




RESEARCH ARTICLE

A Core Outcome Set for Exercise and Physical Activity Interventions for Musculoskeletal Disorders

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Abstract

Background: Musculoskeletal disorders (MSKD) create a significant burden on individuals and society. Physical activity is an effective way of self-managing MSKD. Global health policy routinely recommends the instigation of management approaches to support people with MSKD to engage in physical activity. However, there is considerable heterogeneity in outcome measurement and establishing whether interventions are effective or not.

A way of addressing this is to develop a core outcome set (COS). This study aims to identify a COS for exercise and physical activity interventions for people with MSKD.

Methods: Guidance from the COMET initiative was followed. The study had two phases.

1) A systematic search of effectiveness studies investigating interventions that aim to increase physical activity levels in people with MSKD was conducted. All outcome concepts evaluated were extracted from the included studies.

2) Patients with MSKD and expert stakeholders then participated in an online and workshop-based consensus process. In accordance with other COS development studies, 70% agreement was required for a concept to be included in the final COS.

Results: Phase 1: 25 studies were identified from the systematic searches and 50 conceptually different outcomes were extracted.

Phase 2: 14 group members were recruited to the consensus phase. Function, Patient satisfaction, Physical activity, Quality of Life, Pain, Cost-effectiveness, Self-efficacy, Knowledge to

plan future exercise, Utilisation of health services were the concepts that reached the 70% threshold for inclusion in the final COS.

Conclusions: This study provides a COS that could provide an outcome measurement strategy in interventions that aim to increase exercise and physical activity in people with MSKD.

Keywords

Musculoskeletal diseases, Physical activity, Consensus, Review, Core outcome set

List of Abbreviations

CINAHL: Cumulative Index to Nursing and Allied Health Literature; COMET: Core Outcome Measures in Effectiveness Trials; COS: Core Outcome Set; EPA: Exercise and Physical Activity; ERS: Exercise Referral Scheme; MEDLINE: Medical Literature Analysis and Retrieval System Online; MSKD: Musculoskeletal Disorder; OA: Osteoarthritis; PICO: Population, Intervention, Comparator, Outcomes; pMSKD: People Living with a Musculoskeletal Disorder; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCT: Randomised Controlled Trial

Introduction

Musculoskeletal disorders (MSKD), such as low back pain, arthritis, or osteoporosis, are the 2nd largest cause of years lived with disability [1]. They create a significant burden on individuals and health economies,

with 28.4 million working days lost in 2019 due to MSKD [2]. The prevalence of MSKD is expected to continue to rise [3]. MSKD are a diverse group of disorders that have a range of pathophysiological causes but are linked anatomically [4] and by the similar pain and dysfunction they cause leading to physical, biological, psychological and social consequences for people living with MSKD (pMSKD) [5-7].

There are management strategies that are specific to each of the many MSKD to target specific structures or physiological processes, however a core management approach across MSKD is to support an increase in exercise and physical activity (EPA) levels [8,9]. EPA is recognised to be beneficial for pMSKD and to prevent onset also, however despite these potential benefits pMSKD are twice as likely to be inactive compared to those without MSKD [2]. This is due to a range of biological, psychological and social factors [10] and demonstrates the increased difficulty that pMSKD are faced with when trying to access EPA. To attempt to address this, EPA interventions are a commonplace management strategy [11,12], employed by health services, aiming to support pMSKD to become more active and reduce the burden of their MSKD whilst improving uptake and maintenance of EPA. A wide range of EPA interventions have been used to support pMSKD to engage in EPA. These include walking [13], self-management programmes [6], exercise referral schemes [14] and home based EPA interventions [15].

A key issue with EPA interventions for pMSKD is the lack of a defined approach to outcome measurement [10]. One systematic review investigating exercise and physical activity (EPA) interventions that were designed to improve EPA uptake in pMSKD found limited evidence that participants were more likely to increase their level of moderate intensity EPA compared to usual care [14]. One major limitation reported in this review and others was the inconsistency of outcomes used in interventional studies [14,16]. Further studies have reported this leads to difficulty in comparing or pooling data between studies due to heterogeneity of outcomes [17,18]. Consequently, this creates challenges for clinicians, healthcare organisations and policy makers when applying health care research in practice as it is difficult to understand if EPA interventions are effective and worth investment [19]. Improvements in policy for MSKD also advocate increased consumer-centred outcomes to support understanding of interventions that support pMSKD [11].

To reduce variation in outcome measurement and support improved consistent outcome measurement, it is recommended that a COS, or an agreed standardised collection of outcomes, be developed for EPA interventions [20]. The COS should represent the minimum that should be measured and reported in trials of interventions [19]. This will support benchmarking

and comparison of similar services to reduce variation in delivery. The Core Outcome Measures in Effectiveness Trials (COMET) initiative provides guidance and resources to support COS development using a standardised approach [19] and the core outcome set-standards for reporting (COS-STAR) checklist provides guidance for reporting [21]. COS have been produced for related subject areas, such as for clinical trials for non-specific low back pain [18], standardized outcome reporting in low back pain [22], and rehabilitation in musculoskeletal disorders [23]. However, searches of the (COMET) database identified that no COS has been developed to measure the effectiveness of EPA interventions that support pMSKD.

Though there are similarities with other COS focused on MSK conditions, no other COS can be found that specifically support interventions that aim to improve EPA in people with MSKDs. The need to support EPA in pMSKDs is well documented. This study aims to produce a COS to support standardisation and understanding of what outcomes are important when supporting pMSKDs into EPA.

Methods

The COMET Handbook was followed to undertake this COS development [19], which also recommends to follow the COS-STAR checklist [21], which this study has done.

A two-phased COS development method was used. Phase 1 was a systematic search of the literature undertaken in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines [24] and the Cochrane handbook for systematic reviews of interventions [25]. All outcome concepts from effectiveness studies of EPA interventions that have a primary outcome of increasing EPA in pMSKD were sourced. Phase 2 was a consensus process undertaken in line with COMET guidelines [19] using expert patients and stakeholders to agree which concepts derived from the phase 1 systematic searches are most important and must be included in the final COS. The consensus phase consisted of an online stage, followed by a face-to-face consensus workshop.

Phase 1: Systematic search of the literature

A search strategy was undertaken in May 2017 to identify EPA intervention studies that had a primary outcome of increasing physical activity. The PICO (population, intervention, comparator, outcome) that provides the basis for the systematic search is presented in Table 1.

Five databases were searched in September 2017: MEDLINE (EBSCO), CINAHL (EBSCO), Cochrane (Wiley), SportDiscus (EBSCO), Web of Science (Thomson Reuters, now Clarivate). Titles, abstracts, and full-text articles were screened independently by two authors (AT,

Table 1: PICO for systematic review.

Population	Includes people living with MSKD
Interventions	Exercise/physical activity intervention
Comparator	Any
Outcome	Physical activity

TP). Any non-concordance that could not be resolved between the two reviewers were discussed and a consensus reached; any outstanding disagreements were resolved using a third author (SM). Articles were included if they were a randomised controlled trial, included populations with MSKD, and a primary outcome measure to evaluate physical activity participation was used. Non-English studies, studies including participants < 18-years-old, studies with physical activity not as a primary outcome, and studies with no EPA interventions were excluded. Since the study team were only interested in identifying outcome measures used within included trials, quality assessment was not required.

A data extraction form, aligned with COMET guidance [19], was developed to capture essential information from included studies. Data extracted included study characteristics, outcome concepts and outcome measurement instruments utilised. The data extraction form was piloted by two authors (AT, TP) to test for consistency and utility. The outcome concepts used in each study were then extracted by one author (TP) and checked for accuracy by a second author (RM). Outcome concepts were reviewed by three authors (AT, SM, RM) for duplication, relevance, and definition to create a list of mutually exclusive outcome concepts. This list of outcome concepts was taken forward to phase 2.

Phase 2: Consensus

Phase 2 was a consensus approach split into an online phase and a workshop phase, the aim of which was to agree which of the outcome concepts derived from phase 1 must be included in the final COS. This phase was conducted according to COMET guidance [19]. This guidance suggests that the selection of participants for consensus activities should be pragmatic but relate to the context of the COS being developed. Consequently, patients who had participated in an EPA intervention that aimed to increase their level of activity were invited to participate in this study, along with expert clinicians, researchers, health service managers, and commissioners. Ethics approval was sought and granted by the NHS Health Research Authority and Sheffield Hallam University.

Virtual consensus stage

An online questionnaire, participant information sheet, and an instructional video about the consensus process were produced (all were available in paper form at request for participants in the consensus process).

The recruited participants were directed to online resources to access participant information and the questionnaire. The questionnaire asked participants to rate the importance of each outcome concept in relation to assessing the effectiveness of an EPA intervention. Outcome concepts were rated using a 9-point Likert scale that ranged from 1-9, with 1 = not important to 9 = extremely important. The questionnaire was electronically submitted and one author (RM) collated results.

Concept ranking following the voting results was undertaken between three members of the study team (AT, SM, RM). Concepts were placed into one of three groups: Consensus of high importance for inclusion in the COS, consensus of low importance for inclusion in the COS, or consensus not achieved. Ranking was based on judging the mean, median and mode of the total scores from voting of importance on a 1-9 Likert scale. One author (AT) had the final decision if non-concordance occurred between the three authors.

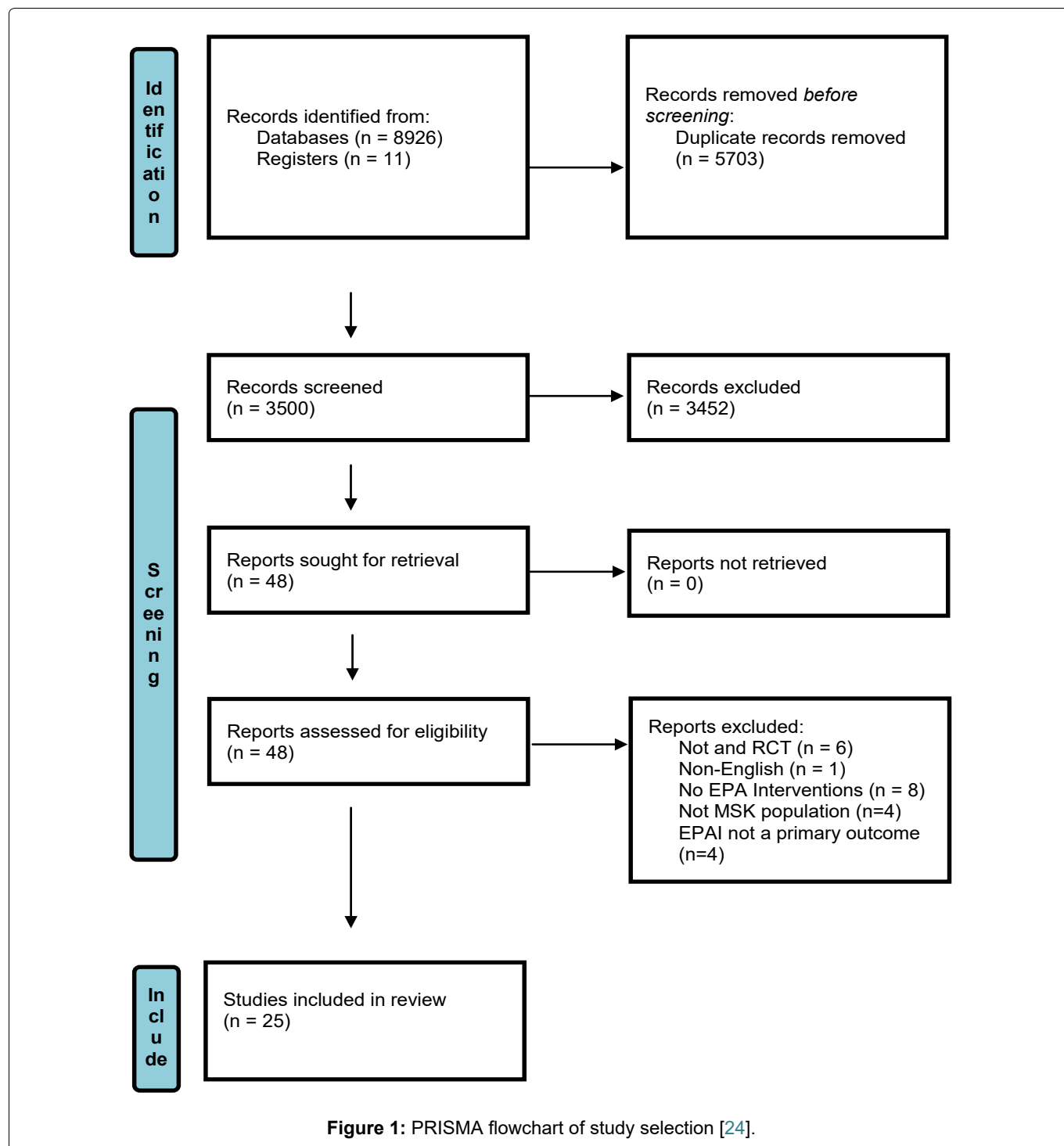
Consensus workshop stage

A consensus workshop was convened for all the participants who had participated in the virtual stage. The workshop participants were supplied with clear instructions as to the content and aims of the workshop. In accordance with COMET guidance this included requesting the group to consider if any further outcome concepts not derived from phase 1 should be included.

The voting and ranking from the online questionnaire were presented to workshop participants. Participants were then divided into three groups, this included a group of exclusively patients (to ensure patients did not feel intimidated by professionals), with the remainder of the participants divided into two groups. Following this, participants were invited to discuss those concepts that did not reach consensus during the online stage. Participants were then asked to vote electronically using 'yes' or 'no' responses as to whether each concept must be included in the final COS or not. All voting results were sent electronically and anonymously to the study team, where results were immediately collated and presented back to the workshop participants.

Participants were then reorganised into three mixed groups consisting of both patients (as it was clear they had confidence to voice their views) and healthcare professionals to ensure the broadest possible discussions took place in the next round of discussions. Participants were asked to vote for a second time on which of the outcome concepts must be in the final COS, using 'yes' or 'no' responses as to whether each concept must be included in the final COS or not. All voting results were immediately collated by the study team.

To be considered suitable for inclusion in the COS, 70% of participants had to agree that the concept must be included in the COS. Although it is an arbitrary



figure, a 70% cut off has been used in the development of other COS [26], and COMET discuss a 70% threshold representing the majority in a consensus group [19]. The study team agreed that 70% would result in a manageable list of final concepts, whilst not being too stringent to exclude key outcomes [19].

Results

Phase 1: Systematic review

Following removal of duplicates, 3500 records were screened, leading to 48 full text studies being retrieved, of which 23 were excluded resulting in 25 studies being included for data extraction (Figure 1).

The 25 papers (Table 2) extracted exhibited wide-

ranging properties. Populations studied within these studies were: Knee osteoarthritis (OA) (n = 8) [27-34], Low back pain (n = 3) [35-37], after total knee or hip replacement (n = 3) [38-40], sedentary populations with MSKDs (n = 2) [41,42], Hip OA (n = 2) [43,44], Neck and shoulder pain (n = 1) [45], Ankle sprain (n = 1) [46], after primary lumbar disc surgery (n = 1) [47], shoulder impingement syndrome (n = 1) [48], depression, overweight or obese (n = 1) [49], fibromyalgia (n = 1) [50], Lumbar radicular pain (n = 1) [51].

Studies were predominantly hospital-based physiotherapy clinics (n = 15) [27,30-32,34-37,39,40,43,44,47,48,51]. Others were set in leisure centres (n = 2) [41,42], Hydrotherapy pools (n = 2) [33,38], parks and forests (n = 2) [49,50], adult day

Table 2: Extracted study characteristics and outcome concepts.

First Author and Year	Country	Setting	Purpose	Population	Outcome Concepts
Bennell, et al. (2016) [27]	Australia	Departments of Physiotherapy, University of Melbourne, and University of Queensland.	To investigate whether a 12-week physical therapist-delivered combined Pain Coping Skills Training (PCST) and exercise (PCST/exercise) is more efficacious and cost effective than either treatment alone for knee Osteoarthritis (OA).	Knee osteoarthritis (OA)	Pain, physical function, Quality of life, physical performance.
Blangsted, et al. (2017) [45]	Denmark	Office environment.	Evaluates the effect of two different worksite physical-activity interventions on neck-shoulder symptoms, together with perceived work ability and sick leave among office workers.	Neck and shoulder pain	Pain, workability.
Bleakley, et al. (2010) [46]	Ireland	Accident and emergency department and University based sports injury clinic.	To compare an accelerated intervention incorporating early therapeutic exercise after acute ankle sprains with a standard protection, rest, ice, compression, and elevation intervention.	Ankle sprain	Function, pain, swelling, physical activity, self-reported function, range of movement, strength, mechanical stability, postural stability, single leg hop test.
Chan, et al. (2011) [35]	Hongkong	Physiotherapy outpatient dept.	Examine the effect of adding aerobic exercise to conventional physiotherapy treatment for patients with chronic low back pain (LBP) in reducing pain and disability.	Low back pain	Pain, functional disability, physical fitness.
Cortés Godoy, et al. (2014) [28]	Spain	Home care and adult day care centre patients in Madrid.	Compare the effectiveness of massage therapy as a co-adjuvant treatment for Knee OA.	Knee OA	Pain, functionality, stiffness, agility, dynamic balance, and lower limb strength.
Costa, et al. (2009) [37]	Australia	Outpatient physical therapy.	To investigate the efficacy of motor control exercise for people with chronic low back pain.	Low back pain	Pain, activity, activity limitation, overall measure of change.
De Rooij, et al. (2016) [30]	Netherlands	Secondary outpatient physiotherapy clinic.	To evaluate the efficacy on physical functioning and safety of tailored exercise therapy in patients with knee osteoarthritis (OA) and comorbidities.	Knee OA	Physical functioning, pain, Physical activity, fatigue, psychological functioning, frailty, global perceived effect, knee-specific variables.
Farr, et al. (2010) [29]	USA	University campus setting, with certified physical trainers.	To determine the effect of a structured RT intervention on overall levels of moderate and vigorous intensity physical activity (MVPA) in patients with early-onset knee OA.	Knee OA	Anthropometric measures, pain, physical activity, Leisure time PA and exercise habits.
French, et al. (2013) [43]	Ireland	Four academic teaching hospitals in Dublin, Ireland, physiotherapy clinics.	To determine the effectiveness of exercise therapy (ET) compared with ET with adjunctive manual therapy (MT) for people with hip osteoarthritis (OA); and to identify if immediate commencement of treatment (ET or ET & MT) was more beneficial than a 9-week waiting period for either intervention.	Hip OA	Physical function, Active hip range of motion (ROM), pain, pain medication usage, general health status, psychological wellbeing, patient satisfaction, walking distance.
Gusi, et al. (2008) [49]	Spain	Forest tracks or public park, with qualified exercise leaders.	To assess the cost utility of adding to the standard "best care" a supervised walking programme that also included strengthening and stretching exercises.	Depression, overweight or obese with MSKD	Health related QOL, anxiety, depression, health care costs.

Harrison, et al. (2005) [41]	England	Leisure centre with exercise officer.	To assess the effectiveness of a primary care referral scheme on increasing physical activity at 1 year from referral.	Sedentary people with MSKD	Physical activity, satisfaction with and demand for information.
Haxby Abbott, et al. (2015) [31]	New Zealand	Outpatient Physiotherapy and Orthopaedics Departments - Dunedin Hospital.	(1) Investigate the effects of manual therapy combined with exercise therapy, compared with exercise therapy alone in improving pain, disability, and physical function. (2) Compare the effects of delivering the physical therapy intervention using periodic booster sessions versus not using booster sessions in improving pain, disability, and physical function at 1-year follow-up.	Knee OA	Pain, stiffness, and physical function.
Hurley, et al. (2015) [36]	Ireland	Participating hospital physiotherapy clinics.	The primary objective was to determine the difference between groups in mean change in functional disability at 6 months after randomization. Secondary objectives were to: 1. Determine the difference between groups in mean changes in pain, health-related quality of life, psychosocial beliefs, days of sick leave, daily PA levels, exercise self-efficacy, readiness to change, patient satisfaction. 2. Determine the difference between groups in cost- effectiveness and cost utility of the alternative treatment programmes. 3. Determine the difference between groups in the level of adherence to each intervention. 4. Complete a qualitative exploration of participants' experience of each intervention.	Chronic low back pain	Functional disability, pain, health-related quality of life, psychosocial beliefs, self-reported PA, self-efficacy, stage of exercise behaviour change, patient satisfaction.
Jakobsen, et al. (2014) [39]	Denmark	Patients on a surgical waiting list in a hospital, seen in physiotherapy clinic.	The main objective of this study was to conduct 7 weeks of supervised, well-described physical rehabilitation with a physiotherapist present and compared with the same regime without a physiotherapist present.	Post Total knee replacement	Functional performance, isometric knee strength, leg press power, pain, effusion, ROM, Self-reported function and quality of life, prosthetic migration, inflammatory response.
Johansson, et al. (2009) [47]	Sweden	Orthopaedic clinics and physiotherapy clinics.	To compare clinic- based physiotherapy with a behavioural approach to a home-based training programme.	Post primary lumbar disc surgery	Back pain related disability, the level of physical training and possible walking distance, kinesiophobia, coping, pain, Generic health-related quality of life, patient satisfaction, Therapies given by other caregivers.
Jorge, et al. (2015) [32]	Brazil	Physiotherapy clinics.	To determine the effect of a progressive resistance exercise (PRE) program on women with osteoarthritis (OA) of the knee.	Knee OA	Pain, function, Quality of life, function, strength, Global improvement, side effects, walking distance.
Juhakoski, et al. (2011) [44]	Finland	An outpatient physiotherapy primary care setting.	To evaluate the short- and long-term effectiveness of exercise training in people with hip osteoarthritis.	Hip OA	Pain, physical function, performance-based outcome scores, adherence.

Liebs, et al. (2012) [38]	Germany	Hydrotherapy pool and physiotherapy department.	To evaluate if the timing of aquatic therapy influences clinical outcomes after total knee arthroplasty (TKA) or total hip arthroplasty (THA).	Post total knee of hip replacement	Physical function, leg specific stiffness and pain, patient satisfaction, quality of life.
Lim, et al. (2010) [33]	South Korea	Outpatient clinic at Seoul National University Bundang Hospital.	To design and test the effectiveness of an aquatic exercise (AQE) and land-based exercise (LBE) program to enhance knee function and reduce body fat in patients with obesity and knee OA.	Knee OA	Body fat composition, pain, physical function, and quality of life.
Mannerkorpi, et al. (2010) [50]	Sweden	The study was conducted in parks and forests led by physical therapists or trained exercise leaders.	The objective of this study was to investigate the effects of moderate-to-high intensity Nordic walking (NW) on functional capacity and pain in fibromyalgia (FM).	Fibromyalgia	Health status, function, activity limitation, walking distance, the rate of perceived exertion, blood pressure, Physical activity, anxiety, depression, muscle tenderness, local pain score, fatigue.
Marzetti, et al. (2014) [48]	Italy	Outpatient clinic of Geriatrics and Physiatrics, University Hospital by physiotherapists.	To compare the effects of neurocognitive therapeutic exercise, based on proprioception and neuromuscular control with traditional therapeutic exercise in patients with shoulder impingement syndrome.	Shoulder impingement syndrome	Physical ability, symptoms of Upper extremity, ROM, pain, strength, physical ability in daily living tasks, patient satisfaction.
Mau-Moeller, et al. (2014) [40]	Germany	Hospital Setting, physiotherapy clinics.	This clinical study was conducted to compare the effectiveness of two in-hospital range of motion (ROM) exercise programs following total knee arthroplasty (TKA).	Post total knee replacement	ROM, static postural control, physical activity, pain, length of hospital stay, clinical, functional, and quality-of-life outcomes.
Murphy, et al. (2010) [42]	UK (Wales)	Sports centre with exercise specialist.	Evaluate effectiveness of the Welsh national exercise referral scheme. Process evaluation considering interventions delivery and economic evaluation.	Sedentary people with MSKD	Physical activity, anxiety and depression, health utility, health related QOL, health status, motivation to exercise, self-efficacy, social support, programme attendance, programme implementation fidelity.
Thackeray, et al (2010) [51]	USA	Spine clinics and physical therapy clinics.	This study was a preliminary investigation of the effectiveness of Nerve root block injection, with or without subsequent physical therapy, in people with low back pain and sciatica.	Lumbar radicular pain	ROM, Neurologic assessment, pain, disability, fear avoidance, perception of the degree of change in their condition from the beginning of treatment.
Knoop, et al. (2012) [34]	Netherlands	Outpatient rehabilitation centre.	To investigate whether an exercise program, initially focusing on knee stabilization and subsequently on muscle strength and performance of daily activities is more effective than an exercise program focusing on muscle strength and performance of daily activities only, in reducing activity limitations in patients with knee osteoarthritis (OA) and instability of the knee joint.	Knee OA	Activity limitation, pain, global perceived effect, self-reported knee joint instability, adverse events, therapists assessed patient-perceived training intensity, adherence, physical activity.

centres (n = 1) [28], universities (n = 1) [29], work place (n = 1) [45], accident and emergency department (n = 1) [46].

Studies were mainly from western regions of the globe: Europe (excluding Scandinavia) (n = 12)

[28,30,34,36,38,40-43,46,48,49], Scandinavia (n = 5) [39,44,45,47,50], Australasia (n = 3) [27,31,37], United States (n = 2) [29,51], Asia (n = 2) [33,35], Brazil (n = 1) [32].

Concept extraction

Concepts extracted from the included studies were found to have considerable levels of duplication as some concepts such as pain, function and patient experience were common outcomes. In total, 50 different outcome concepts were extracted from the included studies (Table 3). All studies had physical activity as a primary outcome.

Phase 2: Consensus phase

Sixteen participants were recruited to the consensus phase. This included expert patients (n = 7) with MSKD

who had participated in an EPA intervention, senior physiotherapists (n = 3) with extensive knowledge of MSKD and EPA interventions, researchers (n = 2) with experience in this field, a healthcare manager (n = 1), a healthcare commissioner (n = 1), a public health representative (n = 1), and an exercise professional (n = 1) specialising in supporting people with MSKD. All 16 participants completed the online questionnaire.

Online consensus

Table 3 shows the 50 outcome concepts after participants completed the virtual phase questionnaire.

Table 3: Concepts extracted from the literature, ranked following the online vote.

Concept	Number of Studies in which the Concept was Used	Mean	Median	Mode
Patient Satisfaction	5	8.25	8.5	9
Quality of Life	11	8.08	9	9
Self-Efficacy	2	8.0	8	8
Programme Attendance	1	8.0	8	8
Physical Activity	25	7.75	8	9
Function	12	7.73	9	9
Clinical Outcomes	1	7.45	8	9
Coping	1	7.42	8	9
Psychological Functioning	3	7.30	8.5	9
Motivation to Exercise	1	7.55	8	9
Perception of Change in Condition	2	7.42	8	9
Health Status	3	7.36	8	9
Adherence	2	7.25	8	8
Programme Implementation Fidelity	1	7.13	7	6
Activity Limitation	2	7.0	7	5
Workability	1	6.91	8	8
Fear of Movement	2	6.90	8.5	9
Pain	22	6.83	7.5	8
Cost-Effectiveness/Health Care Costs	4	6.83	7.5	5
Anxiety	3	6.82	7	9
Disability	4	6.73	8	9
Pain Medication Usage	1	6.67	7.5	8
Inflammation Flare Ups	1	6.64	7	9
Autonomy (Freedom to Act)	1	6.60	7	8
Physical Fitness	4	6.58	6.5	8
Side Effects	2	6.55	8	8
Fatigue	2	6.55	7	9
Psychological Beliefs	1	6.55	7	9
Satisfaction and Demand for Information	1	6.55	7	8
Frailty	1	6.50	6.5	5
Depression	3	6.45	7	9
Satisfaction of the Needs for Competence	1	6.25	6.5	5
Strength of Joints	2	5.91	6	9
Social Support	1	6.58	6	5
Stage of Exercise Behaviour Change	1	6.50	6	6

Leisure Time	1	6.09	6	5
Vitality	1	6.0	5.5	5
Strength	6	6.0	5	5
Range of Movement	6	5.91	5	9
Balance/Postural Stability	3	5.73	5	5
Self-Reported Exertion	1	5.67	5	4
Stiffness	3	5.64	6	8
Walking Distance	2	5.64	6	5
Swelling	2	5.55	6	8
Agility	1	5.45	4	4
Therapies given by other Care Givers	1	5.36	6	6
Neurological Assessment	1	5.11	5	5
Joint Specific Variables	1	5.09	5	4
Muscle Tenderness	1	4.50	4.5	3
Measures of Body Size, Shape and Movement	3	3.91	2	2

A pragmatic balance between mean, median and mode data was used to guide ranking. Ranking was undertaken to guide discussion in the workshop, i.e., to identify which concepts that had not reached a consensus of high or low importance in the COS. These findings were taken forward to the consensus workshop.

Consensus workshop

One patient and one public health representative were unable to attend the workshop. All other participants attended resulting in 14 participants. Initially participants were asked if there were any outcome concepts they would add to the list. One additional concept was identified by the group prior to the first voting round, this was: Referral/utilisation of health care services.

Following small group discussions, participants were asked to vote (yes or no) which of the 51 outcome concepts should be included in the final COS. Following this, groups were reorganised, and further discussion of key concepts took place. A second additional outcome concept was identified at this stage: 'Knowledge to plan further exercise'. This concept was discussed and added to the concept list. Participants were asked to vote (yes or no) for a second time for which of the 52 outcome concepts must be in the COS.

Final core outcome set

Table 4 presents the overall ranking of the 52 concepts after two rounds of voting. Nine outcome concepts reached a 70% threshold after the second voting round. The remaining 43 outcome concepts were ranked below the agreed 70% consensus level required for inclusion in the COS. The 9 concepts with 70% or more consensus were presented to and ratified by the group as the final COS.

Discussion

As far as we are aware, this is the first study to define

a COS for EPA interventions to support pMSKD. The systematic searches identified 50 independent concepts that were used for investigating the effectiveness of EPA interventions in RCTs. A further two concepts were added to this list during the consensus workshop stage. Following consideration of these 52 outcome concepts, workshop participants arrived at a consensus that nine must be included in the COS. These were: function, patient satisfaction, physical activity, quality of life, pain, cost-effectiveness/healthcare costs, self-efficacy, knowledge to plan future exercise, referral/utilisation of health services.

The final COS contains concepts that are frequently used in studies of effectiveness of EPA interventions in pMSKD, with 6 out of 8 of the most frequently used concepts (Physical activity, pain, function, quality of life, patient satisfaction, cost-effectiveness) extracted included in the COS. Physical activity was used as an outcome concept in all the studies as its inclusion in effectiveness studies was a pre-requisite in the systematic search phase of this study.

The inclusion of two concepts ('self-efficacy' and 'knowledge to plan future exercise') demonstrates the need for behavioural change concepts to be measured as part of EPA interventions. Self-efficacy is defined as 'people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives' [52]. The need for integration of self-efficacy theory into EPA interventions has been advocated for some years [53]. However, how this might be achieved is not well understood as there could be numerous internal and external factors that affect self-efficacy [53]. Positive insights for integrating self-efficacy are available. In a recent systematic review and meta-analysis [54] it was found that EPA interventions participants were twice as likely to increase EPA in interventions that prioritised self-efficacy. Although self-efficacy was included in the final COS with a strong consensus (78.6%) it was only

Table 4: Final outcome concept rankings.

	Concept	Percentage Consensus
Final COS (Concepts reaching 70% consensus or more)	Function	100%
	Patient Satisfaction	100%
	Physical Activity	92.9%
	Quality of Life	92.9%
	Pain	85.7%
	Cost Effectiveness/Health care costs	85.7%
	Self-Efficacy	78.6%
	Knowledge to plan future exercise	71.4%
	Referral/utilisation of health services	71.4%
Concepts not making the final COS (Consensus below 70%)	Perception of change in condition	64.3%
	Clinical outcomes	50.0%
	Psychological functioning	42.9%
	Motivation to exercise	42.9%
	Programme attendance	42.9%
	Range of movement	35.7%
	Health status	35.7%
	Activity limitation	35.7%
	Pain medication usage	35.7%
	Stage of exercise behaviour change	35.7%
	Strength	28.6%
	Autonomy	28.6%
	Balance/postural stability	28.6%
	Satisfaction of the needs for competence	28.6%
	Adherence	21.4%
	Coping	21.4%
	Inflammation/flare ups	21.4%
	Social support	21.4%
	Walking distance	21.4%
	Workability	21.4%
	Self-reported exertion	14.3%
	Fear of movement	14.3%
	Physical performance/fitness	14.3%
	Joint specific variables	14.3%
	Neurological assessment	14.3%
	Satisfaction and demand for information	14.3%
	Vitality	14.3%
	Fatigue	7.1%
	Side effects	7.1%
	Agility	7.1%
	Measures of body size, shape, and movement	7.1%
	Disability	7.1%
	Leisure time	7.1%
	Muscle tenderness	7.1%
Programme implementation fidelity	7.1%	
Psychosocial beliefs	7.1%	
Therapies given by other caregivers	7.1%	
Anxiety	0.0%	
Depression	0.0%	
Strength of Joints	0.0%	
Stiffness	0.0%	
Swelling	0.0%	
Frailty	0.0%	

extracted twice from the studies derived from the phase 1 systematic searches. This perhaps indicates a disconnect between the design of interventions in the literature compared to the consensus group in this study that included patients.

'Knowledge to plan future exercise' was one of the two concepts derived by the consensus workshop participants. This concept was felt to be important as it represents whether EPA intervention participants have gained sufficient knowledge to plan and adhere to ongoing EPA independently. This is supported in behavioural change literature with knowledge and gaining information thought to be a key part of behavioural change interventions to support ongoing adherence [55,56]. Both self-efficacy and knowledge acquisition are core parts of behavioural change models such as the Transtheoretical Behavioural change model (TTM) [57], the WHO behavioural change model to support adherence [58], and also the behavioural change wheel [59].

The other concept to be derived by the consensus workshop participants was referral/utilisation of healthcare services. This relates to services that pMSKD access related to their condition, and if EPA interventions can change an individual's level of healthcare utilisation. Although the systematic searches in phase 1 of this study did not provide studies specifically reporting on healthcare utilisation, this seems to be a regularly used outcome in studies about MSKD [60-62]. Cost-effectiveness/healthcare costs were also included within the final COS. The consensus workshop participants deemed referral/utilisation of healthcare services' to be distinct from this. However, studies investigating interventions for MSKD have included utilisation of healthcare services to establish costs or cost effectiveness of services [63,64]. When applying this COS in practice, consideration of combining these two concepts into one could be considered.

Although it appears no other studies have developed a COS for supporting EPA interventions in pMSKD, COS has been developed in similar populations or interventions. Core outcome domains have been produced for MSKDs. One such being a core outcome domain development for clinical trials for non-specific low back pain [18]. Two hundred and Eighty global experts participated in the Delphi study including 15 patients, with a steering group of low back pain experts defining outcome concepts and having a final say on the COS. Four outcome domains - Physical functioning, pain intensity, health-related quality of life and number of deaths - resulted. A COS for exercise interventions for people living with multiple sclerosis have been produced [65]. An international consensus meeting was used to identify the COS from the International Classification of Functioning disability and health core sets [66]. Both these COS development studies show how derivation of a COS can be done by similar but nuanced methodology.

Strengths and weaknesses

COMET [19] recommends that the size and members of expert consensus panels should be pragmatically considered with reference to the subject in question. The size of the consensus group (n = 14) in this study is low compared to other COS consensus groups. In some COS development studies international panels have been used [18,67]. However, the range of participants in this study was representative of the interested parties related to EPA interventions for pMSKD. It is possible that this COS could be repeated with a larger group or international participants which may provide more confidence in the COS. However, the COS was derived from a list of outcome concepts that had been used in a global range of studies, providing further basis for confidence in the COS.

Strengths of this study are the rigorous systematic searches of the literature undertaken in accordance the Cochrane Handbook for Systematic Reviews of Interventions [25] and PRISMA guidance [24] to derive the list of outcome concepts to use in the consensus phases. The study followed COMET methodology [19], and derived outcome concepts from a representative group of experts that included - in accordance with COMET initiative recommendations - expert patients to identify the critically important outcome concepts that must be used in a final COS. In this study grey literature searches were not undertaken, and only papers published in the English language were used, meaning there is a possibility of relevant information not having been retrieved.

Two concepts were identified on the day of the consensus workshop (referral/utilisation of health services, and knowledge to plan future exercises) and both concepts were included in the final COS. It is acknowledged that a possibility of bias towards these concepts by the consensus group took place, or they were the subject of more discussion than other concepts, which led to their inclusion. However, requesting consensus group participants to derive concepts on the day of the meeting is in accordance with COMET methodology [19].

Research and clinical implications

This COS is helpful in two ways: It creates an opportunity for future researchers investigating EPA interventions for MSKD to understand how they could standardise their data collection in ways that are meaningful to relevant stakeholder groups. The fundamental lack of standardisation has been identified as one of the key reasons for not being able to fully understand the effectiveness of EPA interventions for pMSKD. Secondly, EPA interventions are widely used to support pMSKD [8,12] and the COS will allow clinical services to start to consider and standardise their outcomes for patients. Researchers and clinicians

must still choose valid and reliable measures that reflect the COS to evaluate the effectiveness of their EPA intervention. This provides some flexibility to either choose measures for interventions that support any pMSKD or for interventions supporting specific MSKD such as for LBP or shoulder problems. The standardisation and benchmarking that this COS provides creates the opportunity to compare similar interventions both nationally and internationally and in doing so enable understanding of where variation exists between EPA interventions for pMSKD.

Conclusion

The benefits of EPA interventions to enable pMSKD to self-manage their condition are well known, EPA interventions are widely used to facilitate this transition. This study utilised PRISMA [68], Cochrane [25] and COMET [19] guidelines, patients and key stakeholders to agree nine outcome concepts that should be used in evaluations of the effectiveness of EPA interventions for pMSKD. The study had a comparatively low number in the consensus group, though there was representation from a range of stakeholder groups and patients. The study has produced a COS which could be used in research investigating EPA interventions. In addition, the COS supports clinical services to evaluate the effectiveness of their EPA interventions and develop interventions in ways that optimise these important outcome concepts for relevant stakeholders.

Declarations

Ethics approval

Ethics approval was obtained from the NHS Health Research Authority, East Midland- Leicester South Research ethics committee. IRAS project ID: 225119: REC Reference 17/EM/0342.

Ethics permission was also obtained from Sheffield Hallam University Ref: 2017-8/HWB-HSC-02.

Informed consent was obtained from all subjects.

Competing interests

The authors declare that they have no competing interests.

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literature and synthesis but also in supporting literature synthesis skills in the research group.

Authors' contributions

AT undertook literature synthesis, recruitment, consensus group organisation and write up. RM undertook consensus group design, literature extraction, data gathering and participated in write up. TP undertook literature synthesis and data extraction. DH designed search strategy and provided systematic search expertise. MK undertook participant recruitment and workshop design. SM Provided consensus group expertise, and design, and contributed to write up. All authors read and approved the manuscript.

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