BMJ Open Effectiveness of behavioural change techniques in physiotherapy interventions to promote physical activity adherence in patients with hip and knee osteoarthritis: a systematic review protocol

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ABSTRACT

Introduction Osteoarthritis (OA) is a common degenerative articular disease, the highest cause of individual level disability and a significant socioeconomic burden to healthcare services. Patient education and physical activity (PA) prescription are recommended components of interventions in several healthcare guidelines and are commonly provided by physiotherapists. However, these interventions lack long-term clinical effectiveness. Patient adherence to PA prescription requires patients to modify their PA behaviour and appears critical in maintaining symptomatic improvements. This systematic review aims to evaluate the effectiveness of behavioural change techniques (BCTs) used in physiotherapy interventions to improve PA adherence.

Methods and analysis Medline, Cochrane and PEDro registers of Controlled Trials, EMBASE, CINAHL and PsycInfo databases, and key grey literature sources will be rigorously searched for randomised controlled trials that compared a physiotherapy intervention incorporating BCTs with other therapies, placebo interventions, usual care or no-treatment. Two independent researchers will conduct literature searches, assess trial eligibility, extract data, conduct risk of bias assessment (using Cochrane risk of bias tool), classify BCTs and evaluate the quality of the body of literature following Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines. Narrative synthesis of key outcomes will be presented and meta-analysis will be performed if included trials are clinically homogenous, based on their intervention and comparator groups and outcome measures. This review will be reported in line with the Preferred Reporting Items for Systematic review and Meta-Analysis guidelines.

Ethics and dissemination Research ethics approval is not required. This review will help inform clinicians and researchers on the most effective behavioural change techniques used in physiotherapy interventions to enhance adherence to PA prescription for patients with lower limb OA. The findings will be disseminated through

Strengths and limitations of this study

- This systematic review will be the first to rigorously search for, and evaluate the effectiveness of, behavioural change techniques (BCTs), using the behavioural change taxonomy V1, in physiotherapy randomised controlled trials (RCTs) to promote physical activity (PA) adherence in patients with lower limb osteoarthritis (OA).
- This research will offer physiotherapists and other clinician's evidence-based guidance in selecting BCTs to enhance adherence to PA prescription in patients with lower limb OA.
- Several heterogeneous interventions comparison groups, variabilities in OA severity, and a limited number of trials are anticipated based on a scoping search. This may preclude metaanalysis, affecting the overall level of evidence for RCT groupings and therefore not enabling firm conclusions on BCT effectiveness to be established.

publication in a peer-reviewed journal and conference presentations.

Trial registration number PROSPERO CRD42016039932.

BACKGROUND

Osteoarthritis (OA) is a common degenerative disease that causes patients significant pain and reductions in function, social engagement and quality of life. OA results in considerable societal healthcare costs and resource utilisation. In UK, OA is the most common cause of individual disability, where it is estimated to affect approximately 8.5 million people.³ Annually, OA symptoms are estimated to be responsible for approximately 2 million general practitioner visits in the UK, with an expenditure totalling 1%



of the country's gross national product.³ OA primarily affects the hip and knee synovial joints, with an overall point prevalence of 11% and 24%, respectively⁴.

Healthcare interventions that incorporate education and physical activity (PA)/exercise prescription are recommended for the non-pharmacological management of OA in several international guidelines. 1 3 5 6 Physiotherapists are commonly the primary healthcare practitioner to whom patients with lower limb OA are referred and are well placed to deliver these interventions. Although education and PA interventions are effective at reducing short-term OA symptoms and clinical outcomes, they lack long-term effectiveness. 11 With estimates that 50%-70% of patients do not comply with physiotherapy PA recommendations, 12 13 adherence has been identified as a critical reason for this lack of longterm effectiveness. As OA is a life-long condition, with point prevalence and incidence increasing with age,⁴ long-term adherence to PA recommendations is critical to maintain the short-term improvements seen in a patient's pain, 15 function 16 and disability. 17

Due to healthcare costs and time constraints, physiotherapy appointments are often limited in number and focus on short-term outcomes only. As there is usually a gradual decrease in clinical contact time between patient and therapist, long-term PA will most likely continue without supervision in the home/community. As the positive effects of PA reduce if discontinued, and patient adherence diminishes when physiotherapist supervision ceases, long-term adherence to recommendations is important and requires patients to change and sustain this change in PA behaviour.

Despite the importance of monitoring PA adherence, at present there is limited evidence to suggest the most appropriate outcomes to measure the maintenance of PA in patients with lower limb OA.²¹ A recent systematic review concluded that no recommendations could be made for any PA adherence outcomes in patients with chronic musculoskeletal pain²² due to methodological issues with diagnostic accuracy trial design. Furthermore, none of the seven outcomes identified in the review were validated on patients with OA. A further systematic review identified PA adherence measures used in self-management interventions for patients with musculoskeletal pain.²³ Six of the 47 trials in the review included participants with lower limb OA, with three of these incorporating exercise diaries and three a multi-item measure to measure PA adherence.²³

Behavioural change interventions incorporate synchronised techniques that target specific patient health behaviours. ²⁴ Behavioural change interventions are usually complex ²⁵ and commonly reported inconsistently in trials, ²⁶ ²⁷ making them difficult to replicate in clinical practice. ²⁸

Incorporating 'active' behavioural techniques (eg, pacing and self-regulatory skills)²⁹ into interventions, which encourage patients to participate in their own symptom management has demonstrated greater

effectiveness than 'passive' techniques²⁸ (provision of information and advice) at maintaining PA behaviours on patients with OA.⁷

Behavioural change techniques (BCTs) are the active components in behaviour al change interventions. Michie *et al* (p. 82) define BCTs as 'an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour' and include techniques such as 'reinforcement', 'self-monitoring' and 'feedback'. The identification of BCTs has allowed for specific techniques to be transparently highlighted within interventions and subsequently demonstrated clinical effectiveness. ²⁷

Intervention fidelity is the degree to which an intervention's active ingredients are delivered as intended. Intervention fidelity assessment is especially important in behavioural change interventions as it can help determine whether the treatment effect is due to the interacting BCTs or from a variation in the delivery of the intervention protocol. In Behaviour Change Taxonomy V1²⁷ has been developed to help authors identify BCTs and improve consistency of reporting, I allowing trials to comply with CONSORT, Medical Research Council and Template for Intervention Description and Replication guidelines for the transparent reporting of interventions and its use should therefore improve intervention fidelity assessment.

Existing PA systematic reviews examining BCTs have focused on broad patient populations, ²⁹ ^{37–43} diabetes, ⁴⁴ cardiovascular disease 45 and rheumatoid arthritis (RA). 46 To date, only one systematic review⁴⁰ has examined BCT use in physiotherapy practice treating patients with lower limb OA and chronic low back pain with an associated paper assessing each trial's intervention fidelity.³³ This scoping review identified 33 BCTs used within physiotherapy self-management interventions with no trial (out of n=22) demonstrating 'high' treatment fidelity (>80% of components present).33 Therefore, individual BCT effectiveness was difficult to measure and meta-analysis was not conducted. Furthermore, the grey literature was not searched, meaning up to 10% of eligible trials were not included, 47 the review did not target a specified health behaviour (PA adherence) and focused on group classes only. Physiotherapists most commonly treat patients with lower limb (hip and knee) OA individually (1:1), 48 and tailoring an intervention to the patients' particular situation is critical to enhance adherence to PA prescription. 49 Furthermore, recent systematic reviews suggested that 1:1 treatments may provide greater improvements on pain and function than group classes on patients with knee OA⁵⁰ and RA,⁴⁶ respectively.

Identifying effective BCTs within interventions for patients with chronic conditions is a research priority for the National Institute of Clinical Excellence with 'social support', 'feedback and monitoring' and 'goals and planning', suggested as integral components of programmes to support PA behavioural change. 30 Additionally, in systematic reviews of PA behaviours, 38 43 44 the BCTs'

'instruction on how to perform the behaviour', 'demonstration of the behaviour', 'problem-solving' and 'use of follow-up prompts' have been identified as strategies within effective interventions.

As the largest healthcare provider of exercise prescription to patients with musculoskeletal pain in the National Health Service, ⁸ physiotherapists are well placed to deliver interventions that incorporate BCTs. However, physiotherapists need to increase their understanding of patients' PA behaviours and motivations to enhance adherence to their recommendations.⁵¹ Although physiotherapists are encouraged, 52 53 and attempt, 54 to use behavioural change interventions in their clinical practice, recent evidence suggests that they lack the knowledge base to do so effectively.⁵⁴ A recent systematic review suggested that while incorporating behavioural change into physiotherapy programmes can enhance patient PA adherence, the most effective BCTs have not been determined.⁵⁵ Furthermore, there is a lack of standardised definitions and understanding of BCTs used in physiotherapy interventions when treating patients with OA.

Therefore, the aim of this systematic review is to identify which BCTs used in individual physiotherapy interventions to improve adherence to PA recommendations are most effective in treating patients with lower limb (knee and hip) OA symptoms.

OBJECTIVES

- ▶ To identify BCTs used in individual outpatient physiotherapy interventions to increase or maintain PA adherence outside of the clinic in patients with hip and knee OA.
- ▶ To evaluate the clinical effectiveness (on outcomes of PA, adherence, pain, function, quality of life, self-efficacy and adverse effects) of BCTs used in individual outpatient physiotherapy interventions to increase or maintain PA adherence outside of the clinic in patients with hip and knee OA.

METHODS

This systematic review will be conducted according to a predefined protocol (CRD42016039932) which complies with recommendations from the Cochrane Collaboration Musculoskeletal group⁵⁶ and Centre of Reviews and Dissemination guidelines,⁵⁷ and will be reported following Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.⁵⁸

Eligibility criteria

- 1. Trial design: Randomised controlled trials (RCTs) including protocols, results and fidelity papers where available.
- 2. Participants: Adult participants (≥18 years) with hip and/or knee OA. Diagnosis can be based on acknowledged symptoms, self-reported joint pain or radiographic evidence due to the inconsistency of criteria used across guidelines for hip and knee OA

- diagnosis.⁴ RCTs whose participants have OA with other chronic coexisting articular pathologies⁵⁹ that contribute >25% of their population will be excluded⁵⁶ (eg, septic arthritis, inflammatory joint disease, gout, articular fracture, hemochromatosis). Trials whose participants have had,^{49 60} or are awaiting,^{8 49} surgery for OA treatment (eg, joint arthroplasty) will be excluded, as PA adherence behaviours in this patient population may be different.⁶¹
- Interventions: Any structured outpatient physiotherapy programme that incorporates a BCT that appears on the V1 Taxonomy²⁷ as defined by Michie et al that focuses on maintaining or increasing patient PA adherence when away from the physiotherapy clinic (eg, at home or in community). BCTs can include, but are not exclusively: 'prompt self-monitoring of behaviour', 'goal setting', 'social support'62 and 'reinforcement'. 27 The intervention must be delivered individually by a physiotherapist (with the profession stated clearly) although follow-up or 'booster' sessions may take different forms (eg, telephone calls). Other members of a multidisciplinary team may be involved in any aspect of the patient's management provided that the physiotherapist is the primary healthcare professional involved and their role can be established by the researcher. Trials that incorporate carers or peer support will be included as long as the patient is the primary target of the physiotherapy intervention.
- 4. Comparators: Other therapies, placebo interventions, 'no treatment', 'usual care' will be included. RCTs that examined two physiotherapy interventions incorporating BCTs will be included provided that there are different BCTs in each intervention arm, therefore allowing their effectiveness to be determined. RCTs that include cointerventions will be included if the comparison group receives the same cointervention, thereby enabling the effectiveness of the BCTs to be evaluated.
- 5. Outcomes: It is preferable for trials to have measured PA adherence. Therefore, the main outcomes of interest include PA (eg, pedometers, self-report questionnaires)²¹ and adherence measures (eg, exercise diaries),²³ although other clinical outcomes of effectiveness (pain, function, quality of life, self-efficacy and adverse effects) will be considered provided they are collected with validated measures.⁴⁹ A note will be made during data extraction whether the trial measured PA adherence specifically and this will interpreted in the discussion section. Only trials that measured PA adherence will be considered for meta-analysis.
- 6. Language: Trials that are not written in English will be excluded (at full text stage).

Search methods for trial identification

Medline (OVID) from 1946, the Cochrane Register of Controlled Trials (CENTRAL) from 1940, EMBASE from 1946, the Physiotherapy Evidence Data base (PEDro) from 1999, Cumulative Index to Nursing and Allied Health Literature (CINAHL) from 1937 and PsycInfo (OVID) from 1806, will be searched. 56 The clinicaltrial. gov trial register and WHO's trial portal will be searched for relevant trials.⁵⁶ Grey literature will be searched on the 'ZETOC' and 'Conference Proceedings Citation

Index' websites. Reference lists of all included trials and relevant review articles and a citation search using 'web of science' will be conducted. The search strategy for Medline (table 1) has been developed in consultation with a subject-specific librarian and will be adapted for use in other databases. Search terms are informed from recent systematic reviews investigating OA, 50 63 64 physiotherapy,

Table 1 Search strate	gy to be used for the MEDLINE electronic database
Database	Search terms
	Search terms 1) exp osteoanthritis/ 2) osteoanthrisk.w. 3) (dependance adj2 arthritis).tw. 4) arthrosis.tw. 5) Or 1-4 6) Arthrosis.tw. 5) Or 1-4 7) Invertible of the search of the sea
	62) randomi?ed.ab. 63) placebo.ab.
	63) placebo.ab. 64) drug therapy.fs.
	65) randomly.ab. 66) trial.ab. 67) groups.ab.
	68) Or/ 60-67 69) exp animals/ not humans.sh.
	70) 68 not 69 71) 5 and 12 and 50 and 59 and 70

behavioural and education interventions 9 50 55 $^{63-65}$ and the scoping search to identify keywords in relevant trials. 7 66 RCT filters, as recommended by the Cochrane Collaboration, will be used to prioritise sensitivity over specificity. 47 $^{67-69}$

Study selection and data management

Two independent researchers (MJW, ChG) will conduct the initial searches, review abstract and titles, read the full text of included trials or those where uncertainty remains, review relevant reference lists and conduct the citation search. In cases where the two researchers cannot agree on eligibility, a third researcher (AR, subject and methodological expertise) will mediate. Initial search results will be uploaded to Refworks prior to the review of titles and abstracts. Included trials will be managed through EndNote. A PRISMA flow chart will be used to provide transparency of the number of trials included or excluded at each stage.

Data collection process and analyses

Two independent researchers (MJW, SF) will use a standardised data extraction form developed from the Cochrane Back and Neck group template to record information on participants, trial setting, eligibility criteria, risk of bias assessment, methodology design, intervention, outcome measures (with special attention on PA adherence measures), assessment time points, PA adherence BCTs within the intervention, the deliverer of BCTs and any training they undertook and the main trial results. ⁷⁰

Data extraction will include detail on trial treatment fidelity. Although several checklists exist to assess intervention fidelity,⁷¹ The National Institutes of Health Behaviour Change Consortium's (NIHBCC) checklist is unique in its focus on behavioural change trials and has demonstrated validity and reliability.³² The NIHBCC checklist has 40 components and was developed in 2011⁷³ from the initial version which had 25 components. 32 The NIHBCC's checklist comprises five domains: 'Treatment design', 'Training Providers', 'Delivery of Treatment', 'Receipt of Treatment' and 'Enactment of Treatment skills'. Although Toomey *et al* 33 did not find any association between trial date and fidelity, the consideration and assessment of fidelity is a relatively contemporary concept and the scoping search revealed several trials conducted prior, or at a similar time, to the NIHBCC checklists creation. While it is not the primary research question in this systematic review, trials treatment fidelity needs to be acknowledged when determining intervention effectiveness. Therefore, in order not to overtly penalise trials but to aid interpretation, each domain on the NIHBCC checklist will be judged as 'present' or 'absent' by two independent researchers (MJW, SF) but no score will be given to individual items. These details will be included as part of the narrative synthesis and interpreted in the discussion when drawing conclusions regarding BCT effectiveness.

The data extraction form will be piloted on the full texts of several included RCTs to ensure reliability and will be altered as necessary to optimise data collection. Any disagreement between researchers will be resolved through discussion. If agreement cannot be reached, a third reviewer (AR) will mediate. Where there are multiple reports of the same trial, data will be extracted using separate forms and collated on a single form subsequently. Trial authors will be contacted by email if information is missing or unclear.

Two independent researchers (MJW, SF) will code interventions using the 'Behaviour Change Taxonomy'. 27 BCTs and their associated hierarchy will be included as a component of the data extraction. As per training instructions, the associated text and page number will be recorded and the BCT will be given a 'score' of + (present in all probability) or ++ (present beyond all reasonable doubt)⁷⁴ to facilitate further discussion. Only BCTs that are directed at PA adherence behaviour will be coded.⁷⁴ Trials that have available protocols and fidelity papers will also be coded. 40 The researchers will undergo online training on the use of the taxonomy and the coding process will be piloted a priori. To ensure that a 'postlearning effect'⁷⁵ is minimised, a period of integration will be observed after the training, and coders will meet regularly to minimise discrepancies in taxonomy understanding and enhance agreement. Taxonomy use will be piloted a priori, and coder agreement will be calculated using Cohen's Kappa statistic. Any disagreement between the researchers will be resolved by researcher consensus. In the event that consensus cannot be reached, a third researcher (ID, expertise in subject area of behavioural change) will mediate the decision (objective 1).

Risk of bias assessment

Two independent researchers (MJW, SF) will use the Cochrane Risk of Bias tool to assess the internal validity of included trials. 76 The tool was developed by a research working group and is recommended for use in systematic reviews. It uses domain-based evaluation rather than a check list or scoring system to assess internal validity⁷⁶ and allows review authors space to justify their conclusions.⁷⁷ The tool addresses six domains: 'sequence generation', 'allocation concealment', 'blinding', 'incomplete outcome data', 'selective outcome reporting' and 'other' sources of bias. A judgement of 'high', 'unclear' or 'low' risk of bias will be made for each domain. A judgement of 'Unclear' will be allocated to a domain where insufficient information is provided. Trials will be screened for selective outcome reporting by comparing outcomes used in the finalised articles with registered protocols. If no trial protocol exists, outcomes from the trials published methods and results sections will be compared and a judgement of 'unclear' will be allocated.⁵⁸ When assessing trials risk of bias, researchers will pay special attention to the 'blinding' domain. Blinding of the treating physiotherapists and trial participants is often problematic; however, assessor blinding is achievable and important.⁷⁶

Therefore, trials will be judged to have overall 'low risk' for the blinding domain if the assessor is adequately blinded. ⁷⁶ The risk of bias assessment across trials will be displayed graphically using REVMAN 5.3.

Data presentation

A table will be presented that details the BCTs used in each trial. The total number of BCTs (individually and hierarchal groups) used across trials, their frequency per trial and how accurately they were reported will be detailed (objective 1).⁴⁰ A 'risk of bias' table showing internal validity decisions within and across trials will also be presented. A 'characteristics of included trials' table with PICOS data with explicit detail noting:

- ► Intervention: fidelity assessment, whether other intervention providers were involved in BCT delivery and any training in physiotherapist BCT delivery.
- ▶ Outcomes: Trials that used a PA adherence measure.

Data synthesis

Narrative synthesis will be reported following stages as recommended by Cochrane Qualitative Research Group. 78

Developing a preliminary synthesis

Trials (≥2) will be grouped together if they are clinically homogenous as determined by two researchers (MJW, SF), based on:

- ► Interventions: specific BCTs with or without cointerventions
- ► Comparator groups
- ► Outcome measure domains⁷⁹

The results of groupings will be presented in tables (objective 1).

Assessing the robustness of the synthesis

Each table and statement will include information detailing overall quality of evidence for each grouping. The quality of the body of evidence for each outcome will be evaluated using the GRADE approach (Grading of Recommendations, Assessment, Development and Evaluation). ORADE determines overall quality of evidence based on risk of bias, inconsistency, indirectness, imprecision of results and publication bias. The quality of evidence will be adjudicated as 'high', 'moderate', 'low' or 'very low' based on the guidance from the GRADE working group by two researchers (MJW, SF), with a third researcher (AR) asked to mediate if consensus cannot be reached.

Exploring relationships within and between trials

Further textual descriptions will accompany the tables to highlight key points on trial population, BCTs identified and accuracy of reporting, intervention fidelity assessment, the BCT intervention provider and their training or outcome measures that could explain the differences in results as outlined in the tables.

BCT effectiveness

Individual BCT effectiveness will be determined narratively and supported quantitatively by the use of its 'percentage effectiveness ratio'.⁸¹ Trial interventions will be categorised as 'effective' or 'ineffective' with effective trials demonstrating a significantly greater effect on PA or adherence outcome measures when displayed in a forest plot. The ratio will be calculated by dividing the number of times that the BCT was part of an 'effective' intervention by the number of times the BCT was used in all trials (objective 2).⁸¹

Meta-analysis

Based on the scoping search, it is anticipated that eligible trials will demonstrate high intervention, comparator and outcome variability (clinical heterogeneity). 79 Therefore, when meta-analysis is indicated, a random effects model will be used to calculate effect sizes based on the groupings outlined in the narrative synthesis (objective 2). The risk ratio with 95% CIs and mean differences (MD) with 95% CIs will be used to measure the treatment effect of dichotomous and continuous outcomes, respectively. The standardised mean difference will be used to measure continuous outcomes where several measures are used within one outcome domain.⁷⁹ Where mean data are not available and trial authors do not respond to an email request for raw data (a maximum of three follow-up emails), the median will be used as an estimate of the mean.82

Sensitivity analysis

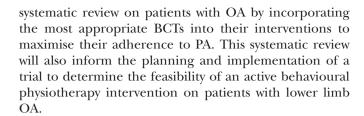
A sensitivity analysis will be conducted to determine whether excluding high risk of bias RCTs has influenced the findings of the meta-analysis to enable further discussion (objective 2).

Meta-bias

Publication bias will be assessed by use of funnel plots where meta-analysis includes $\geq \! 10$ trials. Meta-analyses will be tested for 'small-study effects' by comparing fixed and random effects sizes where the random-effects model will show greater intervention effect sizes for trials with smaller sample sizes. 83

DISCUSSION

Patients with OA currently display the highest level of individual level disability in the UK. Interventions incorporating BCTS have the potential to increase long-term patient adherence to PA recommendations, increasing patient function and quality of life, and physiotherapists are well placed to deliver them. At present, there is a lack of understanding of specific BCTs used in physiotherapy interventions when treating patients with OA. This review will help identify BCTs currently being used in physiotherapy clinical practice and recommend those which are the most effective at reducing lower limb OA symptoms and encouraging long-term patient PA adherence. Clinicians will be able to apply the evidence from this



LIMITATIONS

Several heterogeneous interventions, comparison groups, variability of OA severity and time periods and a limited number of trials (15-20) are anticipated based on the scoping search. This may preclude meta-analysis, affecting the overall level of evidence for RCT groupings. Furthermore, the fidelity assessment and BCTs within interventions may be poorly reported, making it difficult to determine the effectiveness of individual BCTs with consideration of the degree to which the intervention was delivered as intended.

ETHICS AND DISSEMINATION

No research ethics approval is required for this systematic review as no confidential patient data will be used. It is intended that the results of this systematic review will be disseminated through publication in a peer reviewed journal and conference presentations.

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Contributors All authors conceived the focus of the systematic review. MW is a PhD student and AR (lead supervisor), JD and CaG are supervisors. MW drafted the initial version of the protocol manuscript. AR, CaG and JD provided critical guidance on the direction, methodological decisions and proposed analyses. MW developed the search strategy and data extraction form that was piloted by MW and ChG/SF, respectively. All authors reviewed and commented on each draft of the systematic review protocol. MW is the guarantor of the review.

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