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University College Cork, Ireland Coláiste na hOllscoile Corcaigh 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).

7 Choice of outcomes is a crucial consideration in the planning and conduct of trials of health 8 interventions (Heneghan et al., 2017), in synthesising evidence about intervention effects 9 (Clarke, 2007), and in producing clinical practice guidelines (Health, 2014). Outcomes, in 10 this context, are what we examine to determine effects of interventions on aspects of health 11 relating to benefits and harms. Outcome measurement instruments (OMIs) are how we 12 measure these outcomes. Choice of outcomes can influence sample sizes, data sources, and 13 length of follow-up in trials (Velentgas, 2013). Tugwell et al. (2007) argue that a trial is only 14 as good as its outcomes, as intervention effects can only be inferred from those outcomes 15 measured and reported. Interpretations of intervention effects can influence research and 16 applications of health psychology findings in practice (Gargon et al., 2018). Outcome choice 17 therefore has the potential to impact on clinical care, including changes to existing practice or 18 introduction of new treatments. The aim of this paper is to introduce and discuss approaches 19 to determining what outcomes to measure in health psychology research, as well as how to 20 measure these outcomes. To do this, we outline existing issues with outcome selection and 21 reporting, introduce core outcome sets (COSs), outline best practice guidelines in how to 22 develop and measure COSs, and discuss benefits and potential challenges of COSs in health 23 psychology.

24

25 Current issues in outcome selection and reporting

26 Considerable heterogeneity in outcomes evaluated and reported across trials significantly

27 limits interpretability and synthesis of intervention effects (Jones & Kaplan, 2003;

28 Schmucker et al., 2014). Examination of outcome heterogeneity across health psychology

29 trials is scarce, as are concerted efforts to address potential heterogeneity within the

30 discipline. This is particularly true in relation to trials of intervention for health behaviours

31 such as diet, physical activity, and medication adherence. However heterogeneity has been

32 examined and reported for a number of outcomes relevant to health psychology to date. For

33 instance, a recent review of 405 trials of brief alcohol interventions identified 2,641 unique 34 outcomes (Shorter et al., 2019). A review of 126 infant feeding studies in the context of 35 childhood obesity prevention also reported significant heterogeneity in outcomes, with 15% 36 of outcomes reported only once (Matvienko-Sikar, Griffin, et al., 2018); the two most 37 frequently reported outcomes were reported in only just over half of the reviewed studies 38 (Matvienko-Sikar, Toomey, et al., 2017). Similarly, reviews of interventions to increase 39 physical activity include a range of physical activity outcomes, including step counts, energy 40 expenditure, and type, frequency, intensity and duration of physical activity (Carr et al., 41 2019; Lock et al., 2020; Malik, Blake and Suggs, 2013; McEwan et al., 2016). Further, one 42 recent review (Lock et al., 2020) noted variations in observed effectiveness of physical 43 activity interventions based on type of outcome examined (e.g. step-based outcomes, minutes 44 of exercise, metabolic equivalents or energy expenditure). Heterogeneous approaches to 45 evaluating health outcomes highlight a lack of consensus about what should be measured, 46 with potential implications for reported effectiveness of health psychology interventions.

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48 Similar issues have been observed with heterogeneous use and reporting of OMIs. In a 49 review of 10,000 trials of 1940 interventions for schizophrenia, 2194 different measurement 50 instruments were used; 1142 of these measurement scales were used only once (Miyar et al., 51 2013). Similarly, a recent review of OMIs for depression and anxiety identified 80 different 52 OMIs (Obbarius et al., 2017). Though research has not specifically focused on potential 53 heterogeneity in how health psychology relevant outcomes are measured, variability in 54 measurement approaches can be seen in existing reviews. For instance a recent review of 55 medication adherence noted that adherence can be measured by self-report, pill count, 56 electronic medication monitors, and pharmacy refill records (Morrissey et al., 2017); this 57 heterogeneity has been noted over 20 years of empirical research on medication adherence 58 (Holmes et al., 2014). Heterogeneity of outcomes and OMIs significantly limits synthesis of 59 effects to determine the most efficacious interventions (Clarke, 2007).

60

61 **Core Outcome Sets**

62 An approach to potentially address issues of outcome heterogeneity described above, is the

63 development and use of standardised approaches to outcome measurement and reporting.

64 Core outcome sets (COS) represent one such approach. COSs are the standardised minimum

65 set or group of agreed-upon outcomes that should be measured and reported in any trial of a

66 specific health area (Williamson et al., 2017; Williamson et al., 2012). COSs can also be used

67 in other research such as observational studies, and in clinical audit (Potter, Holcombe, Ward,

68 Blazeby, & Group, 2015; Webbe et al., 2017; Williamson et al., 2017) and practice, as

69 advocated for by the International Consortium of Health Outcome Measurement (ICHOM).

70 Another approach to standardised description of diseases and specific health conditions is the

vise of the World Health Organisation and the International Classification of Functioning,

- 72 Disability and Health (ICF) Research Branch core sets. Guidance on the development of core
- result re

sets-projects2). Unlike COSs however, ICF core sets aim to describe disease in a standardised

- 75 way, rather than standardisation of outcomes in health trials.
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77 It is important to note that COSs are not necessarily intended to be the only outcomes 78 measured in a given study. Researchers can measure and report additional outcomes also, but 79 the COS represents the *minimum* set of outcomes that should be included (Williamson et al., 80 2017). The most recent review of COS development identified 307 published COS studies 81 (Gargon et al., 2018). COSs have been developed across 31 health and disease categories, 82 including mental health, pregnancy and childbirth, substance dependence, and infectious 83 diseases (Gargon et al., 2018). The majority of COS studies published to date relate to the 84 areas of rheumatology, cancer, neurology, and the heart and circulation (Gargon et al., 2018). 85 The breadth of development of COSs across health areas positions them as a useful tool and 86 approach for health psychology given the focus on psychological, behavioural and 87 biobehavioural aspects of health and well-being. Similarly, there is scope to develop COSs 88 for use in trials of health psychology interventions for a range of health conditions and 89 behavioural outcomes.

90

91 **Developing Core Outcome Sets.**

92 Determining the outcomes to include in a COS is considered the first step of the process that 93 involves determining *what* to measure. Once a COS has been developed, *how* to measure the 94 COS must then be determined; this is discussed below. The development and use of COSs is 95 promoted and supported by the Core Outcome Measures in Effectiveness Trials (COMET) 96 Initiative. The COMET Initiative is an international initiative established in 2010 with the

97 aims of raising awareness of existing problems with outcome measurement and reporting; 98 encouraging evidence-based COS development and uptake; and promoting involvement of 99 patients (or their representatives), healthcare professionals, and researchers in the 100 development and uptake of COSs. The COMET Initiative provides resources to support 101 researchers to develop and use COSs, which are available via their website 102 (http://www.comet-initiative.org/). Resources include a publicly searchable database of 103 completed and on-going studies related to COSs, including protocols, systematic reviews and 104 completed COSs. This facilitates identification of existing COSs for use in research and also 105 potential for overlap and collaboration with other research groups conducting similar COS 106 work. Additional resources include a comprehensive COMET Handbook (Williamson et al., 107 2017) providing guidance on COS development; standards for developing COSs (Kirkham, 108 Davis, et al., 2017); guidelines for reporting COS protocols (Kirkham et al., 2019); and 109 reporting of COSs (Kirkham et al., 2016). Each of these guidelines were developed using 110 rigorous consensus methods, are openly accessible and provide support and guidance 111 throughout the COS process. The COMET Initiative website also provides useful patient 112 resources including plain language summaries and videos about COSs (http://www.comet-113 initiative.org/).

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115 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, 116 117 Davis, et al., 2017; Kirkham et al., 2016; Kirkham et al., 2019; Williamson et al., 2017) these 118 stages are only presented in brief here. The first stage is to define the scope of the COS in 119 terms of the health condition, the target population and the interventions for which the COS 120 will be applicable (Williamson et al., 2017). The second stage is to assess the need for a COS 121 by investigating whether a relevant COS already exists. The third and fourth stages are to 122 develop and register the COS development protocol (Kirkham, Davis, et al., 2017; Kirkham 123 et al., 2019). The fifth stage involves determining the level and scope of stakeholder 124 involvement; a checklist of considerations for inclusion of public research partners is 125 available on the COMET website (http://www.comet-initiative.org/). Stage six, determining 126 what to measure, involves a number of steps (Williamson et al., 2017); see Figure 1. These 127 include: a) systematic review(s) to identify all potentially relevant outcomes; b) consideration 128 of outcome similarities and overlap, c) grouping outcomes into outcome domains, e.g. using 129 the 38-item COMET taxonomy (Dodd, Williamson, Blazeby, & Clarke, 2017); d) reaching

130 consensus on outcomes for inclusion using an online eDelphi (as recommended by COMET),

131 and a subsequent face-to-face consensus meeting. The end product of these stages is a COS

132 containing a minimum set of outcomes agreed upon by stakeholders as essential to be

133 measured and reported in all trials of a specific health outcome.

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135 How to measure core outcomes. Once agreement has been reached on the what, the next 136 step is to decide how to measure the outcomes included in the COS. This involves selecting 137 or developing appropriate outcome measurement instruments (OMIs) or other measurement 138 approaches. Online resources and tools, such as the National Institute of Health funded 139 Patient-Reported Outcomes Measurement Information System (PROMIS) can be a useful 140 resource to select high quality OMIs for commonly relevant outcomes. In the specific context 141 of core outcome set measurement, the COnsensus-based Standards for the selection of health 142 Measurement INstruments (COSMIN) Initiative is an international initiative founded in 2005 to promote and support evidence-based selection of the most suitable outcome measurement 143 144 instruments. The COSMIN initiative primarily focuses on patient-reported outcome measures 145 (PROMs) of health status along domains including symptom experiences, functional status, 146 quality of life, and well-being (Butt, 2016; Fleischmann & Vaughan, 2018). The COSMIN 147 methodology can also be used for the selection of other OMIs.

148 COSMIN provides resources and support for identification and selection of outcome 149 measurement instruments for outcomes within a COS, which are available on the COSMIN 150 website (www.cosmin.nl). The COSMIN taxonomy of measurement properties for patientreported health outcomes (Mokkink et al., 2010) for instance, outlines three quality domains, 151 152 containing different measurement properties. These domains are reliability, validity, and 153 responsiveness; interpretability is also included as a quality aspect of OMIs (Mokkink et al., 154 2010). Prinsen et al. (2016) provide a 4-step guideline on how to select OMIs for COSs. The 155 first step involves conceptual considerations of the construct and target population. The 156 second step involves identifying all existing OMIs (see Terwee, Jansma, Riphagen, & de Vet, 157 2009, and http://database.cosmin.nl for useful resources). The third step involves assessing 158 the quality of identified OMIs, which can be guided by the COSMIN taxonomy (Mokkink et 159 al., 2010), the COSMIN 10-step guideline for performing systematic reviews of OMIs 160 (Prinsen et al., 2018), and the COSMIN Risk of Bias checklist (Mokkink et al., 2018; Terwee

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

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164 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.

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170 **Evidence syntheses and building empirical bases.** Comprehensive evidence syntheses play 171 an important role in evaluating the global body of evidence on the effectiveness of health 172 psychology interventions. As noted by Molloy et al. (2018), progressing the science and 173 practice of health psychology relies on systematic syntheses of evidence from interventions 174 and trials. These systematic reviews and meta-analyses also provide reliable and clinically 175 informed aids to decision making in practice (Coyne, Thombs, & Hagedoorn, 2010). 176 Engagement with and use of COSs facilities improvement of evidence synthesis through 177 standardisation of outcomes and OMIs used within and across trials. For instance, use of a 178 recently developed infant feeding core outcome set for childhood obesity prevention 179 interventions (Matvienko-Sikar, Byrne, et al., 2018; Matvienko-Sikar, Byrne, et al., 2017) 180 will standardise outcomes measured across trials in an area with considerable heterogeneity 181 in outcome assessment (Matvienko-Sikar, Griffin, et al., 2018). As childhood obesity is a 182 significant global health challenge, this has the potential to improve understanding of 183 psychologically informed interventions in this area. Using COSs to develop a more 184 comprehensive evidence base can also inform future intervention development, refinement 185 and/or adaptation. Use of COSs can also facilitate implementation of treatment interventions 186 in practice by ensuring that research includes outcomes of importance to patients and 187 healthcare professionals who make decisions about treatments. This can significantly improve patient and public health (Heneghan et al., 2017). 188

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

192 perspectives and opinions of key stakeholders at various stages (Williamson et al., 2017). A 193 recent survey of COS developers indicated that patients, service users, and carers have been 194 included in 87% of COS development to date, with increased engagement evident over time 195 (Biggane, Brading, Ravaud, Young, & Williamson, 2018; Gorst et al., 2016). There is also 196 evidence of increased international stakeholder engagement, for instance in South American 197 and African countries (Gargon et al., 2018). Stakeholder involvement ensures inclusion of 198 outcomes of clinical importance and that are relevant to, and reflect priorities of stakeholders 199 (Biggane et al., 2018; Chalmers et al., 2014; Byrne, 2019). For instance, rheumatoid arthritis 200 patient stakeholders identified fatigue as a core outcome to examine in trials, while prior to 201 this, fatigue was not routinely measured (Kirwan & Hewlett, 2007). Similarly, in 202 development of a COS for trials of interventions to optimise prescribing in older adult care 203 homes, 41 outcomes were identified from interviews and focus groups with stakeholders that

204 were not identified in a systematic review of outcomes (Millar et al., 2017).

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206 Inclusion of stakeholders in COS development also increases the likelihood of COS uptake 207 and use (Staniszewska & Denegri, 2013). For instance, a recent examination with patients, 208 healthcare providers, industry and regulatory agency representatives found that engagement 209 of end-users in COS development is a key factor in influencing uptake of rheumatology 210 COSs (Tunis et al., 2017). Similarly, a qualitative study of nephrologists perspectives of 211 COSs in haemodialysis found that buy-in from gatekeeper stakeholders, such as dialysis 212 providers, is important for COS uptake and implementation (Tong et al. 2017). The use of 213 stakeholder engagement and patient and public involvement (PPI) in the development and 214 use of COSs in health psychology can therefore have a significant and sustained impact on 215 health psychology research, clinical practice (Biggane et al., 2018) and healthcare provision 216 (Kirkham, Clarke, et al., 2017).

217

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). 224 One reason why clinical trial findings are often not translated into policy and practice is 225 inappropriate choice of outcomes (Heneghan et al., 2017). As noted, inclusion of 226 stakeholders, including policy makers, ensures that relevant and appropriate outcomes are 227 measured and increases likelihood of uptake and use of COS in relevant contexts, such as in 228 policy and practice. Similarly, organisations and funding bodies can advocate for the use of 229 COSs (Hughes et al., 2019). For instance, the National Institute of Health Research in the UK 230 and Health Research Board in Ireland specify that funding applications consider and include 231 COSs where available and appropriate (HRB, 2018; NIHR, 2019). To date, there is limited 232 evidence to support increased translation of research findings resulting from inclusion of 233 stakeholders in COS development and uptake. However, this is reflective of existing 234 challenges and gaps in knowledge of how best to translate of much health research, including 235 health psychology, into policy and practice (Brownson & Jones, 2009; Kazak & Steele, 2011; 236 McAteer, Di Ruggiero, Fraser, & Frank, 2018; Michie et al., 2013).

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238 **Open Research.** Recent evidence of replication and reproducibility issues in psychology 239 (Open Science, 2015), including in health psychology (Cybulski, Mayo-Wilson, & Grant, 240 2016), highlight issues related to openness and transparency in research conduct and 241 reporting. Open and transparent research approaches are paramount to improve scientific 242 rigour (Cybulski et al., 2016; Hagger, 2019; Open Science, 2015), and a more transparent and 243 open approach to health research has been called for in a recent editorial in *Health* 244 Psychology Review (Hagger, 2019). Open research is based on principles of sharing, fairness, 245 inclusion and equity, and an important rationale of open science is that knowledge is a 246 product of social collaboration (Bezjak et al., 2018). COS development adopts this approach 247 from the outset through inclusion and integration of stakeholder views and input in 248 determining what should be measured in trials in specific health areas. In this sense COS 249 development is aligned with the aim of open research to change the value, conduct and 250 dissemination of research, and who is involved in these processes (Bezjak et al., 2018). As 251 noted previously, standardisation of outcome examination and reporting using COSs can also 252 improve conduct and reporting of trials, with potential to minimise issues such as outcome 253 reporting bias in health psychology research.

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256 COS Challenges

257 Despite the importance and perceived usefulness of incorporating COSs in health 258 psychology, a number of challenges exist in relation to their development and use. COS 259 development requirements can be context specific and so not all COS development projects 260 will encounter the same challenges. A summary of some main challenges in COS 261 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 262 263 technologies such as videoconferencing for stakeholder meetings, as has been done in a 264 number of COS and OMI development studies (Beuscart et al., 2018; Williamson et al., 265 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 266 267 development of conceptual frameworks and item banks (Korst et al., 2018). However, 268 availability and appropriate consideration of financial support and funding needed for COS 269 development, including for researchers working on COS development, remains important for 270 successful and timely completion and dissemination of COSs. Better support for development 271 of COSs from research funders, through project or trial methodology funding is needed. 272 Given the systematic approaches to development of COSs and OMIs, funders can be 273 confident in robust scientific methods underlying such research The Health Research Board 274 in Ireland for instance, currently has funding built in to a larger funding stream around trials 275 of interventions, to support development of COS. While the impact of this funding support 276 has yet to be seen, it is a clear step in the right direction of supporting researchers to better 277 determine the core outcomes to include in trials of health interventions.

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279 Other challenges related to enabling and facilitating meaningful stakeholder engagement and 280 contribution across stages of COS development. For instance, recruiting sufficient 281 representative stakeholders from relevant groups, maintaining communication during 282 development stages, and minimising attrition between rounds of COS development are 283 challenging (Biggane et al., 2018). Engaging and involving stakeholders from low and 284 middle-income countries is also important to improve the international applicability of COSs 285 and the trials in which they are used (Davis et al. 2018). To date, only 16% of COSs have 286 included stakeholders from low and middle-income countries however, and so efforts should 287 be improved to include these stakeholders (Davis et al., 2018). Challenges of stakeholder

288 engagement in the selection of OMIs in particular relate to evaluating the quality of OMIs, 289 which may be beyond the remit of stakeholder input. The COMET handbook (Williamson et 290 al., 2017) and COSMIN guidance (Prinsen et al., 2016) provide potential solutions to some of 291 these issues and so they will not be outlined further here. Finally, where COSs include a large 292 number of outcomes requiring full and appropriate reporting this could prove challenging in 293 some instances due to journal word counts. Approaches such as use of supplementary files 294 accompanying publications can ensure that all outcomes are reported and accessible however. 295 In addition, there are initiatives to support publication of COSs within journals. One such 296 example is the CoRe Outcomes in WOmen's and Newborn health (CROWN) Initiative, 297 which supports and encourages reporting of COSs, as well as embedding of COSs in research 298 practice.

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300 Conclusion

301 COSs represent a useful approach for conducting, reporting, and improving health 302 psychology research. Development and use of COSs in health psychology can lead to better 303 conduct and reporting of trials, and more cohesive and robust evidence syntheses that 304 enhance knowledge and implementation of health interventions. This can lead to significant 305 beneficial impacts on future health psychology research and the application of research 306 finding in policy and practice. In addition, COSs can help to promote open and transparent 307 health psychology research practices. Overall, COS can help to move health psychology 308 research forward through these processes, and through stakeholder engagement, leading to 309 significant and meaningful changes in patient and public health and healthcare.

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