A key focus and strength of health psychology is the development and evaluation of interventions, programmes and strategies (herein called 'interventions') across a spectrum of health conditions to improve health and well-being across the life-span. Findings of reviews and meta-analyses of trials of health psychology interventions influence intervention implementation. This in turn impacts significantly on patient and public health, and healthcare services (Heneghan, Goldacre, & Mahtani, 2017).

Choice of outcomes is a crucial consideration in the planning and conduct of trials of health interventions (Heneghan et al., 2017), in synthesising evidence about intervention effects (Clarke, 2007), and in producing clinical practice guidelines (Health, 2014). Outcomes, in this context, are *what* we examine to determine effects of interventions on aspects of health relating to benefits and harms. Outcome measurement instruments (OMIs) are *how* we measure these outcomes. Choice of outcomes can influence sample sizes, data sources, and length of follow-up in trials (Velentgas, 2013). Tugwell et al. (2007) argue that a trial is only as good as its outcomes, as intervention effects can only be inferred from those outcomes measured and reported. Interpretations of intervention effects can influence research and applications of health psychology findings in practice (Gargon et al., 2018). Outcome choice therefore has the potential to impact on clinical care, including changes to existing practice or introduction of new treatments. The aim of this paper is to introduce and discuss approaches to determining what outcomes to measure in health psychology research, as well as how to measure these outcomes. To do this, we outline existing issues with outcome selection and reporting, introduce core outcome sets (COSs), outline best practice guidelines in how to develop and measure COSs, and discuss benefits and potential challenges of COSs in health psychology.

Current issues in outcome selection and reporting

Considerable heterogeneity in outcomes evaluated and reported across trials significantly limits interpretability and synthesis of intervention effects (Jones & Kaplan, 2003; Schmucker et al., 2014). Examination of outcome heterogeneity across health psychology trials is scarce, as are concerted efforts to address potential heterogeneity within the discipline. This is particularly true in relation to trials of intervention for health behaviours such as diet, physical activity, and medication adherence. However heterogeneity has been examined and reported for a number of outcomes relevant to health psychology to date. For

instance, a recent review of 405 trials of brief alcohol interventions identified 2,641 unique outcomes (Shorter et al., 2019). A review of 126 infant feeding studies in the context of childhood obesity prevention also reported significant heterogeneity in outcomes, with 15% of outcomes reported only once (Matvienko-Sikar, Griffin, et al., 2018); the two most frequently reported outcomes were reported in only just over half of the reviewed studies (Matvienko-Sikar, Toomey, et al., 2017). Similarly, reviews of interventions to increase physical activity include a range of physical activity outcomes, including step counts, energy expenditure, and type, frequency, intensity and duration of physical activity (Carr et al., 2019; Lock et al., 2020; Malik, Blake and Suggs, 2013; McEwan et al., 2016). Further, one recent review (Lock et al., 2020) noted variations in observed effectiveness of physical activity interventions based on type of outcome examined (e.g. step-based outcomes, minutes of exercise, metabolic equivalents or energy expenditure). Heterogeneous approaches to evaluating health outcomes highlight a lack of consensus about what should be measured, with potential implications for reported effectiveness of health psychology interventions.

Similar issues have been observed with heterogeneous use and reporting of OMIs. In a review of 10,000 trials of 1940 interventions for schizophrenia, 2194 different measurement instruments were used; 1142 of these measurement scales were used only once (Miyar et al., 2013). Similarly, a recent review of OMIs for depression and anxiety identified 80 different OMIs (Obbarius et al., 2017). Though research has not specifically focused on potential heterogeneity in how health psychology relevant outcomes are measured, variability in measurement approaches can be seen in existing reviews. For instance a recent review of medication adherence noted that adherence can be measured by self-report, pill count, electronic medication monitors, and pharmacy refill records (Morrissey et al., 2017); this heterogeneity has been noted over 20 years of empirical research on medication adherence (Holmes et al., 2014). Heterogeneity of outcomes and OMIs significantly limits synthesis of effects to determine the most efficacious interventions (Clarke, 2007).

Core Outcome Sets

An approach to potentially address issues of outcome heterogeneity described above, is the development and use of standardised approaches to outcome measurement and reporting. Core outcome sets (COS) represent one such approach. COSs are the standardised minimum

set or group of agreed-upon outcomes that should be measured and reported in any trial of a specific health area (Williamson et al., 2017; Williamson et al., 2012). COSs can also be used in other research such as observational studies, and in clinical audit (Potter, Holcombe, Ward, Blazeby, & Group, 2015; Webbe et al., 2017; Williamson et al., 2017) and practice, as advocated for by the International Consortium of Health Outcome Measurement (ICHOM). Another approach to standardised description of diseases and specific health conditions is the use of the World Health Organisation and the International Classification of Functioning, Disability and Health (ICF) Research Branch core sets. Guidance on the development of core sets are outlined elsewhere (Selb et al., 2015; https://www.icf-research-branch.org/icf-core-sets-projects2). Unlike COSs however, ICF core sets aim to describe disease in a standardised way, rather than standardisation of outcomes in health trials.

It is important to note that COSs are not necessarily intended to be the only outcomes measured in a given study. Researchers can measure and report additional outcomes also, but the COS represents the *minimum* set of outcomes that should be included (Williamson et al., 2017). The most recent review of COS development identified 307 published COS studies (Gargon et al., 2018). COSs have been developed across 31 health and disease categories, including mental health, pregnancy and childbirth, substance dependence, and infectious diseases (Gargon et al., 2018). The majority of COS studies published to date relate to the areas of rheumatology, cancer, neurology, and the heart and circulation (Gargon et al., 2018). The breadth of development of COSs across health areas positions them as a useful tool and approach for health psychology given the focus on psychological, behavioural and biobehavioural aspects of health and well-being. Similarly, there is scope to develop COSs for use in trials of health psychology interventions for a range of health conditions and behavioural outcomes.

Developing Core Outcome Sets.

Determining the outcomes to include in a COS is considered the first step of the process that involves determining *what* to measure. Once a COS has been developed, *how* to measure the COS must then be determined; this is discussed below. The development and use of COSs is promoted and supported by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative. The COMET Initiative is an international initiative established in 2010 with the

aims of raising awareness of existing problems with outcome measurement and reporting; encouraging evidence-based COS development and uptake; and promoting involvement of patients (or their representatives), healthcare professionals, and researchers in the development and uptake of COSs. The COMET Initiative provides resources to support researchers to develop and use COSs, which are available via their website (http://www.comet-initiative.org/). Resources include a publicly searchable database of completed and on-going studies related to COSs, including protocols, systematic reviews and completed COSs. This facilitates identification of existing COSs for use in research and also potential for overlap and collaboration with other research groups conducting similar COS work. Additional resources include a comprehensive COMET Handbook (Williamson et al., 2017) providing guidance on COS development; standards for developing COSs (Kirkham, Davis, et al., 2017); guidelines for reporting COS protocols (Kirkham et al., 2019); and reporting of COSs (Kirkham et al., 2016). Each of these guidelines were developed using rigorous consensus methods, are openly accessible and provide support and guidance throughout the COS process. The COMET Initiative website also provides useful patient resources including plain language summaries and videos about COSs (http://www.comet-initiative.org/).

How to develop a Core Outcome Set. As in-depth guidance on the stages of COS development following COMET Initiative guidelines is published elsewhere (Kirkham, Davis, et al., 2017; Kirkham et al., 2016; Kirkham et al., 2019; Williamson et al., 2017) these stages are only presented in brief here. The first stage is to define the scope of the COS in terms of the health condition, the target population and the interventions for which the COS will be applicable (Williamson et al., 2017). The second stage is to assess the need for a COS by investigating whether a relevant COS already exists. The third and fourth stages are to develop and register the COS development protocol (Kirkham, Davis, et al., 2017; Kirkham et al., 2019). The fifth stage involves determining the level and scope of stakeholder involvement; a checklist of considerations for inclusion of public research partners is available on the COMET website (http://www.comet-initiative.org/). Stage six, determining what to measure, involves a number of steps (Williamson et al., 2017); see Figure 1. These include: a) systematic review(s) to identify all potentially relevant outcomes; b) consideration of outcome similarities and overlap, c) grouping outcomes into outcome domains, e.g. using the 38-item COMET taxonomy (Dodd, Williamson, Blazeby, & Clarke, 2017); d) reaching

consensus on outcomes for inclusion using an online eDelphi (as recommended by COMET), and a subsequent face-to-face consensus meeting. The end product of these stages is a COS containing a minimum set of outcomes agreed upon by stakeholders as essential to be measured and reported in all trials of a specific health outcome.

How to measure core outcomes. Once agreement has been reached on the what, the next step is to decide how to measure the outcomes included in the COS. This involves selecting or developing appropriate outcome measurement instruments (OMIs) or other measurement approaches. Online resources and tools, such as the National Institute of Health funded Patient-Reported Outcomes Measurement Information System (PROMIS) can be a useful resource to select high quality OMIs for commonly relevant outcomes. In the specific context of core outcome set measurement, the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) Initiative is an international initiative founded in 2005 to promote and support evidence-based selection of the most suitable outcome measurement instruments. The COSMIN initiative primarily focuses on patient-reported outcome measures (PROMs) of health status along domains including symptom experiences, functional status, quality of life, and well-being (Butt, 2016; Fleischmann & Vaughan, 2018). The COSMIN methodology can also be used for the selection of other OMIs.

COSMIN provides resources and support for identification and selection of outcome measurement instruments for outcomes within a COS, which are available on the COSMIN website (www.cosmin.nl). The COSMIN taxonomy of measurement properties for patient-reported health outcomes (Mokkink et al., 2010) for instance, outlines three quality domains, containing different measurement properties. These domains are reliability, validity, and responsiveness; interpretability is also included as a quality aspect of OMIs (Mokkink et al., 2010). Prinsen et al. (2016) provide a 4-step guideline on how to select OMIs for COSs. The first step involves conceptual considerations of the construct and target population. The second step involves identifying all existing OMIs (see Terwee, Jansma, Riphagen, & de Vet, 2009, and http://database.cosmin.nl for useful resources). The third step involves assessing the quality of identified OMIs, which can be guided by the COSMIN taxonomy (Mokkink et al., 2010), the COSMIN 10-step guideline for performing systematic reviews of OMIs (Prinsen et al., 2018), and the COSMIN Risk of Bias checklist (Mokkink et al., 2018; Terwee

et al., 2012). The final step involves making recommendations on the selection of OMIs for a COS (Prinsen et al., 2016).

Benefits of COSs in Health Psychology

Adopting the use of COSs in health psychology can have a number of beneficial implications for the field, including evidence syntheses, establishing evidence bases, integrating stakeholder views, translating research into policy and practice, and conducting research in an open and transparent manner.

Evidence syntheses and building empirical bases. Comprehensive evidence syntheses play an important role in evaluating the global body of evidence on the effectiveness of health psychology interventions. As noted by Molloy et al. (2018), progressing the science and practice of health psychology relies on systematic syntheses of evidence from interventions and trials. These systematic reviews and meta-analyses also provide reliable and clinically informed aids to decision making in practice (Coyne, Thombs, & Hagedoorn, 2010). Engagement with and use of COSs facilities improvement of evidence synthesis through standardisation of outcomes and OMIs used within and across trials. For instance, use of a recently developed infant feeding core outcome set for childhood obesity prevention interventions (Matvienko-Sikar, Byrne, et al., 2018; Matvienko-Sikar, Byrne, et al., 2017) will standardise outcomes measured across trials in an area with considerable heterogeneity in outcome assessment (Matvienko-Sikar, Griffin, et al., 2018). As childhood obesity is a significant global health challenge, this has the potential to improve understanding of psychologically informed interventions in this area. Using COSs to develop a more comprehensive evidence base can also inform future intervention development, refinement and/or adaptation. Use of COSs can also facilitate implementation of treatment interventions in practice by ensuring that research includes outcomes of importance to patients and healthcare professionals who make decisions about treatments. This can significantly improve patient and public health (Heneghan et al., 2017).

Integration of stakeholder views. Stakeholder engagement is considered best practice in health research (Byrne, 2019), and development of COSs involves incorporation of

perspectives and opinions of key stakeholders at various stages (Williamson et al., 2017). A recent survey of COS developers indicated that patients, service users, and carers have been included in 87% of COS development to date, with increased engagement evident over time (Biggane, Brading, Ravaud, Young, & Williamson, 2018; Gorst et al., 2016). There is also evidence of increased international stakeholder engagement, for instance in South American and African countries (Gargon et al., 2018). Stakeholder involvement ensures inclusion of outcomes of clinical importance and that are relevant to, and reflect priorities of stakeholders (Biggane et al., 2018; Chalmers et al., 2014; Byrne, 2019). For instance, rheumatoid arthritis patient stakeholders identified fatigue as a core outcome to examine in trials, while prior to this, fatigue was not routinely measured (Kirwan & Hewlett, 2007). Similarly, in development of a COS for trials of interventions to optimise prescribing in older adult care homes, 41 outcomes were identified from interviews and focus groups with stakeholders that were not identified in a systematic review of outcomes (Millar et al., 2017).

Inclusion of stakeholders in COS development also increases the likelihood of COS uptake and use (Staniszewska & Denegri, 2013). For instance, a recent examination with patients, healthcare providers, industry and regulatory agency representatives found that engagement of end-users in COS development is a key factor in influencing uptake of rheumatology COSs (Tunis et al., 2017). Similarly, a qualitative study of nephrologists perspectives of COSs in haemodialysis found that buy-in from gatekeeper stakeholders, such as dialysis providers, is important for COS uptake and implementation (Tong et al. 2017). The use of stakeholder engagement and patient and public involvement (PPI) in the development and use of COSs in health psychology can therefore have a significant and sustained impact on health psychology research, clinical practice (Biggane et al., 2018) and healthcare provision (Kirkham, Clarke, et al., 2017).

Translation of research into policy and practice. Ensuring that health psychology research findings can be translated and used in policy and practice is essential for effecting meaningful change. Translation is the process of adapting research findings to clinical and public health practice (Michie et al., 2013) that facilitates reduction of gaps between research and evidence based practice (Holmes, Scarrow, & Schellenberg, 2012). It has been noted that it can take up to 17 years for research findings to influence healthcare (Morris, Wooding, & Grant, 2011).

One reason why clinical trial findings are often not translated into policy and practice is inappropriate choice of outcomes (Heneghan et al., 2017). As noted, inclusion of stakeholders, including policy makers, ensures that relevant and appropriate outcomes are measured and increases likelihood of uptake and use of COS in relevant contexts, such as in policy and practice. Similarly, organisations and funding bodies can advocate for the use of COSs (Hughes et al., 2019). For instance, the National Institute of Health Research in the UK and Health Research Board in Ireland specify that funding applications consider and include COSs where available and appropriate (HRB, 2018; NIHR, 2019). To date, there is limited evidence to support increased translation of research findings resulting from inclusion of stakeholders in COS development and uptake. However, this is reflective of existing challenges and gaps in knowledge of how best to translate of much health research, including health psychology, into policy and practice (Brownson & Jones, 2009; Kazak & Steele, 2011; McAteer, Di Ruggiero, Fraser, & Frank, 2018; Michie et al., 2013).

Open Research. Recent evidence of replication and reproducibility issues in psychology (Open Science, 2015), including in health psychology (Cybulski, Mayo-Wilson, & Grant, 2016), highlight issues related to openness and transparency in research conduct and reporting. Open and transparent research approaches are paramount to improve scientific rigour (Cybulski et al., 2016; Hagger, 2019; Open Science, 2015), and a more transparent and open approach to health research has been called for in a recent editorial in *Health Psychology Review* (Hagger, 2019). Open research is based on principles of sharing, fairness, inclusion and equity, and an important rationale of open science is that knowledge is a product of social collaboration (Bezjak et al., 2018). COS development adopts this approach from the outset through inclusion and integration of stakeholder views and input in determining what should be measured in trials in specific health areas. In this sense COS development is aligned with the aim of open research to change the value, conduct and dissemination of research, and who is involved in these processes (Bezjak et al., 2018). As noted previously, standardisation of outcome examination and reporting using COSs can also improve conduct and reporting of trials, with potential to minimise issues such as outcome reporting bias in health psychology research.

COS Challenges

Despite the importance and perceived usefulness of incorporating COSs in health psychology, a number of challenges exist in relation to their development and use. COS development requirements can be context specific and so not all COS development projects will encounter the same challenges. A summary of some main challenges in COS development is presented here. Firstly, given the multiple stages involved in development of COSs and associated OMIs, the process can be time consuming and labour intensive. Using technologies such as videoconferencing for stakeholder meetings, as has been done in a number of COS and OMI development studies (Beuscart et al., 2018; Williamson et al., 2017), can help minimise some cost and resource issues. Research is also on-going to identify more resource friendly approaches to COS development (Gorst et al. 2019), such as through development of conceptual frameworks and item banks (Korst et al., 2018). However, availability and appropriate consideration of financial support and funding needed for COS development, including for researchers working on COS development, remains important for successful and timely completion and dissemination of COSs. Better support for development of COSs from research funders, through project or trial methodology funding is needed. Given the systematic approaches to development of COSs and OMIs, funders can be confident in robust scientific methods underlying such research The Health Research Board in Ireland for instance, currently has funding built in to a larger funding stream around trials of interventions, to support development of COS. While the impact of this funding support has yet to be seen, it is a clear step in the right direction of supporting researchers to better determine the core outcomes to include in trials of health interventions.

Other challenges related to enabling and facilitating meaningful stakeholder engagement and contribution across stages of COS development. For instance, recruiting sufficient representative stakeholders from relevant groups, maintaining communication during development stages, and minimising attrition between rounds of COS development are challenging (Biggane et al., 2018). Engaging and involving stakeholders from low and middle-income countries is also important to improve the international applicability of COSs and the trials in which they are used (Davis et al. 2018). To date, only 16% of COSs have included stakeholders from low and middle-income countries however, and so efforts should be improved to include these stakeholders (Davis et al., 2018). Challenges of stakeholder

engagement in the selection of OMIs in particular relate to evaluating the quality of OMIs, which may be beyond the remit of stakeholder input. The COMET handbook (Williamson et al., 2017) and COSMIN guidance (Prinsen et al., 2016) provide potential solutions to some of these issues and so they will not be outlined further here. Finally, where COSs include a large number of outcomes requiring full and appropriate reporting this could prove challenging in some instances due to journal word counts. Approaches such as use of supplementary files accompanying publications can ensure that all outcomes are reported and accessible however. In addition, there are initiatives to support publication of COSs within journals. One such example is the CoRe Outcomes in WOmen's and Newborn health (CROWN) Initiative, which supports and encourages reporting of COSs, as well as embedding of COSs in research practice.

Conclusion

COSs represent a useful approach for conducting, reporting, and improving health psychology research. Development and use of COSs in health psychology can lead to better conduct and reporting of trials, and more cohesive and robust evidence syntheses that enhance knowledge and implementation of health interventions. This can lead to significant beneficial impacts on future health psychology research and the application of research finding in policy and practice. In addition, COSs can help to promote open and transparent health psychology research practices. Overall, COS can help to move health psychology research forward through these processes, and through stakeholder engagement, leading to significant and meaningful changes in patient and public health and healthcare.

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