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Implementation fidelity of physiotherapist-delivered group education and exercise interventions to promote self-management in people with osteoarthritis and chronic low back pain: A rapid review Part II*



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ABSTRACT

Background: Implementation fidelity is the extent to which an intervention is delivered as intended by intervention developers, and is extremely important as it increases confidence that changes in study outcomes are due to the effect of the intervention itself and not due to variability in implementation. A paucity of literature exists concerning implementation fidelity in physiotherapy research.

Design and objectives: This rapid review aimed to evaluate the implementation fidelity of group-based self-management interventions for people with osteoarthritis (OA) and/or chronic low back pain (CLBP). *Method:* Group-based self-management interventions delivered by health-care professionals (including at least one physiotherapist) involving adults with OA and/or CLBP were eligible for inclusion. The National Institutes of Health Behaviour Change Consortium Treatment Fidelity checklist was used to assess fidelity and applied independently by two reviewers.

Results: In total, 22 studies were found. Fidelity was found to be very low (mean score 35%) within the included studies with only no studies achieving >80% on the framework. The domain of Training of Providers achieved the lowest fidelity rating (10%) across all studies.

Conclusions: Overall levels of implementation fidelity are low in self-management interventions for CLBP and/or OA; however it is unclear whether fidelity is poor within the trials included in this review, or just poorly reported. There is a need for the development of fidelity reporting guidelines and for the refinement of fidelity frameworks upon which to base these guidelines.

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1. Background

Implementation fidelity has been defined as 'the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions' (Bellg et al., 2004), or the extent to which the core components of an intervention are delivered as intended in the intervention protocol (Gearing et al., 2011). Implementation fidelity is imperative in all stages and phases of intervention development and implementation as it helps to increase scientific confidence that changes in the study outcomes are due to the influence of the independent variable or the intervention being investigated and not due to variability in the

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implementation of the intervention (Borrelli, 2011). The importance of ensuring and reporting fidelity in clinical trials, particularly in pragmatic trials, cannot be understated. What works in theory is only as effective as what happens in practice, and by evaluating the fidelity of an intervention throughout, it enables the point at which the intervention has failed or been successful to be determined, allowing results to be interpreted with confidence (Dusenbury et al., 2003; Bellg et al., 2004; Gearing et al., 2011). Complex interventions are defined by the Medical Research Council (MRC) as interventions with several interacting components (Craig et al., 2008). As these numerous components have even more potential to affect or influence outcomes separately, and fidelity within complex interventions may be more difficult to address (Craig et al., 2008), it is especially important to incorporate adequate intervention fidelity planning and reporting into trials of this nature.

Chronic low back pain (CLBP) and osteoarthritis (OA) are among the most prevalent and costly chronic musculoskeletal pain (CMP) conditions in the developed world (World Health Organisation, 2003; Buchbinder et al., 2013). Increased waiting lists and

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demands on healthcare services mean that group-based interventions that attempt to enhance self-management for multiple prominent conditions are attractive to healthcare providers (Walsh et al., 2013). Self-management has long been recognised as an important aspect of the healthcare of people with chronic conditions (Wagner, 1999), however evidence for its effectiveness in CMP conditions is conflicting (Oliveira et al., 2012; Kroon et al., 2014) and the effectiveness of self-management interventions for multiple conditions is poorly researched. This review of implementation fidelity was conducted in conjunction with a rapid review of the effectiveness of group-based physiotherapy-led exercise and education interventions to promote self-management for people with OA and CLBP. The review of effectiveness found little difference between the effectiveness of these interventions in comparison to individual physiotherapy or usual general practitioner (GP) care. However, without an assessment of implementation fidelity, it is difficult to fully interpret the results of effectiveness.

In 2005 the National Institutes of Health Behaviour Change Consortium (NIHBCC) developed a 25-component checklist for assessing the reporting of fidelity within trials (Borrelli et al., 2005). The checklist was updated in 2011 to include 40 components, with the expansion mostly concerning the fidelity of implementation of the theoretical model underpinning the intervention and theorybased 'active ingredients' or mechanisms of action, better description of the intervention and selecting appropriate providers (Borrelli, 2011). Although the NIHBCC framework has been in existence for almost a decade, and was specifically developed for use in pragmatic behaviour change studies, it is still not used widely in the development or reporting of behaviour change clinical trials (Robb et al., 2011). Studies that have used the framework often address only some of the five domains (Mars et al., 2013) or use a self-simplified version (Culloty et al., 2010). Previous commentaries on the NIHBCC framework have deemed it inflexible and time and labour-intensive (Leventhal and Friedman, 2004), however other studies argue that the importance of ensuring fidelity outweighs the cost and time (Mars et al., 2013), and the authors of the framework themselves call for 'flexible adaptation' within the five domains with respect to provider experience and participant learning styles (Borrelli, 2011). Although other fidelity frameworks exist (Carroll et al., 2007; Gearing et al., 2011), this particular framework was chosen as it is the only one specifically developed for behaviour change interventions in real-life pragmatic clinical settings and has been previously found to be reliable and valid (Borrelli et al., 2005; Johnson-Kozlow et al., 2008). To the best of our knowledge, no fidelity reviews have yet been published using the updated 2011 checklist. Likewise, no existing reviews of selfmanagement interventions for CMP conditions have thoroughly evaluated fidelity within these trials (Carnes et al., 2012; Oliveira et al., 2012; Kroon et al., 2014), and although topical within psychology and educational research (Maynard et al., 2013), a significant dearth of literature exists regarding implementation fidelity within physiotherapy or CMP research.

In recent times, rapid review and 'evidence summary' methodologies have been gaining popularity in response to the need for timely evidence to address pressing health service issues and have emerged as a streamlined approach to collating and evaluating evidence (Khangura et al., 2012). Rapid reviews are seen as 'literature reviews that use methods to accelerate or streamline traditional systematic review processes' (Ganann et al., 2010, p. 1) and are becoming more widespread to ensure timely evidenceinformed decision making and practice for clinicians (Branas et al., 2000; Foxcroft and Milne, 2000; Ahmadzai et al., 2013). Cochrane systematic reviews (commonly viewed as the gold standard of literature review) can take up to two years to complete, whereas rapid reviews typically are completed within one to six months (Ganann et al., 2010) and have previously been completed in a variety of areas ranging from the effectiveness of emergency department 'short stay units' (Konnyu et al., 2012) to paediatric surgical procedures (Ahmadzai et al., 2013). With an increasing focus on knowledge translation and closing the evidence-practice gap (Grimshaw et al., 2012), rapid reviews are an effective way to accelerate the dissemination of synthesised evidence for specific interventions, thus 'supporting the development of clinical interventions and/or health service programmes' (Khangura et al., 2012, p. 2) and maximising implementation.

The gold standard for the most effective and efficient rapid review methodology has not yet been established (Ganann et al., 2010; Harker and Kleijnen, 2012), nor has consensus on the definition of a rapid review been reached (Khangura et al., 2012). However, the literature has highlighted the importance of transparency to enable replication and the reporting of the assessed risk of bias of included studies over extensive searching as methods of ensuring rigour within rapid reviews (Watt et al., 2008; Ganann et al., 2010). Rapid reviews are not intended to replace full systematic reviews and often sacrifice important elements of systematic reviews, such as comprehensive searching with no language restrictions and indepth meta-analysis of results, because of restricted timelines. Due to these limitations, inferences made from rapid review findings must be interpreted with more caution than those made from the findings of a systematic review. The aims of this rapid review were to provide a timely and specific review of the implementation fidelity of group-based, physiotherapy-led self-management interventions for people with OA and/or CLBP, and additionally, to contribute to the interpretation of the results of the effectiveness review.

2. Methods

2.1. Searches and selection

To expedite the search process whilst preserving rigour and preventing bias, a two phase approach was undertaken. In phase one the most recent relevant systematic reviews were identified and used as sources of relevant primary trials. This was followed by phase two which identified relevant studies that had been published since the search date of the most recent review identified in phase one. The electronic databases of Medline (Ovid), Embase, Cinahl, Cochrane Database of Systematic Reviews (Phase 1 only) and Cochrane Register of Controlled Trials (Phase 2 only) were searched. Phase one searched combined terms for 'self-management education' AND 'exercise', 'CLBP'OR 'OA' OR 'chronic musculoskeletal pain' AND 'reviews' (no limit - 26/08/13). Phase two was conducted using the same combination of terms as phase one with the addition of 'physiotherapy' AND 'group' and the substitution of 'trials' for 'reviews' (Appendix). Reference lists of included studies were screened in addition to identification of studies from citation lists of known authors in the area. The criteria for inclusion of studies are described in Table 1. Due to the lack of consensus regarding the most appropriate outcome measures for selfmanagement interventions (Nolte et al., 2013) it was decided not to exclude studies on the basis of outcome measure. Two review authors (ET and DH) independently screened all systematic reviews identified in both phases. Reviewers resolved any disagreements through consensus and if consensus could not be achieved, a third reviewer (LCM) independently screened the study in question and the decision of the majority was taken.

2.2. NIHBCC Treatment Fidelity checklist

The NIHBCC checklist addresses components within five specific fidelity domains: Study Design, Training of Providers, Treatment

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