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Systematic review

What is the effect of low back pain self-management interventions with exercise components added? A systematic review with meta-analysis

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ABSTRACT

Background: Best practice guidelines endorse self-management and exercise in chronic low back pain (CLBP) management. The majority of existing self-management interventions (SMIs) do not include exercise components, and the effect of SMIs with exercises on CLBP and disability remains unclear.

Objectives: To systematically review the evidence for the effect of SMIs with an exercise component added, on pain and disability in people with CLBP.

Design: Systematic review with meta-analysis.

Method: An electronic search of randomized controlled trials (RCTs) with SMIs with exercises was performed in 5 databases. Standardised Mean Difference (SMD) and 95% confidence interval (CI) were calculated using a random-effects model for meta-analysis at short-term, intermediate, and long-term follow-up points. The level of evidence was synthesized using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

Results: 09 RCTs were included in the review and the GRADE quality assessment revealed low-quality evidence for all meta-analyses across 3 follow-up points. Effect sizes (ESs) for pain were -0.28 , -0.36 and -0.21 for short-term, intermediate, and long-term respectively, and -0.30 , -0.25 and -0.20 for short-term, intermediate, and long-term for disability, respectively. 6 out of 09 studies included tailored exercise programmes and exercise components differed widely in their content and delivery.

Conclusions: There is low-quality evidence that SMIs with exercises added have moderately positive effects on pain and disability in patients with CLBP compared to control interventions involving usual care, typically consisting of access to medication, exercise, advice, education, and manual therapy.

1. Introduction

Low back pain (LBP) is one of the major causes of activity limitation, work disability and sick leave among adults (Buchbinder et al., 2013) and a leading contributor to the number of years lived with disability worldwide (Vos et al., 2015). It has reported a lifetime and a global prevalence of 84% (Airaksinen et al., 2006) and 31% (Hoy et al., 2012), respectively. LBP is classified by duration as acute (pain lasting less than six weeks), sub-chronic (6–12 weeks), or chronic (more than 12 weeks) (Koes et al., 2010). More than 85% of all the patients encountered in the primary care setting with LBP present with pain of unknown nociceptive drive (Maher et al., 2017), and this is classified as “non-specific low back pain” (NSLBP).

Exercise is considered the most effective intervention compared to

other LBP management approaches (Hayden et al., 2005; Van Middeloop et al., 2010; Searle et al., 2015). European guidelines (Airaksinen et al., 2006) and the National Institute for Health and Care Excellence (NICE) guidelines (NICE, 2021) recommends exercises as a first-line treatment option for chronic LBP (CLBP). NICE guidelines also strongly recommend self-management as a key option at all steps of the management pathway to “provide people with advice and information, tailored to their needs and capabilities, to help them self-manage their CLBP” (NICE, 2021).

Self-management is characterised by individuals using strategies and learning skills to daily manage and monitor their own health while playing a pivotal role in the management of their condition (May 2010; Carnes et al., 2012). A recently published concept analysis study has defined self-management as the “ability of an active, responsible,

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informed and autonomous individual to live with the medical, role and emotional consequences of his chronic condition(s) in partnership with his social network and the healthcare provider(s)" (Van de Velde et al., 2019). Furthermore, Jonkman et al. (Jonkman et al., 2016), have provided an operational definition for Self-Management Interventions (SMIs) which defines these as interventions designed to equip patients with the skills to actively participate and be responsible for the management of chronic diseases for their optimal function, by knowledge acquisition, and using a combination of at least two of the following: stimulation of independent sign/symptom monitoring, medication management, enhancing problem-solving and decision-making skills for medical treatment management, and changing their physical activity, dietary, and/or smoking behaviour.

Given the importance of self-management in CLBP, many SMIs are being implemented and tested (Buhrman et al., 2004; Chaleat-Valayer et al., 2016; Irvine et al., 2015; Johnson et al., 2007; Haas et al., 2005; Von Korff et al., 1998, 2005; Shebib et al., 2019; Zadro et al., 2019); however, conclusions are inconsistent. A recent systematic review, existing self-management programmes have revealed moderate quality evidence to support moderate effects on pain intensity and small to moderate effect on disability in people with chronic LBP (Du et al., 2017). Another review revealed small effects on pain and disability in people with NSLBP of any duration (Oliveira et al., 2012). In the series of rapid reviews published by Toomy and colleagues, (Toomey et al., 2015a, 2015b), they found no significant difference of effectiveness between SMIs and usual management.

Despite the known benefits and recommendations (Oliveira et al., 2012), not all SMIs for CLBP include exercise or physical activity. Those that do include exercise vary in their content and mode of delivery (Du et al., 2017). To date, no review has determined the effect of SMIs with an exercise component added, on pain and disability in people with CLBP. Therefore, this systematic review and meta-analysis aimed to estimate the effect of SMIs with exercise components on pain and disability at short-, intermediate- and long-term follow-up in patients with CLBP and to summarise the characteristics of the SMIs with exercise including content and mode of delivery.

2. Methods

2.1. Literature search

A computerised search was performed in the following databases from the earliest record to August 2020 to retrieve evidence, including grey literature: PUBMED, MEDLINE (OVID), CINHAL, EMBASE (OVID) and Cochrane Central Register of Controlled Trials. The standard search strategy recommended by the Cochrane Collaboration Back Review Group (Furlan et al., 2009) was followed to identify CLBP randomized clinical trials (RCTs), followed by the search for "self-management", "self-care" and "self-management interventions" as text words and Medical Subject Headings (MeSH) terms. The specific search strategy is outlined in Appendix 1. Cited reference retrieval was also conducted. Initially, two reviewers independently screened all titles, abstracts, and full texts for eligibility. Any disagreement was resolved through a consensus meeting or consulting the third reviewer. Authors were contacted necessarily, to obtain further information. References and trial reports were managed using EndNote.

2.2. Eligibility criteria

2.2.1. Types of studies

Only RCTs published in full by peer-reviewed, English language journals were included.

2.2.2. Population

Trials that examined adults (≥ 18 years) with LBP for more than six weeks were included. LBP was defined as "pain occurring in the

lumbosacral region with radiation limited to above the knee, without signs of nerve root compromise" (Waddell and Schoene, 2004). Studies that included participants with specific causes for LBP such as previous surgeries, infection, malignancy, fractures, inflammatory disease, pregnancy or neurological deficits were excluded (Henschke et al., 2009).

2.2.3. Intervention

Based on the definition proposed by Jonkman et al. (2016), studies of interventions with active participation and control by individuals in the management of their CLBP were included. Given this, to qualify the inclusion criteria, SMIs were required to have an element of knowledge provision and a combination of at least two from; stimulation of independent symptom monitoring, medication management, enhancing problem-solving and decision-making skills for medical treatment management, and changing their behaviour (Jonkman et al., 2016). Moreover, only trials that included an exercise programme as a part of the SMI were qualified for the review.

2.2.4. Comparison

RCTs were included if they investigated an SMI as described above and had a control intervention including standard care or usual care consisting of advice and education, access to medication, physiotherapy, supervised exercise and acupuncture. Trials were excluded if pain intensity and disability were not considered as primary or secondary outcomes.

2.2.5. Outcomes

Primary outcomes for this study were pain intensity and disability.

2.3. Study protocol

The review protocol was published in the PROSPERO International Prospective Register of Systematic Reviews (Rathnayake et al., 2019). The protocol title was changed from "The effectiveness and specificity of exercise interventions in low back pain self-management programmes" to the current title to reflect the review questions clearer.

2.4. Risk of bias assessment

The methodological quality was evaluated using the revised Cochrane risk of bias (RoB) tool 2 for RCTs (Sterne et al., 2019). This tool criterion includes five domains (i) bias arising from the randomisation process, (ii) bias due to deviations from intended interventions, (iii) bias due to missing outcome data, (iv) bias in the measurement of the outcome and (v) bias in the selection of the reported results. A RoB judgement was assigned to each of these domains as one of three levels of 'Low risk of bias', 'Some concerns', or 'High risk of bias'. Due to the nature of the SMIs, it is difficult to blind the researcher or participants to the interventions. However, to judge the bias in the measurement of the outcome, blinding of the outcome assessors was required. Outcome assessor could be intervention provider or patient (in self-reported outcomes). RevMan software package 5.3 was used in quality appraisal, statistical analysis and meta-analysis (Collaboration, 2015; Cochrane, 2015).

2.5. Data extraction

Data were extracted independently by two reviewers using a standardised form, including details regarding participant characteristics, study design, follow-up, self-management intervention (type, duration, and the number of sessions), exercise component characteristics, control group and outcomes.

2.6. Data analysis

Outcome data of pain intensity and disability, including their mean scores, standard deviations and sample sizes, were extracted at 3-time points: short-term (closest to 4 weeks, up to 12 weeks), intermediate (closest to 6 months, 13–26 weeks) and long-term (closest to 1 year, over 26 weeks) (Furlan et al., 2009). Standardised mean difference (SMD) and the 95% confidence intervals (95% CI) were calculated, and SMD was used to interpret the clinical relevance. A negative value of SMD indicates a mean difference in the outcomes favouring SMIs(34). The Cochrane guidelines acknowledge that the term effect sizes (ES) typically refer to versions of the standardised mean difference and recommend using the term SMD in preference to ES(34). SMD <0.2 was considered a small effect, 0.2–0.5 moderate, and >0.5 large (Warsi et al., 2003). Inconsistency between trials was estimated by looking at both I^2 tests and P values of the χ^2 tests. A random-effects model was used for the meta-analysis, assuming that some of the dispersion in observed effects reflects real differences in effect size across studies irrespective of

their I^2 values (Borenstein et al., 2010; Deeks et al., 2019). This approach also assumes that the different studies estimate different, yet related, intervention effects (Borenstein et al., 2010; DerSimonian and Laird, 1986).

2.7. Quality of evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework was used to assess the quality of evidence across studies (Schünemann et al., 2013). According to this framework, meta-analyses of RCTs were initially categorised as high-quality evidence and were downgraded by one level for each serious flaw present in the following overall domains based on; limitations in study design or execution (1–2 levels) when less than 80% trials reporting high risk of bias according to Cochrane RoB tool 2, inconsistency of results (1–2 levels) when $I^2 > 50\%$ and $p < 0.05$ on the χ^2 tests with minimal or no overlap of confidence intervals, indirectness of evidence (1–2 levels) if participants, interventions, or outcomes measures

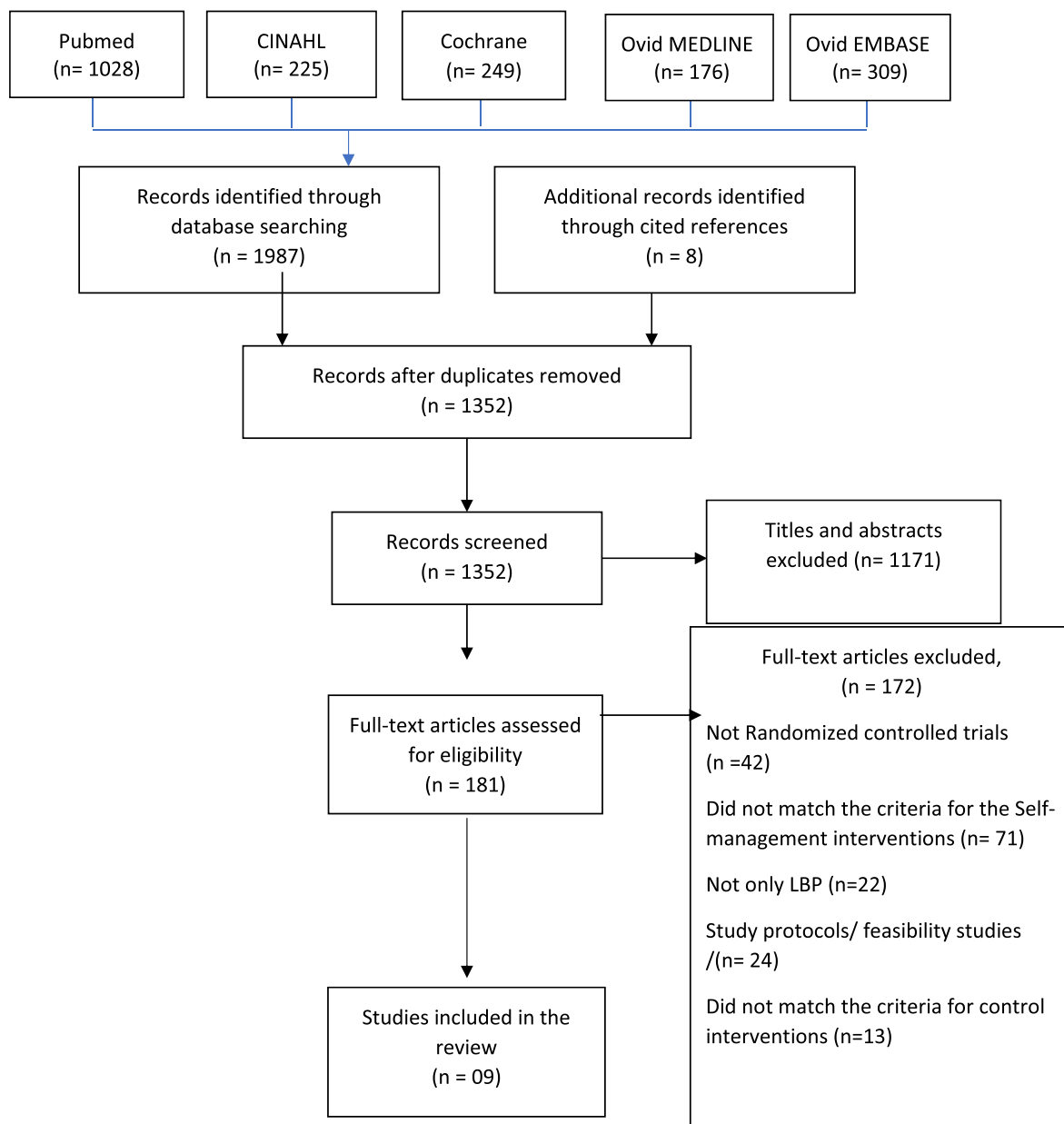


Fig. 1. PRISMA flow chart of selection of trials.

from included studies were essentially different, imprecision (1–2 levels) based on wide confidence intervals and publication bias (1–2 levels) if funnel plot presented asymmetrical distribution or due to selective outcome reporting (Schünemann et al., 2013). Based on this, GRADE approach results in an assessment of the quality of a body of evidence in one of **four grades**, including high, moderate, low and very low (Schünemann et al., 2013).

3. Results

3.1. Search results

This review was organised and presented according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (Moher et al., 2009). The search process is presented in Fig. 1. After removing the duplicates, 1352 articles were screened for titles and abstracts. This screening identified 181 potentially eligible articles. The full text of these articles was scrutinised for eligibility according to the inclusion/exclusion criteria. After consideration, two authors agreed that 172 articles be excluded from further analysis. Out of these 172 studies, 42 studies were not RCTs, 71 did not fulfil the SMI criteria, 22 studies had used subjects with multiple conditions, 24 articles were study protocols or feasibility studies, and 13 studies did not fulfil the requirements for the comparison group. Therefore, 09 original studies were fully critically appraised.

3.2. Risk of bias assessment

The risk of bias of the included trials is summarised in Fig. 2. Five trials (Buhrman et al., 2004; Chaleat-Valayer et al., 2016; Johnson et al., 2007; Zadro et al., 2019) detailed random allocation sequence generation and four (Chaleat-Valayer et al., 2016; Haas et al., 2005; Zadro et al., 2019) had described the concealment of allocation sequence. For measurement for the outcome bias, only two (Chaleat-Valayer et al., 2016; Von Korff et al., 2005) trials reported using blinded assessors to obtain outcome data. The remaining studies had self-reported outcome measure tools submitted by patients using online tools (Buhrman et al., 2004; Irvine et al., 2015; Shebib et al., 2019), by post or email (Johnson et al., 2007; Haas et al., 2005; Zadro et al., 2019). For

participant-reported outcome measures, the participant is considered the outcome assessor and regarded as a high risk of bias. The reported outcomes are likely to be influenced by the knowledge of the intervention received (Chandler et al., 2019). All trials reported according to pre-defined results, and five trials (Chaleat-Valayer et al., 2016; Irvine et al., 2015; Johnson et al., 2007; Shebib et al., 2019; Zadro et al., 2019) had pre-registered trial protocols. For missing outcome data bias, three studies (Irvine et al., 2015; Zadro et al., 2019) had >5 dropout rate. Only 1 study reported a statistically significant difference in the baseline characteristics of the participants in their gender, ethnicity and health status (Von Korff et al., 1998). Overall, the included 09 RCTs showed low quality (Fig. 2).

3.3. Study characteristics

In total, 09 RCTs were eligible and recruited 1866 participants (Table 1). Trials had recruited study participants from the community (Buhrman et al., 2004; Irvine et al., 2015; Haas et al., 2005; Zadro et al., 2019), primary care, hospitals and healthcare settings (Johnson et al., 2007; Von Korff et al., 1998, 2005), through employers (Shebib et al., 2019) and healthcare workers from hospitals (Chaleat-Valayer et al., 2016).

3.4. Control interventions

All included studies (Buhrman et al., 2004; Chaleat-Valayer et al., 2016; Irvine et al., 2015; Johnson et al., 2007; Haas et al., 2005; Von Korff et al., 1998, 2005; Shebib et al., 2019; Zadro et al., 2019) reported broadly similar content in their control interventions across the trials. Participants of these studies had usual care with access to primary care including pain medication, advice, education, exercise and ancillary services such as physiotherapy or chiropractic treatments. Out of these nine, four studies provided supplementary education material designed for LBP management and education (Johnson et al., 2007; Haas et al., 2005; Von Korff et al., 1998; Shebib et al., 2019).



Fig. 2. Risk of bias summary evaluated using quality appraisal criteria for RCTs from Cochrane Risk of Bias tool 2 (Sterne et al., 2019).

Table 1
Characteristics of included studies.

Authors, Year	Subjects	Follow up duration	Self-malmanagement Intervention	Exercise component in the experimental group self-malmanagement Intervention	Control	Outcome measures and instruments
Buhrman et al. (2004)	51 CLBP patients from the community Mean age 44.6 ± 10.4 EG: n = 22 CG: n = 29	8 weeks 3 months post-randomisation	A 6-week internet-based cognitive behavioural self-help treatment with telephone support including treatment consisted of education, cognitive skill acquisition, behavioural rehearsal, generalisation and maintenance.	Stretching and physical exercises on an individualised graded activity basis with structured information, relaxation exercises	Usual care consisting of access to primary care, pain medication, exercise, manual therapy and advice	Pain: Pain diary (0–100) ↓ = better Disability: Pain Interference subscale of MPI (0–6) ↓ = better
Chaleat-Valayer et al. (2016)	342 healthcare workers with recurrent LBP EG: n = 171 Mean age 47.1 ± 8.5 CG: n = 171 Mean age 47.3 ± 8.5	12 month 18 month 24 month post randomisation	2-h education session, five weekly 90-min group exercise training sessions in the workplace, and a home-based self-management programme.	One physiotherapist led five weekly 90-min training sessions with coaching 8–10 participants based in the workplace. Each session composed of a 15-min warm-up with rhythmic exercises, followed by 60 min of stretching and mobilising the spine (including relaxation of the lumbar spine and stretching of the hamstrings, gluteal, quadriceps, psoas and adductors, as well as pelvic tilt awareness exercises) and 15 min involving respiratory and postural work. A booklet for self-managed home exercises (at least 10 min) and the French version of the <i>Back Book</i> .	Usual care consisting of access to primary care, pain medication, exercise, manual therapy and advice	Pain: VAS (0–100) ↓ = better Disability: QBPDS (Score of 0–100) ↓ = better
Irvine et al. (2015)	398 CLBP patients from public EG: n = 199 CG: n = 199.	8 weeks 16 weeks post-randomisation	An 8 week multiple-visit online FitBack intervention Based on the self-tailored cognitive-behavioural approach, designed aiming to encourage users to adopt appropriate pain prevention behaviours. Participants also received 8 programme emails with content and prompt related to CLBP self-management.	Instructional videos on specific strength and stretching exercises tailored by job type (sitter, stander, driver, lifter). Messages in the weekly emails, links within the activity picker, and recommendations within the FitBack programme repeatedly link users to the video content.	Usual care consisting of access to primary care, pain medication, exercise, manual therapy and advice	Pain: 10- point “pain dial” (1-10); ; ↓ = better Disability: A 10- item scale (1-10) ; ; ↓ = better.
Johnson et al. (2007)	234 LBP patients consulting their GPs EG: 116 Mean age: 47.3 ± 10.9 CG: n = 118 Mean age: 48.5 ± 11.4	3 months 9 months 15 months post-randomisation	A 6-week community-based programme including eight 2-h group exercise session comprised of active exercise and education led by 2 physiotherapists using a CBT approach to cover self-management elements of back pain, including problem-solving, pacing and regulation of activity, challenging distorted cognitions, and help to identify helpful and unhelpful thoughts.	2-h group exercise session focused on independent control of LBP and resumption of normal activities and home exercise and physical activity plan including paced activity programmes, engagement in previously voided activities of daily living and resumption of hobbies and leisure activities.	Usual care consisting of access to primary care, pain medication, exercise, manual therapy and advice supplemented by an educational pack	Pain: 100 mm VAS ↓ = better Disability: RDQ (0–24) ↓ = better
Haas et al. (2005)	109 community-dwelling seniors with CLBP Average age 77.2 ± 7.7 EG: n = 60 CG: n = 49	26 weeks (6 months) post-randomisation	A 6-week workshop led by 2 trained laypeople with a weekly class of 2.5 h taught from a structured protocol designed to enhance self-efficacy including general principles of chronic conditions, an overview of self-management principles, care-seeking options; community resources; exercise; relaxation; nutrition; medication and side-effects; skills-building; learning from others; sharing	General exercises and relaxation exercises	Usual care consisting of access to primary care, pain medication, exercise, manual therapy and advice Online education on LBP	Pain: MVK pain scale (0–100) ↓ = better Disability: MVK disability scale (0–100) ↓ = better

(continued on next page)

Table 1 (continued)

Authors, Year	Subjects	Follow up duration	Self-malmanagement Intervention	Exercise component in the experimental group self-malmanagement Intervention	Control	Outcome measures and instruments
Von Korff et al. (1998)	255 back pain patients enrolled in a health maintenance organization EG: 129 Mean age: 49.4 ± 11.7 CG: 126 Mean age: 50.3 ± 10.9	3 months 6 months 12 months post randomisation	with others; goal setting; action plans; feedback; and problem-solving. Four 2-h classes 1 time a week led by 2 trained volunteer laypersons with knowledge delivery, action planning goal setting, professionally developed self-care materials including a self-care book, videotape on LBP self-management and exercises	A 25 min videotape demonstrating LBP exercises	Usual care consisting of access to primary care, pain medication, exercise, manual therapy, and advice supplemented by a book on back care	Pain: NPS (0–10) ↓ = better Disability: RDQ (0–23) ↓ = better
Von Korff et al. (2005)	240 CLBP patients enrolled in a health maintenance organization EG: 119 Mean age: 49.7 ± 9.0 CG: 121 Mean age: 49.8 ± 9.8	2 months 6 months 12 months 24 months post-randomisation	4 in-person visits including a visit with a 90-min visit with a psychologist, a 60 min and a 30 min visit with a PT and a last 30-min visit with a psychologist 7–10 days later.	A 25 min videotape demonstrating LBP exercises, Home exercise programme with stretching and strengthening exercises relevant to the action plan and goals by a PT after a standardised mechanical examination of the back.	Usual care consisting of access to primary care, pain medication, exercise, manual therapy, advice and physical therapy	Pain: NPS (0–10) ↓ = better Disability: RDQ (0–23) ↓ = better
Shebib et al. (2019)	177 Employees and their dependents at participating employers, across 12 locations in the US with CNSLBP Average age: 43.0 ± 11.0 EG: 113 CG: 64	12 weeks post-randomisation	A 12-week digital care programme consisting of exercises, CBT, education articles, peer support discussions, activity and symptom tracking through a digital app on a tablet computer	Sensor-guided physical therapy exercises and aerobic activities; 3 times per week	Usual care consisting of access to primary care, pain medication, exercise, manual therapy, and advice 3 digital education articles,	Pain: VAS (0–100) ↓ = better Disability: MVK disability scale (0–100) ↓ = better
Zadro et al. (2019)	60 CLBP patients from the local community and waiting list of an outpatient Physiotherapy Department Average age: 67.8 ± 6.0 EG: 30 CG: 30	8 weeks 3 months 6 months post-randomisation	An 8-week unsupervised home-based exercise programme using Nintendo Wii U console with Wii Fit U software including 3 home visits by a PT	A standardised programme of 60 min including 5 min Yoga, 25 min strengthening, 10 min Aerobic and 20 min balance exercises with video and audio instructions and feedback according to the pressure on the balance board; 3 times per week. Flexibility to remove the exercises during the initial functional assessment by the PT and add any from the remaining exercises.	Usual care consisting of access to primary care, pain medication, exercise, manual therapy and advice	Pain: NRS (0–11) ↓ = better Disability: RMDQ (0–24) ↓ = better

Key: CLBP: Chronic low back pain, CNSLBP: Chronic non-specific low back pain, LBP: Low back pain EG: Experimental group, CG: Control group, PT- Physiotherapist, VAS: Visual analogue scale, NPS: Numerical pain scale, NRS: Numerical rating scale, CBT: Cognitive Behavioural Therapy, QBPDs: Quebec back pain disability scale, RDQ: Rolland disability questionnaire, MVK scale: Modified Von Korff scale, MRQ: Modified Roland Questionnaire.

3.5. Content of the self-management interventions

3.5.1. Theoretical frameworks

In addition to the exercise component, most of SMIs were based and developed using cognitive behavioural models. Examples of the claimed models were the cognitive-behavioural model of chronic pain (Buhrman et al., 2004), chronic disease self-management programme (Haas et al., 2005) and cognitive behavioural approach (Irvine et al., 2015; Johnson et al., 2007).

3.5.2. Exercise component characteristics

Types of exercise that were included but not limited to, were stretching (Buhrman et al., 2004; Chaleat-Valayer et al., 2016; Irvine et al., 2015; Von Korff et al., 2005), strengthening (Irvine et al., 2015; Von Korff et al., 2005; Zadro et al., 2019), aerobic or cardiorespiratory exercises (Chaleat-Valayer et al., 2016; Shebib et al., 2019; Zadro et al., 2019) and relaxation exercises (Buhrman et al., 2004; Chaleat-Valayer et al., 2016; Haas et al., 2005) with a majority of programmes including combinations of different types. One study used a Nintendo Wii U console with Wii Fit U software (Zadro et al., 2019), and another trial used

Bluetooth wearable motion sensors guided exercises (Shebib et al., 2019). Further, exercises were focused on encouraging graded activity (Buhrman et al., 2004; Johnson et al., 2007), staying active (Chaleat-Valayer et al., 2016), management of flare-ups (Von Korff et al., 2005), adaptive coping (Chaleat-Valayer et al., 2016) and resumption of ceased daily or leisure activities (Johnson et al., 2007; Von Korff et al., 1998).

Six studies reported tailored exercise for the participants (Buhrman et al., 2004; Irvine et al., 2015; Johnson et al., 2007; Von Korff et al., 2005; Zadro et al., 2019), while one reported exercise being tailored according to the job type (Irvine et al., 2015) and another according to self-reported baseline measures (Buhrman et al., 2004). In three trials, physical assessments of the subjects were carried out by physiotherapists before the allocation of tailored exercises (Von Korff et al., 2005; Zadro et al., 2019). One trial reported the availability of a personal coach for all the participants to support unlimited remote support through the intervention but failed to mention if the exercise programmes were individualised for the subjects (Shebib et al., 2019).

Only three trials provided the frequency and duration of home exercises. Reported frequencies included daily (Chaleat-Valayer et al.,

2016) and 3 times per week (Zadro et al., 2019). The duration of each session of the home exercise ranged from 10 (Chaleat-Valayer et al., 2016) to 60 min (Zadro et al., 2019). Only one study detailed the expected level of intensity during the home exercises, which was reported as 12–13 on the Borg scale (Zadro et al., 2019).

3.5.3. Delivery of SMIs

Trials used, audio-visual materials (Buhrman et al., 2004; Irvine et al., 2015; Von Korff et al., 1998, 2005; Zadro et al., 2019), written (Chaleat-Valayer et al., 2016; Von Korff et al., 1998) and digital education material (Buhrman et al., 2004; Irvine et al., 2015; Shebib et al., 2019). The sessions were facilitated by physiotherapists (Chaleat-Valayer et al., 2016; Johnson et al., 2007; Von Korff et al., 2005; Zadro et al., 2019), psychologists (Von Korff et al., 2005) and trained laypeople (Haas et al., 2005; Von Korff et al., 1998). The duration of the intervention was of 6 weeks (Buhrman et al., 2004; Johnson et al., 2007; Haas et al., 2005), 8 weeks (Irvine et al., 2015; Zadro et al., 2019) and 12 weeks (Shebib et al., 2019). Details were not available in three studies (Chaleat-Valayer et al., 2016; Von Korff et al., 1998, 2005).

3.6. Outcome analysis

3.6.1. Effect on pain intensity

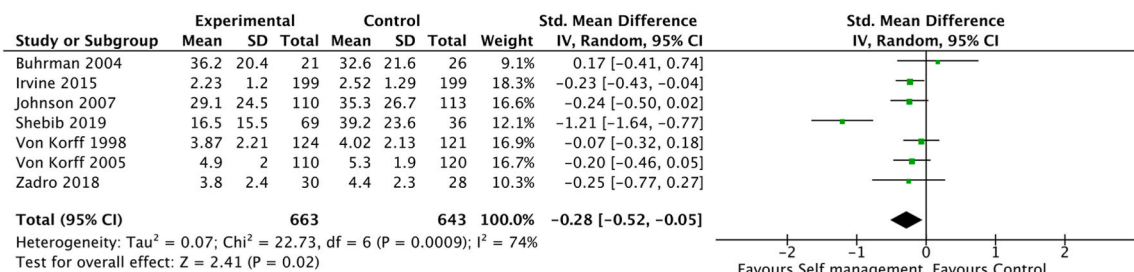
Seven (Buhrman et al., 2004; Irvine et al., 2015; Johnson et al., 2007; Von Korff et al., 1998, 2005; Shebib et al., 2019; Zadro et al., 2019), five (Irvine et al., 2015; Johnson et al., 2007; Haas et al., 2005; Von Korff

et al., 1998, 2005) and four (Chaleat-Valayer et al., 2016; Johnson et al., 2007; Von Korff et al., 1998, 2005) studies reported short-term, intermediate and long-term data of pain intensity, respectively (Fig. 3). SMIs showed significant and moderate effects on pain in all short term [SMD = -0.28, 95% CI (-0.52, -0.05), I² = 74%], intermediate [SMD = -0.36, 95% CI (-0.60, -0.12), I² = 75%] and long-term [SMD = -0.21, 95% CI (-0.36, -0.07), I² = 18%] based on low quality of evidence according to GRADE framework (downgraded for risk of bias and inconsistency at short-term, intermediate and long-term follow-up points).

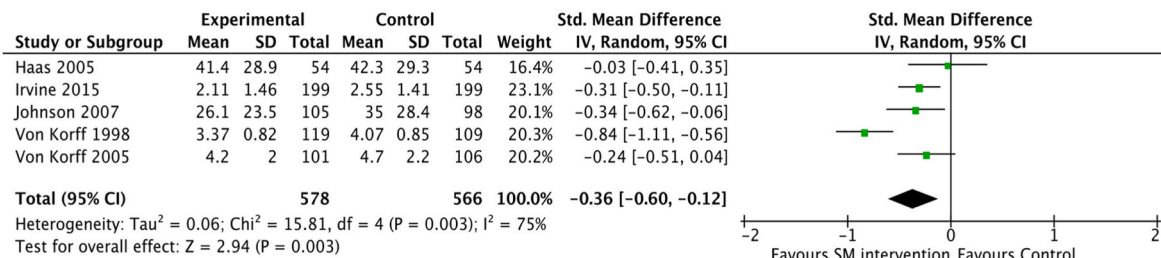
3.6.2. Effect on disability

Seven (Buhrman et al., 2004; Irvine et al., 2015; Johnson et al., 2007; Von Korff et al., 1998, 2005; Shebib et al., 2019; Zadro et al., 2019) five (Irvine et al., 2015; Johnson et al., 2007; Haas et al., 2005; Von Korff et al., 1998, 2005) and four (Chaleat-Valayer et al., 2016; Johnson et al., 2007; Von Korff et al., 1998, 2005) trials reported short-term, intermediate and long-term data of disability, respectively (Fig. 4). Similar to effects on pain intensity SMIs yielded significant and moderate effects on disability in all short term [SMD = -0.30, 95% CI (-0.52, -0.08), I² = 70], intermediate [SMD = -0.25, 95% CI (-0.37, -0.13), I² = 0%] and long-term [SMD = -0.20, 95% CI (-0.33, -0.07), I² = 0%], based on low quality of evidence according to the GRADE framework (downgraded for risk of bias and inconsistency at short-term, intermediate and long-term follow-up points).

Short-term effect



Intermediate effect



Long-term effects

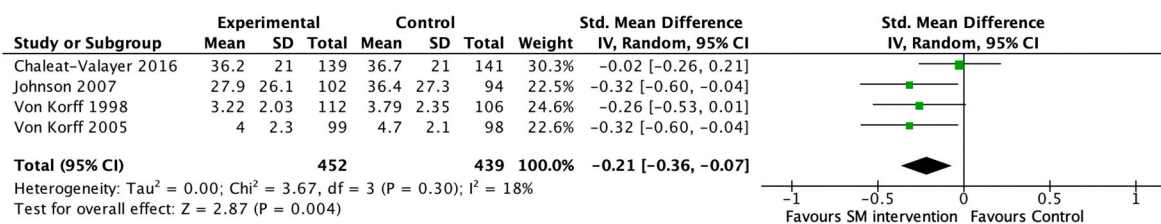
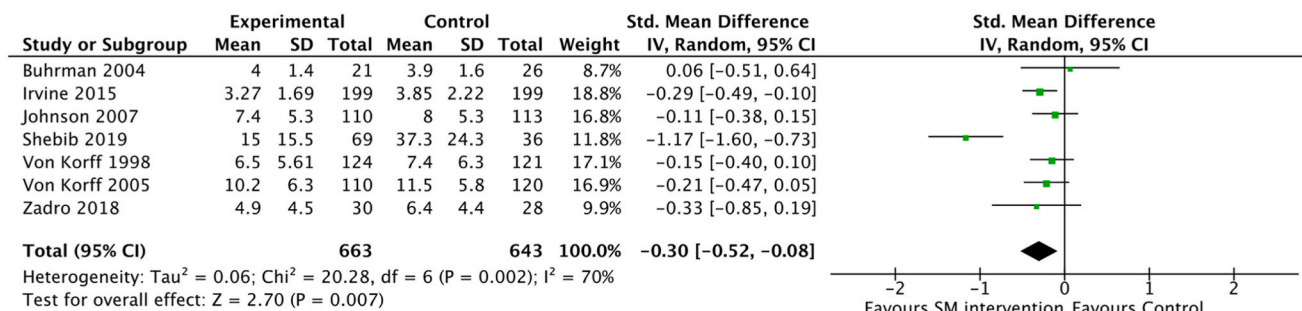
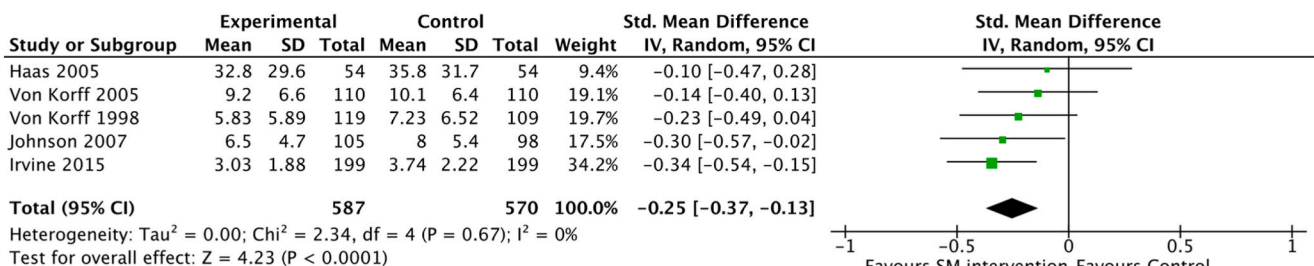


Fig. 3. Forest plots of comparison: Short-term, intermediate and long-term effect on pain intensity.

Short-term effect



Intermediate effect



Long-term effect

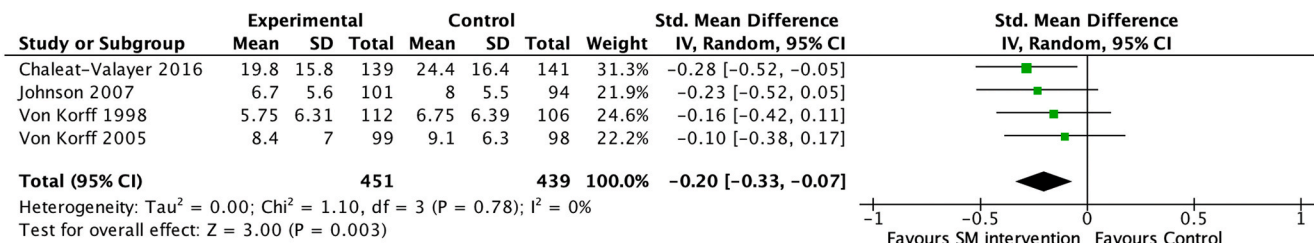


Fig. 4. Forest plots of comparison: Short-term, intermediate and long-term effect on disability.

4. Discussion

This review is the first to systematically investigate the effect of SMI's specifically with exercise component added, on pain and disability in CLBP patients. The results demonstrate low-quality evidence for SMIs with added exercise component having moderate but significant positive effect both on pain and disability of individuals with CLBP, across short-term, intermediate and long-term periods compared to control interventions involving usual care typically consisting of access to medication, exercise, advice, education, and manual therapy. Considerable heterogeneity was identified within the exercise component of the reviewed SMIs both in content and mode of delivery, with only 60% of the SMIs including any form of tailoring to person's needs.

These results are generally in agreement with conclusions of previous systematic reviews that SMIs are generally effective in the management of CLBP (Du et al., 2017; Oliveira et al., 2012), however, there are some differences. A meta-analysis by Du et al. (2017), evaluating SMIs in CLBP reported moderate effect on pain at all follow-up points but, in disability the moderate effects were maintained only short-term and no longer present at the intermediate and long-term follow up. In contrast, Oliveira and colleagues (Oliveira et al., 2012) found that self-management had only small effects on pain and disability compared to minimal interventions in CLBP patients across short and long-term points. Out of the total 26 trials included in Du et al. (2017), and

Olivera et al. (Oliveira et al., 2012), meta-analyses, less than half (12 studies) evaluated SMIs with exercise added. The remaining fourteen trials evaluated SMIs centred around education and cognitive behavioural approach. This current study meta-analysis of SMIs including exercise and demonstrating moderate but significant positive short-term, intermediate and long-term effects both in pain and disability, compared to standard care consisting of access to medication, advice, education, exercise and manual therapy, may suggest that SMIs with exercise added may be superior in improving pain and disability of patients with CLBP. This is in agreement with existing large body of evidence demonstrating that exercise alone can bring long-term benefit in managing LBP (Hayden et al., 2005; Van Middelkoop et al., 2010; Searle et al., 2015), including reducing disability and pain while improving fitness and occupational status of people with CLBP (Henchoz and So, 2008). Therefore, SMIs and exercise in combination may be critical in maximising the potential for long-lasting benefits of complex and multifactorial CLBP.

Heterogeneity both in content and mode of delivery of SMIs reviewed in this current study was observed with a significant variation in theories used in the design of the exercise components. Overall, the majority of studies included in this review failed to report exercise prescription details such as frequency, intensity or duration of the exercises. In addition, although recommended within guidelines and management approaches for CLBP (NICE, 2021), tailoring exercises to

person's needs and capabilities was not always considered. There is growing evidence that subgrouping of CLBP to target management leads to superior improvements in pain and disability in CLBP populations compared to generalised management approach (Sheeran et al., 2013; Luomajoki et al., 2018; Leboeuf-Yde et al., 1997). Nevertheless, given the considerable variation of studies included, it is difficult to ascertain the effect of tailoring of exercises on the CLBP and associated disability from this study results. Therefore, it would be worth considering incorporating tailored exercise programmes within SMIs to produce superior outcomes in CLBP.

4.1. Limitations

Although this study indicates a positive effect of SMIs with exercise on pain and disability, the quality of evidence is still low, and with substantial heterogeneity among studies and the SMIs evaluated. Whilst measures were taken to minimise the statistical interference in the analyses including use of random-effect model for meta-analysis (Deeks et al., 2019), the heterogeneity of the reviewed articles still means that clinical application of this study results remains uncertain. Given the varied, multiple time-points of the follow-up periods, only a small number of studies were eligible for the one time-point analysis of the outcome measures. This study also demonstrated the importance of sufficiently describing the comparator intervention. In future research, as well as experimental intervention, greater care must be taken when selecting and describing the comparator to allow for conducting high quality evidence synthesis and clinical applicability.

4.2. Clinical and research implications

This study focussed on the role of SMIs with exercise added in managing pain and disability of patients with CLBP. Although of low-quality evidence, the SR and meta-analysis demonstrates that SMIs with exercise component have moderate but significant short- intermediate- and long-term effects on pain and disability in patients with CLBP. Whilst heterogeneity of included trials doesn't allow for direct comparisons, this study outcomes are superior when compared to recent systematic reviews and meta-analyses including SMIs both with and without exercise. Given the overwhelmingly positive physical and psychological benefits of exercise, adding exercise to SMIs is favourable option for management CLBP and in line with the existing recommended clinical guidelines (Airaksinen et al., 2006; NICE, 2021).

Of consideration, however, is the low-quality evidence compounded by the vast heterogeneity and limited theoretical underpinning of the existing SMIs, and insufficient intervention detail both in content and mode of delivery. Future research needs to focus on following a stepwise approach for the development of SMIs for CLBP including the theoretical basis of the proposed intervention effect detailing the action of each component included. High quality SMIs need to then be evaluated in future high-quality RCTs with concealed allocation, blinded assessor and intention to treat analysis, and appropriate sample size to increase the certainty of evidence about the effects of different types of exercise included within CLBP interventions, tailored or not tailored, and compared with varying modes of delivery of the interventions.

5. Conclusion

This study reviewed RCTs to explore the effect of SMIs with added exercise component on pain and disability in patients with CLBP compared to control interventions involving usual care typically consisting of access to medication, exercise, advice, education, and manual therapy. The review found low quality evidence that SMIs with exercise added have a moderate but significant, short-, intermediate- and long-term positive effect both on pain and disability in patients with CLBP. Vast heterogeneity in the SMIs' content, frequency, duration and intensity was demonstrated, as well as not all exercise programmes were

tailored according to persons' need and capabilities. More high-quality studies are necessary to strengthen the evidence regarding the effects of SMIs with exercise added in managing patients with CLBP.

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Appendix 1. Supplementary data

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