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Advancing Technology Design to Support Patient-Centred Experiences in Decentralised Clinical Trials

Eoin Gamble, M.Sc.

Head of School: Prof. Chris McCusker

Supervised by: Dr Conor Linehan & Prof. Ciara Heavin

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School of Applied Psychology,

University College Cork, Ireland

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For Pat and Sue

Abstract

Decentralised clinical trials (DCTs) are medical trials in which some of the activities that traditionally take place in a face-to-face clinical setting are replaced with technology tools that allow for remote patient participation. Industry stakeholders and regulatory bodies often describe DCTs as patient-centred, highlighting their potential to enhance retention, adherence, and participation. However, the challenge of ensuring that technology meaningfully enhances a patient-centred experience calls for continued refinement.

This thesis investigates how technology can be designed to better support patient experiences in DCTs. By critically evaluating the assumption that DCTs are fundamentally supportive of the patient experience, the thesis employs empirical data and theoretical frameworks to create tools for improving future technology design through four complementary studies.

The first study in Chapter 3 presents a systematic scoping review of retention strategies in published clinical trials. The study frames retention strategies in terms of participant motivation, highlights effective approaches, and demonstrates the value of applying theoretical frameworks to guide technology design decisions. By applying behavioural and psychological theory Self-Determination Theory, these insights offer guidance for designing technology that better supports participant engagement and retention, such as tailoring experiences to individual needs, reinforcing competence, and supporting relational connection.

The second study in Chapter 4 uses qualitative interviews with 15 clinical research staff to explore perceptions of delivering a patient-centred experience in decentralised trials. Thematic analysis identified the limited quality and frequency of interactions with patients, alongside six related themes. While DCTs improve accessibility, they introduce complexities that can affect patient engagement and retention, highlighting the need for additional support,

streamlined technology, and collaboration with staff and patients to enhance the patient-centred experience.

The third study in Chapter 5 uses qualitative interviews to explore the lived experiences of 14 individuals' participation on decentralised clinical trials, focusing on the challenges and opportunities of remote participation. Using a thematic analysis this study identified six main themes, including positive experiences with remote participation, co-ownership, and the hidden workload of participation. The findings highlight the need for technology that supports participants' well-being and experience, and for collaboration with stakeholders to enhance engagement beyond basic remote access.

The final study in Chapter 6 builds on these findings by presenting a set of design cards to guide the design and ideation of patient-centred technology in DCTs. The cards were developed by synthesising insights from the preceding studies involving participants and trial staff, alongside relevant literature, and were evaluated through practitioner feedback following their use in workshop activities. This offers a novel approach and practical guidance grounded in a patient-centred care model, Self-Determination Theory, and empirical evidence from this research. They can be applied to inform the design of future DCT technology, supporting interventions that are more engaging and ultimately improving the patient experience. By integrating insights from the previous studies, the cards provide actionable guidance for technology practitioners, translating evidence and theory into design decisions that enhance patient-centred experiences in DCTs.

Collectively, the four studies presented in this thesis investigate and help inform how technology can be designed to better support patient experiences in decentralised clinical trials, combining a systematic review, qualitative insights from staff and participants, and a practical design outcome. The research synthesises evidence from the literature, staff perspectives, and participant experiences to inform the creation of design cards, which provide guidance for

developing patient-centred technology in DCTs. By integrating these complementary studies, the thesis offers a coherent foundation linking empirical findings, theoretical guidance, and design practice.

Table of Contents

Abstract **3**
Table of Contents **6**
Declaration: **9**
List of Tables: **10**
List of Figures: **11**
Publications from This Thesis **14**
Chapter 1: Introduction **15**
Thesis Aim 16
Objectives 17
Method and Philosophical Standpoint 21
Layout of the Thesis 23
Contribution of the Thesis 25
References: Chapter 1 29
Chapter 2: Literature Review **34**
Clinical Trials: A Broad Overview 34
Patient Centricity 38
Decentralised Clinical Trials: Overview 41
Introduction to DCTs and Participant Benefits 42
Practical Advantages and Industry Benefits 43
Technology in DCTs 43
Participant Experience and Engagement 44
Stakeholder and Practitioner Perspectives 45
Challenges and Opportunities in Designing Decentralised Trial Technology 46
Designing Technology to Support Patient Experience in DCT 46
HCI and Design Approaches to Supporting Patient Experience in Healthcare Technology 46
Limitations of Existing Design Approaches in the Context of DCT 47
Role of Behavioural and Psychological Theory in Understanding Engagement and Experience 48
Challenges in Translating Theory into Design Practice 48
Importance of Empirical Perspectives from Staff and Participants 49
Design Supports, Artefacts, and Tools as a Means of Integrating Theory, Evidence, and Practice 50
Outline Arguments for PhD Research 51
References: Chapter 2 53
Chapter 3: Establishing Requirements for Technology to Support Clinical Trial Retention: Systematic Scoping Review and Analysis Using Self-determination Theory **66**
Abstract 66
Introduction 68

Background 69
Methods 75
Results 80
Discussion 106
References: Chapter 3 113
Reflections on Chapter 3 120
Chapter 4: Adaptation of Clinical Research Staff to Decentralised Clinical Trials and Impacts on the Patient-Centred Experience: Qualitative Interview Study 123
Abstract 123
Introduction 125
Methods 127
Results 131
Discussion 154
Conclusions 158
References: Chapter 4 161
Reflections on Chapter 4 168
Chapter 5: Understanding the Experiences and Needs of Participants in Decentralised Clinical Trials: A Qualitative Analysis 170
Abstract 170
Introduction 171
Methods 175
Findings 179
Discussion 201
References: Chapter 5 208
Reflections on Chapter 5 216
Chapter 6: Design and Evaluation of Ideation Cards to Support the Patient-Centred Design of Decentralised Clinical Trial Technology 219
Abstract 219
Introduction 220
Methods 225
Design and Development of Cards 226
Evaluation Methodology 235
Findings 239
Discussion 256
References: Chapter 6 264
Chapter 7: Discussion 274
Gap Between Patient-Centred Claims and Experiences 275
The Double-Edged Nature of Decentralisation 275
Relational Dynamics Shaping Participation 276
Technology Design and Its Impact on Experience 277
Patient-Centred Experiences in DCTs: Alignment With Patient Needs 278
Theory-Informed Approaches to Guide DCT Technology Design 279

Socio-Technical Complexity Shaping Patient Experiences 280
Implications for Design 281
Strengths and Limitations 282
Strengths 282
Limitations 287
Future Research Recommendations 290
Conclusion 293
References: Chapter 7 295
Appendices 300

Declaration:

This thesis is my own work and has not been submitted for another degree, either at University College Cork or elsewhere.

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Eoin Gamble

List of Tables:

Chapter 3

Table 3.1: The quantitative papers identified with the various percentages of participant retention achieved, therapeutic area, and study population 81

Table 3.2: The qualitative papers identified, therapeutic area, study participants, and trial population. 84

Table 3.3: Selected articles with the identified higher-order themes based on self-determination theory and analysis of theory in articles. 86

Chapter 4

Table 4.1: An overview of the participants interviewed in the study 130

Chapter 5

Table 5.1: Summary of Study Participants - Overview of interviewed participants (all names are pseudonyms). 177

Chapter 6

Table 6.1: Patient-centred themes, definitions, and sub-themes 230

Table 6.2: Summary of Study Participants - Overview of interviewed participants (all names are pseudonyms). 236

List of Figures:

Chapter 1

Figure 1.1: Thesis Map - Chapters, Objectives, and Contributions 20

Chapter 3

Figure 3.1: PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. 77

Figure 3.2: Higher-order themes and abstracted subthemes describing the types of strategies observed within each theme. 89

Chapter 4

Figure 4.1: Key themes and subthemes identified in the study. CRS: clinical research staff; DCT: decentralised clinical trial. 131

Chapter 5

Figure 5.1: Findings - Themes and Sub-themes - illustrates the key themes and sub-themes that developed from the study 180

Chapter 6

Figure 6.1: Examples of the front and back of the Patient-Centred Design Cards 231

Figure 6.2: Examples of the Patient-Centred Design Cards. 232

Figure 6.3: Findings - Theme and Sub themes 241

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I am grateful for the opportunity to pursue a PhD. I need to remind myself not everyone has the chance to take on such a journey, one that only a select few pursue, and that I am very fortunate to have had the experience, to recognise it as a great achievement, and to fully appreciate it. This opportunity has allowed me to explore questions I care about, grow, learn, and understand new concepts and approaches, discover what I'm capable of, and be challenged in ways that have shaped both my professional and personal growth. It is a rare and valuable experience, and I am thankful to have had the chance to see it through to completion.

Publications from This Thesis

Peer-reviewed publications

Gamble, E., Linehan, C., & Heavin, C. (2023). Establishing requirements for technology to support clinical trial retention: systematic scoping review and analysis using self-determination theory. Journal of Medical Internet Research, doi:10.2196/38159

Gamble, E., Heavin, C., & Linehan, C. (2025). Adaptation of Clinical Research Staff to Decentralized Clinical Trials and Impacts on the Patient-Centred Experience: Qualitative Interview Study. Journal of Medical Internet Research, doi:10.2196/62947

Journal articles currently under review reviewed

Gamble, E., Heavin, C., & Linehan, C. (2026). Understanding the Experiences and Needs of Participants in Decentralised Clinical Trials: A Qualitative Analysis. medRxiv, 2026-01. doi:10.64898/2026.01.12.26343978

Journal articles awaiting submission

Gamble, E., Heavin, C., & Linehan, C. (2026). Design and Evaluation of ideation cards to support the patient centred design of Decentralised Clinical Trial Technology

Contribution of First Author

This thesis includes peer-reviewed articles as chapters for which I was the first author. I was responsible for conceptualising the research, conducting data collection, analysing the findings, and overseeing the writing and publication process.

Chapter 1: Introduction

Clinical trials are a fundamental component of modern evidence-based medicine and remain the most reliable method for assessing the value and effects of medical interventions, including drugs and medical devices (Friedman et al., 2015). Clinical trials generate evidence for the efficacy, benefits, and potential harm of various treatments across diseases (Yusuf, 1999). These trials have transformed healthcare decision-making by shaping how we determine whether a treatment does more good than harm (Sackett & Cook, 1994a). Conducting clinical trials involves substantial costs, with patient recruitment and retention representing two of the most expensive components (Chaudhari et al., 2020). Rising costs can impede the development of new treatments and create challenges for organisations seeking to continue trial operations (Probstfield & Frye, 2011). Ensuring participants are successfully recruited, retained, and engaged is therefore essential for both the scientific validity and cost-efficiency of trials (Brueton, Tierney, et al., 2014; Coday et al., 2005; Liu et al., 2018).

In response, industry stakeholders, regulatory bodies, and pharmaceutical companies have introduced initiatives to make trials more accessible, improving retention, engagement, and the overall patient experience (Coyle et al., 2022a; Jong et al., 2022; Minetti et al., 2025). Guided by the goal of delivering a patient-centred experience, this approach emphasises addressing patients' needs throughout the trial (Tong et al., 2022). The rise of decentralised clinical trials (DCT) reflects this orientation, as they aim to lessen the demands placed on participants and foster a more patient-centred trial (Sinha et al., 2024). DCTs minimise the need for site visits and enable data collection and trial interactions via digital platforms directly from participants' homes (De Brouwer et al., 2021; J. Moore et al., 2022).

While DCTs are widely described as "patient-centred" (Rogers et al., 2022; Sinha et al., 2024), it is unclear whether the remote nature, technology, and experience at the core of these trials genuinely support patient-centred experiences. The shift to technology-mediated

DCTs reduces direct human contact, places technology at the centre of interactions, and can increase the demands on patients to collect and manage their own data (Petrini et al., 2022). These changes introduce new unintended risks of disengagement, potentially undermining the patient-centred goals the model is intended to achieve. Thus, this raises an important practical and theoretical concern: the design of DCTs may not, in practice, align with patients' actual needs and provide positive experiences.

Despite the growing adoption of DCTs, few studies have examined how the technology-mediated and remote nature of these trials shape patient experiences in practice. As a result, guidance remains limited on how to design DCT technology in ways that meet patients' needs, enhance engagement, and enable meaningful interactions between patients and trial staff. Addressing this gap is important, as enhancing the patient experience is central to achieving true patient-centricity, which in turn can improve retention, adherence, and overall trial quality. This thesis directly addresses this gap by advancing empirical understanding of patient experiences in decentralised clinical trials and offering evidence-based insights to inform the design of DCT technology that supports patient-centred experiences.

This thesis sits at the intersection of Human-Computer Interaction (HCI), design research, digital health, and clinical trials. Specifically, it contributes to HCI research concerned with patient-centred design, decentralised supporting technologies, and the development of design methods for translating stakeholder experiences, empirical evidence, and established theoretical and conceptual frameworks into technology design practice.

Thesis Aim

The aim of this thesis is to understand and help inform how technology can be designed to better support patient experiences in decentralised clinical trials. Specifically, it investigates patterns of patient engagement and experiences across clinical trials, including decentralised

contexts, and examines how these insights can be translated into guidance for the design of DCT technology. Through this work, the thesis extends current understanding of how decentralised trial models shape patient experiences and provides evidence-informed guidance for designing technology that better supports patient experiences.

Objectives

The research is structured around four sets of objectives, each corresponding to an area of investigation that builds understanding and directly informs design decisions for DCT technologies.

Establishing requirements for technology

- To identify effective retention strategies used in clinical trials.
- To determine the theoretical principles underlying these strategies that can inform the design of trial technology.

These provide an initial understanding of how trials engage and retain participants. This objective is addressed through the study in Chapter 3, which analyses reported retention strategies using self-determination theory to reveal the behavioural and motivational mechanisms they rely on, and to identify factors that technology could support to improve patient experiences. This step ensures that design decisions are grounded in the practical realities of trial participation.

Understanding clinical research staff perspectives

- Investigate how clinical research staff perceive DCTs, with attention to how remote models and technology mediation affect patient centricity.

- Identify the operational, relational, and contextual challenges and opportunities staff encounter during DCTs.

These objectives capture the operational, practical, and relational aspects of DCTs from the perspective of research staff. Understanding staff practices, constraints, and insights is essential because they are uniquely positioned to observe how trial type affects patients' experiences, and the impacts of decentralised approaches on participation. Chapter 4 addresses this objective by exploring staff perceptions of how patients experience and interact with decentralised trials, generating insights to guide technology design. Capturing staff perspectives on the challenges they face, and their views of patients' experiences, ensures that design recommendations respond to both staff realities and patient needs.

Understanding participant experiences

- Examine participants' experiences in DCTs, including interactions with staff and technology, and the impacts of remote participation.
- Explore factors that influence participants' overall experience, engagement, motivation, and satisfaction.

These objectives provide direct insight into patient experiences, highlighting what works well in DCTs, and where difficulties arise. This objective is addressed through Chapter 5, which investigates participants' experiences in decentralised trials, capturing the practical, emotional, and relational factors that shape engagement and satisfaction. By identifying these factors, this stage ensures that design solutions are responsive to real-world patient needs and expectations.

Applying insights to design

- Develop a set of design cards that integrate findings from the previous chapters to support patient-centred technology design.
- Evaluate the design cards with DCT technology practitioners to assess their effectiveness in guiding design decisions and ideation processes.

These objectives translate the insights gained from literature, staff, and participants into a practical tool for designers. This objective is addressed through Chapter 6, which develops and evaluates a set of design cards with DCT technology practitioners, ensuring the tool is validated and effective. By involving practitioners in testing, the research confirms that the tool can guide technology development to enhance patient experiences.

The objectives progress from understanding existing practices and experiences through literature, staff, and participants, to producing and testing a practical design resource. By first examining retention strategies, the research identifies aspects of trial participation that technology can support. Next, exploring the impacts of decentralised clinical trials in real-world contexts provides insight into challenges and opportunities for both staff and participants, ensuring recommendations are grounded in practice. Finally, translating these insights into a tool for technology practitioners applies evidence-informed guidance directly to design decisions, systematically addressing the aim of improving technology to support patient experiences during DCTs.

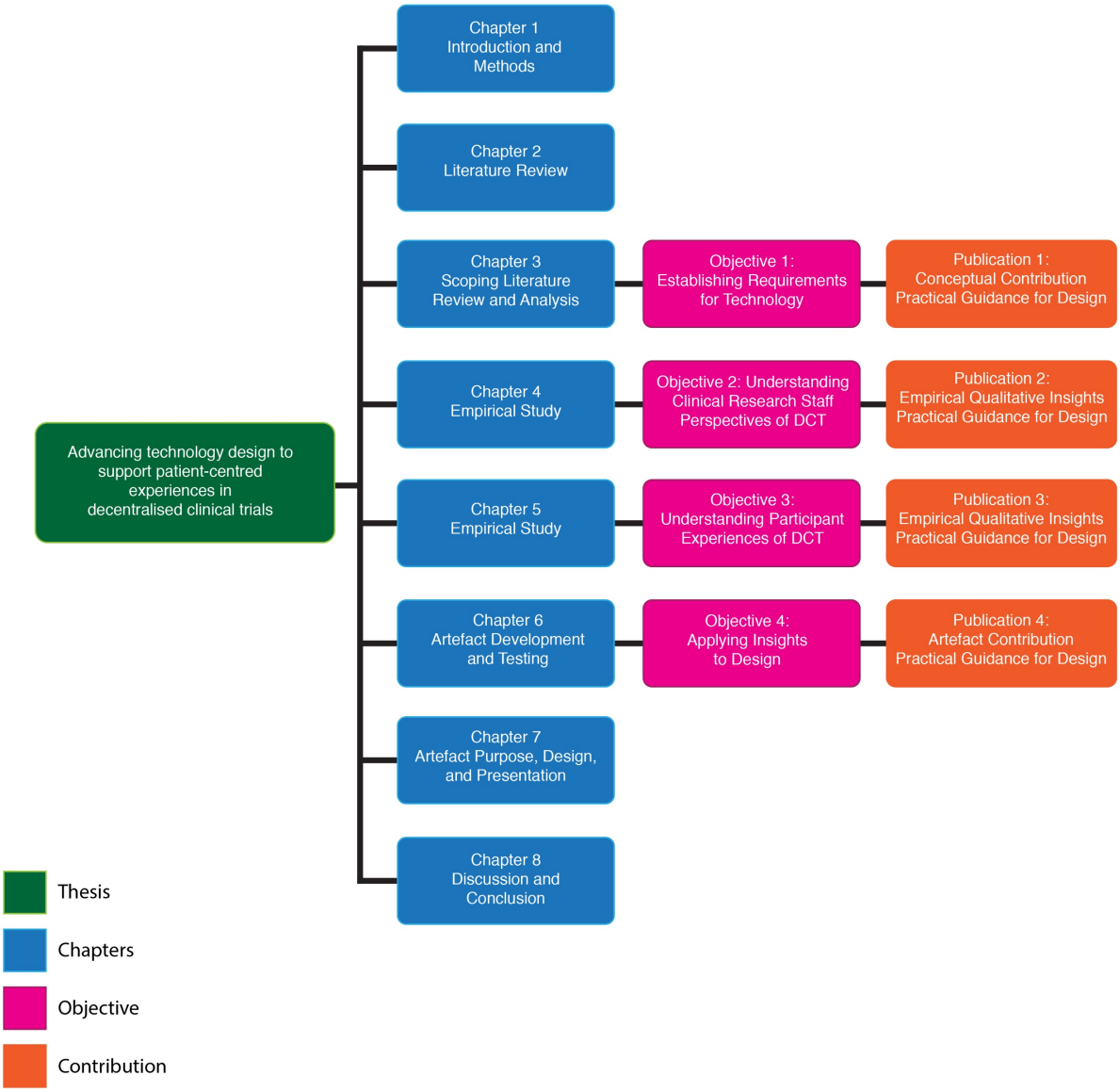


Figure 1: Thesis Map - Chapters, Objectives, and Contributions

Method and Philosophical Standpoint

This section presents the rationale for adopting a pragmatic approach to conceptualising and conducting this research.

Design research frequently draws on a pragmatist stance, focusing on using concepts that can be operationalised to guide design projects and inform practical decision-making (Dalsgaard, 2014), taking a perspective that values knowledge for its practical utility (McCarthy & Wright, 2004). Consistent with this, my research adopts a pragmatic approach: rather than attempting to identify every factor influencing patient experiences in decentralised clinical trials (DCTs), the aim is to develop a set of actionable principles to inform the design of patient-centred technologies. Pragmatism here guides the focus on knowledge that can directly support design decisions and prioritises practical impact to inform DCT technology design.

As discussed in Chapter 2, decentralised clinical trials are shaped by multiple factors, including the involvement of multiple stakeholders, the remote nature of participation, and the technologies used. Understanding patient experience in these trials is complex. It is influenced by individual circumstances, health context, technologies provided, and interactions with research stakeholders experiences in DCTs (Boyd et al., 2024a; Gregg et al., 2020; Singh et al., 2023), making context-sensitive, qualitative insights critical. A pragmatic approach helps navigate this complexity by shaping research questions and sequencing methods to produce context-sensitive insights, ensuring findings are grounded in real-world experience and directly usable for design.

Pragmatism accepts multiple forms of knowledge and methods. It does not assume that there is one absolute truth, and focuses on producing knowledge that supports effective action and problem solving (Allemang et al., 2022). It is a philosophical perspective that treats practical outcomes and real-world effects as central to how meaning and truth are understood (Hevner, 2007). Knowledge is evaluated by its ability to generate meaningful actions and

improvements in practice (McCarthy & Wright, 2004). Pragmatism also emphasises that knowledge is participative and depends on the technology, situations, actions, and circumstances in which it arises (McCarthy & Wright, 2004). Because knowledge is situated, the ways individuals engage with these elements shape how they interpret their experiences. Experience is understood as a process of sense-making. Individuals interpret and give meaning to the people, things, and situations that make up their felt life (Wright & McCarthy, 2010). A pragmatic researcher focuses on the research question and practical ways to address it, prioritising real-world issues over engaging in philosophical debates about the nature of truth or reality (McBeath, 2022). From this perspective, knowledge is judged by its ability to inform decisions and guide design actions in practical contexts, including patient-centred DCT technologies (Hevner, 2007; McCarthy & Wright, 2004). This pragmatic approach underpins the thesis, emphasising that the value of knowledge lies in what it enables designers and practitioners to accomplish.

In line with contemporary applications of pragmatism in applied research and design studies, this approach frames knowledge as arising from experience and inquiry, highlighting how beliefs and actions interact in specific research contexts to generate insights that are meaningful for those developing clinical trial technology (Morgan, 2014). As a research approach, pragmatism supports selecting methods of inquiry guided by the goal of producing knowledge that is useful (Melles, 2008). Qualitative methods were selected and sequenced to support this stance, thereby enabling insights that are both contextually grounded and directly applicable to technology design. The multi-method design of this work, spanning literature review and analysis, empirical studies, and the creation and testing of design materials, reflects a pragmatist orientation toward using multiple forms of evidence to address practical problems. My interpretation was an active part of the analytic process, with themes and conclusions shaped by my judgement and close engagement with the data (Kaushik & Walsh, 2019).

Consistent with a pragmatist approach, the goal of this work was to produce insights that are useful and actionable rather than universally generalisable (Goldkuhl, 2012). This pragmatist stance informs the overall research design, integrating literature review, empirical studies, and design activities to address the experiential needs of clinical trial participants in DCT technology design.

Layout of the Thesis

The study in Chapter 3, a systematic scoping review (Arksey & O'Malley, 2005) and analysis (Braun & Clarke, 2006), provided foundational evidence on strategies to support technology design, generated theory-informed insights using self-determination theory (SDT) (Deci & Ryan, 2008a), and identified key insights for further investigation. Studies 2 and 3 explored the impacts of decentralised clinical trials on participant experiences and practitioner perspectives, producing context-specific knowledge directly relevant to real-world trial practice (Braun & Clarke, 2021a). Insights from Chapter 3, combined with empirical findings from the studies in Chapter 4 and 5 and relevant literature frameworks, informed the design of the study in Chapter 6. In Chapter 6, design cards were tested and semi-structured interviews were conducted and analysed (Braun & Clarke, 2021a) to validate that the tool addressed practical needs and supported users effectively. By sequencing the studies in this way, the research moved progressively from evidence synthesis to understanding lived experiences and finally to developing actionable tools. This approach drew on multiple sources of evidence, exemplifying a pragmatist orientation in which methods and knowledge are judged by their usefulness in guiding practice.

Qualitative methods were chosen to capture the complexity and richness of patient experiences, understand the impact of decentralised clinical trials, and explore practitioner and trial participants' perspectives in context-specific ways (Braun & Clarke, 2006, 2021a). These

methods enabled the exploration of context-dependent, provisional knowledge, capturing the richness of experiences and practices that inform actionable insights (Denzin & Lincoln, 2018; Morgan, 2014). The approaches taken supported the research in uncovering nuanced insights that would be difficult to capture through quantitative methods (Denzin & Lincoln, 2018). In addition, the study in Chapter 6 used qualitative methods to gather technology practitioner feedback and validate the design cards developed from the earlier studies, ensuring the tools were relevant and usable for design purposes. Pragmatism framed the research approach, ensuring methods were both contextually grounded and oriented toward producing insights that could inform real-world trial practice and design, including the development of a tool to support patient-centred technologies and their understanding (Cornish & Gillespie, 2009).

Finally, the research approach has practical implications for the design of patient-centred clinical trial technologies. The scoping review identified strategies likely to improve patient engagement and motivation, the empirical studies highlighted real-world experiences of participants and practitioners, and the design card toolkit translates these insights into actionable guidance for innovation, designers, and technology leaders. Together, these outcomes demonstrate how a pragmatist, qualitative approach can produce evidence that is not only contextually grounded but also immediately useful for improving technology development.

Contribution of the Thesis

The aim of this thesis is to understand how to approach the design of technology to better support patient experiences in decentralised clinical trials (DCTs). In pursuing this aim, the thesis makes contributions to clinical trials research, decentralised technology design, and practice. These include conceptual and theoretical insights, empirical findings, practical design guidance, and an artefact in the form of patient-centred design cards. Together, these contributions inform Human–Computer Interaction and design research by advancing how patient-centred technologies can be designed within the complex context of decentralised clinical trials.

Firstly, the thesis makes a conceptual contribution. Digital tools are seen as a way to improve participant retention (Frampton et al 2020), and there is growing interest in how digital intervention design can help sustain participant engagement and retention in clinical research (Terceiro et al., 2025). Recent research highlights that interventions informed by behavioural theory within DCTs can play a key role in supporting participant engagement and retention (Coyle et al., 2022a). Extending this conversation, this thesis contributes conceptually by examining participant retention through the lens of self-determination theory (SDT) (Deci & Ryan, 2008a). My research frames retention not just as procedural strategies but as a motivational process shaped by participants' needs for autonomy, competence, and relatedness. By analysing retention through this lens, the study in Chapter 3 uncovers aspects of participant engagement that previous research has largely overlooked, showing how psychological processes underpin commonly used retention strategies. This work contributes a distinctive perspective by explicitly framing trial participant retention strategies as a psychological approach rather than merely strategic approaches, offers a novel perspective on trial participant retention and engagement, demonstrating how behavioural science theory can be applied to interpret and evaluate practices in meaningful and supportive ways. This approach provides a

new insight into why participants might engage or disengage, offering a richer, theory-informed understanding that goes beyond existing literature. This conceptual framing contributes to broader debates in HCI and digital health design by reinforcing and extending the view that sustained engagement depends on motivational and psychological conditions that support meaningful participation (Peters et al., 2018).

The second contribution of my research is practical guidance for design. DCTs face challenges with participant engagement and adherence, highlighting the need for guidance to address these issues (Koller et al., 2025). At the same time, research on DCT platforms notes the limited guidance on how these technologies should be designed to meet diverse user needs (Copland et al., 2024). To address how these insights can inform trial technology design, the study in Chapter 3 synthesised evidence on strategies used in clinical trials to support participant retention and examined these through the lens of SDT. Rather than simply cataloguing strategies, the thesis demonstrates how specific practices relate to participants' motivational needs, revealing design-relevant nuances that prior guidance has not addressed. By combining this evidence with SDT, the research translates behavioural science theory into actionable guidance, offering a foundation for designing and evaluating technology aimed at supporting retention in clinical trials. This practical guidance highlights strategies most likely to sustain engagement and meet psychological needs, providing insights that extend beyond what has been detailed in the literature. Furthermore, the empirical findings, along with the knowledge generated in producing the patient-centred design cards, offer additional practical guidance by providing both evidence and a tangible tool that can be directly applied to DCT technology design. This research contributes to HCI design literature by providing empirically grounded design guidance derived from real-world clinical trial evidence (Sas et al., 2014), and by operationalising behavioural theory into actionable design knowledge, extending ongoing efforts within HCI to bridge theory and design practice (Dalsgaard & Dindler, 2014).

Recent work highlights how improving the trial journey requires integrating patient and clinician perspectives into the development of digital trial systems (Minetti et al., 2025). Other research has revealed the importance of understanding how DCTs are experienced and perceived by participants and stakeholders to support meaningful enhancements (Rogers et al., 2022) and to explore participants' experiences and perceptions to inform future design (Coyle et al., 2022a). This thesis directly addresses this by providing empirical qualitative insights into the perspectives of clinical research staff on the impacts of decentralised clinical trials (DCTs) on both participants and staff, that directly contribute to this conversation. Staff perspectives were examined through an integrated lens, combining clinical trial conventions, self-determination theory, and patient-centred care frameworks, revealing how operational and relational factors are experienced in practice. These findings go beyond existing literature by documenting real-world operational and relational challenges faced by staff, which are rarely discussed in DCT guidance. They identify challenges in supporting participants, including operational and organisational constraints that can limit patient-centred practices and affect staff capacity to perform their roles as they would like. For example, staff highlighted that limited synchronous interactions with participants made it harder to detect emotional or practical issues, illustrating design implications not previously empirically documented. The findings also show gaps between DCT design intentions and staff perceptions of how these affect participants' experiences, providing insight for practical improvements. These findings contribute to CSCW and socio-technical literature by highlighting the coordinative, relational, and compensatory work involved in bridging gaps in DCTs, which can be understood as articulation work and invisible labour (Star & Strauss, 1999), and by situating this labour within broader accounts of how care work is distributed and obscured in digital systems (Berg, 1999). Overall, this contribution has practical implications for designing and evaluating DCTs in ways that genuinely support both staff and participants.

This thesis makes a further empirical contribution by analysing trial participants' lived experiences of decentralised clinical trials (DCTs). Participant experiences were examined using an integrated theoretical lens, combining clinical trial conventions, self-determination theory, and patient-centred care frameworks, offering insight into how trial processes are experienced and where improvements may be needed, an approach largely absent in prior DCT research. It identifies aspects of patient-centred care and elements of a preferred experience that are missing in practice. For example, participants highlighted how they navigate remote trials, including emotional, practical, and relational dimensions, demonstrating how trial processes influence patient-centred experience, and highlighting considerations for design. They offer insight into how DCTs can be designed and delivered to better support patient-centred experiences and reveal considerations for design. These findings highlight gaps in current approaches, complement the staff perspectives reported earlier in this thesis, and provide practical insight for designing and evaluating DCTs in ways that genuinely support participants' needs. These findings extend HCI research on self-care and digital health self-management (Ancker et al., 2015; Trupia et al., 2021), and broader clinical trial research, by framing participation in decentralised clinical trials as sustained patient work. In doing so, they situate DCT participation within CSCW accounts of invisible and distributed work in socio-technical systems (Gorman et al., 2018; Schmidt & Bannon, 1992; Star & Strauss, 1999).

Finally, the thesis makes an artefact contribution, with applied methodological and practical relevance through the development and validation of a set of patient-centred design cards to support the design of DCT technology. Recent research highlights key gaps in supporting patient experience in DCTs. Singh et al. (2023) note limited guidance on the comprehensive design of decentralised trials, including technology. Copland et al. (2024) emphasise the need for solutions that meet diverse user needs, Minetti et al. (2025) highlight challenges to make DCTs more appealing, and Krishnaraj et al (2026) point to the complex

factors shaping patient experience, emphasising the importance of genuinely patient-centred approaches. Here, the cards were created as a practical tool to guide designers and technology professionals, prioritising patient-centred considerations when developing DCT systems and experiences. They represent a novel applied methodological contribution, translating qualitative and theoretical insights from participants and staff into a structured approach for design. For example, interviews with practitioners demonstrated how the cards could inform design decisions in real scenarios, highlighting their utility beyond theoretical application. This represents a unique contribution. To my knowledge, this is one of the first tools to combine empirical findings, theoretical frameworks, and design guidance in this way for DCTs, representing an original approach to supporting patient-centred design. Grounded in empirical evidence, patient-centred care frameworks, and self-determination theory, the cards provide guidance on design priorities. By connecting evidence, theory, and practice, the design cards offer a tangible tool for improving DCT technologies, ensuring that participant needs are central to design. This artefact contribution sits within the tradition of research through design in HCI (Zimmerman et al., 2007), and contributes to HCI design and digital health literature by extending the use of design cards as a method into an empirically grounded, patient-centred design context.

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Chapter 2: Literature Review

This chapter is organised around the four key areas of the thesis. It begins with an overview of clinical trials, highlighting their role in advancing medical research. Next, I introduce the concept of patient centricity, explaining how it has emerged as a central principle in contemporary clinical research and its importance for the success of clinical trials. I then turn to decentralised clinical trials, a technology-mediated approach that has grown in prominence, and examine how it relates to patient centricity. Finally, I discuss how theory and process of design can be drawn upon in developing more patient-centred DCTs.

Clinical Trials: A Broad Overview

Clinical trials are studies that evaluate how well one or more treatments work by comparing outcomes among participants with a specific disease or condition (Meinert & Tonascia, 1986). In practice, this means researchers track how patients respond to treatments over time and compare outcomes between groups (Hariton & Locascio, 2018). Trials are considered the most reliable method for testing new interventions such as drugs and medical devices and provide evidence regarding their effectiveness, potential benefits, and possible harms, thereby informing treatment decisions in contemporary medicine (Friedman et al., 2015; Stanley, 2007). For example, a new diabetes medication might be tested over several months in participants with diabetes to see if it lowers blood sugar more effectively than existing treatments (J. Rosenstock et al., 2019). By generating robust clinical evidence, trials play a crucial role in advancing healthcare, granting patients access to innovative therapies, and guiding medical practice (James et al., 2015; Sackett & Cook, 1994a; Yusuf, 1999).

A key part of any trial is gathering data from participants to assess treatment outcomes and monitor adverse effects (Sackett & Cook, 1994a). Traditionally, clinical trials are conducted at healthcare facilities, known as sites, and are overseen by clinical staff (Bhide et

al., 2018a). These trials usually involve face-to-face interaction between researchers and participants and provide access to the procedures available in a clinical setting (Cummings, 2021). As outlined by Umscheid et al. (2011), the conduct of a traditional clinical trial follows a structured process designed to assess the safety and efficacy of new treatments. In their account, researchers develop a detailed protocol outlining the trial's objectives, participant criteria, treatment regimens, and data collection methods. This protocol undergoes rigorous review by ethics committees to ensure participant safety and scientific validity. Participants are then recruited based on predefined inclusion and exclusion criteria, and informed consent is obtained. Umscheid et al. (2011) discuss how the trial progresses through several phases: Phase I focuses on safety and dosage, Phase II evaluates efficacy and side effects, Phase III compares the new treatment with standard treatments, and Phase IV monitors long-term effects post-approval. Throughout the trial, data is collected and analysed to determine the treatment's effectiveness and any adverse reactions. Upon completion, results are submitted to regulatory bodies for review and potential approval, contributing to evidence-based medical practice. Traditional site models follow a centralised approach and require participants to attend in person, reflecting a longstanding method of trial conduct that has shaped clinical research practices for decades. Overall Umscheid et al. (2011) emphasises that while this procedural account emphasises scientific and regulatory structure of traditional trials, it also reveals an underlying reliance on participants' motivation and capacity to comply with study demands, highlighting a tension between operational efficiency and human experience.

Beyond their scientific importance, clinical trials also carry substantial economic implications. The costs of conducting trials are considerable, and bringing a new drug to market requires significant investment (Wouters et al., 2020). These costs can slow the development of new medicines, as successful trial completion is essential, potentially impacting pharmaceutical companies, patients, and consumers (Collier, 2009). Moreover, rising expenses

may influence the long-term feasibility of certain trials in the future (Bentley et al., 2019), affecting the overall progress of medical innovation.

Recruitment and then retention of participants is critical to the success of trials, given their complexity and associated costs (Chhatre et al., 2018; McDonald et al., 2006). Recruitment involves identifying and selecting suitable participants (Wilson et al., 2018), presenting the study, obtaining informed consent, and enrolling them (Chhatre et al., 2018). For participants, this means understanding the study, deciding to join, and committing time and effort to follow the trial schedule. Insufficient recruitment can lead to significant additional costs due to delays (McDonald et al., 2006; Probstfield & Frye, 2011). Retaining participants in clinical trials is a significant challenge, as patient motivation diminishes over time (Furimsky et al., 2008). Implementing strategies and approaches to maintain engagement is therefore essential (Leathem et al., 2009). Further emphasising that understanding and supporting participant experiences is central to trial success (Planner et al., 2019), which is not just ethically important but also economically significant. Low recruitment and poor retention increase costs, making retention efforts critical (Brueton et al., 2013; Oostenbrink et al., 2003). Once enrolled, maintaining engagement and retention is essential for valid and reliable trial results (Brueton et al., 2013; Chhatre et al., 2018; Coday et al., 2005).

Patient experiences are not uniform across clinical trials and can vary considerably. The experience of participation is shaped by contextual features such as trial phase, therapeutic area, intervention type, duration, visit frequency, study procedures, and wider logistical demands (Getz et al., 2020; Smith et al., 2021). For example, trials involving frequent site visits, complex procedures, intensive monitoring, or extended participation periods may place greater demands on participants than less intensive studies (Getz et al., 2020). Clinical trial populations span a wide range of health contexts, including healthy volunteers in early-phase studies and patients with varying levels of disease burden, multimorbidity and individuals with

life-limiting or terminal illness (Hanlon et al., 2019; Karakunnel et al., 2018). Recognising this variability is important for understanding patient experience and for designing technologies that can accommodate participant needs and circumstances.

Patient-centric approaches aim to redesign trials around participant experience, which DCTs attempt to operationalise. This human-centred perspective establishes a bridge to patient-centred design, indicating that DCT should be evaluated not only for operational efficiency but also for their impact on support, motivation, burden, and engagement.

Taken together, the literature consistently highlights that retention is central to trial success, impacting scientific accuracy, operational efficiency, and costs. Participant burden, whether from time, travel, or study demands, directly influences engagement and the likelihood of continued participation. In this context, recognising and supporting participants' experiences and motivations is therefore critical, both scientifically and operationally. Participant withdrawal can introduce bias, extend timelines, increase costs, and delay product approval (Akl et al., 2012; Coley et al., 2008; Grill & Karlawish, 2010; Ioannidis et al., 2014). High dropout rates are common; on average, 30% of participants leave trials prematurely, and 80% of sites fail to meet enrolment targets, often causing delays of six months or more (Yaakov et al., 2021). Recruitment costs can reach $6,533 per patient, with replacing participants who drop out costing up to $19,533 for non-compliant participants (Moore et al., 2018).

While operational and financial pressures pose significant challenges for trial conduct, participant burden is another key factor affecting retention, including exposure to experimental therapies, time-consuming assessments, travel requirements, and disruption to personal and professional life (Dorsey & Kieburtz, 2021). How participants perceive and cope with these demands influences whether they remain in the trial. Factors influencing dropout include logistical challenges, study demands, psychosocial factors, treatment complexity, demographics, and broader social and cultural context (Atwood et al., 1992; Good & Schuler,

1997; Moser et al., 2000a; Stasiewicz & Stalker, 1999b). The wide range of these challenges highlights the complexity of effectively addressing patient dropout.

Patient Centricity

Building on these challenges, patient-centric approaches aim to better align with the needs, preferences, and experiences of participants (The Lancet Regional Health – Western Pacific, 2025). Patient-centricity has emerged as a key principle in contemporary clinical research (U.S Food & Drug Administration, 2024), reflecting a growing recognition of the need to design trials around the people who take part. This shift is not merely ethical or aspirational, it has practical implications for how trials are designed, conducted, and experienced, directly influencing engagement, retention, and the validity of data collected.

There are varied definitions of patient-centricity in clinical trials, generally referring to placing the patient at the centre of all trial activities through sustained and respectful engagement aimed at achieving the best possible experience and outcome (Yeoman et al., 2017) and it is recognised as essential for trial success. Being patient centred enables patients to manage information and make decisions aligned with their preferences, values, and beliefs (Robbins et al., 2013). A patient-centric approach emphasises collaboration, accommodates individual preferences and experiences, and seeks to minimise participant burden throughout the study (Getz, 2015). Broad guidance on patient-centredness highlights the importance of addressing patient needs across all trial phases, from design to outcome reporting (Getz, 2015), to enhance engagement, ownership, and the relevance of trial experiences (Katsanis et al., 2021). In line with this, Mullins et al. (2014) suggest that clinical trials should transform the evidence generation process to be more patient centred, so they are designed and conducted in ways that reflect patient needs and preferences.

The shift towards patient-centred models has begun to actively shape how trials are designed and conducted. The pharmaceutical industry and regulatory bodies have increasingly recognised its practical importance in shaping trial design and conduct (Stergiopoulos et al., 2020). This trend reflects growing acknowledgement of the patient's essential role in trial success (du Plessis et al., 2017; Katsanis et al., 2021). Regulatory bodies such as the U.S. Food and Drug Administration (FDA) have been instrumental in advancing this agenda through initiatives like Patient-Focused Drug Development (U.S Food & Drug Administration, 2024). Similarly, the European Medicines Agency and the Clinical Trials Transformation Initiative (Clinical Trials Transformation Initiative (CTTI), n.d.) have embedded patient-centred principles into their frameworks, signalling an international effort to operationalise patient-centricity across regulatory and industry practices. Major pharmaceutical companies, including Johnson & Johnson, GSK, Pfizer, Bayer, Sanofi, and AstraZeneca, have also adopted patient-centric programmes as central elements of their research and development strategies (Katsanis et al., 2021).

This transition is also driven by a changing patient population. Today's trial patients are informed and increasingly expect personalised care delivered with compassion and genuine concern for their well-being (Attree, 2001). The notion of the patient as a passive subject is giving way to one of active partnership (Duffett, 2017). Critically, meaningful participation requires intentional design; technology or structural changes alone do not automatically produce engagement. The contemporary trial patient is an aware, technology-driven, and informed collaborator whose participation is essential to the overall success of trials (Sharma, 2015). The growing influence of patient voices across the research lifecycle, through independent patient coalitions (Boutin et al., 2017), disease-specific advocacy groups (Rose, 2013), online communities (deBronkart, 2013), and social media platforms (Frost & Massagli, 2009; Greene et al., 2011), has directly impacted how trials are planned and communicated.

These developments have not only elevated patient expectations but also made improving the trial experience a central concern.

Central to patient-centricity is the concept of patient experience, which emphasises the patient's needs and perspectives throughout a trial (Getz, 2015) and can serve as a measurable indicator of the effectiveness of patient-centred approaches. Recognising the importance of patient-centricity, industry stakeholders have identified the need to provide patients with more meaningful experiences (Hoos et al., 2015). Generally, the patient experience is defined as the sum of all interactions shaped by an organisation's culture that influence patient perceptions across the continuum of care (Wolf & Jason, 2014a), as well as factors that shape participation and engagement throughout a clinical trial (Dobra et al., 2023a). But there is a lack of a formal definition of patient experience in the clinical trials (Planner et al., 2019). Research indicates that positive patient experiences can improve engagement, satisfaction, and adherence to trial procedures (Carli Lorenzini & Olsson, 2022; Dewulf, 2015), increase participation, retention, and enrolment, and support trials' financial impact when combined with patient-centric solutions (Gul & Ali, 2010a; Levitan et al., 2018). These outcomes highlight how patient-centred approaches materially influence trial conduct and success.

The patient-centred conceptual grounding has informed a range of industry initiatives aimed at embedding patient perspectives within trial design and evaluation. Du Plessis (2017) frames patient-centric approaches as active partnerships, in which collaboration and listening are central, guiding how organisations can make meaningful differences for patients. Patient-centric initiatives in clinical trials, focus on the planning and design stages (Lamberti & Awatin, 2017). These include involving patient advocacy groups in trial design (Cobb et al., 2015), engaging patient advisory boards, and collecting patient perspectives through surveys and interviews (Shippee et al., 2015). Crowdsourcing techniques broaden input on trial protocols (Leiter et al., 2014). Sharma (2015) outlines a broader set of patient-centred

approaches, including early patient involvement in drug development, promoting transparent communication among patients, clinicians, and biopharma, and leveraging technology to support patient education, engagement, and retention. Mobile nursing services allow trial assessments in patients' homes (Stergiopoulos et al., 2020).

Digital solutions are also widely recognised as central to patient-centred research (Gregg et al., 2020; Stergiopoulos et al., 2020), and calls for industry adaptation have linked technological advances with the broader patient-centric movement (Sharma, 2015). Legislative and institutional initiatives, including the 21st Century Cures Act, FDA guidance, and collaborations between the National Institutes of Health and the National Science Foundation, have further encouraged the integration of digital methods into trial conduct (Inan et al., 2020; U.S Food & Drug Administration, 2020). A central focus of the patient-centred movement has been the development and implementation of decentralised clinical trials (DCT). These trials use digital and remote methods and are now widely recognised as a leading approach for implementing patient-centred principles.

Decentralised Clinical Trials: Overview

In this section, I provide an overview of decentralised trials (DCT) and outline their nature. DCTs are studies that allow participants to take part remotely, often from home, using digital tools, rather than attending a traditional research site for all activities. This section outlines the methodologies employed during DCTs and their benefits. DCTs illustrate how patient-centred principles can be operationalised, while also highlighting challenges in translating ideals into lived participant experiences.

The convergence of policy, technology, and patient-centred priorities has given rise to DCTs, now recognised as a prominent approach within clinical research. A variety of terms have been used to describe this model, including site-less (Hirsch et al., 2017a), remote

(Alemayehu et al., 2022a), direct-to-participant and virtual studies (Dorsey et al., 2020a). Over time, decentralised clinical trials have become the most widely adopted term (Santa-Ana-Tellez et al., 2023a), reflecting the broader move toward research that can be conducted beyond the walls of traditional clinical sites (Van Norman, 2021a). The COVID-19 pandemic further accelerated this shift by making in-person trial activities less feasible (McDermott & Newman, 2020). DCTs have emerged as a response to the increasing focus on patient-centred research, relying on digital tools to enable participation outside traditional sites, with methodologies ranging from fully virtual trials to hybrid approaches that combine in-person and remote elements (Rogers et al., 2022).

Introduction to DCTs and Participant Benefits

Benefits to participants lie in their remote nature, with the aim of reducing travel and logistical burden while enabling data collection and interactions without frequent site visits (Coyle et al., 2022a; De Brouwer et al., 2021; Moore et al., 2022). DCTs are increasingly framed as a way to improve patient experiences in trials and enhance patient centricity (Minetti et al., 2025). Remote trials, including hybrid models that blend traditional and virtual approaches, have been argued to further strengthen patient experience (Yaakov et al., 2021). DCT approaches aim to support patients' individual needs and preferences, enhancing the patient-centred experience and reducing participant burden (Dockendorf et al., 2021a). Sinha (2024) highlights that technology-driven DCTs can improve communication and understanding, increase engagement and inclusion, support recruitment and retention, and promote patient safety and wellbeing, while also offering flexibility, convenience, and access to care. DCTs prioritise patient-centred approaches and employ advanced technologies to limit or eliminate the need for in-person interactions, enhancing accessibility, fostering inclusivity, and addressing patients' specific needs (Hudej & Aumiler, 2025). While these benefits are often highlighted, they may be context-dependent, and evidence that communication, understanding, and

engagement are consistently improved across all populations is limited. Participants report feeling more comfortable with hybrid or fully remote trials, where additional interactions and guidance from trial sites enhance their experience (Barge & Floody, 2025), highlighting the central role of staff–participant interactions in shaping perceived comfort and engagement.

Practical Advantages and Industry Benefits

DCT removes geographical barriers, shortens study timelines, and enables real-world data collection that is generalisable and cost-effective (Yaakov et al., 2021). They are associated with a range of potential benefits to those running trials, including improved recruitment (Wilkins et al., 2021), access to more diverse populations (Petrini et al., 2022), enhanced retention (Kaye et al., 2012), protocol adherence (Stegemann et al., 2016), and shorter trial timelines (DiMasi et al., 2023). They also reduce burden by minimising site visits (Jong et al., 2022), support patient engagement (Dockendorf et al., 2021a), lower costs, and expand data collection opportunities (Coert et al., 2021). However, these potential advantages are balanced by challenges such as participant attrition and the need to critically evaluate whether operational benefits translate into improved participant experience (Daniore et al., 2022a).

Technology in DCTs

Delivering DCTs depends on a range of digital technologies that enable remote participation and shape how patients experience trial activities. These technologies are used at various stages to underpin and support DCTs, including mHealth applications (mobile apps for health tracking and study management) (Hernandez-Ramos et al., 2021), smartphones and wearables for remote monitoring (devices for remote monitoring of patient data) (Izmailova et al., 2018; Taylor et al., 2020), electronic consent (eConsent; digital platforms for obtaining informed consent) (Noor et al., 2021), electronic patient-reported outcomes (ePROs; tools for patients to report health data electronically) (Coons et al., 2015; Dockendorf et al., 2021a), and telehealth

consultations (remote video or phone visits between patients and clinicians) (Jong et al., 2022; Law & Wason, 2014). These technology tools support remote data capture, communication between patients and investigators, and reduced reliance on physical site visits (Petrini et al., 2022). Across the literature, digital tools used in DCTs are frequently associated with claims of improved participation and experience, including ease of participation (Coyle et al., 2022c), flexibility (Rogers et al., 2022), satisfaction (Miyata et al., 2023), increased personalisation (van Boven et al., 2025), enhanced convenience (Vayena et al., 2023), and improved patient engagement (Hird et al., 2016).

Thoughtful design, rather than mere tool availability, shapes how participants interact with a trial, affecting motivation, satisfaction, and overall experience. As the primary interface between participants and the trial, technology has the potential to enact patient-centred principles, yet participant and stakeholder experiences are not fully captured and evidence for claimed benefits remains limited (Rogers et al., 2022). Well-designed digital interfaces that integrate data, provide guidance, and support communication are linked to higher participant acceptance (Reale et al., 2025), whereas fragmented systems increase burden and inefficiency (Copland et al., 2024). However, evidence remains limited on how digital tools influence engagement, retention, or participant experience across diverse populations.

Participant Experience and Engagement

Research indicates that participants are generally receptive to DCTs, appreciating the potential to reduce travel and logistical burden (Minetti et al., 2025). Participants also report positive experiences with digital tools and telehealth, and a willingness to participate in future trials (Reale et al., 2025). Nevertheless, concerns have been raised about reduced face-to-face interactions and the shifting of trial responsibilities onto participants (Coyle et al., 2022c). Low adherence and engagement are also reported, indicating that participation alone does not

guarantee improved experience or outcomes (Koller et al., 2025). Active patient involvement is noted as important for aligning trial processes with participant needs, and relational factors like trust and communication are acknowledged as significant (Coyle et al., 2022c) , yet how these mechanisms influence outcomes in decentralised contexts remains under-explored. A systematic review found limited qualitative evidence on participant experiences in DCTs, with insufficient data to confirm their impact on recruitment or retention, highlighting the need for further study (Copland et al., 2024).

Stakeholder and Practitioner Perspectives

Research highlights the importance of trial staff and stakeholder involvement in DCT success (Coyle et al., 2022c). Studies focus on staff perceptions or anecdotal observations, with few systematically linking practitioner actions to participant outcomes. Workload redistribution to both participants and staff is acknowledged, but there is minimal research on long-term effects of this burden, or on how organisational structures can mitigate it. Multi-stakeholder coordination appears to be underexplored, despite its potential to shape trial experience and outcomes. Broader calls to better understand the experience of clinical trials (Planner et al., 2019; Signorell et al., 2021) emphasise the need to examine how DCT design aligns with participant needs. Addressing these gaps underpins the thesis aim of advancing DCT technology design to support patient-centred outcomes in practice.

Although DCTs reduce travel and logistical burden, they can shift responsibilities onto participants, such as managing devices, self-monitoring, or reporting outcomes, which may influence their engagement and overall experience. Existing literature frequently assumes that remote participation inherently improves patient experience (Weber et al., 2026), yet empirical evidence across diverse populations and trial contexts is sparse. Low adherence and engagement persist, and mechanisms by which engagement, trust, and communication

influence outcomes are under-explored. Studies often do not clearly operationalise how patient involvement translates into measurable improvements in experience, retention, or satisfaction.

Challenges and Opportunities in Designing Decentralised Trial Technology

Designing Technology to Support Patient Experience in DCT

Designing technology to support patient experience has become a central concern in DCTs, as digital systems increasingly mediate how patients encounter, understand, and participate in research (Minetti et al., 2025; Reale et al., 2025). Rather than simply enabling remote trial conduct, technologies actively shape patient experience by determining access to trials, how communication occurs, how information is presented and understood, and how engagement and participation are sustained (Jean-Louis & Seixas, 2024; Petrini et al., 2022). Human Computer Interaction (HCI) research on patient-facing digital health technologies similarly demonstrates that interfaces, interaction flows, and system design choices influence access to care, communication, comprehension of information, and capacity to engage meaningfully in health-related activities (Dodson et al., 2024; Wilcox et al., 2013). Across these bodies of literature, patient experience is shown to emerge not as an incidental outcome of digitalisation, but as the result of deliberate design decisions and embedded practices that shape interaction, responsibility, and engagement within technology-mediated health contexts (Aytekin et al., 2025; Baines et al., 2022).

HCI and Design Approaches to Supporting Patient Experience in Healthcare Technology

HCI and related design disciplines offer a range of approaches that explicitly centre the patient experience in the development of health technologies. Approaches are focused on engaging users in the design process and making systems more usable, accessible, and meaningful to use. User-centred and human-centred design methodologies emphasise understanding users' tasks, contexts, and needs through ongoing research, contextual inquiry, and iterative testing,

so solutions are grounded in the real-world (Göttgens & Oertelt-Prigione, 2021; Harte et al., 2017).

Participatory design (Teixeira et al., 2011) and co-design practices extend this involvement by positioning patients and stakeholders as active partners throughout the design lifecycle, enabling shared problem framing, ideation, and evaluation that reflect diverse experiences and priorities (Sanz et al., 2021). Complementary methods such as journey mapping (Philpot et al., 2019), service design (Patrício et al., 2020), and UX research (Gilbert, 2022), provide structured approaches to capture patients' emotional, cognitive, and overall experience, helping to identify and address issues proactively. The strength of these approaches lies in centring users through observation, empathy, iteration, and collaboration, producing technologies that support patient engagement, understanding, and wellbeing (Harte et al., 2017; Henni et al., 2022).

Limitations of Existing Design Approaches in the Context of DCT

Although user-centred, participatory, and experience-oriented design methods hold promise for healthcare technology research, their implementation within DCTs can be limited by structural and regulatory constraints. Traditional HCI and design frameworks assume relatively unmediated access to end users for observation, co-design, and iterative testing; however, in DCTs, access may be constrained by the complex nature of trials and restrictions such as privacy regulations (Bierer & White, 2023), the longitudinal nature of trials (Galbraith et al., 2002), trial governance (McNair, 2022), and limited involvement of patients (Tong et al., 2022). Clinical research often reduces experience to narrow indicators such as trial satisfaction (Tantoy et al., 2021), with an overarching focus on reducing burden (Sine et al., 2021). Furthermore, the limited measurement of patient experiences in trials (Planner et al., 2019) challenges understanding. This reveals gaps in approach, especially when contrasted with HCI approaches that actively focus on sustaining user engagement and wellbeing through design

(Peters et al., 2018). Addressing these gaps requires the development of novel approaches that reconcile the rigour and regulatory imperatives of clinical research with the nuanced, participant-centred insights offered by HCI, thereby enabling more robust and meaningful design interventions in DCT contexts.

Role of Behavioural and Psychological Theory in Understanding Engagement and Experience

Behavioural and psychological theories offer a valuable lens for understanding patient experience and are considered central for improving the design, usability, and implementation of health systems (Mohammadzadeh et al., 2025), while HCI research emphasises the need for stronger theoretical grounding (Slovak et al., 2023). In HCI and healthcare, these theories have been used to support behaviour change, inform intervention design (Medlock & Wyatt, 2019), and promote user engagement (Geelen et al., 2025), yet their application to the design of technology for decentralised clinical trials (DCTs) remains limited. Self-Determination Theory (SDT), in particular, provides a robust framework for examining motivation and the fulfilment of psychological needs, making it well suited to explain patient engagement (Ballou et al., 2022). However, its potential for guiding the design of DCT technology and fostering patient-centred digital experiences remains underexplored. Further discussion of Self-Determination Theory and other relevant behavioural theories is provided in Chapter 3.

Challenges in Translating Theory into Design Practice

Translating behavioural and psychological theory into design practice remains a persistent challenge. Many theoretical constructs are abstract, limiting their direct applicability in day-to-day design decisions (Sands & Aunger, 2021; Voorheis et al., 2023). Translating concepts like motivation or engagement into specific DCT technology features can be challenging; it requires careful consideration to ensure that theoretical constructs retain practical meaning while remaining actionable. These challenges are amplified by the complexity and diversity of

real-world contexts in which participants interact with DCT technologies and the types of DCT technologies being designed for. Research in digital health and HCI highlights a challenge between theory and practice, with designers struggling to operationalise behaviour change techniques into concrete technology features (Voorheis et al., 2022). This gap highlights the need for methods that can bridge theory and practice, providing actionable guidance to inform the design of patient-centred digital interventions.

Importance of Empirical Perspectives from Staff and Participants

HCI and design research highlights the importance of grounding design in the experiences of those directly involved in a phenomenon (Bayliss et al., 2017; Göttgens & Oertelt-Prigione, 2021; Müller & Schaaf, 2025). Similarly, in decentralised clinical trials, understanding the range of factors that shape participants' experiences is essential, as qualitative research captures real-world constraints, lived experiences, and unintended consequences. Such methods reveal the diversity of perspectives and experiences that might otherwise be overlooked, ensuring that insights reflect the complexity of real-world contexts (Forman et al., 2008). Qualitative research generates rich, descriptive data that illuminates individual experiences and their context, enabling a more holistic understanding of the phenomena (Renjith et al., 2021). Using qualitative research methods can help understand context and inform solutions (Hamilton & Finley, 2019). This approach surfaces several challenges. Recruitment for qualitative interview research is challenging due to difficulties in identifying and engaging eligible participants, and achieving diversity and sample size for meaningful analysis (Bonisteel et al., 2021). Qualitative research with patient populations must navigate ethical and regulatory constraints, such as protecting confidentiality, obtaining informed consent, and managing sensitive interactions, which can add procedural complexity and delay data collection (Sanjari et al., 2014). Furthermore, coordinating interviews within healthcare settings presents logistical hurdles, such as aligning schedules across participants and clinical

staff, negotiating institutional gatekeeping, and adapting to operational constraints (Bonisteel et al., 2021). The pool of participants with direct experience in DCT is hard to identify and relatively narrow, and this complicates sampling and engagement for qualitative research.

Design Supports, Artefacts, and Tools as a Means of Integrating Theory, Evidence, and Practice

One approach that HCI research has explored to bridge the gap between theory, evidence, and practice is the use of design supports or artefacts, such as frameworks (Ball et al., 2025), toolkits (Nadal et al., 2022), and design cards (Nurain et al., 2024). These artefacts help structure attention, prompt reflection, and guide decision-making, enabling designers to integrate theoretical insights and empirical evidence directly into practical design processes. By providing tangible, reflective tools, artefacts offer a means to translate abstract knowledge into actionable design decisions (Marquardt et al., 2017; Nadal et al., 2022; Velt et al., 2020), making them a promising approach for supporting patient-centred technology in DCTs.

Taken together, the literature reviewed above highlights key challenges and opportunities for designing technology that supports patient experience. Across these studies, design in DCT appears constrained by gaps in understanding patient experience, restricted access to key stakeholders, and minimal integration of behavioural theory into technology design. This thesis addresses these gaps by generating insights into patient and staff experiences, integrating behavioural theory, qualitative evidence, and patient-centred care frameworks, and translating these into actionable guidance using an artefact of design card. This integrated approach aims to generate patient-centred design guidance that is both evidence-informed and practically applicable in the context of the design of technology in decentralised trials. Building on these insights, patient-centredness extends beyond convenience; it involves designing for the lived experience of participation, including how technology shapes motivation, connection, and support. These principles provide a lens for

evaluating whether new trial models, such as decentralised trials, genuinely reflect patient-centred values or simply reproduce existing burdens in new forms.

Outline Arguments for PhD Research

The intersection of several fundamental factors underscores the importance of my research. In this literature review, I highlight the critical role of clinical trials as the foundation for developing new clinical treatments and interventions. Patient retention becomes crucial within this context, as a trial's success relies on sustained recruitment and retention throughout the study. Retaining participants is vital for collecting comprehensive, trustworthy data that determines the effectiveness and safety of experimental treatments.

My research focuses on recent DCT and technological advancements in trial execution that have shifted how clinical trials are conducted, with a growing focus on remote participation (Rogers et al., 2022; Sinha et al., 2024). As the clinical trial industry embraces these approaches, DCTs are expected to enhance the patient experience (Weber et al., 2026). However, these technologies present opportunities and challenges. As technology advances, strategies used in digital experiences affecting patients in remote trials must evolve to deliver on the promise of a patient-centred experience. Ensuring a positive patient-centred experience is crucial for enhancing participation and retention. This patient-centred focus is a clinical trial industry initiative, and an ethical obligation endorsed by governing bodies and regulatory agencies in clinical trials and healthcare.

DCT trials may be perceived as patient-centred, and the technologies integral to the modern patient experience. However, questions remain about whether these trials and supporting technologies genuinely deliver patient-centred experiences. Despite the growing interest in patient-centredness, a research gap exists, particularly regarding the intersection of decentralised trial technology and patient-centredness. Addressing these gaps is essential for

optimising DCTs to enhance patient-centredness, support trial experiences, and enable retention.

My research underscores the need for a more comprehensive understanding to support technology design and strategies that deliver a more patient-centred trial experience. Enhancing patient-centred approaches within the decentralised clinical trial process is not just theoretical, but essential. It can improve the patient experience, contribute to better retention rates, and ensure the success of clinical trials.

To achieve this, the research combines qualitative insights, behavioural science principles, and patient-centred care frameworks, ensuring that findings are systematically translated into guidance that can inform design and practice. DCT technologies should be designed to support the goal of patient centricity, guiding technology strategies that prioritise patients throughout the trial. As DCT technologies evolve, strategies must ensure that technology enhances rather than compromises patient-centred experiences, maintaining both ethical standards and trial effectiveness.

Technology is expected to make trials more convenient, accessible, and patient-centred, thus improving the overall patient experience. However, limited robust evidence supports the claim that remote trials offer a genuinely patient-centred experience. My research aims to address this gap by investigating the specific conditions, approaches, features, and functions necessary to enhance the patient experience during DCTs. The lack of comprehensive research highlights the need for a deeper understanding of how technology-mediated trials impact patients' experiences.

By integrating behavioural science, qualitative insights, and patient-centred care frameworks into the design of DCT platforms, we can improve the patient experience and create a more supportive environment. My research's ultimate contribution lies in its potential

to enhance patient-centred decision-making for clinical trial technologies. The thesis aims to inform the understanding of patient-centred approaches, establish more effective practices, advance remote trial research, and enhance the satisfaction of trial participants. In summary, my research is driven by the pivotal role of clinical trials in health, the importance of patient experience to this process, the shift towards remote trials, the value of a patient-centred experience, and the potential for design and behavioural science to advance clinical trials.

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Chapter 3: Establishing Requirements for Technology to Support Clinical Trial Retention: Systematic Scoping Review and Analysis Using Self-determination Theory

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Author Contributions: EG and CL conceived of the study. Searches, screening, and data extraction were conducted by EG and checked by CL. EG wrote the manuscript with support from CL and CH. CL and CH supervised the project. All the authors discussed the results and contributed to the final manuscript.

Abstract

Background: Retaining participants in clinical trials is an established challenge. Currently, the industry is moving to a technology-mediated, decentralised model for running trials. The shift presents an opportunity for technology design to aid the participant experience and promote retention; however, there are many open questions regarding how this can be best supported. We advocate the adoption of a stronger theoretical position to improve the quality of design decisions for clinical trial technology to promote participant engagement.

Objective: This study aimed to identify and analyse the types of retention strategies used in published clinical trials that successfully retain participants.

Methods: A systematic scoping review was carried out on 6 electronic databases for articles published from 1990 to September 2020, namely CINAHL, The Cochrane Library, EBSCO, Embase, PsycINFO, and PubMed, using the concepts "retention," "strategy," "clinal trial," and "clinical research." This was followed by an analysis of the included articles through the lens of self-determination theory, an evidence-based theory of human motivation.

Results: A total of 26 articles were included in this review. The motivational strategies identified in the clinical trials in our sample were categorized into 8 themes: autonomy; competence; relatedness; controlled motivation; branding, communication material, and marketing literature; contact, tracking, and scheduling methods and data collection; convenience to contribute to data collection; and organisational competence. The trials used a wide range of motivational strategies. Notably, the trials often relied on controlled motivation interventions and underused strategies to support intrinsic motivation. Moreover, traditional clinical trials relied heavily on human interaction and "relatedness" to support motivation and retention, which may cause problems in the move to technology-led decentralised trials. We found inconsistency in the data-reporting methods and that motivational theory–based approaches were not evident in strategy design.

Conclusions: This study offers direction and a framework to guide digital technology design decisions for future decentralised clinical trials to enhance participant retention during clinical trials. This research defines previous clinical trial retention strategies in terms of participant motivation, identifies motivational strategies, and offers a rationale for selecting strategies that will improve retention. It emphasises the benefits of using theoretical frameworks to analyse strategic approaches and aid decision-making to improve the quality of technology design decisions.

Keywords: clinical trial; clinical research; retention strategies; participant retention; technology strategy; decentralised clinical trial; participant motivation; patient centric; engagement strategies; self-determination theory

Introduction

Trial Retention and the Changing Landscape

Once a participant is enrolled in a clinical trial, retaining the participant and keeping them engaged and participating in the trial protocol is essential to the conduct of a valid and reliable trial (Coday et al., 2005) and to avoid the costs associated with patient withdrawals (Oostenbrink et al., 2003). Clinical trial researchers and practitioners must implement strategies for supporting patient retention in a trial (Brueton et al., 2013). However, there is a surprising lack of research that seeks to understand, from both theoretical and practical perspectives, how to best retain participants once they are enrolled in a trial (Daykin et al., 2018).

Two recent developments in the conduct of clinical trials have motivated this study. First, clinical trial researchers and practitioners have begun using digital tools as part of their trial experience (Frampton et al., 2020; Inan et al., 2020; Rosa et al., 2015), permitting improved patient-clinician communication to take place remotely (Wootton, 2001). Technology such as apps and wearables are often championed as a way to improve the overall patient experience during clinical trials. Such technologies present both opportunities and challenges to the clinical trial process and must be carefully designed to meet the desired outcomes. Second, there has been a move toward a remote decentralised clinical trial (DCT) model. For the most part, physical visits to a clinical centre are eliminated, data capture takes place using mobile devices, and web-based participant-reported outcomes and interactions between trial staff and patients predominantly use technologies such as telemedicine (Coyle et al., 2022c). However, there remains an open question regarding the strategies, features, and

functions that potential trial technologies should contain to best support participant retention. To answer this question, we reviewed evidence from existing research to identify, describe, and then analyse what strategies practitioners currently use to motivate participants or patients retained in clinical trials.

Background

In discussing the support of participant retention in clinical trials, we refer to the strategies and tactics used by trial designers and trial staff to keep patients enrolled and from withdrawing or "dropping out" of a clinical trial (Brueton et al., 2013; Chaudhari et al., 2020). The retention of participants can be a major challenge, as over time, a participant's motivation to remain in a study may decrease (Furimsky et al., 2008). Strategies for addressing retention are used regularly with varying success rates, and retention costs are consistently high across all phases of trials (Sertkaya et al., 2016). Research to identify effective retention strategies has increased in recent years (Abshire et al., 2017), but there is a lack of evidence for the effectiveness of individual strategies (Kearney et al., 2017) and a need for more focus on retention-specific research (Daykin et al., 2018).

Previous research has identified a range of motivations for participating in clinical trials. For example, many participants become involved owing to the altruistic desire to help others with the disease or condition in question (Andersen, 2007). Other participants hope to attain health benefits, gain access to new treatments, improve their treatment, gather new data about the disease, access laboratory testing, or take part because of trust in the physician (Bevan et al., 1993; Udrea et al., 2009). Additional factors include the perceived benefits to society, the amount of care and attention received while enrolled in a study, research interest (Cheung et al., 2008), their personal values (Gross & Fogg, 2001), and financial benefits or monetary compensation received (BeLue et al., 2006; Cheung et al., 2008; Udrea et al., 2009). Despite

these initial motivators to enlist in a trial, poor patient retention is frequently encountered during the conduct of trials.

Research suggests that the average patient attrition or dropout rate for a clinical trial is 30% (Alexander, 2013), but dropout rates can range from 5% to 70% (Marcellus, 2004). A variety of reasons are cited for patients withdrawing from trials, including life and study demands, logistics, lack of motivation, and overall commitment (Janson et al., 2001). The timing of follow-up and scheduling contacts can also affect patients remaining in a trial (Stasiewicz & Stalker, 1999a), as can the complexities encountered during treatment (Good & Schuler, 1997). Demographic characteristics such as age, gender, lower income, education, and literacy can predict both enrolment and patient attrition rates (Cooley et al., 2003). Factors such as culture, community practices, political outlook, and geography (Marcellus, 2004) are cited as influential factors. Attrition and noncompliance are attributed to the accessibility of health care information, consumer empowerment, and mistrust of research, all of which affect trial validity (Gross & Fogg, 2001). Other factors affecting patient participation during a trial process include unrelated illness, side effects, forgetting, and competing external stressors (Atwood et al., 1992). Personal, emotional, and psychosocial factors are cited as predictors of patient dropouts (Moser et al., 2000a).

Owing to the problems identified with retaining participants in clinical trials, trial practitioners have developed practices related to both the design and implementation of trials that are intended to improve participant retention. Previous systematic reviews assessed the retention approaches in health care and clinical settings. For example, Robinson et al (2007) set out to describe the range of retention strategies implemented in health care research, classifying their findings into 12 themes: community involvement, study identity, study personnel, study description, contact and scheduling methods, reminders, visit characteristics, benefits of study, financial incentives, reimbursement, nonfinancial incentives, and special

tracking methods. Research showed that studies had a median of 17 strategies across a median of 6 themes. The most frequently reported strategies dealt with the themes of participant contact, scheduling, and minimizing patient burden. Robinson et al (2015) published an updated review in 2015. The findings highlighted that the use of a larger number of retention strategies appeared to result in the retention of more participants. The study also highlighted the inability to identify what retention strategies were the most effective and the need for further research to evaluate the effectiveness of different strategies.

Several other relevant reviews were conducted, including the 2014 Cochrane review by Brueton et al (2013), which aimed to quantify the effect of retention strategies used in 38 trials. Six types of strategies were evaluated: incentives, communication strategies, new questionnaire format, participant case management, behavioural and methodological interventions, and monetary incentives for questionnaire responses. There are several other reviews, including reviews examining recruitment and retention strategies in mental health trials (Liu et al., 2018), reviews identifying the characteristics of participants that might predict retention in trials involving children (Robinson et al., 2016), and a review analysing the use of patient incentivisation to improve retention rates (Booker et al., 2011).

Existing research has identified that using a larger number of retention strategies appeared to retain more study participants. However, existing research does not provide a robust explicit rationale for why this is the case (Robinson et al., 2015). Owing to the shift to technology-led decentralised trials, we suggest that there is a need to explore participant retention in the context of both technology design and DCT. We advocate the adoption of a stronger theoretical position is required to improve the quality of technology-design decisions regarding participant motivation and retention.

Supporting Participant Motivation Through Study Design

Several psychological theories exist that could prove beneficial in understanding how to guide participant behaviour through trial design. These theories include the theory of planned behaviour (Ajzen, 1985), health belief model (Rosenstock, 1977), goal-setting theory for motivation (Locke & Latham, 2002), and transtheoretical model (Prochaska & Velicer, 1997). We suggest that the self-determination theory (SDT) provides a particularly useful lens through which to evaluate the retention strategies currently used in trials. The SDT is particularly applicable to the clinical setting because of the exploration of autonomy and autonomous self-regulation as core concerns and considerations of autonomy as an ethical mandate for patients to partake in medical research (Deci & Ryan, 2012b). The SDT is a framework commonly used for guiding the design (Peters et al., 2018) and evaluation of digital health tools (Villalobos-Zúñiga & Cherubini, 2020). The SDT has been shown to be relevant and useful in studies involving clinical trial research and in health care settings (Deci & Ryan, 2012b; Ng et al., 2012; Williams et al., 2006). The SDT is appropriate for understanding engagement and behaviour changes related to digital experiences and technology design (Peters et al., 2018).

Self-determination Theory

The SDT identifies the 3 basic psychological needs of competence, autonomy, and relatedness, and meeting these basic needs has been consistently shown to be associated with effective, motivated performance (Deci & Ryan, 2012a). All 3 needs should be met to stimulate intrinsic autonomous human motivation, optimise performance, and regulate individuals' behaviours (Ryan and Deci, 2000). The 3 basic psychological needs defined by the SDT are described in the following sections (Deci & Ryan, 2012a; Peters et al., 2018).

- Autonomy (acting in accordance with one's goals and values): Autonomy refers to a sense of willingness and acting with a sense of volition and motivation in accordance

with a person's personal goals and values, which connects autonomy with meaning and purpose.

- Competence (feeling able and effective): Competence refers to the perception of being capable and effective. Optimal challenges, positive feedback, and opportunities for learning have been shown to enhance a sense of competence.
- Relatedness (feeling connected and a sense of belonging to others): Relatedness is defined as a sense of belonging and connectedness, with its core consisting of an individual's feeling of closeness to and connection with others.

This is in contrast with controlled motivation, in which one's behaviour is a function of external contingencies, such as control, coercion, and obligation. In controlled motivation, rewards or punishments are used as motivation, and people engage as they believe that is what is expected of them (Deci & Ryan, 1987). Controlled motivation involves compliance with pressure, and autonomous motivation involves behaving with a sense of volition, agency, and choice (Williams et al., 1999). The consequences of controlled motivation are internal apprehension and pressure with lower performance and motivation (Ryan, 1982). Autonomous and controlled motivation lead to different outcomes, with conditions supportive of autonomy and competence facilitating growth tendencies and conditions that control behaviour damaging those tendencies (Ryan and Deci, 2000).

Controlled motivation refers to approaches in which one's behaviour is a function of external contingencies of reward and punishment, and actions such as coercion and obligation are associated with this motivation (Moller et al., 2006).

Deci and Ryan (2008) suggest that there are 2 main types of motivation: intrinsic and extrinsic motivations. Intrinsic motivation is behaviour driven by internal motivators and rewards. This construct describes the natural inclination toward fulfilment, growth, enthusiasm, and satisfaction inherently arising from engaging in a behaviour. Intrinsic

motivation requires supportive conditions to thrive, and non-supportive environments can disrupt this motivation. By contrast, extrinsic motivation refers to behaviour driven by imposed conditions, external motivators, or offers of rewards for performance in an activity and can vary considerably in autonomy (Ryan & Deci, 2000). Both intrinsic and extrinsic motivations represent intentional behaviour but vary in their relative autonomy. Intrinsic motivation is in many ways superior to extrinsic motivation, as an extrinsically motivated action tends to dissipate when given external controls are withdrawn (Hassenzahl, 2010). The quality of experience and performance can vary based on whether one is acting for intrinsic or extrinsic reasons (Ryan & Deci, 2000).

This Study

This study built upon and added to previous reviews on patient retention in clinical trials. Similar to previous studies (Robinson et al., 2015), we first identified and described the strategies used in trials that successfully retained participants. This review followed the methodological framework for systematic scoping reviews proposed by Arksey and O'Malley (2005). Subsequently, and novel to this review, we performed a theory-based analysis of the identified retention strategies through a modern theory of motivation, Self-Determination Theory (SDT) (Deci & Ryan, 2012a). Using the SDT as a theoretical lens helped us examine the strategies to understand the motivational approaches used for patient retention in clinical trials. In addition, we reviewed the selected articles to establish whether the authors of existing studies applied a formal or named theoretical approach to influence and inform the development of the strategic approaches used to retain participants. Overall, our methodology enabled us to identify strategies, opportunities, and knowledge gaps and make recommendations for further research.

Methods

Identifying Relevant Studies

The search strategy targeted peer-reviewed published articles whose primary focus was on retention strategies and used the concepts of "retention," "strategy," "clinical trial," and "clinical research." Initial search was conducted on 6 electronic databases: CINAHL, The Cochrane Library, EBSCO, Embase, PsycINFO, and PubMed (see Multimedia Appendix 1). These databases were selected, as they were considered the most likely to contain the type of studies we were pursuing. Searches were conducted once in June and again in September 2020. The search strategy was limited to journal articles published from 1990 to 2020. The start date of 1990 was chosen because the authors concluded that 1990 and the years thereafter would have seen the availability and use of technology for running trials and incorporation of a variety of contemporary strategies for patient retention in clinical trials. Articles were considered for review only if they were published in the English language.

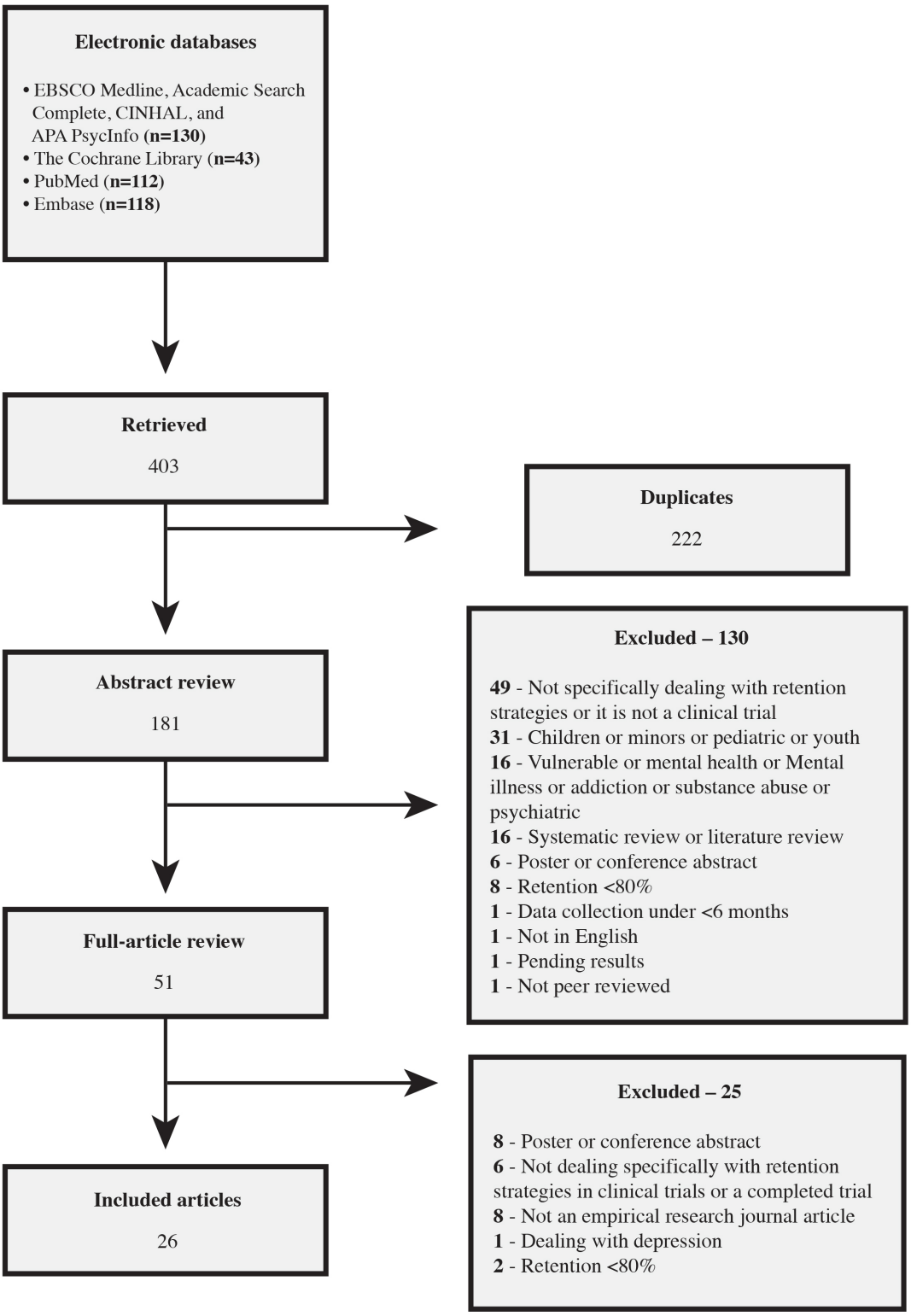
Study Selection

Study selection was an iterative process. The process involved searching the literature, followed by screening to aid in the reduction of papers for inclusion (see Multimedia Appendix 2). Studies that were considered relevant were included if they conducted quantitative or qualitative research and were peer-reviewed publications. To be eligible for inclusion, papers needed to explicitly mention "clinical trials" or "clinical research" and "patient retention strategies" in the paper title, introduction, or keywords. Articles were required to describe the retention strategies used to retain enrolled patients in a clinical trial or evaluate those retention strategies' effects or effectiveness. We included quantitative studies if they had an ≥80% retention rate, and the trial took place for a minimum of 6 months. Qualitative studies were included if they discussed retention strategies used in a clinical trial. The exclusion criteria for articles included not explicitly mentioning retention strategies in clinical trials or if the interventions used were not explicitly described in the article. An article was not eligible for

consideration if the trial population was vulnerable or high-risk participants in areas such as substance abuse and addiction, mental health trials, patients with psychological issues, or children. We excluded articles if the trial had <80% retention rate or if the research lasted <6 months. In addition, systematic reviews were not included in our research.

We retrieved a total of 403 relevant articles for further analysis. After removing duplicates, there were 44.9% (181/403) potentially relevant papers for the initial title and abstract screening. During this screening, if it was not possible to exclude an article, we obtained the full-text version and assessed eligibility based on it. Studies that did not meet the inclusion criteria were excluded. In total, 28.2% (51/181) of studies were included in the full article review following this comprehensive search strategy and screening process. Of these 51 studies, 25 (49%) were omitted: 8 (32%) studies were excluded because they were poster or conference abstracts, 6 (24%) studies were rejected because they did not explicitly deal with retention strategies in clinical trials, 8 (32%) studies were excluded because they were not empirical research studies, 2 (8%) studies had <80% retention rate, and 1 (4%) study considered vulnerable or high-risk participants. This review left 51% (26/51) of articles for inclusion. Refer to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



Charting the Data—Data Extraction

The next stage involved extracting information from the included qualitative and quantitative research studies. From each article, we recorded pertinent data (Textbox 1). We focused on relevant information with the aim of understanding the types of trials being conducted. The authors identified a list of retention strategies considered relevant to the participants enrolled and used during the clinical trial. Bias and potential errors were reduced by 2 reviewers analysing the information during the data extraction process. Data from each article meeting the inclusion criteria were extracted by EG, who independently screened the literature search for relevant results at both phase 1 (titles and abstracts) and phase 2 (full-text articles). Then, CL independently assessed the studies for eligibility and accuracy.

Textbox 1. Extracted pertinent data.

Extracted pertinent data.

Quantitative papers

- Paper title
- Authors and publication date
- Retention results at 6 months, 9 months, 12 months, or 2 years
- Therapeutic area or type of trial conducted
- Trial population

Qualitative papers

- Paper name
- Authors and publication date
- Therapeutic area type of trial conducted
- Qualitative method
- Trial population

Analysis Methods

We developed a mixed inductive and deductive method for analysing and interpreting the retention strategies in our sample based on a thematic analysis process (Braun & Clarke, 2006). First, initial codes were generated through open coding and applied to the data. Specifically, this process involved the researcher labelling each retention strategy with a descriptive code (see Multimedia Appendix 3). Second, the open-coded retention strategies were deductively sorted into a set of theoretically important, predefined themes based on the SDT (refer to Textbox 2 for a list of these themes). This process allowed us to visualise the types of motivational strategies used by the studies in our sample according to a theoretically relevant perspective. Two reviewers independently coded the data to reduce the possibility of error and reach consensus. This evidence was summarized and presented for review.

Textbox 2 - Definitions of the higher order themes that were used to deductively classify open coded data.

Autonomy

- Interventions that create conditions that enable participants to take ownership of their actions and show willingness and volition concerning their behaviour

Competence

- Interventions that create conditions that enable participants to feel able and effective; experiencing opportunities and support such as positive feedback, education, training; and learning opportunities

Relatedness

- Interventions that create conditions that enable participants to feel connected to others, offer a sense of belonging, or assist an individual's feeling of closeness to and connection with others

Controlled motivation

- Interventions in which behaviour is prompted by the external contingencies of reward, coercion, and obligation

Branding, communication material, and marketing literature

- Interventions using branding, communication material, and marketing literature to communicate with, promote the study to, and engage with patients during the trial process

Contact, tracking, and scheduling methods and data collection

- Interventions and approaches that aid with the scheduling of patients to attend trial clinics and that aid in the tracking of patients during the trial and methods that aid in the collection of data from patients during the trial process

Convenience to participate to collect data

- Interventions used to bring convenience to participants to enable data collection

Organisational competence

- Operational management approaches, organization, skills, behaviours, and competencies to support organisational performance

Results

This review identified 26 studies that reported retention strategies in clinical trials. Of the 26 studies, 16 (62%) were quantitative (Table 1), and 10 (38%) were qualitative (Table 2). The quantitative studies sampled were conducted between 2004 and 2020. The maximum participant retention rate in the studies identified was 97.8%. The duration of the trials whose retention rates were recorded ranged from 6 months to 2 years. A mix of populations was identified in the 16 quantitative studies. Of these 16 studies, 4 (25%) studies focused on low-income groups, and the remaining 12 (75%) studies had various study populations. Regarding the types of trials, HIV prevention trials (n=3) and intervention studies (n=3) were the most common types of trials, followed by cancer (n=2) and diabetes trials (n=2).

A variety of study populations were enlisted to the qualitative research studies selected, and the participants were predominantly a mix of roles from site and study teams involved in conducting clinical trials. Table 2 highlights a variety of types of trials and study populations. The remaining studies focused on an assortment of trials. The 10 qualitative studies identified were conducted between 2005 and 2020. The most used method for gathering data was interview techniques (3/10, 30%), followed by surveys (2/10, 20%), a combination of surveys and interviews (2/10, 20%), focus groups (2/10, 20%), and workshops (1/10, 10%).

Table 3 shows the articles associated with the respective higher-order themes based on the strategies observed and displays whether theory influenced strategy design. In addition to

the 4 themes taken directly from the SDT, 4 higher-order themes were generated during the analytical process. These additional higher-order themes were used to classify the data reviewed as follows: (1) branding, communication material, and marketing literature; (2) contact, tracking, and scheduling methods and data collection; (3) convenience to participate to collect data; and (4) organisational competence.

The coded strategies extracted were further inductively organized into subthemes that describe the types of strategies observed within each higher-order theme (Figure 2). The supporting subthemes and the respective retention strategies are summarized and presented for each theme in Figure 2.

Table 1. The quantitative papers identified with the various percentages of participant retention achieved, therapeutic area, and study population.

Paper	Authors / publication date	Retention @ 6 months	Retention @ 9 months	Retention @ 12 months	Retention @ 2 years	Therapeutic area type of trial conducted	Trial Study population
A collaborative approach to the recruitment and retention of minority patients with diabetes in rural community health centers	2009 - Davis, Richard M., et al.	90.9%	-	82.40%	-	Telemedicine-based diabetes self-management intervention	Minority Adults ≥35 years of age with type 2 diabetes
A review of strategies used to retain participants in clinical research during an infectious disease outbreak: The PREVAIL I Ebola vaccine trial experience	2018 - Browne, Sarah, et al.	-	-	97.80%	-	Vaccine trial follow-up	18 to 90 years old (median 30 years)
Effective recruitment and retention strategies for older members of rural minorities	2008 - Burns, Dorothy, et al.	94%	91%	-	-	Type 2 diabetes	Rural African American women - over 55
Engaging African American breast cancer survivors	2013 - Germino, et al	-	-	87% - 11 months	-	Intervention trial	Caucasian and African American

in an intervention trial: culture, responsiveness and community							breast cancer survivors
Impact of financial reimbursement on retention rates in military clinical trial research: A natural experiment within a multi-site randomized effectiveness trial with active duty service members	2019 - Novak, Laura A., et al.	-	95%	-	-	Collaborative care study	U.S. active duty Service members
Lessons learned for recruitment and retention of low-income African Americans	2020 - Taani, Murad H., et al.	83.1%	-	-	-	Hypertension self-management	Low income African American
Maximizing participant retention in a phase 2B HIV prevention trial in Kampala, Uganda: The MTN-003 (VOICE) Study	2018 - Wynne, Joshua, et al.	94%	95%	92%	-	HIV prevention	HIV high risk women
Novel strategies implemented to ensure high participant retention rates in a community based HIV prevention effectiveness trial in South Africa and Zimbabwe	2009 - Gappoo, Sharika, et al.	-	-	-	94%, 93% and 89% across 3 sites	HIV prevention trial	HIV negative, sexually active females
Patient-centered recruitment and retention for a randomized controlled study	2018 - Chhatre, Sumedha, et al.	-	-	-	between 74-83% across 3 sites	Prostate cancer	Localized prostate cancer patients
Recruiting and retaining low-income, multi-ethnic women into randomized controlled trials: Successful strategies and staffing	2012 - Barnett, Josephine, et al.	94%	-	-	-	Increase breastfeeding	Women from low-income, minority populations

Recruitment and retention of Latinos in a primary care-based physical activity and diet trial: The Resources for Health study	2007 - Eakin, Elizabeth G., et al.	81%	-	-	-	Randomized controlled trial (RCT) of a physical activity and dietary intervention	Low-income, predominantly Latino patients in a primary health care clinic
Retention strategies and factors associated with missed visits among low income women at increased risk of HIV acquisition in the US (HPTN 064)	2014 - Haley, Danielle F., et al.	93%	-	94%	-	HIV prevention trials.	Women aged 18–44 in zip code with high poverty and HIV prevalence
Strategies to improve recruitment and retention of older stroke survivors to a randomized clinical exercise trial	2014 - Taylor-Piliae, Ruth E., Daniella Boros, and Bruce M. Coull.	81%	-	-	-	Exercise randomized clinical trials (RCTs) among stroke survivors have	Community-dwelling men and women, aged 50 years or more, and were at least 3 months post stroke (range 53 months to 10 years)
Strategies to recruit and retain older Filipino–American immigrants for a cancer screening study	2005 - Maxwell, Annette E., et al.	-	-	88%	76%	Cancer prevention, screening and treatment trials	Female Filipino–American immigrants over 40 years of age
Successful recruitment and retention strategies for a randomized weight management trial for people with diabetes living in rural, medically underserved counties of South Carolina: the POWER study	2004 - Parra-Medina, Deborah, et al.	79%	-	81 .5%	-	Weight management programs and usual care	Adults ages 45 years and older with overweight adults with diabetes, living in rural, medically under- served communities
Successful Strategies for Practice-Based Recruitment of Racial and Ethnic Minority Pregnant Women in a Randomized Controlled Trial: the IDEAS for a	2016 - Goff, Sarah L., et al.	-	-	97.3% - 18 months	-	Randomized controlled trial (RCT) of an intervention	Low-income, racial/ethnic minority women

Healthy Baby Study							

(a) Not available.

(b) RCT: randomized controlled trial.

Table 2. The qualitative papers identified, therapeutic area, study participants, and trial population.

Paper	Authors / publication date	Therapeutic area and type of trial conducted	Study participants	Qualitative method	Trial population
Best Practice Guidance for the Use of Strategies to Improve Retention in Randomised Trials: Results From Two Consensus Development Workshops	Brueton et al, 2017	_(a)	UK clinical trials units, statisticians, clinicians, RCT (b) coordinators, research scientists, research assistants, and data managers associated with RCTs participated	Workshop	—
Community Health Worker Perspectives on Recruitment and Retention of Recent Immigrant Women in a Randomized Clinical Trial	Choi et al, 2016	Randomized trial to promote mammogram and Pap tests	Community health workers	Focus groups	Korean Americans
Culturally Competent Strategies for Recruitment and Retention of African American Populations into Clinical Trials	Otado et al, 2015	Mixed studies	25 study coordinators	Survey or interview	Individuals with diverse cultural backgrounds, with the majority being African Americans
Evaluating and Improving Recruitment and Retention in an mHealth Clinical Trial: an Example of Iterating Methods During a Trial	Pfammatter et al, 2017	mHealth(c) intervention to preserve and promote CVH(d)	Target population	Survey	College freshmen
Participant Retention Practices in Longitudinal Clinical Research	Abshire et al, 2017	Longitudinal studies—mixed	Study team	Survey and in-depth, semi structured interviews	—

Studies With High Retention Rates					
Recruitment, Recruitment, Recruitment'—the Need for More Focus on Retention: a Qualitative Study of Five Trials	Daykin et al, 2018	Randomized trials—mixed	Trial team members—chief investigators, trial managers, nurses, and research administrators	Semi structured interviews	—
Strategies for Retaining Study Participants in Behavioral Intervention Trials: Retention Experiences of the NIH Behavior Change Consortium	Coday et al, 2005	Behavioural intervention trials—studies targeted toward disease prevention through behaviour change	15 university-based sites	Focus groups	Mixed
Use of Strategies to Improve Retention in Primary Care Randomized Trials: a Qualitative Study with In-depth Interviews	Brueton et al, 2014	Primary care randomized trials	29 UK primary care chief and principal investigators, trial managers, and research nurses	In-depth interviews	—
Identifying Research Priorities for Effective Retention Strategies in Clinical Trials	Kearney et al, 2017	—	Chief investigators or clinical trial units	Survey	—
Recruitment and Retention of Older Adults in Assisted Living Facilities to a Clinical Trial Using Technology for Falls Prevention: a Qualitative Case Study of Barriers and Facilitators	Meekes et al, 2020	Physical function	Scheme managers, therapists, and researcher	Semi structured interviews	Older adults living in assisted living facilities

(a) Not available.

(b) RCT: randomized controlled trial.

(c) mHealth: mobile health.

(d) CVH: cardiovascular health.

Table 3. Selected articles with the identified higher-order themes based on self-determination theory and analysis of theory in articles.

Paper	Branding, communications material and marketing literature	Contact, tracking, scheduling methods and data collection	Convenience to participate in order to collect data	Organisational competence	Controlled motivation	Autonomy	Competence	Relatedness	Theory mentioned
Abshire et al, 2017	X	X	X	X	X	X	X	X	
Barnett et al, 2012	X	X	X		X				
Browne et al, 2018		X						X	
Brueton et al, 2014	X	X	X		X	X		X	
Brueton et al, 2017	X	X			X				
Burns et al, 2008		X	X		X	X		X	
Chhatre et al, 2018		X		X	X			X	
Choi et al, 2016			X	X	X			X	
Coday et al, 2005	X	X	X	X	X	X	X	X	
Davis et al, 2009		X	X		X			X	
Daykin et al, 2018	X	X	X	X		X	X	X	
Eakin et al, 2007		X	X			X			
Gappoo et al, 2009		X	X		X	X	X	X	
Germino et al, 2013			X		X	X	X	X	
Goff et al, 2016		X		X	X	X			
Haley et al, 2014	X	X	X	X	X			X	
Kearney et al, 2017		X		X					
Maxwell et al, 2005		X			X		X	X	

Meekes et al, 2020	X						X	X	
Novak et al, 2019					X				
Otado et al, 2015		X	X		X	X		X	
Parra-Medina et al, 2004		X			X	X		X	
Pfammatter et al, 2017		X			X			X	
Taani et al, 2020		X		X	X		X	X	
Taylor-Piliae et al, 2014	X	X	X		X	X		X	
Wynne et al, 2018		X		X					

Higher Order Theme - Autonomy

This theme described interventions to enable participants to self-endorse and take ownership of their actions, offering flexibility and empowering participants' willingness and volition concerning their behaviour. The retention strategies coded under "Autonomy" were inductively grouped into 3 subthemes.

Flexibility, Accommodating, and Tailored to Participant

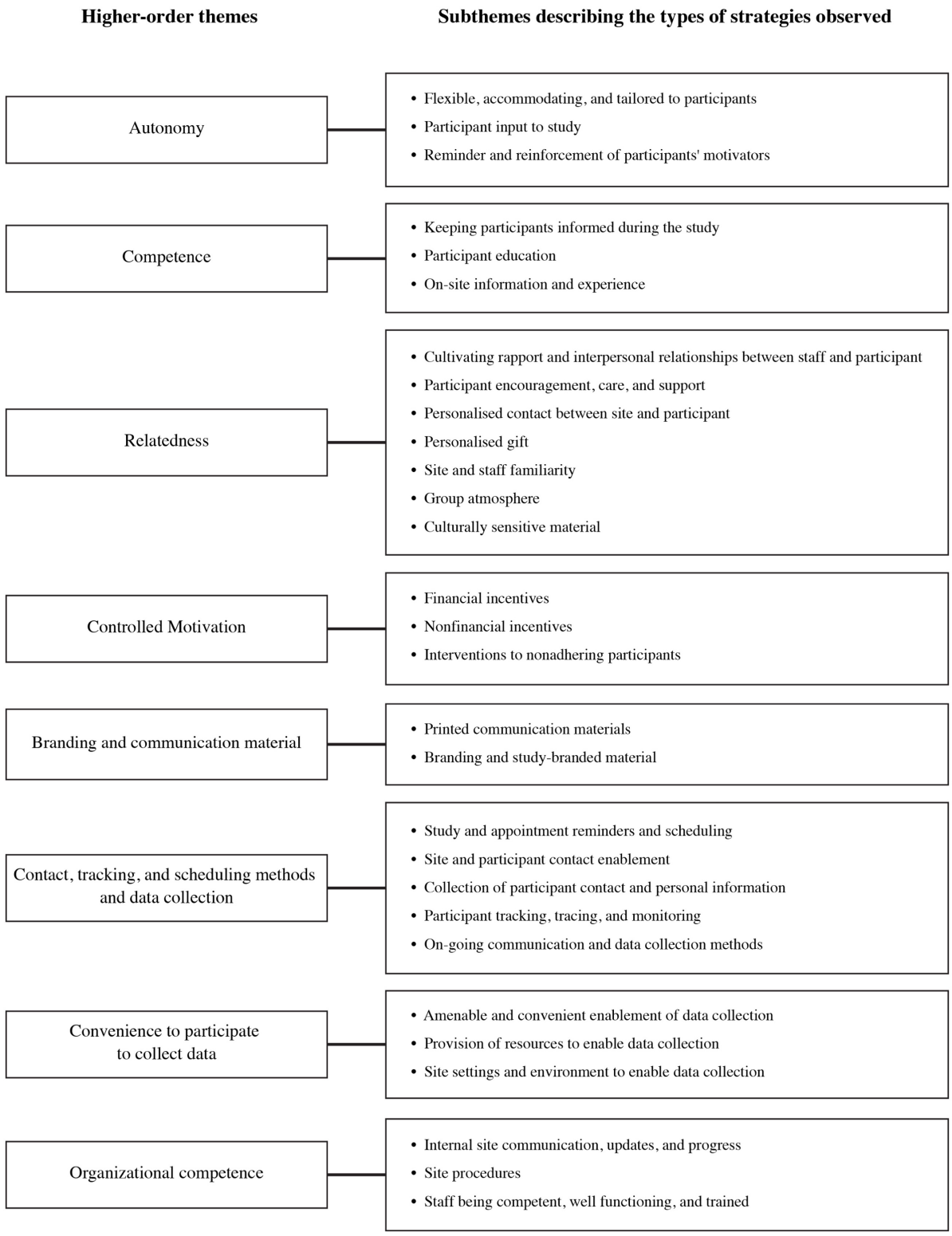
Studies used a range of strategies that attempted to improve participants' autonomous experience by tailoring elements of the study experience, offering flexibility, and accommodating participants during the trial. The strategies observed included consideration of the participants' circumstances, such as scheduling trial-related calls at a convenient time (Germino et al., 2011). Staff made accommodations according to personal situations (Parra-Medina et al., 2004) and provided home follow-ups where necessary (Brueton, Stevenson, et al., 2014). Staff anticipated and were responsive to participants' needs, creating flexible protocols (Goff et al., 2016), and negotiated with participants regarding the amount of data they would collect (Coday et al., 2005). Flexible appointments were offered (Daykin et al.,

2018), including after hours and weekends (Otado et al., 2015), and participants with difficulties attending clinics or who "no-showed" numerous times were accommodated (Eakin et al., 2007). Participants were given a "break" from calls, and messages were not left on every call attempt (Coday et al., 2005). Tactics included data collectors offering flexibility to participants (Germino et al., 2011), staff behaving in a respectful manner (Otado et al., 2015), and site staff troubleshooting challenges encountered by participants (Taylor-Piliae et al., 2014). Participants were consulted on the best time to call, data collection windows were extended, tests were modified and rescheduled, and the frequency and number of contacts of participants were reconsidered if the burden became substantial (Coday et al., 2005). Staff encouraged participants to bring items from home to make themselves comfortable and adapted their approaches to individual participants' situations (Abshire et al., 2017).

Participant Input to Study

Some studies offered participants the opportunity to offer input directly to the study approach. A range of methods was observed, including involving community members in study planning and implementation (Burns et al., 2008), listening to participants' concerns regarding the study and personal issues, and being sensitive to participants' needs (Otado et al., 2015). After visit, staff inquired about participants' well-being, feelings about the studies, and possible concerns (Otado et al., 2015). Clinics provided suggestion boxes, and signage was used, encouraging participants to notify the coordinator if waiting times exceeded 10 minutes (Gappoo et al., 2009).

Figure 2. Higher-order themes and abstracted subthemes describing the types of strategies observed within each theme.



Reminder and Reinforcement of Participants' Motivators

During the trials, staff engaged participants and reminded them of the benefits of involvement and of the participants' personal drivers to partake in the trial. This approach was used to remind and reinforce the personal drivers and independent commitment made by participants to partake in the trial. Instances included staff discussing the benefits and highlighting the advantages accrued from taking part in the study (Abshire et al., 2017; Parra-Medina et al., 2004). Participants were sent letters from their Doctor of Medicine, and staff discussed motivations, benefits, and reasons for joining the study, reminding participants of their commitment and encouraging follow-through while emphasising the importance of helping others (Coday et al., 2005).

Higher Order Theme - Competence

This theme describes the observed strategies that aimed to enable the participants to feel able and effective. Strategies included offering support such as positive feedback, education, training, and learning. The retention strategies coded under "Competence" were inductively grouped into 3 subthemes.

Keeping Participants Informed During the Study

Strategies used in a number of studies attempted to keep participants informed about the trial, specifically about trial activities and progress, giving participants knowledge and understanding of aspects related to the studies. The methods observed included sending participants personalised letters with an update on study activities and selected study findings (Maxwell et al., 2005). Staff motivated participants by supporting them to feel confident and safe, feedback was provided on performance, and participants shared positive experiences (Meekes et al., 2021).

Participant Education

This subtheme describes interventions intended to educate and improve the participants' understanding of trial procedures, disease management, and health. The strategies observed

included delivering intervention material in person and staff reviewing and training participants (Germino et al., 2011). Advice and education were provided by staff to participants during the trial (Meekes et al., 2021), addressing participants' health literacy (Taani et al., 2020), offering clear and transparent data collection procedures (Daykin et al., 2018), and highlighting the need for complete data (Coday et al., 2005). Studies hosted educational discussion forums and group discussions related to disease management, encouraging participants to invite the study team to provide education and conduct testing at family gatherings and reunions (Abshire et al., 2017).

On-site Information and Experience

The research found strategies in studies wherein staff endeavoured to create an on-site experience that was understandable to participants and encouraged a comforting experience, enabling greater comprehension and comfort at the site. Participants were encouraged to bring a blanket or pillow from home to make themselves comfortable (Abshire et al., 2017). Signage positioned in the clinic waiting areas and bathrooms communicated with and gave direction to participants; a liaison officer was deployed for waiting participants to provide guidance and share information about the expected waiting periods (Gappoo et al., 2009).

Higher Order Theme - Relatedness

The strategies observed in this theme aimed to enable participants to feel connected, offer a sense of belonging, and assist an individual's closeness to others. The retention strategies coded under "Relatedness" were inductively grouped into 6 subthemes.

Cultivating Rapport and Interpersonal Relationships Between Staff and Participant

Trials used interventions conducive to cultivating interpersonal relationships, building rapport, and fostering connections and affiliations between participants and study staff. Methods to enhance retention included the moral compass of individual trial team members (Daykin et al.,

2018) and staff alleviating participant fear and doubts (Browne et al., 2018). Trial teams aimed to maintain good relationships (Choi et al., 2016) and build trusting (Burns et al., 2008), respectful, and confidential relationships with participants (Gappoo et al., 2009). Staff tried to maintain a good rapport (Brueton, Stevenson, et al., 2014; Otado et al., 2015), keep contact using social media (Haley et al., 2014), be charismatic (Taylor-Piliae et al., 2014), and build continued interpersonal relationships with participants (Daykin et al., 2018). The staff adopted a nonpatronizing approach in which showing traits of being approachable and supportive were regarded as necessary (Meekes et al., 2021).

Participant Encouragement, Care, and Support

As for this subtheme, the studies used several interventions, including behaving in a manner that offered encouragement and displayed care and support to participants. Some examples include the researchers showing characteristics of being approachable and supervising and providing support to participants with the aim of making them feel confident and safe (Meekes et al., 2021). Staff used informal interpersonal relationship strategies by showing a caring nature (Daykin et al., 2018). Staff gave participants genuine attention and care and fulfilled their needs using community resources, such as medication (Choi et al., 2016). When dealing with participants, staff listened, helped with problem-solving, and used verbal thanks (Coday et al., 2005). Staff made accommodations, communicated with enthusiasm, showed concern for personal situations (Parra-Medina et al., 2004), and offered personalised attention and encouragement (Taylor-Piliae et al., 2014). The people in participants' contact list, including relatives, friends, significant others, physicians, and health clinics, were called and asked to encourage participants and promote the benefits of continued participation (Coday et al., 2005). Participants with strong personalities taking part in the study and peers sharing positive experiences and cheering and clapping for each other were used to create an environment of encouragement (Meekes et al., 2021). A newsletter consisting of testimonials of former

participants was circulated, and staff offered encouragement by reminding participants of the importance of helping others and the national scope of the group (Coday et al., 2005).

Personalised Contact Between Site and Participant

Studies highlighted staff exercising strategies such as the personalisation of contacts made and interactions and touchpoints with participants. Examples include sending individualized (Germino et al., 2011) and personalised letters with an update on study activities (Maxwell et al., 2005). These included personalised notes and cards maintaining ongoing individualized contact and engagement, such as those given on holidays and birthdays and those conveying thank you and greetings (Abshire et al., 2017; Chhatre et al., 2018; Coday et al., 2005; Germino et al., 2011; Haley et al., 2014; Taani et al., 2020). Cards were sent from the group or staff to check on the status of a participant who became ill, in the event of a family death or illness (Coday et al., 2005), and to offer condolences (Abshire et al., 2017). Staff would also follow-up if participants became ill during the trial, even if the participants' illness had nothing to do with the trial (Daykin et al., 2018). Staff sent email greetings for birthdays, holidays, and important events (Pfammatter et al., 2017). Electronic systems generated automated birthday greetings and reminder telephone call lists for research staff (Parra-Medina et al., 2004). To build rapport, staff made monthly calls (Haley et al., 2014), made touch-base calls, or sent touch-base emails between scheduled visits (Coday et al., 2005). After visit, calls were made to inquire about participants, gauge their feelings, and hear concerns regarding the study (Otado et al., 2015).

Personalised Gift

Studies used personalised approaches such as mailing personalised gifts to participants every 2 months (Germino et al., 2011). Examples of such gifts included gifts of pictures of the participants with their child, peers, or staff (Coday et al., 2005). In another study, calendars

featuring artwork created by the participants or their grandchildren were sent to trial participants in mail correspondences (Abshire et al., 2017).

Site and Staff Familiarity

The strategies observed emphasised participants' familiarity with the study staff and trial site. Examples of these strategies included conducting the trial research at community health centres with which participants might be familiar (Davis et al., 2009). Staff wore name tags (Gappoo et al., 2009) and uniforms (Meekes et al., 2021). Participants were allocated to 1 team member as a primary contact (Abshire et al., 2017), and the same staff members were deployed throughout the follow-up period, aiding the development of strong staff-participant relationships (Abshire et al., 2017; Burns et al., 2008). Partnership with local, well-known, and trusted clinics and clinicians increased the credibility of the study and aided retention (Taani et al., 2020).

Group Atmosphere

The study sites sought to create an atmosphere within the study group that was positive for participants. An example of this is staff maintaining a comfortable atmosphere in the study group during sessions (Meekes et al., 2021).

Culturally Sensitive Materials

Sites used culturally appropriate language and study symbols in study material to ensure that it would be acceptable to rural, older African American participants (Burns et al., 2008).

Higher Order Theme - Controlled Motivation

This theme describes interventions using strategies that attempt to influence participant behaviour through external contingencies such as reward and coercion. The retention strategies coded under "Controlled motivation" were then inductively grouped into 3 subthemes.

Financial Incentives

Trials used financial incentives to encourage retention and engagement. Participants were compensated for their continued involvement in the trial. The financial incentives observed in our sample of studies included gift cards (Davis et al., 2009; Taylor-Piliae et al., 2014), gift certificates (Coday et al., 2005), reimbursements (Novak et al., 2019), and cash (Abshire et al., 2017; Brueton, Stevenson, et al., 2014; Burns et al., 2008; Goff et al., 2016; Taani et al., 2020). Compensation was given to participants upon completion of various stages of the trial (Barnett et al., 2012; Coday et al., 2005; Germino et al., 2011; Haley et al., 2014; Maxwell et al., 2005; Parra-Medina et al., 2004) and for providing questionnaire responses (Brueton et al., 2017). Contributions to participants' churches were also made (Choi et al., 2016).

Nonfinancial Incentives

Several nonfinancial incentives or small gifts were also used to encourage and reward participants for continued participation in the trial. Nonfinancial (Brueton et al., 2017) incentives included T-shirts, tote bags, pens, magnets, key rings, mugs, and certificates of completion (Brueton et al., 2017; Davis et al., 2009). Community resources, such as additional medication and referrals, were used to fulfil the needs of participants (Choi et al., 2016). Parking validation, tickets, and lunch (Otado et al., 2015) were the other incentives used. Award systems (Gappoo et al., 2009), lottery systems (Gappoo et al., 2009; Maxwell et al., 2005), coupon raffles (Burns et al., 2008), gifts (Germino et al., 2011), retention events such as spa days and luncheons (Haley et al., 2014), and annual events at entertainment venues (Abshire et al., 2017) were also used. The opportunity to receive medical procedures and consultation was provided (Coday et al., 2005). Lifestyle-related incentives were provided (Coday et al., 2005) to encourage participants, and a booklet and supporting DVD and CD were used to promote physical activities (Taylor-Piliae et al., 2014).

Interventions for Non adhering Participants

This subtheme describes interventions delivered by trial staff upon recognising a participant's lack of adherence to the study protocol or in the event that a participant becomes nonresponsive or noncompliant or misses visits. For example, in many studies, staff responded immediately to missed appointments by visiting the participant on the same or subsequent day to reschedule the appointments (Gappoo et al., 2009) or contacting them by telephone (Chhatre et al., 2018; Parra-Medina et al., 2004), by letter (Maxwell et al., 2005), or using several approaches, including text, email, phone call, postcard, and via social media, depending on participant responses (Pfammatter et al., 2017). For interviews, participants who were uncontactable received personalised letters and emails (Barnett et al., 2012). Other approaches included staff emphasising the need for complete data, making expectations clear to participants at initial contact, or begging and pleading with the participants (Coday et al., 2005). Coordinators and site directors visited participants that were deemed "difficult" (Gappoo et al., 2009).

Higher Order Theme - Branding and Communication Material

The first theme describes interventions that use branding, communication material, and marketing literature to communicate with, promote to, and engage participants during the trial process. The retention strategies coded under "Branding and communication material" were inductively grouped into 2 subthemes.

Printed Communication Material

Printed communication material was used in many studies in our sample. The observed strategies included the use of letters and traditional postal services for routine communication with participants (Brueton et al., 2017; Brueton, Stevenson, et al., 2014). Studies sent newsletters to participants (Abshire et al., 2017; Coday et al., 2005; Daykin et al., 2018; Taylor-Piliae et al., 2014) to keep them informed about general trial news (Brueton, Stevenson, et al.,

2014). Study brochures provided participants with relevant contact information (Barnett et al., 2012), and studies used professionally printed questionnaires (Daykin et al., 2018).

Branding and Study-Branded Materials

Many studies emphasised the importance of including study-related branding in communication material. For example, studies provided participants with study logo–branded materials, such as magnets (Barnett et al., 2012), branded gospel music tapes, audiotapes, potholders (Coday et al., 2005), key chains, T-shirts (Haley et al., 2014), and branded artwork calendars (Abshire et al., 2017). The wearing of uniforms with a logo was also considered important (Meekes et al., 2021). Studies conducted by universities and government-funded agencies used their brand associations (Meekes et al., 2021).

Higher Order Theme - Contact, Tracking, and Scheduling Methods

This theme describes strategies, interventions, and approaches that aid with scheduling participants to attend trial clinics and tracking participants and methods that aid with data collection during the trial process. Strategies coded under "Contact, tracking, and scheduling methods" were inductively grouped into 5 subthemes.

Study and Appointment Reminders and Scheduling

This subtheme describes appointments and scheduling approaches used and considered valuable strategies to retain participants, including study and visit reminders (Abshire et al., 2017; Browne et al., 2018; Gappoo et al., 2009). Participants received appointment cards for follow-up visits (Gappoo et al., 2009), postcard reminders (Barnett et al., 2012), and visit reminders, and calendars showing the sequence of visits for the study duration were issued at enrolment (Wynne et al., 2018). Staff engaged participants with reminders of their upcoming appointments and clinic visits (Browne et al., 2018) via telephone calls (Davis et al., 2009; Otado et al., 2015), postcards (Haley et al., 2014; Otado et al., 2015), or reminder letters (Coday

et al., 2005; Gappoo et al., 2009; Haley et al., 2014). The timing of the approach was important, and before or leading up to a visit or a scheduled appointment, a phone call was triggered (Coday et al., 2005; Davis et al., 2009; Gappoo et al., 2009; Wynne et al., 2018). The staff gave in-person and postal reminders during the week preceding the scheduled visit (Gappoo et al., 2009) and sent letters about the study and upcoming visits at regular intervals (Abshire et al., 2017). At the visits, participants received an in-person reminder of the upcoming interview (Barnett et al., 2012). The retention approach also included general contact and scheduling (Abshire et al., 2017) and multiple rescheduling of visits for participants (Coday et al., 2005). As a scheduling technique, research staff disclosed incentives to participants when scheduling visits by telephone (Parra-Medina et al., 2004). The research team attempted to contact participants 3 times by phone, texts, or emails, and if unsuccessful, a letter was sent (Taani et al., 2020). Scheduling and calendar software, visit window reports, and prompts were used by site staff (Coday et al., 2005).

Site and Participant Contact Enablement

The strategies in this subtheme offered participants multiple ways to enable participants to contact sites. Examples included sites providing participants with study-labelled material with the study's contact information and business card containing phone numbers (Barnett et al., 2012), selecting appropriate individuals with responsibility for participant contact, and allocating a study's primary point of contact to a group of participants (Abshire et al., 2017). Sites provided participants with toll-free numbers to enable communication (Burns et al., 2008; Davis et al., 2009; Haley et al., 2014). Participants provided additional contact information, including those of family members or friends, to allow for multiple means of contact (Davis et al., 2009).

Collection of Participants' Contact and Personal Information

The strategies observed in this subtheme included the collection of participant contact and personal information. The approaches incorporated participants providing their own contact and location information and the contact information of additional individuals to allow multiple means of communication (Abshire et al., 2017; Barnett et al., 2012; Daykin et al., 2018; Gappoo et al., 2009; Wynne et al., 2018). Alternate contact lists were established (Taylor-Piliae et al., 2014), and reference for contacting these individuals and permission to mention the trial name were noted (Gappoo et al., 2009). The contact information was reviewed with the participants and updated if necessary (Abshire et al., 2017; Barnett et al., 2012; Davis et al., 2009). Staff checked the clinic database and participant charts for updated numbers to replace incorrect details (Eakin et al., 2007) and updated the locator forms at each visit (Gappoo et al., 2009). Studies requested participants to provide full family names and nicknames by which they were known in their communities and to describe the area in which they lived, allowing for more effective follow-up in rural areas (Browne et al., 2018).

Participant Tracking, Tracing, and Monitoring

This subtheme describes interventions for participant tracking, tracing, and monitoring that were used as strategies for supporting retention endeavours and included procedures, methods, and systems for tracking participants and monitoring data return. Tracking methods were used to inform retention efforts and facilitate communication among team members (Abshire et al., 2017). Sites collected detailed participant locator information (Gappoo et al., 2009), and the attendance and progress of participants were monitored (Gappoo et al., 2009; Kearney et al., 2017; Parra-Medina et al., 2004; Taylor-Piliae et al., 2014). Participants' progress was tracked through the study (Goff et al., 2016) using the tracking system (Parra-Medina et al., 2004) and spreadsheets or databases (Abshire et al., 2017). To maintain a good tracking system of participants including phone availability, notes and sites recorded call attempts (Coday et al., 2005; Gappoo et al., 2009). To ensure a comprehensive participant search process, staff

executed a checklist of techniques (Abshire et al., 2017) and generated a list of participants who attended follow-up visits (Wynne et al., 2018). Staff checked rosters, directory listings, transfers, addresses, or phone changes (Coday et al., 2005). Searches were also conducted using web-based prison and incarceration records and jail databases (Abshire et al., 2017; Haley et al., 2014). Death registries and the local newspaper obituary were also used to locate participants (Haley et al., 2014). Staff searched the medical records of participants who were typically more difficult to contact for any upcoming clinic visits (Barnett et al., 2012). Staff visited participants' homes and used personal delivery of reminders and court documents when locating participants (Abshire et al., 2017). Other methods used to locate participants included the use of phone numbers, email, texting, social media, and internet searches (Abshire et al., 2017), and GPS was used to identify homes in areas that are difficult to access (Gappoo et al., 2009). Letters were sent to ask participants to inform sites about changes in address or telephone numbers (Maxwell et al., 2005). Lists of participants who missed visits were created and distributed to community outreach workers (Wynne et al., 2018), and staff were alert and responsive to potential signs of participant dropout (Coday et al., 2005). Monthly reports identified potential problem sites, staff meetings were held to address the issues, and community outreach workers discussed challenging cases. They used locator information to trace participants and understand the reason for nonattendance (Wynne et al., 2018). Browne et al (Browne et al., 2018) discussed how trials in Liberia hired trackers from local communities who were familiar with the local culture, geographic area, community leaders, residents, and population. Local teams embraced cultural norms and had local knowledge, and trial participants were assigned to a tracker who spoke with family and friends to locate mobile participants. Owing to the participants' lack of access to mobile phones, the phone number of one of the participants was collected and used as a central contact number to cover a group of

participants. The phone number of a community store was also used, and store employees would locate the participants.

Ongoing Communication and Data Collection Methods

The research found that several trials implemented strategies facilitating ongoing communication and the collection of data from participants. Examples included employing several staff members to collect data, manage retention (Abshire et al., 2017), and make frequent follow-up contact (Burns et al., 2008). Team members, including the principal investigator (Coday et al., 2005), visited participants, collected information (Browne et al., 2018; Gappoo et al., 2009), and used the telephone to contact participants (Brueton, Stevenson, et al., 2014; Taani et al., 2020). Staff re-contacted participants at intervals for short interviews (Maxwell et al., 2005), and ongoing communication took place through various means such as text, email, letter, and phone (Brueton et al., 2017; Brueton, Stevenson, et al., 2014; Taani et al., 2020). Staff repeated attempts to recontact participants (Eakin et al., 2007), and they gave participants a break from contact and did not leave messages at every call attempt (Coday et al., 2005). Nurses reinforced clinic messaging in the various communities in which participants resided (Browne et al., 2018), and plain English was used during data collection (Brueton et al., 2017).

Higher Order Theme - Convenience for Data Collection

The strategies observed in this theme centred on convenience to contribute to data collection. Staff used strategies to make the trial more conducive to data collection. The retention strategies coded under “Convenience to participate in collecting data” were inductively grouped into 3 subthemes.

Amenable and Convenient Enablement of Data Collection

Several interventions were adopted to optimise retention when collecting data by offering flexibility to participants and attempting to reduce the data collection burden on them, accommodating the participants' lifestyle, and making the trial procedures more convenient for the participant when providing data. Examples included the flexibility of data collectors (Germino et al., 2011) and streamlining appointments (Brueton, Stevenson, et al., 2014) to accommodate participants. To facilitate participation, staff were accommodating when scheduling face-to-face interviews and visits and scheduled visits around other appointments (Coday et al., 2005). Participants tolerance for data collection activities was addressed by shortening visits, collecting "primary" measures first before collecting other data, modifying tests, and rescheduling appointments if participants were injured or ill (Coday et al., 2005). Proposing home visits (Brueton, Stevenson, et al., 2014; Coday et al., 2005; Haley et al., 2014) and conducting interventions in participants' homes (Burns et al., 2008; Eakin et al., 2007; Gappoo et al., 2009) were considered convenient and helped alleviate transportation difficulties. Sites performed assessments and interventions at the same location (Taylor-Piliae et al., 2014), implemented short patient visits (Haley et al., 2014), and made additional trips to collect samples (Germino et al., 2011). Some trials used community-based visit locations for convenience (Haley et al., 2014). For participants who faced partner violence, arranging a safe meeting place was proposed (Abshire et al., 2017). Strategies included being flexible by accommodating participants' schedules, after-hour and weekend appointments (Otado et al., 2015), and Saturday and evening clinics (Gappoo et al., 2009). Sites offered appointments outside traditional workdays (Haley et al., 2014), extending hours (Coday et al., 2005) and widening time windows of 4 to 6 weeks to achieve more success in reaching participants (Eakin et al., 2007). Some studies offered participants the option to return questionnaires or return to sites for follow-up and found more convenient ways to collect participant data, such as via the web or telephone (Brueton, Stevenson, et al., 2014), and if participants moved location, they

were offered alternate options such as phone or mail visits (Coday et al., 2005). Scheduling calls per participants' convenience (Germino et al., 2011) and asking whether an alternate number was better to call on (Coday et al., 2005) was deemed meaningful for participant retention. Conducting calls on weekday evenings and weekends (Barnett et al., 2012; Eakin et al., 2007) and modifying the number of contacts if perceived as too burdensome to a participant were other strategies used (Coday et al., 2005). Factors used to optimise retention included new questionnaire formats, convenience in data collection such as web-based collection, the reduction of time participants spent in follow-up activities, and the reduction of types of data collected (e.g., long questionnaires and biomedical specimens) (Brueton, Stevenson, et al., 2014). The decrease in outcome measure burden was considered effective (Daykin et al., 2018), and for working or hard-to-reach participants, an award system for completed visits was implemented to allow them to jump the queue (Gappoo et al., 2009).

Provision of Resources to Enable Data Collection

Strategies used by sites to collect data from participants included arranging and providing resources to participants before, during, and after gathering data. Sites provided transportation to participants to get them to the trial sites (Abshire et al., 2017; Davis et al., 2009; Gappoo et al., 2009; Haley et al., 2014). Carpools were arranged (Coday et al., 2005), and sites reimbursed participants for transportation or gasoline (Abshire et al., 2017; Coday et al., 2005). Sites also provided metro or bus cards (Haley et al., 2014) to facilitate transport and enable participants to visit trial sites. Free car parking was arranged (Daykin et al., 2018) and made available and accessible (Coday et al., 2005; Taylor-Piliae et al., 2014), and expenses were reimbursed (Abshire et al., 2017) to the participant. Sites provided participants with toll-free numbers (Burns et al., 2008; Davis et al., 2009) and toll-free phone lines (Haley et al., 2014) to facilitate site contact. A clinic attendance letter was provided to present to a school or employer (Gappoo et al., 2009). For participants with responsibilities for children, childcare was organized

(Abshire et al., 2017; Haley et al., 2014), and help was offered to arrange babysitting (Coday et al., 2005). Participants were provided with postage-paid return envelopes to mail back questionnaires (Coday et al., 2005). Troubleshooting the challenges participants were encountering (Taylor-Piliae et al., 2014) and providing resources such as medication to fulfil participants' additional needs were other strategies that were followed (Choi et al., 2016). Sites also provided a community resource guide with lists of local social services and food pantries, and woman well-care was handed out (Haley et al., 2014).

Site Settings and Environment to Enable Data Collection

The subtheme showed that sites endeavoured to create an environment that was familiar and calming for the participants to enable comfortable surroundings throughout the trial. The research was conducted at established locations with which participants were familiar, such as community health centres (Davis et al., 2009). Participants were encouraged to bring items from their homes to make themselves comfortable (Abshire et al., 2017). Family movies were played in waiting areas, and client liaison officers were employed to work with participants (Gappoo et al., 2009). Meals, coffee, and snacks were provided at the trial sites after testing (Abshire et al., 2017).

Higher Order Theme - Organisational Competence

This theme describes strategies centred on operational management approaches, organization, procedures, skills, and competencies to aid sites' optimal performance. The retention strategies coded under "Organisational competence" were inductively grouped into 4 subthemes.

Internal Site Communication, Updates, and Progress

As part of this subtheme, there were several strategies that centred on-site communication efforts, progress, and updates for sites. These included regular team conference calls, retention workshops throughout the study (Haley et al., 2014), provision of study updates, and letters of

progress reports (Chhatre et al., 2018). Research highlighted the importance of good site relationships, regular contact (Kearney et al., 2017), and internal communication among members of research teams (Abshire et al., 2017; Taani et al., 2020). Methods included study teams examining tracking methods, reviewing the latest retention rates, discussing ideas, strategizing, providing support, making changes, and adopting revised retention strategies (Abshire et al., 2017). Monthly reports were used to help identify potential problem sites, and lists of participants who missed their visits were also created and distributed (Wynne et al., 2018).

Site Procedures

Studies emphasised procedures, processes, goal setting, and monitoring as part of retention efforts. Examples included sites using clear and transparent data collection procedures (Daykin et al., 2018) and staff attending or being present at most sessions (Goff et al., 2016). A systematic checklist of techniques for participant searches was used, including spreadsheets and databases, enabling the monitoring, evaluation, adjustment, or innovation of retention strategies (Abshire et al., 2017). Sites set daily participant contact goals, implemented friendly competition (Abshire et al., 2017), and used incentives (Daykin et al., 2018) as means to engage sites. Procedures such as recording call attempts to discern participants' availability and taking notes on whether a message was left were followed (Coday et al., 2005).

Staff Being Competent, Well Functioning, and Trained

The subtheme included strategies focusing on the enhancement of the competencies, capabilities, and experience of site staff and training-aided trial retention strategies. Examples included study and site training (Haley et al., 2014), improving the phone skills of callers (Coday et al., 2005), and providing training to staff (Goff et al., 2016) at points such as initiation and triggered training (Kearney et al., 2017). Providing intensive training and support on study protocols, including retention techniques, focused on providing staff education on

empathy, sensitivity, and mock interviews in preparation for the team engaging with participants (Abshire et al., 2017). The experience of trial team members (Daykin et al., 2018); staff bonding (Coday et al., 2005); effective, organized, and persistent trial team functioning (Abshire et al., 2017); the competency of health workers (Choi et al., 2016); and the ability to anticipate and respond to participants' needs (Goff et al., 2016) were all deemed necessary to aid retention. The accessibility to research staff, including physicians' ongoing involvement in the study and staff staying up to date to answer any arising participant questions (Chhatre et al., 2018), also aided retention. Team development approaches (Taani et al., 2020) and developing collaboration with clinic staff (Goff et al., 2016) were also fundamental to these strategies. Consultation with other sites regarding best practices (Haley et al., 2014), the use of team approaches, and employing several staff members were also deemed important to retain participants. Some studies employed a full-time staff member dedicated to implementing retention strategies and optimising participant follow-up; the team offered strategic support, including adapting or developing new approaches to overcome retention barriers (Abshire et al., 2017).

Theoretical Framework

Upon review, none of the identified papers explicitly mentioned the use of theory to guide trial design and implementation (Table 3). On the basis of our analysis, a formal theoretical approach to understanding and supporting human motivation is lacking in the reviewed literature. Conversely, if a theoretical framework was used to form strategies or influence strategic direction, the authors of the identified papers did not share this knowledge.

Discussion

Principal Findings

This systematic review of participant retention in clinical trials was conducted to identify and describe the strategies currently being used in trials that successfully retain participants. We

analysed the retention strategies observed in our sample of papers through a modern theory of motivation called the SDT to reveal patterns in the strategies. Specifically, we classified each strategy based on components of the SDT that speak to different types of human needs satisfaction (e.g., the need for autonomy or the need for relatedness). We used this to reveal a picture of the diverse motivational strategies implemented to retain participants in clinical trials. From the 26 articles included, we identified examples of interventions that create conditions for all 3 SDT motivational themes, namely autonomy, relatedness, and competence, and strategies that fit into the controlled motivation themes. Most studies had a mix of several different strategic retention themes, highlighting the diversity of strategies used as part of trials (Table 3). Relatedness was the most prominent theme and had the largest number of associated subthemes. A substantial number of studies also showed the use of strategies based on controlled motivation. Of the strategies used that did not fit into our motivational model, contact, tracking, and scheduling methods and data collection yielded the most results. Although they did not fit into our participant motivation framework, they play an important role when conducting a trial. None of the papers reviewed explicitly mentioned the use of a theoretical framework guiding their retention strategy design decisions or as part of the formulation of strategies to retain participants. Theory consideration may have occurred during this process, but it was not evident in this collection of papers.

Use of Controlled Motivation

A substantial proportion of the reviewed papers used motivation strategies that, upon analysis through our framework, can be characterized as controlled motivation. These strategies were used to influence participant behaviour through external contingencies such as reward and coercion—financial and nonfinancial incentives and interventions such as reminders used for uncontactable and non-adhering participants. Traditionally, these strategies were considered integral for promoting participant engagement and clinical trial retention. However, it is

important to note that according to the SDT, these controlled motivation strategies can have a detrimental effect and create conditions and influence participants in ways not conducive to remaining motivated (Ryan & Deci, 2000). The outcomes may include damaging motivational tendencies, lower performance, and possible demotivation to continue participating in the trial. Practitioners and designers may need to re-examine their reliance on these strategies because of the potential negative repercussions and potential to undermine retention. If these strategies are essential, they could be augmented with more autonomous and relatedness- and competence-based motivational approaches.

Importance of Relatedness and Human Interaction

A recurring theme in patient retention literature is the importance of interpersonal relationships for engaging and motivating participants (Burns et al., 2008; Choi et al., 2016), and our study supported this point. Furthermore, our findings emphasised the reliance of existing trials on creating conditions for relatedness and the importance of human interaction during those trials. These strategies relied on staff and participants interacting with each other; staff's responsiveness to, encouragement of, and communication with participants; and staff showing their human, respectful, genuine, caring, and considerate side. The behaviours and personal characteristics of staff and rapport and positive interactions with participants are integral to strategic approaches, and this illustrated the importance of rapport and interrelationships during the trial. The findings reinforced the importance of relatedness to participant motivation and retention. Replicating these interactions, strategies, and delivery of methodologies through technology will be challenging and potentially impractical for the new landscape of DCT. There are challenges and opportunities for designing technology and creating digital strategies and conditions that can enhance relatedness for participants as trials continue to move to the decentralised model.

Role of Theory in Informing Patient Retention Strategies

The reviewed articles showed a surprising lack of research seeking to understand participant motivation from theoretical and practical perspectives (Table 3). A number of strategies used in the trials studied encompassed characteristics that are likely to create the conditions for motivation. However, the reviewed papers did not explicitly report the use of a theoretical framework of motivation when making decisions about which strategies should be used. In terms of theoretical motivation frameworks, there was little evidence that strategy was guided by a coherent understanding of human motivation, as several strategic approaches displayed characteristics that fit into the description of controlled motivation, which could, in turn, demotivate participants. We advocate using the theoretical framework of the SDT to guide the research and design of digital retention strategies. Using a theory-driven approach can aid in designing a digital strategy by assisting in the understanding of why and how an intervention works. Using a theoretical motivation framework as part of clinical trial technology retention strategies will help close the gap between current retention strategies and the design and implementation of digital retention strategies.

Strategy Implementation

Past research has identified that using a larger number of retention strategies produces better retention results (Robinson et al., 2015). There is very little guidance on which strategies are appropriate for use in which context. Designers and researchers have just been encouraged to use a wide range of strategies. In our findings, we see that there is often reliance on trial staff and their experience to implement motivational strategies. It is difficult to imagine how we can replicate these important functions when trials move to decentralised, technology-facilitated models in which less human interaction is involved. When planning trials, we are not provided with actionable information other than using several different types of strategies, which is inefficient and difficult to justify for technology developers. Moving to the digital space will require a more measured and theory-driven approach to devising digital retention strategies.

Doing so can allow the implementation and measurement of individualized, tailored strategies for participants.

Intrinsic Participant Motivation

Many of the strategies reviewed focused on the operational and process approaches of sites; trial design; and contact, tracking, and data collection methods. All are interdependent elements for an organized trial experience for participants and are essential to ensure as seamless an experience as possible for the participant. Nevertheless, they do not contribute directly to participants' intrinsic motivation or fit into the SDT model for motivation. We found a small sample of intrinsic motivation examples, such as staff reminding participants of their motivators, including benefits of involvement, and reminding them of original drivers to partake in the trial. To create more motivational experiences for participants, we suggest a more strategic focus on the participants' personal motivators and delivering individually tailored strategies that emphasise these intrinsic motivators.

Data Reported

The data-reporting approaches presented in the reviewed papers were often represented differently in the different studies observed. There were various reporting approaches to calculating the retention figures, and the interpretation of overall retention differed from one study to another. Owing to various interpretations, the variety of approaches made it challenging to represent and compare data regarding retention across trials. As we progress, this variety of approaches may obscure the ability to compare data to identify and evaluate effective retention strategies based on successful retention results. Standardisation of reporting and a common approach to reporting retention results would be beneficial.

Implications for Designing Technology

Applying the SDT framework in the design and evaluation of digital strategies and using the insights identified and organized in this paper will aid in defining the targeted strategic

approaches. The insights and guidelines can be used for clinical trial participant technology design, offering a defined model to explain psychological approaches and provide actionable insights into digital retention strategies. This approach will aid the comprehension of the strategies, functions, features, and types of content that will assist improved engagement through technology experiences that support participant motivation by focusing on our digital experiences that concentrate on autonomy, relatedness, and competence. Using this approach and the clarity gained will allow us to advance patient digital retention strategies and create supportive conditions for improved methods for motivating participants. The methodology can enable us to recognize the strategies that might best serve to target the various psychological needs defined by the SDT to motivate and engage participants at multiple stages during their trial experience. The practice can clarify what kind of retention engagement we are trying to create and the reactions and types of motivation that might be elicited from each strategy. By using the SDT, it would provide designers with clarity and direction to tailor strategies that focus on the 3 basic psychological needs of participants defined by the SDT. Having clear goals regarding the variety of motivational retention strategies implemented will enable clear testing parameters to evaluate participants' feedback and assess behavioural goals and effects on participants' psychological needs for each strategy. Moreover, this will allow us to identify strategies that may not support the conditions needed for motivation. Our analysis can act as a source for implementing technology-based trial supports and behaviour-influencing digital strategies with clear motivational and behavioural goals for digital technology.

Limitations and Future Research

As with all qualitative analyses, the authors used their judgment when coding strategies by theme and subtheme, and we acknowledge that this approach allows room for error. Owing to our inclusion and exclusion criteria, this review featured strategies from quantitative papers with a threshold of ≥80% retention. This approach could have potentially omitted several

strategies that may have benefited the review. The search approach used a limited number of keywords and omitted MeSH (Medical Subject Headings) terms because of the specific topic of interest, and this may have reduced the number of records extracted. The framework proposed by Arksey and O'Malley (2005) was followed, but hand searching was not performed during the systematic review, as it was not considered essential to review every retention strategy. Our aim was to reveal the patterns of patient retention strategies more broadly. Future research will present opportunities for both academia and practice. The use of the SDT as a part of strategic interventions should be examined in future work, as we attempt to support both participants' experiences and practitioners' attempts to develop more engaging digital experiences. Opportunities are also presented to conduct research on digital engagement strategies that could create conditions for relatedness interventions to aid retention during trials.

Conclusions

As technology advances, strategies and approaches used in digital tools for direct patient engagement will need to become more precise and more user centred to bridge the gap in retaining the 30% of patients who withdraw from trials. Retaining participants is a multifaceted phenomenon, with various personal, emotional, health, environmental, cultural, design, and contextual factors affecting retention during the trial process. The diversity of motives as to why a participant might join or drop out of a trial highlights the complexity of retaining patients in trials and the need to address participant motivation during the trial process. To develop the science of clinical trial retention in the context of digital technology, it is vital to improve research designs and methodologies centred on the digital space. This review underscores the importance of studying participant retention strategies through a theory of motivation. It enabled us to gain clarity on the previous retention strategic approaches used and define those strategies in terms of participant motivation. The research allowed us to identify strategies that fit into a motivational model and offer direction for designers. This examination is an early

step in using the SDT framework to guide digital technology design and strategies for enhancing participant motivation during trials.

Conflicts of Interest: This project received funding from Novartis Pharmaceutical company to partially support the first author's PhD studies. The first author is currently employed by Thread Research, a technology organisation in the clinical trial space that may be affected by the research reported in the enclosed paper. I have disclosed those interests fully to the Journal of Medical Internet Research, and my academic institution has an approved plan for managing any potential conflicts arising from this arrangement.

Abbreviations:

DCT: Decentralised Clinical Trials

SDT: Self-Determination Theory

Multimedia Appendix of Supplementary Files:

Multimedia Appendix 1: Database-specific search strategy material and search terms.

Multimedia Appendix 2: Search result articles and specific exclusion rationale.

Multimedia Appendix 3: Extracted segregated data by theme and sub theme.

Multimedia Appendix 4: List of main themes and sub-themes describing types of strategies observed.

All files are available in the Supplementary Material repository (see Appendices).

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Reflections on Chapter 3

This paper allowed me to explore patient retention strategies in clinical trials and understand the mechanisms that keep participants engaged. I decided to map the literature to identify approaches used in traditional trials, aiming to understand how engagement and retention operate at a site level, a key challenge in clinical trials. Given the central role of motivation in supporting engagement and retention, and the importance of theory in guiding HCI analysis, I chose self-determination theory (SDT) as an analytical lens. Applying SDT helped me interpret strategies in terms of intrinsic motivation, rather than focusing solely on procedural aspects, which is not commonly reflected in the design of technologies used in clinical trials. At this stage I was interested in exploring how digital tools could be designed to support engagement, while recognising that the mechanisms sustaining participant retention in conventional trials might not transfer directly. This work established a theoretical foundation to guide subsequent research on decentralised trials, highlighting where technology might support, or fail to replicate, relational and motivational mechanisms central to participant experience.

Conducting the scoping review required learning to apply SDT systematically across diverse retention strategies. Categorising strategies that did not fit neatly into SDT constructs highlighted the need for flexibility in theory and coding. Early in the process, I was tentative, often pausing and relying on my supervisor for reassurance. Later, I recognised that my initial thinking around coding was quite rigid, assuming there was a single "correct" way that could not be challenged. Reflecting on this helped me adopt a more open and iterative approach, considering alternative interpretations and allowing my thinking to be more flexible. These experiences strengthened my understanding of the scoping review method and how theory can structure and make sense of complex information.

Applying SDT revealed that retention and engagement strategies in clinical trials are reliant on and sustained more by human interaction and relational factors than solely by

procedural or financial incentives. This challenged my early assumptions that digital tools could fully replicate human engagement and emphasised the centrality of intrinsic motivation for retention. The process clarified how relatedness, competence, and autonomy shape participant experience and prompted me to consider how these constructs could guide the design of patient-facing technology. It also highlighted the limits of SDT, showing that the theory is broad and that contextual nuances are important, suggesting that additional frameworks or complementary approaches might be needed. Overall, this theoretical grounding transformed observed practices into structured insights that could bridge research and design, providing guidance for thinking about retention in both conventional and decentralised trials.

Reflecting on this paper highlighted the centrality of relational needs as motivational mechanisms in clinical trial retention. While these mechanisms are well established in traditional trials, decentralised trials present a particular challenge: supporting relational activities may be more difficult when interactions are remote and mediated by technology, with potential consequences for retention and engagement. This raises the question of how these mechanisms are experienced in practice by both clinicians and participants in DCTs. This reflection also clarified directions for future research and identified critical areas to explore in decentralised clinical trials, shaping my thinking about the next stages of the thesis without pre-empting the studies themselves.

Through this study, I was trying to understand how retention strategies operated in practice and how digital tools might be designed to support them. Working through the review challenged my initial simplicity and highlighted the sophistication and complexity of the behavioural science underpinning these strategies, showing that engagement and retention are shaped by multiple, interacting psychological and motivational mechanisms. It also prompted

me to question whether current approaches at research sites fully account for participants' experiences.

The study highlighted the rudimentary nature of some existing strategies and the need to consider both relational and motivational mechanisms when designing technology interventions. This process strengthened my ability to think critically about how theory, particularly SDT, can be interpreted and applied in practice. Overall, the study provided practical insights that informed the questions I would explore in subsequent research, especially around understanding how engagement is maintained when participants interact primarily through digital tools rather than in-person support.

Chapter 4: Adaptation of Clinical Research Staff to Decentralised Clinical Trials and Impacts on the Patient-Centred Experience: Qualitative Interview Study

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Author Contributions: EG and CL conceived the study. EG, CL, and CH contributed to protocol development and obtained ethics approval. EG researched literature, recruited participants, and conducted data analysis with review from CL and CH. EG wrote the first and subsequent drafts of the manuscript. All authors reviewed and edited the manuscript and approved the final version

Abstract

Background: Industry stakeholders, academic experts, and regulatory bodies emphasise the importance of prioritising a patient-centred experience in clinical trials to enhance retention, adherence, and trial participation. Concurrently, there has been a notable rise in the adoption of technology-mediated decentralised methodologies for conducting clinical trials. Nonetheless, is a truly patient-centric approach being achieved? The shift to decentralised approaches risks prioritizing operational efficiency and remote data collection over the nuanced and diverse needs of participants. This raises critical questions about whether the

current implementation of decentralised clinical trials (DCTs) fully aligns with the principles of patient centredness.

Objective: Using a qualitative approach, our study aims to understand the perceptions of clinical research staff (CRS) of this transition and its impact on delivering a patient-centred experience.

Methods: A total of 15 CRS with experience of facilitating DCTs were interviewed, and transcripts were analysed.

Results: Our findings reveal 1 superordinate theme—the quality and frequency of interactions with patients and CRS are limited—and six main themes: (1) increasing demands of the CRS role, (2) creating difficulties for patients, (3) knowing the patient and understanding their experience, (4) impacts on forming and maintaining CRS-patient relationship, (5) difficulty in delivering desired level of support and care, and (6) perceived affects to conduct of a trial. While DCTs offer advantages in improving accessibility, they introduce new complexities that can negatively impact patient engagement, retention, and the CRS-patient relationship.

Conclusion: This study offers insights into the perspectives of CRS on delivering a patient-centred experience in DCTs. It highlights the benefits of DCTs alongside the challenges they present, emphasising the need for additional support, training, streamlined technology, and resources to help CRS adapt to evolving trial dynamics. To fully realize the patient-centred potential of DCTs, technology and trial designers must recognise the complex interplay of factors shaping the patient experience. This requires collaboration with CRS and patients to address the diverse needs of all stakeholders, prioritizing the broader aspects of the patient experience beyond at-home convenience and data collection.

Keywords: decentralised trials; decentralised clinical trial; DCT; remote trials; clinical research technology; site experience; patient centredness; patient experience; participant-centric trials; human centred

Introduction

Background

Clinical trials play a crucial role in testing new treatments and advancing medical knowledge (Sackett & Cook, 1994a) by evaluating specific interventions on human participants (Stanley, 2007), and they are traditionally conducted through in-person visits to health care sites (Bhide et al., 2018a). However, developments in the United States, such as the 21st Century Cures Act, demonstrate increasing legislative support for using technology for facilitating CRS-patient interactions in pharmaceutical research (Inan et al., 2020; U.S Food & Drug Administration, 2020). Clinical trials are undergoing a shift, with a growing emphasis on adopting technology-mediated approaches (de las Heras et al., 2022a; Hirsch et al., 2017a). Terms such as "decentralised" (Van Norman, 2021b), "remote" (Alemayehu et al., 2022a), "direct-to-participant," and "virtual studies" (Dorsey et al., 2020a) have emerged to describe this approach to trial design and execution. In addition to the fully remote approach, hybrid trials incorporate decentralised and site-based elements (Rogers et al., 2021). "Decentralised Clinical Trial" (DCT) has emerged as the unified term to describe this type of trial (Santa-Ana-Tellez et al., 2023a). For conceptual clarity, this paper uses "DCTs" to refer to these types of trials.

DCTs use digital technologies to facilitate remote patient participation in research as well as data collection and communication (Petrini et al., 2022). Data collection and assessments are now often carried out in participants' homes through technology (Moore et al., 2022), replacing traditional on-site data collection, minimising physical site attendance, and emphasising participant-technology interactions over interactions with site staff (Coyle et al.,

2022a). This includes integrating technologies such as smart devices, wearables, and sensors for data collection and processing (Izmailova et al., 2018). Electronic patient-reported outcomes are collected using mobile apps or web interfaces (Coons et al., 2015), while telehealth technology facilitates remote interactions, reducing or eliminating the need for in-person visits (Jong et al., 2022).

The concept of patient centredness has become paramount in drug development and clinical trials (Stergiopoulos et al., 2020), with patient-focused drug development receiving significant attention from governing bodies (U.S Food & Drug Administration, 2024). Patient centredness is defined as addressing the needs of the patient across all phases of a trial, including design, activation, enrolment, data collection, completion, and outcome reporting (Li et al., 2022a). This concept emphasises the patient's experience during a trial (Getz, 2015) and stresses that the trial design supports the needs and preferences of participants (Santa-Ana-Tellez et al., 2023a). Concepts such as person centredness (Slater, 2006) and patient centredness (Mead & Bower, 2000a) are directly linked to various components of the delivery of care that contribute to the patient's overall needs and experience. Key aspects such as different forms of patient well-being (Kuipers et al., 2019), satisfaction (Cowie, 2012), relationships (Zhao et al., 2016a), autonomy (Louw et al., 2017), support and organisational systems (McCormack et al., 2015), personalisation (Lewis, 2011), trust (Ferguson et al., 2013), and communication and education (Langberg et al., 2019a) are interconnected within the centredness definitions, contributing to a deeper understanding what constitutes a patient-centred experience.

Objectives

DCTs and patient-centred concepts converge because decentralised methods are increasingly viewed as supportive of patient centredness (Inan et al., 2020), contributing to a patient-centred experience (Jong et al., 2022) by aiming to reduce patient burden and enhance patient

experience (Dockendorf et al., 2021b). DCT technology vendors promote DCT methods and technology as patient first, human centred, built for patients, designed to meet the needs of the patient, and centred around patient needs. Nevertheless, trial participant attrition has reportedly been a common problem in remote studies (Daniore et al., 2022a), indicating that there is still work to be done to enhance the patient-centred experience in such trials. As the field progresses, there is an increasing demand for additional research to delve into stakeholders' perspectives on DCTs (Rogers et al., 2022). Further investigation has been recommended to explore the effects of decentralised methods on stakeholders' challenges and patient participation experiences (Coyle et al., 2022a; Suman et al., 2022a). Therefore, it is imperative to evaluate the effectiveness of current practices in achieving this goal. We used semi structured interviews to capture the perspectives of clinical research staff (CRS; principal investigators, study coordinators, and site nurses, i.e., individuals who play an integral role in the patient experience during a DCT) on the impact of DCTs regarding the experience of coordinating and carrying out trials and their impressions of how DCTs affect the patient experience. This research investigates challenges in supporting patients, maintaining the CRS-patient relationship, and fostering patient engagement during DCTs. It aims to enhance the understanding of the practical implications of the transition to DCTs from the perspective of CRS and identify how this shift impacts the delivery of a patient-centred experience.

Methods

Research Design

We undertook a qualitative study using semi structured interviews to understand the perceptions of CRS transitioning to decentralised technology-mediated methods for conducting trials and the impact of this shift on delivering a patient-centred experience. These interviews enabled CRS to share their perspectives (Hermanowicz, 2002a) and provide first-hand accounts (Riessman, 2008a). Reflexive thematic analysis, as outlined by Braun and Clarke (2021a), was

used to identify and organize meaningful patterns in the data, offering insights into participants' perspectives and the underlying themes.

Ethical Considerations

The study was approved by the social research ethics committee of University College Cork (2022-215) on January 20, 2023. Participation was voluntary, and upon recruitment, participants were provided with electronic information sheets and consent forms outlining the study's purpose and procedures. All participants provided written informed consent before engaging in this research. Personal details were anonymized, and sensitive data were removed from the transcripts. Participants were informed of their right to withdraw from the study at any time. No compensation was provided to the participants.

Data Collection

The research was conducted between February 1, 2023, and June 30, 2023. Interviews were conducted on the web via Microsoft Teams video call to accommodate participants' schedules and locations. Each interview was conducted by the first author and lasted approximately 1 hour. The interview guide was developed based on a review of the literature to address the research question (Multimedia Appendix 1). It featured questions drawn from the literature (Wolf & Jason, 2014a) and focused on the patient experience, the staff-patient relationship, and keeping patients engaged during a trial. The research team engaged in discussions to refine and enhance the interview guide. The interviews followed a conversational approach, mixing open-ended (DiCicco-Bloom & Crabtree, 2006a) and follow-up probe questions (Kvale & Brinkmann, 2009a), with interviewees given the opportunity to elaborate on their experiences through prompts or follow-up questions to explore themes in greater depth, ensuring detailed accounts relevant to the research question. All interviews were recorded and transcribed using Microsoft Teams and checked for accuracy by the first author. After completing 15 interviews, we concluded that we had sufficient data to address our research question.

Data Analysis

We followed the 6-phase reflexive thematic analysis process outlined by Braun and Clarke (2021a). The first author independently coded the data, identifying relevant codes and themes that aligned with the research question. Collaborative discussions were held with co-authors to refine the codes and themes, leading to consensus on the final interpretations. The first phase involved familiarization with the data through transcription, listening to recorded interviews, reading and rereading the transcripts, and noting initial ideas. During phase 2, initial codes were generated by systematically working through the data to identify meaningful patterns related to the research question. Reflection and refinement ensured that the codes were accurate and representative of the data and aligned with the research question. Phase 3 involved organizing the codes into potential broader themes. Further refinement ensured that the themes were clear, specific, and accurately represented the data. Phase 4 entailed reviewing, refining, and evaluating the themes to ensure that they were logically related to each other and aligned with the data. Collaborative discussions supported the identification of overarching themes, subthemes, and 1 superordinate theme that encompassed 3 themes. Phase 5 consisted of continued analysis, culminating in the final refinement of themes, with clear definitions and names assigned to each theme. Phase 6 focused on producing the analysis, with each theme supported by detailed descriptions and quotes, ensuring that the findings were grounded in the participants' accounts. Examples illustrating key phases of the data analysis process are provided in Multimedia Appendix 2 (Braun & Clarke, 2021a).

Participants

Table 1 presents an overview of the interviewees recruited for their professional expertise in remote, hybrid, decentralised trial formats and outlines their years of experience conducting clinical trials (Knoke, 1993). The participants' work included studies sponsored by commercial parties as well as those that were investigator initiated. Participants were recruited from varied sites and roles across different Western countries to ensure that a range of experiences were

captured. Each of the trial staff had previously conducted some form of remote trial, directly interacted with patients, and used a range of technologies, including patient apps and diaries, patient monitors, and telehealth. Participants were recruited initially through an established professional network, which proved instrumental in facilitating introductions to clinical research professionals with experience in DCTs. These initial connections facilitated a snowball recruitment approach, where participants referred us to colleagues within their own networks, providing access to professionals with relevant expertise and perspectives on DCTs.

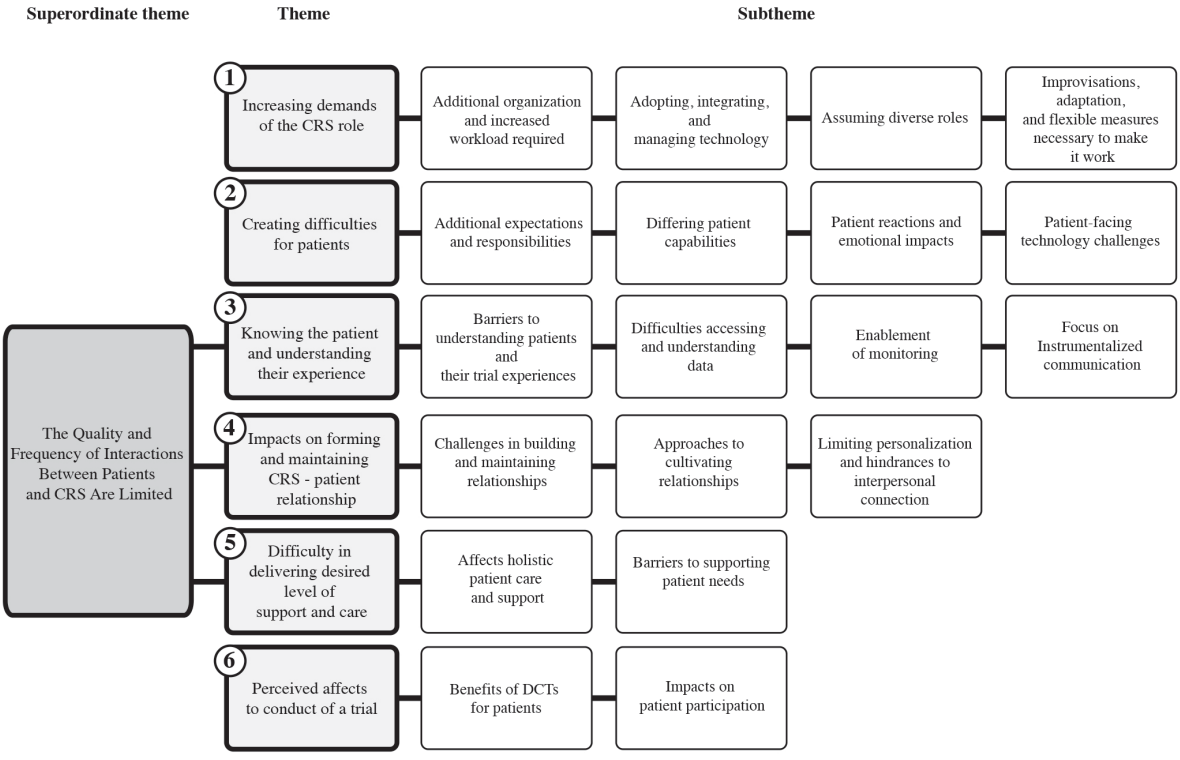
Table 1. An overview of the participants interviewed in the study.

Role	ID	Facility	Experience (y)	Location
Senior research nurse	SRN1	Research centre	20	Ireland
Principal investigator	PI1	Research centre	20	USA
Senior research nurse	SRN2	University hospital research centre	5	Ireland
Clinical research coordinator	CRC1	Research centre	13	Spain
Clinical research coordinator	CRC2	Research centre	12	USA
Clinical research coordinator	CRC3	Research centre	4	USA
Clinical research nurse	CRN1	University hospital research centre	3	Ireland
Clinical research coordinator	CRC4	Research centre	3	USA
Principal investigator	PI2	Research centre	25	Belgium
Principal investigator	PI3	Academic medical centre	15	USA
Clinical research coordinator	CRC5	Research centre	4	USA
Clinical research coordinator	CRC6	Research centre	3	USA
Clinical research coordinator	CRC7	Research centre	5	Canada
Study coordinator	SC1	Research centre	3	Canada
Research assistant	RA1	Research centre	3	USA

Results

Our findings were structured around six themes (themes 3 to 5 are placed within a superordinate theme that identifies how the quality and frequency of interactions between patients and CRS are limited in DCTs): (1) increasing demands of the CRS role, (2) creating difficulties for patients, (3) knowing the patient and understanding their experience, (4) impacts on forming and maintaining CRS-patient relationship, (5) difficulty in delivering desired level of support and care, and (6) perceived affects to conduct of a trial. Each theme has several subthemes, as illustrated in Figure 1.

Figure 1. Key themes and subthemes identified in the study. CRS: clinical research staff; DCT: decentralised clinical trial.



Theme 1: Increasing Demands of the CRS Role

This theme reveals the increased demands placed on CRS due to the nature of DCTs. It highlights an increased need for organisation and workload management. When discussing

their roles, participants highlighted the expanding scope of responsibilities, requiring them to assume diverse roles and implement improvisations, adaptations, and flexible measures to effectively support patients.

Additional Organisation and Increased Workload Required

CRS noted that remote trials create new tasks and require additional effort compared to face-to-face trials. Impacts include the need to work overtime and deal with late-night calls to address patient-facing technology issues, at times disrupting staff work-life balance:

> *There have been evenings where my day's supposed to be 8 to 5 and I have a call at 9-10 o'clock at night with the patient because their diaries aren't working and it is important for them to do it to start the study drug the next day and they literally cannot, and it is very impactful for us, because we try to have that healthy work-life boundary.* [SC1]

Participants highlighted the need for heightened organisation for successful DCT implementation. Increased efforts are needed during initial visits, involving addressing scheduling issues, aligning site visit resources, coordinating patient contact, and managing appointments. Sustaining communication with remote patients necessitates extensive follow-up and relies on CRS organizing frequent communication via telephone, SMS text message, and email. During a DCT, providing general patient support requires CRS to make a more conscious effort, with challenges particularly evident when supporting older participants who require additional assistance adapting to the technology. Furthermore, there is a need for the trial staff to supplement the technology experience with human interaction to bridge the technology and remote gap:

> *We try and educate them here as best we can, and sometimes we could be two or three hours going over the same thing.* [CRN1]

Assuming Diverse Roles

A notable shift has occurred in the trial staff's role, which now includes training patients on technology and providing comprehensive device instructions. The evolved role involves offering technology support as well as follow-up support for seamless technology use. CRS also serve as the primary point of contact for addressing patient issues within the trial setting. Patients directly contact CRS rather than relying on trial support services, and CRS act as an intermediary between patients, sponsors, and trial technology vendors. This expanded responsibility includes addressing technology support, device-related issues, software challenges, and telephone and password problems:

> *I think clinical trials are changing and adapting to technology and so that's kind of changed our role in clinical trials and following up with patients and doing phone calls and texting and emails, that's just part of being a study coordinator now and it can be like very scattered braining for coordinators*. [CRC6]

Adopting, Integrating, and Managing Technology

Participants emphasised the need for additional technical skills to support patients when conducting a DCT. CRS point to an increased workload, exacerbated by the trial technology's manual and laborious nature; the lack of standardization; and the need to engage with diverse, complex technologies used across the trial portfolios:

> *So, we have to be very versatile, and we have to know all these systems because these vendors don't provide us with all that information*. [PI2]

CRS highlighted the difficulties of misalignment between technology vendors, sponsors, and the practical needs of the trial site. They stressed the importance of vendors being aware of site-specific challenges and integrating site feedback to effectively address technological issues. Furthermore, some CRS felt that technology solutions emphasised administrative

processes that overlook the perspectives and needs of both sites and patients, hindering trial efficacy.

Improvisations, Adaptation, and Flexible Measures Necessary to Make It Work

CRS discussed the importance of an adaptive and improvised problem-solving approach to ensure the smooth operation of DCTs. Their approach included proactive engagement with patients beyond established trial protocols, such as unscheduled calls, check-ins, tailored email support, and providing handwritten instructions on device use. In addition, CRS described using patient diary entries and data proactively to initiate meaningful conversations in remote interactions. They highlighted flexibility and adaptability as crucial, noting the need to adjust protocol expectations, provide additional telephone support, and schedule remote visits based on patient availability. CRS indicated that they had to rely on instinct and intuition, drawing upon their professional background and experience in their approach to patients. They felt that the limitations of technology meant that they had to develop an awareness of patient patterns and trial-related behaviours.

> *I'd say it's mostly my personal approach. Every coordinator works their trials in a different way. I've been in research for a few years now, and so I've kind of developed that on my own...I think instincts is a good word. It is challenging. You never know. Officially, I use my background and research to kind of gauge when I may need to reach out to patients.* [CRC5]

CRS indicated that, at times, they needed to use workarounds to overcome the challenges of the provided technologies, remote interactions, and DCT limitations, including patient literacy and connectivity complications. They would circumvent the help desk by directly addressing patient needs, acting as intermediaries, and assuming help desk responsibilities, all to ensure continued patient trial participation:

I tried to be as savvy as I can about all the technology that I can be the help desk. I'm not being paid for it, the help desk are being paid for it, the help desk should be doing it. But I don't want to put that burden on a patient saying you know, wait and call the help desk. And they don't have a help desk in the local language, and they have to wait for translator and it's taking away time from them, which might mean that they will back out. I know that. [PI2]

Theme 1 Discussion

Remote tools and methods can improve trial efficiency and reduce burdens (Hanley et al., 2023a). However, our findings echo those of Coyle et al (2022a), highlighting the extra burden on trial staff when using DCT technologies. Our study underscores how the introduction of DCTs has heightened demands on CRS, necessitating additional responsibilities, burdens, and organisational efforts. Our research further underscores how CRS grapple with burdens throughout trials, similar to findings from Rogers et al (2022), who identified the challenges that CRS face in providing technical support to patients during DCTs. Our study outlines how CRS roles are evolving in response to DCTs, necessitating the acquisition of additional skills to ensure trial success and effectively support patients. CRS face new challenges and must adapt to the technology focus and remote nature of these trials, at times assuming roles for which they may not be formally qualified. Rogers et al (2022), who reviewed how CRS face challenges in learning to manage trials using new technologies (Inan et al., 2020), suggest that trial site teams may not have the skills to support digital clinical trials. Our findings suggest that CRS are adjusting to the demands of DCTs, a process that requires additional time and effort to ensure trial success. CRS demonstrate adaptability and resourcefulness in response to inadequate existing structures, using workarounds and instinctive strategies. Our findings indicate that DCTs do not fully cater to CRS needs during the trial and may restrict their ability to perform their roles as they envision them. However, these necessary adaptations may bring

about negative consequences and disrupt workflows, have unintended side effects, change trial approaches, and lead to potential adverse impacts.

Theme 2: Creating Difficulties for Patients

Theme 2 focuses on CRS perceptions of the challenges encountered by patients participating in DCTs. This theme discusses the additional expectations placed on DCT participants, their varying capabilities, the emotional impact of being part of a DCT, technology challenges, and the multifaceted nature of challenges within the decentralised setting.

Additional Expectations and Responsibilities

CRS discussed the growing expectation that patients will assume more responsibilities in DCTs compared to traditional trials. Participants discussed how patients are expected to undertake tasks such as frequent diary entries, which can become overwhelming. Patients are expected to manage trial-related technology tools, with technology vendors assuming that patients have a comprehensive understanding of the technical hardware and software:

> *To just give them a little bit of information and give them a little bit of training like, hey, this is on you, now we'll just check on you every now and then. That's very much like we just push you out there to the wolves and we're going to just let you sink or swim. Even though that's not the case. But that's how they may feel and that's how it feels to us as well.* [CRC3]

Differing Patient Capabilities

CRS noted challenges in supporting patients from specific demographic groups, particularly regarding their varying comfort levels with technology. They observed a lack of familiarity and technological literacy challenges, especially among older participants, which posed barriers during a DCT. The disparity between technology solutions and patients' technical proficiency impacted their ability to operate devices and participate effectively in DCTs:

> *Some of our patients have a lot of difficulties using technology. It's insane. The challenges that they face. And I have been on the phone with one person for around 45 minutes trying to walk that person through how to get back into that application on their study device because they had no idea what they were looking at…it's challenging for them, and they don't understand how to use it.* [RA1]

Patient Reactions and Emotional Impacts

Participants described the emotional impacts on patients due to the decentralised and technology-mediated nature of DCTs. Frustration with these trials influences the overall patient trial experience and can even lead to withdrawal of consent. CRS observed that patients, particularly older adults who face heightened demands due to the nature of DCTs, experience emotional strain, leading to feelings of being overwhelmed, diminished confidence, anxiety, and increased stress:

> *We have had patients, if they become frustrated with their piece of technology, specifically the example that comes to mind is an electronic diary like patient-reported outcomes. If they do become frustrated with that, for whatever reason, if they have technical issues that they have to contact support a lot or have to contact the site a lot, they withdraw consent.* [CRC2]

CRS noted that the nature of DCTs could undermine the development of trust with patients. The limitations of, and the absence of interpersonal interactions in, technology-mediated communication can hinder the trust-building process between CRS and patients, contrasting with on-site trial experiences. Consequently, patients may feel more like trial subjects than individuals receiving personalised care. CRS highlighted how some patients had indicated that they preferred conventional trial methods, which exacerbates the challenges faced by trial sites:

> *You wouldn't have the same level of trust as, say, patients that are coming on site, because obviously they don't build or develop a relationship with the research nurse and the same with the doctor*. [SRN1]

Conversely, some CRS highlighted how DCT experiences with more comprehensive remote monitoring technologies can reassure patients, positively impacting their well-being during the trial. Patient perception and awareness of efficient trial staff monitoring provide reassurance. Regular informed data reviews with CRS can also reassure patients, boosting their confidence and trust in the CRS and technology used as part of a DCT:

> *But with the patients with the digital devices, they know they're being watched every day. They know they're being monitored every day. So, they have this assurance that they feel confident that they're okay. There's somebody watching them, someone looking out for them...I think primarily, the patient feels looked after and has great reassurance of being monitored*. [SRN2]

Patient-Facing Technology Challenges

CRS discussed the challenges that patients face with trial technology, which make the DCT process harder. These include difficulties with device use, connectivity problems, malfunctions, usability concerns, and Wi-Fi–related issues, leading to increased burdens and hindrances for patients and CRS during the trial experience:

> *I have a patient that we did so much calling back and forth and emailing back and forth over weeks with IT before the resolution was that she just had to drive into town every day. Twice a day to do her diaries to be compliant*. [SC1]

> *It's the layout on the screen and the buttons themselves that have been a slight problem as well…it doesn't always transform from a desktop to a mobile screen properly, which also is a huge confusion for patients*. [CRC7]

Theme 2 Discussion

Advocates for DCT tools and techniques emphasise their potential to alleviate patient burden in trials (Hanley et al., 2023a); for example, Dorsey et al (2015a) suggest that data collection becomes passive for patients using DCT technologies. These technologies can also allow CRS to monitor patients' symptoms and provide informed feedback, which can reassure patients. However, similar to Cummins et al (2023), our study suggests that DCTs impose additional expectations and responsibilities on participants. Previously, Moser et al (2000a) suggested that personal, emotional, and psychosocial factors significantly influence patient attrition in clinical trials. Trust is a pivotal component of both person-centred care (Wolf et al., 2017) and patient-centred care (Ferguson et al., 2013). It facilitates patient participation in research (Mainous, 2006) and enhances retention (Chhatre et al., 2018; Coyle et al., 2022a; Natale et al., 2021a). Our findings highlight several adverse emotional impacts observed in patients during DCTs, including feeling overwhelmed and frustrated, with a notable impact on patient trust. Our findings challenge the suggestions that DCTs reduce patient burden and promote a patient-centred experience and indicate the potential for negatively impacting patient retention.

Superordinate Theme: The Quality and Frequency of Interactions Between Patients and CRS Are Limited

We identified an overarching superordinate theme (Figure 1) based on consistent observations made by CRS. The limited quality and frequency of interactions between patients and CRS, stemming from the remote, technology-mediated nature of DCTs, emerged as a central organizing concept in our analysis. This limitation impacts several important components of patient-CRS interactions, serving as a primary obstacle to effective patient management, support, understanding, and care. Three main themes were identified within this superordinate theme, and these are outlined in the following subsections.

Theme 3: Knowing the Patient and Understanding Their Experience

Theme 3 discusses how carrying out a trial in a remote or decentralised manner has implications for how CRS understand patients and their experiences. Our data highlight the efforts needed to overcome barriers to comprehending patient experiences, accessing relevant data, enabling effective monitoring, and the instrumentalising of communication.

Barriers to Understanding Patients and Their Trial Experiences

CRS noted that the lack of direct patient oversight in DCTs limits their ability to monitor and understand patients and their experiences throughout the trial. The constraints imposed by DCTs contribute to challenges in understanding the patient's experiences beyond protocol adherence as well as hinder timely assistance and support. Unlike on-site interactions, DCTs provide fewer insights into patient experiences, and CRS face challenges in monitoring medication adherence, which they perceive may be carried out more effectively during traditional, in-person visits:

> *It's very difficult, to be honest, you don't have the same visibility of how compliant a patient is either. It's not only around compliance with the study, if they were taking medication or that kind of thing, it's easier for them to come into clinic to have oversight of that as well.* [SRN1]

Remote interactions in DCTs present challenges in obtaining important patient information and understanding. Prompts from the patient are needed to understand when they are having issues. The absence of informal dialogues and in-person interactions hinders CRS awareness of pertinent patient details, affecting the evaluation of patient conditions and the timely recognition of changes in patient conditions:

> *You're able to pay attention to the little things in a patient when they come into the office. They may seem a little bit more tired than the last time you saw, or you may*

> *notice that their skin may look different, or their veins when you normally you blood draw that their veins don't look the same as they did, you know. So you pay attention to the very little things that can possibly save a patient's life.* [CRC3]

CRS depend on patient questionnaires to identify issues and comprehend patient needs. However, the types of data collected compromise CRS awareness of patient conditions and hinder informed discussions, evaluations, and individualized feedback, posing challenges in tailoring support. The limitations in technology-driven reports diverge from traditional trial site insights, impacting the depth of support provided. The remote and technological nature of DCTs delays CRS recognition of patient needs and hinders the delivery of comprehensive support. CRS also encounter challenges determining when to initiate patient contact and providing timely support beyond trial protocol expectations and data collection requirements. Establishing communication with remote patients is challenging and complicates the trial staff's role, leading to additional stress. It requires concerted efforts to connect and coordinate schedules between CRS and patients, and it is common for patients to be unresponsive to calls or messages.

Difficulties Accessing and Understanding Data

The participants highlighted the complexity involved in analysing, identifying, and understanding the collected trial data, which made related tasks laborious. Limitations in technologies for data observation and analysis in DCTs can lead to delayed issue detection, burdensome data processes, and insufficient reports or insights to support patients. Some CRS reported relying on informal methods, such as using Microsoft Excel, to analyse patient data and identify changes or symptom patterns. They also noted a time lag in patient compliance awareness and challenges in acquiring real-time data:

> *Every vendor portal is very different, for some of them you literally have to click into every single diary to see that data and then go back and refilter. And it's a very*

cumbersome process. Even to get a week's worth of data, especially when you're looking at multiple and different results from patients, there's no easy way to export that data. [SC1]

Enablement of Monitoring

CRS praised the advancements in DCT technology for enabling remote patient monitoring, including tracking patient progress, medication adherence, and symptoms. This capability empowers CRS to identify concerns and manage patients. In addition, technology centralizes data and documentation, streamlining access and facilitating longitudinal comparisons of patient information. Furthermore, some technologies enhance staff-patient interaction by providing insights into patient patterns, thereby informing and enabling more effective communication. Notifications enable timely interventions, and data readings enable analysis, both ensuring patient safety and well-being through remote monitoring:

The person you're ringing can see your blood pressure, can see your oxygen level, can see your weight, can see pulmonary artery pressure. So when they tell you, No. You know your blood pressure is okay. Your weight is okay. You're basing it on fact, and they know you can see it, so that's it. They've confident in what you say, and they're reassured by what you say. [SRN2]

Focus on Instrumentalised Communication

CRS highlighted that patient contact in a DCT is primarily prompted by formal problems, such as compliance concerns, irregular diary entries, and compliance or data discrepancies, which then necessitate site follow-up. Our data highlighted how remote visits focus solely on a business-only and data collection approach. Structured assessments during remote visits, centred around specific questions, reinforce this formal, data-centric dynamic, resulting in a lack of casual conversation and personal connection opportunities and restricting the interpersonal relationship between CRS and patients:

You know, you talk about business, and you get through what you need to get through and then the visit is usually terminated...Usually the visit concludes at that point as opposed to an ongoing banter back and forth about whatever. [PI1]

But when you're on the phone, you have exact questions that you're going to ask them. There really isn't any time for chitchat. [CRC6]

Theme 3 Discussion

Research has shown that effective patient care depends on the trial staffs' ability to understand and respond to individual experiences (Weston et al., 1989a). Fogel (2018) outlined the significance of the trial staff's ability to maintain awareness of participants' feelings throughout the trial process. Our research suggests that DCTs pose barriers for CRS in understanding patients and their trial experiences, stemming from the absence of direct patient oversight and the constraints of technology-based interactions. These limitations hamper the trial staff's ability to fully understand the patient's needs. The crucial role of CRS in supporting patients' experiences and the gap in understanding patients' experiences in DCTs leads to a disparity in effectively supporting patients throughout such trials. CRS discussed how DCTs necessitate a business-oriented, data collection approach during remote patient interactions, particularly during communication driven by trial protocols. They noted how a lack of patient compliance is the primary trigger for reaching out to patients outside of established protocols. These instrumentalised communication approaches may diminish their sense of autonomy, and this depersonalisation can adversely affect patient satisfaction, motivation, trust, patient outcomes, and participation. It is important to note that our study emphasised how some DCT technologies can facilitate enhanced patient monitoring. These findings resonate with those of Coravos et al (2019), showcasing how DCT technologies enable real-time symptom alerts (Aiyegbusi et al., 2023a; Sommer et al., 2018a) and provide pertinent patient data and information on study activities.

Theme 4: Impacts on Forming and Maintaining CRS-Patient Relationship

Theme 4 discusses the impacts of DCTs on forming and maintaining CRS-patient relationships. It examines the dynamics surrounding these relationships during DCTs, addressing challenges in connection building, developing interpersonal bonds, and the various ways in which these relationships are cultivated.

Challenges in Building and Maintaining Relationships

Several challenges were identified in building and maintaining relationships, including limitations in developing connections with patients due to the remote nature of DCTs. CRS highlighted that the absence of face-to-face interactions at trial sites poses hurdles in establishing meaningful connections. Unlike traditional on-site trials, DCTs present more significant challenges due to limited interactions, removing opportunities for creating positive rapport and impeding the formation of the typical bonds developed during on-site trials. Participants also discussed issues with DCT technology functionality, pointing to a lack of dedicated mechanisms to support the interpersonal dynamic between the trial staff and the patient:

> *My biggest challenge is just being able to form that relationship and letting the patient know, making them feel comfortable enough to talk to us as often as they would need to and to be open with us*. [CRC5]

Approaches to Cultivating Relationships

CRS noted that jointly navigating technology challenges with patients fostered camaraderie through increased interaction during remote technological issues. Increased interaction with patients during their health challenges allows CRS to provide assistance, strengthening the CRS-patient relationship. Furthermore, trial data and readings collected using patient-facing technology provide CRS with patient insights and serve as a focal component, contributing to personalised insights and calls and, in turn, supporting relationship development. Relationships

are further enhanced by personalising patient information, proactively providing tailored support notes, engaging in conversations about personal matters, staggering interactions, and showing genuine interest:

> *You'd have a bond with all the patients, but it would be stronger with the patients that would be in bigger trouble because the readings are gone off. But because you sort out that, and you either sort out their medication or get them into hospital. They trust you and therefore the bond it is stronger.* [SRN2]

Limiting Personalisation and Hindrances to Interpersonal Connection

CRS discussed how patient interactions and technology limited personalisation and hindered interpersonal connection, resulting in an impersonal and generic patient experience. They discussed various issues affecting the connection and bond with their patients, which could potentially lead to patient attrition. They highlighted the limited opportunities to build rapport, develop lasting connections, and enhance interactions, particularly due to the challenges of maintaining a connection remotely without past interactions or shared experiences with patients. By removing in-person engagement, DCTs and technology-driven experiences may leave patients feeling a lack of human care, fostering a perception of trials as cold and impersonal. Simultaneously, SMS text message and telephone interactions, prioritised for efficiency, may further diminish emotional understanding due to their brevity:

> *Ideally, we want to provide the best medical care possible, whether we're around or not, so we want patients to have a good experience with the technology. We want them to have a good experience with the medication that we're providing to them and with whatever telehealth visits that we are providing. But it is challenging because we don't have a chance to form that sort of bond that we would with our traditional patients that we see more often.* [CRC5]

CRS noted that DCTs can contribute to a sense of estrangement for both CRS and patients. Remote patients risk being reduced to numbers in the system, and CRS may overlook them due to on-site priorities, potentially leaving them feeling neglected. CRS also expressed concern about the absence of individualized attention for patients and the challenge of providing personalised care in remote trials:

> *Sometimes I've even caught myself doing it where I'm like, who even is this person that I have to contact today? Like, I don't even recognise their name because I could tell you about that person when they came into the site four months ago. But now they kind of just fade into a number in the system...I don't want to say dehumanizes, but it definitely takes away from that relationship when they go remote*. [RA1]

CRS discussed how questions arise regarding patient concerns for their data, utility, and overall contribution to the trial. Patients' perception of their data disappearing into a void and their limited understanding of where the data they provide go and how these data are used raises questions about the value and meaning of their participation, as does the limited positive feedback to patients through technology. CRS acknowledged the importance of on-site face-to-face interactions, which allow for direct communication, enabling them to assess patients' comfort levels, provide tailored support, build connections, and focus on their needs, fostering a humanized approach to care. Some technologies support CRS, and for those with access, video platforms help replicate the in-person experience, enabling the delivery of person-centred care remotely.

Theme 4 Discussion

The relationship between CRS and participants is crucial for fostering positive trial experiences (Gillies & Entwistle, 2012a). Similarly, the relationship between patients and their health care professionals is fundamental to the concept of patient-centred or person-centred care (Zhao et al., 2016a). Relationships are not merely psychological concepts; they are integral to human

motivation and self-determined behaviour (Deci & Ryan, 2012a) and serve as a cornerstone for retaining participants and sustaining their motivation throughout a trial (Gamble et al., 2023a). Mohr et al (1999) highlight the correlation between CRS fostering personalised relationships with patients and increased treatment adherence. Personalisation can enhance relatedness (Deci & Ryan, 2012). Fogel (2018) highlights the significance of personalising clinical trial interactions to support a successful trial's execution. Similarly, De Silva (2014) underscores the importance of personalisation as a critical component of the person-centred care concept. Our findings highlight how DCTs can negatively impact the formation of relationships and interpersonal connection between CRS and patients and restrict opportunities for personalisation and connection. DCTs face considerable hurdles in both motivating (Gamble et al., 2023a) and maintaining a patient-centred experience due to the indispensable role of human connection in care (Sharp et al., 2016) and staff traditionally enabling the patient experience (Wolf & Jason, 2014a). The challenges in relationships, interpersonal connections, and personalisation stem from technological limitations, remote constraints, and limited human connection. DCTs struggle to replicate the vital human element necessary for delivering patient-centred trial experiences. As a result, DCTs will face challenges in adherence as well as in effectively motivating, engaging, and retaining patients.

Theme 5: Difficulty in Delivering Desired Level of Support and Care

Theme 5 explores the challenges for CRS in delivering the desired support and care to their patients. This theme underscores the difficulties that CRS face in achieving their intended level of support, highlighting intricate and multifaceted challenges in addressing diverse and individualized patient needs.

Affects Holistic Patient Care and Support

CRS voiced concerns about the patient centricity of DCTs, noting a misalignment with patient-centred principles. Some believed that these trials prioritise data and project management over patient needs, hindering a patient-centred experience. The limitations of DCTs restrict the trial site's ability to support a patient-centred experience compared to traditional on-site approaches:

> *They don't get the patient-centric experience. They don't. That's what I'm trying to tell you. They don't. They're just a collecting tool for the industry that we are facilitating, and we have to explain that this is all very cool. Distant...Again, as I started this conversation, these things are set up from a data management and a project management point of view, never from a site or a patient's point of view...So we are calling it patient centric. But the device is literally shoved down my throat, and then they go, "Is it patient centric?"* [PI2]

CRS noted challenges in maintaining patient care in the DCT setting, which impacted clinical support and posed potential barriers to fulfilling care roles. Some CRS did not view DCTs and remote approaches as synonymous with patient care. Delivering care through short, remote calls using technology was considered challenging. CRS expressed uneasiness about perceived care levels, with concerns that patients might question the care provided in a DCT. On-site interactions were deemed more impactful for personalised, in-person engagements, contrasting with remote DCTs, which raised concerns about patient safety and the appropriate use of investigational products, requiring a delicate balance in maintaining patient interactions:

> *With the traditional setup, it's obviously a higher level of patient care because you're physically bringing the patient in.* [CRC2]

DCTs and remote settings hinder CRS from fully understanding and addressing patients' emotional and psychological well-being. Participants revealed challenges in offering emotional

support to patients and perceived that patients may interpret this as a lack of empathy, validation, and acknowledgment from the site, potentially straining empathetic connections:

> *It can come off as we don't care about the patient emotionally, the sponsor doesn't really care about the patient, doesn't care about them as an individual, they are just seeing them as our participant. And obviously that's not true. But when you don't put in those measures to effectively monitor someone's emotional state or even just ask them how they're doing. It can come off as extremely cold and just unfeeling.* [RA1]

Barriers to Supporting Patient Needs

CRS face various challenges in providing technical and troubleshooting support. Among these are inadequate site support capabilities for executing remote technical assistance, which make it difficult for CRS to guide patients remotely and lead to delays in resolving support issues:

> *So definitely trying to help someone remotely with technology is one of the most frustrating things I think I've ever faced because a lot of the times I can't see what that person is looking at. I log into my account on the sponsor's website, my view is completely different from a patient's view. So the patient might be looking at a home screen that looks completely different than mine and so I have to figure out, how do I get them to what I need them to get through when I can't even see what the heck they're seeing, whereas being physically on site I can see everything.* [RA1]

Inadequate help desk support presents challenges for patients, who experience poor response times to their issues, leading to frustration for both patients and CRS. As a result, CRS are often forced to take on help desk roles or refrain from using the help desk altogether. This results in a misalignment between the support provided and patient requirements. Some CRS also expressed frustration at being expected to perform technical support tasks for which they are not qualified. These inherent challenges contribute to trial staff frustration amid the myriad of issues they encounter:

> *Being an IT worker that I'm not qualified to be, trying to walk them through their technology, walk them through repairing things*. [RA1]

Our study highlights the challenges of a reactive trial staff support model in DCTs, in which patients typically initiate contact during challenging personal and technical situations. Some CRS described this model as reactive in nature, resulting in crisis management rather than proactive intervention. CRS identified challenges in comprehending and addressing patient support needs, often experiencing delays in recognising the intricacies of patient needs. Participants discussed challenges with timely communication and follow-up support mechanisms, compounded by limited patient availability and unresponsiveness. These factors delay patient communication and hinder the trial site's ability to provide timely support:

> *It's definitely harder to recognise when a patient needs support when we're doing remote interactions*. [CRC6]

Furthermore, CRS encounter challenges during onboarding and initially educating patients regarding trial requirements, particularly in ensuring their competence with technology, processes, and tools. Participants noted that the onboarding process can be challenging and time consuming, remote education further complicates support, and real-time assistance is lacking. Overall, CRS emphasised the effectiveness of on-site support, highlighting its advantages in providing comprehensive and interactive assistance to patients compared to remote methods.

Theme 5 Discussion

At the core of the patient-centred trial concept is the need to address each patient's individual needs (Santa-Ana-Tellez et al., 2023a). Research by Moser et al (2000a) highlights the importance of addressing patients' personal, emotional, and psychosocial aspects to enhance retention in clinical trials. Similarly, Ferrell et al (2019a) emphasise the critical role of compassion and nonphysical support for trial patients. Furthermore, Keshtkar et al (2024)

demonstrate that empathy enhances patient satisfaction with their care and contributes to favourable patient outcomes. Interconnected support components are crucial in DCTs to ensure successful troubleshooting, uphold data integrity (Apostolaros et al., 2020a), and maintain clinical support aligned with good clinical practice (Vijayananthan & Nawawi, 2008). In addition, fostering patient competence is essential for retention (Gamble et al., 2023a) and continued motivation (Deci & Ryan, 2012a). Johnson and Marsh (2023) highlight the challenges involved in supporting the practical trial needs of patients, and Polhemus et al (2019) support patients' technology needs. Our study supports these insights and outlines the challenges that CRS face in supporting patient needs within a DCT context, emphasising the limitations imposed by site capabilities and technology in offering adequate support in their absence.

Theme 6: Perceived Affects to Conduct of a Trial

Theme 6 uncovers the impacts of DCTs on trial conduct, exploring the dual nature of their benefits and challenges. It examines how DCTs influence crucial aspects such as patient retention, engagement, responsiveness, and compliance and highlights benefits such as ease of participation, convenience, flexibility, and patient empowerment.

Benefits of DCTs for Patients

Some CRS outlined several ways in which DCTs benefit patients, enhancing their overall experience. These included ease of participation and increased eligibility due to reduced barriers. By minimising logistical burdens, such as travel to clinic visits, DCTs help patients alleviate stress and avoid exposure to potential hospital-acquired infections. CRS perceived that patients appreciated being in the familiar environment of their homes, which is especially beneficial for those considered vulnerable, with family members and caregivers also experiencing reduced travel demands. In addition, some CRS viewed DCTs as enabling greater

participation and convenience, especially among younger patients who welcome the reduced need for on-site visits and tend to prefer digital diaries over paper diaries:

> *It improves eligibility because it eliminates a lot of the logistical barriers*. [PI3]

Moreover, some CRS perceived DCT technologies as empowering for patients, involving them directly in health monitoring and fostering control and understanding of their health through measurements and insights, instilling a sense of ownership in patients. Remote health monitoring enabled by certain DCT technologies allows CRS to collect factual and relevant patient data, which are then used to enhance the support they provide patients. Regular data reviews reassure patients and improve monitoring and support effectiveness. Some CRS felt that DCTs were seen to enable flexible and efficient trials, saving time through quick assessments, remote communication, and information sharing, while telehealth was viewed as effective for assessing patient concerns and reducing paper-based processes, thereby improving trial efficiency:

> *They have control, they have power, and where maybe traditionally you feel you have no power, that you go to doctor, he gives you tablets, but there might be no explanation. You don't know the mechanism of what's going on, where we go to pains to say why we're increasing tablets, why we're decreasing tablets, and you're able to show them the next time they're in, or if they're in hospital the next day, how the drug reacted and how their pressures came down. So they can physically see how things are working*. [SRN2]

Impacts on Patient Participation

CRS outlined the multifaceted impacts and challenges affecting patient trial participation. These include reduced patient comfort in opening up during conversations and a reluctance to share important health updates or concerns. Compliance with the trial protocol is impacted, with missed diary entries, for example, necessitating significant site efforts to re-engage

patients. CRS also noted compliance being affected by technology issues and slow site responsiveness. Furthermore, delays in accessing patient data affect CRS ability to identify noncompliance. Conversely, on-site care and monitoring can aid patient adherence to protocols. CRS perceived lower patient engagement, responsiveness, and commitment levels in DCT settings. The DCT approach may impact patients' understanding of study details and their willingness to participate in future trials because some patients decline trial involvement due to technological reluctance and their unfamiliarity with site staff. DCTs also impact accountability, responsibility, and patients' understanding of their roles, with obstacles such as forgetfulness and non-responsiveness further impacting participation. In addition, ongoing consent and retention may be affected, and challenges faced during DCTs could lead to higher dropout rates:

> *I know that if I didn't put that effort in, which isn't expected of us, that we would have noncompliance or patients dropping out or lost to follow-up because it's hard to work with*. [SC1]

Theme 6 Discussion

Minimising patient burden is crucial for retaining patients in trials (Natale et al., 2021a), and DCTs promise to reduce patient burden (de las Heras et al., 2022a). Logistical hurdles such as travel time and distance to trial sites pose significant barriers to patient participation (Adams et al., 2022a). DCTs address these challenges by offering convenience and flexibility (Apostolaros et al., 2020a; Izem et al., 2024a). Our research suggests that CRS perceive DCTs as providing enhanced ease of participation, reduced logistical burdens, time savings, and, in some cases, increased patient control over their health, findings that align with previous research. The benefits inherent in these measures give patients autonomy, allowing them flexibility, convenience, and empowerment, enabling them to exercise volition over their health and ownership of their trial experience. The importance of supporting autonomy cannot be

understated because patient autonomy is regarded as an ethical mandate in medical research (Owonikoko, 2013a) and a vital factor in sustaining motivation (Deci & Ryan, 2012a). However, our study also suggests that CRS perceive DCTs as having detrimental effects on the conduct of trials, affecting retention (Coday et al., 2005), accountability (Owonikoko, 2013a), and understanding of patients (Kearney et al., 2018a), all of which are crucial to successful clinical trial outcomes.

Discussion

We conducted 15 expert interviews and performed reflexive thematic analysis to explore CRS perspectives on executing DCTs. By focusing on CRS experiences and perceptions, we developed rich insights about the types and nature of additional tasks needed to make this type of trial work and how remote participation affects the CRS-patient dynamic and patient experiences. The findings highlight the heightened demands placed on CRS within DCTs. We offer several insights into the implications of transitioning to DCTs and their impact on clinical trial practices.

Implications for Trial CRS

Our data underscores the evolving working dynamics and conditions, increased demands, and an expansion of the CRS's role to include technology support. CRS must adjust to new ways of supporting, monitoring, and interacting with patients remotely. These changes necessitate additional expectations and require increased time and effort from CRS, mirroring challenges observed in other contexts (Herbsleb, 2016), when remote, technology-mediated approaches replace face-to-face interactions. The evolving technical expectations of CRS within DCTs may require a reimagining of their roles and necessitate formal adjustments to role expectations. Consequently, it is imperative to reassess and update training and professional development programmes to ensure that CRS are equipped with the necessary skills for navigating the technical challenges of DCTs (Inan et al., 2020). This re-evaluation underscores

the importance of enhanced training in remote communication and support, IT, and digital proficiency. These programmes can support successful practice in DCTs and prepare CRS for future DCT advancements. Our observations indicate that, despite retaining responsibility for patient care and trial delivery, CRS experience a loss of control and diminished ability to influence patient behaviour compared to traditional trials. This loss of control and influence hampers their ability to support patients and fulfil their roles to their desired standards. Our data show that CRS adapt to the challenges of conducting a DCT and find ways to make it work. This adaptability is crucial for maintaining patient engagement, upholding care standards, ensuring operational efficiency, and achieving trial success. However, as observed in other contexts (Poon et al., 2021), the integration of new technology-mediated approaches into established practices can have hidden or unintended consequences for CRS. These may include increased cognitive load, potential for errors, reduced job satisfaction, and burnout.

Implications for DCT Design

A concern highlighted with conducting clinical trials in a decentralised manner is the potential for negative impacts on critical factors essential to successful trial execution. CRS identified that patient engagement, responsiveness, commitment, retention (Coday et al., 2005), accountability (Owonikoko, 2013a), and compliance (Besch, 1995) may all be adversely affected within DCT contexts. If this is indeed the case, it necessitates strategic reconsiderations from a trial design and technology choice perspective. Our observations suggest that while DCTs offer the potential to overcome some challenges associated with traditional on-site clinical trials, such as improving accessibility and convenience (Rogers et al., 2022; Simmons et al., 2022) for patients, they introduce new complexities that CRS and patients must overcome, including challenges with support, communication, understanding patient experiences, and engagement, as well as technical complexities and the burdens and expectations placed on patients. Our research suggests that transitioning from traditional on-

site trials to DCTs requires rethinking the design of patient engagement practices. Approaches that are practical in traditional, in-person trials may not be suitable for DCTs. The CRS-patient relationship plays a pivotal role in patient-centred and person-centred paradigms (Gillies & Entwistle, 2012a; Zhao et al., 2016a) and is an important component in successful trials (Gamble et al., 2023a). Furthermore, CRS perceived that additional aspects such as personalisation (Lewis, 2011), trust (Ferguson et al., 2013), well-being (Kuipers et al., 2019), and satisfaction (Cowie, 2012) are also impacted. These elements are integral to a positive patient experience and play a significant role in achieving favourable outcomes. DCTs have the potential to significantly improve the access, inclusivity, and diversity of trial participants (Jong et al., 2022). Our observations reveal that DCTs offer an instrumentalised, mechanistic, and transactional experience for patients, which, based on the evidence, affects personal interactions and fosters a detachment from CRS. CRS discussed various challenges faced by patients, particularly older adults. These challenges may hinder the participation of certain groups and, in turn, exacerbate disparities in trial representation. When envisioning the future of DCTs and trial design, emphasis should be placed on prioritizing greater patient choice and flexibility to accommodate the crucial need for patient autonomy (Deci & Ryan, 2012a; Owonikoko, 2013a). We speculate that a more flexible and adaptive trial could be instrumental in addressing patient challenges related to competence issues, technological capabilities, accessibility factors, and the necessity for human connection, while also providing patients with choices to meet their individual needs.

Implications for Technology Design

Our observations indicate that there should be a careful consideration of both trial site and patient-facing technologies to better understand how they can address the challenges outlined in this paper. Our data suggest that current DCT technologies, which primarily focus on data collection, would benefit from focusing more on supporting the experience of patients.

Technology that supports an understanding of patients' experiences and creates conditions for personalisation (Lewis, 2011), trust (Ferguson et al., 2013), well-being (Kuipers et al., 2019), and CRS-patient relationships (Gillies & Entwistle, 2012a; Zhao et al., 2016a) would enhance the overall experience. Resolving patient issues, such as ease of use, accessibility, and reliability, can reduce barriers to acceptance and enhance adoption and use (Chammas et al., 2015). We suggest applying a theoretical and behavioural science–grounded approach to inform strategic directions for patient-facing technology, guide interventions, shape design, and define solutions tailored to meet patient psychological needs and supporting behaviours (Gillies & Entwistle, 2012a; Pagoto & Bennett, 2013a). Our results highlight the critical need to involve diverse stakeholders in future design processes to develop more comprehensive and inclusive technologies, with benefits in doing so (Nilsen et al., 2020). Stakeholders, including technology vendors, designers, behavioural scientists, regulatory bodies, patients, CRS, and pharmaceutical companies, must continue engaging with the complexity of the challenge. Leveraging our findings, designers can focus their efforts on addressing the issues outlined, ensuring that technological solutions align with both trial staff and patient needs and support optimal experiences and effective technological solutions for all concerned.

Limitations and Future Research

The shared themes and insights from our interviews are not intended to represent universal applicability. Rather, they provide a foundation for understanding and serve as a springboard for further research and discussion. This research focuses exclusively on the perspectives of trial staff involved in DCTs. While the analysis of CRS experiences and observations is valuable for providing insights into trial conduct, impacts, and perceived patient experiences, future research should incorporate the perspectives of patients, pharmaceutical companies, and technology vendors to provide a comprehensive view of DCTs. Technology is a key enabler of DCTs. However, these trials also depend on nontechnological elements, such as home health

visits and other patient-centric approaches, that support the model but were not addressed in this paper. Future research may offer promising opportunities for both academia and practice. We recommend expanding on stakeholder perspectives, particularly through a further investigation of how DCTs are experienced and perceived by patients. In addition, focusing on specific technological experiences may offer a better understanding of the perspectives surrounding these technologies. Moreover, future studies should explore integrating behavioural science into the DCT design approach to better support participants' experiences and practitioners' efforts to deliver more patient-centred trial experiences. Research should also investigate strategies to support CRS in DCTs, including tailored training programmes, help desk assistance, and support structures that address the unique challenges of remote trial environments. Finally, investigating lessons from successful technology adoption in health care could provide valuable insights into overcoming barriers and leveraging enablers for technology integration in DCTs, helping the clinical trial ecosystem adopt proven strategies for success.

Conclusions

First, we must acknowledge that one of the primary goals of clinical trials is to collect patient data while navigating complex challenges such as regulatory compliance, patient burden, study objectives, safety, scalability, protocols, and ethical considerations. Despite the many benefits of a remote approach, such as improved accessibility and data collection, DCTs have fundamentally altered trial dynamics for both patients and CRS. Approaches that work in traditional face-to-face trials may be less effective in the context of DCTs, leading to unique challenges. CRS play a crucial role as indispensable mediators, harmonizing the relationships between patients, support systems, and trial protocols. As workplaces evolve with increasing technological mediation, CRS face challenges that inevitably impact their working dynamics and, potentially, their performance. To adapt effectively to DCTs and the evolving trial

dynamics, CRS need adequate support and resources, such as enhanced training, effective change management strategies, and access to technology with a patient-centred focus. Furthermore, technology platforms that streamline administrative burdens, tasks, and workflows, while offering actionable insights, can enable CRS to provide more robust patient care and manage trials more efficiently. Despite DCTs being promoted as a patient-centred approach to trials, our research suggests that significant progress is still needed to realize this vision. The focus on patient-facing technologies designed solely for data collection, which is understandably vital for clinical trials, and the shift toward remote, less frequent, and more limited CRS-patient interactions introduce new challenges for the overall patient trial experience. Relying on CRS to support the patient experience without adequately understanding each patient's unique needs undermines their ability to fulfil this role. While DCTs and the technology solutions used show promise, they often fail to support key aspects of a patient-centred trial experience, potentially even detracting from it. A patient-centred experience extends beyond convenience and reduced travel, encompassing a complex interplay of personal, emotional, health, environmental, cultural, design, and contextual factors. Refocusing DCTs and how technology enhances these trials is necessary to support patients' diverse and personalised needs with clear evidence of benefits. Prioritizing conditions and technologies that enhance the patient experience in DCTs while maintaining rigorous data collection standards can create a more balanced and effective approach to DCTs, ultimately benefiting both patients and CRS. This focus on both patient experience and trial staff support would further enhance the success of DCTs. Theoretically, DCTs are not merely a logistical innovation but a transformation of the traditional paradigms of clinical research. They necessitate a rethinking of the roles of technology, trial staff, and patients in achieving the conditions for scientific and experiential success. Future research should enable the integration of insights from sociotechnical systems theory, human-centred design, and patient-centred

care, which can help refine the theoretical frameworks underpinning DCTs, ultimately shaping their future evolution.

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Data Availability: The datasets generated or analysed during this study are not publicly available due to participants not granting consent to make the dataset available. In line with university guidelines and the participants' signed consent, we have ensured that all data handling was conducted in accordance with ethical guidelines and confidentiality. We have provided some data excerpts in the study.

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Abbreviations:

CRS: clinical research staff

DCT: decentralised clinical trial

Multimedia Appendix of supplementary files:

Multimedia Appendix 1: Interview guide.

Multimedia Appendix 2: Reflexive thematic analysis process and outputs.

All files are available in the Supplementary Material repository (see Appendices).

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Reflections on Chapter 4

At this stage, patient centricity and patient experience emerged as key areas of focus within the research, due to their conceptual and practical importance to DCTs. Insights from the first study highlighted the centrality of relationships in supporting patient experience, retention, and engagement, which drew my attention to clinician-patient relationships emphasised in patient-centred care frameworks. Applied alongside SDT, these frameworks offered a more nuanced understanding of patient needs and experiences and provided a lens for interpreting the implications for how DCTs are structured and delivered.

The motivation for this study was to explore how patients experience decentralised, remote, technology-mediated trials through staff perspectives. Staff were in a unique position to compare traditional trials with DCTs and observe the impacts of decentralised delivery on both patients' experiences and their own work. These insights helped build understanding of patient experience in DCTs and could, in turn, inform which aspects of trials might be prioritised in design and planning.

Recruiting participants for this study was a considerable challenge, requiring extensive networking and persistence to engage staff across multiple sites. Their perspectives, once gathered, were invaluable in shaping my understanding of what was happening in DCTs. Many observations directly challenged industry claims, revealing gaps between these narratives and the practical realities of DCT. Staff highlighted that patients' needs are not always being met, and their insights illuminated both practical constraints and opportunities for improving experiences. Through this process, I observed the additional effort staff invested to support patients and maintain trial delivery, including workarounds and relational support, which clarified the practical challenges inherent in DCTs.

The combination of SDT, patient-centred frameworks, and broader literature enabled me to identify mechanisms in play and consider how design interventions could better support both staff and patients. Crucially, it highlighted that staff occupy a unique position in bridging patient and trial experiences, offering insights that literature alone could not provide, and providing a grounded basis for understanding where patient-centred principles succeed or fall short in practice.

Staff perspectives provided insight into how remote delivery affects both staff and patients, but including the patient voice directly would further strengthen the research. This stage clarified the direction for subsequent research, highlighting the importance of understanding patient experience in practice rather than relying solely on literature or staff accounts.

This study strengthened my ability to integrate multiple lenses to interpret complex phenomena and enhanced my understanding of the challenges involved in supporting patients in DCTs, including the limitations of technology, the continued importance of human-relational support, and the frustrations faced by research staff working with decentralised trial methods. The remote nature and technology used in DCTs were often rudimentary, at times failing to support patients and, in some cases, actively hindering them, contradicting industry claims about DCT trials. These challenges were compounded by the relational and organisational work required by staff to support patient experience and engagement. Together, these observations highlighted that patient experience in DCTs emerges from the interaction between technology, trial structure, staff practices, and organisational processes, demonstrating the sociotechnical nature of these challenges and showing that the convenience of remote delivery and the use of technology alone do not create a patient-centred experience.

Chapter 5: Understanding the Experiences and Needs of Participants in Decentralised Clinical Trials: A Qualitative Analysis

This article is currently under review for publication in a peer-reviewed journal: Gamble, E., Heavin, C., & Linehan, C. (2026). Understanding the Experiences and Needs of Participants in Decentralised Clinical Trials: A Qualitative Analysis.

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Author Contributions: EG and CL conceived the study. EG, CL, and CH contributed to protocol development and obtained ethics approval. EG researched literature, recruited participants, and conducted data analysis with review from CL. EG wrote the first and subsequent drafts of the manuscript. All authors reviewed and edited the manuscript and approved the final version.

Abstract

Background: Experts across industry, academia, and regulatory bodies increasingly stress the importance of prioritising participant experiences in clinical trials. Simultaneously, the shift towards decentralised approaches is reshaping how trials are designed and conducted, with a direct impact on the experiences of the participants involved.

Objective: This study aims to gain a deeper understanding of the experiences of participants taking part in Decentralised Clinical Trials, focusing on the unique challenges and opportunities presented by remote trial participation, and the tools and organisational processes that support participation.

Methods: This exploratory qualitative study involved interviews with fourteen individuals who had personal experience participating in remote or decentralised clinical trials. The interview transcripts were analysed using reflexive thematic analysis to identify key patterns and insights.

Results: We generated six main themes: (1) Positive experiences with remote participation, (2) co-ownership and meaningful engagement, (3) increasingly fragmented care and support, (4) confusion and uncertainty in navigating the trial, (5) need for human interaction and connection, (6) the hidden workload - navigating the burdens of remote trial participation. While the remote trial is an adaptable and sustainable model offering several benefits for participants and potential for clinical trials, it introduces complexities and challenges for participants that can negatively impact engagement and experience.

Conclusion: This study recognises both the potential benefits and challenges introduced by remote trial participation. It underscores the need for technology that not only streamlines trial processes but also responds to the needs, experiences, and well-being of participants. This requires rethinking trial technology features and functionality, strengthening collaboration with stakeholders, and focusing on elements of the participant experience that go beyond remote access and rudimentary data collection.

Keywords: Decentralised trials; DCT; Remote trials; Patient facing technology, Participant experience; Patient experience; Patient centredness; Patient Engagement, Participant-centric trials; Human centred.

Introduction

Background

Clinical trials are essential for testing new treatments and advancing medical understanding (Sackett and Cook, 1994). They traditionally involve participants making frequent in-person

visits to clinical sites (Bhide et al., 2018b). Recently, trials have increasingly adopted technologically mediated approaches that reduce site visits by supporting recruitment, intervention delivery, study visits, outcome assessment, and data collection (Alemayehu et al., 2022b; de las Heras et al., 2022b; Dorsey et al., 2020b; Hirsch et al., 2017b). The use of such technology is intended to enhance convenience and flexibility for participants (Apostolaros et al., 2020b; Izem et al., 2024b), to increase efficiency, reduce burden (Hanley et al., 2023b), and enable passive data collection (Dorsey et al., 2015b). Terms like decentralised (Van Norman, 2021c), remote (Alemayehu et al., 2022b), direct-to-participant, virtual (Dorsey et al., 2020b), and hybrid trials that blend decentralised and site-based components (Bruin, 2020) have emerged to describe these approaches. For clarity, in this paper, we refer to 'remote,' 'virtual,' 'hybrid' trials, or 'Decentralised Trials' collectively as Decentralised Trials (DCTs). Participant retention remains a challenge in remote studies (Daniore et al., 2022b). To date, there is limited evidence on patients' experiences in remote or decentralised clinical trials (Lalanza et al., 2023). As these models become more common, understanding how participants experience them is increasingly important.

Recent studies have set out to understand people's experiences when engaging with DCT approaches. For example, telehealth and remote monitoring are shown to be generally acceptable, with participants valuing reduced clinic visits and the opportunity for daily health monitoring (Artanian et al., 2021). Broader surveys of patients suggest a preference for hybrid models that combine remote and on-site visits but suggest a need to personalise trial organisation to patient needs and conditions (Nguyen et al., 2022). Some patients report satisfaction with remote visits and electronic data collection, including overall feasibility and low burden (Pugmire et al., 2022; Sommer et al., 2018b), but concerns persist. For example, a survey on patient perspectives of DCTs found that, although participants appreciated the approach, reduced contact with clinical staff could limit engagement and motivation

(Aiyegbusi et al., 2023b). Participants also encounter technical difficulties with videoconferencing and self-monitoring applications, which require additional support and reminders to use effectively (Hu et al., 2021; Steinhilber et al., 2025). Challenges with app usability suggest that digital literacy plays a role in shaping participant experience and may impact participation (Sarraju et al., 2022a). Participants have expressed a desire for tailoring trial delivery to individual preferences and health conditions, and has been shown to increase willingness to participate (Nguyen et al., 2022). Regular communication with study staff is important to maintaining trust and engagement in remote settings (Coyle et al., 2022d; Naz-McLean et al., 2022). Positive feedback and regular contact with research staff reinforce the value of ongoing support throughout participation (Sarraju et al., 2022a). Decentralised approaches may require more support mechanisms than traditional trials, they offer the potential to improve patient safety, treatment efficacy, and communication (Gerber et al., 2021), while also reducing the burden on participants (Nguyen et al., 2022).

In parallel with increasing technological mediation in clinical trials, regulatory bodies are placing greater emphasis on patient-centredness and patient-focused drug development (U.S. Food & Drug Administration, 2026), that is, designing trials that better reflect the needs, preferences, and lived experiences of participants (Santa-Ana-Tellez et al., 2023b). Patient-centredness aims to address patients' needs across various stages of a trial, including design, enrolment, data collection, and outcome reporting (Li et al., 2022b). In healthcare more broadly, the patient experience has been defined as the sum of all interactions, shaped by an organisation's culture, that influence patient perceptions across the continuum of care (Wolf & Jason, 2014b), and factors that influence participation and engagement throughout the clinical trial (Dobra et al., 2023b). Importantly, research suggests that many of the same factors that shape patient experience in traditional trial settings also apply in remote trials, despite differences in format (Coyle et al., 2022d). These include compassion, cultural sensitivity,

spiritual support, and personalised attention (Ferrell et al., 2019b). Positive experiences are also linked to interactions with other patients, building trust with the researchers, and expertise of the research team (Gorzynska et al., 2022). Other contributions include courteous, knowledgeable study staff, clear communication about study procedures (Smailes et al., 2016), and support throughout participation (Squires et al., 2013). Regular communication, responsiveness, multiple contact methods, and a genuine sense of care all enhance the patient experience (Boyd et al., 2024b). Furthermore, participants can face psychological and physical burdens (Naidoo et al., 2020), time demands, frequent clinic visits (McKinney et al., 2021), transportation issues, clinic wait times (Mattson et al., 1985) and frequent changes in staff (Henzlova et al., 1994). Negative experiences are tied to participant burden, as well as waiting around and infrequent or impersonal communication (Boyd et al., 2024b). In contrast, trial designs that reduce participant burden have been shown to improve engagement (Pogorzelski et al., 2023).

Taken together, these findings suggest that many of the core aspects shaping patient experience in traditional trials remain relevant in decentralised settings. However, the remote nature and greater reliance on technology may alter how these factors are encountered and addressed. This study specifically examines how digital tools and remote approaches affect participants' needs, motivation, perceptions, sense of support, and relationships with the research team. These factors are central to engagement, retention, and overall trial success (Gamble et al., 2023b). While there is growing insight into DCT dynamics, ongoing calls for research (Coyle et al., 2022b; Suman et al., 2022b) highlight the need to better understand how decentralised models can more effectively support meaningful, participant-centred participation. Although research has explored participants' needs in traditional trials, there is limited understanding of their lived experiences in decentralised trials, particularly regarding how technology-mediated interactions and remote engagement shape motivation, support, and

relationships with research teams. This study addresses these gaps by drawing on semi-structured interviews with former participants, providing first-hand accounts of how participants experience decentralised trials and how their needs, motivations, and relationships are influenced by remote models. For conceptual clarity, we use the term participants to refer to both trial patients and participants throughout this paper.

Methods

Research Design

We conducted a qualitative study using semi-structured interviews to explore participants' experiences in remote trials that utilised decentralised, technology-driven methods for trial conduct. Our questions focused on the remote nature of these trials and how the use of technology in these trials impacted the participant experience. Semi-structured interviews were used to gather data, allowing remote trial participants to share their perspectives (Hermanowicz, 2002b), and provide first-hand accounts (Riessman, 2008b) of participants' experiences. Reflexive Thematic Analysis (RTA), as described by Braun and Clarke (Braun and Clarke, 2021a), was employed to identify meaningful patterns in the data, themes, and provide insights into participants' perspectives.

Participants

Participants were recruited for their direct experience relevant and informative to the study's aim of exploring participation in remote, hybrid, and decentralised clinical trial formats (Patton, 1990). To ensure participants met the study's eligibility criteria, an online screening questionnaire was developed using the Qualtrics platform (see Supplementary Material 3). This questionnaire assessed participants' eligibility for the study. Individuals were eligible if they were over 18 years of age and had direct experience participating in a remote, hybrid, or decentralised clinical trial. The questionnaire included both multiple-choice and open-ended questions to capture key demographic information and relevant trial experience. Participant

recruitment online was supported by individuals within patient advocacy networks, who facilitated introductions to people with relevant experience and provided guidance on online communities suitable for promoting the study. Advocates and participants in our study shared the online screening questionnaire within relevant communities and personal networks, helping to expand the study's reach. This approach enabled access to individuals with a range of backgrounds, perspectives, and experiences of remote trials. Engaging with advocacy networks ensured that recruitment was informed by those with insight into patient communities, supporting the inclusion of experienced participants who might not typically be reached through conventional recruitment strategies.

Participants were recruited from a range of countries, including Italy, Kenya, the Czech Republic, the United States, England, Switzerland and Scotland, who had been involved in various types of studies, including commercially sponsored and investigator-initiated trials. All participants had prior experience with remote trial formats and had interacted with technologies such as patient apps, electronic diaries, patient monitoring tools, and telehealth solutions. The study adopted a broader, multi-study recruitment approach for two main reasons. First, including participants from different countries and trial types allowed for capturing experiences across diverse systems, cultural contexts, and technological infrastructures. Second, recruitment challenges made it difficult to enrol sufficient participants from any single trial, necessitating a pragmatic strategy that drew on individuals across multiple studies. The resulting sample was intentionally heterogeneous, spanning clinical areas and technologies, which provided a wide range of perspectives. However, this diversity also limited the ability to draw general conclusions, as participants experiences were shaped by different technologies, protocols, durations, and health contexts. Table 1 provides an overview of the study participant group.

Table 1. Summary of Study Participants - Overview of interviewed participants (all names are pseudonyms).

Name	Gender	Age Range	Trial Clinical Area	Completed Trial	Trial Duration	Technology used	Country
Mary	Female	54-64	Oncology	Yes	3 months	Electronic Diaries / Patient Portals	Italy
Celia	Female	45-54	Rare Diseases	Yes	12 months	Electronic Diaries / Phone calls	Czech Rep
Jordan	Female	18-24	Behavioural intervention trial	Yes	12 months	Telemedicine / Remote Monitoring Devices	USA
Robin	Female	55-64	Neurology	Yes	5 months	Telemedicine / Remote Monitoring Devices / Electronic Diaries	England
Mia	Female	45-54	Respiratory	Yes	Ongoing	Remote Monitoring Devices / Electronic Diaries	England
Cassie	Female	55-64	Gastroenterology	Yes	12 months	Telemedicine / Electronic Diaries	Scotland
Mark	Male	55-64	Behavioural intervention trial	Yes	12 months	Telemedicine / Patient Portal / Patient app	England
Jessica	Female	65+	Respiratory	Yes	3 months	Remote Monitoring Devices / Electronic Diaries	England
Emma	Female	55-64	Respiratory	Yes	Full Trial Duration	Telemedicine / Electronic Diaries / Patient app	England
Rose	Female	35-44	Dermatology	Yes	6 Months	Telemedicine / Patient Portal / Patient app	Kenya
Helen	Female	35-44	Endocrinology	Yes	2 months	Telemedicine / Electronic Diaries	Switzerland
Lilly	Female	45-54	Immunology	Yes	12 months	Electronic Diaries / Patient Portal	Switzerland
Kim	Female	65+	Respiratory	Yes	6 months	Remote Monitoring Devices	England
Sonya	Female	45-54	Behavioural intervention trial	Yes	12 months	Remote Monitoring Devices / Electronic Diaries	England

Data Collection

Data collection took place between September 2024 and March 2025. To accommodate participants' schedules and locations, interviews were held online via Microsoft Teams video calls. Each interview, conducted by the first author, lasted approximately one hour. The interview guide was designed based on a review of the literature to ensure alignment with the

research question (see Supplementary Material 1). The questions were drawn from existing literature (Wolf and Jason, 2014) and focused on understanding participants' experiences with the remote nature of the trial, their interaction with technology, the trial's conduct, the participant-clinician relationship, the support received, and their specific needs. A collaborative process took place between the research team to refine and enhance the interview guide. A conversational approach was used during the interviews, incorporating open-ended (DiCicco-Bloom and Crabtree, 2006) and follow-up probe questions (Kvale and Brinkmann, 2009), allowing interviewees to elaborate on their experiences. The interviews were recorded and transcribed via Microsoft Teams, with the first author verifying their accuracy. After completing fourteen interviews, and in line with Braun and Clarke's subjective view that data saturation is a context-dependent, interpretative judgment (Braun and Clarke, 2021b), it was determined that sufficient data had been collected to effectively address the research question.

Data Analysis

The authors followed the six-phase Reflexive Thematic Analysis (RTA) framework outlined by Braun and Clarke (Braun and Clarke, 2021a). The first author was responsible for independently coding the data, identifying relevant codes and themes that aligned with the research objectives. A collaborative refinement process took place through discussions with co-authors, ultimately reaching an agreement on the final interpretations. In Phase 1, the first author became familiar with the data by transcribing and listening to the recorded interviews and reading and re-reading the transcripts, and documenting initial thoughts and observations. Phase 2 entailed generating initial codes through a systematic analysis of the data, to detect significant patterns, a time-consuming process that required reflection to keep them precise and aligned with the research question. In Phase 3, codes were grouped into potential themes and refined through an iterative process, revisiting codes and transcripts to ensure they stayed clear, specific, and closely tied to the participants' data. Phase 4 involved reviewing and refining

themes to ensure alignment with the data, with collaborative discussions helping to challenge interpretations and define coherent overarching themes and sub-themes. Phase 5 involved final refinement, where themes were clearly defined, named, and organised into main themes and sub-themes through collaborative discussions, ensuring titles accurately reflected participants' experiences. In Phase 6, the analysis was presented, with each theme supported by detailed descriptions and participant quotes, ensuring that the findings were rooted in the participants' experiences. Examples of the data analysis are provided in Supplementary Material 2.

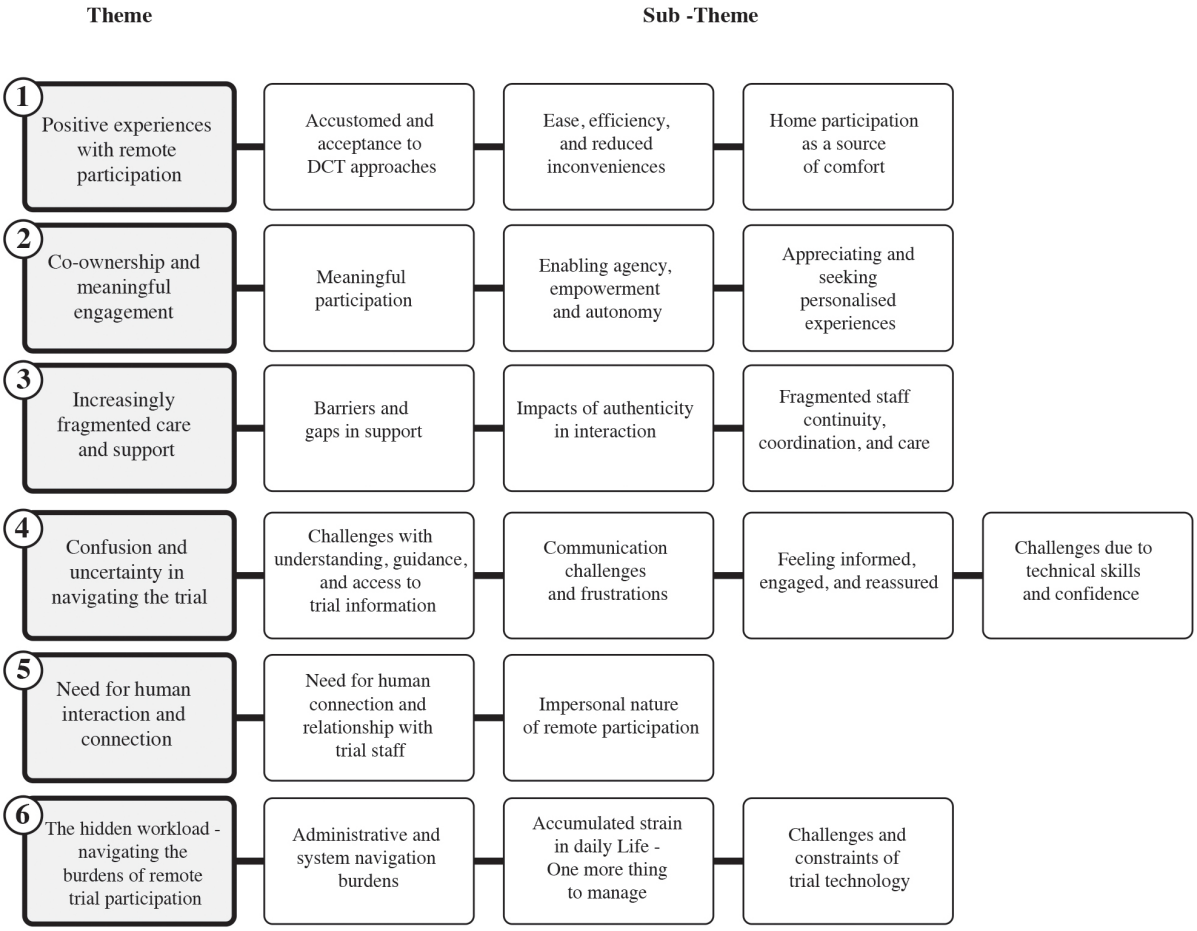
Ethical Considerations

The University Social Research Ethics Committee (SREC) granted approval for the study in June 2024. Participation in the study was voluntary, and participants received electronic information sheets and consent forms that clearly explained the study's purpose and procedures during the recruitment process. Personal details were anonymised, sensitive information was removed from transcripts, and participants were informed of their right to withdraw at any stage. No compensation was provided, ensuring participation was motivated solely by interest in contributing to the research.

Findings

Our findings are structured around six themes: (1) Positive experiences with remote participation, (2) Co-ownership and meaningful engagement, (3) Increasingly fragmented care and support, (4) Confusion and uncertainty in navigating the trial, (5) Need for human interaction and connection, and (6) The hidden workload - navigating the burdens of remote trial participation. Each theme has several sub-themes, as illustrated in Figure 1.

Figure1. Findings – Themes and Sub-themes - illustrates the key themes and sub-themes that developed from the study.



Theme 1 - Positive experiences with remote participation

This theme captures participants' generally positive experiences with elements of remote trials, particularly the benefits of easier access and fewer barriers to participation. Completing trial activities from home was seen as convenient, helping them avoid the logistical and physical challenges of in-person visits. Overall, participants were familiar with remote formats and viewed them as an acceptable and practical way to engage with a trial.

Sub theme - Accustomed and acceptance to DCT approaches

There was a broad acceptance and in some cases a preference for remote approaches in trials. This was influenced by several factors. Some participants' were familiar with remote working

and technology use, particularly through their jobs. To some, remote monitoring and trial tasks were seen as routine and manageable. Some viewed remote monitoring as a suitable approach for managing chronic conditions. Other participants, particularly those less familiar with technology, described initial hesitation, but they became more comfortable over time. Overall, participants supported and some even advocated for the continued use of remote methods in clinical research.

> *"So actually, what we did on the trial was totally normal for me. It's how I've operated for the last eight years."*- Mark

> *"I didn't realise there'd be so many apps to go with it. But it's actually fine. Once you understand what each one's for, and once you've done it a couple of times, it's so easy."* - Mia

Sub theme - Ease, efficiency, and reduced inconveniences

Participants described the remote trial as manageable and accessible, highlighting the removal of inconveniences like travel, public transport, and needing to navigate hospital environments. This not only saved time and lowered personal costs but also eased the physical and health-related strain of attending a site. Compared to paper-based methods, participants discussed how remote approaches reduced both cognitive and administrative burdens, requiring less effort. Patient-facing technology played a key role by simplifying involvement, supporting adherence through convenient data collection, and enabling efficient participation without disruption. Flexible scheduling options further contributed to a smoother experience, allowing participants to reschedule easily when needed. Additionally, participants appreciated access to upgraded medical equipment for use at home, enhancing their overall engagement.

> *"I didn't need to leave the house to go to a study site. I didn't have to brave public transport. I didn't have to brave car parking. Sick people in the hospital, any of that. It didn't need me to go to hospital. It takes two hours each way, and then there's an awful*

lot of sitting around and I work full time. So to go to a study site involves time, expense, and health concerns." - Lilly

"I think the remote nature was brilliant because it meant that you weren't having to traipse up to London several times to go and blow into bits of kit once or twice to see what happens." - Kim

Sub theme - Home participation as a source of comfort

Home-based participation was linked to feelings of flexibility, privacy, low pressure, and enhancing the overall experience. Beyond convenience, it offered comfort and a relaxed setting that helped normalise the process and put participants at ease. However, one participant pointed out that the relaxed home environment could sometimes reduce motivation.

"I'm at my own home, dressed the way that I want. Don't have to get prepared to go out into public…. it's more flexible because I'm at my own home and I'm in a place that I feel comfortable and so it generally feels positive to me… I'm safe here. I can talk to the researchers, and I can do it in my private space." - Jordan

Theme 1 Discussion

Similar to Davies and Slykerman (2025) our research highlighted how participants generally accepted decentralised methods. However, we also found that their initial level of comfort varied depending on their technological competency. Those with more experience, such as remote workers, adapted and valued the technology, while others initially struggled, but comfort generally improved over time. These findings are consistent with previous research indicating that varying levels of digital familiarity among stakeholders can influence the ease of participation in decentralised clinical trials (Izem et al., 2024b). Notably, participants viewed the DCT model positively, as it helped lower barriers to participation. Past research has highlighted several barriers in traditional trials, including time commitments, frequent clinic visits (McKinney et al., 2021), transportation issues, and long waiting times at sites (Mattson

et al., 1985), all of which contributed to participant frustration (Boyd et al., 2024b). Logistical hurdles, such as travel time and distance to trial sites, also pose significant challenges to participation (Adams et al., 2022b). Many of these burdens are largely removed in remote trials and were appreciated by the participants. Remote activities can fit into daily life. Participants valued the flexibility, better home equipment provided, and reduced administrative burdens compared to paper methods, supporting the idea that DCTs can lower elements of participation burden and support flexibility (Apostolaros et al., 2020b; de las Heras et al., 2022b). Reduced burden is particularly important for retaining participants in clinical trials (Natale et al., 2021b) and improving engagement (Pogorzelski et al., 2023).

Theme 2 - Co-ownership and meaningful engagement

This theme highlights the role of participants as active partners in remote clinical trials, emphasising their sense of co-ownership and meaningful engagement. Participants attributed personal significance to their involvement, shaping their motivation and commitment. The trial experience was strengthened when participants felt empowered, with greater agency and autonomy during the process. Additionally, a desire for personalised experiences that align with individual needs and preferences.

Sub theme - Meaningful participation

Participants described a sense of ownership in the trial, feeling like partners rather than just subjects. While enthusiasm was high at the start, some experienced the relationship as one-sided and sought greater recognition and validation. When their role, knowledge, and contributions were acknowledged, it helped build trust and fostered a stronger connection to the trial.

> *"I tend to just do, I don't tend to think about myself. I think I manage my situation by being focused on doing. I'm finding meaning in what I'm doing. That's what works for me."* - Sonya

For some, involvement was also seen as personally meaningful and intellectually rewarding. Participants appreciated the chance to gain new knowledge, insight into their health, and contribute to something larger than themselves. Motivations ranged from curiosity and self-data analysis to altruism, with participants valuing the opportunity to make a societal impact, even when it involved personal sacrifice.

> *"But perhaps 5-10 years down the line, there will be something that will come from that or, either directly from that, or someone, somewhere will then read that and it will set them off in a different direction that will benefit mankind."* - Cassie

For some, the trial technology fostered a sense of inclusion and a connection to the trial. Others found emotional or practical benefits, especially during periods of ill health or social isolation. Some participants saw it as a way to preserve their independence; others appreciated the break from routine that the trial provided. Some found comfort in self-monitoring, the novelty of the technology, or simply the distraction it offered from their health concerns.

> *"It gives me something that I feel like I'm doing something useful, and it gives me something to take my mind off everything else, really. So if I'm doing that twice a day and making sure I've done it all properly and whatever, I think that's good for me."* - Mia

Sub theme - Enabling agency, empowerment and autonomy

Participants experienced a sense of empowerment through active participation, with autonomy and flexibility enhancing their involvement. This empowerment was strengthened by reviewing feedback and metrics, as well as by familiarity and competence gained through prior experiences, which fostered greater control and agency throughout the trial. Technology played a key role by supporting self-management, allowing participants to work at their own pace and control task completion and decision-making. Participants preferred autonomy in scheduling

and access to information, but frustration arose when they felt a lack of control over the technology, highlighting the need to balance flexibility with effective support mechanisms.

> *"I like the autonomy. That was great…. I like the fact that it relied mostly on me."* - Sonya

Sub theme - Appreciating and seeking personalised experiences

Participants described frustration and disengagement caused by standardised messages, templated approaches, and rigid procedures. Some felt the experience was impersonal and unresponsive to their needs. Where personalisation was lacking, participants sometimes felt emotionally distant or disconnected from the trial.

> *"It was very impersonal. And it's like bulk mailing from a study team."* - Lilly

> *"And as I said, it was far less personal. It didn't feel like the people really got to know me at all. It was just perfunctory questionnaires."* - Robin

In contrast, participants highlighted the positivity of a personalised trial experience, especially in communication styles, feedback mechanisms, and flexible protocols. When these elements were tailored to individual needs, participants felt more supported and engaged, reporting greater satisfaction when interactions felt individualised and responsive.

> *"They really made sure that everything was personalised according to my level of knowledge, according to my interest, according to what I already knew. And so that I didn't have to sit through yet another hour of, for example, education on the material itself. If I already know it, then that is wasted time for both them and me. So it was actually quite smart that way."* - Helen

Personalised care, adaptable technology, and attentive clinical support fostered a sense of being valued, encouraging openness and reinforcing engagement with the trial. Some participants

deepened their connection by relating feedback from technology to their physical experiences, which strengthened their sense of ownership and meaning.

Theme 2 - Discussion

Our research showed that participants' motivation reflected a layered mix of altruism, personal growth, and both symbolic and material benefits. Participants described a sense of ownership over their experience, viewing themselves as active contributors motivated by validation, impact, and meaningful contribution. This aligns with past research showing that personal meaning and altruism are powerful motivators in clinical trial participation (Walsh and Sheridan, 2016), and that intrinsic motivation, rooted in personal values and goals, supports sustained motivation (Deci and Ryan, 2008), a finding that held true even in the remote context of participants' trials. Autonomy played a central role in shaping experience, expressed through flexibility and convenience, which enabled participants to exercise control over how and when they engaged with the trial. But autonomy also introduced new responsibilities that, if unsupported, could become burdensome and undermine motivation. As both an ethical requirement (Owonikoko, 2013b) and a psychological need (Deci and Ryan, 2012a), autonomy must be carefully supported through systems that offer clarity, feedback, and reassurance. Personalisation was equally important and aligns with previous research showing that participants value trials tailored to their individual needs (Nguyen et al., 2022). It's also a key factor shaping trial experiences (Ferrell et al., 2019b). Participants valued interactions and feedback that acknowledged their individual roles and progress. These personalised touchpoints helped reinforce their sense of agency, purpose, and connection to the trial's broader goals, factors known to support engagement and retention (Gamble et al., 2023b). Yet, in decentralised settings, opportunities for this kind of tailored engagement can be limited (Gamble et al., 2025a). In contrast, treating participants as partners improves engagement and leads to better outcomes (Mayberry et al., 2019; Morrison et al., 2014).

Theme 3 - Increasingly fragmented care and support

Participants discussed the fragmented nature of care and support in remote clinical trials. Gaps in support structures and limited clinician understanding of participants' experiences, disjointed continuity of trial staff, a lack of medical coordination and integrated care further disrupted the trial experience.

Sub theme - Barriers and gaps in support

Participants reported gaps in support during remote trial participation, including delays in responses, slow resolution of technical issues, and limited, timely, emotional, or clinical input. The lack of immediate assistance led to feelings of uncertainty, isolation, and frustration, with support described as insufficient and reactive. Limited access to clinician guidance and expert advice compounded concerns about responsiveness. Technological platforms were perceived as detached, relying on automated replies and asynchronous email communication, while structural barriers such as restricted communication windows and geographical limitations further hindered real-time problem-solving and access to care. In contrast, when participants had direct access to troubleshooting, emotional support, and post-trial assistance, their experience improved markedly. Responsive technology and self-tracking tools fostered feelings of safety and reassurance, with many emphasising that timely support was a critical component of care in remote trials.

> *"The frustration of not being able to get the support you want when you need it and not being able to see the person when you need them to ask one or two questions when something has come up, you need to talk to someone as soon as possible……. And also just the fact that I have to get someone to help me, and it has to be through an email. Then that feels, oh my God, they're so far away. You just realise that there's a big barrier."* - Rose

Sub theme - Impacts of authenticity in interaction

Participants described how clinical research staff sometimes lacked understanding of their lived experiences, exacerbated by limited feedback channels and the absence of direct clinical observation. Some felt unheard and unable to fully express themselves due to restricted communication methods, limited response options, and reporting constraints. These barriers, amplified by the remote trial setting, increased frustration and created a sense of being misunderstood, which ultimately reduced participants' confidence in their care. In contrast, when clinicians showed empathy and understanding to participants, it enhanced the overall experience. Opportunities to provide feedback during in-person visits and to be genuinely listened to helped participants feel valued and cared for, highlighting the importance of clinician empathy in the trial process.

> *"It was frustrating because I felt like there was a resource they wanted and they did not really want to hear what the patients say beyond what they wanted to hear."* - Rose

> *I don't think you were asked to reflect and give feedback regularly enough. And so it was very much driven by the researchers. They've got this set idea of what they were going to do and what needed to happen, but they didn't sort of then get feedback and check that it was working for the people as it went along."* - Robin

Sub theme - Fragmented staff continuity, coordination, and care

Fragmented continuity in trial staffing negatively affected the patient experience, as participants encountered different research staff, leading to a lack of consistency and disjointed communication. This caused frustration.

> *"Because every time there are different people who reply to you, you have to start from the beginning. I thought they would have some kind of file with all my information, but every time it seems like they are reading this information for the first time."* - Mary

Poor coordination of care further impacted participants, who faced fragmented medical support and had to navigate their care independently. Limited interaction between research staff and family doctors, along with delegation of care to external providers, made it difficult for participants to connect with the relevant medical team, resulting in a sense of detachment and increased burden. In some cases, the absence of timely expert intervention, especially during emergencies, left participants feeling unsupported and added to their stress.

> *"Then I would have to fill out the questionnaire that things are not going well, and sometimes I had to seek medical help pretty quickly, and that was more stressful and difficult to arrange…… they would just call me and say you should go to the doctor and ask him to do these blood tests or this analysis. If you're feeling bad."* - Celia

In contrast, when continuity and coordination were present, participants felt better supported, which enhanced their overall trial experience.

Theme 3 - Discussion

Our findings suggest that DCTs can reduce research staff oversight and limit their ability to respond effectively to participant needs. This reduction in support contributed to frustration among participants, who sometimes experienced a sense of inadequate care. These results align with Gamble et al. (2025a), who describe similar challenges in supporting participant needs across decentralised settings. Participants in our study also reported that fragmented care, disconnected support systems, and limited coordination created both emotional and practical burdens, leaving them to manage issues alone. These gaps in care served as a stressor and impacted their overall experience. The importance of a sense of care (Boyd et al., 2024b) and support (Squires et al., 2013) is critical to supporting the patient experience. Integrated and continuous care is often highlighted as an important aspect of patient-centred care (Youssef et al., 2020) and effective patient care requires responsiveness to individual needs (Kearney et al., 2018b; Weston et al., 1989b). However, staff changes (Henzlova et al., 1994) can disrupt

key elements such as continuity, support, and medical coordination, all of which are especially important in decentralised clinical trials (Jardien-Baboo et al., 2021a; Langberg et al., 2019b). The remote nature of DCTs intensifies these challenges by limiting in-person availability and immediate support. While remote models may offer flexibility and autonomy, without accessible, empathetic systems, participants can experience these responsibilities as burdensome, resulting in feelings of disconnection, abandonment, and emotional strain.

Theme 4 - Confusion and uncertainty in navigating the trial

This theme highlights the challenges participants faced in understanding various aspects of the trial. Ambiguity, a lack of clear guidance, and limited access to educational resources contributed to confusion, uncertainty, and difficulty navigating the trial process. Communication challenges further compounded issues, and participants sought but did not always receive feedback and reassurance. Additionally, varying levels of technical confidence presented further obstacles.

Sub theme - Challenges with understanding, guidance, and access to trial information

Some participants described their experience in remote trials as a "black box," reflecting a lack of clarity and understanding about how the trial worked, their role, and the part technology played in data collection. This ambiguity limited their engagement, increased frustration, and sometimes led them to question their own understanding and abilities, causing stress and uncertainty. These issues could be heightened in remote settings, when participants struggled to grasp trial processes and expressed a need for more structured guidance.

> *"I didn't quite see how they would be able to correlate my data on a daily basis to how I was feeling and then what I was thinking, and you know all of these things. .....honestly, I didn't see the point of it and how it would relate to the other data."* - Helen

This lack of clarity was compounded by difficulties in accessing and understanding trial information. Some participants struggled with the clarity of the materials provided and digital barriers that hindered comprehension. Difficulties in navigating online information further compounded these issues, limiting their ability to engage effectively with the trial process and increasing stress.

> *"All the information about this medication is online…. But sometimes that information online it tries to be very bullet points and then sometimes it's not easy to understand."*
> - Mary

Participants highlighted a need for more structured training and clear user instructions. Inadequate induction and broad guidelines left many feeling unprepared and unsupported, undermining confidence and engagement. Foundational knowledge was seen as crucial to reducing uncertainty and lowering barriers to participation.

> *"I think that's the poor induction, if I'm honest. I think also, we did a follow up call after about a week…. and that was when she said by the way, all the other people I have spoken to did not realise that you have to fill in this."* - Jessica

> *"But it was very limited training because at the beginning it seems easy….. I thought that was enough, but then in the real moments was not enough."* - Mary

Sub theme - Communication challenges and frustrations

Participants faced barriers in reaching the right person and needed to make extra effort to connect with appropriate staff. Limited communication channels, combined with the absence of nonverbal cues in remote settings, made engagement more difficult and left some feeling frustrated. Ineffective communication, such as delays, gaps in responses, and automated replies, led to a sense that their concerns weren't being fully addressed, which in turn contributed to disengagement and diminished the overall patient experience. This lack of

responsiveness also reinforced a preference for in-person interactions, which were seen as clearer and more supportive.

> *"I had to take a list of number of phones and try to phone everyone to try to find a solution ….. And the first no reply, second no reply, this was difficult for me…. In the moment that you need to quickly reply, this is a problem ….. It seems like when you call, it's to a call centre. There is something automatic and they reply to you in an automatic way, without really understanding the situation*." - Mary

Sub theme - Feeling informed, engaged, and reassured

Some participants described how technology-enabled feedback and visual metrics supported their engagement, boosted confidence, and made the experience more enjoyable. For some, the technology provided feedback offered insight into their trial journey, creating a sense of progress, involvement, and even perceived health improvements. Participants stressed the importance of feedback being dynamic, meaningful, and personalised. Some felt the trial app could better deliver this information, helping to maintain motivation, offer reassurance, and prevent feelings of disconnection. When feedback was delayed or missing, especially at key moments, it left some feeling overlooked, unsupported, and disconnected. A lack of meaningful feedback and information, both during and after the trial, led some to feel unimportant or forgotten, particularly when they weren't updated on their contributions or the outcomes of the research.

> *"If I could see the data points, the data collection points, and what's to come, that would be great in the study, providing much more guidance. … I would have loved to have known that my blood sample made it each time, not the results, because I knew it took time to process. But I would have loved to have known that they'd got what I'd sent them."* - Lilly

Sub theme - Challenges due to technical skills and confidence

Participants experienced challenges related to varying levels of technical skills and confidence. Some felt intimidated by the technology provided, struggling with setup or specific devices, and some would have preferred paper-based instructions. There was a contrast between initial impressions of patient-facing technology and the reality of using it in practice, which created further challenges. Although the systems seemed easy at first, difficulties arose once the trial began. Some participants struggled using the technology as expected, which affected their ability to meet trial expectations and led to feelings of intimidation and low confidence.

> *"I suppose initially, when we were trying to set up the technology, I did think, oh no, this is a bit intimidating. If I was in the room with this person, they could actually just put the information on my iPad, or my phone, and I wouldn't have to do anything."* - Robin

Theme 4 - Discussion

We identified challenges in participants' understanding and training related to the trial, including ambiguity, inconsistent communication, and a lack of structured support. These left some participants feeling unprepared and anxious. Past research on patient retention in clinical trials has identified patient competence as a key factor in engagement and retention (Gamble et al., 2023b), competence acts as a core psychological need (Deci and Ryan, 2008), that drives motivation and ongoing participation in clinical trials. Our findings show how easily this sense of competence can be disrupted and how digital access alone is not enough to support this sense of competence. A clear understanding of study procedures (Smailes et al., 2016) is crucial to reducing uncertainties and enhancing participants' confidence throughout the trial. Feedback, both data updates and relational, are essential for engagement (Gamble et al., 2023b), when delivered empathetically, contextually, and timely it enhances the experience, competence, and strengthening participants' connection to the trial. Like findings in other DCT research (Gamble

et al., 2025a), challenges in communication between the research team and participants extended beyond technical support. Clear, timely communication and feedback are central to building participants' sense of competence. They need reassurance about their role, progress, and contributions through feedback that is empathetic, contextual, and relational. Communication and feedback are not just operational tasks, they are relational tools that convey care, value, and inclusion (Boyd et al., 2024b). When responsibility falls entirely on the participant without sufficient understanding or feedback, it can create emotional and practical strain, potentially affecting retention, adherence, and data quality. These challenges are compounded by potential issues of digital exclusion in terms of both people and the technology (Wilson et al., 2024). Assumptions about technological literacy and autonomy can obscure the reality that patients' skills, confidence, and access vary. Competence, then, is shaped not only by what participants are expected to do, but by how they are supported cognitively, practically, and emotionally.

Theme 5 - Need for human interaction and connection

This theme highlights an erosion of social interaction in remote trials and participants' need for meaningful connection. Some participants perceived their involvement as transactional, lacking personal engagement and depth in interactions with trial staff. A sense of disconnect and limited relationship-building diminished their experience, contributing to feelings of isolation. Reduced interaction with trial personnel reinforced this sense of detachment. Participants sought greater human connection and valued opportunities for more personal engagement throughout the trial.

Sub theme - Need for human connection and relationship with trial staff

Participants' experiences revealed a lack of meaningful personal connection with trial staff, reflecting a broader sense of disconnection in remote clinical trial settings. Some participants

reported not getting to know the research team and a lack of opportunities to build relationships, which contributed to feelings of detachment and a sense of impersonality.

> *"There's really no relationship. There's no touch. There is really no assessment, like it's not really human. You feel like there's a disconnect."*- Rose

Participants expressed a desire for human connection, highlighting how personal interactions contribute to a more supportive and humanised trial experience. They valued in-person contact with research staff, which helped build trust, comfort, and a sense of being respected. Informal conversations and the presence of friendly, familiar staff, especially nurses, offered emotional reassurance and helped participants navigate concerns or uncertainties during the trial. These friendly, informal exchanges fostered trust, reassurance, and a genuine feeling of being cared for.

> *"Even though it is remote and it's about technology and it's about data, it's really the people who I got the chance to interact with and that I got to work with. Like the study nurse that I mentioned before. For example, she was lovely and she was very understanding."* - Helen

Despite being provided with digital tools, participants still relied on human coordination and contact to feel confident and cared for. Participants viewed in-person visits as more thorough and attentive, providing better oversight and emotional support. This helped manage anxiety and strengthened motivation to remain engaged. Participants expressed a desire for more in-person interaction during these trials and suggested participant community-building mechanisms to foster connections during trials.

> *"My experience was that face-to-face I would get much more information. The doctors would get to see me physically as well, you know, a physical examination and so on. So that was the component that during the virtual communication, was missing."* - Celia

Sub theme - Impersonal nature of remote participation

Participants expressed a desire to be recognised as individuals, but the structure and delivery of remote trials at times left them feeling like data providers rather than people. The experience was described as clinical or inhuman, shaped by impersonal, standardised digital platforms. Digital responses came across as detached, and the remote format was seen as an incomplete substitute for direct human support.

> *"You are more like a robot because you're communicating with something you don't really have a relationship with, and you're just giving - This is happening, This is happening, This is happening. You know, (*gesture regarding giving data, giving data, giving data*) It's only like it's not really human."* - Rose

The lack of face-to-face contact, non-verbal cues, and informal conversation reduced the depth of interaction with trial staff, making appointments feel cold and distant. Some participants felt these interactions were less meaningful than in-person visits. Inconsistent communication and time-zone challenges contributed to a sense of detachment, feeling overlooked or dismissed, and feelings of efficiency prioritised over empathy. These experiences deepened participants' desire for more human connection and recognition during trial participation.

> *"It did just feel like you entered into taking part in something where you were really revealing personal information and how you felt in your mood, and in some ways, I didn't find it helpful that it was remote at all. It didn't work for me. I think I needed to sit with someone in a room and have ease of contact."* - Robin

Theme 5 - Discussion

Our study found that remote trials can weaken the relational dynamic between participants and research teams, limiting both personalisation and opportunities for interpersonal connection. Negative experiences centred on impersonal communication (Boyd et al., 2024b), with participants in our study describing experiences that felt impersonal or transactional, which

could diminish motivation and long-term commitment. However, it is important to recognise that not all remote trials resulted in a lack of connection. In some cases, participants appreciated the opportunities where interpersonal interaction with research staff was part of the process and highlighted the positive impacts of this. Human connection is recognised as central to therapeutic engagement and the relationship between trial staff and participants, playing a vital role in promoting positive experiences in clinical trials (Gillies and Entwistle, 2012). Relationships form a critical foundation for participant retention (Gamble et al., 2023b), supporting treatment adherence throughout the trial process (Mohr et al., 1999), and fulfil a psychological need for motivation (Deci and Ryan, 2008). While remote models offer clear logistical benefits, they also risk compromising a core element of patient-centred or person-centred care (Zhao et al., 2016b).

Theme 6 - The hidden workload - navigating the burdens of remote trial participation

This theme highlights the hidden workload for participants associated with remote trial participation, emphasising the burdens placed on participants. Navigating administrative tasks and trial systems added complexity, often requiring significant effort to manage. Challenges with trial technology further compounded these difficulties, creating additional barriers to engagement. Participants felt the responsibilities placed on them and relied on informal or external support networks to cope with these demands. Furthermore, they faced several personal challenges, and trial responsibilities were one more thing for them to manage while also managing their health.

Sub theme - Administrative and system navigation burdens

Some participants described the administrative burden and complexity of navigating remote trial systems as a source of frustration. Tasks like scheduling, managing communications, and handling study responsibilities felt disjointed and time-consuming. These difficulties were made worse by rigid protocols and inflexible systems that didn't accommodate participants'

needs or offer clear pathways for assistance. Furthermore, the inconvenience of required travel for in-person visits and tests also impacted the participant experience.

> *"It is frustrating, and that does actually need much more effort from me. Whereas if there was a button to say or question, have you been vaccinated, or are you preparing to be vaccinated, yes or no. And then will you be pausing your medication? Yes, from when? When are you starting the pause, and then when are you picking up again? That would be super helpful."* - Lilly

At times, participants felt that too much responsibility was placed on them, managing tasks, making decisions, and handling emergencies in the absence of sufficient support. Participants expected the systems to be straightforward but found themselves navigating confusing processes alone, which created stress, uncertainty, and a sense of isolation. The combined effect of inflexible procedures and lack of adaptability negatively shaped their experience.

> *"It seems that I have to take the responsibility myself. And this is the thing that makes me more isolated. OK, now I have to make some decisions that maybe I am not an expert to take."* - Mary

Sub theme - Accumulated strain in daily Life - One more thing to manage

Beyond the challenges of navigating trial systems, participants described the ongoing emotional and practical toll of trial participation as it unfolded alongside daily responsibilities, health fluctuations, and the heightened anxiety and stress caused by illness, as well as other life events. This wasn't just about any one task being difficult; rather, it was about the gradual build-up of demands over time, which could erode motivation and make trial tasks feel like yet another obligation in an already unpredictable situation. For some, they underestimate the long-term demands and what started as manageable tasks, like completing digital diaries or managing technology, became harder to prioritise due to disease management or the fatigue of long-term involvement. Adherence was sometimes impacted not by intention, but by

forgetfulness, stress, or the difficulty of managing multiple demands at once. Trial participation, while important, became "one more thing to manage" in an already complex context of illness and everyday life.

> *"Days when the Crohn's was particularly bad. And I just didn't want to move. Or if I thought, I've got to be online now, and I might have to run to the toilet. I never did. But that was always in the back of your mind."* - Cassie

Sub theme - Challenges and constraints of trial technology

Participants described a range of technology-related challenges that negatively affected their experience. Frustration arose from unreliable technology, system glitches, poor connectivity, and usability issues that disrupted task completion and data submission. Some noted that individuals with more serious health conditions might struggle with the technology provided. Expectations for seamless, intuitive digital experiences were at times unmet; some participants described the tools as rigid, outdated, uninspiring, and frustrating to use. Technology issues increased anxiety, impacted mood and motivation, and added to the emotional burden of remote participation. Additional barriers included conflicts between device preferences, platform limitations, and the inconvenience of managing multiple devices. For some, the cumulative demands, frequent data entry, excessive information, and manual assessments led to technological fatigue and reduced engagement.

> *"I was saying I can't click on this. I would send an email saying I've tried this and I can't get this into the text box, and she would then talk to the technical support, and they would come back and say, have you got the font size increased on the phone? Or will you need to take that off and then do this, and you're like, oh, what a hassle."* - Cassie

> *"I think at the start, I thought it was easy. It was just like pa, pa, pa, and I'm done. As you move on, it gets overwhelming. It gets a bit tiring. It gets a bit boring. When you started, you think it's easy. But as you go on, it's not that easy."* - Rose

There was a reliance on participants' personal formal, informal, and external support networks in using technology. Some participants deferred decision-making or understanding to family members or other external sources of support. This reliance created a passive role for participants, highlighting the reliance on family navigating the complexities of trial technologies.

> *"I had my youngest with me when I was in person at the hospital, and I didn't really understand what they were on about, but the person in the hospital said to my son, do you understand it? And he went, yes, there you are, you're sorted."* – Cassie

Theme 6 - Discussion

Participants in this study described several burdens that made trial participation feel laborious and emotionally taxing, echoing prior research on how excessive burden harms participant experience (Boyd et al., 2024b). Although remote tools are often promoted as convenient, flexible, and efficient, reducing participant time investment and enabling more passive data collection (Apostolaros et al., 2020b; Dorsey et al., 2015b; Hanley et al., 2023b; Izem et al., 2024b; Rogers et al., 2021), participants frequently faced friction, constraints, and additional trial responsibilities. The cumulative effect of having "one more thing to manage" heightened emotional stress, as technical, administrative, and health-related demands became entangled. This burden risked undermining participant retention and agency, particularly when informal technology support became essential for coping. Reliance on external support networks, such as family, shifted responsibility and could create passive participant roles, while also imposing burdens on family members providing support. This dependence highlights possible design and usability flaws and raises equity concerns for participants without access to such support. The

findings reveal a disconnect between the efficiency goals of remote trials and the complex, emotionally charged realities faced by participants who must simultaneously manage illness, personal life, and trial demands. While remote models aim to promote autonomy, without adequate supporting systems this autonomy can become a burden, exposing a disconnect between self-management ideals. Managing trial burdens and technology may seem minor in isolation but can become overwhelming when layered with health and day to day challenges.

Discussion

We conducted 14 interviews and employed thematic analysis to explore the perspectives of remote clinical trial participants regarding their involvement in DCTs. By focusing on participants' experiences and perceptions, we gained valuable, in-depth insights into their involvement in these trials. Our findings highlight how participants typically embrace remote trials and can find meaning as partners and co-owners in trial tasks. There is also often an erosion of participant experiences, a lack of personalisation, and understanding of participants. The study sheds light on the broader implications of remote trial participation and its impact on the participant experience.

Implications for Participants

The shift toward remote and decentralised clinical trials is reshaping the participant experience, offering clear benefits but also significant challenges. While these models improve convenience and accessibility, they can also impose social, practical, emotional, and cognitive burdens. Convenience is valued but not sufficient to sustain engagement or ensure a positive experience. Several elements central to participant satisfaction may be undermined, including compassion and personalised attention (Ferrell et al., 2019b); relationships with staff; social interaction and trust-building (Shepherd et al., 2023; Gorzynska et al., 2022); clear communication (Smailes et al., 2016), regular contact and feedback (Sarraju et al., 2022a); and a genuine sense of care (Boyd et al., 2024b). Participants also report practical difficulties,

including issues with usability and digital literacy (Sarraju et al., 2022b). Viewed through a behavioural science lens (Deci and Ryan, 2012a), we can see that autonomy, relatedness, and competence are all affected, core psychological needs that must be supported to maintain motivation and retention (Gamble et al., 2023b). If these needs are not recognised and addressed, there is a risk that remote models may feel less engaging or even alienating for some participants. To address this, DCTs must evolve to prioritise inclusive, flexible approaches and support systems that respond to diverse participant capabilities, preferences, needs, and levels of confidence, offering multiple ways to engage, support, and resolve issues efficiently. Emotional needs also matter (Moser et al., 2000b) and support should extend to provide ongoing care, opportunities for connection (Mead and Bower, 2000), and personalisation (Nguyen et al., 2022). These elements can help build trust (Gorzynska et al., 2022), reassurance (Albrecht et al., 2008), and a sense of connection (McClary et al., 2023; Morgan et al., 2017), and contribute to positive experiences. Barriers remain, including assumptions about digital readiness (Tung et al., 2024), entrenched models, and the challenge of investing in more personalised, less scalable approaches. Yet clear enablers exist: early patient involvement through co-design (Mackey et al., 2025a), piloting and testing tools with diverse user groups (Blanchard, 2023) and embedding feedback loops to support continuous improvement. Addressing these issues enables a more human-centred approach that strengthens engagement and retention by reflecting what truly matters to participants. Trial designs must therefore move beyond convenience and efficiency to embed personalisation, flexibility, and holistic support throughout, laying the foundation for ongoing, tailored support aligned with participant needs.

Implications for trial design

Given these needs, trial designs should reflect the diverse and often complex experiences of participants by embedding personalisation, flexibility, and ongoing support throughout the study. Similar to past research (Artanian et al., 2021; Pugmire et al., 2022; Sommer et al.,

2018b) our study highlights that DCTs address some of the challenges of traditional on-site clinical trials (Gul and Ali, 2010) by improving convenience for participants. However, participants differ widely in their need for reassurance, feedback, and human contact to stay engaged. Our findings show participants experience DCTs as detached and mechanistic, underscoring the need to adapt approaches for remote, technology-mediated settings. To genuinely support participants, trial design must go beyond procedural efficiency, remote clinical trial designers must also aim to prioritise personalisation and flexibility, along with coherent, ongoing support that integrates emotional, relational, and practical needs. Trial design must account for this, embedding systems that help participants feel informed, capable, and genuinely supported. Fully remote or rigid models do not suit everyone. Some participants rely on in-person interaction to build trust and feel secure, while others need regular communication to stay engaged and feel supported. Traditionally, research teams have supported retention through personalised and relational support (Gamble et al., 2023b; Nguyen et al., 2022), but decentralised models can disrupt these connections. Our research highlights the importance of viewing the participant experience holistically, recognising that clinical, psychological, emotional, and practical factors are interconnected. Participation is not just about procedural compliance; it's also about feeling valued, safe, supported, and positively engaged throughout. To achieve this, trial design should anticipate variation across participants from the outset. Hybrid models tailored to individual circumstances (Nguyen et al., 2022) and consistent, meaningful interactions with study staff are key to building relationships, sustaining trust and motivation (Coyle et al., 2022d; Naz-McLean et al., 2022; Sarraju et al., 2022a). At the same time, practical constraints such as limited staff resources and operational pressures make tailored support or site visits difficult. This is where thoughtful technology design can play a crucial role, enabling flexible and responsive ways to meet participants' needs, but the technology must be intentionally designed to support and sustain those needs throughout the

trial. Here, trial design intersects with technology choices, which can help extend flexibility and responsiveness.

Implications for the design of technology to support remote clinical trials

Technology is the primary interface through which participants experience DCTs, and can shape how they feel supported, connected, and engaged. Consistent with prior research (Gamble et al., 2025a; Rogers et al., 2021), our findings show that current technologies prioritise data collection and efficiency (technical aspects) while neglecting emotional, relational, and humanising elements (social aspects). This creates a socio-technical imbalance, reflecting what socio-technical theory describes as a misalignment between technical systems and users' social needs (Bainbridge, 2004). In the context of DCTs, these social needs can be understood through a participant-centred lens, which emphasises involvement, communication, support, and contextual fit. Guided by socio-technical considerations, technologies should therefore integrate technical functionality with these social dimensions alongside data capture. Features such as two-way messaging, personalised communication, context-sensitive feedback, and real-time monitoring of well-being can help participants feel acknowledged and supported, aligning with broader calls for patient-centred trials (Santa-Ana-Tellez et al., 2023b). Emerging technologies offer further opportunities, AI can enhance communication, feedback, and relational elements with personalised communication via natural language processing (NLP) (Nadkarni et al., 2011), and adaptive content tailored to individual learning needs (Sari et al., 2024). Virtual assistants (Gamberini et al., 2021), can provide immediate, tailored responses and support while escalating more complex concerns to human staff. With consent, AI can also analyse text, voice, or facial expressions to detect signs of frustration, distress, or disengagement (Kapoor and Verma, 2024), and monitor shifts in mood and health status, along with real-time measures of emotional well-being (Adikari et al., 2022). Implementing these innovations may require regulatory frameworks and oversight

processes to evolve to support participant-centred approaches and AI-enabled functionalities. Although AI and GenAI present significant opportunities, technology design must be grounded in behavioural science theory (Pagoto and Bennett, 2013). Frameworks such as Self-Determination Theory (Deci and Ryan, 2012b) support autonomy, competence, and relatedness, which can enhance participant motivation and ultimately retention (Gamble et al., 2023b). Practical enablers include applying usability heuristics (Nielsen, 2005), contemporary design principles (Helander, 2014), and inclusive co-design with diverse stakeholders (Abid et al., 2024). Participant-facing technology in DCTs offers the chance to support diverse needs throughout the trial, acting as a true companion. Realising this potential requires technology stakeholders to rethink current approaches and intentionally design tools that sustain participant needs throughout the trial.

Limitations and future research

The insights from our interviews provide an informed starting point rather than a final or universally applicable conclusion and serve as a foundation for further exploration. Future research should examine and test how behavioural science can guide the design of remote decentralised technologies across diverse trial contexts and populations to support participant-centred experiences. Specifically, co-design activities with diverse participants groups and technology stakeholders need to be explored as a way to develop and refine functionality that reflects real-world use and lived experience. Further studies are required to test and adapt these findings across various trial contexts and populations. Longitudinal studies following participants throughout trial journeys can provide insight into evolving needs, while studies focused on training trial staff in remote engagement techniques can enhance relational support. Finally, integration of behavioural science frameworks into trial protocols and technology development warrants exploration to improve participant motivation and retention across diverse trial contexts.

Conclusion

This research suggests that DCTs have long-term viability as a trial approach. They offer an effective and acceptable model, improving access and convenience while giving participants comfort, autonomy, and empowerment. However, the socio-technical opportunities and challenges in running remote DCT trials are complex. Digital exclusion can arise not just from individuals' limited resources or abilities, but also from the design and accessibility of the technologies and infrastructures that support participation. Our findings reveal a complex and fragile participant journey shaped by the remote setting, technology, and trial participation. While remote trial models reduce some burdens, they can also introduce psychological, emotional, and practical challenges. In this context, strategies that have proven effective in traditional site-based trials, including approaches to supporting and engaging participants, may not translate effectively to decentralised trials. These challenges risk undermining the overall experience if left unaddressed, especially in the context of isolation and ill health. Clinical trials face the challenge of balancing the collection of high-quality data, ensuring regulatory compliance, maintaining participant safety, managing participant burden, and upholding scientific integrity. Without intentional focus on participants' needs, a participant-centred experience can be overlooked. Convenience alone does not guarantee a positive experience. Emotional, psychological, and practical needs shape how participants interact with trials. Designing with these factors in mind is essential to building models that are both effective and sustainable. Given these complexities, a human-centred approach that emphasises participants' experiences is essential in decentralised trials. Approaching technology as a relational partner and trial companion, while integrating participants insights into its design, can strengthen engagement, trust, and retention. This study highlights the lived experiences of trial participants. It calls on stakeholders to respond to the findings, integrate them into design, and consider how technology might best support participant-centred experiences.

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Author Contributions: EG, and CL conceived the study. EG, CL, and CH contributed to protocol development and obtained ethics approval. EG researched literature, recruited participants, and conducted data analysis with review from CL and CH. EG wrote the first and subsequent drafts of the manuscript. All authors reviewed and edited the manuscript and approved the final version.

Ethical approval: The ethics committee of University College Cork approved this study (SREC Log umber: 2024-021)

Consent to participate: All participants provided written informed consent prior to engaging in this research.

Data Availability: In line with university guidelines and the participants' signed consent, we ensure that all data handling is conducted in accordance with ethical guidelines and confidentiality, with the study participants not granting consent to make the dataset available.

Abbreviations:

DCT: Decentralised Clinical Trials

Multimedia Appendix of supplementary files:

Supplementary Material 1 – Interview Guide

Supplementary Material 2 – Example Thematic Data Analysis

Supplementary Material 3 – Online Screener

All files are available in the Supplementary Material repository (see Appendices).

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Reflections on Chapter 5

Following the second paper, staff perspectives offered valuable insights into the delivery of decentralised clinical trials but also highlighted the limits of understanding patient experience without directly hearing from participants, making engagement with participants necessary to build a more complete picture. At this stage of the PhD, the literature had been reviewed and staff experiences examined, so participant perspectives were a natural next step. The study was exploratory, focused on understanding participants' experiences of remote, technology-mediated trials rather than evaluating specific interventions. While the work was situated within a design-oriented PhD, the aim was to develop a grounded understanding of participation in decentralised trials. This understanding was intended to inform later research stages without pre-empting specific design solutions.

Recruiting participants for this study proved extremely challenging. It took nine months to complete and required extensive outreach to pharmaceutical companies, advocacy groups, industry professionals, and my own network. Many individuals were unresponsive, unwilling to support the research, or indicated that I was on my own. Some patient advocacy groups requested financial compensation, highlighting the transactional nature of some interactions. Nevertheless, a few individuals were incredibly supportive, helping to identify participants and even participating themselves, for which I am deeply grateful. Despite this support, finding individuals who had actually participated in decentralised trials remained difficult, reflecting both the limited prevalence of these trials in Ireland and broader practical challenges of conducting academic research.

Directly engaging with participants deepened my understanding of patient experience in decentralised trials. It revealed that participants actively sought personalised engagement, exercised agency, and found participation meaningful. At the same time, it reinforced the ongoing importance of human connection and highlighted burdens associated with fragmented

support, communication challenges, and everyday workload. While participants were generally positive about remote participation, they navigated multiple practical and emotional challenges. Their perspectives added nuance to insights from staff, illustrating motivations, perceived benefits, resilience, and the context in which participation occurred. Overall, this stage emphasised the complexity of patient experience, balancing empowerment and burden, and showed how theoretical frameworks such as self-determination theory and patient-centred care can illuminate both motivations and practical realities.

Engaging directly with participants expanded my conceptual understanding of patient experience and engagement. It confirmed the centrality of human interaction and relationships while highlighting both the limits and potential of technology to facilitate connections when participants are remote. I gained insight into how autonomy and ownership extend beyond task completion to encompass meaningful participation. Many participants described feeling a sense of co-ownership of the trial and using participation to exercise meaning and control over aspects of their condition.

The study also highlighted the fragility of the participant experience. Even seemingly simple issues, such as poor communication, limited knowledge, fragmented coordination, or lack of support, could have a significant negative impact. At the same time, decentralised trials can reduce inconvenience and support autonomy, providing meaningful benefits for participants. Integrating patient-centred care frameworks with self-determination theory deepened my understanding of how participant needs, relational factors, motivation, and contextual influences interact. This strengthened the practical insights developed across the three studies and offered a richer lens for interpreting both staff and patient perspectives in decentralised trials.

Insights from this study clarified the direction for subsequent research. While the study did not aim to design interventions directly, it highlighted gaps in how both trials and technology support patient experience. Existing DCT technologies often focus on data collection rather than supporting engagement or the broader patient experience. These findings prompted me to consider how digital tools could be designed to support patient-centred approaches across diverse platforms and systems. They shaped the trajectory of my research towards exploring how insights from behavioural science, self-determination theory, and patient-centred frameworks can guide the design of trial technologies. The study reinforced the importance of providing designers and technology professionals with tools and guidance to make informed decisions, regardless of the specific technology used, emphasising the need to bridge the gap between theory, evidence, and practical design considerations.

Chapter 6: Design and Evaluation of Ideation Cards to Support the Patient-Centred Design of Decentralised Clinical Trial Technology

This article is currently in preparation: Gamble, E., Heavin, C., & Linehan, C. (2026). Design and Evaluation of ideation cards to support the patient centred design of Decentralised Clinical Trial Technology

Author Contributions: EG and CL conceived the study. EG, CL, and CH contributed to protocol development and obtained ethics approval. EG researched literature, recruited participants, and conducted data analysis with review from CL. EG wrote the first and subsequent drafts of the manuscript. All authors reviewed and edited the manuscript and approved the final version.

Abstract

Background: Despite widespread recognition of the importance of patient centricity in decentralised clinical trials, limited practical guidance exists to support technology designers' ability to genuinely embed patient needs in digital trial technologies.

Objective: This study aimed to develop and evaluate a set of Patient-Centred Design Cards to support patient-centred thinking in the ideation and design of decentralised clinical trial technologies.

Methods: The Patient-Centred Design Cards were developed through an evidence based process. Eight DCT technology practitioners participated in ideation workshops using the cards and were interviewed to explore their perceptions of the cards as a tool for patient-centred

ideation and design in DCT technology. Transcripts were analysed using reflexive thematic analysis to identify key themes.

Results: We generated six main themes: (1) A structured approach to patient experience in DCT technology design, (2) Supporting creative engagement with patient experience, (3) Bringing the patient needs into focus, (4) A credible resource for aligning teams, (5) Organisational and practical barriers to meaningful patient-centred practice, and (6) Anticipated use and impact of the cards in future DCT practice.

Conclusion: This study provides early evidence on the value of design cards as a practical tool for supporting meaningful patient-centred ideation in the design of decentralised clinical trial technologies. It highlights the role of a structured yet flexible approach in helping technology practitioners engage with and reflect on DCT participants experiences and support more patient-centred, reflective and innovative design decisions.

Keywords: Decentralised clinical trials; patient-centred design; design cards; clinical trial technology; patient experience; human-centred design

Introduction

Clinical trials evaluate the safety and efficacy of therapies or interventions (Nichol et al., 2010), generating evidence to support treatment development (Joffe & Weeks, 2002), and advancing medical knowledge (Sackett & Cook, 1994a). Traditionally, participants attended in-person study visits at clinical sites (Bhide et al., 2018a). Technology-mediated decentralised trials (DCTs) (Van Norman, 2021b) now enable remote patient access, data collection, and communication (Petrini et al., 2022), improving convenience, flexibility, and reducing logistical burdens (Adams et al., 2022a; Apostolaros et al., 2020a; Izem et al., 2024a). However, this shift from site-based, face-to-face interactions to remote, technology-mediated

engagement can introduce challenges for patient experience, participation, and retention (Alemayehu et al., 2022a; Dorsey et al., 2020a; Gamble et al., 2025b).

Regulators, sponsors, and the wider industry increasingly emphasise patient-centredness, positioning it as a central goal of contemporary clinical trial design (Santa-Ana-Tellez et al., 2023a; U.S. Food and Drug Administration, 2025). A patient-centred experience involves meeting participants' needs across all phases of the trial, from recruitment to outcome reporting (Getz, 2015; Li et al., 2022a). Past research has highlighted core elements of patient-centred care (Greene et al., 2012; Kitson et al., 2013; Mead & Bower, 2000c; Scholl et al., 2014), yet DCT technologies are often designed primarily to optimise data collection and operational priorities (Gamble et al., 2025b; Rogers et al., 2022). Socio-technical theory underscores the risks of such misalignment, showing that when technical systems are not integrated with social and human needs, user experience and engagement suffer (Scacchi, 2004). Similar patterns have been observed in other sectors, such as global software development, where introducing new technologies altered collaboration and interaction dynamics (Herbsleb & Mockus, 2003), raising concerns about the loss of social and human elements that are critical to the patient experience (Greenhalgh et al., 2020).

To address these challenges, we developed a set of cards intended to support reflection, discussion, and decision-making focused on patient experience in DCT technology. The study is guided by the following research question: How do DCT technology practitioners perceive the Patient-Centred Design Cards as a tool to guide reflection on patient centricity, ideation, and design? Our contributions are two-fold: (i) the Patient-Centred Design Cards as an evidence-based tool to support patient-centred ideation and design decisions across the DCT journey, and (ii) an analysis of DCT technology practitioners' perspectives on the cards, providing insights into their perceived value, role in guiding ideation and design decisions, and the challenges of integrating patient-centred approaches into technology practice.

Patient Centredness

The concept of patient-centredness is increasingly recognised as essential to the design and delivery of robust clinical trials. Broadly, it refers to addressing patients' needs across all phases, from initial design and enrolment, through data collection, to outcome reporting (Li et al., 2022a). Closely tied to this is the concept of patient experience, defined as the sum of all interactions shaped by an organisation's culture that influence patient perceptions across the continuum of care (Planner et al., 2019; Wolf & Jason, 2014a), and as the factors that shape participation and engagement throughout a clinical trial (Dobra et al., 2023a). These factors support more inclusive, acceptable, and effective research and trials (Getz, 2015). Evidence suggests that enhancing patient experiences can lead to greater engagement, higher satisfaction, improved retention, better adherence to trial protocols, and stronger financial performance for trials (Carli Lorenzini & Olsson, 2022; Dewulf, 2015; Gul & Ali, 2010a; Levitan et al., 2018). However, there is a lack of a formal definition of patient experience in the clinical trials (Planner et al., 2019). Regulatory bodies increasingly emphasise patient centricity, particularly through patient-focused drug development initiatives (U.S. Food and Drug Administration, 2025), encouraging trial designs that reflect participants' needs, preferences, and lived experiences (Santa-Ana-Tellez et al., 2023a). Major pharmaceutical companies, including Johnson & Johnson, GSK, Pfizer, Bayer, Sanofi, and AstraZeneca, have incorporated patient-centred approaches into their development strategies (Katsanis et al., 2021). Patient-centred frameworks highlight responsiveness to individual experiences (Weston et al., 1989a), different forms of patient well-being (Kuipers et al., 2019), personalised care (Lewis, 2011), positive patient–clinical team relationships (Zhao et al., 2016a), human connection in care (Sharp et al., 2016), and the trust that these interactions build (Ferguson et al., 2013). Digital technologies are increasingly acknowledged as essential to patient-centred research (Gregg et al., 2020; Stergiopoulos et al., 2020), with growing calls for the industry to align technological innovation with the wider patient-centric agenda (Sharma, 2015).

Decentralised Clinical Trials (DCT)

Decentralised clinical trials (DCTs) have emerged partly in response to the growing focus on patient-centricity. They use digital tools to enable participation outside traditional trial sites and are often argued to be inherently patient-centred (Rogers et al., 2022). Technology supports data collection and communication with trial sites and enables assessments at home, as well as interactions through mobile apps and computers (De Brouwer et al., 2021; Moore et al., 2022). This shift from face-to-face to remote interaction facilitates the key trial elements, including recruitment, intervention administration, study visits, outcome assessments, and data collection (Alemayehu et al., 2022a; de las Heras et al., 2022a; Dorsey et al., 2020a; Hirsch et al., 2017a). These technologies aim to improve convenience and flexibility for participants (Apostolaros et al., 2020a; Izem et al., 2024a), increase efficiency, reduce burden (Hanley et al., 2023a), and enable passive data collection (Dorsey et al., 2015a). While DCTs improve convenience and efficiency (Garjani et al., 2023; Khozin & Coravos, 2019), the shift from site-based to technology-mediated interactions can weaken relational and experiential elements that are central to patient-centred care, affecting engagement, retention, and overall experience (Gamble et al., 2025b, 2026). Evidence from participants and research staff further indicates that remote, technology-mediated interactions often lack personalisation, weaken interpersonal connections, and increase staff burden (Gamble et al., 2023a, 2025b, 2026). These relational deficits are closely tied to engagement and retention, underscoring the urgency of embedding patient-centred principles directly into DCT technology design. *"They don't get the patient-centric experience. That's what I'm trying to tell you. ….. these things are set up from a data management and a project management point of view, never from a site or a patient's point of view…So we are calling it patient centric. But the device is literally shoved down my throat, and then they go, is it patient centric?"* (Gamble et al., 2025b). These challenges illustrate a critical gap: while DCT technology facilitates participation, it does not inherently ensure that trials are patient-centred in practice, leaving technology designers without practical guidance

to translate principles into usable technology. These gaps in patient-centred implementation highlight the need for tools that support deliberate design decisions, ensuring technology both meets operational goals and patient experiential needs.

Designing tools that support ideation /design work

Developing tools to support ideation and guide design has become a common practice in design research and human-computer interaction (HCI) (Peters et al., 2021). Design tools help translate abstract concepts and academic research into more actionable guidance, particularly during the early stages of design and ideation. A variety of tools have emerged to support ideation, design thinking, and decision-making, grounded in theoretical frameworks and research. These include design cards based on frameworks (Lucero & Arrasvuori, 2010), models (Nadal et al., 2022), and theroy (Bekker & Antle, 2011; Konstanti et al., 2022). Design cards have gained popularity as practical aids for creativity, collaboration, and critical reflection, providing a tangible format for integrating inspiration and key knowledge into design (Lucero et al., 2016). Cards typically include creative prompts, human insights, user perspectives, and practical methods (Hsieh et al., 2023), often with keywords, visuals, or open-ended questions to stimulate discussion (Bornoe et al., 2016). Other principles include clear textual descriptions, simplified visuals, and real-world examples (Perez et al., 2019), and cards are often designed to be visually appealing, abstract, and flexible across contexts (Aarts et al., 2020).

When used effectively, these tools support idea generation while also encouraging reflection as shown by more focused thinking, clearer direction, and more deliberate, informed design decisions. The literature highlights several indicators of successful application of the cards. For example, cards can clarify and focus the direction of design work (Lucero & Arrasvuori, 2010), facilitate communication across teams (Lafrenière et al., 1999), and support users in articulating and generating ideas (Bornoe et al., 2016). They are especially useful in

early ideation phases, where divergent thinking and exploration are most needed (Hsieh et al., 2023), and have been shown to encourage creative thinking (Peters et al., 2021). Beyond these, cards can promote empathy and support engagement (Sleeswijk Visser et al., 2007), provide inspiration for new directions of exploration (Hsieh et al., 2023), all of which are indicators of successful reflection and ideation in practice.

In addition to supporting individual and team ideation, design cards also play a crucial role in fostering shared understanding among stakeholders, aiding collaboration and alignment during the design process (Kwiatkowska et al., 2014; Logler et al., 2018). This collective engagement can further reinforce reflective thinking, especially when teams are required to justify or adapt design decisions. By making theoretical insights more accessible, design tools like this help turn abstract ideas into tangible, actionable elements of the design process (Dalsgaard & Dindler, 2014; Velt et al., 2020). Cards can be used in a range of scenarios including working independently, part of a collaborative team, or involving clients and users in the process (Tseng, 2020).

To address these gaps, this study introduces the Patient-Centred Design Cards, which operationalise abstract patient-centred principles into actionable DCT technology design decisions. These cards focus specifically on patient centred experience in DCT contexts, bridging the gap between abstract principles and concrete technology design decisions. By prompting reflection on patient centric experiences, the cards guide teams in identifying design gaps and embedding patient-centred thinking throughout ideation and development, ensuring technologies support engagement, continuity, and holistic care.

Methods

Design and Development of Cards

Key concepts and literature used for cards

The card-based format was chosen to help practitioners interpret, negotiate, and apply patient-centred considerations within the practical constraints of decentralised trial technology design ideation. Our development process was informed by two empirical studies on patient-centred experiences in decentralised clinical trials (Gamble et al., 2025b, 2026), alongside established frameworks and reviews of patient-centred care that outline core principles and dimensions of patient centredness (Berwick, 2009; Greene et al., 2012; Grover et al., 2022; Hughes et al., 2008; Jardien-Baboo et al., 2021b; Kitson et al., 2013; Langberg et al., 2019a; Lusk & Fater, 2013; Mead & Bower, 2000c; Santana et al., 2019; Scholl et al., 2014; Shaller, 2007; Sturgiss et al., 2022; Wolfe, 2001) and empirical research on patient experience in clinical trials (Boyd et al., 2024a; Gregg et al., 2020). As patient-centred care in healthcare does not always translate directly to trial context. Supplementary Material 1 presents a table overview of the 20 factors included in the final card set, including their definitions and sources.

Design philosophy and underlying assumptions

The following design philosophy and underlying assumptions guided the creation of the cards, reflecting values around patient-centred, reflective, and flexible design. The design cards aim to sensitise participants to patient-centred considerations rather than providing direct answers. Rather than prescribing specific solutions, the cards are crafted to inspire interpretation and provoke reflection. This approach allows participants to generate their own ideas, engage in discussion, and make connections relevant to the design task (Alkhuzai & Denisova, 2021). Patient-centredness is conceptualised as interpretive and context-dependent, shaped through stakeholder judgement rather than a fixed checklist or procedural outcome. The cards were designed to support use across a range of roles involved in decentralised clinical trial technology design, including product teams, innovation functions, trial operations, and

strategic decision-making. This broader applicability reflects the intention that the cards support deliberation across multidisciplinary perspectives, enabling richer discussion and shared interpretation during design activities.

Cards design context and constraints

Rather than being tied to specific systems, platforms, or current technical capabilities, the cards focus on explaining broad patient experience considerations. This reflects the diversity of technologies, infrastructures, and constraints that shape decentralised clinical trials in practice, including differences in technical ecosystems, regulatory environments, and degrees of access to patients and clinical sites (Sinha et al., 2024). Anchoring the cards in specific solutions or technologies would have limited their relevance across these varied conditions.

Cards design principles

The cards aim to support a design approach that encourages creative exploration, consideration of ideas, and supports creative thinking within the broader design process (Roy & Warren, 2019). The cards focus on experiential needs, helping teams integrate patient-centred considerations while working within the constraints of their own systems and workflows. Their interpretive nature ensures that the cards can be adapted across different trial types, technologies, and organisational conditions, supporting flexible application. The cards prioritise experiential focus over system functionality, reflection (Hsieh et al., 2023) over prescribed guidance, and flexibility (Roy & Warren, 2019) over rigid procedures. Their adaptability allows them to be used non-linearly across different contexts, making them suitable for a variety of tasks and design problems (Nurain et al., 2024; Roy & Warren, 2019). The flexibility of the cards supports use by multidisciplinary teams and individuals with varying roles and levels of expertise, enabling them to operate as flexible tools rather than rigid step-by-step artefacts (Roy & Warren, 2019). These values directly informed the design of the

cards, resulting in guidance and prompts that are interpretive, adaptable, and focused on experiential patient needs rather than system-specific instructions.

Practical modes of use of cards

The cards would be most effective when used in a team based collaboration setting (Roy & Warren, 2018), such as early prototype or concept development, but can also be used at later stages of implementation or as part of review sessions evaluating an existing system (Hsieh et al., 2023). Cards can be used in a range of scenarios including working independently, collaboratively, or with clients and users (Tseng, 2020). Participants can review the cards individually or in a group, reflecting on patient-centred implications, sharing perspectives, and collectively exploring how the insights might inform design decisions. A typical session may involve participants selecting cards individually or in small groups, discussing the prompts and reflective questions, combining related cards to explore broader themes, and identifying priorities for design. Usage in a group setting is recommended to maximise discussion and ensure reflection remains focused (Mosely et al., 2021). Facilitation can help participants navigate the interpretive nature of the cards, resolve ambiguities, support collaboration across multidisciplinary teams, and encourage deeper reflection by prompting discussion and helping participants explore multiple perspectives (Aguirre et al., 2017; Mosely et al., 2021). The cards are also suitable for individual use when time or resources are limited, with prompts supporting self-directed reflection, allowing practitioners to engage independently. The effectiveness of the cards depends on users having sufficient time, contextual knowledge, and willingness to engage in interpretive reflection. In contexts with limited time, reduced expertise, or minimal opportunity for discussion, the depth of insight generated may be constrained. Their value is therefore closely linked to the degree of engagement and interpretive effort applied during use.

The cards design approach

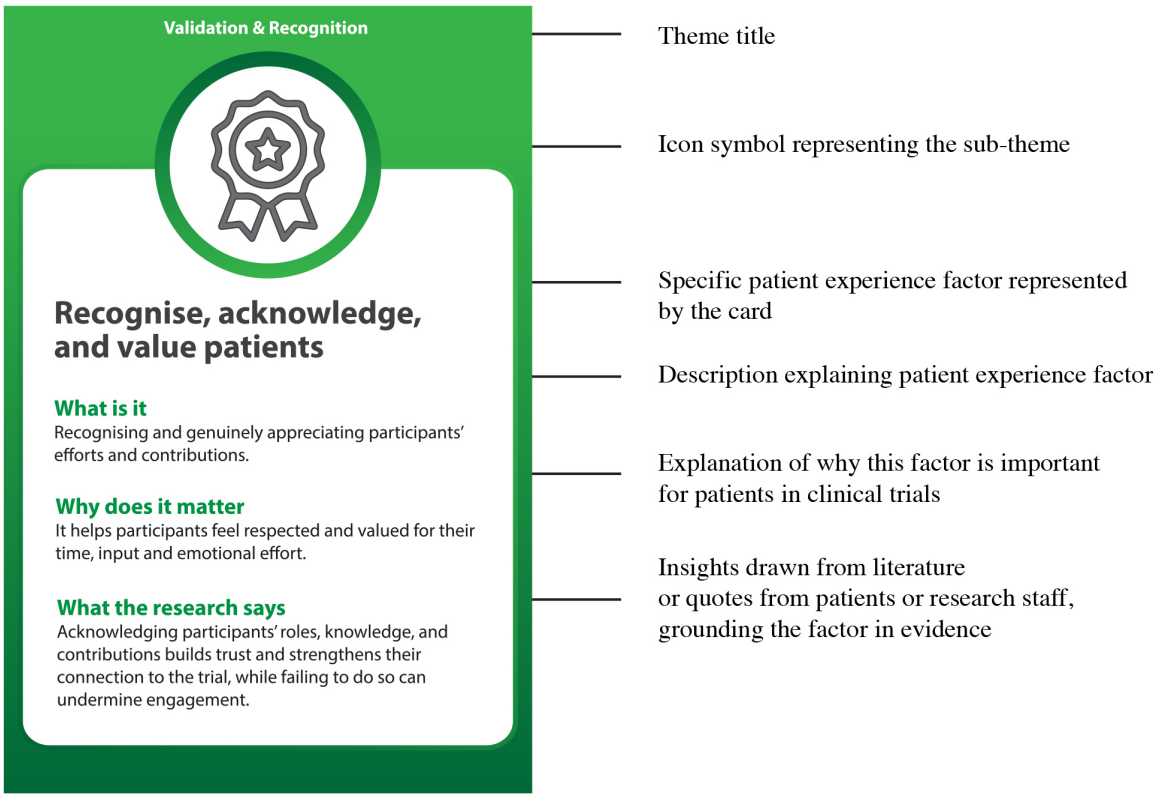
The design approach aimed to make conceptual frameworks accessible and support the translation of research into practical applications (Nurain et al., 2024; Shin et al., 2024) and empirical findings into actionable design knowledge (Sas et al., 2014). It encompasses various types of design knowledge, including insights, methods, and means for ideation (Hsieh et al., 2023), while offering creative stimuli and domain-specific guidance (Roy & Warren, 2018). Each card in the deck highlights a factor that influences a patient-centred experience. The design goal was to create a visually appealing yet flexible artefact (Aarts et al., 2020). Following visual design considerations for organising cards and established heuristics (Alkhuzai & Denisova, 2021), the card set comprises 20 patient experience sub-themes organised into seven overarching categories: human-centred interactions (red), trust & safety (yellow), validation & recognition (green), competence & confidence (pink), autonomy (purple), seamless and integrated experience (blue), and supportive environment (orange). Each sub-theme was assigned to the category most closely aligned with its definition, supporting intuitive navigation and helping participants understand how individual factors relate to broader aspects of patient experience. These structural and visual choices were intended to enhance consistency of interpretation across the deck while making the relationships between sub-themes and categories easier to understand. Following Alkhuzai and Denisova's design card heuristics (Alkhuzai & Denisova, 2021), colour and layout were used to differentiate categories, including tilted and colour-coded cards. Together, these decisions provide a coherent framework for organising the 20 sub-themes and support both usability and interpretation (see Table 1). The cards' design, based on playing cards, was intended to make them easy to handle and interact with, supporting user engagement.

Table 1: Patient-centred themes, definitions, and sub-themes

Main Theme	Definition	Sub Themes
Human-centred interactions (Red)	Focuses on relationships, making trials more human. It's about making interactions feel personal, connected, warm, empathetic and meaningful rather than transactional.	• Fostering positive staff-patient relationships • Humanising trial interactions • Recognising the whole patient • Personalising interactions, information and engagement • Being responsive and attentive to patients
Trust & Safety (Yellow)	Focuses on protection, observation, and reassurance. So, patients feel secure, their wellbeing is safeguarded, and the trial team can monitor and respond effectively.	• Observing and monitoring the patient and experience
Validation & Recognition (Green)	Highlights acknowledgment, respect, and appreciation. So, patients feel heard, valued, and recognised for their effort and contributions.	• Giving the patient a voice • Recognising, acknowledge, and value patients
Competence & Confidence (Pink)	Targets knowledge, skills, and understanding. Keeping patients informed, educated, and confident in their ability to participate successfully.	• Sharing updates, information and feedback with patients • Providing education • Supporting participant understanding
Autonomy (Purple)	Centres on choice and control so patients can actively shape their participation, with flexibility and options that adapt to their preferences and circumstances.	• Giving patients flexibility, options and control • Making trial materials and systems accessible • Designing for convenience
Seamless and Integrated Experience (Blue)	Emphasises efficiency, coordination, and convenience. Reduces friction in processes, aligns clinical parties, and ensures the trial is smooth and manageable.	• Efficiency and streamlining • Coordinating trial teams and systems • Ensuring continuity across trial teams
Supportive Environment (Orange)	Focuses on emotional and social support. Encourages and assists participants proactively and reactively, creating a welcoming, positive context. Inclusive of support networks.	• Supporting participants when they need it • Fostering a positive environment • Including support networks

Figure 1: Examples of the front and back of the Patient-Centred Design Cards.

Front of Card (Information Side) - Explains the concept and evidence



Back of Card (Ideation Side) - Applying the insight in design

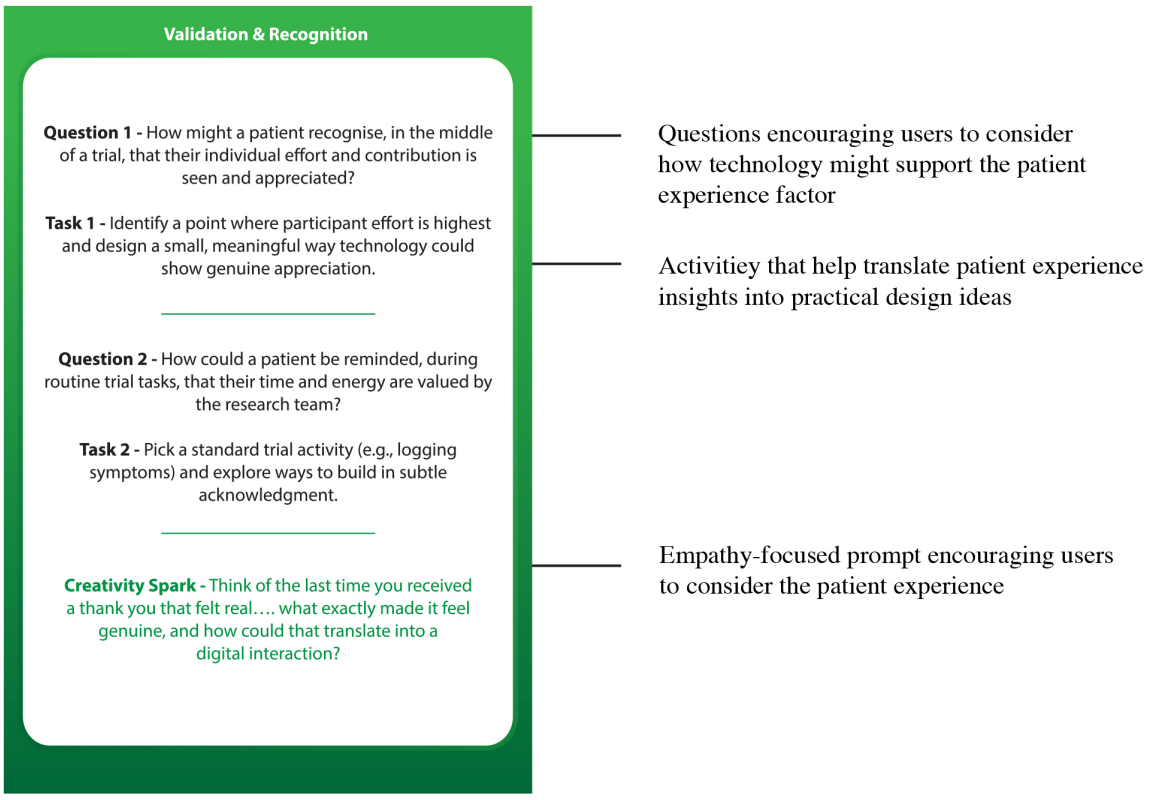


Figure 2: Examples of the Patient-Centred Design Cards.



Front of cards rationale

This front side of the cards presents concise title descriptions of the patient experience sub theme, organised around three guiding questions: What is it? Why does it matter? and What the research says. This format was chosen to give users an immediate understanding of each factor's meaning and relevance while grounding it in evidence. Each card has a clear, descriptive title summarising the patient experience sub-theme. The title allows participants to quickly identify the card's focus, distinguish it from others, and provide a consistent anchor for discussion and reflection. The first description, the What is it section, defines the patient experience sub-theme in clear, actionable terms. Providing a precise description aims to support participants immediately identify the focus of the card and situates the concept within the broader context of decentralised clinical trials. The second description, Why does it matter, explains the significance of the factor, connecting to patient-centred outcomes. By articulating why the sub-theme is important, the aim is for workshop participants to understand its relevance to both patient experience and design decisions. The What the research says description anchors the card in empirical evidence, literature findings, or observations from prior studies, including quotes from trial staff or patients. Presenting real-world insights ensures the factor is not treated abstractly, providing credibility and supporting informed design decisions. Collectively, these groupings aim to guide users from conceptual understanding (What is it) to relevance and importance (Why does it matter) and finally to evidence-based grounding (What the research says). By presenting the information in a consistent, digestible structure, users can quickly familiarise themselves with the factors and use them as a basis for idea generation and shaping design concepts.

Back of cards rationale

The other side of the card provides design-prompt questions (Roy & Warren, 2019) and tasks to make the patient experience factors actionable, helping users think practically about how technology can respond to patient needs. These questions aim to guide participants to consider

the patient experience factor in the context of real-world design problems, and encourage participants to analyse existing systems, anticipate potential gaps in patient experience, and identify ways technology could support patient needs. The tasks questions are intended to make the patient experience factors actionable, helping users think practically about how design decisions could translate into features or workflow improvements. These prompts aim to encourage reflection on these sub-themes in the context of specific trial moments and challenge users to translate patient experience insights into concrete ideation solutions. Because empathy is an important element in experience design (Wright & McCarthy, 2008), the creativity spark question prompts users to consider situations from a more empathetic perspective, encouraging a deeper consideration of patients' experiences. These prompts are designed to engage participants' imagination and empathy by inviting reflection, consider emotional impacts, and subjective experiences. Overall, these activities are intended to stimulate ideation, guide ideation, and help users explore ways technology can actively support a patient-centred experience. The combination of structured design-prompt questions and creativity spark activities aims to balances analytical thinking, practical application, and creative exploration.

Iterative development process of cards

Building on prior work with card-based design methods, the card set evolved through repeated cycles of discussion and revision (Darzentas et al., 2019; Van Bogart et al., 2023) to improve clarity and usability. Categories and structures were adjusted based on feedback and reflection. This iterative process ensured that the cards remained usable, understandable, and aligned with their intended purpose.

Longevity and adaptability of cards

The content of the cards was intentionally kept broad to ensure relevance across different trial types, technologies, and evolving contexts (Badani et al., 2025; Rosa et al., 2021). By avoiding reliance on specific systems or platforms, the cards maintain applicability even as technologies

and infrastructures change. This design decision supports long-term usability and adaptability within decentralised clinical trial environments.

Scope and limitations of cards

While the cards are designed to guide reflection and ideation, it is important to clarify what they are not intended to do. They do not provide ready-made solutions, act as decision rules, or undermine the value of user research or co-design activities (Hassenzahl & Tractinsky, 2006; Meskó & deBronkart, 2022). Rather, the cards are intended to be used alongside established technology design approaches. Similarly, the cards are not intended to override practical or operational constraints within a trial. Design decisions must be grounded in the realities of trial implementation, regulatory requirements, and organisational context. The cards can complement, rather than replace, established patient-centred approaches (Lamberti & Awatin, 2017; Plessis et al., 2017; Shippee et al., 2015; Tong et al., 2022), and may be integrated with other methods to support robust outcomes. They are not evaluation tools, nor are they intended to prescribe correct or optimal design solutions. Instead, they function as reflective prompts that support interpretation and deliberation rather than assessment or decision enforcement.Team composition is also important, and for the best results, engagement with people from different disciplinary backgrounds and some familiarity with design, technology, or patient experience and DCTs would be beneficial (Jean-Louis & Seixas, 2024; Krause-Jüttler et al., 2022). When using the cards, the scope of insight is another important consideration; the cards highlight factors that support patient-centred experiences but do not cover all possible factors and are not a substitute for broader organisational, regulatory, or operational analysis.

Evaluation Methodology

We used a qualitative approach in this study to evaluate the design cards as an innovation tool, with the aim of understanding our study participants' experiences of using them and their views

on how the cards could support the design of technologies that promote patient-centred trial experiences.

Study participants

We recruited a purposive sample of eight product leaders with experience in DCT technology to participate. The sample included three women and five men from the USA, Ireland, and the UK, with expertise spanning product leadership, product strategy, technology design, product management, and clinical trial conduct. All were professionally familiar with patient centricity and regarded it as an important concept within their DCT organisation. Recruitment was via an existing professional network of DCT experts. An overview of the participants is provided in Table 2.

Table 2: Summary of Study Participants - Overview of interviewed participants (all names are pseudonyms).

Role	ID	CT Experience	Gender	Geography
Senior Designer	Tony	10 years	Male	Ireland
Director Product	Mike	10 years	Male	USA
Director Strategy	Jessica	25 years	Female	UK
Director Product	Susan	15 years	Female	USA
Head of Product	Robert	15 years	Male	USA
Senior Manager Consulting	Ciara	20 years	Female	Ireland
VP Product Strategy	Frank	20 years	Male	UK
Senior Designer	Brian	8 years	Male	USA

Process for introduction to cards and ideation workshop

The ideation session was conducted as a one-to-one workshop lasting approximately one hour. Participants received all study materials in advance, including a scenario, persona, and explanatory documents for the design cards. At the start of their workshop, the researcher

reviewed the purpose of the cards and discussed the concepts they represented. Due to time constraints, participants were given six cards in advance of the workshop, and asked to select three to focus on during the session. Participants worked individually, selecting cards and articulating ideas and concepts aloud. The researcher engaged interactively throughout, asking and clarifying questions, prompting participants to elaborate on emerging ideas, and exploring the ideas. Discussions often included reflections on the implications of particular ideas and their potential impacts. This interactive facilitation supported participants in thinking more deeply about each concept, refining and expanding ideas in a flexible, iterative manner.

Supporting tools

To complement the patient-centred design cards, participants were provided with a small set of supporting tools to guide engagement and reflection. A patient persona document was provided to illustrate a participant in a DCT, highlighting their needs, motivations, potential challenges and grounding the participants' thinking (see Supplementary Material 3). Personas are widely used in design to maintain focus on user needs and inform decision-making (Miaskiewicz & Kozar, 2011; Pruitt & Adlin, 2006). Study participants were provided with a document to guide engagement with the patient-centric design cards (see Supplementary Material 4). The document outlined the context of the exercise, namely the design of digital tools to enhance patient-centred experiences in decentralised clinical trials and provided instructions for how to use the cards. It explained the structure of the cards, describing the concept side (intended to support understanding of patient-centred principles) and the action side (designed to prompt reflection, tasks, and creative ideation).

The document included a scenario to provide context and frame the environment for technology ideation. It described a common trial interaction, showing how a patient might experience the trial journey and where technology could support or hinder care. Scenarios help designers explore context-specific solutions and anticipate real-world use (Carroll & Rosson,

1990). The document also clarified that the exercise was exploratory, aimed at generating ideas rather than producing polished solutions, and encouraged participants to engage with the cards and prompts in a flexible, creative manner. While these elements were provided to inform ideation and design considerations, they were not the primary focus of our research, and their use was neither analysed nor evaluated within this study.

Data collection

Directly after each individual workshop, participants were interviewed to explore their experiences using the design cards and their perspectives on how the cards could support the design of technologies promoting patient-centred trial experiences. The interviews were conducted online via Microsoft Teams between 1 October and 1 November 2025, to accommodate participants' schedules and locations. Each interview was led by the first author and lasted approximately 40 minutes. An interview guide (see Supplementary Material 5) was used to ensure consistency across interviews while allowing participants to share their perspectives freely. The guide was developed based on the concepts presented in the design cards and goals of the design cards. Interviews were recorded, transcribed via Microsoft Teams, and checked for accuracy by the first author. All recordings were anonymised. Participation was voluntary, and the study received ethical approval from the Social Research Ethics Committee at University College Cork (Log 2024-301, 29 May 2025).

Data analysis

Data were analysed using Braun and Clarke's six-phase Reflexive Thematic Analysis (RTA) framework (Braun & Clarke, 2021a). RTA was chosen for its suitability in exploring participants' subjective experiences and capturing patterns in their reflections. The first author led the initial coding of the data, identifying codes and potential themes relevant to the research questions. These preliminary interpretations were then refined collaboratively through discussions with a co-author, resulting in a consensus on the final thematic structure. In the

first phase, the first author familiarised themselves with the data by transcribing the interviews, reviewing the video recordings, and reading the transcripts multiple times, noting early observations and reflections. Phase two involved generating initial codes to capture meaningful patterns across the dataset. During phase three, codes were organised into candidate themes, which were iteratively reviewed against the data to ensure clarity, specificity, and strong alignment with participants' contributions. Phase four focused on refining and reviewing themes, with collaborative discussion supporting the challenge and clarification of interpretations, leading to coherent main themes and sub-themes. In phase five, themes were clearly defined, labelled, and structured into a final thematic framework, with names reflecting the participants' experiences accurately. Finally, phase six consisted of presenting the analysis, supported by detailed narrative descriptions and illustrative participant quotes, grounding the findings firmly in the data.

Findings

Our findings are structured around six themes: (1) A structured approach to patient experience in DCT technology design, (2) Supporting creative engagement with patient experience, (3) Bringing the patient needs into focus, (4) A credible resource for aligning teams, (5) Organisational and practical barriers to meaningful patient-centred practice, (6) Anticipated use and impact of the cards in future DCT practice. Each theme has several sub-themes, as illustrated in Figure 3.

Theme - A structured approach to patient experience in DCT technology design

The design cards provided a structured approach for guiding reasoning in patient-centred technology design. They helped participants organise complex information, prioritise considerations, and navigate challenges systematically. The cards acted as cognitive anchors, supporting methodical engagement at the individual level while offering a shared reference for teams to ensure consistent attention to patient-relevant elements without prescribing solutions.

Sub Theme - Cognitive scaffolding for patient-centred design

Participants noted how the cards' structure supported cognitive processes, acting as anchors that clarified pathways for decision-making, organised complex information, and reduced ambiguity in navigating design problems. They emphasised how the structured sequence, layout, and segmentation of the cards guided their reasoning from general concepts to specific considerations, allowing a methodical approach to design challenges while retaining flexibility to explore solutions. Both the front and back of the cards were noted as useful: they provided concise contextual explanations, highlighted key actions, and supported structured thinking without being restrictive. Participants noted that the structure helped consider trade-offs and multiple perspectives while staying focused on patient-centred objectives.

> *"But the questions and the tasks and the creativity spark. I think tied it together nicely and provided direction of how I was supposed to think of this theme…..I think that's where for me the value really comes in, it is the is providing a framework."* – Frank

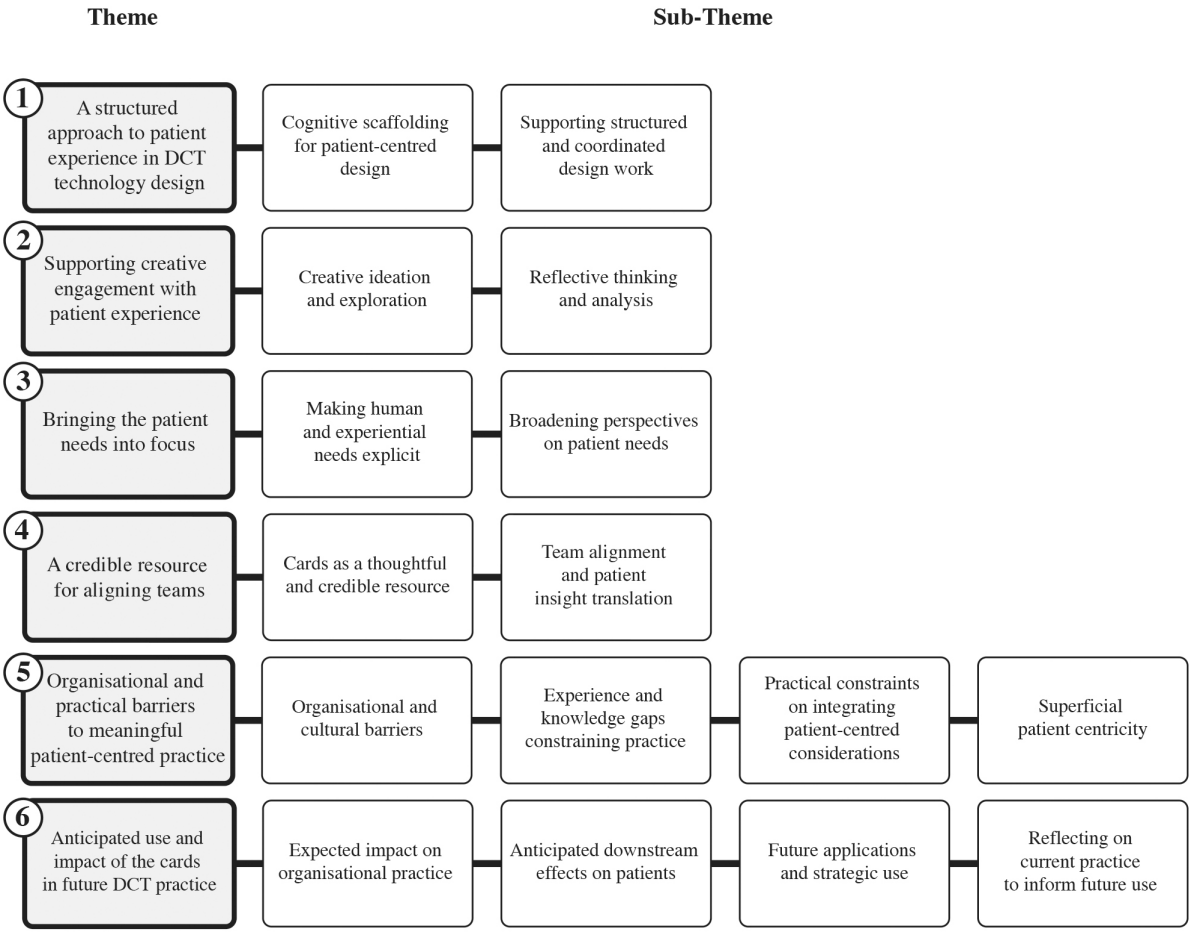
Sub Theme - Supporting structured and coordinated design work

The cards were considered a practical tool that could enhance coordinated and design activities. Participants highlighted that the organisation of, and explanations in the cards might serve as reference points and shared touchpoints, helping team members navigate workflows, maintain clarity across tasks, and align perspectives across roles during practice. Some suggested that the cards could support efficient early-stage practice and integration with existing team processes, fostering design approaches that were actionable and patient-focused.

> *"I think they provided a framework of what my idea should try and solve, but I don't think it necessarily hindered my thought process, nor did it kind of kind of boost it in any certain direction. It just allowed me to focus in on one aspect and kind of kept it on*

theme, so I didn't branch out too much and lose sight of what I was trying to solve." – Mike

Figure 3: Findings -Theme and Sub themes



Theme - Supporting creative engagement with patient experience

Participants reported that the design cards supported creative, idea-driven, and reflective thinking during workshops and could inform future technology design. The cards were described as helping generate novel ideas, consider multiple perspectives, and critically examine assumptions, supporting structured individual thinking while offering potential benefits for collaborative exploration.

Sub Theme - Creative ideation and exploration

Participants noted the design cards acted as catalysts for creative thinking, translating familiar experiences into novel contexts and generating ideas that might not have emerged spontaneously, while providing concrete examples, simplifying concepts and offering a fresh approach to ideation. The prompts were appreciated for their clarity, relevance, and actionability, stimulating novel thought processes. The cards also supported shaping ideas during the session by guiding exploratory thinking and highlighting key concepts. They encouraged critical engagement with assumptions, helped maintain focus on ideation, and highlighted nuanced considerations of potential solutions, which they reported would enable the development of practical and implementable concepts. The participants noted the structure and prompts enhanced the overall quality of their ideation, guiding a more deliberate and progressive exploration of possibilities.

> *"I find that they definitely get the juices flowing…. I found that they were a perfect springboard for jumping into the ideation process."* - Tony

In addition to individual ideation, the cards could facilitate broader exploration of potential solutions, prompting participants to consider alternatives beyond initial assumptions and follow a theme-first approach. This was seen as fostering divergent thinking, integration of multiple perspectives, and non-linear problem-solving. They highlighted the possible role of the cards for collaborative exploration, noting that the structured framework aligned team thinking, encouraged contributions from multiple participants, and enabled shared solutions, supporting both individual and group-based ideation.

> *"I said earlier, it would be a great way to run a meeting. a creative, value added, quality meaningful, next steps meeting."* – Robert

Sub Theme - Reflective thinking and analysis

During the workshop the cards were seen as a way to foster structured, reflective thinking and analysis, and seen as a way of supporting richer and more layered conversations. They provided a built-in reflective loop, encouraging participants to consider multiple aspects of the design process, including personal experiences, broader perspectives, and unmet needs, while organising reasoning and promoting thoughtful interpretation rather than directly going to task execution. The cards acted as prompts for deeper analysis, challenging professional assumptions, supporting critical engagement, and encouraging pauses to evaluate ideas before ideation and consider alternative solutions.

> *"I was referencing the middle card and the first card to kind of check if I was aligned. And I think that was helpful as opposed to just getting a question and a task. I think having all three cards and looking back and refreshing myself to see what the theme was and if my answers were on track."* - Brian

They noted the interdependent nature of the cards, which complemented one another and promoted integrative thinking. This enabled exploration of multiple directions under a common theme and enhanced the overall quality of creative and reflective practice. The approach struck a balance between structure and flexibility. The cards helped participants stay focused on design objectives while allowing space for individual judgement and supporting an iterative, systematic approach.

> *"I mean there's the individual cards on their own did a really nice job of it. When you start putting them together, the creativity of bouncing back between cards, I would read one and I'd be like I had a thought linked to another. not to mention if I've been taking notes, I definitely would have been drawing arrows and connecting things between them."* - Robert

Theme - Bringing the patient needs into focus

Participants reported that the cards influenced how patient needs were understood and prioritised by making experiential, emotional, and human considerations more explicit. These considerations were brought into active focus and shaped how participants interpreted patient experience. The cards supported sense-making around patient needs, with participants suggesting this reframing had relevance in broader technology development beyond the immediate design activity.

Sub Theme - Making human and experiential needs explicit

During the workshop, the cards helped surface human, experiential, and emotional considerations for decentralised trials, including emotions, interactions, and moments of friction, which often remain implicit or secondary to operational concerns. By outlining patient-centricity into recognisable elements across the participant journey, the cards supported a more grounded understanding of patient-centred design without presenting these considerations as new or corrective.

> *"I suppose someone that's looking to design a DCT platform and wants it as patient centric as possible, I think from the cards I have seen, that it's making it as humanised and as equal to attending an on-site visit, and that all their needs are met."* - Ciara

Participants described that the cards encouraged a more holistic view of the participant experience, prompting attention to cumulative and interconnected needs, recognising emotional and functional factors, and acknowledging tensions between trial priorities and participant needs. They suggested that this reframing could support a shift from viewing patient-centredness as a set of discrete principles to understanding it as an integrated perspective that cuts across the entire trial experience.

> *"If you have those cards and you are forced to think about those user requirements from a participant lens."* – Jessica

Empathy also emerged as a mechanism activated using the cards during the workshop, fostering deeper engagement. Rather than eliciting empathy as an emotional response alone, the cards supported reflection on participant experiences through structured reflection and repeated exposure. They prompted participants to place themselves in the patient's position, consider assumptions underlying design choices, and reflect on how decisions might be experienced over time.

> *"They helped guide my consideration of how they may be feeling or how they're interacting with the platform, so it was a different starting point…… I could just imagine these being used as you know, a starting point to build empathy, just like we use user personas and user journeys."* - Brian

Sub Theme - Broadening perspectives on patient needs

The cards were described as offering a different starting point for design thinking, one that foregrounded sense-making rather than immediate problem-solving. They structured engagement with patient considerations in a way that was fundamentally different from usual practices. By introducing new questions and encouraging consideration from multiple angles, the cards supported re-examining how patient needs were defined and prioritised. This process was seen as likely to sit alongside existing work practises, influencing how technology practitioners might approach challenges and interpret design constraints.

> *"It provided me with questions that I've never asked myself before when thinking about what is a patient experience during a clinical trial."* - Mike

The cards encouraged a deliberate pause before solution generation during the sessions, prompting higher-level consideration of patients' experiences and perspectives before narrowing into specific ideas. This approach supported active sense-making and enabled practitioners to consider previously overlooked elements of patient experience. Some practitioners suggested this reframing could disrupt habitual, solution-first approaches

traditionally taken in tech companies and support a more exploratory mode of thinking in which assumptions could be questioned and alternative perspectives considered.

> *"I think people who have been involved with various different technologies along the way and have seen it done may fall into that trap of 'this is the way we've always done it' or this is how we've done it before, but the cards can help challenge that."* - Susan

Participants also emphasised the perceived novelty of the cards, not only in their format but in the way they structured engagement with the patient experience. Despite their novelty, participants felt the cards were not difficult to use or challenging to adopt in practice, and they reported no barriers to integration into industry practices, noting that the cards could realistically fit into existing workflows.

> *"I don't see any reasons why anybody would have any impediments to using these."* - Tony

Theme - A credible resource for aligning teams

Participants viewed the design cards as a credible, research-informed resource that could support individual reflection and team collaboration. They suggested the cards might help teams align around patient-centred priorities, improve communication across roles, and translate participant insights into actionable design decisions. By combining evidence-based guidance with practical applicability, the cards were seen as providing a structured research led approach to engage with design challenges while keeping patient considerations central.

Sub Theme - Cards as a thoughtful and credible resource

Participants acknowledged that the cards reflected a substantial research-informed effort, combining evidence-based insights with experiential knowledge to support engagement with design challenges. The thoughtfulness and depth of the cards reinforced their credibility and gave some participants confidence in the cards as a guide for design reasoning. Participants

perceived that this credibility would enable users to approach tasks with confidence and engage methodically with design challenges.

> *"The big difference is it shows like a degree of prep….. It shows a researched and thoughtful approach to packaging each of these."* - Robert

Some participants also reported that the insights, clarity and credible presentation of the cards made engaging with them enjoyable and insightful.

> *"I did find them clear and helpful. But I have to say that when I did read them, I was looking forward to reading more of them, normally I'm not a big reader. I prefer not to have to read anything. I'm a visual person, but I have to say in this case I actually I enjoyed reading them and I find them insightful."* – Tony

Other participants' sense of credibility was further reinforced by the cards' grounding in research and real-world experience, which made the cards feel realistic and relatable. This grounding in research supported participants' confidence in using the cards as a tool and encouraged considered exploration of patient-centred design challenges.

> *"For each card, when you provided what the research says, that's the piece that made it more real than the other contexts, in the cards that provided a glimpse into things … that put it at a more human element of what others are experiencing."* - Mike

Sub Theme - Team alignment and patient insight translation

Participants reported that the cards could serve as a shared reference for discussions within an organisation, offering a shared structure to guide discussion and align teams around patient-centred priorities. By clearly framing design considerations, the cards were perceived as a tool that might help align team discussions and clarify priorities, reducing time spent on uncoordinated or redundant efforts in meetings. Participants suggested that the cards could support the application of patient insights into concrete design actions. They indicated that the

cards might help overcome barriers to accessing real participant perspectives by making implicit knowledge explicit and by bridging gaps between clinical understanding and technical implementation. This would allow teams to systematically integrate nuanced patient needs into planning while maintaining focus on the participant experience.

> *"The first one gives me context like what do you mean by trust and safety? So, I get that. We're now all on the same page, so everyone in the room knows what trust and safety means. And then the what is it, why does it matter, and what does the research say, that gives me a layer of depth on it."* – Robert

Theme - Organisational and practical barriers to meaningful patient-centred practice

Participants reported that organisational, cultural, and structural factors constrained engagement with patient-centred practice. These barriers influenced how patient-centred approaches were prioritised, legitimised, and integrated, or side-lined, within DCT development activities.

Sub Theme - Organisational and cultural barriers

Participants described organisational culture as a central factor constraining consistent patient-centred design. Human-centred elements are often considered secondary to operational priorities or regarded as 'nice-to-have', reflecting a broader apathy toward patient-focused approaches as they observed in practice. Even when technology was intended to be human-centred, participants noted that this goal was often aspirational rather than realised in practice. They indicated that the perception of tools like the design cards as non-essential could limit future engagement, as organisational norms prioritised delivery and speed over deliberate patient-focused considerations. Regulatory constraints, including IRB considerations, also were described as shaping the feasibility of patient-centred practices, possibly restricting meaningful interventions. Technocentric habits and operational focus were reported as

pervasive, potentially reinforcing a culture in which patient-centred approaches were deprioritised. Collectively, these norms were described as constraining practical application and limiting the capacity of teams to integrate patient-centred thinking consistently across design activities.

> *"In many, many scenarios, all those pieces that are actually a key part of a really effective design get considered as a nice to have and then they aren't done."* - Jessica

Strategic and commercial priorities shaped technology decisions limiting attention to patient-centred practices. Business imperatives and organisational processes prioritised speed, deliverables, and cost, encouraging a focus on immediate outputs rather than broader human-centred goals. While the design cards were seen as potentially valuable, participants noted that adoption would depend on alignment with organisational strategy. Initiatives not clearly linked to business objectives were perceived as unlikely to gain support. Patient-centred considerations were often treated as "nice-to-have" features, undervalued within commercial frameworks, or deprioritised without evidence demonstrating impact on study outcomes. Time, cost, and delivery pressures were described as reinforcing a short-term, business-focused approach to development, limiting investment in patient-centred design. Technology for non-fully remote trials was perceived as helpful but non-essential, leaving improving technology with a patient-focus outside the scope of consideration.

> *"There's no ROI. That's a provocative statement, but my mind goes right to the business. Very few pharma companies look at the technology in the same light that an AD driven game on your phone would think of putting the user centre… The nature of our business prevents these types of things from getting beyond, we need data collection. We need scheduling and compliance… So someone's got to do a real committed researched ROI to show pharma that if you implement X, Y and Z. and prove it. That your study's going to complete sooner."* – Robert

Effective use of the design cards would depend on organisational support, leadership endorsement, and the maturity of both individuals and the organisation. Without these conditions, entrenched habits and structural rigidity could limit meaningful engagement with patient-centred practices, increasing the risk of superficial consideration of participants' experience. Participants noted that, in traditional processes, the absence of deliberate consideration and structured tools tended to lead to gaps and reduced responsiveness to patient needs.

> *"I think the challenge is always going to be, yeah, yeah, yeah, yeah. We know all that. people sort of taking a very high level skimmed attitude towards it….. I think you'd have to have a really strong buy in from the leadership of whatever team, say it's your product team, to do this"* - Jessica

Sub Theme - Experience and knowledge gaps constraining practice

Participants described gaps in knowledge, relevant experience, and reflective capacity that limited practical engagement with patient-centred practice. In fast-paced product environments, limited opportunities for reflective work reduced depth and constrained the ability to anticipate participant needs or critically examine experiential implications beyond immediate functional requirements. These constraints were compounded by challenges in translating clinical knowledge into the decentralised clinical trials context, particularly when participant experience had to be deduced rather than directly observed.

> *"I think that if I was designing a DCT trial. Definitely would use all of these, and yes, they probably would inform other sponsor companies, but if they don't know the answer to the questions, they can't put it into practice."* - Ciara

Engagement with patient-centred considerations was shaped by professional background and prior experience. The utility of tools such as the design cards would vary according to familiarity with clinical research, patient experience, and reflective design practices. Where

such experience was limited, gaps in patient understanding and experiential awareness were likely to persist, constraining consistent application of patient-centred principles across teams.

Sub Theme - Practical constraints on integrating patient-centred considerations

Participants identified workflow constraints as a significant barrier to implementing patient-centred approaches noting both observed constraints in their own work and anticipated limitations in broader organisational settings. Existing strategic and technical decisions were difficult to revisit, restricting opportunities for deeper evaluation of features or reconsideration of experiential implications once development was underway or completed. Consequently, patient-centred considerations become harder to integrate when design decisions had already progressed beyond early stages. Process integration challenges further were seen as limiting engagement. Participants described difficulty embedding patient-centred strategies within established workflows, especially without formal processes to support their use. Fragmented thinking within product development and inefficient design approaches increased the risk of overlooking experiential considerations.

> *"Thinking about it more broadly and holistically. I think the road map was very narrow and it was quite difficult to challenge those decisions that had been made early on about what it did and didn't do."* - Jessica

Time and workload pressures compounded these barriers. Competing deadlines and delivery demands reduced capacity for reflection and pushed focus towards project-specific tasks rather than broader participant experience. Time constraints were seen as a challenge that would restrict engagement with patient-centred thinking and reinforcing reactive, technology-driven approaches.

> *"Everybody's always on a deadline. I need this feature we've promised it to x-pharma company by next Tuesday. You know we're on a deadline. I haven't got time to think about that."* – Jessica

Sub Theme - Superficial patient centricity

Several participants felt their organisation performs poorly when it comes to patient-centred design, while others highlighted a lack of patient focus and involvement across design, testing and development processes, noting that the human side of participation is often overlooked. Limited or no involvement and interaction with patients during the design and testing of technology was commonly reported, with some emphasising that requests for patient input were ignored. Technology was described as being developed without a clear understanding of patient needs, which are frequently overlooked within company processes, resulting in tools that may not reflect patients' needs and preferences.

> *"We need to design more with the participant needs in mind rather than just the study needs and that's what it feels like. It feels like we're designing almost like the patient is secondary…… The question we're not asking, is it the tool that the participant wants in the first place? This is the tool we want them to have, but is it the tool that the patient wants? And are there other tools we haven't been thinking about that the patient actually does want."* - Tony

Frustration was also expressed that technology often prioritised data collection rather than supporting patients' experiences. Some particpants further suggested that patient centricity in decentralised clinical trials is frequently defined at a superficial level, serving more as a symbolic identity or broad label than as a set of enacted practices that genuinely achieve patient-centred outcomes.

> *"It was like we're patient centric because we're providing a technology enabled service…. Patient centric is just a catch all phrase, isn't it? But there's a lot beneath it. I think that's the disconnect."* - Jessica

Theme - Anticipated use and impact of the cards in future DCT practice

Participants anticipated that the cards could be used not only during workshops but also as a structured tool to integrate patient-centred considerations into future processes and organisational decision-making. They described the cards as supporting strategic planning, evaluation, and systematic reflection, enabling teams to embed patient insights consistently across workflows and support alignment across roles and functions, which participants anticipated would translate into improved experiences for trial participants.

Sub Theme - Expected impact on organisational practice

Practitioners suggested that the cards could enhance organisational practice by providing a structured framework for more meaningful ideation and encouraging reflection beyond habitual ways of working. They expected such effects both within their teams and across broader organisational contexts. This structure was seen as making patient-centred work more feasible within commercial environments, with potential to save time, resources, reduce inefficiencies and possibly even contribute to shortening design and development cycles. Some practitioners reflected that the cards might have helped improve previous DCT products, noting that several concepts were implementable rather than aspirational. Beyond design activities, the cards were also described as a means to advocate for patient-centred improvements within organisations, providing a tangible tool to support discussion and justify design decisions.

"I think If we had those cards, maybe we might have done a better job." - Ciara

Sub Theme - Anticipated downstream effects on patients

Some participants suggested the cards could highlight opportunities to improve DCT design by drawing attention to patient experiential gaps that might otherwise be overlooked. Most viewed the cards as useful in shaping technologies and processes to foster a more positive participant experience, ensuring systematic consideration of patient needs. Implementing the cards was expected to support a better overall trial experience, embedding patient-centred

considerations consistently across the participant journey and enhancing engagement and satisfaction. Some practitioners also linked improvements in participant experience to potential downstream effects on trial conduct. Using the cards and associated themes as part of a design approach could support patient adherence and retention, as aligned experiences foster sustained engagement. These anticipated benefits were considered indirect effects of improved patient-centred design rather than guaranteed outcomes.

> *"It would benefit the trial in the long run, you'll be getting better retention and patient has a better experience."*- Ciara

> *"It feels that from what we've looked at today, that yes, there's definitely additional tools that we can give to participants that could potentially make their life and experience better. Whereas I kind of feel maybe I've been thinking about the needs of the participant from the study perspective but not from a human perspective."*- Tony

Sub Theme - Future applications and strategic use

Practitioners suggested that the cards could provide a structured mechanism to support quality-assured decision-making within development processes. They noted the cards could help evaluate alignment with participant needs, ensure accountability for patient perspectives, and guide considerations during user-requirements, testing, or technology validation. The cards were interpreted as offering actionable prompts to enhance confidence in decisions and enable more systematic consideration of patient-focused criteria. They were seen as most useful early in development or during structured workshops and collaborative sessions, immediately actionable, potentially embeddable within development tickets, and adaptable to project-specific contexts. The cards would complement, rather than replace, direct patient input.

> *"I would say we should be evaluating our solutions along every one of these particular categories of experiences and then the cards help make sure that we are answering it from every aspect."* - Susan

Beyond individual projects, practitioners envisioned the cards as tools to integrate patient experience into technical development. They could inform product management decisions, structure design processes, and make patient needs explicit criteria, bridging experiential insights with technical implementation. At a strategic level, the cards could help embed patient-centred thinking across organisational processes, supporting product line focus, leadership decisions, team alignment, and reinforcing a broader culture of patient-informed practice.

> *"In my opinion, the strategic leader that shows up with this has already won the day."*
>
> - Robert

The practitioners proposed that the cards could facilitate structured ideation and innovation based on their workshop experiences and reflections on prior projects. Specifically, the cards were seen as supporting brainstorming, team-based ideation, and innovation labs while focusing on patient-centred priorities. They suggested that the cards could help embed ethical considerations by providing structured criteria for reflection on protocol and human-centred aspects, potentially supporting ethics discussions systematically. Operationally, practitioners expected the cards could be incorporated into planning, checkpointing, and pre-development discussions across agile workflows, encouraging consistent application of patient-centred principles throughout the product lifecycle. Finally, practitioners indicated that the cards could foster team reflection and learning. Similar to familiar tools such as personas or heuristics, they anticipated that the cards would encourage shared understanding, alignment between product, design and engineering teams, and iterative learning, supporting structured engagement with patient-centred insights across teams.

Sub Theme - Reflecting on current practice to inform future use

Practitioners reported that the cards could serve as a structured tool for reflecting on and evaluating existing practice, informed by workshop experiences and reflections on past projects. They highlighted and questioned assumptions embedded in their DCT company

design approaches. The cards were seen as a mechanism to draw attention to areas where conventional practices might overlook patient perspectives, prompting broader thinking, challenging established definitions of success, and addressing structural gaps in DCT technology design practice.

> *"At the companies I've worked at, we've never really asked these questions."* - Mike

> *"I definitely think it's bringing up questions that, I may have made assumptions about just because we've done it that way in the past, when you speak about patient engagement from a solution perspective, it almost always means some type of reminders in the app. Well, no that's not what patient engagement is holistically."* - Susan

Additionally, participants suggested that the cards could prevent premature solutioning and pausing before making technology decisions. Participants indicated that the cards revealed gaps in existing remote trial design and broader decentralised clinical trial practices. They noted that prior approaches often lacked depth in addressing patient needs, with current processes overlooking key experiential considerations. By surfacing these gaps, the cards supported proactive reflection and informed consideration of alternative approaches, assumptions from past projects, and highlighting the need for more nuanced attention to participant experience.

> *"We definitely wouldn't have looked at the design of DCT protocols with this depth in mind."* - Ciara

Discussion

Findings indicate that technology practitioners found the patient-centred design cards to be a useful and engaging approach to supporting ideation around supporting patient needs in the context of clinical trial technology design. In the discussion that follows, we consider the value of the cards in four key areas: how they can support more reflective design and simpler working

time practices, how they can enhance practitioners' understanding of patient experience, how they challenged industry rhetoric around patient centricity, and how they can influence the design of patient-centred DCT technologies.

Structuring reflective and deliberate design practice

The findings indicate that the design cards supported practitioners in clarifying, focusing and deepening their approach to tasks with patient-centred considerations. Participants described how the cards prompted reflection on core principles and highlighted aspects of patient experience that are often overlooked in DCT technology design. The cards reoriented participants' thinking, encouraging more deliberate engagement with ideation processes and decision-making. In this way, patient-centredness was engaged not as a static framework, but as a context-sensitive perspective requiring dynamic interpretation of design implications for participants, addressing recognised conceptual ambiguity in patient experience in clinical research (Planner et al., 2019). The cards functioned as cognitive and interpretive scaffolds that structured how participants engaged with design challenges, offering a clearer direction for interpreting relevant factors. They also provided creative stimuli and domain-specific guidance to support thinking between abstract patient-centred principles and situated experiential considerations (Roy & Warren, 2018). This approach supported reflective (Lucero et al., 2016) and explorative thinking (Hsieh et al., 2023), enabling participants to examine assumptions and consider patient perspectives in a structured manner (Wölfel & Merritt, 2013). For practice, the design cards were seen as a tangible mechanism to integrate patient-focused thinking into technology design workflows. They can enhance ideation (Hsieh et al., 2023)(Hsieh et al 2023), and align teams around shared understanding (Bunæs et al., 2023) while preventing premature solutioning (Thomas & McDonagh, 2013). The cards were seen as potential boundary objects that can adapt to different viewpoints but maintain a shared identity to allow for collaboration (Mark et al., 2007), and regarded as tools that could support alignment of

perspectives across roles. Participants suggested the cards would provide a framework for team discussions, translating individual insights into shared knowledge, supporting dialogue, and enabling structured, collaborative reasoning across roles (Bunæs et al., 2023; Lucero et al., 2016; Roy & Warren, 2018). Participants anticipated that the cards could be particularly valuable early in development, during workshops, or in planning sessions, helping to embed patient considerations systematically across organisational processes. These findings suggest that design cards can operationalise patient-centredness as a dynamic, interpretive perspective used in DCT technology design, providing a bridge between abstract principles and lived experiences, and offering a tangible means to embed patient-informed thinking in both individual and team-based design processes.

Enhancing practitioner understanding of patient experience

Patient-centredness in DCT technology design extends beyond functional requirements, encompassing emotional, relational, and experiential dimensions of the participant journey. By making these aspects explicit, the cards sensitised and orientated the study professionals interviewed toward a foundational conceptual understanding of patient experience, highlighting previously overlooked human needs and the interdependencies between different elements of trial participation (Li et al., 2022a). The design cards made patient needs visible, prompting practitioners to empathetically consider participants' feelings, relationships, and overall experiences (Thomas & McDonagh, 2013). The cards encouraged holistic thinking across the patient journey, highlighted interdependencies between trial priorities and participant needs, and prompted empathetic reflection (Roy & Warren, 2018) on how design decisions might affect experience over time. Together, the cards reframed patient-centredness as an integrated, interpretive perspective, encouraging consideration of trial participants needs and experiences (Santa-Ana-Tellez et al., 2023a) and helping address the lack of a formal definition of patient experience in clinical trials (Planner et al., 2019). These findings suggest

the patient-centred design cards can support practitioners in identifying and prioritising emotional and human needs even when direct patient access is limited. They offer a mechanism to integrate empathy into workflows, encourage holistic consideration of interdependent patient experiences, and support more nuanced, patient-centred decision-making throughout technology design. Conceptually, this positions patient-centredness as a distinct, foundational interpretive practice that requires active engagement with participants' experiences rather than a static checklist.

Organisational reality of patient-centred rhetoric

Our findings indicate that, organisational, cultural, and structural factors often limit the ability to design for patients' experiential needs. Commercial and delivery pressures prioritise speed, cost, and measurable outputs, shaping design priorities, while patient-centred activities may receive limited attention, particularly as sponsors or customers often do not make these a core focus and can be framed as discretionary or difficult to resource (Gorichanaz, 2025). Structural rigidity and entrenched workflows further constrain human-centred practices, making leadership support and organisational maturity critical enabling conditions (Müller et al., 2024). Gaps in focus, reflective capacity and knowledge of patients' needs reduce teams' ability to anticipate participant needs or critically assess the experiential consequences of design decisions an important component of experiential design (Wright & McCarthy, 2008). Together, these factors highlight a tension between the stated ideals of patient centricity and practical enactment. These findings indicate that patient-centred tools alone may be insufficient to transform practice in the face of structural barriers, as seen in e-health contexts (van Velsen et al., 2022). Their value depends on the broader organisational context, including culture, leadership endorsement, and opportunities for considered thinking (Gorichanaz, 2025). Effective support for patient-centred approaches depends on organisations and sponsors providing alignment, leadership endorsement, and resourcing, which allows design teams to

prioritise the end user and embed patient-centred principles throughout ideation, design, and implementation. When sponsors explicitly prioritise patient-centred outcomes, technology companies are more likely to develop tools that genuinely support patients' needs. Without these conditions, engagement risks being superficial rather than genuinely patient-focused and intended improvements in patient experience may fail to materialise. By framing patient centricity as contingent rather than inherent, this perspective provides a critical lens on the misalignment between industry narratives and technology design reality. It demonstrates that the enactment of patient-centred principles depends not just on the availability of tools, but on the interplay between organisational priorities, team knowledge, and reflective practice.

Implications for designing patient-centred DCT technologies

Our findings suggest that using the cards to promote a patient-centred focus in DCT technology design can encourage consideration beyond solely operational data collection optimisation and towards decisions that are supportive of the patient experience. Practitioner feedback indicates that embedding this perspective could better enable experiential needs to influence feature prioritisation, workflow structures, and definitions of successful system outcomes. These findings point to ways in which a patient-centred focus may influence the structure and behaviour of DCT technologies themselves, shaping how systems are designed to also support participants' needs. An important focus in digital health technology is enabling meaningful use, with research highlighting the value of designing technologies that facilitate meaningful use in practice (Ahern et al., 2011). Patient-centred reasoning may help ensure that technologies place greater emphasis on patient-relevant functionality, where experiential considerations influence which features are prioritised as central within the system architecture. Patient-centred reasoning may also inform workflow structures (Ozkaynak et al., 2020) and system behaviours, helping tasks, prompts, and interactions better align with participants' needs and preferences, as suggested in other health contexts (Crossnohere et al., 2021).

Research shows the importance of maintaining focused priorities across teams and ensuring that requirements are consistently communicated (Nguyen & Mougenot, 2022); maintaining explicit patient-focused priorities in system requirements may help ensure these considerations remain visible throughout technology development. This can help keep DCT platforms grounded in participant needs, rather than being driven primarily by technological capabilities (Gasson, 2003). Technologies are more likely to remain relevant to evolving patient populations and trial designs, offer scalability, guide metrics for success, and support ethical obligations by helping ensure participant needs are prioritised as well as efficiency and data collection. Collectively, these practices can create a foundation for patient-centred DCT technology, and are likely to support patient competence, autonomy, trust, engagement and retention throughout the trial experience. Patient-centred design cards thus act as a practical tool that complements rather than replace internal expertise and exemplars of user-centred practice, such as co-design (Sanz et al., 2021), user testing (Dabbs et al., 2009), focus groups (Lehoux et al., 2006) and direct patient feedback (de la Torre et al., 2025), helping teams combine structured guidance with direct patient insight.

Future Research

This study explored the use of the patient-centred design cards in a specific workshop context, providing insight into their role in supporting reflective, deliberate, and collaborative design practice. Future work could investigate their adoption in real-world technology development, examining how structured reflection tools influence decisions, team alignment, and integration of experiential considerations during actual DCT product design. Research could also examine their use as a reflective tool embedded within ongoing design projects, exploring how they shape designers' reasoning, encourage deliberation, and support the application of patient-centred principles in practice. Further studies could investigate integrating the cards into user research and co-design activities, using them to guide trial participants in generating

ideas and providing input for the different experiential categories represented by the cards, helping to inform design decisions directly from patient perspectives. Longitudinal studies could assess the effects of repeated use, considering whether engagement with the cards over multiple projects strengthen patient-centred reasoning and embeds reflective practices within organisational routines.

Limitations

Several limitations of this study should be acknowledged. The sample size was small and purposively recruited from a professional network of decentralised clinical trial experts, known to the researcher. This approach ensured participants possessed relevant experience and familiarity with patient-centred design principles, but it may limit the generalisability of the findings to other groups, such as designers with less trial experience or stakeholders from different cultural or organisational contexts. Additionally, the prior professional relationships between the researcher and participants may have influenced responses, potentially shaping the openness or criticality of feedback and the ideas generated during the ideation sessions. We used a pre-agreed, structured interview guide with neutral questions to avoid leading participants and minimise the influence of prior familiarity. The study relied on a single, one-to-one ideation session with each participant. While this allowed for in-depth exploration of individual reflections and iterative engagement with the design cards, it did not capture the effects of repeated use over time or the dynamics of collaborative design processes, which could influence how the cards are applied in practice. The researcher's active facilitation and prompting, although intended to encourage deeper reflection, introduces the potential for interviewer influence on participants' responses, which may have shaped certain perspectives. Despite these limitations, the study offers rich and detailed insights into the use of design cards to support patient-centred innovation and design within decentralised clinical trial technology.

Conclusion

We report the design and evaluation of the patient-centred design cards, a structured reflection tool to support the integration of patient-centred principles into DCT technology design. Findings show that the cards helped practitioners internalise patient experiences, reinforce understanding of patient-centredness, and prompt deliberate reflection on technology choices. Participants highlighted their value in building empathy, surfacing emotional and experiential needs, and encouraging critical evaluation of assumptions. The cards were also perceived as providing a shared framework for dialogue, enabling alignment across roles and disciplines, and supporting the potential incorporation of patient insights into technology design and organisational processes. Participants also suggested that the cards could be applied beyond individual projects to embed patient-centred thinking across design practices, highlight the gaps between stated patient centred values and enacted practice, and inform ethical and strategic development of DCT technologies. Overall, the findings illustrate participants' perspectives on how structured reflection tools can translate abstract patient-centred principles into actionable guidance in technology design.

Multimedia Appendix of supplementary files:

Supplementary Material 1: Card Set Overview with Definitions and Sources

Supplementary Material 2: Patient-Centred Design Cards - Full Set

Supplementary Material 3: Patient Persona

Supplementary Material 4: Card Instructions

Supplementary Material 5: Interview Guide

All files are available in the Supplementary Material repository (see Appendices).

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Chapter 7: Discussion

Guidance on what constitutes a patient-centred experience in decentralised clinical trials, and how technology can support it remains limited. My research takes a pragmatic approach, applying qualitative methods to a set of studies that examine the literature and explore patient participation in decentralised clinical trials from the perspectives of trial staff and patients. It also investigates the use of a design tool from the perspective of DCT technology practitioners. The intention is to leverage their combined insights to inform and guide technology design. The thesis begins with a systematic scoping review that examines and categorises the strategies used by previous researchers to improve patient retention in clinical trials, identifying strategies that could be used in technology design and providing a foundation that shaped the focus and direction of the subsequent studies.

Following this review, my subsequent studies examine how patients experience participation in decentralised clinical trials, and how clinical research staff support them, highlighting both the challenges and the value that emerges when trials are remote, technology-mediated, and integrated into daily life. The research culminates in a fourth study (Chapter 6) that produces a design artefact that translates these insights into practical tools for ideation and decision-making in the design of tools to support DCTs. Taken together, these studies provide novel insights and practical contributions, which I will synthesise to demonstrate how patient experiences, staff practices, and technology design can be integrated to support patient-centred design in DCTs. Although conducted within the context of decentralised clinical trials and digital health, the insights generated by this research contribute more broadly to Human-Computer Interaction (HCI) and design research. Moreover, the thesis demonstrates how integrating theory, frameworks, and empirical research can inform the patient-centred design of technology, and offers sponsors and technology professionals practical guidance for understanding and shaping patient experience in decentralised trials.

Gap Between Patient-Centred Claims and Experiences

Despite DCTs being widely positioned as patient-centred in literature (Rogers et al., 2022; Sinha et al., 2024), and by industry commentators (Gretton, 2020; Weil & Carswell, 2022), the findings of this thesis indicate that they do not consistently meet participants' needs in practice. The impacts of the remote nature of these trials and the technology at their core can limit the realisation of patient-centred trial experiences. Across the empirical studies, a clear gap emerged between dominant narratives of DCTs and participants' observed and lived experiences of trial participation. Specifically, empirical findings from participants and clinical research staff demonstrate that this framing is only partially realised in practice, with both groups reporting that support for participation and the management of participant experiences varies considerably (Chapters 4, 5). Building on these insights, findings from technology professionals' interviews indicate that these technologies are rarely developed through sustained collaboration with patients, and patients' needs are not consistently foregrounded in the design and focus of these systems (Chapter 6). This misalignment can not only constrain participant engagement and retention, but also create ethical concerns, including psychological strain, additional burdens, and undue stress for participants managing trial requirements alongside challenging health circumstances. This research also challenges dominant industry narratives that frame DCTs as inherently patient-centred. My research identifies three key mechanisms underlying this gap: the double-edged nature of decentralisation, relational dynamics, and technology design.

The Double-Edged Nature of Decentralisation

First, the double-edged nature of decentralisation explains why patient-centricity is not automatically achieved. While decentralisation is often argued to improve trial accessibility (Dockendorf et al., 2021b) and reduce the burden of participation (Rogers et al., 2022), the findings of this research confirm that it enhances access and alleviates certain practical trial

burdens, such as travel and logistical complexity (Ghadessi et al., 2023), which participants valued. At the same time, decentralised trials introduce and amplify operational, cognitive, emotional, and engagement-related challenges, including uncertainty about procedures, difficulties navigating technologies, limited available support, and reduced opportunities for immediate guidance or clarification. Managing participation alongside the physical and emotional demands of their condition, often in relative isolation, can exacerbate patients' stress and frustration (Chapters 4 and 5). These findings contrast with literature that primarily presents DCTs as improving participant experiences (Jean-Louis & Seixas, 2024; Weber et al., 2026). They demonstrate how participants experience trial participation in practice, particularly in contexts where clarity, support, and responsiveness are limited (Chapters 4 and 5). The results highlight how the experiential burdens are introduced when remote trial processes interact with patient circumstances. While decentralisation can reduce certain practical barriers, it can simultaneously introduce unanticipated consequences and new sources of burden that compromise patient-centred experiences.

Relational Dynamics Shaping Participation

Second, relational dynamics between staff and participants represent a critical mechanism in clinical trials, where interactions with trial staff have traditionally played a central role in supporting participants' psychological and practical needs, sustaining motivation and continued participation. Previous research with European regulators highlighted that DCTs have the potential to negatively affect opportunities relationship building with participants when face-to-face contact is limited, potentially weakening trust and rapport (Jong et al., 2022). My research confirmed that these relational dynamics were affected in DCTs, influencing the development and sustainability of these critical relationships for both staff and participants. Clinical research staff in my research reported challenges in building and maintaining relationships, understanding participants, and providing personalised, responsive care (Chapter

4). Similarly, research staff and participants described interactions as impersonal (Chapter 4 and 5), instrumentalised (Chapter 4) and noted a reduced sense of authenticity in trial interactions, expressing a preference for connection (Chapter 5). My research highlights that relationships between research staff and patients function as a key motivational mechanism and are crucial for sustaining engagement, retention, and effective trial participation (Chapter 3). Addressing these relational gaps is essential for supporting participants' motivation and engagement. This requires designing trial processes and technologies that actively embed mechanisms to support and sustain patient–staff relationships, recognising that while technology cannot replace these relationships, it can facilitate aspects of relational support and interaction currently limited in DCT. By intentionally integrating relational and psychological considerations, these interventions address gaps in DCTs systems, highlighting elements currently insufficiently considered in DCT design (Chapter 6).

Technology Design and Its Impact on Experience

Third, technology design further explains the gap between the promise of patient-centred decentralised trials and participants' experiences, where systems often prioritise data and processes over engagement and experiential support. Although the technologies used to support decentralised trials are often framed as supporting patient-centric approaches (Stern, 2024), this research suggests they primarily function as data collection tools, tracking patient progress, medication adherence, and symptoms (Chapter 4). Participants and clinical research staff reported that, while these systems supported trial operations, they offered limited support for engagement, understanding, personalisation, and connection, ultimately constraining the depth of support provided (Chapters 4 and 5). Beyond operational and data-driven functions, these technologies exhibited technical and usability constraints that increased cognitive burden and impacted participant engagement (Chapters 4 and 5). Technology professionals similarly acknowledged that patient needs are rarely prioritised in design, as operational requirements

and data collection demands typically take precedence (Chapter 6), challenging narratives that frame these technologies as inherently patient-centred. Broader literature highlights the benefits of DCT solutions and digital tools for enabling access, outcomes, convenience, and adherence (Narasimhan, 2023), yet my findings reveal a gap between the theoretical potential of digital trial technologies and their current design and implementation. Trial technologies, while fulfilling access, operational and data collection needs, could be enhanced to better support participants' understanding, engagement, personalisation, and connection, enabling more meaningful participation and experiences. These limitations highlight a core design challenge and demonstrate that trial technologies currently provide limited support for participants' experiences, highlighting the need for design that integrates operational efficiency with patients' experiential needs.

Patient-Centred Experiences in DCTs: Alignment With Patient Needs

Taken together, these empirical findings suggest that the challenges to achieving patient-centricity in DCTs cannot be consistently attributed to a single design or implementation decision. Patient-centred experiences emerge from the interplay of trial processes, relational dynamics, and technological design, shaping how participants perceive, engage with, and are supported throughout participation, a dynamic that can unintentionally undermine support and engagement when misaligned. While each element is often addressed independently in research and practice, my findings demonstrate that such misalignment compounds burden, weakens support, and limits engagement for patients. This underscores that patient-centredness in DCTs is an emergent property of how trial structures, relationships, and technologies are designed and enacted together, highlighting opportunities for design interventions that actively support participant experience. The design cards developed in this research provide a practical way to navigate this complexity. By making patient-centric needs more visible and actionable, they guide designers to prioritise key considerations and ensure important aspects of patient

experience are not overlooked and that they can be used in varied technological and organisational contexts. In doing so, the cards translate qualitative and theoretical insights into actionable prompts that support effective decision-making in complex DCT design scenarios.

Theory-Informed Approaches to Guide DCT Technology Design

The findings of this thesis suggest that a patient-centred experience in decentralised clinical trials should be understood as a complex, psychologically grounded process shaped by cognitive, emotional, and relational factors, rather than being defined solely by convenience or remote delivery. Drawing on Self-Determination Theory (Deci & Ryan, 2008a), as a sensitising lens, the analysis highlights how participants' needs for autonomy, competence, and relatedness are supported or constrained within DCTs. SDT both provides an analytical lens for interpreting the challenges observed in DCT participation and demonstrates, based on these findings, that it can also serve as a practical framework for designing DCT technologies. By explicitly considering autonomy, competence, and relatedness to support intrinsic motivation, trial systems can be designed to better support participants' psychological needs (autonomy, competence) and relational needs (relatedness), thereby enhancing engagement and overall participant experience.

These insights are complemented by patient-centred care frameworks (Hughes et al., 2008; Kitson et al., 2013; Langberg et al., 2019a; Mead & Bower, 2000c; Wolfe, 2001), which emphasise the importance of relational, emotional, and supportive dimensions. By synthesising these lenses, the thesis identifies mechanisms through which psychological, relational, and care needs interact to shape participant experiences, demonstrating how DCTs may fail to meet core needs when these elements are misaligned. A patient-centred experience is therefore not achieved solely through operational efficiency, or the convenience of remote participation, but emerges from the interplay of trial processes, technology, and relational support. This dual

perspective positions participant experience as both psychologically informed and conceptually grounded, offering a more nuanced understanding of how experiences are shaped, supported, or disrupted in DCTs.

Socio-Technical Complexity Shaping Patient Experiences

These findings highlight the socio-technical complexity of DCTs (Carayon et al., 2011). In line with socio-technical thinking, and similar to other research highlighting design complexity in healthcare sociotechnical systems (Premanandan et al., 2025), this thesis demonstrates that participant experiences emerge through the interaction of trial technologies, processes, contexts and the people involved. The thesis shows that when these elements are misaligned, participants can experience unintended gaps in practical needs, care and support, ultimately impacting autonomy, competence, and relatedness (Chapters 4 and 5), indicating that patient experience is shaped not by any single component but by how these components work together in practice. These gaps provide a clear rationale for targeted design interventions that address both practical demands and underlying psychological needs. Through an examination of these socio-technical impacts and experiences, the findings reveal that structural configurations and technological design features actively enable or limit psychologically supportive experiences. This suggests that focusing solely on convenience or remote participation cannot produce authentically patient-centred outcomes.

Implications for Design

These conceptual insights have direct implications for design. They demonstrate that patient-centredness in DCTs cannot be achieved through remote participation, technology, or procedural adjustments in isolation. This thesis provides the foundation for designing digital technologies that actively support participants' psychological and practical needs, including autonomy, competence, and relatedness, while embedding mechanisms that facilitate relational support and care, and enable effective participation in trial processes. In practice, technology should mediate these mechanisms, enhancing the participant experience rather than serving solely as a tool for operational efficiency or data collection. This perspective directly informs the design artefact presented in this thesis and offers guidance for designers and researchers to integrate patient needs, psychological mechanisms, and practical requirements alongside procedural and technological solutions.

The findings of this thesis highlight actionable insights for improving participant experience in decentralised clinical trials. Synthesising empirical evidence from participants and clinical research staff (Chapters 4 and 5), the research identifies design considerations that support patient-centred aspects of trial participation. These insights have been translated into a set of patient-centred design cards, which are underpinned by and validated against principles from patient-centred care (Berwick, 2009; Greene et al., 2012; Grover et al., 2022; Hughes et al., 2008; Jardien-Baboo et al., 2021b; Kitson et al., 2013; Langberg et al., 2019a; Lusk & Fater, 2013; Mead & Bower, 2000c; Sturgiss et al., 2022; Wolfe, 2001) and self-determination theory (Deci & Ryan, 2008a), making relational, supportive, and emotional elements of participation tangible and actionable for designers.

While design tools are widely recognised in human–computer interaction (Lucero et al., 2016) as effective for bridging research and practice, their application in the context of DCTs has been limited. Existing literature surrounding DCT rarely provides applied tools that

integrate qualitative insights into the development of decentralised trial technologies that aim to support patient-centric experiences. The design cards address this gap by providing structured guidance that links empirical evidence, conceptual frameworks, and theory with practical design decisions. They offer a tangible method for ensuring participants' needs remain central, supporting autonomy, competence, relatedness, and relational care. This represents both a methodological and practical contribution and is one of the first applied tool in DCTs to directly translate qualitative evidence into actionable design guidance. It also complements the conceptual and theoretical insights presented earlier, demonstrating how research findings can be operationalised to enhance participant experience in DCTs.

Taken together, this discussion demonstrates that while decentralised clinical trials offer clear advantages in flexibility and reduced logistical burden, patient-centricity emerges through participants' experiences and the interaction of trial processes, relational dynamics, and technology design, with misalignment across these elements limiting the potential benefits of decentralisation in practice. By integrating empirical findings with psychological and patient-centred care frameworks, this thesis positions patient-centredness in DCTs as an emergent, context-dependent process, rather than an inherent property of decentralised models.

Strengths and Limitations

The thesis has several strengths and limitations, which are outlined below.

Strengths

This work takes an integrated and pragmatic approach to understanding how best to design technology that supports patient experiences in decentralised clinical trials. It combines patient-centred care principles with Self-Determination Theory (Deci & Ryan, 2008a) to provide a foundation that is both theoretically informed and practically useful. This foundation informed the development of design cards, a practical resource translating theory into actionable

guidance for patient-centred digital tools. The cards were developed based on findings from the literature review, and qualitative analysis of semi-structured interviews, drawing on perspectives from patients, research staff, and DCT technology practitioners to ensure their relevance and applicability. They can serve as an approach for guiding the ideation, evaluation, and refinement of DCT technology, supporting broader patient-centred strategies, enhancing engagement, and improving alignment between technology and patient needs. The work reflects a synthesis of multiple qualitative insights and practical considerations, providing principles that can inform both the design and implementation of technology that meaningfully supports patient-centred experiences in decentralised trials and broader technology design for clinical trials.

A strength of this thesis lies in the clear and coherent programme of work. The four papers are not isolated studies but build on one another to develop a connected line of inquiry. Overall, the work adopts a pragmatic, integrative approach, synthesising theoretical and practical insights to inform patient-centred technology design. The first study in Chapter 3 examined strategies for patient retention and engagement in traditional trials, which raised questions about how these approaches might be affected in the context of decentralised trials. It also distinguished between different types of retention strategies, clarifying which strategies drive engagement and why, providing a conceptual contribution that informed technology design requirements. This insight directly informed the next two studies. The programme culminated in the development of a novel design tool, grounded in empirical evidence, and validated by DCT practitioners to support the creation of patient-centred technology experiences. Together, the papers provide a comprehensive understanding of patient-retention and experiences in decentralised trials.

Another strength of this PhD is its originality through a holistic approach that incorporates the perspectives of clinical trial staff, patients with experience of DCTs, and DCT

technology professionals. The work addresses an area that remains under-explored, largely because the rapid uptake of decentralised clinical trials following COVID-19 and the limited research into their impact on the patient experience and how technology should be designed to support the patient experience. The thesis brings together perspectives that are rarely combined in the context of DCT, drawing on behavioural science, design research, and patient experience. This interdisciplinary lens allows the research to ask questions that have not been considered in depth before. The work also takes a distinctive methodological approach by using insights from the empirical studies to shape the development of the Patient-centred design cards, linking real-world evidence with practical design outputs. As part of this, I created a set of design cards to support decision-making around technology experiences in decentralised trials, offering a resource that did not previously exist. By integrating findings from multiple studies and stakeholder perspectives, this approach synthesises theoretical and practical knowledge in a way not previously seen in the literature. Taken together, these elements give the thesis a clear and demonstrable contribution that sets it apart from existing literature.

The robustness of this research lies in its methodological design. The studies drew on qualitative approaches that allowed for rich exploration across the studies in Chapters 4, 5 and 6 of the experiences of trial researchers, participants involved in running and taking part in trials, and DCT practitioners who engaged with the design cards. Reflexive thematic analysis was used across all three papers, supporting careful examination of assumptions and ensuring that interpretations were firmly grounded in the data. The research was conducted iteratively, with the findings from the first study (Chapter 3) on retention strategies in traditional trials shaping subsequent questions about the impacts of these strategies in decentralised clinical trials. Methodological breadth is evident through the inclusion of Chapter 3, a systematic scoping review, followed by analysis through the lens of self-determination theory, which allowed the work to combine inductive and theory-driven perspectives. The design cards from

the study in Chapters 6 were shaped by evidence from Chapters 4 and 5 and by key frameworks from the literature, ensuring they reflected both real-world experiences and research evidence. The studies (Chapters 4 and 5) accessed a participant group that is typically difficult to recruit for interview-based research, providing valuable insight from individuals. Studies were conducted with wide-ranging international participants from several countries, including the USA, Ireland, the UK, Spain, Belgium, Kenya, the Czech Republic, Switzerland, and Italy, enhancing the diversity and transferability of the findings. Transparent coding processes strengthened trustworthiness (Appendix Chapter 4, 5 and 6), while careful ethical consideration supported the inclusion of remote participants and maintained high standards of participant care. Taken together, these features demonstrate a rigorous, responsive, and credible methodological approach.

A further strength lies in the rigorous research process of implementing the research across all four papers. The first study in Chapter 3, a systematic scoping review, followed the methodological framework of Arksey and O'Malley and applied a mixed inductive and deductive approach to analyse retention strategies using thematic analysis. The review followed PRISMA guidelines to support comprehensive and transparent reporting (Appendix Chapter 3), and details of the search strategies and full extracted data are included in the appendices to maintain transparency (Appendix Chapter 3). The studies in Chapters 3, 4, 5 and 6 employed Braun and Clarke thematic analysis, with NVivo used to manage data and facilitate coding, while Chapter 3 used Excel (Appendix Chapter 3, 4, 5 and 6). Across all qualitative studies, initial codes were iteratively developed into final themes through multiple rounds of discussion and review, often collaboratively with the supervisor to ensure robust interpretation. The design cards were iteratively developed, with multiple iterations refined based on analysis, reflection, and stakeholder feedback before finalisation. Collectively, these practices

demonstrate a systematic, transparent, and reflective research process, ensuring that findings and outputs are grounded in data, rigorously analysed, and methodologically robust.

The work makes a meaningful contribution to both theory and practice. It extends understanding of patient-centred experiences in decentralised clinical trials, an area that remains under-researched, and highlights gaps in how patient needs are currently considered. The research applies patient centred care frameworks and self-determination theory to examine both the literature and evidence gathered, showing how behavioural and psychological frameworks can be used to inform design. The design cards from Chapter 6 provide a tangible, empirically grounded tool for supporting patient-centred technology experiences, linking behavioural science theory directly to design practice. Furthermore, insights from the study in Chapter 3 on the motivational impact of different retention strategies provide conceptual clarity for future technology-based interventions, linking behavioural science theory directly to design practice. Collectively, these contributions offer new insights and resources that were not previously available, bridging the gap between empirical research, theory, and practical application.

The research is grounded in real-world relevance, drawing on insights from trial participants (Chapter 5), clinical research staff (Chapter 4), and decentralised clinical trial technology professionals (Chapter 6). Findings from Chapter 3 provide technology designers with insights and practical guidance on designing technology that effectively supports participant retention and engagement. The design cards were shaped directly by these stakeholders, ensuring they respond to genuine needs in practice. By engaging with participants across multiple roles and contexts, the work produces a tool that is immediately applicable to technology developers, trial teams, sponsors, and regulatory bodies, supporting decisions that improve patient experiences. By anchoring the work in practical experience, this thesis

achieves a robust alignment between technological design guidance and patient needs, enhancing both its relevance and its scholarly contribution.

A further strength of the thesis lies in the breadth and depth of the four papers, which collectively explore the topic from multiple perspectives. The first study (Chapter 3) examined literature on retention and patient engagement, providing a theoretical foundation. The second study (Chapter 4) gathered insights from research staff, the third (Chapter 5) focused on trial participants themselves, and the fourth engaged DCT technology practitioners (Chapter 6). Taken together, these studies present multiple layers of evidence and perspective. They enable the thesis to develop a rich, multifaceted understanding of patient-centred experiences in decentralised clinical trials, including what it is like to take part in a DCT, the challenges of running and supporting trials in this context, and the difficulties involved in creating technology to support patients effectively.

Limitations

Chapter 3 relied on a literature review with inclusion criteria that only captured quantitative studies reporting 80 percent or higher retention, and the search used a limited set of keywords. This approach may have omitted relevant retention strategies reported in studies with lower retention rates or that framed retention using different terminology. Chapter 4, 5 and 6 drew primarily on qualitative interviews with patients, research staff, and technology practitioners, providing rich, broad insight into experiences and perceptions within decentralised trials. The sample size in each study reflected the challenges of accessing participants and professionals in these specialised contexts (Bonisteel et al., 2021). Recruiting participants for this research was particularly challenging due to the complexity of the decentralised trial ecosystem. Accessing patients, clinical researchers, and decentralised clinical trial (DCT) professionals is difficult, as these groups are not typically facilitated or directly accessible through stakeholders such as pharmaceutical companies or trial sites. Recruitment is shaped by institutional policies,

privacy considerations, and access to decentralised trials and professionals in the field, as seen in other contexts (Sanjari et al., 2014).

Given these barriers, the number of participants included represents a strong sample for qualitative inquiry within a hard-to-reach field. This sample size aligns with evidence that qualitative interviews often reach saturation within 9–17 participants (Hennink & Kaiser, 2022). Smaller samples are also appropriate for narrowly focused studies with specialised or homogeneous participants, where themes emerge from fewer interviews (Hennink & Kaiser, 2022). Importantly, the sample was also diverse, reflecting a range of experiences across patient and professional groups within this complex ecosystem. Participants in the study in Chapter 5 had experience across multiple trial types and conditions, providing diverse and nuanced perspectives. Taken together, the sample size and heterogeneity of participant experiences may limit the generalisability of the findings, while also offering a contextually grounded understanding of perspectives and experiences across decentralised trials. Despite these constraints, the sample captured perspectives from individuals who are typically difficult to reach, adding breadth to the study. This approach reflects the practical realities of researching specialised populations and ensures that the findings are grounded in the experiences of participants and professionals actively engaged in decentralised trials.

Data analysis in this thesis was primarily conducted by a single coder with iterative discussions and checks with a co-researcher, supporting consistency, depth, and nuanced interpretation. The resulting themes reflect the researchers' informed perspectives and interpretive lens, providing insight into patterns across the studied contexts. This approach represents a robust and coherent method for generating design-relevant knowledge that is both credible and grounded in the data. Nonetheless, as with all qualitative inquiry, the findings are shaped by the researchers' interpretive lens (Sandelowski & Leeman, 2012), meaning that

alternative theoretical or analytic perspectives might highlight different aspects of research participants' data.

The findings of this thesis are not intended to support statistical generalisation beyond the sampled populations. Instead, they offer analytical generalisation (Lim et al., 2021) by identifying patterns, mechanisms, and design-relevant insights that may inform understanding of patient experience in decentralised clinical trial contexts. The findings reflect experiences across diverse trial types, conditions, participant populations, and technologies. This diversity (Brewer & Scandlyn, 2022) enabled identification of patterns and mechanisms relevant across DCTs but limits direct transfer to any single trial context, as factors such as digital literacy, prior trial experience, condition type, and technology design may influence individual experiences. Consequently, the findings support analytical rather than statistical generalisation. Access to participants in the study in Chapter 5 was constrained by the decentralised nature of the trials. Participants were difficult to reach due to privacy considerations. In addition, the limited number of decentralised trials currently running (Jiang et al., 2025) and the longitudinal nature of trials (Park et al., 2023) further restricted the pool of potential participants. The sample included only individuals who had completed their trials and were willing to take part in research, which may underrepresent the perspectives of those who withdrew or chose not to engage in studies. The sample size may also have limited the identification of rarer experiences or perspectives.

In Chapter 6, contributors had prior professional relationships with the researcher. While this did not undermine the relevance of their insights, it may have influenced how experiences were framed and should be considered when interpreting and extending the findings. To manage potential bias and uphold ethical standards, interviews were conducted using an interview guide, with questions and procedures (Appendix Chapter 6) agreed by the study team to ensure consistency and focus on eliciting participants' experiences rather than

confirming assumptions. Overall, the findings should be interpreted as contextually grounded and illustrative, providing insights into mechanisms and design-relevant considerations within decentralised, technology-mediated trials. Their value lies in informing reflection, design decision-making, and future research in similar contexts, rather than supporting universal claims about patient or staff experiences.

Future Research Recommendations

Future research should move beyond broad endorsements of DCTs and focus on how technology can actively support participants. For example, studies have evaluated user-centred design features or co-design processes in digital health contexts, showing how design elements relate to user experience and usability outcomes (Bargas-Avila & Hornbæk, 2011; Kujala, 2003). These approaches provide a framework for investigating how specific design decisions could influence participant engagement and trial experience.

The design cards developed in this thesis offer a practical foundation for such work, but their utility needs empirical evaluation. Future research could assess the effects of using the design cards in DCT design processes through comparative or mixed-method studies that combine quantitative indicators (e.g., engagement and retention metrics) with qualitative data from participants and practitioners. Such evaluations should examine whether and how the cards support design decisions, the functionality of resulting technologies, and participant experiences in diverse trial contexts, rather than assuming benefit; for example, a mixed-method evaluation of digital tools co-designed with participants demonstrated how usability metrics, user engagement, and perceived experience can change after iterative design refinements in a clinical research context (Mackey et al., 2025b).

Co-design has been recognised as a practical method for creating solutions in technology design (Sanders & Stappers, 2008). Future work could extend the use of the design

cards within co-design workshops that involve patients, caregivers, and research staff in iterative development of trial technology solutions. Studies have shown that co-design workshops can lead to digital health tools that are relevant to user needs (Tay et al., 2021). Trials that embed these co-designed tools in real-world settings will also help assess generalisability across patient populations, conditions, and trial modalities. Additional research efforts could implement the cards in technology co-design workshops where patients and research staff collaboratively develop and refine technology solutions for particular trial systems or tools. Studies of participatory design in digital health have shown that iterative co-creation with users and practitioners improves engagement, attendance, and satisfaction (Branitsky et al., 2024; Lundell et al., 2022). Patients could use the cards to generate and refine potential solutions, providing feedback on whether and how proposed features meet their needs. Evaluations that combine qualitative analysis of the design process with quantitative usability and engagement metrics provide robust evidence to guide iterative refinement (Lundell et al., 2022). Process measures can include ease of use, engagement, and clarity during workshops, while outcome metrics could assess the relevance and applicability of the design solutions to participant experience, as well as their potential impact on engagement, retention, and overall trial experience. This approach demonstrates how mixed-method assessments in co-design can directly inform tool validation and broader application, similar to how participatory research has been used to refine digital health interventions.

My research shows that behavioural science theory, particularly self-determination theory (SDT) (Deci & Ryan, 2008a), provides a practical framework for understanding motivation and engagement in digital health and clinical trial contexts. I have argued that applying SDT to trial technology design could guide the development of features that actively support these psychological needs. Future studies should experimentally compare SDT-informed design features with non-SDT alternatives to evaluate their impact on need

satisfaction and behavioural outcomes. Studies could use A/B or factorial experimental designs to compare SDT-informed features against non-SDT alternatives, measuring engagement, adherence, and satisfaction (Miller et al., 2021). Within-subject designs with repeated measures could assess changes in participant behaviour and psychological need satisfaction over time, as seen in longitudinal repeated-measure SDT-informed digital health research where constructs such as autonomy, competence, and relatedness were measured at multiple time points alongside behavioural outcomes in a web-based physical activity intervention (Hooker et al., 2024). Mixed-method evaluations combining quantitative data and qualitative feedback would provide deeper insights into how participants experience these features (Østervang et al., 2024).

The rapid development of digital technologies presents further opportunities to enhance patient-centred trials. Apps, wearable devices, and remote monitoring platforms can provide timely information, interactive guidance, and personalised feedback to help participants manage their trial experience and remain engaged (Goodday et al., 2024). Future research could explore how these technologies influence engagement, competence, retention, adherence, and satisfaction using real-world deployment studies, while identifying which specific features are most effective in supporting participation (Nowell et al., 2023). By focusing on both the potential and the limitations of technology, including the need to tailor and optimise design to sustain engagement, research can guide the development of patient-centred tools that enhance the trial experience while respecting participants' autonomy and care (Pratap et al., 2020).

Additional research efforts should empirically investigate the link between patient-centred experience design in clinical trial supporting technology and measurable outcomes such as patient retention, recruitment, adherence, engagement, and associated financial impacts. For example, controlled evaluations could compare patient-centred designed technology with standard implementations, similar to HCI studies that empirically evaluate

usability, task completion, and user satisfaction between interfaces developed through structured human-centred design processes and less optimised versions (Harte et al., 2017). Demonstrating that features explicitly designed to support patient-centricity translate into these outcomes would provide robust evidence for the value of patient-centred approaches, both in improving participant experiences and enhancing the efficiency and effectiveness of clinical trials. Such evidence could then justify and guide the development of tools and frameworks that help technology teams systematically design for patient-centricity.

Conclusion

This thesis has argued that although decentralised clinical trials (DCTs) are widely described as patient-centred, their implementation and supporting technology do not always fully realise these goals. While DCTs aim to improve participants' experiences and reduce burden, their technology-mediated and remote nature can introduce challenges that affect how patients engage with and experience participation. Existing research provides limited insight into these experiences, leaving a gap in understanding how such insights can guide technology design to better support patient-centred trials. As trials become increasingly decentralised, it is essential to understand how these factors influence patient experiences and use these insights to inform technologies that truly support participants.

The thesis adopted a pragmatic approach to generate actionable insights for designing technology to support patient experiences in DCTs. It combined conceptual lenses, including Self-Determination Theory and patient-centred care frameworks, with multi-stakeholder perspectives from interviews with patients and clinical research staff. These lenses helped interpret empirical data, while interviews provided direct insight into experiences and practices. The research was structured in four parts: a literature review of patient retention strategies, exploration of research staff perspectives, examination of patient experiences, and

the development and evaluation of a design tool to support patient-centred technology design. By integrating conceptual lenses with empirical insights, this approach translates evidence into practical guidance for designing technologies that support patient-centred experiences in DCTs.

The research provides a rich understanding of how DCTs can support patient-centred experiences and engagement, highlighting the dynamic relationship between digital tools, trial procedures, and human interactions. Conceptually, it frames participant retention as a motivational process shaped by autonomy, competence, and relatedness, rather than a set of strategies, offering a novel lens to interpret engagement and trial practices, and a foundation for designing technology to support motivation and engagement. Empirically, it integrates insights from research staff and participants, revealing operational, relational, and experiential factors that influence how DCTs are experienced and highlighting gaps between design intentions and real-world experience.

Building on these insights, a set of patient-centred design cards was developed to guide technology design for DCTs. The cards provide a structured approach to incorporating participant needs, insights from Self-Determination Theory and patient-centred care frameworks, and practical design considerations, offering designers a tangible tool to embed patient-centred principles. By translating the thesis findings into an actionable resource, the cards enable technology-mediated trial processes to better support patient centricity, engagement, and experience, ensuring participant needs remain central throughout trial design and delivery.

By showing how experiences are shaped by the interplay of technology, the remote nature, trial processes, and human interactions, the research provides evidence-informed guidance for creating genuinely patient-centred trial systems. The design cards offer a practical tool for applying these insights, supporting interventions that better meet participants' motivational,

emotional, and practical needs. More broadly, this work highlights the value of integrating frameworks, theoretical perspectives, and empirical evidence to inform practice-based DCT technologies. Ultimately, this thesis contributes conceptual understanding and practical resources to advance decentralised trials that truly place participants at the centre of how clinical research is designed, conducted, and experienced.

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Appendices

Supplementary Material

The supplementary materials associated with this thesis, including a supporting guide document, are available in the online repository accompanying this submission.

https://osf.io/rht3u/overview?view_only=1f24be0119a744ebbf76745706cffef9

The files are organised by chapter as listed below.

Chapter 3 Supplementary Material

Multimedia Appendix 1: Database-specific search strategy material and search terms.

Multimedia Appendix 2: Search result articles and specific exclusion rationale.

Multimedia Appendix 3: Extracted segregated data by theme and sub theme.

Additional File 1. PRISMA Checklist for Systematic Scoping Review

Chapter 4 Supplementary Material

Multimedia Appendix 1: Interview guide.

Multimedia Appendix 2: Reflexive thematic analysis process and outputs.

Chapter 5 Supplementary Material

Supplementary Material 1: Interview Guide

Supplementary Material 2: Example Thematic Data Analysis

Supplementary Material 3: Online Screener

Additional File 1. COREQ Checklist for Chapter 5

Chapter 6 Supplementary Material

Supplementary Material 1: Card Set Overview with Definitions and Sources

Supplementary Material 2: Patient-Centred Design Cards - Full Set

Supplementary Material 3: Patient Persona

Supplementary Material 4: Card Instructions

Supplementary Material 5: Interview Guide

Supplementary Material 6: Example Thematic Data Analysis

Additional File 1. COREQ Checklist for Chapter 6