**The effectiveness of interventions and intervention components for increasing physical activity and reducing sedentary behaviour in people with persistent musculoskeletal pain: a systematic review and meta-analysis**

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 Conflicts of interest

The authors declare no conflicts of interest.

**Abstract**

This systematic review and meta-analysis investigated the effectiveness of physical activity (PA) and sedentary behaviour (SB) interventions on PA and SB levels in people with persistent musculoskeletal pain. We explored the effectiveness of behaviour change techniques (BCTs), the use of behaviour change theory and non-PA/SB outcomes. Randomised controlled trials of PA or SB interventions for people with persistent musculoskeletal pain were eligible. Twenty-three studies were included. Quality of evidence was assessed using the GRADE approach. Meta-analysis demonstrated a small effect for PA post-intervention (Hedge’s g = 0.321, CI 0.136 to 0.507, p = 0.001, very low-quality evidence). There was no effect for longer-term follow-up PA (low quality evidence) or SB outcomes (very low-quality evidence). There was a small effect for studies with low risk-of-bias at longer-term follow-up PA. Self-report PA outcomes, PA and education interventions, non-self-selected PA, a combination of supervised and unsupervised PA and a combination of individual and group-based interventions had larger effects. Heterogeneity was moderate to considerable. Risk-of-bias, assessed using Cochrane risk-of-bias tool (version two), was generally low. Five promising BCTs were identified: ‘adding objects to the environment’, ‘goal setting (outcome)’, ‘action planning’, ‘monitoring outcome(s) of behaviour by others without feedback’ and ‘feedback on outcome(s) of behaviour’. In conclusion, there is evidence for a modest benefit for PA interventions immediately post-intervention, however the quality of evidence is very low. There was no evidence for longer-term follow-up PA or SB. Higher quality studies of PA and SB interventions that use objective measures are needed. PROSPERO registration: CRD42020180260.

**Perspective**

This review investigated the effects of physical activity and sedentary behaviour interventions on physical activity and sedentary behaviour levels in people with persistent musculoskeletal pain. Current evidence shows a modest benefit for interventions on physical activity post-intervention but not at longer-term follow-up or on sedentary behaviour at any time-point, however quality of evidence is low to very low.

**Keywords:** systematic review, meta-analysis, physical activity, sedentary behaviour, persistent musculoskeletal pain

1. **Introduction**

Persistent musculoskeletal pain conditions are some of the leading causes of disability worldwide.97 Low back and neck pain are reported to be the leading causes of disability and ‘other musculoskeletal disorders’ are eighth on the list.97 Persistent musculoskeletal pain is defined as pain lasting longer than three months that is experienced in bones, joints, muscles, tendons and other soft tissues.74 The terms ‘persistent’ and ‘chronic’ pain are used interchangeably in the literature; in this study, the term persistent is used throughout.

Persistent musculoskeletal pain affects people’s ability to do physical activities such as walking and household chores, and commonly affects sleep, relationships and work.14 Higher walking disability is associated with greater risk of death in people with osteoarthritis.68 People with persistent musculoskeletal pain also often have co-morbidities, including psychological problems,85, 92 cardiovascular disease92 and obesity.20

The World Health Organization define physical activity (PA) as “any bodily movement produced by skeletal muscles that requires energy expenditure.” This “includes exercise as well as other activities which involve bodily movement and are done as part of playing, working, active transportation, house chores and recreational activities.”71 Exercise is defined as “a subcategory of physical activity that is planned, structured, repetitive, and purposeful in the sense that the improvement or maintenance of one or more components of physical fitness is the objective.”71 Low back pain and osteoarthritis are two of the most common, most costly and most debilitating persistent musculoskeletal pain conditions. However, people with persistent low back pain are less active than matched healthy controls82 and those with the condition that have higher disability are more likely to have lower PA levels.54 Similarly, only small to moderate numbers of people with hip and knee osteoarthritis meet PA guidelines.99

PA is safe for people with persistent musculoskeletal pain35 and can be effective at improving physical function and quality of life.34, 35, 69, 89 PA is associated with reduced premature mortality,29 and is effective in reducing the impact of numerous associated health problems common in people with persistent musculoskeletal pain.52, 86, 88 PA is recommended in national guidelines for management of osteoarthritis,66, 78 low back pain and sciatica.67, 77 PA promotion and exercise therapy are also recommended as part of first line treatment for low back pain.33 National public health campaigns have recommended reducing sedentary behaviour (SB) to improve the management of long-term health conditions, such as persistent musculoskeletal pain.75

Recent systematic reviews and meta-analyses on PA interventions in people with persistent musculoskeletal pain all have limitations.28, 55, 70 One review55 performed their meta-analysis defining their follow-up period from post-randomisation, rather than from post-intervention. The length of PA interventions varies greatly and therefore, what is considered long-term follow-up may coincide with still being in the intervention period, meaning this approach does not provide accurate estimates of immediate post-intervention effects and longer-term maintenance effects. Another review28 found a small effect at medium-term follow-up and no effect at long-term follow-up, but did not do an immediate post-intervention analysis. This is important for comparing post-intervention with longer-term follow-up effects. One review70 only included objective PA outcomes, however, many studies include only self-report measures and such measures also compliment objective data, therefore excluding these measures reduced the scope of the review. Another review separated their self-report and objective results and did not calculate a combined pooled effect.55 These reviews were also limited by including preliminary/pilot studies with small sample sizes, which may alter the precision of results.55, 70

To our knowledge, no systematic reviews or meta-analyses in people with persistent musculoskeletal pain have examined the effects on PA levels according to the nature of the intervention, including the mode of PA, or intervention characteristics such as setting of PA or method of intervention delivery, and this may be important due to the large variation in ways of performing PA. Moreover, we are not aware of any reviews examining the effects of interventions aimed at reducing sedentary behaviour (SB) in people with persistent musculoskeletal pain.

Behaviour change techniques (BCTs) are the components of interventions directly affecting behaviour; the ‘active ingredients’.60 Identification of effective BCTs within interventions can allow identification of potentially important intervention components that help bring about behaviour change.60 Rigorous testing of behaviour change theory can help inform intervention design, as well as provide explanations for why they may or may not be effective.59, 80 Therefore, theories are fundamental in behaviour change intervention design.59 To our knowledge no reviews have explored the use of behaviour change theory in interventions aimed at increasing PA or reducing SB in people with persistent musculoskeletal pain.

An updated review is needed, which overcomes the above limitations of previous reviews, comparing post-intervention and longer-term follow-up outcomes in full randomised controlled trials (RCTs), that includes self-report and objective PA measures. Therefore, we aimed to provide an up-to-date review on the effect of PA interventions on PA levels in people with persistent musculoskeletal pain. Additionally, we reviewed interventions for reducing SB in this population. We also explored the effects of risk-of-bias, outcome measure type, nature of the intervention, type and setting of PA and method of intervention delivery. We explored any associations between number of behaviour change techniques (BCTs, i.e., intervention contents60) and effect sizes and explored potential effectiveness of specific BCTs, as well as identifying the use of theory in the interventions. Lastly, we reviewed findings for non-PA/SB health-related outcomes.

**2. Methods**

This review is reported consistent with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement62 (see supplementary material) and is registered with the International Prospective Register of Systematic Reviews (PROSPERO: CRD42020180260).

*2.1 Search Strategy*

Search terms were derived from knowledge of the research area and by reviewing the search strategies in similar reviews, and were agreed by two authors (GB, MU). Specific RCT search filters were included in the search strategy.21, 53 A search of MEDLINE, Embase, CINAHL, SportDiscus, PsycINFO, PEDro and CENTRAL electronic databases was initially performed on 28/05/20 and 29/05/20 and was updated on 24/06/2021. Databases were searched from inception until the date of the search (see supplementary material for MEDLINE search strategy). This search strategy was adapted for the other databases, with consistent search terms throughout. The reference lists of similar systematic reviews and meta-analyses were also searched to identify relevant studies.

*2.2 Selection of studies*

*2.2.1 Screening*

Search results were exported into Endnote93 and duplicates removed. Results were imported into Rayyan QCRI software72 for title and abstract screening. One author (GB) screened all titles and abstracts independently against the eligibility criteria. Two authors (MU, AH) independently screened 50% each of the titles and abstracts. Conflicts were resolved by discussion. Of the remaining articles, full texts were retrieved and reviewed, and three authors (GB, MU, AH) finalised the articles via consensus.

*2.2.2 Eligibility criteria*

Eligible studies were those published in English language in peer-reviewed journals. We included RCTs or cluster-RCTs. We excluded quasi-RCTs and preliminary/pilot studies.

The population of interest was adults (aged ≥18 years) with persistent musculoskeletal pain (i.e., pain lasting ≥3 months, experienced in bones, joints, muscles, tendons and other soft tissues.74) We only included those with persistent spinal pain (including lumbar, thoracic and cervical) and persistent peripheral joint pain (upper and lower limbs). We included participants with multiple pain sites. Participants that had undergone surgery but met the inclusion criteria of adults with PMP were included, but those awaiting surgery were excluded, due to the likelihood of uncertain and varied long-term management.

We excluded studies of patients with non-musculoskeletal pain or cancer-related pain, and those with rheumatological conditions such as fibromyalgia or rheumatoid arthritis as these are distinct conditions.45

We included studies of any interventions aimed at increasing PA levels or adherence to PA, or studies seeking to reduce SB. We used the World Health Organization’s definition of PA: “any bodily movement produced by skeletal muscles that requires energy expenditure.” which “includes exercise as well as other activities which involve bodily movement and are done as part of playing, working, active transportation, house chores and recreational activities”.100 We defined SB as: “any waking behaviour characterized by an energy expenditure ≤1.5 metabolic equivalents (METs), while in a sitting, reclining or lying posture”.65, 95 Interventions of any duration and with any length of follow-up were included. Multi-component interventions where all the components were aimed at increasing PA or reducing SB were included. We excluded multi-component interventions with elements aimed at changing behaviours other than PA or SB (e.g., diet), or that included medical interventions (e.g., injections). We excluded site-specific exercises (e.g., neck exercises) unless aimed at increasing overall PA levels or reducing SB. We included studies with all types of control group and studies with multiple intervention arms.

Our co-primary outcomes of interest were objective or self-report measures of PA or SB (e.g. accelerometry). All measures were included that measured PA levels, PA adherence or SB levels. If studies included both objective and self-report measures, the objective measure was included in the meta-analysis. For studies that used multiple self-report or objective measures, we included the main outcome in the original study. If the main outcome was not reported, we used the outcome that was more commonly used to measure PA/SB.

2.3 *Data extraction*

One author (GB) independently extracted data for all included studies. Two authors (MU, AH) checked the accuracy of data extraction (50% of studies each), with ambiguities resolved by discussion.

Extracted data included: study and participant characteristics, intervention and control characteristics, PA settings, methods of PA delivery and providers. BCTs were coded from intervention and control using the BCT Taxonomy version one (BCTTv1).60 A coding system was developed, with ‘confident’ meaning we were fully confident that the BCT was present, or ‘tentative’, meaning there was uncertainty. One author (GB) has received formal training in using BCTTv1 (http://www.bct-taxonomy.com/). The other authors (MU, AH) involved in coding are experienced with using the taxonomy. Behaviour change theories were classed as being used in an intervention when the theory used was explicitly stated in the article or intervention description. Use of theories was coded as ‘informed by theory’, ‘applied theory’, ‘testing theory’ or ‘building or creating theory’.73 For primary outcomes, we extracted mean values and standard deviations (SD) from each study at post-intervention and longer-term follow-up time points, where available. Post-intervention outcomes were defined as outcomes that were collected immediately after the intervention period ended. Longer-term follow-up outcomes were defined as the longest follow-up time-point of any study that collected outcomes beyond immediate post-intervention. Where this data was unavailable, we emailed study authors requesting the data. For non-PA/SB health-related outcomes (e.g., pain), we recorded which were significant and which were not significant.

*2.4 Assessment of risk-of-bias*

Risk-of-bias was assessed in each included study using version 2 of the Cochrane risk-of-bias assessment tool for randomised trials91 and additional considerations were used for cluster-randomised trials.30 Risk-of-bias domains included bias arising from: the randomisation process (including addition of bias arising from the timing of identification and recruitment of participants in relation to timing of randomisation in cluster-randomised trials), deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of results. For each study, each domain was judged as being either ‘low risk-of-bias’, having ‘some concerns’ or being ‘high risk-of-bias’. Studies were judged as low risk-of-bias if all domains were judged as ‘low risk-of-bias’, as ‘some concerns’ if one or more domains were judged as ‘some concerns’ and high risk-of-bias if one or more domains were as judged as ‘high risk-of-bias’.

For the studies with self-report outcomes, we assessed these as low risk-of-bias in the measurement of the outcome domain if the outcome was validated. If we could not find evidence of the outcomes being validated, we assessed this as ‘some concerns’.

Risk-of-bias assessments were conducted independently by one author (GB), and two authors (MU, AH) independently assessed 50% each of the studies. Disagreements were resolved by discussion.

*2.5 Data synthesis and analysis*

*2.5.1 Meta-analysis, subgroup-analysis and meta-regression*

Meta-analyses were performed using Comprehensive Meta-analysis software Version 3.12 For all meta-analyses and subgroup analyses we used the random-effects model, due to suspected heterogeneity. For our primary meta-analyses, we calculated the effect sizes using Hedge’s g and 95% confidence intervals (CIs) for PA and SB outcomes immediately post-intervention and at longer-term follow-up. The Hedge’s g effect sizes were interpreted as: small = 0.2, medium = 0.5 and large = 0.8. We conducted a sensitivity analysis including studies only of low risk-of-bias. We conducted pre-planned subgroup analyses on PA outcomes for: outcome measure type (self-report versus objective), PA type (self-selected, non-self-selected, combination), PA setting (supervised, unsupervised, combination) and intervention delivery method (individual, group-based, combination). For the study with two intervention arms,10 we split the control group sample in half whilst keeping the same mean and standard deviation to ensure these participants were not double counted in the meta-analysis.

Statistical heterogeneity was assessed using Cochran’s Q and the I2 test37. I2 values of above 80% were assessed as considerable, between 60% and 80% were assessed as substantial, between 40% and 60% as moderate and below 40% as unimportant.23 Publication bias was assessed by inspecting funnel plots and using the Begg-Mazumbar Kendall’s tau5 and Egger test.27 We conducted a trim and fill adjusted analyses25 to calculate a new effect size after ‘trimming’ the funnel plot of small studies and then estimating the number of missing studies by ‘filling’ the funnel plot with the omitted and estimated missing studies around the new effect size. We calculated the fail-safe number of negative studies that would be required to nullify (make p > 0.05) the effect.81 We performed a meta-regression to identify potential moderators of PA levels. The potential moderators were number of BCTs (‘confident’ only) present in the interventions and number of treatment sessions.

*2.5.2 Behaviour change components*

We narratively synthesised behaviour change theory use in terms of how many studies used behaviour change theory, extent of theory use73 and theories used.

We calculated the number of BCTs used across intervention and control groups and recorded the number of times each BCT was coded. We identified BCTs for which there was evidence of effectiveness.58 We considered that interventions showed evidence of effectiveness when there were statistically significant differences (p <0.05) in PA or sedentary levels between trial groups at either point measured in our meta-analyses. An “effectiveness percentage”, a measure to reflect potential effectiveness, was calculated as the number of times a BCT had been a component of an effective intervention, divided by the total number of interventions in which the BCT had been a component. Effective percentages were calculated only for BCTs used in two or more interventions.32

*2.5.3 Secondary outcomes*

Due to many different non-PA/SB health-related outcomes, we categorised these outcomes (e.g., related to pain, function, psychological) and identified statistically significant and non-significant findings. We calculated the number of times each outcome category was reported and how often they were statistically significant or non-significant at either post-intervention or at their longest follow-up, if they reported further follow-up time points. We then calculated the percentage that each outcome category demonstrated statistically significant results.

* 1. *Quality of evidence*

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE)1 was used to evaluate the quality of the evidence for our primary outcomes. GRADE enables a judgement of high, moderate, low or very low for each outcome, across five domains: risk-of-bias, indirectness of evidence, inconsistency of results, imprecision of effect size and publication bias.

*2.7 Deviations from registered protocol*

See supplementary material for details of deviations from the protocol, reasons for these deviations and the effect on the results. None of the deviations had a significant effect on the results.

**3. Results**

*3.1 Study selection*

The search yielded 30,551 results, and 18,570 remained after removing duplicates. Eighty-six articles remained after title and abstract screening. A further 57 articles were excluded after reviewing the full texts (see figure 1 for the PRISMA flow diagram). Of the remaining 29 studies, eight authors were contacted for further PA outcome data; two supplied the data9, 10 and six not providing data were excluded.6, 15, 36, 42, 44, 79 Thus, 23 studies were included.2-4, 7, 9, 10, 13, 18, 19, 31, 38, 39, 43, 46, 48, 51, 57, 64, 76, 84, 87, 98, 103

*3.2 Characteristics of included studies*

Table 1 summarises the characteristics of the included studies. Twenty studies were RCTs and three were cluster-RCTs. Year of publication ranged from 2006 to 2021. Twenty-two studies had PA interventions and one aimed at reducing SB.

*3.2.1 Participants characteristics*

The 23 studies included 4,012 participants; 2103 were in the intervention groups and 2487 (65.3%) were female. Mean age was 61.38 years (range 46 to 85). Seven studies included participants with persistent low back pain,3, 4, 48, 51, 57, 84, 87 eight had participants with knee osteoarthritis,2, 7, 9, 19, 31, 38, 64, 98 one included participants with hip osteoarthritis,10 five included both knee and hip osteoarthritis,13, 39, 43, 46, 76 one included chronic musculoskeletal pain but did not specify the location or origin,18 and one included lower limb osteoarthritis (hip, knee, ankle or foot).103 Four studies2, 3, 43, 48 with 575 participants reported ethnicity, and 422 (73.39%) were Caucasian. Employment was reported in nine studies;7, 10, 38, 48, 57, 64, 87, 98, 103 the mean percentage employed was 53.9% (range 15.8% to 91%). Six studies reported co-morbidities,10, 18, 19, 38, 43, 64 with cardiovascular disease, lung diseases, orthopaedic problems, cancer, diabetes, hypertension and mental health conditions being reported in at least two studies. Ethnicity, employment and co-morbidities are not reported in table 1 due to the low number of studies reporting this information.

*3.2.2 Intervention characteristics*

See table 1 for details of the intervention aimed at reducing SB.3 There were 23 interventions in 22 studies of PA interventions; one study had two intervention arms.10 Interventions varied from four weeks87 to 24 months.2 Two interventions were solely web-based.13, 48 Eighteen interventions consisted of non-self-selected PA, with 11 of these consisting of exercise,2, 4, 7, 9, 10, 19, 31, 39, 57, 64, 103 three of walking,10, 48, 51 three combining exercise and walking43, 87, 98 and one offering exercise and functional activities.76 Three interventions combined self-selected and non-self-selected PA; the non-self-selected component was physiotherapy prescribed exercise.18, 38, 46 Two interventions offered self-selected PA only.13, 84

Interventions provided: counselling/coaching with PA,2, 4, 7, 9, 18, 48, 84, 103 education with PA13, 19, 43, 46, 51, 57, 76 and education and counselling with PA.10, 31, 38, 64, 87 Two interventions provided PA only.39, 98

Interventions offered: only supervised PA,4, 9, 31, 57 only unsupervised PA3, 13, 38, 48, 51, 64, 84 and combined supervised and unsupervised PA.2, 7, 10, 18, 19, 39, 43, 46, 76, 87, 98, 103 Interventions were delivered individually,3, 4, 7, 9, 13, 18, 38, 46, 48, 51, 64, 76 group-based39, 57, 87 and combined individual and group.2, 10, 19, 31, 43, 84, 98, 103 The number of interactive sessions (excluding online) was reported in 20 studies, ranging from two to 54 sessions. Of five studies including online components, one had nine modules,13 one had 11 modules,46 one had weekly engagement48 and two provided unlimited access to resources.64, 84

*3.2.3 Control group characteristics*

Two control groups received no intervention,3, 13 four had the same or similar PA as the intervention group with less or without the additional behavioural component,2, 7, 9, 103 three received a similar behavioural component with different PA,31, 51, 64seven had a minimal or less intense PA-based intervention,10, 19, 39, 43, 57, 64, 84 one had the same self-management component but a different PA component31 and seven received usual care.4, 18, 38, 46, 48, 76, 98

One study was a three arm RCT, with the intervention arms consisting of Nordic walking and strength training and the control group consisting of home exercise.10 We determined the home exercise group as the control group as this group was designated as the control by the study authors. The control group received a much less intensive intervention (table 1).

*3.2.4 Physical activity and sedentary behaviour outcomes*

Seventeen studies had only self-reported PA outcomes,2-4, 9, 10, 18, 19, 38, 39, 43, 51, 57, 64, 76, 84, 87, 103 three only objective outcomes31, 48, 98 and three had a combination of self-report and objective.7, 13, 46

Twelve different PA self-report measures were used. Six of the measures were used more than once; Physical Activity Scale for the Elderly (PASE) was used six times, a Numerical Rating Scale (NRS) for exercise adherence was used four times, and the Global Physical Activity Questionnaire (GPAQ), International Physical Activity Questionnaire (IPAQ), Freiburg Questionnaire and Short Questionnaire to Assess Health-Enhancing PA (SQUASH) were each used twice. For objective PA outcomes, accelerometers were used five times and pedometers were used in one study. One study used the Global Physical Activity Questionnaire for measuring SB3 and this was the only self-report outcome used for SB. Accelerometers were used in three studies to objectively measure SB.13, 46, 98

Four studies measured outcomes of specific intensities of PA. One measured minutes per week doing moderate to vigorous PA,3 one measured minutes per day doing moderate to vigorous PA,46 one measured days per week doing 30 minutes or more of moderate to vigorous PA76 and one measured minutes per day doing three or more MET-minutes of PA.31

*3.3 Risk-of-bias assessment*

Risk-of-bias is displayed in figure 2. Eighteen studies were assessed as low risk-of-bias. Five had ‘some concerns’’; three of these used unvalidated NRS PA outcome measures,2, 9, 19 one used an activity diary,4 and one lacked detail of the randomisation process and of baseline data for each study group.103 The latter study also had ‘some concerns’ as there was no information about whether there were any deviations from the intended intervention. No studies were judged as being at high risk-of-bias.

*3.4 Meta-analysis*

Twenty-one post-intervention PA outcomes from 19 studies were included in our meta-analysis; one study contained two intervention arms,10 and we included two outcome measures for one study as they reported longer-term outcomes for self-report outcomes, but only post-intervention outcomes for objective outcomes.7 Pooled data from these 21 outcomes showed a small effect in favour of the interventions (Hedge’s g = 0.321, CI 0.136 to 0.507, p = 0.001, very low certainty evidence) (Figure 3), with considerable heterogeneity (Q = 117.2834 p = 0.008, I2 = 83%). In the funnel plot there was asymmetry, with one study far to the right (see supplementary material). However, neither Begg and Mazumdar’s rank correlation test (tau = 0.27619, p = 0.08) nor Egger’s regression test (intercept = 1.996, p = 0.261) were significant, demonstrating no evidence of publication bias. Pooled data from the 12 studies presenting longer-term PA outcomes showed no effect (Hedge’s g = 0.197, CI 0.061 to 0.332, p = 0.005, low certainty evidence) (Figure 4), with moderate heterogeneity (Q = 26.85459 p = 0.005, I2 = 59%). Again, there was evidence of funnel plot asymmetry, with one study far to the right (see supplementary material). Begg and Mazumdar’s rank correlation (tau = 0.12121, p = 0.58) and Egger’s regression (intercept = 0.167, p = 0.947) tests were not significant.

Meta-analysis for post-intervention SB outcomes, with three studies, was not significant (Hedge’s g = -0.203, CI -0.702 to 0.295, P = 0.424, very low certainty evidence) (Figure 5) and there was no evidence of heterogeneity (Q = 5.55 P = 0.062, I2 = 63.97%). There was no effect for longer-term follow-up SB outcomes in two studies (Hedge’s g = 0.011 CI -0.183 to 0.204, P = 0.914, very low certainty evidence) (Figure 6), nor was there significant heterogeneity (Q = 0.379 P = 0.538, I2 = 0%). Table 2 presents all meta-analyses. Due to the small number of studies in both SB analyses, we did not test for publication bias. See table 3 for GRADE ratings and justification for ratings.

*3.4.1 Sensitivity analysis*

There was a marginally smaller effect for studies with low risk-of-bias at post-intervention for PA (Hedge’s g = 0.257, CI 0.115 to 0.399, p < 0.001), with substantial heterogeneity (Q = 42.305 p < 0.001, I2 = 64.54%). There was a small effect size for PA at longer-term follow-up for studies with low risk-of-bias (Hedge’s g = 0.202, CI 0.045 to 0.360, p = 0.012), and heterogeneity was substantial (Q = 26.71611 p = 0.002, I2 = 66.31%). We did not perform a sensitivity analysis for SB outcomes as all studies were judged as low risk-of-bias.

*3.4.2 Subgroup analysis*

Subgroup analysis was performed only for post-intervention PA outcomes (see table 2), as there were insufficient studies for longer-term follow-up outcomes. Studies containing only self-report outcomes had a larger but still small effect size (Hedge’s g = 0.350, CI 0.113 to 0.586, p = 0.004); interventions consisting of PA and education showed the highest effect size, which was a medium effect (Hedge’s g = 0.749, CI 0.003 to 1.495, p = 0.049); non-self-selected PA was the only type of PA that showed any effect (Hedge’s g = 0.384, CI 0.158 to 0.610, p = 0.001); a combination of supervised and unsupervised PA showed the largest effect size, although this remained small (Hedge’s g = 0.447, CI 0.130 to 0.764, p = 0.006) and a combination of individual and group-based intervention delivery methods showed the highest effect size, although this also remained small (Hedge’s g = 0.491, CI 0.054 to 0.927, p = 0.028).

*3.4.3 Adjustment for publication bias and fail-safe number of studies*

Several analyses were adjusted for publication bias (see table 2). The majority of the adjusted analyses originally underestimated the effect sizes. For our main meta-analysis, the effect remained small after adjustment for post-intervention PA outcomes and increased to a small effect for longer-term follow-up PA outcomes. Post-intervention SB was unchanged after adjustment and longest follow-up for SB had too few studies to be adjusted. The fail-safe number of studies needed to nullify the effect was high for post-intervention PA outcomes (N = 302).

*3.4.4 Meta-regression for physical activity outcomes*

The number of sessions did not moderate the effect size of interventions at post-intervention (β = 0.0216, CI -0.0520 to 0.0952, p = 0.57, R2 = 0.00) or at longer-term follow-up (β = 0.0267, CI -0.0126 to 0.0659, p = 18, R2 = 0.12). A summary of the meta-regression outcomes is presented in table 4. The meta-regression outcomes for number of BCTs is described in section 3.5.

*3.5 Behaviour Change Techniques*

None of the studies referred to the intervention contents as BCTs or referred to the BCT taxonomy (BCTT), so all interventions were coded using the BCT Taxonomy version one60 to extract BCTs.

A total of 219 BCTs was delivered to PA and SB intervention and control groups; 177 were delivered to the intervention groups only. In the interventions, there were 31 different BCTs from 13 BCT clusters. Most BCTs were in the ‘Goals and planning’ (n=33) and ‘Feedback and monitoring’ (n=34) clusters. The number of BCTs identified for each intervention (PA and SB) ranged from three13 to fourteen,43 with an average of seven BCTs.

The majority of BCTs were present more than once in interventions, however, 10 BCTs were only present once: ‘behavioural contract’, ‘social support (emotional)’, ‘salience of consequences’, ‘monitoring of emotional consequences’, ‘pros and cons’, ‘non-specific reward’, ‘social reward’, ‘pharmacological support’, ‘reduce negative emotions’ and ‘body changes’.

Among six studies in the meta-analyses showing effectiveness for PA outcomes,7, 19, 38, 43, 76, 98 the BCT ‘credible source’ was present in all six interventions; ‘instruction on how to perform a behaviour’ and ‘self-monitoring of behaviour’ were present in five interventions;, ‘problem solving’, ‘action planning’ and ‘demonstration of the behaviour’ were present in four of the interventions; ‘goal setting (behaviour)’ and ‘behavioural practice/rehearsal’ were present in three interventions and ‘feedback on behaviour’ and ‘graded tasks’ were present in two of the interventions. Several BCTs were present only once in the effective interventions (table 5).

BCT effectiveness percentages are presented in table 5. Of the BCTs that were components of two or more PA interventions, one BCT had an effectiveness percentage of 67%: ‘adding objects to the environment’ and four had effectiveness percentages of 50%: ‘goal setting (outcome)’, ‘action planning’, ‘monitoring outcome(s) of behaviour by others without feedback’ and ‘feedback on outcome(s) of behaviour’. One BCT had a percentage of 0%: ‘Monitoring of behaviour by others without feedback’ (See supplementary material for BCTs).

One study focused on reducing SB, demonstrated post-intervention effectiveness3 and included the BCTs of: ‘goal setting (behaviour)’, ‘behavioural contract’, ‘social support (unspecified)’, ‘information about health consequences’, ‘prompts/cues’, ‘credible source’ and ‘adding objects to the environment’.

Meta-regression for number of BCTs did not moderate the intervention effect at immediate post-intervention (β = -0.0031, CI -0.0155 to 0.0092, p = 0.62, R2 = 0.00) or at longer-term follow-up (β = 0.0095, CI -0.0060 to 0.0249, p = 0.2304, R2 = 0.07).

Study protocols were available for eight trials;8, 17, 40, 41, 47, 49, 63, 83 however, the highest number of BCTs was present in a trial without an available protocol.43

Forty-four BCTs were coded as ‘tentative’; 39 of these were in the interventions. We only included BCTs in this analysis that were coded as ‘confident’.

*3.6 Use of theory*

Twelve studies explicitly identified using at least one behaviour change theory. The majority used one theory,4, 19, 43, 46, 48, 57, 76, 84, 87 two used two theories18, 64 and one used three theories.2 Among these studies, three were judged as being informed by theory,18, 46, 84 five as applying theory,2, 4, 48, 57, 76 three as testing theory19, 43, 87 and one study built/ created theory64 (see table 6). Social Cognitive Theory and the Transtheoretical Model were used three times each and were the most used theories. Self-efficacy Theory, the Health Action Process Approach and Operant Conditioning were used in two studies. Goal Setting Theory the Rubicon Model of Action Phases, the Capability-Opportunity-Motivation-Behaviour model and Theoretical Domains Framework were each used in one study.

Three of the six effective studies used theory. One study tested the Transtheoretical Model,19 one tested Social Cognitive Theory43 and one applied operant conditioning.76

*3.7 Health-related (secondary) outcomes*

One study did not have any outcome measures besides PA.76 Two studies did not report between group differences in secondary outcomes.31, 103 Of the twenty studies reporting between-group results for health-related outcomes, other than PA/SB, thirteen showed between group statistical significance in at least one outcome.3, 4, 7, 10, 13, 18, 19, 38, 39, 43, 57, 64, 98

Due to large variation in the outcome measures we grouped them into seven categories: pain, function, psychological, quality of life, physical/functional performance, cardiovascular health/risk factors and medication use. Table 7 displays the studies that had significant outcomes in each category. Functional outcomes (self-report measures of physical function or disability) were the most common, being measured in 18 studies. Psychological outcomes were significant at either post-intervention, longer-term follow-up, or at both time-points in 58.3% of the studies where they were measured; the highest of all outcome categories that were measured in two or more studies (for details of outcomes see supplementary material).

**4. Discussion**

To our knowledge, this is the first systematic review and meta-analysis to evaluate immediate post-intervention and longer-term follow-up for both PA and SB in full RCTs in people with persistent musculoskeletal pain. For post-intervention PA, our meta-analysis of 21 outcomes showed a small effect in favour of the interventions (Hedge’s g = 0.321, CI 0.136 to 0.507, p = 0.001, very low certainty evidence). Meta-analysis of twelve PA outcomes for longer-term follow-up showed no effect (Hedge’s g = 0.197, CI 0.061 to 0.332, p = 0.005, low certainty evidence). Few studies reported SB outcomes and our meta-analysis of three outcomes for post-intervention and two for longer-term follow-up showed no significant effect, with evidence rated as very low quality. Due to the quality of evidence being very low or low, these results need to be interpreted with caution as the real effect of PA and SB interventions could be different. Risk-of-bias was generally low for PA outcomes and our sensitivity analysis including outcomes with low risk-of-bias only slightly reduced the effect size for post-intervention PA. However, the effect size of our sensitivity analysis for PA at longer-term follow-up increased to demonstrate a small effect. All studies including SB outcomes were judged as low risk-of-bias.

This is the first systematic review and meta-analysis to investigate differences between self-selected PA, non-self-selected PA and combinations of the two. Non-self-selected PA was the only PA type that showed any effect. To our knowledge, this is also the only study to perform subgroup analysis of PA outcomes by the nature of the interventions, the setting of PA and the method of intervention delivery in this population. From our analysis, it appears that interventions that combine PA with education are more effective than those than combine PA with counselling/coaching, those combining PA with education and counselling and those with PA only. It also seems that interventions combining supervised and unsupervised PA are more effective than supervised and unsupervised alone, and those combining individual and group-based interventions are more effective than those that are solely individual or group-based immediately post-intervention, although the effect sizes remain small. Our analysis demonstrated a slightly higher effect size for self-report outcomes only and showed no effect for objective outcomes only. Therefore, the absolute magnitude of effect is likely to be smaller than the results shown in our main meta-analysis. Lastly, to our knowledge this is the first study to do a thorough analysis of the impact of publication bias on PA levels in people with persistent musculoskeletal pain. Our findings show that most of our adjusted analyses originally underestimated the effect sizes. Meta-regression demonstrated that the number of sessions did not moderate the effect size for post-intervention or longer-term follow-up PA outcomes.

We performed an in-depth analysis of BCTs in the PA interventions by using an established taxonomy60 and method for estimating effectiveness.58 There was substantial variation across studies in which BCTs were included; we identified only three BCTs that were present in at least half of the included studies. We found six BCTs that were present in more than half of the six studies showing effectiveness for PA outcomes, however, only one of these had an effectiveness percentage of 50%: ‘action planning’. The other BCTs with effectiveness percentages of 50%, were ‘goal setting (outcome)’, ‘monitoring outcome(s) of behaviour by others without feedback’ and ‘feedback on outcome(s) of behaviour’. The BCT ‘adding objects to the environment’ had an effectiveness percentage of 67%, the highest in our study. An effectiveness percentage of 50% or above suggests potential effectiveness, however, we cannot confidently conclude that they are likely to contribute to a more effective intervention. Meta-regression showed that the number of BCTs did not moderate the PA effect size at post-intervention or longer-term follow-up. We identified seven BCTs in the one intervention that was aimed at reducing SB; a study that demonstrated effectiveness at reducing SB.3

Ours is the first systematic review to examine the use of theory in PA and SB interventions for people with persistent musculoskeletal pain and we judged use of theory using a common system.73 The one study aiming to reduce SB was not theoretically based.3 Twelve of the 22 PA studies reported using a theoretical foundation for their interventions.2, 4, 18, 19, 43, 46, 48, 57, 76, 84 Most of these studies only applied theory in their intervention design.2, 4, 48, 57, 76 Three tested theory19, 43, 87 and one built/created theory,64 although this study did not demonstrate effectiveness for increasing PA levels. Evidently, more theoretically based intervention studies are needed, especially studies which test and develop theory.

Studies reported a broad range of non-PA/SB health-related outcomes. The most commonly reported outcomes were in the function and pain categories. Psychological was the only outcome category where more than 50% of the studies with these outcomes showed any significant between-group changes, aside from cardiovascular health and risk factors which were only reported in one study.

Several findings from our meta-analysis are comparable with similar previous reviews. Our results demonstrated a small effect for PA outcomes immediately post-intervention but no effect at longer-term follow-up. However, our sensitivity analysis including studies with low risk-of-bias only showed a small effect for PA at longer-term follow-up, suggesting higher quality studies show results more in favour of longer-term outcomes. Other studies of PA for people with persistent musculoskeletal pain have examined differences in effects at different follow-up points. One systematic review and meta-analysis reported a small significant effect at medium-term follow-up but no effect at long-term follow-up28 and another found no effect when using longest follow-up measures.102 Together, these findings suggest the need to improve maintenance of PA after the intervention period.

Consistent with our findings, previous reviews also reported no significant effects for objectively measured PA at any time point.55, 70 Also in line with our findings, one review55 reported much lower numbers of studies with objective outcomes compared with self-report, and their effects are also higher for self-report. This is shared with another review102 which did not perform meta-analysis for objective outcomes due to insufficient studies. Discrepancies between self-report and objective measures of PA and SB have also been reported in a large population-based epidemiological study; with participants reporting less sedentary time and higher levels of vigorous PA by self-report compared with accelerometry.26 It appears that self-report measures consistently overestimate PA levels compared with objective measures. More studies are needed which use objective measures of PA and SB, thereby overcoming the issues of recall and reporting bias with self-report.96

Our risk-of-bias assessments were considerably different to similar systematic reviews and meta-analyses.55, 102 Studies included in these reviews were mostly assessed as having bias due to lack of blinding55 and incomplete outcome data.102 A likely explanation for the differences in risk-of-bias assessments is that we used the most recent version of Cochrane risk-of-bias tool (RoB2), which recognises that unblinded trials and missing outcome data do not always lead to bias and judgements are dependent on context.91 For example, it is often not possible to blind participants to their intervention in PA trials, but these trials could still be of high scientific quality. In these circumstances, the latest risk-of-bias tool allows a judgement of low risk-of-bias, whereas the original Cochrane risk-of-bias tool would automatically have led to unblinded trials being judged as high risk-of-bias.91 Furthermore, if the reasons for missing outcome data are unrelated to the outcome being assessed (e.g. failure of a measuring device), then risk-of-bias can be assessed as low using the latest risk-of-bias tool.91 The original Cochrane risk-of-bias tool would have led to these situations being judged as high risk-of-bias.

We coded 31 different BCTs across all PA interventions included in our study. This is similar to another similar review that reported 28 different BCTs in effective interventions and 31 in ineffective interventions.55 In contrast, another similar review28 coded 43 different BCTs across all interventions. The BCTs ‘instruction on how to perform a behaviour’ and ‘behavioural practice/rehearsal’ were two of the most common BCTs in our review. This is consistent with other PA/exercise reviews of studies of people with persistent musculoskeletal pain.11, 28, 55, 56, 101 These BCTs were also two of the most common in the effective studies in our review. However, ‘instruction on how to perform a behaviour’ had an effectiveness percentage of only 25% and ‘behavioural practice/rehearsal’ had an effectiveness percentage of only 30%; suggesting that despite being often present in interventions, they may not be essential components.

We found the BCT ‘action planning’ to have one of the highest effectiveness percentages (50%). This BCT was also found to have the highest short-term effectiveness in a review of PA promotion for lower limb osteoarthritis.101 In our study, the BCTs ‘goal setting (outcome)’, ‘monitoring outcome(s) of behaviour by others without feedback’ and ‘feedback on outcome(s) of behaviour’ also had effectiveness percentages of 50%. ‘Goal setting (outcome)’ and ‘monitoring outcome(s) of behaviour by others without feedback’ were only present in four interventions and ’feedback on outcome(s) of behaviour’ was only present in two interventions in our review. The BCT with the highest effectiveness percentage in our study, ‘adding objects to the environment’ (67%), was present in just three interventions. These BCTs are also not reported as common BCTs in other similar reviews. Perhaps these BCTs warrant further investigation, particularly as goal setting and environmental changes are associated with behavioural maintenance.50 Furthermore, only one BCT associated with behavioural maintenance; ‘self-monitoring of behaviour’,50 was used in more than half of the included interventions.

*4.1 strengths and limitations*

This review has many strengths. The protocol was prospectively registered on the PROSPERO database, we followed the PRISMA guidelines62 and multiple authors were involved in each stage of the review. The use of the most recent Cochrane risk-of-bias tool is considered a strength due its comprehensiveness, despite the tool showing low interrater reliability and challenges in its application.61 These issues were mitigated by all the authors discussing application of the tool prior to using it, using the detailed guide accompanying the tool and discussing any disagreements to reach consensus.61 We used the established GRADE criteria to assess the quality of evidence. In addition to standard meta-analysis techniques, we assessed the impact of publication bias and performed adjusted analyses; the first study of PA interventions in this population to do this. This is the first systematic review and meta-analysis to investigate differences in the nature of interventions and between a number of intervention components: the type of PA, setting of PA and method of delivery. Additionally, our in-depth analysis of BCTs allowed greater exploration of the active components in interventions. This study also provides unique insights into the use of theory in interventions and non-PA/SB health-related outcomes. We only included full RCTs and the majority of studies in our review were low risk-of-bias.

We encountered substantial heterogeneity in the interventions and control groups. This is common in both persistent pain and PA literature and is expected considering heath behaviour change interventions are often complex.60 We followed the Cochrane reviewer’s handbook to attempt to disentangle this by conducting meta-regression analyses and subgroup analyses. However, the variation in control group characteristics may have significant influence on results as an intervention compared with an active control may show a smaller between group difference than an intervention compared with an inactive control. Moreover, such variations in the nature, length and intensity of interventions are likely to have influenced the results. This leads to uncertainty in study outcomes. Length of follow-up also varied widely between studies. The outcome measures used, and type of data derived from each outcome also varied greatly. Although the validity of the outcome measures used was generally a strength, more standardisation and consistency, with use of objective measures, would strengthen confidence in the meta-analysis findings. The type of PA may also have considerable impact on the level of change detectable by certain outcome measures. For example, accelerometry and outcomes measuring steps/day are likely to detect greater changes in PA in walking interventions compared with strength-based interventions. This further leads to uncertainty in the absolute effect of interventions.

Another limitation is the small number of studies in several of our subgroup analyses. There was only one study with solely self-selected PA and three with a combination of self-selected and non-self-selected PA. Considering activities that are enjoyable, that resemble individual’s values and that are personally relevant are more likely to result in maintenance of behaviour,50 it seems important that the choice of PA be driven by the participant.

Only three of the studies included power calculations and reported adequate power for PA outcomes.2, 4, 84 Therefore, we cannot be sure if these studies were adequately powered to detect PA outcomes and the results of this review should be interpreted with caution.

Several studies reported outcomes for SB, but the presence of only one study specifically aimed at reducing SB is a concern considering the health detriments of sitting are independent of moderate to vigorous PA.90 This study was also limited by using only a self-report measure and having no follow-up beyond the intervention period. With only one SB study we were unable to analyse potential effectiveness of the BCTs for this outcome.

The key aim of our study was to analyse PA and SB outcomes. A secondary aim was to investigate changes in non-PA/SB health-related outcomes. As this was a secondary aim, we did not perform meta-analysis to quantitatively synthesise these outcomes. This limits the inferences we can make from this data; specifically, we cannot assess the clinical relevance of these outcomes. Nonetheless, it enabled us to highlight the most reported type of outcomes and how often these outcomes demonstrated statistically significant results.

Lastly, we were unable to include all the identified relevant studies as our requests to obtain additional data from six authors were unsuccessful. The inclusion of these studies could have affected the results of this review.

*4.2 Implications for clinical practice*

Due to the heterogeneity of outcome measures and types of data collected, we were only able to pool the PA and SB outcome data using the Hedge’s g effect estimate. Therefore, we were unable to determine the overall magnitude of change in PA levels and cannot infer clinical relevance of these outcomes. In one of the studies showing statistically effective outcomes,76 their intervention group showed mean longer-term PA levels above 150 minutes/week of moderate to vigorous PA, demonstrating health-enhancing levels of PA.16 For people with lower extremity joint problems, 45 mins of moderate to vigorous PA is the minimum threshold to improve low function or sustain high function.24 Three or more days a week of moderate or greater PA is recommended to enhance function and reduce falls in older adults (≥65 years).16 This study included participants with knee and hip osteoarthritis with a mean age of 65 years and reported a mean of five days doing ≥30 mins moderate to vigorous PA in their intervention group at longer-term follow-up.76 However, they did not report functional outcomes so we cannot determine if their changes in PA led to clinically relevant functional gains.

 Another study reporting statistically effective increases in PA also reported mean PA levels of more than 150 minutes/week in their intervention group.43 However, this study only reported significant functional improvements at post-intervention and not at longer-term follow-up. This study did not report intensity of PA, so it is possible that PA intensity was insufficient to sustain gains. Neither of these studies measured PA objectively, so it is possible their effect estimates may be overestimated.

We were unable to determine the clinical relevance of the other studies demonstrating statistical effectiveness7, 19, 38, 98 due to the outcomes not translating to measurable PA levels or lacking estimated minimal clinically important differences. To our knowledge, the PA levels required to affect non-PA/SB outcomes, other than function, are not reported in people with persistent musculoskeletal pain.

Our BCT effectiveness percentages are based on statistical significance. Therefore, we cannot determine whether these BCTs are likely to lead to clinically effective outcomes.

*4.3 Implications for future research*

It is clear that there is a need for higher quality studies of interventions aimed at increasing PA and reducing SB. Future research might benefit from adopting similar interventions that have been demonstrated to be effective to enable better comparisons of their effectiveness. Trials need to be adequately powered to detect changes in PA/SB and need longer-term follow-ups beyond the intervention period. Intervention descriptions need to have sufficient detail for interventions to be replicated,22 and the active components (e.g., BCTs) easily identified. This will allow better investigation of potential mechanisms of action. We recommend that future research prioritises using objective device-based PA/SB measures and report this in minutes per intensity level so this can be compared in line with recommended guidelines such as the recent World Health Organization guidelines. This would help clinical translation of research findings. Researchers should target PA that is chosen by the participant in line with their values and what they enjoy. Identifying and/or developing theory is a key step in developing complex interventions,22 and interventions would likely benefit from better applying and building theory. Researchers should focus on incorporating BCTs or strategies that focus specifically on maintenance of behaviour, as well as initial change.

We utilised a pre-registered definition of persistent musculoskeletal pain.74, 94 Similar to other reviews28, 45, 55, 102 we did not include cancer and rheumatic pain as this would have further increased heterogeneity in the samples. Thus, we recommend that future research is needed to explore this issue in these specialist populations.

Finally, future research should identify the level of PA that is required to meaningfully affect broader health outcomes in people with persistent musculoskeletal pain.

**5. Conclusion**

Increasing PA and reducing SB is challenging but essential for people with persistent musculoskeletal pain due to the multitude of health benefits. Evidence suggests that interventions have a small effect on PA levels immediately post-intervention but no effect at longer-term follow-up and no effect on SB levels at any time point. However, these findings should be interpreted with caution and clinical relevance of these effects could not be determined. Our findings suggest that PA combined with education, combinations of supervised and unsupervised PA, and combinations of individual and group-based interventions may be most beneficial. We identified several BCTs that may be of benefit and warrant further exploration of their effectiveness. Despite the risk-of-bias being generally low across studies, the quality of evidence is either low or very low. Higher quality studies of theoretically-based interventions that target PA and SB, and that are well reported are needed in order to be able to confidently guide clinical practice.

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Figure Legend:

Figure 1: PRISMA Flow Diagram

Figure 2: Risk-of-bias assessments

Figure 3: Meta-analysis of post-intervention physical activity outcomes

Figure 4: Meta-analysis of longer-term follow-up physical activity outcomes

Figure 5: Meta-analysis of post-intervention sedentary behaviour outcomes

Figure 6: Meta-analysis of longer-term follow-up sedentary behaviour outcomes

Table legend:

Table 1: Study, participant and intervention characteristics

Table 2: Main meta-analysis and subgroup analysis

Table 3: Summary of findings and quality of evidence (GRADE)

Table 4: Meta-regression

Table 5: Behaviour change techniques effectiveness percentages

Table 6: Behaviour change theory in studies

Table 7: Studies with significant health-related outcomes other than physical activity/sedentary behaviour