results influenced those views and opinions. Study authors, particularly the researcher conducting the interviews (IF), believed that the management of AIWG required systematic improvements and that the current standard of management likely reflected the views and preferences of clinicians, and the design of psychiatric services, rather than patients tasked with managing AIWG and a SMI.

The research team thus engaged in a series of reflexive processes to ensure that the data collected best represented participant experiences. Aside from working with SUAN in the recruiting centre to ensure questions within the interview guide were patient-centred and free of researcher bias, the research team also undertook the following reflexive processes:

1. Conduct of data analysis was undertaken by multiple members of the research team not involved in interviewing to promote objective assessments of experiences. Several members of the research team did not work in psychiatry, which also promoted objectivity of assessment.
2. Negative cases analysis was conducted.[349] Conflicting information to the themes being developed were proactively looked for by researchers involved in data analysis to explore whether counter or alternative theories explaining the data could be identified. This process also informed additional recruitment activities and/or amendment of questions within the interview guide.
3. Once agreed upon by all researchers, participants were offered the opportunity to member-check themes for accuracy and validity. Final themes were reviewed and updated accordingly.

6.3.6 Ensuring quality within the study design

To ensure a rigorous study was conducted, quality criteria outlined within the framework established by Lincoln and Guba (1985) [350] informed the design, conduct and analysis of this research. Adhering to this 'gold standard' in ensuring rigour in qualitative research includes demonstrating: [350,351]

1. Credibility (i.e., internal validity); the truth in research interpretation, presentation of findings and value of data.
2. Dependability (i.e., reliability); the stability of data over various conditions.
3. Confirmability (i.e., objectivity); the reflection of findings according to participants, and not the researchers.
4. Transferability (i.e., external validity); the extent to which study findings apply in other groups or settings.

An overview of purposeful methods accounted for within the study design to ensure each quality criterion was sufficiently addressed are outlined in Table 27.[350]

Table 27 - Overview of how each quality criterion within Lincoln and Guba's 1985 framework was demonstrated through study design and reporting.[350]

Criterion with Lincoln and Guba quality framework	Methods of demonstrating adherence
1. Credibility	• Applying a methodological approach to conducting qualitative research that is methodologically congruent with study aims and intended outputs. • Prolonged engagement with data analysis. • Member-checking of results. • Diversity of team members involved in data analysis, including those with extensive

	experience in qualitative researchers and those who did not work in psychiatric practice. ● Negative case analysis. ● Primary author conducting interviews engaging in reflexivity.
2. Dependability	● An audit trail was kept in sufficient detail to allow for a theoretical independent person to follow the chain of evidence leading from initial documentation to study findings. ● Primary author conducting interviews engaging in reflexivity.
3. Confirmability	● Investigator triangulation of data i.e., three members of the research team independently conducted data analysis prior to collectively discussing results. ● Keeping of an audit trail (as outlined). ● Primary author conducting interviews engaging in reflexivity.
4. Transferability	● Purposive sampling whereby a purposely diverse group of participants with lived experience of SMI and AIWG were sought. ● Recruitment cessation based on collective agreement of data sufficiency, rather than *a priori* agreement of sample size. ● A thick description of study participants, setting and context in which the study occurred was made available in the research report.

6.4 Results

6.4.1 Participant sociodemographic information

Seventeen participants took part in individual semi-structured interviews, each lasting 45-60 minutes. Participant clinical and sociodemographic information is contained in Table 28.

Table 28 - Summary characteristics of participants.

Characteristic	**Summary**			
% Female	76%			
Age in years Mean (range)	51.5 (26 - 66)			
Body Mass Index (BMI) Mean (range)	31.2 (22.5 - 40.6)			
Employment status	Employed	Unemployed/ State support		
	65%	35%		
Living arrangements	With family (independent of family of origin)	With family of origin	Alone	
	76%	18%	6%	
Primary diagnosis	Schizophrenia or associated subtype	Bipolar affective disorder	Major depression	
	24%	35%	41%	
Duration of mental illness	<1 year	1-5 years	5-10 years	>10 years

6.4.2 Aim 1 – To explore the management experiences of those who have encountered unwanted AIWG

An overview of themes developed explaining participant experiences of managing unwanted AIWG can be found in Figure 14.

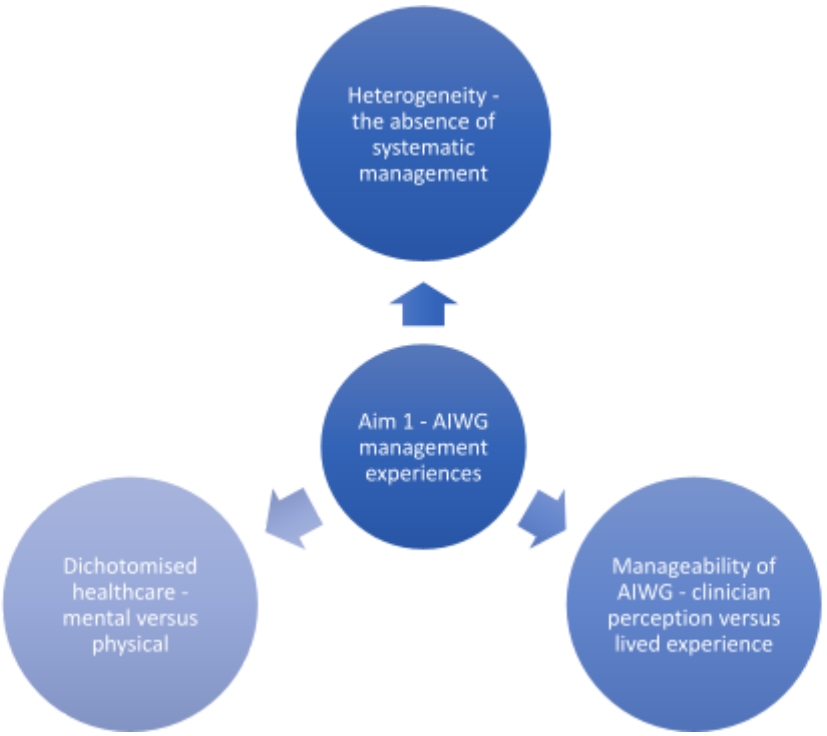


Figure 14 - Thematic map of the identified themes relating to AIWG management experiences.

6.4.2.1 - Heterogeneity - the absence of systematic management

Significant heterogeneity in experiences of AIWG management was apparent at the level of the individual (e.g., responsiveness to intervention), clinician (e.g., experience of a collaborative management), and psychiatric service (e.g., participant access to exercise interventions). A systematic approach to management appeared largely absent, with participant reports of experiences ranging from minimal support to shared management between psychiatric and endocrinology services. Weight gain secondary to antipsychotic treatment not being systematically seen as the responsibility of psychiatric services to collaboratively manage was identified as a significant source of heterogeneity. Participants across varying settings reported a

prevailing narrative that the burden of responsibility of AIWG management was left with them to navigate, often unsupported.

P16 – "*There was just a complete emphasis on personal responsibility and very little appreciation from staff of what you were dealing with, because maybe they had never had that experience of having those intense cravings. With several different doctors, never once was anything other than diet and lifestyle recommended".*

Absence of collaborative management responsibility was also perceived by participants through the absence of preparative information on antipsychotic weight gain liability and proactive management methods, continued clinician recommendations to implement self-led behavioural interventions, independent of success of prior trials, and clinician reluctance to intensify management.

P6 – "*A lot of the answers that were being offered, well go away and try this yourself and you know, if you try this yourself, come back to us, sure some people don't gain the weight at all, or that's a pity you just happen to be in the group that do".*

P7 – "*I haven't been given any advice, whether it's alternative medication, or training, or anything like that…I'm left to row my own boat".*

Whilst a largely self-led management approach was acceptable amongst participants with comparatively minor weight increases, this approach led most to feel that failure to effectively manage AIWG was within their control.

P13 – "I always felt like a bit of a failure really and having to apologize and justify my weight gain".

Beyond minor weight increases, participants reported that behavioural changes alone were insufficient to manage AIWG. Where pharmacological adjuncts were available, participants with experiences of moderate or severe AIWG reported finding these interventions as more helpful than lifestyle modifications alone.

P11 – *"I would not have been able to lose that weight on my own…it would have taken years to lose what I've lost with Ozempic®".*

Participants reported use of metformin specifically was helpful in plateauing continuing AIWG and in reducing food cravings, both of which were valuable outcomes to participants in addition to weight reversal.

P5 – "*I think the metformin obviously helps because I don't have that urge to come in and eat lots of stuff".*

P11 – "*It [metformin] didn't really have a massive effect, but it keeps things stable…it does play a role in weight management in terms of antipsychotics. It's better for prevention more than an actual therapy to reverse".*

However, participants with experiences of severe AIWG reported that changing to a lower-risk or stopping antipsychotic treatment had the most significant impact upon AIWG manageability, including effectiveness of behavioural changes.

P14 – *"They switched the olanzapine to Seroquel® and although it's not perfect, it's much, much better, much less weight gain…for somebody who would be on olanzapine, that [lifestyle] course would be inappropriate because you wouldn't be able to get out of it what you needed".*

Many participants described being unaware of the option of changing antipsychotic or use of pharmacological adjuncts to manage AIWG.

P3 – *"You saying those three things, the diet and lifestyle, switching to another medication, or trying an add-on, I was not aware that that existed. I didn't even know that there were alternatives to quetiapine".*

Participants with experiences of different psychiatric services reported access to intensified management was dependent upon care being provided by clinicians or teams who adopted a holistic approach.

P6 – *"Now I'm under the care of [service] and they reviewed my medication, and the team did listen to me about the weight gain being a factor and part of my unwellness and they swapped the olanzapine for quetiapine to try and change that".*

Amongst those with experiences of collaborative management, engagement with multi- and inter-disciplinary clinicians experienced in AIWG management was identified as particularly valuable.

P5 - "*It was great when I was able to speak with a pharmacist and I felt, I think I have a voice now, somebody can hear what I'm concerned about".*

P13 – "*There's no judgment, I just feel able to relax around [endocrinologist] and just be honest and open about how I feel…I kind of hang on to that, really valuable".*

In cases of positive experiences of managing AIWG, aspects of management approaches reported as effective and preferable are summarised in Figure 15.



Figure 15 - Participant descriptions of aspects of effective AIWG management interventions.

6.4.2.2 - Manageability of AIWG - clinician perception versus lived experience

All participants spoke about the uniqueness of managing weight gain induced by antipsychotic treatment, including intensity of food cravings and loss of appetite control. Table 29 gives an overview of participants' experiences of managing

antipsychotic-induced appetite increases in cases of both mild (P5, P9) and severe (P1, P13) AIWG.

Table 29 - Descriptions of experiences of weight gain and appetite increases secondary to antipsychotic treatment.

Participant 1	*"It's a hunger you just can't do anything about, you know, food doesn't, food doesn't satisfy it. So, it's insatiable, you just can't. I couldn't find way really, any other way really other than be hungry. I could eat twice the amount of dinner and you're still as hungry as when you started".*
Participant 5	*"Often at night when I was going to bed, I was sneaking in food to the bedroom, which I never did in my life before and it was like, I kept saying "what is going on here?".*
Participant 9	"*I mean you are out of control in your thoughts when you're psychotic but then you're given this drug that taints these thoughts, but then your physical self is out of control because you're just filling that need within you [to eat]".*
Participant 13	*"Zyprexa® seems to just make me balloon out…I just couldn't get enough of the food; I just couldn't get enough. I was just completely out of control, there was no satiety. There was no, I just couldn't get enough. It was fatty foods; it was carbs and as much as possible".*

Participants described a disconnect between what they perceived to be the clinicians' perception of their ability to manage AIWG through self-intervention, and their experience of AIWG management without additional clinician intervention.

P6 – *"You're trying to get across, I'm really trying my best here you know, but feeling that maybe they didn't think you were making enough of an effort".*

P16 – "*There was the sense that this was simple if you only follow this certain number of steps. The problem is that those steps, in the context in which people find themselves, can be incredibly difficult, if not impossible, to follow".*

Many participants described difficulties in implementing behavioural changes due to contextual factors, including antipsychotic side-effects, fluctuating psychological health and physical consequences of AIWG. Participants reported the impact of these variables was frequently unaccounted for in management advice received.

P2 – "…*people say shake it off and try and go out and get a bit of exercise, but when I was up at the weight I was, it was 95kg I went up to, that's 49kg up to 95kg. I found it hard to go out walking for exercise because physically my knees couldn't take it because of my body weight".*

Amongst participants with experiences of being on low-, medium- or high-risk antipsychotics relating to risk of AIWG, an absence of differentiated clinician advice was reported. This contrasted starkly with participant experience of manageability when prescribed different antipsychotics.

P16 – "*When you're not on these drugs or when you're on less of them, or when you're on ones that don't have quite that effect, you're just simply not as hungry. Your appetite isn't as intense. I don't know if I would be able to do all those things [lifestyle changes] as well or stay at a healthy weight if I was on a larger dose, if I was on the medicines that I was on when I gained a lot of weight."*

The difference between clinician's perception and participant experience of AIWG manageability potentially contributed to difficulties participants encountered in accessing management interventions requiring clinician collaboration, including changing antipsychotic and accessing pharmacological adjuncts.

P4 – "*Even my own doctor when I said to him about this injection [semaglutide]…he knew everything I'd been through, why is he making me wait when he knows this is going to be an issue?".*

P16 – *"Is there still something of a stigma as in why that's [pharmacological adjuncts] the absolute last resort, is it because of the potential side-effects or is it because we feel that people should be handling this themselves?".*

Continual clinician recommendations to implement self-led behavioural changes could worsen participant sense of isolation, internalised stigma, and reduce likelihood of future help-seeking due to anticipated stigmatising interactions.

P10 – "*…it leaves me feeling kind of isolated as well because how it looks is that I am not making an effort to improve my position and then I don't want to see people and be judged for it…being overweight and having mental health issues, I just don't want to be perceived as lazy".*

Where participants perceived clinicians displayed an understanding of the unique challenges of managing weight gain induced by antipsychotic treatment, participants reported reduced psychological distress.

P6 – "*To hear from a professional that actually this is really hard, this can happen, it has happened in your case, there are things you can do to lessen it, but you may always have a bit of a battle on your hands…just to take some of the shame away".*

6.4.2.3 - Mental versus physical healthcare – a false dichotomy

Dichotomisation of physical and mental health care within psychiatric services was an additional barrier participants described in accessing AIWG management support. Many participants reported clinicians minimised concerns about AIWG liability or occurrence.

P3 – "*Any time I brought it up…it would be kind of invalidated in that like, don't be so silly, look at how well you're doing, don't be worrying about gaining a few pounds".*

Some participants reported perceiving there to be, or explicitly being presented with, a choice between physical and mental health when discussing the impact of AIWG on them with clinicians, particularly when requesting a change in antipsychotic.

P11 – "My experience over the 12 years was there's your medications, take them and be happy. The whole 'would you rather be skinny and unstable or overweight and stable' and you're just like, come on!"

Participants described a bidirectional relationship between their physical and mental health and the impact that unmanageable AIWG could have on their recovery from mental illness.

P4 – "OK, my mental health is bad, but this [weight gain] is a mental health problem too…it's a huge thing for me".

Many participants described self-reducing or stopping antipsychotic treatment to reverse AIWG.

P10 - "I came off that [olanzapine], I was having a hard time managing my mental health, but I'd lost a lot of the weight, and it was kind of down to…yeah, I, I stopped it".

6.4.3 - Aim 2: To elicit the values and preferences of those who have experienced unwanted AIWG regarding preferred management.

Figure 16 provides an overview of the four themes of patient-centred AIWG management described by participants.

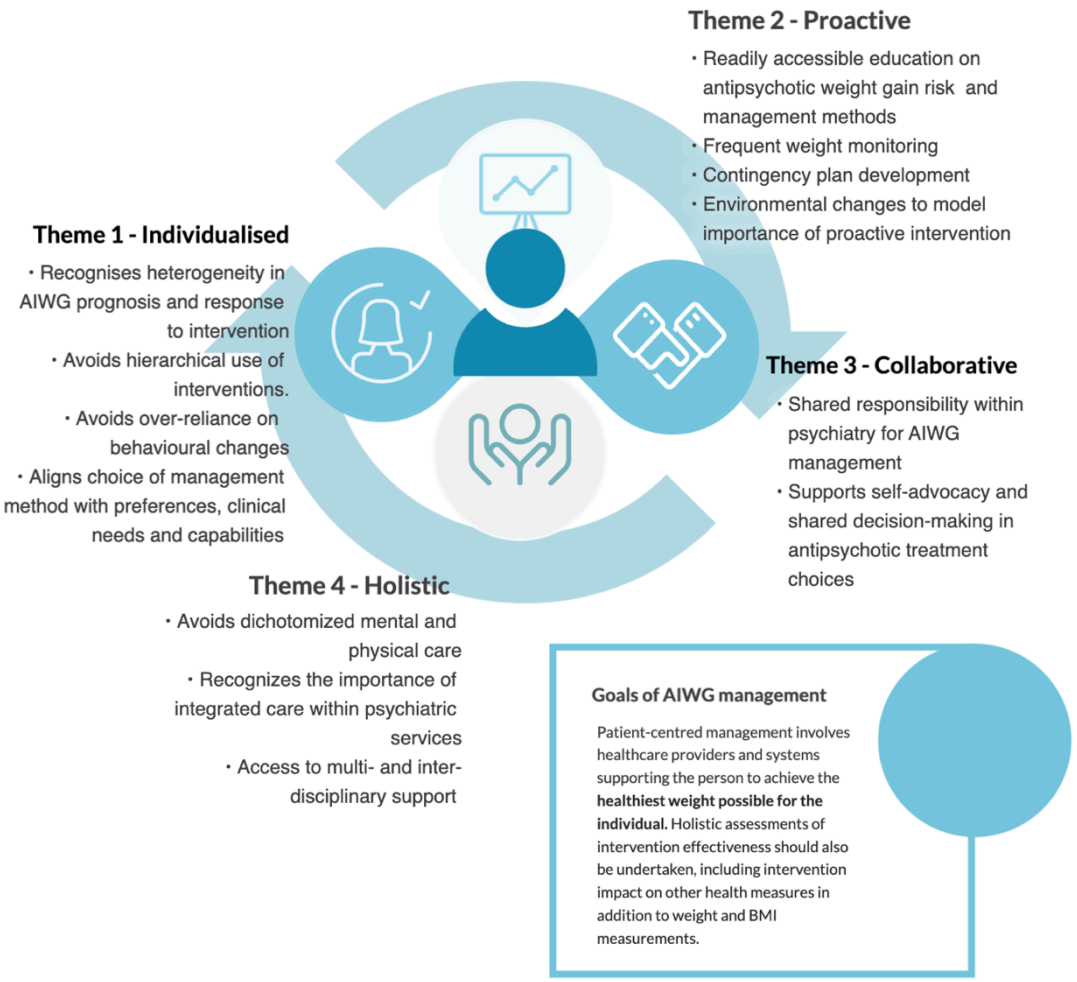


Figure 16 - Participant view of pillars encompassing improved AIWG management practices.

6.4.3.1 – Individualised management

Participants were presented with the current stepwise AIWG management approach, beginning with behavioural/dietary and exercise interventions as the standard management intervention, followed by consideration of changing antipsychotic and subsequent use of pharmacological adjuncts e.g., metformin, if preceding options are ineffective.[46] Participants reported recommendation of

behavioural interventions as a uniform first-line intervention oversimplified the complexity of managing AIWG.

P14 – *"It's easy enough to say you need to lose weight, try diet and lifestyle, but you're saying that at a time when a person is at a low…it has to be very structured and what sick person is going to be able to do that?".*

Participants collectively spoke of patient-centred management requiring a more individualised approach.

P9 – *"You could talk about all the different options and then together with the patient decide what's the best for them, rather than the robotic steps, so to make it a more individual approach".*

Individualised management included avoidance of uniform treatment pathways endorsing hierarchical intervention use. One repeated argument against this management approach was heterogeneity in AIWG prognosis and response to intervention.

P16 - "*If somebody comes and they've gained three or four stone over the course of a year, that would seem to be a much different issue than if somebody had gained a few pounds. The same answer shouldn't be the case".*

Those with a personal history of obesity were particularly concerned about recommendations supporting hierarchical intervention use and the assumption that all management interventions are equally applicable to presenting individuals.

P1- *"I wouldn't really think that option 1 [diet and lifestyle] alone will work in practice. It might work for a week but it's not sustainable, particularly if you are big to begin with, I can certainly put on a stone in a week".*

Disagreement with uniform recommendation of behavioural changes as first-line management was also present amongst participants who were severely unwell at antipsychotic initiation.

P6 – "*If you were dealing with psychosis, if somebody has been very ill, they may not be able to make diet and lifestyle changes. In their case the tailoring may involve more preventative use of metformin because they just may not be in that position to make those decisions for themselves that really require being very proactive at a time when you are recovering".*

Other participants expressed concern that recommendations endorsing 'diet and lifestyle' interventions lacked specificity and reinforced their perception that management was primarily their responsibility.

P13 – "*You can feel totally dismissed if someone says, "Oh, diet and exercise", you just end up going, OK, here we go again. Someone that doesn't give you direct, specific, measurable and achievable advice…you just feel like you are getting fobbed off again".*

P16 – "*Option one [diet and lifestyle] is a fob-off, definitely…you feel like a fly and the person is trying to swat you away. What does this mean, diet and lifestyle, what should a person's first step be?".*

Participants who preferred initial use of behavioural interventions recommended these be structured interventions and resourced within psychiatric services and that their initial use should be agreed collaboratively, following due consideration of alternative management options.

P3 – "*It's getting some support on the diet and the lifestyle, but it is more understanding you have options, for me it's that, it's understanding that you have options".*

P16 – *"There could be a structured program in place, things that people can follow…a shared burden in terms of diet and lifestyle".*

Participants expressed a preference for a change of antipsychotic to be explicitly considered with them as a management option given the significant differences they experienced in manageability when prescribed different antipsychotics.

P10 – *"I would probably say switch to lower-risk first and then diet and lifestyle".*

Participants viewed pharmacological adjuncts as relevant and acceptable interventions and requested these be offered earlier than currently endorsed.

Interviewer – "*Do you think we should be offering other options like metformin earlier in treatment or not?".*

P4 – *"100%. That would be like if you had cancer, the chemotherapy or radiation or whatever is making you sick, there is immediately an anti-sickness drug…it's not something you wait to be told about".*

P15 – *"Well, that would be the option I would want because then I'd know I'm sticking with the medication that's working and trying to help with the cravings".*

Many participants, particularly those with experiences of AIWG secondary to high-risk antipsychotics and those with a personal obesity history, expressed a preference for preventative use of pharmacological adjuncts.

P5 – *"If it's a known drug for weight gain, it [metformin] should be offered at the beginning…rather than wait six months down the road and then somebody feeling awful about the drug and deciding they want to come off it".*

6.4.3.2 – Proactive management of AIWG

Participants cited proactively addressing AIWG as crucial to effective management and highlighted that recommendations addressing prevention and early intervention are largely missing from current guidance. Contingency planning was one suggestion to operationalise proactive management.

P6 – "*Where are the contingency plans so when it happens, as is often the case, it's not an if, it's a when it happens…that word proactive is what's really the key".*

Use of markers or thresholds to prompt early consideration of intensified management by clinicians and psychiatric services was also suggested.

P6 – "If somebody's BMI has radically increased maybe there should be some marker that identifies that person as somebody that the health service gets involved with quicker".

Participants wanted to be supported in being proactive and highlighted that information and education on AIWG risk is important in informing preparedness for management.

P15 – *"I didn't realize that the medication I was on could cause weight gain…. if I had been educated a little bit more about what my medication side effects were, I would have been able to handle it a bit better. I probably would have considered my diet and lifestyle a bit better".*

Information on AIWG risk and management interventions being accessible and readily available was also highlighted consistently.

P8 – "*Definitely more education on the management options, I think the earlier in the process the better".*

Accessible information was also described as important in reducing potential power asymmetry in discussions between patients and clinicians, which could be worsened by experiences of overweight and obesity.

P4 – *"Knowledge is powerful…if you have the background, it makes you feel like you're being listened to, and you're being recognized".*

Participants also spoke of the importance of services and environments modelling the importance of proactive weight management.

P17 – *"It highlights for you the importance of your own management of the situation and the fact that there is something to be cognizant of, something to be aware of".*

6.4.3.3 Collaborative management

Participants reported an expectation that psychiatric clinicians should be involved in AIWG management and reported that for management to be effective, it needs to be seen as collaborative. This includes being initiated within services where antipsychotics are prescribed.

P6 – "*I think they have a shared responsibility…I think it can't be entirely on them [psychiatrists], but they have expertise and with that comes an authority and a responsibility that the patient doesn't have…if it was seen as such it would be less easy to dismiss concerns".*

A fundamental aspect of collaborative AIWG management endorsed by participants was shared decision-making in choice of antipsychotic treatment, particularly the choice to continue the causative antipsychotic. This should include explicit engagement with patients' assessment of the risks of continued AIWG versus risks of changing antipsychotic.

P15 – "*When I started to notice the weight gain, I was well enough to try another medication".*

P17 – "I would have changed from Seroquel® completely if I had known there was an alternative".

6.4.3.4 – Holistic service provision

Participants described the importance of a holistic approach to care within psychiatric settings. This included integrated care models addressing physical and mental health needs given the burden of risk factors they faced for living with overweight or obesity.

P6 - That dichotomy of, this is the psychiatric services and then you go over here for the physical services, if it's more integrated from the get-go I just think you wouldn't feel abandoned and there would be a much greater chance of you staying compliant with the medication which is for the psychiatric side of things and your well-being in general would be better".

Integrated care would also allow for more prompt access to clinicians experienced in weight management in acute care settings to align with participant preferences for AIWG management.

P8 – "*Earlier in the process to actually engage with the dietician and get advice to guide you in the hospital, because I was kind of working that out myself".*

Where participants had experiences of individualised behavioural interventions being provided by experienced clinicians, their acceptability increased.

P13 – "*…referred me to a dietician along the line and that was terrific, as that was really specific and helpful advice from someone who knows, that's their whole area of expertise".*

Participants also requested longitudinal weight management supports within psychiatric services.

P1 – "*I think the big difference would be to formally have some kind of continuation of the supports that work. So, maybe a check in after 3 months and a check in after 6 months".*

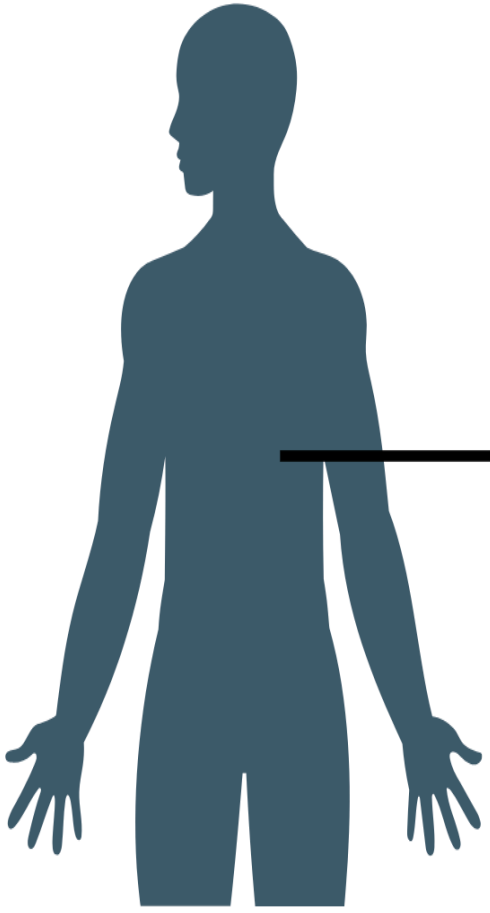
Amongst those with experiences of severe AIWG, integration of endocrinology services into psychiatry settings was suggested to improve access to intensified supports, including anti-obesity medications and psychological support.

P6 – "*Going to the endocrinologist and being listened to and being started on the drug [semaglutide] and even having the empathy of the endocrinologist who kind of, not kind of, but did understand how difficult it is to lose this weight, which was really reassuring. They understood that obesity is a lot more difficult to beat than sometimes the GP or the psychiatrist".*

Participants also expressed a preference for assessment of management effectiveness to look beyond weight measurement alone and towards holistic assessments of health.

P16 – "*Should our aim really be to maximize a person's well-being, their mental and physical well-being and to what extent can that be done in a way that allows people to be different shapes and sizes while being still healthy".*

An overview of changes suggested by participants in management guidance, alongside cultural and structural within services to support implementation of patient-centred AIWG management, are contained in Figure 17.



Guideline recommendations

Avoidance of hierarchical use of interventions
- Individualised management plan considering:
  - Personal risk of obesity (e.g., personal history, prescribed high-risk antipsychotic)
  - Treatment of varying degrees of AIWG
  - Physical and mental health status and capacity
- Reduce over-reliance on behavioural interventions
- Earlier consideration of pharmacological adjuncts

Increase scope of current recommendations
- Increased focus on prevention and early intervention
- Thresholds for considering intensifying management, including speed of early weight gain
- Comprehensive assessment of intervention effects (beyond BMI reductions alone), including patient-important outcomes
- Greater specificity regarding:
  - Effective behavioural interventions
  - Range of pharmacological adjuncts
  - Alternative lower risk psychotropics

Interactions with healthcare providers

- Collaborative approach to management
- Recognise heterogeneity in AIWG prognosis and responsiveness to intervention
- Recognise the wider impact of AIWG (psychological, social)
- Shared risk-taking approach to changing antipsychotic to manage AIWG

Cultural and structural changes

Cultural changes
- Increased shared decision-making in antipsychotic treatment choice, including initial and continued treatment
- Increased focus on holistic care in psychiatric settings

Structural changes
- Increased access to patient information on:
  - AIWG risk and prognosis
  - Range of effective management interventions
- Ease of access to integrated physical health care services in psychiatry
- AIWG management by experienced multi- and inter-disciplinary clinicians

6.5 Discussion

This study is the first to explore several key decision-making criteria relevant to the development of high-quality AIWG management guidance amongst a purposely diverse lived experience group. Feedback was sought regarding the relevance and scope of current AIWG management guidance,[43,46] alongside contextual factors that may help or hinder recommendation implementation. Acceptability and feasibility of management interventions and practices across a range of contexts was elicited. As in general weight management,[60] heterogeneity in responsiveness of AIWG to any intervention was reported by participants. Despite availability of varying management interventions, participants were unaware of, or encountered difficulties accessing, these interventions. Participants reported clinicians largely overestimated the manageability of AIWG through behavioural changes and underestimated the physical and psychological impacts of AIWG. In cases of positive management experiences, these were largely attributed to proactive clinicians which afforded participants access to collaborative and holistic care. Thus, an absence of a systematic and equitable approach to AIWG management was observed within this study. Collectively, these experiences reinforce the need for more effective AIWG management guidance and implementation supports.

6.5.1 Current AIWG management guidance – what works and what is missing?

Participants reported current guidance is oversimplified, lacks the specificity and scope required, and endorses a homogenous management approach to an extensively heterogenous side-effect, both in presentation and manageability. Significant changes in AIWG management guidance were called for by participants due to lack of applicability and transferability across individuals and contexts. Suggested changes include expansion of recommendation scope to address prevention and early intervention, and assessment of intervention effectiveness to align with patient-important outcomes. Participants emphasised that AIWG is a unique cause of weight gain, often in unique contextual circumstances. Thus, its management requires an equally distinctive approach.

Improved recommendations in AIWG management recognise diversity amongst individuals in the initial risk and subsequent trajectory of AIWG and allow for intervention use to be tailored towards risk of overweight or obesity, individual physical and mental health capabilities, and each individual's treatment preferences. Thus, uniform and hierarchical treatment algorithms were strongly disagreed with across participants. Participants expressed a preference for all management options to be considered collaboratively, ideally early in the experience of AIWG, and as part of contingency planning when prescribing medium- or high-risk antipsychotics. Those at high-risk of AIWG generally expressed a preference for more intensive early intervention.

6.5.1.1 Behavioural/dietary and lifestyle changes

Participants largely disagreed with endorsement of uniform recommendation of behavioural changes as first-line AIWG management. Barriers to implementation included the impact of mental illness and antipsychotic treatment on motivation, cognition and capacity, intensity of food cravings and speed of AIWG in at-risk individuals. Lack of resources within psychiatric services to support implementation, and experiences of differential efficacy when used alongside high- versus low-risk antipsychotics, were also barriers to uniform endorsement. In line with results of interventional research demonstrating wide-ranging, and often statistically and clinically insignificant, effect sizes associated with many dietary and lifestyle interventions,[63] participants reported, with exception, much of their attempts to manage AIWG with dietary and lifestyle interventions were ineffective. Thus, participants expressed a preference for guideline recommendations regarding dietary and lifestyle changes to be reflective of the evidence base specific to AIWG management. This includes outlining interventions associated with the largest effect sizes, those deemed ineffective, and their comparative efficacy relative to other recommended interventions.[68,69]

Avoidance of erroneous recommendations of population-level weight management advice and continued recommendations to implement non-specific, or previously ineffective behavioural changes, were highlighted as important given the potential

impact on internalised weight stigma. Strategies to support patients in effectively implementing behavioural interventions were provided and included longitudinal provision within psychiatric services and involvement of peer-support networks.

6.5.1.2 Pharmacological management – switching antipsychotic and pharmacological adjuncts (metformin, topiramate, GLP-1 receptor agonists)

In contrast to its relegated role in current guidance,[46] participants endorsed use of pharmacological adjuncts as highly acceptable interventions. Amongst those at high-risk of obesity - due to treatment or personal history - their preference was for pharmacological adjuncts to be offered as preventative interventions. Participants placed a high value on their use to maintain weight and low resource cost associated with oral adjuncts. Earlier consideration of pharmacological adjuncts was also valuable to participants as it avoided risks associated with changing antipsychotic, namely return, or worsening of, symptoms of mental illness.

Evidence for preventative and treatment roles of pharmacological adjuncts is now increasing and aligning with patient preferences for earlier use.[46] However, participants also valued being informed about the differential risk of weight gain across antipsychotics and the option of switching to manage AIWG, particularly amongst participants prescribed high-risk antipsychotics. Whilst much of the intervention research and subsequent guidance in AIWG management is based on efficacy of interventions to reverse AIWG,[46,63,71] participants suggested novel use of pharmacological adjuncts and assessment of additional outcomes not previously considered, including reduction in food cravings and weight stabilisation.

6.5.2 Functional AIWG management guidance

Participants cited patient-centred AIWG management as being proactive, individualised, holistic, and collaborative. Suggestions to support implementation of these tenets included changes in clinician management guidance, but also in clinician education and the model of service delivery in psychiatric settings. Participants discussed the need for greater support in implementing interventions that target individual behaviour change, but also highlighted the multilevel structural determinants that may lead to, and/or perpetuate, the absence of patient-centred AIWG management in psychiatric settings. This included (i) stigmatizing attitudes amongst clinicians regarding participant's motivation to manage AIWG, (ii) the lack of accessible patient information to inform collaborative decisions about antipsychotic treatment choices and availability of anti-obesity medications, and (iii) the absence of integrated physical health care services within psychiatric settings to support holistic care and early intervention. Participants requested greater clinician education regarding the uniqueness of weight gain induced by antipsychotic treatment, specifically interference with homeostatic mechanisms mediating appetite control and the heterogenous nature of its severity.[37,38,39]

Given its impact on AIWG prognosis,[24] participants described collaborative decision-making in antipsychotic treatment choices as being a fundamental aspect of managing AIWG. The decision to change antipsychotic involves consideration of risk by both prescribers and patients. Participants described weighting of risks differently to that of their treating clinician. As discussed in chapter 5, given their professional training and the role of other structural contexts, including legislative and regulatory frameworks in informing design of services and clinician behaviours, prescribers may prioritise minimising relapse risk and thus, be less likely to offer a change in antipsychotic to manage AIWG. However, most participants in this study associated continuing a weight-gaining antipsychotic with greater personal risk, and subsequently often stopped or reduced their own antipsychotic treatment to reduce AIWG. Participants expressed a preference for a shared risk-taking approach to decisions to change or continue choice of antipsychotic treatment and described

the need for cultural and structural changes in mental health services to support their active engagement in treatment decisions.

Participants valued accessing multi- and inter-disciplinary clinicians when managing AIWG, particularly in managing excess weight resulting in obesity. Access to obesity management clinicians has previously been identified as a facilitator of greater ownership of obesity management within psychiatry.[6,352] Co-produced guidance between psychiatric and endocrinology professions is one novel way to initially address this need, given the current absence of integrated care models in psychiatry.[43] Co-produced guidance would also facilitate integration of new paradigms and practices within weight management in general obesity management into psychiatric practice. This includes person-centred management guidance,[57] and addressing the neurobiological underpinnings of obesity within management strategies.[353]

6.6 Limitations

Despite intentional recruitment efforts, there is less male than female representation among participants within this study. Results may thus be less reflective of male AIWG management experiences and preferences, although I am somewhat reassured by the fact that sex has not been demonstrated to meaningfully impact AIWG risk and trajectory, as seen in chapter 4.[67] However, it is feasible that males and females experience the psychological impacts of AIWG differently. Given the single recruitment site located in the Republic of Ireland, the opportunity to include a culturally diverse participant group was not present, which may limit transferability of results. Five participants were professionally known to the researcher conducting interviews. Whilst extensive efforts were made to reduce its impact, this familiarity may have influenced these participants' responses.

Sociodemographic characteristics that were collected were informed by prioritisation of likely influences on AIWG management practices, including diagnosis, length of treatment and employment status. However, there may have

been other characteristics that were not collected that may also exert influence on the management preferences of those living with a SMI and experiencing AIWG. For example, education level or family history of obesity. Finally, whilst participants with lived experience were involved in study planning, they had no role in data analysis, apart from verifying the accuracy and validity of anonymised, redacted transcripts. Efforts to address this and ensure credibility of study results included offering all participants the opportunity to member-check emerging themes before theme finalisation. However, involvement of a lived experience researcher during data analysis may have contributed important and additional insights not reflected within the analysis presented here.

6.7 Conclusion

Conceptualisation of patient-centred AIWG management by research participants contrasted significantly with the approach endorsed within current management algorithms. Participants reported existing guidance is oversimplified, lacks the specificity and scope required, and endorses a 'one-size-fits-all' management approach to an extensively heterogenous side-effect, both in presentation and in manageability. Management algorithms that prioritise dietary and lifestyle interventions and endorse restricted access to pharmacological adjuncts reflect neither empirical evidence nor patient preference. Prioritisation of largely self-led lifestyle interventions can also inadvertently contribute to internalised weight bias amongst individuals experiencing AIWG by framing management as primarily an individual responsibility. Participants expressed a preference for collaborative AIWG management guidance that prioritises early intervention using the range of evidence-based management interventions, tailored according to AIWG risk, individual ability and preference.

Use of this research in guideline development will ensure recommendations are relevant and applicable and will provide opportunities to maximise the impact of recommendations in practice for those providing and funding psychiatric services. Participants reported clinicians overestimate AIWG manageability using dietary and

lifestyle changes and reported barriers to accessing endorsed alternative management interventions. This included either a change in antipsychotic and/or prescriptions for pharmacological adjuncts. Thus, aside from improved guidance informed by lived experience, extensive efforts to improve uptake of evidence-based, patient-centred AIWG management recommendations among psychiatric clinicians will be required. This should include efforts to address both explicit and implicit sources of weight bias amongst healthcare providers.

Chapter 7 – Discussion

7.1 Chapter description

A summary of key research findings produced within this thesis is provided here. Focus is given to the novelty of findings and their interpretation in the context of available research within AIWG management and the implementation of shared decision-making among individuals with psychosis. The strengths and limitations of the research conducted are also provided. Finally, the implications of research findings for mental health policy, clinical practice, and future research, are outlined.

7.2 Key findings

The overarching aim of this thesis was to address three research questions:

1. Can weight outcomes following antipsychotic initiation be predicted using non-genetic prognostic factors, and used to inform targeted use of management interventions?
2. How can shared decision-making be implemented within antipsychotic prescribing decisions, such that the burden of excess prescribing of medications with a high cardiometabolic burden can be reduced?
3. How is patient-centred management of AIWG conceptualised by those with lived experience of AIWG and SMI, and how does this compare to that contained within currently available management guidance?

The first research question was addressed within chapter 4. Results of several primary studies had suggested that various non-genetic prognostic factors influenced the prognosis of AIWG.[159,160,161] This had subsequently led to influential psychiatric resources, including *The Maudsley Guidelines*,[30] to suggest that some sociodemographic variables, including sex, be considered by clinicians when predicting individual risk of AIWG. However, in the absence of a systematic collation and quality appraisal of this research, the clinical value of non-genetic prognostic factors in influencing the prognosis of AIWG was not known. Thus, whether the current state of non-genetic prognostic factor research could be used to direct AIWG management was unclear. The systematic review conducted represented the

first overall mapping and statistical synthesis of studies examining non-genetic prognostic factors associated with AIWG prognosis and resulted in various recommendations for practice, policy, and future research.

Seventy-eight non-genetic prognostic factors were assessed across 29 studies involving 4,706 participants. Despite the extent of prognostic factor-outcome associations appraised within the review, a key conclusion was that current evidence is not of sufficient quality to support the use of any non-genetic prognostic factor, measured *prior to* antipsychotic initiation, in guiding risk-stratified AIWG management. Defects in study design, conduct, analysis and reporting limited conclusions that could be drawn in the case of the majority of prognostic factor-outcome assessments. Thus, the review did not identify conclusive evidence that commonly-thought prognostic factors including age, sex, or baseline BMI, influence AIWG prognosis to a clinically significant extent. However, *after* antipsychotic initiation, review results identified early BMI trend change as providing strong prognostic information regarding AIWG prognosis at clinically relevant timepoints, including at 12 months antipsychotic treatment. Those who gain the most weight within the first weeks and months of antipsychotic treatment have a worse long-term prognosis, when compared to those with a slower initial trajectory of weight gain.

A key recommendation stemming from review results was that research supporting the prognostic value of BMI trend change within the initial 12 weeks of antipsychotic treatment was of sufficient quality to guide novel, risk-stratified AIWG management. This should include prioritising intensified management to those with the greatest initial weight changes. To guide ease of application in clinical practice, the definition of clinically significant weight gain was included alongside this recommendation (most commonly defined as a ≥5-7% increase in baseline body weight),[25] such that those who experience this extent of weight gain within the first 12 weeks of treatment should be prioritised for switching to a lower-risk antipsychotic, or addition of weight-mitigating pharmacological adjuncts, particularly metformin.[63] Even in the absence of evidence of differential

intervention efficacy among those with varying initial weight change trajectories, those with the greatest weight increases following antipsychotic initiation are likely to derive the largest absolute benefits from average effect sizes associated with intervention strategies.[63,154]

Prognostic factors deserving of prioritization within future confirmatory studies were highlighted within the review's implications for future research. This included the impact of unemployment on increasing the risk of experiencing clinically significant weight gain post antipsychotic initiation, and the requirement for future research to confirm the non-significant findings relating to sex and baseline BMI on AIWG prognosis. Specific methodological and reporting improvements required to establish evidence-based prognostic factor-outcome assessments were also provided. This included recommending future studies adhere to methodological standards available for prognostic factor research,[154,204] whilst also recommending evaluation of prognostic factors and outcomes in a similar fashion to those reported within this review to facilitate meaningful comparison and expansion of the meta-analyses conducted. A requirement for assessment of non-linear relationships between prognostic factors and anthropometric outcomes, alongside a lack of research on potential prognostic factors operating at broader contextual and ecological levels, e.g., area-level social deprivation and healthcare access, were also emphasized within the review's future research recommendations.

An indirect, but key finding of this review, was that despite extensive research to identify additional prognostic factors, the choice of antipsychotic prescribed remains the most significant baseline variable influencing AIWG prognosis.[24] The resultant recommendation for clinical practice and guideline development was that significant differences in the propensity to cause clinically significant AIWG should be accounted for within AIWG management guidance, including in differentiating management pathways among those prescribed high- versus low-risk antipsychotics.[24] Whilst consideration of the antipsychotic prescribed in differentiating AIWG management pathways is a novel recommendation within AIWG management guidance, the prognostic value of prescribing low- versus

high-risk antipsychotics in influencing AIWG prognosis was already reflected within some psychosis management guidelines.

Psychosis and schizophrenia management guidance produced by the Schizophrenia Patient Outcomes Research Team (PORT),[354] Harvard,[355] and the Royal Australian and New Zealand College of Psychiatrists (RANZCP),[356] specifically recommend against using olanzapine as an initial choice of antipsychotic due to its high propensity to induce cardiometabolic side effects, including weight gain, relative to other antipsychotics available. In comparison to significant differences in weight gain risk, efficacy differences between antipsychotics in the treatment of non-treatment resistant schizophrenia are small, and in the majority of cases, lack clinical significance.[24] Other guidelines, including those produced by the American Psychiatric Association (APA),[88] and the National Institute for Health and Care Excellence (NICE),[61] are less prescriptive and instead recommend that choice of antipsychotic should primarily be driven by patient preference for side effects. Weight gain is consistently reported by patients as one of the most distressing side effects of antipsychotic treatment, and is a common reason for non-adherence or reluctance to re-start antipsychotic treatment.[27] As detailed in chapter 1, the WHO's 2018 guidance in managing AIWG recommends that switching psychotropic medication be trialled before other interventions.[46]

Despite such recommendations, diversity within antipsychotic prescribing patterns, aligned to the natural variation in side effect preferences across the diverse range of individuals presenting with psychosis, is not seen. International trends of antipsychotic prescribing patterns within psychosis management consistently demonstrate high prescribing rates of a small number of antipsychotics, and typically those with a considerable burden of cardiometabolic side effects, namely olanzapine.[92,93,94] Thus, a key concern among the research team following completion of the systematic review, was the apparent difficulty within clinical practice in implementing recommendations to optimise antipsychotic prescribing within AIWG management, including reducing initial use of olanzapine and switching to lower-risk antipsychotic medications.[46,355,356] Understanding how to influence clinicians' antipsychotic prescribing behaviours within psychosis

management had not yet been assessed within research internationally. This was the focus of chapter 5, whereby developing knowledge of the influences on prescriber engagement in behaviours required of SDM was addressed within a realist review.

Whilst several prior literature reviews had been undertaken, primarily assessing the efficacy of different interventions in increasing the application of SDM within antipsychotic prescribing,[101,103] this realist review was the first time an implementation science methodology informed the approach to evidence synthesis, and is the most comprehensive review of SDM within psychosis management conducted to date. Adoption of an implementation science methodology was essential in providing an appropriate methodology to study complex behaviour change interventions, such as SDM interventions.[120] Behaviour change interventions are complex interventions,[123] where outcomes are socially contingent, i.e., there is some human reasoning or agency involved in the success or failure of interventions.[120] Furthermore, in psychiatry, SDM interventions are expected to be embedded within existing complex environments, including within systems which have traditionally used paternalistic, clinician-led decision-making, particularly within psychosis management.[96,98,99]

The problem of suboptimal rates of SDM implementation within routine mental health has previously been referred to as "*as much a cultural as a technical problem".*[96] A key driver informing the research conducted relating to SDM was the notion that solutions were being developed to address the problem of suboptimal rates of SDM implementation without having an adequate understanding of what influences clinician's prescribing behaviours,[101,103] not only in increasing their application of SDM, but pivotally, what contexts continue to promote the enduring high rates of clinician-led decision-making.[98,99] It was hypothesized that the neglect of wider structural and contextual factors in the design and implementation of SDM interventions was critical in explaining the lack of standardised use of any intervention within clinical practice.[97,132] This included the impact of meso- (e.g., organisational policies) and macro- (e.g., institutional policies) level contexts on

prescriber behaviours. The novelty of the research questions addressed, and the associated methodology applied, underscores the importance of all realist review findings for clinical practice.

From the realist review, 10 programme theories, including 23 CMOCs, were developed from 106 data sources. Results outlined contexts and associated mechanisms responsible for increasing prescriber engagement in behaviours required of SDM application, and those that encouraged clinician-led decision-making. Whilst understanding contexts responsible for their activation is important, it is the mechanisms responsible for prescriber behaviours that should be the focus of those interested in, or responsible for, increasing application of SDM within psychosis management.[123] Slade previously put forward the argument that SDM implementation within routine mental healthcare could be considered a 'polyvalent concept'; a sociological concept which describes an idea commanding superficial-level agreement and apparent consensus between disparate stakeholders, but which conceals incompatible assumptions and expectations.[96] Realist review findings advanced this idea by explicitly outlining the extent of misalignment between prescriber adoption of behaviours inherent in SDM, including engagement in positive risk-taking and sharing of decision-making responsibility, and the complex cultural, legal, political, and professional realities prominent within mental health settings internationally.

Contexts, and associated mechanisms, identified as reducing prescriber engagement in SDM and increasing the likelihood of clinician-led decision-making included:

1. Mental health legislation and the perceived prioritisation on harm reduction therein creating a fear of exposure to liability in the event of adverse outcomes following their engagement in positive risk-taking.
2. Institutional and organisational cultures of risk-aversion creating fear of individual blame and a perceived lack of trust in prescriber's professional judgement.

3. Cultural and social norms common among clinicians that create a perceived tension between the ethical duties of beneficence and non-maleficence when attempting to increase patient autonomy in decision-making within psychosis management.
4. Inadvertent clinician devaluing of lived experience as a consequence of the prominence of the biomedical model, and its associated focus of symptom reduction and health restoration, within clinician training and professional socialisation.
5. Insufficient resourcing of mental health services creating a focus on crisis management and a resultant pressure on prescribers to prioritise harm reduction over increasing patient autonomy within decision-making.

In contrast, facilitative contexts within the design of local services, and through introduction of purposeful intervention strategies, were also identified. Mechanisms triggered in such contexts, and thus responsible for resultant desirable prescriber behaviours, should be the focus of those interested in designing novel SDM interventions to increase their likelihood of success, and those responsible for translating results of empirically efficacious interventions into real-world settings to ensure evidence-based, facilitative contexts are maintained. Service delivery contexts and intervention strategies that should currently be prioritised for scale-up to increase prescriber engagement in SDM include:

1. Attempting SDM in the context of existing, trusting patient-prescriber relationships; such contexts can increase prescriber engagement in positive risk-taking by providing them with confidence in the appropriateness of increasing patient autonomy within decision-making.
2. Adopting a multidisciplinary team responsibility for SDM implementation within antipsychotic prescribing decisions; a multidisciplinary responsibility for SDM implementation is effective in reducing prescriber fear of sole responsibility for any potential adverse outcomes secondary to engaging in positive risk-taking and reduces prescriber perceived time commitment to implementing SDM.

3. Workforce training and supervision in developing skillsets required of effective SDM application; such training is effective in increasing prescriber confidence in their ability to productively negotiate treatment consultations among people experiencing psychosis.

Despite their popularity within intervention research,[101,103] the inadequacy of the current design of antipsychotic treatment decision aids in encouraging widespread prescriber engagement was the final key finding within the realist review. Although often promoted as a resource-efficient way of operationalising SDM within typically time-limited consultations,[296] this review identified several cognitive barriers among prescribers that decreased their engagement with decision-aids; (i) a perception that decision aid use within psychosis management is reductionist and (ii) their integration within consultations will encourage patient-led decision-making within a perceived critical treatment decision. Patient use of decision aids in such contexts can create a fear among prescribers that they will be deprived of the required influence within treatment decisions to reflect the complexity inherent within effective psychosis management.[24] Thus, the passive integration of antipsychotic treatment decision aids into consultations for the purposes of providing antipsychotic treatment information to clinicians and/or patients is unlikely to achieve widespread uptake within psychosis management.

Review results also outlined the importance of actively developing prescriber trust in information sources influencing their prescribing practices. Thus, another key recommendation specific to the design of antipsychotic treatment decision aids, was the requirement for co-production and incorporation within decision aid design of mechanisms that provide prescribers with the ability to confirm reliability of antipsychotic treatment information. Furthermore, prescribers require flexibility regarding timing of implementation, such that they perceive the tool as supportive, rather than a restriction on their practice.

Finally, in chapter six, patient values and preferences for AIWG management were explored in a qualitative descriptive study among seventeen participants with

experiences of AIWG and mental illness. In considering the research questions to be prioritised within this thesis, the absence of the voice of lived experience within AIWG management guideline development was identified as a major concern. Whilst much qualitative research in the area focusses on the psychological impacts of AIWG,[81] little research had been done in understanding the acceptability and feasibility of AIWG management interventions among people with lived experience. Concerns regarding the potential impacts of inadequate consideration of this lived experience within management guidance was considered in the context of prior research that identified (often internalised) weight bias among healthcare providers in various contexts, and it's influence on weight management recommendations.[83,84,86,87]

As highlighted within a recent Commission on defining and diagnosing clinical obesity in *The Lancet Diabetes and Endocrinology,* strategies to reduce the incidence and prevalence of obesity must be based on scientific evidence, rather than unproven assumptions that assign individual responsibility for the development of obesity.[364] The Commission highlighted that weight-based bias and stigma are major obstacles in efforts to effectively prevent and treat obesity.[357] Of further concern were the experiences of a 'dual stigma' described following interactions with clinicians and healthcare services in research involving those living with obesity and a mental illness.[86] Thus, it was a priority to ascertain patient values and preferences for AIWG management among a purposely diverse lived experience group, and ultimately for this research to be used to amplify the voice of lived experience within AIWG management guidelines. This study was the first to explore several key decision-making criteria relevant to the development of high-quality AIWG management guidance.[66,80] This included ascertaining the feasibility, acceptability, and transferability of recommended AIWG management algorithms and interventions contained therein across various contexts.

Key findings of the study included the contrast between how those with lived experience conceptualise preferred AIWG management versus that which is advocated for within current management guidance.[46] Participants reported that

current guidance is (i) oversimplified, (ii) lacks the specificity and scope required for effectively managing AIWG whilst concurrently living with a SMI, and (iii) endorses a homogenous management approach to an extensively heterogenous side-effect, both in presentation and manageability – including response to any intervention. Whilst perhaps justified as pragmatic, beyond minor weight increases, participants reported that the recommendation to implement behavioural changes as a universal initial management strategy was insufficient to manage AIWG in reality. This contrasts starkly with the prominence such interventions are given within currently available guidance.[46]

There were also unintended consequences of largely unspecific, and assumed self-led, behavioural changes forming the primary first-line management intervention.[46] Participants reported clinicians largely overestimated the manageability of AIWG through behavioural changes and underestimated the physical and psychological impacts of accruing AIWG, often despite participant's continuing efforts to restrict caloric intake and increase energy output. Aside from concerns regarding feasibility, continued clinician recommendations to implement self-led behavioural changes could worsen an individual's sense of isolation and internalised stigma, and reduce the likelihood of future help-seeking due to anticipated stigmatising interactions. Adding further concern, participants reported difficulties accessing any management intervention beyond self-led behavioural changes within interactions with clinicians and psychiatric services. In many cases, when presented with current AIWG management algorithms for feedback,[46] there was a lack of awareness of alternative management interventions currently recommended in the case of ineffective behavioural changes. This highlights the concomitant need for effective implementation supports within future iterations of AIWG management guidance.

Participants called for substantial changes in AIWG management guidance, due to lack of applicability and transferability across contexts. This included much earlier access to pharmacological adjuncts,[46] and greater access to shared decision-making opportunities when considering the choice of initial and/or continued antipsychotic

treatment. Thus, this research concluded that the design of current management algorithms does not reflect (i) our improved understanding of the pathophysiology and neurobiological underpinnings of obesity,[52] (ii) the empirical evidence base outlining the significant lack of effectiveness of current behavioural interventions in managing antipsychotic-induced causes of overweight or obesity,[70] and (iii) the preferences of patients with experiences of managing a SMI and AIWG ranging from mild to extreme increases in weight. Regarding improved AIWG management algorithms, participants cited four tenets of patient-centred AIWG management:

I. Proactive
II. Individualised
III. Holistic
IV. Collaborative

To operationalise this, suggested changes included: (i) expansion of recommendation scope to address prevention and early intervention, and (ii) assessment of intervention effectiveness to align with patient-important outcomes. This includes movement beyond assessment of weight loss and inclusion of other outcomes, including weight maintenance and improved satiety. Participants emphasised that AIWG is a unique cause of weight gain, often in unique contextual circumstances, and requires an equally distinctive approach to management. Improved recommendations in AIWG management recognise diversity in the initial risk, and subsequent trajectory, of AIWG, and allow for tailored intervention use towards risk of overweight or obesity, individual physical and mental health capabilities.

7.3 Implications for practice, policy, and research

The specific implications of the findings within each research package for practice, policy, and future research have been detailed within each respective chapter. Section 7.3 considers any additional implications of the research produced across this thesis and any demonstrated impacts to date.

7.3.1 Additional implications for mental health practice and policy

As intended, the results of this thesis should be used to inform the development of new and comprehensive AIWG management guidelines. Since this work began in 2021, it remains the case that no guideline solely dedicated to AIWG management exists. Improved AIWG management guidelines should adhere to international standards of guideline development,[66] whilst also incorporating new paradigms within obesity management, including focussing on early intervention and individualised care.[358] The latter also includes ensuring equitable access to available evidence-based treatments for those living with obesity, prioritising therapeutic interventions to those most adversely impacted, and liberalising interventions with a demonstrated evidence base in preventing the accumulation of excess adipose tissue and the associated negative impact on the functioning of organs and tissues.[357,358] A diagrammatic overview of a new framework within obesity management for the diagnosis, staging and management of obesity in adults was recently produced by the European Association for the Study of Obesity in Adults (EASO),[358] to align with the concept of obesity as an adipose-based, chronic disease,[48] and is presented in Figure 18.[358]



Figure 18 - The European Association for the Study of Obesity in Adults (EASO) framework for obesity diagnosis, staging and management.[358]

This framework emphasises the concepts of personalised evaluation and management strategies with the objective of improving health.[358] Considered collectively, the research produced within this thesis allows for the first time for many of these constructs within obesity management to be realised within AIWG management. This includes (i) providing personalised care and risk-stratified AIWG management via application of early BMI trend change as a prognostic marker, highlighting those who will benefit most from early, intensive management, (ii) incorporating lived experience into AIWG management guidance and implementation recommendations to promote holistic, patient-centred weight management, and (iii) promoting improved application of SDM within antipsychotic prescribing to diversify antipsychotic prescribing practices, reduce the burden of cardiometabolic disease among individuals prescribed antipsychotics, and improve implementation of early intervention and personalised AIWG management within clinical practice.

As highlighted within each chapter, much of the work within this thesis has been published. Associated recommendations for AIWG management in clinical practice have already begun to demonstrate impact. For example, a *Web of Science* search of the systematic review of prognostic factors published in June 2023 in *European Psychiatry,* shows that this review has been cited nine times, including by research published within high-impact psychiatric journals, for example *Molecular Psychiatry* and *The American Journal of Psychiatry*. The specific recommendation produced from the review that those with the largest early BMI increases should be prioritised for intensified supports was recently reflected in a modified guideline dedicated to the use of metformin as an early intervention within AIWG management.[359] Prior to this, no differentiated management strategies were recommended within any AIWG management guidance.[46] This guideline also incorporated research findings from the qualitative study conducted within this thesis, whereby recommendations developed explicitly considered the overreliance

on behavioural interventions within AIWG management and the resultant impact on patients.[359]

However, even evidence-based and patient-centred AIWG management guidance outlined here, will require adjunctive policy supports to assist effective implementation. The bidirectional nature of physical and mental health was referred to consistently through the voice of lived experience within this thesis, both within results of the qualitative descriptive study or through stakeholder group involvement within the realist review. Within the qualitative study, participants outlined that effective implementation should include prompt access to multi- and inter-disciplinary supports within psychiatric settings where antipsychotics are prescribed and where weight gain often accumulates rapidly.[34,36] However, access to such supports is not standardised within the design of mental health services internationally.[360,361,362] Instead, and as seen within realist review findings, increasingly common features of mental health service delivery models internationally include a focus on acute crisis management and fragmentation of care between acute and community settings.[6,363,364,365] Such features serve as important barriers to integration of physical health services into psychiatric settings.

Thus, efforts are required at policy-level to systematically reduce discontinuity and fragmentation of care. Calls for improved physical health care within mental health, and increased patient access to integrated care models, continue internationally.[6,369] Detailed recommendations regarding the availability, content and context of physical health care for people living with a SMI were recently outlined within *The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness.*[6] The Commission also outlined the accountabilities and responsibilities of governments, health commissioners, health providers, and research funding bodies in implementing the recommendations of the Commission and protecting the physical health of people with mental illness. In individual countries, national health strategies urgently need to give greater consideration to protecting the physical health of individuals with mental illness, who are often left behind from population gains in public health.[6]

Results of the realist review also have wide-reaching implications for mental health policy and practice. The focus of most SDM intervention research has typically been on optimised design of antipsychotic treatment decision aids.[101,103] An assumption underlying this focus is that the primary barrier to SDM application by prescribers within consultations is insufficient knowledge regarding antipsychotic treatments and/or limited time to collaboratively negotiate treatment options with patients.[293] Accordingly, efficient knowledge provision to patients and/or prescribers within consultations via an accessible decision aid should be sufficient to increase SDM application. However, aligning with the inconclusive results of intervention studies,[101] realist review results identified a significantly more complex picture of wider contextual factors systematically decreasing prescriber engagement in SDM. Contexts serving to preclude prescriber perceived ability to engage in SDM were mainly identified at policy- and institutional-level, and to a lesser extent, organisational-level.

If we are to truly promote equitable patient access to opportunities to increased autonomy within decision-making, addressing the impact of wider structural factors detailed in chapter 5 by those in leadership positions within psychiatry will be essential. To provide one detailed example relevant to psychiatric pharmacy, programme theory 7 outlined the positive impacts of adopting a multidisciplinary responsibility for SDM implementation on increasing subsequent prescriber engagement. Team members with expertise in psychopharmacology completing the informational and evaluative work of SDM within antipsychotic prescribing was identified as facilitating medical prescriber engagement in SDM. Such expertise is typically represented by psychiatric pharmacists, or less commonly, a specialist nurse.[230] Whilst pharmacists are recognised experts in medications management,[366] and within psychiatry, often in receipt of a high level of postgraduate training,[367] their involvement within multidisciplinary teams is typically not standardised in mental health.[367,368]

Consider, for example, practice within the Republic of Ireland. Top-down, protocol-driven approaches to the operation of mental health services, and the impact of independent regulation and their associated priorities on institutional and organisational cultures, were identified as key drivers of individual prescriber behaviours. In the Republic of Ireland, the Mental Health Commission (MHC) are responsible for the independent regulation of mental health services since 2002, following the introduction of the Mental Health Act, 2001.[369] The MHC specify that individual care planning within psychiatric settings must be provided by a multidisciplinary team.[370] Their most recent definition of a multidisciplinary team does not explicitly include the presence of pharmacy professionals:[371]

"A mental health team comprising of a variety of professional staff. Core team members should include psychiatrists, psychiatric nurses, clinical psychologists, social workers and occupational therapists. Other specialist therapists may also be available".

The role of psychiatric pharmacists in positively influencing patient care was also not reflected within Ireland's most recent national mental health policy, entitled "*Sharing the Vision: A Mental Health Policy for Everyone".*[372] Thus, the unique benefit of psychiatric pharmacists is not recognised or reflected within Irish mental health policy or regulation.[367,368] A lack of standardised input of psychiatric pharmacy into multidisciplinary teams was also recently identified at a European level.[367] This is despite documented evidence of benefits to patients from receiving pharmacist input into their care, including improved medication adherence and reduced hospitalisation rates.[373] Whilst realist review results should be used by those with the power to shape mental health policy and regulatory practices to advocate for standardised pharmacy input into multidisciplinary teams, this will need to be alongside increased funding for mental health services within both acute care and community settings.

Realist review findings also highlight the need for recovery-orientated practices, including SDM, to be considered within the training and education of psychiatric

clinicians much earlier than currently advocated for. For example, in the UK, a recent report produced by a working group within the Royal College of Psychiatrists on the implications of person-centred care for training highlighted that the core curriculum for psychiatric trainees does not explicitly signpost learning outcomes relevant to SDM, for example, motivational interviewing.[374] The importance of training clinicians in managing value conflicts was another key finding and one for which training within formal psychiatric education also appears limited.[96,374] Whilst not addressed within the report by the Royal College of Psychiatrists,[374] psychiatric clinicians require specific supports, including skillsets provided through formal training, in addressing the tension they commonly feel when implementing SDM among individuals with psychosis, reflecting the tension between deontological (duty-based) ethical frameworks typically emphasised within the formal training of psychiatric clinicians, and teleological (rights-based) frameworks emphasised by advocates for SDM.[96]

7.3.2 Implications for future research

Producing a high-quality AIWG management guideline to align with international standards of guideline development is now required. Applied research on developing guideline recommendations is common in psychiatry,[359,375] and would be particularly useful in documenting decisions that informed recommendation development and assigning associated strength of recommendations. This includes associated resource costs and feasibility of intervention implementation in countries with varying spending on healthcare.[79] Ascertaining clinician views and preferences for AIWG management is essential in developing recommendations that possess clinical utility and in informing effective implementation efforts. Clinician needs within AIWG management have yet to be systematically explored. Whilst some research exists,[74] a similar qualitative descriptive study would ensure a sufficiently detailed outline of clinician needs is generated.[141] Another obvious area of future research not addressed within this thesis is the management of AIWG among children and adolescents prescribed antipsychotics. Guidance on managing AIWG, informed by research specific to intervention efficacy among this cohort and their

preferences,[74] is of significant clinical importance given the increasing use of antipsychotics among younger people.[376]

The results of this research have also prompted a range of other, previously unconsidered, research questions. As seen within the qualitative descriptive study, those with lived experience of AIWG management reported significant differences in manageability of AIWG, particularly effectiveness of dietary and lifestyle interventions, according to the antipsychotic they were prescribed. Prognostic factor research aims to discover and evaluate factors that might be useful as predictors of differential treatment response and in facilitating application of stratified medical management.[115] Future research assessing the comparative efficacy of management interventions among individuals prescribed low- versus high-risk antipsychotics is a priority within AIWG management. Furthermore, whether those with significant early weight gain respond differently to management interventions, compared to those with a slower trajectory of initial weight gain, has also not been explored empirically. As seen in weight management in the general population, significant heterogeneity in responsiveness to intervention is common.[60] Differences in intervention efficacy depending on phenotypic expression of AIWG should be prioritised within future research. Research interviews conducted among individuals with lived experience of SMI management highlighted the importance of peer support networks in effectively managing AIWG. This is something not referred to within current conversations around AIWG management,[46,62,64] and is also worthy of prioritisation.

7.3.3 Plans for dissemination

Dissemination efforts that have been undertaken to date to promote uptake of the results of the three work packages into clinical practice and awareness among key stakeholders include publication of all work within open access journals, interviews with media outlets in Ireland, and presentation at national and international conferences. Work has been done in collaboration with the local communications department in SPMHS and corresponding departments in UCC to develop press releases, healthcare blogs and social media posts to promote all the work

completed within this thesis. Opportunities to speak at scientific conferences in Ireland, the UK and the USA regarding this research on predicting outcomes associated with antipsychotic-induced weight gain, changes needed within guideline development and improving application of shared decision-making within antipsychotic prescribing, have been taken. Ways to build on dissemination efforts conducted to date include liaising with key stakeholders within guideline development in psychiatry, for example, writers of the Maudsley Guidelines. This could also be undertaken in the case of the British Association of Psychopharmacology. In future research projects and on reflection of my experiences throughout this thesis, I believe it would also be prudent to consider including suitable colleagues within research groups, or within advisory group, where appropriate, such that there is a proactive plan for effective dissemination within the early phases of planning research.

7.4 Strengths and limitations

A primary strength of research conducted is the extent to which research questions were informed by current priorities within psychiatric practice and AIWG management. All three research questions were prioritised based on the experience of the first author as a psychiatric pharmacist working in clinical practice, and in consultation with other psychiatric and obesity management clinicians. Hence, all work was designed and undertaken by a multi- and inter-disciplinary research group. This ensured that questions addressed were of significant importance for clinicians and individuals within mental health services and will increase the impact of results for clinical practice. In presenting results of all three work packages, the research team ensured that implications for practice, policy and future research were clearly outlined in discussion sections of research reports that could be easily interpreted by relevant stakeholders. All work was also published, or accepted for publication in the case of the realist review, within Q1 psychiatric journals such that research findings were readily accessible by those with the influence to increase implementation of findings within practice.

The work conducted within this thesis also represents the first attempt to amplify the voice of those with lived experience within AIWG management research. Whilst the first research question quantified the prognostic impact of various non-genetic prognostic factors on anthropometric outcomes, the second and third were developed alongside direct input from those with lived experience of a SMI. Within the realist review, the research group worked in direct consultation with a clinician and lived experience stakeholder group - from review focus to results presentation. Whilst it is expected that this will increase the impact of results for clinical practice and mental health policy at an international level, both the realist review and the qualitative research package also serve to increase the number of people with a SMI, including schizophrenia, actively involved in psychiatric research.

In the case of the realist review, whilst the first in SDM research, this is one of a very limited number of realist reviews conducted within psychiatry.[228] As this work was accepted for publication as a two-part realist review in a detailed format, and within a mainstream psychiatric journal, the intention was to promote the research findings, whilst also publicising the importance of increased application of implementation science within psychiatric research. This need was recently highlighted in *The Lancet Psychiatry Commission on Transforming Mental Health Implementation Research*.[106] It is hoped that publication of the realist review will inspire other psychiatric researchers to consider undertaking realist research, and other implementation science methodologies, when developing credible evidence assessing complex interventions common within psychiatric practice.[106,120]

All research conducted in this thesis adheres to the highest standards of research design, conduct, analysis, and reporting. This includes internationally endorsed methodological and reporting guidelines. Specifically, guidance produced by the Cochrane Prognosis Methods Group was adhered to in the case of the systematic review of prognostic factors,[115] RAMESES methodological and publication guidance within the design and reporting of the realist review,[121] and quality criteria outlined by Lincoln and Guba,[350] and COREQ guidance,[344] in the case of the qualitative descriptive study. Furthermore, given the complexity associated with research

methodologies used, statistical and methodological experts were included as research team members within the systematic and realist reviews to improve the internal validity of research findings. The research team also sought external peer review at project design phase by publishing both protocols *a priori*, such that feedback to enhance study design was routinely sought from outside the direct research team and incorporated prior to review commencement.[67,102]

Work conducted within this thesis is, however, not without limitations. Whilst a significant strength of the research is the extent to which those with experience of a SMI were involved, the severity of every mental illness exists on a continuum. Whilst every effort was made to ensure diverse participation of individuals with lived experience, participants cannot be assumed to represent the full range of experiences. Those living with extremes of a SMI may not have been adequately represented by the lived experience representatives who partook in the realist review, or participants within the qualitative descriptive study. Finally, the overarching aim of the work produced within this thesis was to support systematic and equitable management of AIWG among adults with psychosis. However, aside from use of psychotropic medications, those living with a SMI face a disproportionate number of risk factors for experiencing overweight or obesity. This includes high rates of sedentary behaviour, poverty, stress and weight bias amongst clinicians.[6] Thus, whilst targeted use of interventions with a robust evidence-base in managing AIWG is one important part of obesity management, this thesis does not address many other important determinants of weight status among SMI cohorts.

Of note, within chapter 6 addressing the qualitative work conducted within this thesis, potential ethical implications arising out of increased awareness of varying AIWG management interventions previously unknown to research participants were considered by the research team. The range of management interventions (and the management algorithm) outlined within the interview guide and presented to participants is the recommended approach internationally to management. This information was new to some participants and as a result raised questions as to why they weren't offered such interventions previously. The outcome of the primary

investigators conversations with these participants was that they should raise these questions/options for management with their prescribing clinician. Accordingly, it was agreed that were no significant ethical considerations that required additional safeguarding beyond those already accounted for within the study methodology.

7.5 Conclusion

This doctoral research was conducted in response to the growing calls for dedicated AIWG management guidelines and the need for several knowledge gaps to be addressed before the development of patient-centred and evidence-based management guidance could be undertaken. The aims of this thesis were successfully achieved, which included conducting research addressing (i) the predictability of AIWG via application of non-genetic prognostic factors, (ii) understanding how to implement SDM within antipsychotic prescribing decisions among people experiencing psychosis, and (iii) identifying how those with experience of AIWG and a SMI management conceptualise preferred management. To address this diverse range of research questions, a mixed-methods approach was used. This included systematic review methodology, realist review methodology, and application of a qualitative descriptive approach to conducting qualitative research.

Work completed within this thesis represents a novel body of research with the potential to meaningfully enhance the quality of AIWG management within psychiatry, and application of SDM specific to antipsychotic prescribing within psychosis management. This includes providing the first mapping and statistical synthesis of studies examining non-genetic prognostic factors within AIWG prognostication. This thesis also produced a significant advancement in our understanding of implementing SDM within psychosis management, including structural and contextual factors that exist within psychiatric services internationally and currently preclude standardised integration of SDM into antipsychotic prescribing. Finally, qualitative interviews with individuals with diverse experiences of AIWG and SMI management resulted in the production of research addressing

several key decision-making criteria relevant to the development of high-quality AIWG management guidance.

In the case of all three research questions, important implications for practice and mental policy internationally were clearly highlighted, alongside priorities for future research.

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Appendices

Appendix 1 - Chapter 4: List of protocol deviations

1. Prognostic factors under investigation were initially grouped under 'biological, clinical and sociodemographic' in the protocol. In the final paper, this was renamed as 'non-genetic prognostic factors' as it was agreed that this better explained the range of factors the review could potentially include.

2. In the protocol, it was specified that studies for inclusion must measure potential prognostic factors upon or immediately prior to antipsychotic initiation and referred to these as 'baseline' measurements. This definition was amended after publication of the protocol to allow inclusion of factors that had a baseline measurement and a follow up measurement early in antipsychotic treatment e.g., trend of early body mass index (BMI) increase, early assessment of response to antipsychotic treatment, and changes in appetite in the weeks following antipsychotic initiation. This was amended due to the relevance of such results to the review question. One study that assessed antipsychotic plasma concentration measurement after steady state had been reached and the associated impact on prognosis was also included.

3. In the protocol it was specified that the median or mean dose of antipsychotic prescribed must be included in the study report. Dose range was subsequently added to this list.

4. Preferred effect sizes for extraction in the case of continuous outcomes in the protocol were regression coefficients. This was subsequently further defined as a preference for extraction of unstandardized beta coefficients for ease of interpretation.

5. In the protocol it was specified that a 95% prediction interval would be calculated for prognostic factors where there were 5 or more estimates available from independent studies suitable for meta-analysis. Study numbers precluded this calculation.

6. It was specified in the protocol that a meta-analysis would be conducted by grouping studies together where outcomes were measured at similar time points. The author group subsequently further defined similar timelines this as studies with a follow-up of 0-12 weeks, 12-51 weeks and 52 weeks+. One study that had a follow up time >52 weeks was identified. In the case, relevant study findings were synthesized with studies that had a 52-week follow-up period.

7. In the protocol it was specified how publication bias would be assessed quantitatively. Study numbers precluded this.

8. In the protocol, a list of sensitivity and subgroup analyses were specified that would be conducted in the presence of sufficient study numbers. This was not possible due to insufficient study numbers and study heterogeneity.

9. In conducting literature searches, one study where a full dataset was provided was identified, but analyses reported did not meet prespecified criteria for inclusion. The statistician (JE) re-analysed the datasets to adjust adequately for preferred covariates and to report outcomes relevant to the review.

10. In the protocol, it was originally planned that all GRADE assessments would be done in duplicate and independently. This was changed in the final analysis plan whereby GRADE assessments were completed in full by one author (IF) and results were reviewed independently by two other authors (LS, EC) until consensus was agreed on all decisions. Furthermore, it was subsequently agreed to change initially highlighted GRADE prognostic factor methodology once it was discovered that primarily continuous outcomes were assessed in eligible studies. The initial methodology chosen was relevant for prognostic factor research, but where outcomes assessed were considered binary. The approach subsequently used was by that outlined by Huguet et al,[1] and considers similar categories to rate down and up evidence quality. In line with this approach,[1] it was also agreed to use GRADE tables outlined in the appendix of their 2013 paper rather than GRADEpro web application initially specified in the protocol.

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Appendix 2 – Chapter 4: PRISMA checklist

Part 2 - PRISMA checklist			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
TITLE			
Title	1	Identify the report as a systematic review.	Title
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Abstract
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Introduction
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Introduction
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Table 1 of study paper and reference to published protocol containing detailed methods.
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Search strategy section and reference to published protocol containing detailed methods.
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Not contained in study report.

Part 2 - PRISMA checklist			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
			Contained in protocol paper referenced in study report.
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Study selection section and reference to published protocol containing detailed methods.
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Data extraction and management section and reference to published protocol containing detailed methods.
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g., for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Table 1 of study paper and reference to published protocol containing detailed methods.

Part 2 - PRISMA checklist			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
	10b	List and define all other variables for which data were sought (e.g., participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Data extraction and management section and reference to published protocol containing detailed methods.
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Risk of bias section and reference to published protocol containing detailed methods.
Effect measures	12	Specify for each outcome the effect measure(s) (e.g., risk ratio, mean difference) used in the synthesis or presentation of results.	Data extraction and management section and reference to published protocol containing detailed methods.
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g., tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Data synthesis section and reference to published protocol containing detailed methods.

Part 2 - PRISMA checklist			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Data extraction and management section, data synthesis section and reference to published protocol containing detailed methods.
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Reference to published protocol containing detailed methods.
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Data synthesis section and reference to published protocol containing detailed methods.
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g., subgroup analysis, meta-regression).	n/a due to small study numbers. Methods originally outlined in published protocol.
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	n/a due to small study numbers. Methods originally

Part 2 - PRISMA checklist			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
			outlined in published protocol.
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	n/a due to small study numbers. Methods originally outlined in published protocol.
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Certainty of evidence section and reference to published protocol containing detailed methods.
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Figure 1 of study paper
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Figure 1 of study paper
Study characteristics	17	Cite each included study and present its characteristics.	Table 2 of study paper
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Risk of bias results section
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimates and its precision (e.g., confidence/credible interval), ideally using structured tables or plots.	Findings from meta-analysis section.

Part 2 - PRISMA checklist			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Each prognostic factor-outcome estimate has GRADE evidence quality rating which accounts for risk of bias ratings for each contributing study. Additionally, for use of QUIPS tool, overall study risk of bias rating not recommended, rating of bias amongst each section preferred.
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g., confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Findings from meta-analysis section
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	n/a due to small study numbers.
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	n/a due to small study numbers.
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	n/a due to small study numbers.

Part 2 - PRISMA checklist

Section and Topic	Item #	Checklist item	Location where item is reported
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Figure 2 of study paper
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Conclusions and implications section
	23b	Discuss any limitations of the evidence included in the review.	Limitations section
	23c	Discuss any limitations of the review processes used.	Limitations section
	23d	Discuss implications of the results for practice, policy, and future research.	Conclusions and implications section
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Abstract
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Referenced in study selection and analysis section.
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	List of protocol deviations in thesis appendix 1
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Funding section

Part 2 - PRISMA checklist			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
Competing interests	26	Declare any competing interests of review authors.	Competing interest section
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Data availability statement

Appendix 3 – Chapter 4: Results of database searches

Database searching

PubMed

Date range searched: inception: 9/2/2025
Searcher: IF
Hits: n= 4,507

No.	Search terms	Number of hits
1	Predict*[tw] OR Risk*[tw] OR prognos*[tw] OR outcome*[tw] OR course[tw]	8,704,361
2	"Antipsychotic Agents"[Mesh] OR “First generation antipsychotic*”[tw] OR “First-generation antipsychotic*”[tw] OR “second generation antipsychotic*”[tw] OR “second-generation antipsychotic*”[tw] OR Antipsychotic*[tw] OR neuroleptic*[tw]	92,545
3	"Body Weight Changes/drug effects"[Mesh] OR “Weight gain”[tw] OR “metabolic side effect*” OR “metabolic side-effect*”[tw] OR “Antipsychotic induced weight gain”[tw] OR “Antipsychotic-Induced weight gain”[tw]	101,368
4	Schizo*[tw] OR Psycho*[tw] OR delusion*[tw] OR “first episode psychosis” OR “first-episode psychosis” OR "Psychotic Disorders"[Mesh]	2,349,065
5	#1 AND #2 AND #3 AND #4	1,919
6	(amisulpride OR aripiprazole OR asenapine OR cariprazine OR clozapine OR chlorpromazine OR fluphenazine OR flupenthixol OR haloperidol OR lurasidone OR olanzapine OR paliperidone OR quetiapine OR	74,455

	risperidone OR sulpiride OR ziprasidone OR zuclopenthixol [tw])	
7	(#2 OR #6) AND "Metabolic Syndrome"[Mesh]	241
8	Prospective [tw] AND #3 AND (#2 OR #6)	247
9	#1 AND #3 AND (#2 OR #6)	1,610
10	"Overweight"[Mesh]	266,835
11	(#2 OR #6) AND #10	141
12	correlat* [tw]	2,345,356
13	(#2 OR #6) AND #3 AND #12	204
14	"follow-up stud*"[tw]	642,231
15	(#2 OR #6) AND #3 AND #14	145
Limits set to: English language		4,507

PsycINFO

Date range searched: inception: 9/2/2025
Searcher: IF
Hits: n = 1,058

Search number	Terms applied	Number of hits
1	AB(risk OR predict* OR prognos* OR “risk factor*” OR course*)	1,414,817
2	AB(MM"Neuroleptic Drugs" OR ("first generation antipsychotic*" OR "first-generation antipsychotic*" OR "second-generation antipsychotic*" OR "second generation antipsychotic*")	3,102
3	AB(DE "Body Weight" OR DE "Overweight" OR DE "Weight Control" OR DE "Weight Gain" OR DE "Weight Loss")	42,786
4	AB(DE "Psychosis" OR DE "Acute Psychosis" OR DE "Affective Psychosis" OR DE "Hallucinosis" OR DE "Paranoia (Psychosis)" OR DE "Postpartum Psychosis" OR DE "Reactive Psychosis" OR DE "Schizophrenia" Or “first-episode psychosis” OR “first episode psychosis”)	136,628
5	#1 AND #2 AND #3 AND #4	56

6	AB(amisulpride OR Asenapine OR aripiprazole OR cariprazine OR chlorpromazine OR clozapine OR flupenthixol OR fluphenazine OR haloperidol OR lurasidone OR olanzapine OR paliperidone OR quetiapine OR risperidone OR sulpiride OR ziprasidone OR zuclopenthixol)	33,418
7	(#2 OR #6) AND (MM "Metabolic Syndrome")	132
8	Prospective* AND #3 AND (#2 OR #6)	163
9	#1 AND #3 AND (#2 OR #6)	364
10	(DE "Overweight" OR DE "Obesity")	38,444
11	(#2 OR 6) AND #10	315
12	AB(correlat*)	438,588
13	(#2 OR 6) AND #3 AND #12	137
14	AB(follow-up stud*)	21,706
15	(#2 OR 6) AND #3 AND #14	8
Limits set to: English language		

Embase

Date range searched: inception: 9/2/2025
Searcher: IF
Hits: n = 3,130

Search number	Terms applied	Number of hits
1	predict*:ti,ab,kw OR 'risk*or prognos*':ti,ab,kw OR 'risk factor':ti,ab,kw OR course:ti,ab,kw	4,310,722
2	'first generation antipsychotic*':ti,ab,kw OR 'second generation antipsychotic*':ti,ab,kw OR antipsychotic*:ti,ab,kw OR neuroleptic*:ti,ab,kw OR 'atypical antipsychotic agent':ti,ab,kw OR 'typical antipsychotic':ti,ab,kw OR 'first-generation antipsychotic*':ti,ab,kw OR 'second-generation antipsychotic*':ti,ab,kw	104,314
3	'body weight gain':ti,ab,kw OR ('weight gain':ti,ab,kw OR 'metabolic side effect*':ti,ab,kw OR 'antipsychotic induced weight gain':ti,ab,kw OR 'antipsychotic-induced weight gain':ti,ab,kw OR 'antipsychotic-related weight gain':ti,ab,kw)	111,156
4	'psychosis'/exp OR (schizo*:ti,ab,kw OR psycho*:ti,ab,kw OR delusion*:ti,ab,kw) OR psychosis:ti,ab,kw	1,466,416

5	#1 AND #2 AND #3 AND #4	663
6	amisulpride:ti,ab,kw OR asenapine:ti,ab,kw OR aripiprazole:ti,ab,kw OR cariprazine:ti,ab,kw OR chlorpromazine:ti,ab,kw OR clozapine:ti,ab,kw OR flupenthixol:ti,ab,kw OR fluphenazine:ti,ab,kw OR haloperidol:ti,ab,kw OR lurasidone:ti,ab,kw OR olanzapine:ti,ab,kw OR paliperidone:ti,ab,kw OR quetiapine:ti,ab,kw OR risperidone:ti,ab,kw OR sulpiride:ti,ab,kw OR ziprasidone:ti,ab,kw OR zuclopenthixol:ti,ab,kw	96,398
7	(#2 OR #6) AND 'metabolic syndrome x'/exp	2,425
8	prospective:ti,ab,kw AND #3 AND (#2 OR #6)	54
9	#1 AND #3 AND (#2 OR #6)	926
10	('obesity'/exp OR overweight)	762,108
11	#1 AND (#2 OR #6) AND #10	969
12	correlat*:ti,ab,kw	3,272,560
13	(#2 OR #6) AND #3 AND #12	476
14	'follow-up stud*':ti,ab,kw	84,668
15	(#2 OR #6) AND #3 AND #14	42
Limits set to: English language		

CENTRAL

Date range searched: inception: 9/2/2025
Searcher: IF
Hits: n = 2,864

Search number	Terms applied	Number of hits
1	Predict*:ti,ab,kw OR Risk*:ti,ab,kw OR prognos*:ti,ab,kw OR course*:ti,ab,kw	510,257
2	[Antipsychotic Agents] explode all trees OR 'first generation antipsychotic*':ti,ab,kw OR 'first-generation antipsychotic*':ti,ab,kw OR 'second generation antipsychotic*':ti,ab,kw OR 'second-generation antipsychotic*':ti,ab,kw OR antipsychotic* OR neuroleptic*	19,153
3	[Body Weight Changes] explode all trees OR 'weight gain:ti,ab,kw OR 'metabolic side effect*':ti,ab,kw OR 'metabolic side-effect*':ti,ab,kw OR 'antipsychotic induced weight gain':ti,ab,kw OR 'antipsychotic-Induced weight gain':ti,ab,kw	22,878
4	schizo*:ti,ab,kw OR psycho*:ti,ab,kw OR delusion*:ti,ab,kw OR 'first episode psycho*':ti,ab,kw OR 'first-episode psycho*':ti,ab,kw OR [Psychotic Disorders] explode all trees	212,881
5	#1 AND #2 AND #3 AND #4	609

6	(amisulpride OR aripiprazole OR asenapine OR cariprazine OR clozapine OR chlorpromazine OR fluphenazine OR flupenthixol OR haloperidol OR lurasidone OR olanzapine OR paliperidone OR quetiapine OR risperidone OR sulpiride OR ziprasidone OR zuclopenthixol):ti,ab,kw	15216
7	(#2 OR #6) AND (Metabolic Syndrome)	643
8	Prospective:ti,ab,kw AND #3 AND (#2 OR #6)	166
9	#1 AND #3 AND (#2 OR #6)	756
10	MeSH descriptor: [Overweight] explode all trees	25912
11	(#2 OR #6) AND #10	202
12	Correlate*:ti,ab,kw	58807
13	(#2 OR #6) AND #3 AND #12	62
14	'follow-up stud*':ti,ab,kw	309492
15	(#2 OR #6) AND #3 AND #14	426
Limits set to: English language		

Appendix 4 – Chapter 4: Checklist for Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies – Modified for Prognostic Factor Studies (CHARMS-PF)

Domain and key items	Yes	No	Unclear	Answer	Notes/comments
1. Study report **a.** Did the study protocol make reference to a study protocol? **b.** Did the study protocol make reference to a prespecified statistical analysis protocol?					
2. Source of data/Study design (e.g., prospective cohort study, randomised trial)					
3. Participants a. Participant eligibility and recruitment method – e.g., consecutive participants, geographic location, number of centres, setting (e.g., clinical trial population, healthcare system, clinical practice, inclusion and exclusion criteria b. Participant description [antipsychotic treated group(s)] – including total numbers, sex (% F), ethnicity (% predominant race), age (mean + SD), baseline BMI (mean + SD) c. Details of diagnosis (if >1, record % of each) d. Details of antipsychotic prescription(s) – % prescribed each antipsychotic, antipsychotic dose (mean + SD)					

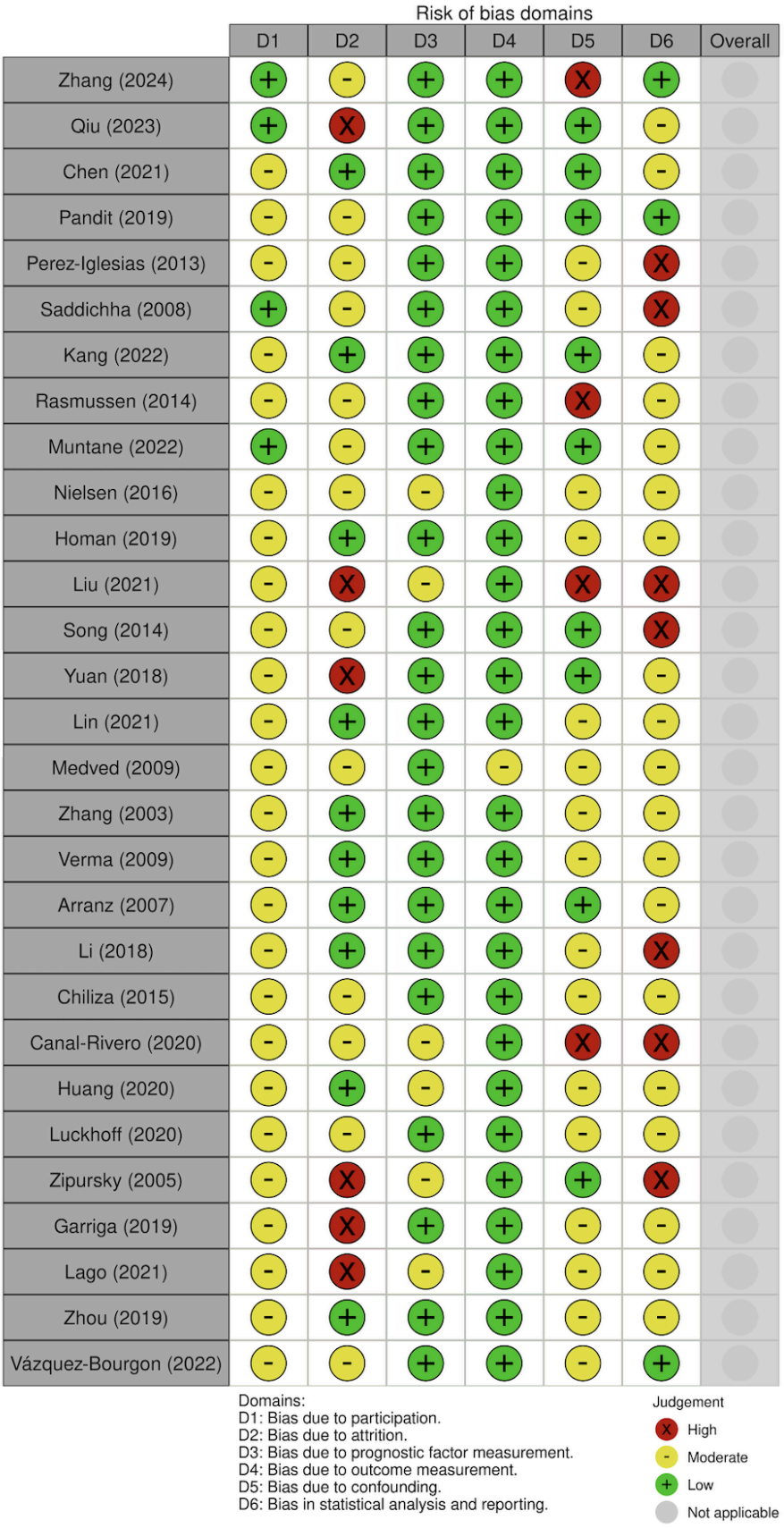
e. Details of previous antipsychotic exposure (if any) – antipsychotic + duration of exposure f. Details of other concomitant medication – agent(s), doses (mean+ SD), % participants receiving same across different groupings g. Study dates					
4. Outcomes to be predicted Definition and method of measurement of outcomes – confirm primary and list secondary outcomes assessed Was the same outcome definition used in all participants? Summary of duration of follow-up (median/mean follow-up time)					
5. Prognostic factors a. Number and type of prognostic factors assessed e.g., clinical, biological and sociodemographic* (list all factors here even those not found to be significant but were controlled for) b. Definition and method of measurement of prognostic factor (where relevant) e.g., how body mass index was defined in those of varying ethnicities, baseline severity of symptoms PANSS vs. BPRS c. Timing of prognostic factor assessment, where relevant e.g baseline BMI (e.g., at presentation, diagnosis, treatment initiation) d. Were prognostic factors assessed blinded for outcome and for each other, if relevant, e.g					

scoring of social functioning as a prognostic factor on weight changes retrospectively. If not relevant e.g., because all PF are objective in their measurement, please endorse not applicable. e. Handling of prognostic factors in the analysis (e.g., continuous, linear, non-linear transformations or categorised)					
6. Sampling size **a.** Was a sampling size calculation conducted and if so, how? **b.** Are the number of participants and number of outcomes or events reported? **c.** Are the number of outcomes or events in relation the number of candidate prognostic factors (events per variable) reported?					
7. Missing data **a.** Number of participants with any missing value (in the prognostic factors and outcomes) **b.** Number of participants with missing data for each prognostic factor of interest (e.g., % lost to follow-up) **c.** Details of attrition (reasons for loss to follow-up) **d.** Methods for handling of missing data (e.g., complete case analysis, imputation, or other methods)					
8. Analysis					

	a. Unadjusted or adjusted prognostic factors reported (or both)? b. In the case of unadjusted prognostic factors reported, method of assessment undertaken (e.g., univariate regression, test of independence) c. In the case of adjusted prognostic factors reported, outline the multivariable modelling methods (e.g., linear or logistic regression) d. In the case of adjusted prognostic factors reported, method for selection of prognostic factors for inclusion in multivariable modelling (e.g., all candidate prognostic factors considered, preselection of established prognostic factors, retain only those significant from univariable analysis) e. How modelling assumptions were checked f. Method for selection or exclusion of prognostic factors (including those of interest and those used as adjustment factors) during multivariable modelling (e.g., backward or forward selection, or full model approach including all factors regardless) and criteria used for any selection or exclusion (e.g., P value, F test) g. Method of handling each continuous prognostic factor (e.g., dichotomisation, categorisation, linear, non-linear) including values used of any cut points and their justification					

9. Results a. Unadjusted and adjusted prognostic effect estimates (e.g., risk ratios, odds ratios, mean differences, beta-coefficients etc;) and the corresponding 95% confidence interval (or standard error or associated measure of variance) + P value for <u>each prognostic factor studied.</u> b. For multivariable analysis, % variation in the dependent variable explained by the combination of prognostic factors c. If applicable – any details of non-linear relationships and whether modelling assumptions hold d. For each extracted adjusted prognostic effect estimate of interest the set of adjustment factors used					
10. Interpretation and discussion a. Interpretation of presented results b. Comparison with other studies, discussion of generalisability, strengths and limitations					

Appendix 5 – Chapter 4: Risk of bias assessment results



Appendix 6 - Chapter 4: GRADE prognostic factor-outcome assessments

Section 1 - GRADE tables for all prognostic factor-outcome associations assessed narratively only.

Table 1 – Prognostic factors and association with risk clinically significant weight gain at all timepoints.

Outcome: Risk of clinically significant weight gain																
			Univariate			Multivariate			GRADE factors							
Prognostic factor	Participant no.	Number of studies (+ study number 1-29)	+	0	-	+	0	-	Phase	Study limitations	Inconsistency	Indirectness	Imprecision	Publication bias	Reasons to upgrade ?	Overall quality
Age (years)	875	4 (2,4,16,23)	0	1	0	1	2	0	1	X	X	✓	✓	✓	No	Low
Sex (M/F)	875	4 (2,4,16,23)	0	1	0	1	2	0	1	X	X	✓	X	✓	No	Low
Ethnicity (white vs. others)	446	1 (2)	0	0	0	0	1	0	1	✓	Unclear	✓	✓	Unclear	No	Low
Lipid metabolite – Ceramide Kinase P(d40:3)	105	1(28)	1	0	0	0	0	0	1	✓	Unclear	✓	X	Unclear	No	Low
Lipid metabolite –	105	1(28)	1	0	0	0	0	0	1	✓	Unclear	✓	X	Unclear	No	Low

Phosphatidylcholine(20:1_22:6)												
Lipid metabolite – Triacylglycerol (12:1e_6:0_22:4)	105	1(28)	0 0 1	0 0 0	1	✓	Unclear	✓	✓	Unclear	No	Low
Employment status (unemployed vs employed)	446	1 (2)	0 0 0	1 0 0	1	✓	Unclear	✓	✓	Unclear	Yes	Moderate
Primary diagnosis	819	3 (2,4,23)	1 0 0	1 1 0	1	X	X	✓	X	✓	No	Low
Comorbid Major Depressive Disorder (Y/N)	446	1 (2)	0 0 0	0 1 0	1	✓	Unclear	✓	X	Unclear	No	Low
Illness severity	446	1 (2)	0 0 0	0 1 0	1	✓	Unclear	✓	✓	Unclear	No	Low
Previous antipsychotic use (antipsychotic-naïve)	709	2 (2,23)	0 0 0	0 2 0	1	X	✓	X	X	Unclear	No	Very low

Inpatient vs outpatient care	446	1 (2)	0 0 0	0 1 0	1	✓	Unclear	✓	X	Unclear	No	Low
Baseline bodyweight	446	1 (2)	0 0 0	0 0 1	1		Unclear	✓	✓	Unclear	No	Low
Baseline BMI (kg/m^2)	166	2 (4,16)	1 0 0	1 0 0	1	X	✓	✓	X	✓ X	No	Low
Pro-inflammatory cytokine - TNF-alpha	78	1(11)	0 1 0	0 1 0	2	X	Unclear	X	Unclear	Unclear	No	Very low
Pro-inflammatory cytokine – ILB	78	1(11)	1 0 0	1 0 0	2	X	Unclear	X	✓	Unclear	No	Very low
Pro-inflammatory cytokine - IL-6	78	1(11)	1 0 0	0 1 0	2	X	Unclear	X	Unclear	Unclear	No	Very low
Cumulative antipsychotic exposure	56	1(16)	0 0 0	0 1 0	1	X	Not applicable	✓	X	Unclear	No	Very low

Response to antipsychotic treatment - positive symptoms	56	1(16)	0	0	0	0	1	0	1	X	Not applicable	✓	✓	Unclear	No	Low
Baseline low density lipoprotein (LDL) cholesterol	56	1(16)	0	0	0	0	1	0	1	X	Not applicable	✓	X	Unclear	No	Very low
Baseline triglycerides	56	1(16)	0	0	0	1	0	0	1	X	Not applicable	✓	X	Unclear	No	Very low
Baseline insulin secretion	56	1(16)	0	0	0	0	1	0	1	X	Not applicable	✓	✓	Unclear	No	Low
Smoking status (Y/N)	263	1 (23)	0	0	0	0	1	0	1	X	Not applicable	X	Unclear	Unclear	No	Very low
Premorbid functioning	263	1 (23)	0	0	0	0	1	0	1	X	Not applicable	X	Unclear	Unclear	No	Very low
Age at illness onset	263	1 (23)	0	0	0	0	1	0	1	X	Not applicable	X	Unclear	Unclear	No	Very low

Duration of illness	263	1 (23)	0 0 0	0 1 0	1	X	Not applicable	X	Unclear	Unclear	No	Very low

Phase = phase of investigation. For uni- and multivariate analyses: + number of events with a significant positive value, 0, number of non-significant events; - number of significant events with a negative value. For all other GRADE ratings: ✓, no serious limitations; X, serious limitations; X, very serious limitations; unclear, unable to rate item based on available information. In the case of inconsistency, this was marked as 'unclear' in the case of single studies where the assessment between the PF and outcome had not been replicated and study quality was downgraded to account for this. This is based on guidance from Huguet et al who recommend downgrading the quality of evidence in such cases as this is an indicator that the literature in this area is not well established. Publication bias was also marked as unclear where the relationship between a prognostic factor and an outcome has only been assessed in a single study. Other parameters under assessment have been marked as unclear when data is missing from the study report and was not provided by study authors on request.

Table 2 – Prognostic factors and association with change in waist circumference assessed at all timepoints.

Outcome: Change in waist circumference (cm)															
			Univariate			Multivariate								GRADE factors	
Prognostic factor	Participant no.	Number of studies (+ study number 1-29)	+	0	-	+	0	-	Phase	Study limitations	Inconsistency	Indirectness	Imprecision	Publication bias	Reasons to upgrade?	Overall quality
Baseline waist circumference	110	1 (4)	0	0	1	0	0	0	1	X	Unclear	✓	Unclear	Unclear	No	Very low
Baseline weight	110	1 (4)	0	0	1	0	0	0	1	X	Unclear	✓	Unclear	Unclear	No	Very low
Baseline BMI (kg/m^2)	110	1 (4)	0	1	0	0	0	0	1	X	Unclear	✓	Unclear	Unclear	No	Very low
Sex (M/F)	110	1 (4)	1	0	0	0	0	0	1	X	Unclear	✓	Unclear	Unclear	No	Very low
Family history of diabetes mellitus (Y/N)	94	1 (14)	0	0	0	1	0	0	1	X	Unclear	X	Unclear	Unclear	No	Low
Age*	94	1 (14)	Unclear			Unclear			1	X	Unclear	X	Unclear	Unclear	No	Very low
Family history of cerebrovascular disease* (Y/N)	94	1 (14)	Unclear			Unclear			1	X	Unclear	X	Unclear	Unclear	No	Very low

Family history of obesity* (Y/N)	94	1 (14)	Unclear	Unclear	1	X	Unclear	X	Unclear	Unclear	No	Very low
Illness severity*	94	1 (14)	Unclear	Unclear	1	X	Unclear	X	Unclear	Unclear	No	Very low
Smoking history* (Y/N)	94	1 (14)	Unclear	Unclear	1	X	Unclear	X	Unclear	Unclear	No	Very low
Diagnosis*	94	1 (14)	Unclear	Unclear	1	X	Unclear	X	Unclear	Unclear	No	Very low
Duration of illness*	94	1 (14)	Unclear	Unclear	1	X	Unclear	X	Unclear	Unclear	No	Very low

Phase = phase of investigation. For uni- and multivariate analyses: + number of events with a significant positive value, 0, number of non-significant events; - number of significant events with a negative value. For all other GRADE ratings: ✓, no serious limitations; X, serious limitations; X, very serious limitations; unclear, unable to rate item based on available information. In the case of inconsistency, this was marked as 'unclear' in the case of single studies where the assessment between the PF and the outcome had not been replicated and study quality downgraded for this measure. This is based on guidance from Huguet et al who recommend downgrading the quality of evidence in such cases as this is an indicator that the literature in this area is not well established. Publication bias was also marked as unclear where the relationship between a prognostic factor and an outcome has only been assessed in a single study. Other parameters under assessment have been marked as unclear when data is missing from the study report and was not provided by study authors on request.

*Numerical results not reported or provided by study author on request

Y/N = Yes/No

Table 3 – Prognostic factors and association with change in weight at all timepoints.

Outcome: Change in weight																
			Univariate			Multivariate			GRADE Factors							
Prognostic factor	Participant number	Number of studies (+ study number 1-29)	+	0	-	+	0	-	Phase	Study limitations	Inconsistency	Indirectness	Imprecision	Publication bias*	Reasons to rate up?	Overall quality
Age	601	3 (8,10,27)	0	0	0	1	0	2	1	X	X	✓	✓	✓	No	Low
Diagnosis (schizophreniform vs. schizophrenia)	446	1 (2)	0	0	0	0	1	0	1	✓	Unclear	✓	✓	Unclear	No	Low
Education	751	2 (1,10)	1	0	0	0	1	1	1	X	✓	✓	✓	Unclear	No	Low
Age at illness onset	526	1 (1)	0	1	0	0	1	0	1	✓	Unclear	✓	✓	Unclear	No	Low
Antipsychotic prescription	69	1(8)	0	0	0	0	0	1	1	X	Unclear	✓	✓	Unclear	No	Low
Duration of illness	526	1 (1)	1	0	0	0	0	0	1	X	Unclear	✓	✓	Unclear	No	Very low
Anticholinergic co-prescription	526	1 (1)	0	0	0	0	1	0	1	X	Unclear	✓	✓	Unclear	No	Low

Baseline hip circumference	526	1 (1)	0 0 1	0 0 0	1	X	Unclear	✓	Unclear	Unclear	No	Low
Duration of untreated psychosis	225	2 (3,5)	1 0 0	0 2 0	1	X	✓	✓	✓	X	No	Very low
Social functioning	174	1 (3)	0 0 0	1 0 0	1	X	Unclear	✓	✓	Unclear	No	Very low
Response to antipsychotic treatment - positive symptoms	700	2 (1,3)	1 0 0	1 0 0	1 + 2	X	✓	✓	✓	Assumed as no evidence of not – as per 2013 advised approach	No	Very low
Response to antipsychotic treatment - negative symptoms	700	2 (1,3)	1 0 0	0 0 1	1 + 2	X	✓	✓	X	Unclear	No	Very low
Response to antipsychotic treatment - general psychopathology	526	1 (1)	1 0 0	0 0 0	2	✓	Unclear	✓	✓	Unclear	No	Low
Response to antipsychotic treatment - total psychopathology	526	1 (1)	1 0 0	1 0 0	2	✓	Unclear	✓	✓	Unclear	No	Moderate
Socioeconomic status	174	1(1)	0 0 0	0 1 0	1	X	Unclear	✓	Unclear	Unclear	No	Very low

Antipsychotic plasma concentration	51	1 (5)	1 0 0	1 0 0	2	X	Unclear	✓	✓	Unclear	No	Moderate
BMI rate change	51	1 (5)	1 0 0	0 0 0	1	X	Unclear	✓	X	Unclear	Yes	Low
Illness severity	566	3 (2,5,8)	0 2 0	0 1 0	1	X	✓	✓	✓	X	No	Low
Baseline fasting glucose	51	1 (5)	0 1 0	0 0 0	1	X	Unclear	✓	X	Unclear	No	Very low
Baseline triglycerides	51	1 (5)	0 1 0	0 0 0	1	X	Unclear	✓	X	Unclear	No	Very low
Baseline total cholesterol	51	1 (5)	0 1 0	0 0 0	1	X	Unclear	✓	X	Unclear	No	Very low
Baseline low density lipoprotein (LDL) cholesterol	51	1 (5)	0 1 0	0 0 0	1	X	Unclear	✓	X	Unclear	No	Very low
Baseline high density lipoprotein (HDL) cholesterol	51	1 (5)	1 0 0	0 0 0	1	X	Unclear	✓	X	Unclear	No	Very low
5HT-2A receptor binding profile	30	1 (6)	1 0 0	0 0 0	2	X	Unclear	X	X	Unclear	No	Very low
Striatal reward activity	69	1(8)	0 0 0	1 0 0	2	X	Unclear	✓	X	Unclear	No	Low

Striatal functional connectivity	81	1(9)	0 0 0	1 0 0	2	X	Unclear	X	✓	Unclear	No	Low
Striatal volume	81	1(9)	0 0 0	1 0 0	2	X	Unclear	X	✓	Unclear	No	Low
Superoxide dismutase (SOD)	293	1 (10)	0 0 0	0 0 1	2	X	Unclear	X	X	Unclear	No	Very low
Catalase (CAT)	293	1 (10)	0 0 0	Results not reported	2	X	Unclear	X	Unclear	Unclear	No	Very low
Glutathione peroxidase (GPx)	293	1 (10)	0 0 0	0 0 1	2	X	Unclear	X	X	Unclear	No	Very low
Malondialdehyde (MDA)	293	1 (10)	0 0 0	Results not reported	2	X	Unclear	X	Unclear	Unclear	No	Very low
Antipsychotic formulation – standard vs. disintegrating tablets	38	1 (17)	0 0 0	1 0 0	2	✓	Unclear	✓	X	Unclear	No	Low
Dietary habits at 3 months	596	1 (20)	0 0 0	1 0 0	1	X	Unclear	✓	✓	Unclear	No	Very low
Early appetite increase	33	1(21)	1 0 0	1 0 0	2	X	Unclear	✓	✓	Unclear	No	Low
Birth weight	23	1 (24)	1 0 0	1 0 0	2	X	Unclear	X	✓	Unclear	No	Very low
Antipsychotic dose	23	1 (24)	0 1 0	0 0 0	1	X	Unclear	X	Unclear	Unclear	No	Very low

Positive symptom burden	69	2 (8)	0 1 0	0 0 0	1	X	Unclear	✓	✓	Unclear	No	Low
Negative symptom burden	69	2 (8)	0 1 0	0 0 0	1	X	Unclear	✓	✓	Unclear	No	Low
Employment status	446	1(2)	0 0 0	1 0 0	1	✓	Unclear	✓	✓	Unclear	Yes	Moderate
Comorbid Major Depressive Disorder	446	1(2)	0 0 0	1 0 0	1	✓	Unclear	✓	X	Unclear	No	Low
Previous antipsychotic use (antipsychotic-naïve)	446	1(2)	0 0 0	0 1 0	1	✓	Unclear	✓	✓	Unclear	No	Moderate
Inpatient vs. outpatient care	446	1(2)	0 0 0	0 1 0	1	✓	Unclear	✓	✓	Unclear	No	Low

Phase = phase of investigation. For uni- and multivariate analyses: + number of events with a significant positive value, 0, number of non-significant events; - number of significant events with a negative value. For all other GRADE ratings: ✓, no serious limitations; X, serious limitations; X, very serious limitations; unclear, unable to rate item based on available information. In the case of inconsistency, this was marked as 'unclear' in the case of single studies where the assessment between the PF and the outcome had not been replicated and study quality downgraded for this measure. This is based on guidance from Huguet et al who recommend downgrading the quality of evidence in such cases as this is an indicator that the literature in this area is not well established. Publication bias was also marked as unclear where the relationship between a prognostic factor and an outcome has only been assessed in a single study. Other parameters under assessment have been marked as unclear when data is missing from the study report and was not provided by study authors on request.

Table 4 – Prognostic factors and association with change in BMI at all timepoints.

Outcome: Change in BMI																
			Univariate			Multivariate				GRADE factors						
Prognostic factor	Participant no.	Number of studies (+ study number 1-29)	+	0	-	+	0	-	Phase	Study limitations	Inconsistency	Indirectness	Imprecision	Publication bias	Reasons to upgrade ?	Overall quality
Lipid metabolite PC Phosphatidylcholines aa C36:5	30	29	0	0	0	1	0	1	1	Very serious	Unclear	X	Unclear	Unclear	No	Very low
Lipid metabolite Cholesteryl esters 20:5	30	29	0	0	0	1	0	1	1	Very serious	Unclear	X	Unclear	Unclear	No	Very low
Lipid metabolite α-aminobutyric acid	30	29	0	0	0	1	0	1	1	Very serious	Unclear	X	Unclear	Unclear	No	Very low
Baseline waist circumference	110	1(4)	0	1	0	0	0	0	1	X	Unclear	✓	Unclear	Unclear	No	Very low
Baseline weight	161	2 (4,5)	2	0	0	0	0	0	1	✓	✓	✓	✓	X	No	Low
Antipsychotic plasma concentration	51	1 (5)	1	0	0	1	0	0	2	X	Unclear	✓	✓	Unclear	No	Moderate
Smoking status (Y/N)	131	2 (5,12)	0	2	0	0	1	0	1	X	✓	X	✓	X	No	Low
Duration of untreated psychosis	73	3 (5,13)	1	0	0	1	1	0	1	X	X	X	✓	X	No	Low

Illness severity	168	2 (5,15)	0 1 0	0 2 0	1	X	✓	✓	✓	Unclear	No	Low
BMI rate change	51	1 (5)	1 0 0	0 0 0	1	✓	Unclear	✓	✓	Unclear	Yes	Low
Baseline fasting glucose	480	3 (5,18,19)	1 1 0	0 2 0	1	X	✓	X	✓	X	No	Low
Baseline triglycerides	480	3 (5,18,19)	0 2 0	0 1 0	1	X	✓	X	✓	X	No	Very low
Baseline total cholesterol	480	3 (5,18,19)	0 2 0	0 1 0	1	X	✓	X	✓	X	No	Very low
Baseline low density lipoprotein (LDL) cholesterol	480	3 (5,18,19)	0 2 0	0 1 0	1	X	✓	X	✓	X	No	Very low
Baseline high density lipoprotein (HDL) cholesterol	480	3 (5,18,19)	1 1 0	0 1 0	1	X	X	X	✓	X	No	Very low
Neocortical 5HT-2A receptor binding capacity (pre-antipsychotic)	30	1 (6)	1 0 0	0 0 0	2	X	Unclear	X	Unclear	Unclear	No	Very low
Age (years)	307	1 (27)	0 0 0	1 0 0	1	X	Unclear	✓	✓	Unclear	No	Low
Diagnosis	381	1 (7)	0 0 0	0 1 0	1	X	Unclear	✓	X	Unclear	No	Low
Antipsychotic dose	498	2 (7,15)	0 0 0	0 2 0	1	X	✓	✓	Unclear	Unclear	No	Low
Concomitant antidepressant use	381	1 (7)	0 0 0	0 1 0	1	X	Unclear	✓	✓	Unclear	No	Low

Trend of early BMI increase	432	2 (5,7)	1 0 0	1 0 0	1	X	✓	✓	✓	Unclear	Yes	Moderate
Duration of illness	515	4 (12,13,15,18)	0 0 1	0 4 0	1	X	✓	X	✓	X	No	Low
Illness severity - positive symptoms	22	1 (13)	1 0 0	1 0 0	2	X	Unclear	✓	✓	Unclear	No	Low
Illness severity - negative symptoms	22	1 (13)	1 0 0	0 0 0	2	X	Unclear	✓	Unclear	Unclear	No	Very low
Family history of diabetes	94	1 (14)	0 0 0	1 0 0	1	X	Unclear	X	Unclear	Unclear	No	Low
Response to antipsychotic treatment - total psychopathology	117	1(15)	0 0 0	0 1 0	1	X	Unclear	✓	x	Unclear	No	Very low
Antipsychotic formulation	38	1 (17)	0 0 0	1 0 0	2	✓	Unclear	✓	X	Unclear	No	Low
Waist-hip ratio	296	1 (18)	0 0 1	0 0 1	1	X	Unclear	X	X	Unclear	No	Very low
Diastolic blood pressure	296	1 (18)	1 0 0	0 1 0	1	X	Unclear	X	✓	Unclear	No	Very low
Total protein	296	1 (18)	1 0 0	0 1 0	1	X	Unclear	X	✓	Unclear	No	Very low
Thyroid Stimulating Hormone (TSH)	296	1 (18)	1 0 0	0 1 0	1	X	Unclear	X	✓	Unclear	No	Very low
Thyroxine (T4)	296	1 (18)	1 0 0	1 0 0	1	X	Unclear	X	✓	Unclear	No	Very low

Albumin	296	1 (18)	0 1 0	0 0 0	1	X	Unclear	X	✓	Unclear	No	Very low
Systolic blood pressure	296	1 (18)	0 1 0	0 0 0	1	X	Unclear	X	✓	Unclear	No	Very low
C-Reactive Protein (CRP)	296	1 (18)	0 1 0	0 0 0	1	X	Unclear	X	✓	Unclear	No	Very low
T3 (Triiodothyronine)	296	1 (18)	0 1 0	0 0 0	1	X	Unclear	X	✓	Unclear	No	Very low
Urea	296	1 (18)	0 1 0	0 0 0	1	X	Unclear	X	✓	Unclear	No	Very low
Prolactin	133	1 (19)	0 0 0	0 1 0	1	X	Unclear	X	✓	Unclear	No	Low
Previous antipsychotic treatment	223	2(19,22)	0 0 0	1 1 0	1	X	X	X	X	X	No	Very low
Substance abuse history	133	1 (19)	0 0 0	1 0 0	1	X	Unclear	X	X	Unclear	No	Low
Early appetite increase	33	1(21)	1 0 0	1 0 0	1	X	Unclear	✓	✓	Unclear	No	Low
Hippocampal subfield volume	90	1(22)	0 2 0	1 1 0	2	X	Unclear	X	X	X	No	Low
Substance misuse (active)	90	1 (22)	0 0 0	1 0 0	1	X	Unclear	X	X	X	No	Very low
Peripheral blood mononuclear cell subtypes	58	1 (25)	0 0 0	3 0 1	2	X	Unclear	X	✓	Unclear	No	Low

Phase = phase of investigation. For uni- and multivariate analyses: + number of events with a significant positive value, 0, number of non-significant events; - number of significant events with a negative value. For all other GRADE ratings: ✓, no serious limitations; X, serious limitations; X, very serious limitations; unclear, unable to rate item based on available information. In the case of inconsistency, this was marked as 'unclear' in the case of single studies where the assessment between the PF and the outcome had not been replicated and study quality downgraded for this measure. This is based on guidance from Huguet et al who recommend downgrading the quality of evidence in such cases as this is an indicator that the literature in this area is not well established. Publication bias was also marked as unclear where the relationship between a prognostic factor and an outcome has only been assessed in a single study. Other parameters under assessment have been marked as unclear when data is missing from the study report and was not provided by study authors on request.

Section 2 - GRADE tables for all prognostic factor-outcome associations assessed via adjusted meta-analysis.

Table 1 – Prognostic factors and association with change in BMI assessed at 52 weeks+

Outcome: Change in BMI (adjusted) at 52 weeks +												
						GRADE Factors						
Prognostic factor	Number of participants	Number of studies (+ study number 1-29)	Number of cohorts	Estimated effect size (95% confidence interval)	Phase	Study limitations	Inconsistency	Indirectness	Imprecision	Publication bias	Reasons to rate up?	Overall quality
Sex (M/F)	536	3 (7,13,19)	3	-0.04 (-0.347 – 0.270)	1	X	✓	✓	X	✓	No	Low
Age (years)	626	4 (7,13,19,22)	4	-0.04 (-0.157-0.07)	1	X	✓	✓	✓	✓	No	Moderate
Baseline BMI (kg/m^2)	536	3 (7,13,19)	3	-0.01 (-0.225 – 0.2)	1	X	✓	✓	X	X	No	Low

Phase = phase of investigation. For uni- and multivariate analyses: + number of events with a significant positive value, 0, number of non-significant events; - number of significant events with a negative value. For all other GRADE ratings: ✓, no serious limitations; X, serious limitations; X, very serious limitations; unclear, unable to rate item based on available information. In the case of inconsistency, this was marked as 'unclear' in the case of single studies where the assessment between the PF and the outcome had not been replicated and study quality downgraded for this measure. This is based on guidance from Huguet et al who recommend downgrading the quality of evidence in such cases as this is an indicator that the literature in this area is not well established. Publication bias was also marked as unclear where the relationship between a prognostic factor and an outcome has only been assessed in a single study. Other parameters under assessment have been marked as unclear when data is missing from the study report and was not provided by study authors on request.

Table 2 – Prognostic factors and association with change in weight assessed at 0-12 weeks.

Outcome: Change in weight at 12 weeks												
							GRADE Factors					
Prognostic factor	Number of participants	Number of studies (+ study number 1-29)	Number of cohorts	Estimated effect size (95% confidence interval)	Phase	Study limitations	Inconsistency	Indirectness	Imprecision	Publication bias	Reasons to rate up?	Overall quality
Sex (M/F)	1197	4 (1,2,3,5)	4	0.236 (-0.086 to 0.0558)	1	X	✓	✓	✓	✓	No	Low
Age (years)	1041	3 (1,2,8)	3	-0.061 (-0.119 to -0.003)	1	X	✓	✓	✓	X	No	Moderate

Phase = phase of investigation. For uni- and multivariate analyses: + number of events with a significant positive value, 0, number of non-significant events; - number of significant events with a negative value. For all other GRADE ratings: ✓, no serious limitations; X, serious limitations; X, very serious limitations; unclear, unable to rate item based on available information. In the case of inconsistency, this was marked as 'unclear' in the case of single studies where the assessment between the PF and the outcome had not been replicated and study quality downgraded for this measure. This is based on guidance from Huguet et al who recommend downgrading the quality of evidence in such cases as this is an indicator that the literature in this area is not well established. Publication bias was also marked as unclear where the relationship between a prognostic factor and an outcome has only been assessed in a single study. Other parameters under assessment have been marked as unclear when data is missing from the study report and was not provided by study authors on request.

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Appendix 7 – Chapter 5: Protocol deviations

1. **Aims** – In the protocol, review aims were specified as understanding how interventions designed to improve SDM during antipsychotic treatment choices work and the impact of contextual factors on intervention success. As highlighted in the published study report, subsequent focussing on prescriber perspective was collaboratively agreed. This was subsequently reflected within the study report aims.

2. **Grey literature searching** – In the protocol, it was stated that several additional databases (Open Grey, ProQuest Dissertations, ResearchGate, Google Scholar, Theses and DART-Europe E-theses Portal) would be considered for grey literature searches. Within the review, only Google Scholar was searches due to volume of data identified within initial searches.

3. **Inclusion of opinion pieces/perspectives:** As specified in the study protocol, these data sources were treated with scepticism initially until further supporting evidence was identified. In the review, and not specified in the protocol, opinion pieces and perspectives were initially not included due to the volume identified within initial searches and these being considered weaker quality sources of data to build and refine programme theories. The exclusion of these data sources was reviewed following initial programme theory refinement and development. Some were subsequently included where ideas discussed therein further refined emerging programme theories developed using more rigorous data sources.

4. **Forward citation searching:** In the protocol, it was outlined how backwards and forwards citation searching would be undertaken using Web of Science. Subsequently, within the review, forward citation searching was done in the case of data sources that were assigned a five-star rating. This was agreed upon based on the number of data sources identified as relevant being initially >100 and to avoid superficial analysis of a larger number of data sources.

5. **Inadequate data or use of data primarily judged to be of poor quality:** In the protocol, it was outlined that in the case of inadequate data or use primarily of data

judged to be of poor quality to support any aspect of the programme theory development and refinement, such statements would be cautiously reported with appropriate qualifiers regarding the quality of supporting data. Within the review, it was subsequently agreed to only include context-mechanism-outcome configurations and programme theories that had sufficient quality data to inform clinical practice and mental health policy. This was due to volume of data retrieved during initial searches producing enough quality data to develop the final 10 programme theories and accompanying 23 context-mechanism-outcome configurations. The option of running additional searches was considered. However, 106 data sources were already included within the review. It was judged that the volume of results would likely become unmanageable should further searches be conducted and sufficient recommendations to meaningfully influence policy, practice and research were already produced from the 10 programme theories. Context-mechanism-outcome configurations that were initially formulated but without sufficient quality of supporting data were not reported within the final study report.

Appendix 8 – Chapter 5: Results of database searches

Database searching (primary search)

PubMed
Date range searched: 1990-present
Date searched: 12/12/2023
Searcher: IF
Hits: n= 182

No.	Search terms	Hits
1	(“shared decision-making” [tiab] OR “shared decision making”[tiab] OR “shared-decision making”[tiab] OR “shared treatment decision making”[tiab] OR “shared treatment decision-making”[tiab])	14,991
2	"Decision Making, Shared"[Mesh] OR "Decision Making"[Mesh]	106,631
3	(“decision process” [tiab] OR “decision support”[tiab] OR "Antipsychotic Agents"[Mesh])	27,061
4	1 OR 2 OR 3	131,489
5	(antipsychotic*[tiab] or anti-psychotic*[tiab])	48,626
6	"Antipsychotic Agents"[Mesh]	59,773
7	5 OR 6	79,762
8	(schizophren*[tiab] or schizoaffective[tiab] or psychosis or psychotic*[tiab])	217,736
9	("Schizophrenia Spectrum and Other Psychotic Disorders"[Mesh] OR) "Psychotic Disorders"[Mesh])	164,296
10	8 OR 9	236,714

11	4 AND 7 AND 10 Limits set to: 1990-present	102
12	Implement*[tiab]	680,633
13	No suitable MeSH heading for 12	n/a
14	4 and 7 and 12 Limits set to: 1990-present	20
15	4 and 10 and 12 Limits set to: 1990-present	40
16	("decision aid"[tiab] OR "decision-aid"[tiab])	2,845
17	intervention*[tiab]	1,377,660
18	No suitable MeSH heading for 17	
19	16 OR 17	1,311,899
18	4 AND 7 AND 17 Limits set to: 1. 1990-present	20

Embase

Date range searched: 1990-present.
Date searched: 6/12/23
Searcher: IF
Hits: n= 620

No.	Search terms	Hits
1	'shared decision making': ti,ab OR 'shared decision-making':ti,ab	19,409
2	'Shared decision making'/exp	15,800
3	'decision making': ti,ab OR 'decision support':ti,ab	288,264
4	1 OR 2 OR 3	293,250
5	'Neuroleptic agent'/exp	34,225
6	antipsychotic*: ti,ab OR 'anti-psychotic*':ti,ab	74,628
7	5 OR 6	91,196
8	Schizo*: ti,ab OR Psychotic*:ti,ab OR psychosis:ti,ab	285,927
9	'psychosis'/exp	58,496
10	8 OR 9	2,957,558
11	4 AND 7 AND 10	736
12	#11 AND ([adult]/lim OR [middle aged]/lim OR [young adult]/lim)	317
13	implement*: ti,ab	935,020
13	4 AND 10 AND 13	236
14	'decision aid': ti,ab OR 'decision-aid':ti,ab	3,891
15	'intervention': ti,ab	1,148,705
16	14 OR 15	1,1515,656
17	4 AND 7 AND 16 AND ([adult]/lim OR [middle aged]/lim OR [young adult]/lim) AND [1990-2024]/py	67

PsycINFO
Date range searched: 1990-present.
Date searched: 6/12/23
Searcher: IF
Hits: 183

No.	Search terms	Hits
1	AB shared decision making OR AB Shared decision-making OR AB shared decision making	3,915
2	MM "Decision Making"	70,407
3	AB decision making OR AB decision support	112,137
4	1 OR 2 OR 3	127,798
5	MM "Neuroleptic Drugs"	19,516
6	AB antipsychotic* OR AB anti-psychotic*	31,884
7	5 OR 6	37,877
8	MM"psychosis"	28,478
9	AB schizo* OR AB psychosis OR AB psychotic*	161,279
10	8 OR 9	167,039
11	4 AND 7 AND 10	230
12	11 and Limiters - Publication Year: 1990-2023 Narrow by Subject Age: - adulthood (18 yrs & older)	122
13	AB implement*	212,789
14	4 and 10 and 13	35

15	15 AND Narrow by Subject Age: - adulthood (18 yrs & older)	20
16	AB decision aid OR AB decision-aid	1,925
17	AB intervention	466,480
18	16 OR 17	468,010
19	4 AND 7 AND 18	111
20	19 and Narrow by Subject Age: - adulthood (18 yrs & older)	41

CINAHL PLUS (Cumulative Index to Nursing and Allied Health Literature)
Date range searched: 1990-present.
Date searched: 6/12/23
Searcher: IF
Hits: 120

No.	Search terms	Hits
1	AB shared decision making OR AB Shared decision-making OR AB shared-decision making	7,108
2	(MH "Decision Making, Shared") OR (MH "Decision Making, Clinical")	40,282
3	AB decision making OR AB decision support	85,235
4	or/1-3	115,040
5	(MM "Antipsychotic Agents")	10,077
6	AB antipsychotic* OR AB anti-psychotic*	11,633
7	or/5-6	11,633
8	(MM "Schizophrenia")	23,515
9	AB schizo* OR AB psychosis OR AB psychotic	38,420
10	or/8-9	38,420
11	4 and 7 and 10	184
12	11 and Narrow by Subject Age: - all adult	10
13	AB implement*	234,910
14	4 and 7 and 13	113
15	4 and 10 and 13 and Narrow by Subject Age: - all adult	24

16	AB decision aid OR AB decision-aid	3,256
17	AB intervention	502,111
18	16 or 17	502,111
18	4 and 7 and 17	86

Cochrane Library
Data parameters: CDSR, Protocols, CENTRAL (trials), Editorials, Special Collections, Clinical Answers
Date range searched: 1990-present.
Date searched: 6/12/23
Searcher: IF
Hits: 775

No.	Search terms	Hits
1	(shared decision making OR shared decision-making OR shared-decision making):ti,ab,kw	2843
2	MeSH descriptor: [Decision Making, Shared] explode all trees	150
3	("decision making" OR "decision support"):ti,ab,kw	217,272
4	or/1-3	21,467
5	MeSH descriptor: [Antipsychotic Agents] explode all trees	5695
6	Antipsychotic*:ti,ab,kw OR anti-psychotic*:ti,ab,kw	11,361
7	or/5-6	11,391
8	MeSH descriptor: [Schizophrenia Spectrum and Other Psychotic Disorders] explode all trees	12,275
9	schizo*:ti,ab,kw OR psychosis:ti,ab,kw OR psychotic*:ti,ab,kw	27,002
10	or/8-9	27,113
11	4 and 10	462
12	implement*:ti,ab,kw	58,275
13	4 and 7 and 12	33

14	"decision aid":ti,ab,kw OR "decision-aid":ti,ab,kw	1436
15	intervention:ti,ab,kw	520,534
16	15 or 16	521,170
17	4 and 7 and 16	75
18	4 and 10 and 16	205

Web of Science (Core)
Date range searched: 1990-present.
Date searched: 6/12/23
Searcher: IF
Hits: 261

No.	Search terms	Hits
1	TI=(shared decision making OR shared decision-making OR shared-decision making)	4,794
2	TI=(decision making OR decision-making OR decision support)	128,817
3	2 or 3	128,817
4	TI=(antipsychotic* OR anti-psychotic*)	23,567
5	TI=(Schizo* OR psychosis OR psychotic*)	183,641
6	3 and 4 and 5	16
7	TI=Implement*	269,952
8	3 and 4 and 7	2
9	3 and 5 and 7	1
9	TI=(decision aid OR decision-aid)	5,058
10	TI=Intervention	272,518
11	9 OR 10	277,529
11	4 and 11	250
12	11 and English language limit	244

Sociological Abstracts
Date range searched: 1990 to present
Date searched: 8/12/23
Searcher: IF
Hits: 64

No.	Search terms	Hits
1	noft((“shared decision making” OR “shared decision-making” OR “shared-decision making”))	591
2	noft("decision making" OR "decision-making" OR "decision support")	56,885
3	2 or 3	56,885
4	noft(antipsychotic* OR anti-psychotic*)	527
5	noft(schizo* OR psychosis OR psychotic*)	3,992
6	3 and 4 and 5	10
7	noft("decision aid") OR noft("decision-aid") OR noft(Implement*)	86,426
8	4 and 7	11
9	3 and 5	15
10	Noft(Implement*)	86,352
11	Noft(psychiatr*)	50,347
12	3 and 10 and 11	168

Scopus
Date range searched: 1990-present
Date searched: 8/12/23
Searcher: IF
Hits: n=368

No.	Search terms	Hits
1	TITLE-ABS("shared decision making") OR TITLE-ABS-KEY("shared decision-making") OR TITLE-ABS("shared-decision making")	22,110
2	TITLE-ABS("decision making") OR TITLE-ABS-KEY ("decision support")	1,128,439
3	2 OR 3	975,874
4	TITLE-ABS("antipsychotic" OR "anti-psychotic")	81,199
5	TITLE-ABS(schizo*) OR TITLE-ABS-KEY (psychosis) OR TITLE-ABS(psychotic*)	268,739
6	3 and 4 and 5	16
7	TITLE-ABS(Implement*)	3,425,480
8	3 and 4 and 7	49
9	TITLE-ABS("decision aid*" OR "decision-aid*")	9,592
10	TITLE-ABS(intervention*)	254,143
11	9 or 10	272
12	4 and 11	192
13	TITLE-ABS(implement*)	317,273
14	TITLE-ABS(psychiatr*)	81,104
15	3 and 13 and 14	4

Google Scholar

Date range searched: 1990-present
Date searched: 24/6/24
Searcher: IF
Hits: 267

No.	Search terms	Hits
1	allintitle: psychosis "shared decision making"	7
2	allintitle: antipsychotic "shared decision making"	6
3	allintitle: "mental health" "shared decision making"	34
4	"shared decision making" "psychosis"	120
5	antipsychotic "shared decision making"	100

Database searching methods – (supplemental searches)

PubMed

Date range searched: 1990-present
Date searched: 24/6/24
Searcher: IF
Additional limits: English language
Hits: 367

No.	Search terms	Hits
1	("risk avers*"[tiab] OR "risk-avers*"[tiab])	2,205
2	("inpatient"[tiab] OR “in-patient”[tiab] OR "acute care"[tiab])	31,252
3	Psychiatr*[tiab]	1,006,484
4	1 AND 2 AND 3	9
5	(schizophrenia*[tiab] OR schizoaffective[tiab] OR psychosis OR psychotic*[tiab])	176,132
5	1 AND 4	17
6	(“risk assessment”[tiab] OR “risk management[tiab]”)	118,452
7	2 AND 4 AND 6	10
8	Psychiatr*[tiab]	1,006,484
9	1 AND 8	184
10	(“positive risk taking”[tiab] OR “positive risk management”[tiab] OR “positive risk-taking”[tiab] OR “therapeutic risk taking”[tiab] OR “therapeutic risk-taking”[tiab])	65
11	8 AND 10	23

12	(“mental health staff”[tiab]) OR (“mental health professional”[tiab])	1,719
13	1 AND 4 AND 12	0
14	4 AND 10 AND 12	0
15	10 AND 12	0
16	(“Antipsychotic prescribing”[tiab] OR “anti-psychotic prescribing”[tiab] OR “psychotropic prescribing”[tiab])	545
17	1 AND 16	0
18	10 AND 16	0
19	Risk*[tiab]	3,198,956
20	16 AND 19	124

Embase

Date range searched: 1990-present.
Date searched: 24/6/24
Searcher: IF
Additional limits: English language
Hits: n = 240

No.	Search terms	Hits
1	'risk avers*':ti,ab OR 'risk-avers*':ti,ab	2,352
2	'inpatient':ti,ab OR 'in-patient':ti,ab OR 'acute care':ti,ab	341,302
3	Psychiatr*:ti,ab	435,964
4	1 AND 2 AND 3	58
5	schizophrenia:ti,ab OR psychosis:ti,ab OR psychotic*:ti,ab	260,363
6	1 AND 5	25
7	'risk assessment':ti,ab OR 'risk management':ti,ab	138,468
8	2 AND 5 AND 7	144
9	'positive risk taking':ti,ab 'positive risk management':ti,ab OR 'positive risk-taking':ti,ab OR 'therapeutic risk taking':ti,ab OR 'therapeutic risk-taking':ti,ab	68
10	3 AND 9	10
11	'mental health staff':ti,ab OR 'mental health professional':ti,ab	2,311

12	1 AND 5 AND 11	0
13	5 AND 9 and 11	0
14	5 AND 9	3
15	‘antipsychotic prescribing’:ti,ab OR 'anti-psychotic prescribing’:ti,ab OR ‘psychotropic prescribing’:ti,ab	856
16	1 AND 15	0
17	9 AND 15	0

PsycINFO
Date range searched: 1990-present.
Date searched: 24/6/24
Searcher: IF
Additional limits: English language
Hits: 637

No.	Search terms	Hits
1	AB risk aversion OR AB risk-aversion	1,797
2	AB inpatient OR AB in-patient OR AB acute care	823,373
3	AB schizo* OR AB psychosis OR AB psychotic*	161,279
4	MM"psychosis"	28,478
5	3 OR 4	189,985
6	1 AND 2 AND 5	4
7	AB risk assessment OR AB risk management	25,839
8	2 AND 5 AND 7	574
9	AB positive risk taking OR AB positive risk-taking OR AB positive risk management OR AB therapeutic risk taking OR AB therapeutic risk-taking	384
10	Psychiatr*	703,111
11	9 AND 10	51
12	AB mental health staff OR AB mental health professional	26,278
13	1 AND 5 AND 12	0

14	1 AND 12	3
15	AB antipsychotic prescribing OR AB anti-psychotic prescribing OR AB psychotropic prescribing	
16	1 AND 15	4
17	9 AND 15	1

CINAHL PLUS (Cumulative Index to Nursing and Allied Health Literature)
Date range searched: 1990-present.
Date searched: 24/6/24
Searcher: IF
Additional limits: English language
Hits: 110

No.	Search terms	Hits
1	AB risk aversion OR AB risk-aversion	297
2	AB inpatient OR AB in-patient OR AB acute care	469,424
3	AB schizo* OR AB psychosis OR AB psychotic	36,545
4	(MM "Schizophrenia")	23,685
5	3 OR 4	45,268
6	1 AND 2 AND 5	0
7	1 AND 5	2
8	AB risk assessment OR AB risk management	40,250
9	2 AND 5 AND 8	81
10	AB positive risk taking OR AB positive risk-taking OR AB positive risk management OR AB therapeutic risk taking OR AB therapeutic risk-taking	194
11	Psychiatr*	136,748
12	10 AND 11	25
13	AB mental health staff OR AB mental health professional	8,015
14	1 AND 5 AND 13	0

15	1 AND 13	2
16	AB antipsychotic prescribing OR AB anti-psychotic prescribing OR AB psychotropic prescribing	579
17	1 and 16	0
18	10 AND 16	0
19	AB risk*	795,028
20	16 AND 19	0
21	AB risk behaviour	23,618
22	16 AND 20	0

Google Scholar
Date range searched: 1990-present
Date searched: 24/6/24
Searcher: IF
Hits: 27,819

No.	Search terms	Hits
1	"positive risk taking" "psychiatry"	1,810
2	"mental health" "positive risk taking"	2,850
3	psychiatry "Risk aversion"	21,000
4	"mental health" "Risk aversion"	23,100
5	"antipsychotic prescribing" "Risk aversion"	30
6	"antipsychotic prescribing" "positive risk taking"	29

Appendix 9 – Chapter 6: COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	IF conducted all research interviews.
Credentials	2	What were the researcher's credentials? E.g., PhD, MD	At the time of undertaking the interviews, IF's credentials were BPharm, MPharm, MSc.
Occupation	3	What was their occupation at the time of the study?	IF is an Irish registered pharmacist, who was undertaking a PhD in clinical pharmacy research and working as a psychiatric pharmacist when this study was conducted.
Gender	4	Was the researcher male or female?	Female
Experience and training	5	What experience or training did the researcher have?	IF completed an 8-week course in qualitative research prior to beginning this work. IF was also supervised by researchers with extensive experience of qualitative research.

Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	Five participants were known to IF through a prior clinical relationship.
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g., personal goals, reasons for doing the research	IF disclosed to all participants that she was a pharmacist undertaking this study as part of her PhD, prior to conducting the interviews.
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g., Bias, assumptions, reasons and interests in the research topic	IF is a registered pharmacist working in psychiatry who is conducting this study as part of a PhD exploring how to improve the management of antipsychotic-induced weight gain in clinical practice. This information was disclosed to participants ahead of the interview.
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g., grounded theory, discourse analysis,	A qualitative descriptive methodology was employed given study aims were not to provide an

		ethnography, phenomenology, content analysis	increasing theoretical, conceptual or highly abstract understanding of the topic, but rather to provide a descriptive summary of the informational content of the data that could be easily understood and implemented by stakeholders.
Participant selection			
Sampling	10	How were participants selected? e.g., purposive, convenience, consecutive, snowball	Purposive sampling guided the sampling strategy whereby participants with a diversity of experiences of AIWG management were purposely recruited to increase credibility and transferability of results.
Method of approach	11	How were participants approached? e.g., face-to-face, telephone, mail, email	Participants attending outpatient services of a psychiatric secondary care setting in the Republic of Ireland were included. Although recruited through one centre, participants were explicitly asked to reflect on all experiences of managing AIWG to capture varying experiences over time and across settings. Participants were primarily recruited via advertisement where participants

			were asked to respond to advertisements placed in outpatient settings. Clinicians could also highlight the study to potentially relevant individuals.
Sample size	12	How many participants were in the study?	Seventeen.
Non-participation	13	How many people refused to participate or dropped out? Reasons?	Not applicable as participants responded to advertisement. No participant dropped out after agreeing to be included and interviewed as part of the study.
Setting			
Setting of data collection	14	Where was the data collected? e.g., home, clinic, workplace	Interviews took place primarily online due to Covid-19 restrictions in place during project planning. Following subsequent lifting of restrictions, two interviews took place in person.
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	No.
Description of sample	16	What are the important characteristics of the sample? e.g., demographic data, date	Participant characteristics are displayed in Table 26 of thesis.
Data collection			

Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	An interview guide was drafted with reference to existing literature and study aims. The guide was reviewed by individuals with experience of a SMI and AIWG (who were not study participants). The guide was amended based on feedback from this group before study commencement and thus, was not piloted. The interview guide was also updated iteratively throughout data collection to incorporate questions addressing emerging concepts.
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	No.
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	Interviews were audio recorded only and supplemented with field notes taken during interviews.
Field notes	20	Were field notes made during and/or after the interview or focus group?	As in 19.
Duration	21	What was the duration of the inter views or focus group?	45-60 minutes.

Data saturation	22	Was data saturation discussed?	Concepts arising from data analysis following early interviews drove subsequent recruitment to test emerging concepts. Thus, participant sample size was not determined *a priori.* Recruitment cessation was based on the concept of 'data sufficiency' i.e., sufficient data was available to meet study aims. Data sufficiency was conceptualised as consensus amongst researchers that a sufficiently detailed and rich aggregate account of AIWG management experiences and preferences for management was reached.
Transcripts returned	23	Were transcripts returned to participants for comment and/or	All participants were offered a copy of their transcript.
Domain 3: Analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	Initially three researchers (IF, EC, LS) double-coded anonymised transcripts independently. Subsequently, a codebook was developed and used amongst all

			members of the research team to discuss emerging findings, develop themes and discuss additional recruitment needs.
Description of the coding tree	25	Did authors provide a description of the coding tree?	As in 24.
Derivation of themes	26	Were themes identified in advance or derived from the data?	Both semantic and latent codes were developed, largely inductively.
Software	27	What software, if applicable, was used to manage the data?	NVivo (Release 1.7.1)
Participant checking	28	Did participants provide feedback on the findings?	Participants were offered the opportunity to member-check themes for accuracy and validity.
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g., participant number	Yes.
Data and findings consistent	30	Was there consistency between the data presented and the findings?	See results section in chapter 6.
Clarity of major themes	31	Were major themes clearly presented in the findings?	See Figures 14 and 16 in chapter 6.

Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	Not applicable.

Appendix 10 – Chapter 6: Ethics approval letter from SPMHS Research Ethics Committee

www.stpatricks.ie

St Patrick's Mental Health Services

PRIVATE & CONFIDENTIAL

May 13, 2022

Ms Ita Fitzgerald
Senior Pharmacist
St Patrick's Mental Health Services

Re: Managing antipsychotic-induced weight gain – patient experiences, perspectives and suggestions for change – a qualitative descriptive study *(Protocol 02/22)*

Dear Ms Fitzgerald,

Thank you for your email of May 12, 2022, responding to queries regarding your application and submitting revised documentation. A sub-committee of the Research Ethics Committee has reviewed your response, and on this basis, I am pleased to inform you that **this study has been granted chair approval** and the full committee will be informed of this outcome at their next meeting.

This approval is granted subject to the following standard conditions:

1. You must adhere fully to the terms and conditions set out in your research protocol.
2. All persons involved in this research who are not employees of St Patrick's Mental Health Services are required to obtain an honorary contract from the hospital. This process should be initiated by the study supervisor. It will be your responsibility to ensure that these contracts are renewed and kept up-to-date as necessary throughout the duration of your study.
3. If there are any material changes to be made to Protocol 02/22 in the next 12 months, you must contact the Research Ethics Committee for approval.
4. You must report back to the Research Ethics Committee no later than 12 months subsequent to this approval letter (May 13, 2023), with a summary report on the progress of this research. This report can be downloaded from the hospital website. Failure to complete this report may result in ethical approval being withdrawn for your research.
5. The committee encourages all researchers to publish the results of their study once it is completed, whether these appear to be positive or negative. We expect to receive copies of your publication(s), presentations and posters that are presented by you and your team.
6. You should provide written confirmation of the destruction of all electronic recordings used for your study.

St Patrick's Mental Health Services – Research Ethics Committee
Please reply to: James Braddock, Research Ethics Committee Administrator, St Patrick's Mental Health Services
P.O. Box 136, James's Street, Dublin 8 (Tel: (01) 2493345; email: jbraddock@stpatsmail.com)
St Patrick's Mental Health Services is an independent not-for-profit charitable trust. Registered in Ireland CHY209

7. The Irish Data Protection Act 2018 gives further effect under national law to the GDPR regulations that became enforceable on the 25th May 2018. Subsequently, the Health Research Regulations were incorporated into the Irish Data Protection Act 2018 under Section 36(2) and came into force on August 8th, 2018. You are encouraged to review the information available on the Health Research Board website: http://www.hrb.ie/funding/gdpr-guidance-for-researchers/. Your submission has been reviewed by the Research Ethics Committee from an ethical perspective only and this approval is not, and should not be, regarded as evidence of compliance with the above legislation. Please note it is the responsibility of the researchers, specifically the data controller and the principal investigator, to ensure and monitor compliance with the relevant data protection legislation.

8. Please complete the attached form and send it via email to regionallibrary@hse.ie. The Directorate of Clinical and Quality Care in the HSE have requested that details of all research projects in Ireland be pooled together in one location, namely, www.lenus.ie, for the purpose of promoting a culture of research and in order to deliver evidence based clinical care. The HSE hope to gain a complete picture of the quality and quantity of healthcare and healthcare-related research in Ireland, and St. Patrick's Mental Health Services have agreed to cooperate with this process. This repository of research activity is managed by Health Librarians based in Dr Steevens' Hospital, and we thank you in advance for emailing this relatively simple form to them at your convenience.

Thank you for your patience and understanding during this review process and we wish you well with your research.

Yours sincerely,

James Braddock
Research Ethics Committee Administrator
St Patrick's Mental Health Services Research Ethics Committee

Encl.

cc. *Ciara Ni Dhubhlaing, Study Supervisor*

Appendix 11 – Chapter 6: Final interview guide

Before we begin**,** I would like to confirm that you have read and signed the informed consent form, that you understand your participation in this study is entirely voluntary, that you may decline to answer any question, and that you may withdraw from the study at any time.

Thank you for agreeing to be interviewed. I want you to remember that you are the expert in all of this. People will have different views and experiences of managing AIWG. These differences are important to us, and we value your unique experience. If you need a break during interviewing, please let me know. There may be times during the interview when I ask to explain things that might seem obvious. This is for the purposes of making sure I don't misinterpret what you say. This should take around one hour, but it can be shorter or longer depending on what you want to tell me. I will be guided by you. Are you ready to begin?

Topic	Question(s)	Prompt(s)
1. Gaining weight from antipsychotic treatment	Q1. Could you tell me about your experience with weight gain caused by your antipsychotic medication? Q2. Can you give me some words to describe your experience with gaining weight from antipsychotics?	- When did you first notice weight gain was a side effect of your antipsychotic? - How much weight did you gain? - Do you continue to gain weight? - How did you learn weight gain was a side effect of your medication? - How has this weight gain impacted you?

		- When this happens, is this something that occupies a lot of your time thinking about, and if so, why do you think that is?
2. Managing antipsychotic-induced weight gain personally	Q1. Could you tell me about how you manage this extra weight yourself? This can include any option or method that you have tried. Q2. Are there any methods that you found particularly helpful (or unhelpful) to reduce or prevent further weight gain? Q3. If any methods were particularly helpful/unhelpful - why do you think that method(s) was successful/unsuccessful? Q3. How does how you manage weight gain change depending on your mental health status? Q4. For those who have tried medications - How did the medication	- What methods (if any) did you use to try to lose, or reduce further weight gain, caused by taking your antipsychotic? - Have you tried diet and lifestyle options to lose weight? If so, could you tell me about what you did? - Have you tried to change your medications to try and reverse - Have you ever tried any medications that could be bought without a prescription or online to manage weight gain caused by antipsychotics?

	help you to manage your weight? Was this different to other approaches you had tried e.g., dietary changes? If so, how?	
3. Experience of managing antipsychotic-induced weight gain – acceptability of interventions provided by healthcare services	Q1. What option(s) have been suggested to you by healthcare providers/services as ways to reduce weight gain caused by antipsychotics? Q2. At what stage of treatment were support options offered to you? Q3. From question 1 - how suitable or acceptable did you feel those choices were? Q4. If support options were offered to you to reduce weight gain from antipsychotics, what follow up was provided to you? This might include asking how well an intervention worked or whether other options should be tried.	- Were a range of management options provided to you? - What lifestyle advice was offered to you? - What dietary advice was offered to you? - Have you been offered additional medications to manage your weight? - If one management option was not suitable, were you offered an alternative management option? - How do you feel about the timing at which interventions were offered? - Have you sought/been offered support from a specialist weight management service

	Q5. Do you think that your physical healthcare was prioritized in your experience of mental health services?	- In the case of dietary advice, were you offered personal/group/general advice?
4. Experience of managing antipsychotic-induced weight gain within the healthcare system – experience with healthcare providers	Q1. Which healthcare providers did you ask for support with managing weight gain caused by antipsychotics? This could include your general practitioner (GP) or someone from your mental healthcare team. Q2. Can you give me some words to describe this experience of speaking with healthcare providers about managing weight gain caused by antipsychotics? Q3. Who do you feel is responsible for managing weight gain caused by antipsychotics? Q4. Do you feel like you were adequately supported (across any setting) in managing this side effect?	- Did you ask for support (management options) from healthcare providers with managing weight gain caused by antipsychotics or was it offered to you first? - Did you ask the person(s) who prescribes your antipsychotic medication for support with managing your weight? - How did the management experiences with healthcare professionals around this side effect leave you feeling? (new) - Did you ask or discuss weight gain caused by antipsychotics with someone outside your mental health team, including a GP, private dietician etc. - If you didn't ask for help or support, why was this?

		- Is discussing your weight with those who look after your mental health or general healthcare provider something you feel comfortable doing? - How did it feel to ask for help with managing weight gain caused by antipsychotics? - Did you feel that you were listened to when you asked for support with managing your weight? - Was there any difference n care provision approach by those who did and did not have experience with AIWG e.g., GP vs. psychiatrist (new)
5. Current standard of management - hierarchical management of antipsychotic-induced weight gain	Currently what is recommended to those who work in healthcare when helping service users manage weight gain caused by antipsychotics is to recommend what is called a 'tiered approach'. This means that first we should offer diet and lifestyle advice to help you manage your weight, then consider changing antipsychotic	- Do you think diet and lifestyle approaches should be tried by everyone before other options, like switching antipsychotics, or trying a medication to reduce appetite, are tried? - Did you discuss switching antipsychotic medication with a healthcare provider to manage weight gain caused by antipsychotics?

	medication and finally, adding in an extra medication to help with weight loss. Q1. Was this type of approach offered to you when managing weight gain caused by antipsychotics? Q2. How appropriate do you think this approach is? Q3. How do you feel about taking an extra medication to treat or prevent current weight gain? Q4. When should medications to manage weight gain caused by antipsychotics be considered? (re-phrased) Q5. How do you feel about a combination of approaches being used to manage weight gain caused by antipsychotics	- Were you ever offered the use of an additional medication to help manage your weight? - Should we apply the same management approach in everyone? - Would you prefer to wait to take an additional tablet to manage your weight until weight gain had occurred? - Would you prefer to wait to take an additional tablet to manage your weight until other options have failed, for example trying a new diet or increasing the amount of exercise you do?

	Q6. Some new medications that are available to reduce weight gain caused by antipsychotics are medications that need to be injected once a day or once a week. How do you feel about this option?	
6. Service user attitude, values, and preferences on AIWG management	Q1. What does improved management of this side effect look like to you? Q2. What would be the most important thing(s) a service should provide to help service users manage weight gain caused by antipsychotics? Q3. How could healthcare providers improve their communication with service users around weight gain caused by antipsychotics?	- Picture if you were to start again with taking an antipsychotic and were experiencing unwanted weight gain, what does improved management look like to you? - How often should weight be checked? - How do you feel about being weighed or weighing yourself? - Should the intensity of supports you are offered change depending on your mental health symptoms?

	Q4. When considering whether to take an antipsychotic that is associated with weight gain, what information about this side effect would you want to know? Q5. Do you think you can be an active partner in deciding what medication to take if you are experiencing mental health symptoms? What does this depend on?	- When should we speak to service users about weight gain that antipsychotics can cause? - How do you feel about interacting with a specialist in exercise like you would interacting with a specialist in food i.e., dietician? - When you are unwell, do you think you can engage in conversations at the point of prescribing around side effects like weight gain?

Closing – I'd like to finish the interview by asking you if there is anything else that you would like to mention that we haven't spoken about thus far?