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TITLE

Effectiveness of behaviour 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 is a common degenerative articular disease, the highest cause of individual level disability and a significant socio-economic burden to healthcare services. Patient

education and physical activity 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 physical activity prescription requires patients to modify their physical activity behaviour and appears critical in maintaining symptomatic improvements. This systematic review aims to evaluate the effectiveness of behaviour change techniques used in physiotherapy interventions to improve physical activity 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 behaviour change techniques 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 behaviour change techniques, and evaluate the quality of the body of literature following Grading of Recommendations, Assessment, Development and Evaluation guidelines. Narrative synthesis of key outcomes will be presented and meta-analysis will be performed if included trails 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 (PRISMA) 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 physical activity prescription for patients with lower limb osteoarthritis. The findings will be disseminated through publication in a peer reviewed journal and conference presentations.

Protocol registration number: PROSPERO CRD42016039932

Key words: behaviour change, osteoarthritis, systematic review, physiotherapy

Strengths and Limitations of this review:

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

BACKGROUND

Osteoarthritis (OA) is a common degenerative disease that causes patients significant pain and reductions in function, social engagement and quality of life[1 2]. OA results in considerable societal healthcare costs and resource utilisation. In the United Kingdom (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% respectively[4].

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 lower

limb OA patients are referred and are well placed to deliver these interventions[7 8]. Although education[9] and PA interventions[10] 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 long term effectiveness[7]. As OA is a life-long condition[14], 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[18]. 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[19]. As the positive effects of PA reduce if discontinued, and patient adherence diminishes when physiotherapist supervision ceases[20], long-term adherence to recommendations is important and requires patients to change their PA behaviour[20].

Behaviour change interventions incorporate synchronised techniques that target specific patient health behaviours[21]. Although physiotherapists are encouraged[22 23], and attempt[24], to use behaviour change interventions in their clinical practice, recent evidence suggests that they lack the knowledge base to do so effectively[24]. Furthermore, a recent systematic review suggested that while incorporating behaviour change into physiotherapy programmes can enhance patient PA adherence, the most effective techniques have not been determined[25]. Behaviour change interventions are usually complex [26] and commonly reported inconsistently in trials[27 28], making them difficult to replicate in clinical practice[29].

Incorporating 'active' behavioural techniques (e.g, pacing and self-regulatory skills)[30] into interventions, which encourage patients to participate in their own symptom management has demonstrated greater effectiveness than 'passive' techniques[29] (provision of information and advice) at maintaining PA behaviours on OA patients[7].

Behaviour change techniques (BCTs) are the active components in behaviour change interventions[31]. Michie et al., (2013, p82) 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[28]**.** The Behaviour Change Taxonomy V1[28] has been developed to help authors identify BCTs and improve consistency of reporting[28], allowing trials to comply with CONSORT[32], Medical Research Council (MRC)[33], and 'Template for Intervention Description and Replication' (TIDieR)[34] guidelines for the transparent reporting of interventions.

Identifying BCTs within interventions for patients with chronic conditions is a research priority for the National Institute of Clinical Excellence (NICE)[31]. Existing PA systematic reviews examining BCTs have focused on broad patient populations[30 35-39], cardiovascular disease[40] and rheumatoid arthritis[41] (RA). To date, one systematic review[38] has examined BCT use in physiotherapy practice. This scoping review identified 33 BCTs used within self-management interventions treating lower limb OA and chronic low back pain patients. However, the grey literature was not searched, meaning up to 10% of eligible trials were not included[42], and no meta-analysis was conducted due to high intervention heterogeneity. Furthermore the review did not target a specified health behaviour (PA adherence) and focussed on group classes only. Physiotherapists most commonly treat lower limb (hip and knee) OA patients individually (1:1)[43], and tailoring an intervention to the patients particular situation is critical to enhance adherence to PA prescription[44]. Furthermore, recent systematic reviews suggested that 1:1 treatments may provide greater improvements on pain and function than group classes on Knee OA[45] and RA[41] patients respectively.

As the largest healthcare provider of exercise prescription to patients with musculoskeletal pain in the National Health Service (NHS)[8], physiotherapists are well placed to deliver interventions that incorporate behavioural techniques to increase PA adherence. However, at present there is a lack of

standardised definitions and understanding of BCTs used in physiotherapy interventions when treating OA patients.

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

1) 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.
2) To evaluate the clinical effectiveness (on outcomes of 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 pre-defined protocol (CRD42016039932) which complies with recommendations from the Cochrane Collaboration Musculoskeletal group (CCMG)[46] and Centre of Reviews and Dissemination guidelines[47], and will be reported following Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [48].

Eligibility Criteria

1) *Trial Design:* Randomised Controlled Trials (RCTs).
2) *Participants*: Adult participants (≥16 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 co-existing articular pathologies[49] that contribute

>25% of their population will be excluded[46] (e.g. septic arthritis, inflammatory joint disease, gout, articular fracture, hemochromatosis). Trials whose participants have had[44 50], or are awaiting[8 44], surgery for OA treatment (e.g. joint Arthroplasty) will be excluded as PA adherence behaviours in this patient population may be different[51].

3) *Interventions*: Any structured outpatient physiotherapy programme that incorporates a BCT that appears on the V1 Taxonomy [28] as defined by Michie et al., (2013) that focuses on maintaining or increasing patient PA adherence when away from the physiotherapy clinic (e.g. at home or in community). BCTs can include, but are not exclusively: 'prompt self-monitoring of behaviour', 'goal setting', 'social support'[52] and 'reinforcement'[28]. The intervention must be delivered individually by a physiotherapist (with the profession stated clearly) although follow up or 'booster' sessions may take different forms (e.g. 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 2 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 co-interventions will be included if the comparison group receives the same co-intervention, thereby enabling the effectiveness of the BCTs to be evaluated.
5) *Outcomes*: All outcome measures.
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[46]. The clinicaltrial.gov trial register and World Health Organisation's (WHO) trial portal will be searched for relevant trials[46]. 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[45 53 54], physiotherapy, behavioural and education interventions[9 25 45 53-55], and the scoping search to identify keywords in relevant trials[7 56]. RCT filters, as recommended by the Cochrane Collaboration, will be used to prioritise sensitivity over specificity[42 57-59].

Study Selection and Data Management

Two independent researchers (MW, 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

Table 1	Search strategy to be used for the MEDLINE electronic database
Database	**Search Terms**
MEDLINE (Ovid) 1946–present	1) exp osteoarthritis/ 2) osteoarthr$.tw. 3) (degenerative adj2 arthritis).tw. 4) arthrosis.tw. 5) Or/ 1-4 6) knee/ 7) exp knee Joint/ 8) knee$.tw. 9) hip/ 10) exp hip joint/ 11) hip$.tw.

	12) Or/ 6-11 13) exp Self Care/ 14) ((self or symptom$) adj (care or help or manag$ or directed or monitor$ or efficacy or admin$)).tw. 15) Patient Education as Topic/ 16) ((health or patient$) adj2 (educat$ or information)).tw. 17) exp Consumer Participation/ 18) ((patient$ or consumer$) adj part$).tw. 19) "Power (Psychology)"/ 20) empower$.tw. 21) Holistic Health/ 22) (holistic or wholistic).tw. 23) "activities of daily living"/ 24) (activit$ adj2 daily adj living).tw 25) social support/ 26) (social adj (support or network$)).tw. 27) (support adj system$).tw. 28) exp Adaptation, Psychological/ 29) (psychologic$ adj (adjust$ or adapt$)).tw. 30) (cope or copes or coping).tw. 31) exp Behavior Therapy/ or exp cognitive therapy/ or self manage$.ti. 32) (adapt$ adj behav$).tw. 33) (behav$ adj (therap$ or intervention$)).tw. 34) health education/ or self efficacy/ or Exercise/ or health behavior/ 35) compliance/ or patient compliance/ 36) conditioning, operant/ 37) exp "Reinforcement (Psychology)"/ 38) operant conditoning.mp. 39) respondent treatment.mp. 40) relaxation.mp. or exp Relaxation/ 41) graded activity.mp. 42) health promotion/ 43) (psycholog* technique or behavio?r technique).mp. 44) behavio?r Change.mp. 45) self efficacy.mp. 46) Motivation/ or motivation*.mp. 47) primary prevention/ 48) Psychology.mp. or Psychology/ 49) Adherence.mp. 50) Or/ 13-49 51) exp Physical Therapy Modalities/ 52) physiotherap$.tw. 53) (physiotherap$ or physical therap$ or pt).mp. 54) physiotherap$.mp. 55) kinesiotherap$.tw. 56) exp Rehabilitation/ 57) rehab$.tw 58) Physical Activity.mp. 59) Or/ 51- 58 60) randomi?ed controlled trial.pt. 61) controlled clinical trial.pt. 62) randomi?ed.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

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 (MW, 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, assessment time points, and the main results[60]. 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[60]. Trial authors will be contacted by email if information is missing or unclear.

Two independent researchers (MW, SF) will code interventions using the 'Behaviour Change Taxonomy'[28]. The researchers will undergo online training on the use of the taxonomy and the coding process will be piloted a priori. Any disagreement between the researchers will be resolved by researcher consensus. In the event that consensus cannot be reached, a mediator (JD, expertise in subject area of behaviour change) will finalise the decision (Objective 1).

Risk of Bias assessment

Two independent researchers (MW, SF) will use the Cochrane Risk of Bias tool to assess the internal validity of included trials[61]. 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 validity[61] and allows review authors space to justify their conclusions[62]. The tool addresses six domains: 'sequence generation', 'allocation concealment', 'blinding', 'incomplete outcome data', and '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[48]. 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[61]. Therefore, trials will be judged to have overall 'low risk' for the blinding domain if the assessor is adequately blinded[61]. 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 groupings) used across trials and their frequency per trial will be reported (Objective 1)[38]. A 'characteristics of included trials' table with PICOS data, and a 'risk of bias' table showing internal validity decisions within and across trials will also be presented.

Data synthesis:

Narrative synthesis will be reported following stages as recommended by Cochrane Qualitative Research Group[63].

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

- Interventions: specific BCTs with or without co-interventions
- Comparator groups
- Outcome measure domains[64]

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)[65]. GRADE determines overall quality of evidence based on risk of bias, inconsistency, indirectness, imprecision of results and publication bias[65]. 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 (MW, SF)[65], 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 BCTs identified, trial populations, interventions or outcomes that may explain differences in results.

Meta-analysis

Based on the scoping search, it is anticipated that eligible trials will demonstrate high intervention, comparator and outcome variability (clinical heterogeneity)[64]. 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 (RR) with 95% confidence intervals (CIs) and mean differences (MD) with 95% confidence intervals will be used to measure the treatment effect of dichotomous and continuous outcomes respectively. The standardised mean difference (SMD) will be used to measure continuous outcomes where several measures are used within one outcome domain[64]. 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[66].

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 discussion (Objective 2).

Meta-bias

Publication bias will be assessed by use of funnel plots where meta-analysis includes ≥10 trials[67]. 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[67].

DISCUSSION

OA patients currently display the highest level of individual level disability in the United Kingdom. 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 OA patients. 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 systematic review on OA patients by incorporating the most appropriate BCTs into their interventions to maximise their adherence to PA. This systematic review will also inform the planning and implementation of a trial to determine the feasibility of an active behavioural physiotherapy intervention on patients with lower limb osteoarthritis.

LIMITATIONS

Several heterogenous 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, and therefore not enabling firm conclusions on BCT effectiveness to be established.

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.

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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Data sharing statement This systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 15/8/2016 Registration number: CRD42016039932. This protocol has been reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines. The final version of this systematic review and its associated data will be published upon completion.

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RESEARCH CHECKLIST

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review: **Included on page 1, 2, 6, 15**
Update	1b	If the protocol is for an update of a previous systematic review, identify as such **N/A**
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number: **Included on Page 1,2,15**
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author: **Included on Page 1**
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review**: Included on Page 14, 15**
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendment: **N/A**
Support:		
Sources	5a	Indicate sources of financial or other support for the review: **Included on Page 15**
Sponsor	5b	Provide name for the review funder and/or sponsor: **N/A**
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol: **N/A**
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known: **Included pages 3-6**
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO): **Included pages 6-7**
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review: **Included pages 6-7**
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage: **Included on pages 8-10**
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could

		be repeated: **Included Pages 8-10**
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review: **Included on Page 10**
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis): **Included on pages 10-13.**
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators: **Included on pages 10**
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications: **Included on pages 10**
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale: **Included Page 6,7**
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis: **Included pages 11, 13**
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised**: Included Pages 12-13**
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ): **Included on Pages 12-13**
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression): **Included on Page 13**
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned: **Included page 11-12.**
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies): **Included pages 11,13**
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE): **Included on pages 12**

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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BMJ Open

Effectiveness of behaviour 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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TITLE

Effectiveness of behaviour 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 is a common degenerative articular disease, the highest cause of individual level disability and a significant socio-economic burden to healthcare services. Patient education and physical activity 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 physical activity prescription requires patients to modify their physical activity behaviour and appears critical in maintaining symptomatic improvements. This systematic review aims to evaluate the effectiveness of behaviour change techniques used in physiotherapy interventions to improve physical activity 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 behaviour change techniques 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 behaviour change techniques, and evaluate the quality of the body of literature following Grading of Recommendations, Assessment, Development and Evaluation 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 (PRISMA) 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 physical activity prescription for patients with lower limb osteoarthritis. The findings will be disseminated through publication in a peer reviewed journal and conference presentations.

Protocol registration number: PROSPERO CRD42016039932

Key words: behaviour change, osteoarthritis, systematic review, physiotherapy

Strengths and Limitations of this review:

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

BACKGROUND

Osteoarthritis (OA) is a common degenerative disease that causes patients significant pain and reductions in function, social engagement and quality of life[1 2]. OA results in considerable societal healthcare costs and resource utilisation. In the United Kingdom (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% respectively[4].

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 lower limb OA patients are referred and are well placed to deliver these interventions[7 8]. Although education[9] and PA interventions[10] 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 long term effectiveness[7]. As OA is a life-long condition[14], 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[18]. 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[19]. As the positive effects of PA reduce if discontinued, and patient adherence diminishes when physiotherapist supervision ceases[20], long-term adherence to recommendations is important and requires patients to change and sustain this change in PA behaviour[20].

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 lower limb OA patients[21]. A recent systematic review concluded that no recommendations could be made for any PA adherence outcomes in chronic musculoskeletal pain patients[22] due to methodological issues with diagnostic accuracy trial design. Furthermore, none of the seven outcomes identified in the review were validated on OA patients. 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 lower limb OA participants, with three of these incorporating exercise diaries and three a multi-item measure to measure PA adherence[23].

Behaviour change interventions incorporate synchronised techniques that target specific patient health behaviours[24]. Behaviour 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 (e.g, pacing and self-regulatory skills)[29] into interventions, which encourage patients to participate in their own symptom management has demonstrated greater effectiveness than 'passive' techniques[28] (provision of information and advice) at maintaining PA behaviours on OA patients[7].

Behaviour change techniques (BCTs) are the active components in behaviour change interventions[30]. Michie et al., (2013, p82) 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[31]. 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[32 33]. The Behaviour Change Taxonomy V1[27] has been developed to help authors identify BCTs and improve consistency of reporting[27], allowing trials to comply with CONSORT[34], Medical Research Council (MRC)[35], and 'Template for Intervention Description and Replication' (TIDieR)[36] 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[46] (RA). To date, only one systematic review[40] has examined BCT use in physiotherapy practice treating lower limb OA and chronic low back pain patients 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 focussed on group classes only. Physiotherapists most commonly treat lower limb (hip and knee) OA patients 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 Knee OA[50] and RA[46] patients respectively.

Identifying effective BCTs within interventions for patients with chronic conditions is a research priority for the National Institute of Clinical Excellence (NICE) 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 (NHS)[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 behaviour 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 behaviour 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 OA patients.

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

1) 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.
2) 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 pre-defined protocol (CRD42016039932) which complies with recommendations from the Cochrane Collaboration Musculoskeletal group (CCMG)[56] 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 co-existing articular pathologies[59] that contribute >25% of their population will be excluded[56] (e.g. 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 (e.g. joint Arthroplasty) will be excluded as PA adherence behaviours in this patient population may be different[61].

3) *Interventions*: Any structured outpatient physiotherapy programme that incorporates a BCT that appears on the V1 Taxonomy[27] as defined by Michie et al., (2013) that focuses on maintaining or increasing patient PA adherence when away from the physiotherapy clinic (e.g. 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 (e.g. 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 2 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 co-interventions will be included if the comparison group receives the same co-intervention, 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 (e.g. pedometers, self-report questionnaires)[21] and adherence measures (e.g. 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 World Health Organisation's (WHO) 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, 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 (MW, 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

Table 1	Search strategy to be used for the MEDLINE electronic database
Database	**Search Terms**
MEDLINE (Ovid) 1946–present	1) exp osteoarthritis/ 2) osteoarthr$.tw. 3) (degenerative adj2 arthritis).tw. 4) arthrosis.tw. 5) Or/ 1-4 6) knee/ 7) exp knee Joint/ 8) knee$.tw. 9) hip/ 10) exp hip joint/ 11) hip$.tw. 12) Or/ 6-11 13) exp Self Care/ 14) ((self or symptom$) adj (care or help or manag$ or directed or monitor$ or efficacy or admin$)).tw. 15) Patient Education as Topic/ 16) ((health or patient$) adj2 (educat$ or information)).tw. 17) exp Consumer Participation/ 18) ((patient$ or consumer$) adj part$).tw. 19) "Power (Psychology)"/ 20) empower$.tw. 21) Holistic Health/ 22) (holistic or wholistic).tw. 23) "activities of daily living"/ 24) (activit$ adj2 daily adj living).tw 25) social support/ 26) (social adj (support or network$)).tw. 27) (support adj system$).tw. 28) exp Adaptation, Psychological/ 29) (psychologic$ adj (adjust$ or adapt$)).tw. 30) (cope or copes or coping).tw. 31) exp Behavior Therapy/ or exp cognitive therapy/ or self manage$.ti. 32) (adapt$ adj behav$).tw. 33) (behav$ adj (therap$ or intervention$)).tw. 34) health education/ or self efficacy/ or Exercise/ or health behavior/ 35) compliance/ or patient compliance/ 36) conditioning, operant/ 37) exp "Reinforcement (Psychology)"/ 38) operant conditoning.mp. 39) respondent treatment.mp. 40) relaxation.mp. or exp Relaxation/ 41) graded activity.mp. 42) health promotion/ 43) (psycholog* technique or behavio?r technique).mp. 44) behavio?r Change.mp. 45) self efficacy.mp.

	46) Motivation/ or motivation*.mp. 47) primary prevention/ 48) Psychology.mp. or Psychology/ 49) Adherence.mp. 50) Or/ 13-49 51) exp Physical Therapy Modalities/ 52) physiotherap$.tw. 53) (physiotherap$ or physical therap$ or pt).mp. 54) physiotherap$.mp. 55) kinesiotherap$.tw. 56) exp Rehabilitation/ 57) rehab$.tw 58) Physical Activity.mp. 59) Or/ 51- 58 60) randomi?ed controlled trial.pt. 61) controlled clinical trial.pt. 62) randomi?ed.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

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 (MW, 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 72], 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 2011[73] from the initial version which had 25 components[32]. The NIHBCC's checklist comprises 5 domains: 'Treatment design', 'Training Providers', 'Delivery of Treatment', 'Receipt of Treatment', and 'Enactment of Treatment skills'. Although Toomey et al., (2015)[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 (MW, 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[70]. Trial authors will be contacted by email if information is missing or unclear.

Two independent researchers (MW, 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 'post learning 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 (JD, expertise in subject area of behaviour change) will mediate the decision (Objective 1).

Risk of Bias assessment

Two independent researchers (MW, 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 validity[76] and allows review authors space to justify their conclusions[77]. The tool addresses six domains: 'sequence generation', 'allocation concealment', 'blinding', 'incomplete outcome data', and '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: Trial's 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 (MW, SF), based on:

- Interventions: specific BCTs with or without co-interventions
- Comparator groups
- Outcome measure domains[79]

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)[80]. GRADE determines overall quality of evidence based on risk of bias, inconsistency, indirectness, imprecision of results and publication bias[80]. 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 (MW, SF)[80], 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 (RR) with 95% confidence intervals (CIs) and mean differences (MD) with 95% confidence intervals will be used to measure the

treatment effect of dichotomous and continuous outcomes respectively. The standardised mean difference (SMD) 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 ≥10 trials[83]. 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

OA patients currently display the highest level of individual level disability in the United Kingdom. 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 OA patients. 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 systematic review on OA patients by incorporating the most appropriate BCTs into their interventions to maximise their adherence to PA. This systematic review will also inform the planning and implementation of a trial to determine the feasibility of an active behavioural physiotherapy intervention on patients with lower limb osteoarthritis.

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.

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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RESEARCH CHECKLIST

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review: **Included on page 1, 2, 7, 17**
Update	1b	If the protocol is for an update of a previous systematic review, identify as such **N/A**
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number: **Included on Page 1,2,18**
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author: **Included on Page 1**
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review**: Included on Page 16, 17**
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendment: **N/A**
Support:		
Sources	5a	Indicate sources of financial or other support for the review: **Included on Page 18**
Sponsor	5b	Provide name for the review funder and/or sponsor: **N/A**
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol: **N/A**
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known: **Included pages 3-7**
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO): **Included pages 7-9**
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review: **Included pages 7-9**
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage: **Included on pages 9**
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could

		be repeated: **Included Pages 10-11**
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review: **Included on Page 10,11**
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis): **Included on pages 11-13, 15**
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators: **Included on pages 11,12**
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications: **Included on pages 12,13**
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale: **Included Page 4,5,8,14**
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis: **Included pages 13-16**
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised**: Included Pages 15,16**
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ): **Included on Pages 15, 16**
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression): **Included on Page 16**
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned: **Included page 14,15.**
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies): **Included pages 16**
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE): **Included on pages 14,15**

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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