Effects of specific muscle activation for low back pain on activity limitation, pain, work participation, or recurrence: a systematic review

ABSTRACT

Background: Specific muscle activation (SMA) is a common treatment for low back pain (LBP) however systematic reviews show variable effectiveness. Eligibility criteria incongruent with original descriptions of the SMA may be relevant.

Purpose: This study aimed to evaluate effectiveness of SMA on activity limitation, pain, work participation or recurrence for people with LBP.

Study Design: Systematic review

Methods: Computer databases were searched for randomised controlled trials (RCTs) published in English to 6 September 2019. Chosen eligibility criteria ensured clinically relevant RCTs were included and trials of poorly defined/executed SMA excluded. Activity limitation, pain, work participation or recurrence outcomes were extracted.

Results: Twenty-eight RCTs were included with 18 being high quality. GRADE quality assessment revealed low to high quality evidence was identified that SMA was more effective than exercise, conservative medical management, multi-modal physiotherapy, placebo, advice and minimal intervention.

Conclusions: This systematic review is the first to evaluate the effectiveness of SMA in accordance with the original clinical descriptions. We found significant evidence supporting the effectiveness of SMA (on its own or combined with other modalities) for the treatment of LBP compared with exercise, conservative medical management, multi-modal physiotherapy, placebo, advice and minimal intervention. Where significant results were demonstrated, the between-group differences were in many comparisons clinically important based on contemporary definitions and an effect size of 0.5 or more. Practitioners should consider SMA as a treatment component in their patients with LBP. Keywords: Physiotherapy, Low back pain, Specific muscle activation, motor control, systematic review, pain, functional ability, work participation, recurrence

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This systematic review was prospectively registered XXXXXXXX.

Ethics approval not required

Research data is available upon request.

No previous presentations or publications of this work have been made

Word count: 239 **Word count:** 3884

BACKGROUND

Low back pain (LBP) is prevalent, costly and a major cause of disability-adjusted life years[32] with a concomitant requirement for effective treatment.[35] Guideline-based treatment aims to minimise potential harm of treatments such as surgery or medication and maximise cost-effectiveness by utilising simple treatments such as advice.[43,46] However, the randomised controlled trials (RCTs) upon which guideline recommendations are based typically show small effect sizes of questionable clinical importance.[23,52,55] Advice is described in guidelines as first line treatment for LBP of all duration[55] despite conflicting evidence on effectiveness.[13,39] Treatment targeting specific mechanisms underpinning LBP, has the potential to demonstrate larger and clinically important effects in RCTs and consequently reduce the burden to society and the individual sufferer.[19-21]

Spinal motor control refers to all of the sensory and motor processes associated with control of movement or posture.[30] Assessment of spinal motor control commonly evaluates the activation of specific muscles, postural alignment and movement.[67] Based on preliminary evidence that motor control strategies are different in people with and without LBP,[38] clinicians hypothesise that the presence or maintenance of LBP is related to these differences, and the resultant increase in tissue loading. This leads to the potential relevance of "normalising" unhelpful motor control strategies as a treatment approach.[30]

A commonly used[5,6] method of addressing unhelpful spinal motor control strategies is low-load activation of the local/deep muscles of the lumbar spine, such as transversus abdominus and lumbar multifidus. This method has evolved from supporting research on the role of these muscles in facilitating optimal intrinsic stiffness of lumbar intervertebral segments through tonic muscle activity, anticipatory control and feedback control[10,29] which may in turn result in reduced pain and improved activity limitation. Once low load specific activation of these muscles is achieved, exercises are then progressed into activation during functional exercises and activities.[61]

The effectiveness of specific muscle activation (SMA) as a component of motor control training for LBP is controversial[26] and has been evaluated in a number of recent systematic reviews.[7,42,64,65] These reviews are notable for variable conclusions regarding effectiveness which may, in part, be due to the exclusion of studies recruiting participants with a purported specific cause of LBP, such as symptomatic spondylolysis

or spondylolisthesis.[53] In addition, no review has used stringent eligibility criteria based on the original descriptions of SMA.[61]

Given the significance of LBP as a global health problem, the potential for specific treatment to demonstrate clinically important effects and the limitations with the existing review literature, a new systematic review with carefully considered eligibility criteria is needed. Therefore, the aim of this systematic review was to determine the effectiveness of SMA for the treatment of LBP on activity limitation, pain, work participation or recurrence.

METHODS

This systematic review was prospectively registered XXXXXXXXX.

Literature search

Computer-aided database searching was undertaken by one author (XX) supported by a health librarian accessing: MEDLINE (1950 to September 6, 2019), EMBASE (1980 to September 6, 2019), Cochrane Central Register of Controlled Trials (to September 6, 2019), CINAHL (1982 to September 6, 2019), and PEDro (to September 6, 2019). The search method used key words for RCTs and the condition based on sensitive search strategies.[71] Key words for the intervention were determined by the authors and cross-checked against previous relevant systematic reviews. The terms for searching MEDLINE were adapted for each database (Supplementary material 1). Additional search strategies included screening of the reference lists of relevant systematic reviews and eligible RCTs. Citations were imported to bibliographic software by one reviewer (XX) with two reviewers (XX and XX) independently applying eligibility criteria to identify potentially relevant trials, initially based on title and abstract then full-text copies. Disagreements were resolved through discussion and input from a third reviewer (XX) if required.

Eligibility criteria

Types of studies

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

Types of participants

Trials needed to recruit participants aged over 18 with primary LBP defined as symptoms between the 12th rib and gluteal fold, and/or low back related leg symptoms of any duration. Any RCT targeting specific spinal conditions that potentially could cause mechanical low back pain amenable to treatment with SMA (e.g. spondylolysis, spondylolisthesis, spinal stenosis, disc disease, degeneration disease, nerve root compromise, spinal surgery) were included. Studies were excluded if they specifically recruited people with no LBP, pelvic pain/dysfunction, pregnancy, continence issues, fracture/dislocation, osteoporosis, spine malformation, skeletal deformities (e.g. Scheuermann kyphosis, scoliosis), leg length discrepancies, spondylitic/rheumatic disorders, cauda equina, cord compression, abdominal surgery, infection, tumour, infection, and systemic/cerebrovascular/neuromuscular diseases (e.g. lupus, Guillain Barre syndrome).

Types of interventions

Only trials evaluating the effectiveness of SMA compared with another treatment were included. All trials were required to describe, within the manuscript or via a direct reference to a protocol paper, specific activation of the local/deep muscles of the lumbar spine[61] focusing on a low level activation (typically no more than 30% of the maximum voluntary contraction) in a low load starting position (typically non-weight bearing). The manuscript had to describe the SMA progressing to functional loading (e.g. walking, lifting, squatting).[61] Specific muscle activation had to be provided by a practitioner with at least a relevant clinical bachelor degree in a 1:1 clinical environment (which was assumed unless the trial specifically described group treatment) of at least three sessions. Cointerventions were allowed but SMA had to form a substantial component of the treatment protocol in at least 50% of participants. “Substantial” was defined as being a necessary component in at least half the treatment sessions. If insufficient detail was provided in the manuscript the reviewers made a judgement regarding eligibility based on discussion between the authors.

Types of comparisons

Any comparison intervention was accepted provided that it did not contain SMA. This included placebo and any active comparison groups.

Types of outcomes

Trials had to report data allowing between-group comparison to be calculated for at least one of overall/back pain (either back pain alone or back and leg pain combined), leg pain, activity limitation, work participation or recurrence.

Quality of evidence

Two reviewers (XX and XX) independently assessed study limitations for each included trial using the PEDro scale. This 10-item rating scale (Table 1) was developed for quality assessment of RCTs by Delphi consensus and has demonstrable reliability.[44] Trials with a rating of at least 6/10 on the PEDro scale were rated as high quality, consistent with previous systematic reviews.

Table 1: PEDro scale items

Item	Description
1	Were eligibility criteria specified?
2	Were participants randomly allocated to groups?
3	Was allocation concealed?
4	Were the groups similar at baseline regarding the most important prognostic indicators?
5	Were all participants blinded?
6	Was there blinding of all therapists who administered the therapy?
7	Was there blinding of all assessors who measured at least one key outcome?
8	Were measures of at least one key outcome obtained from more than 85% of the participants initially allocated to groups?
9	Did all subjects for whom outcome measures were available receive the treatment or control condition as allocated or, where this was not the case, was data for at least one key outcome was analysed by "intention to treat"?
10	Were the results of between-group statistical comparisons reported for at least one key outcome?
11	Did the study provide both point measures and measures of variability for at least one key outcome?

Note: Only items 2 to 11 are included in the calculation of the PEDro score

Data extraction

Data were independently extracted from the included trials by two authors (XX and XX) and recorded on a standardised computer spreadsheet designed and used in previous systematic reviews from our group.[25] Extracted information included sample size, trial setting, population characteristics, intervention detail and outcome data (mean scores, standard deviations, and confidence intervals [CI]). When insufficient data were available from individual trials, the authors were contacted. If present, the documentation of adverse effects related to treatment was recorded. Follow-up data were extracted for short-term (less than 3-months following the date of randomisation), intermediate-term (between 3 and up to 12-months), and long-term (12-months or more) time points.

Analyses

Treatment effects and 95% CIs for continuous data were calculated using the Hedges adjusted g standardised mean difference (SMD) based on mean scores for each group and the pooled standard deviations at the follow-up time point of interest. Treatment effects favouring SMA (e.g. higher levels of function or lower levels of pain) were assigned positive SMD values, with values greater than or equal to 0.2, 0.5, and 0.8 considered to represent small, moderate, and large effect sizes respectively. The pooling of data in a meta-analysis was planned if two or more trials were considered clinically homogeneous and had an I^2 score of < 50%. For comparisons where I^2 was > 50%, meta-analysis was still considered based on visual inspection of the forest plots for consistency. In the event of meta-analyses proceeding in these circumstances, random, as opposed to fixed effects, were calculated in association with a downgrading on the consistency domain of the GRADE table.[64] Risk of publication bias was evaluated using funnel plots generated in REVMAN.

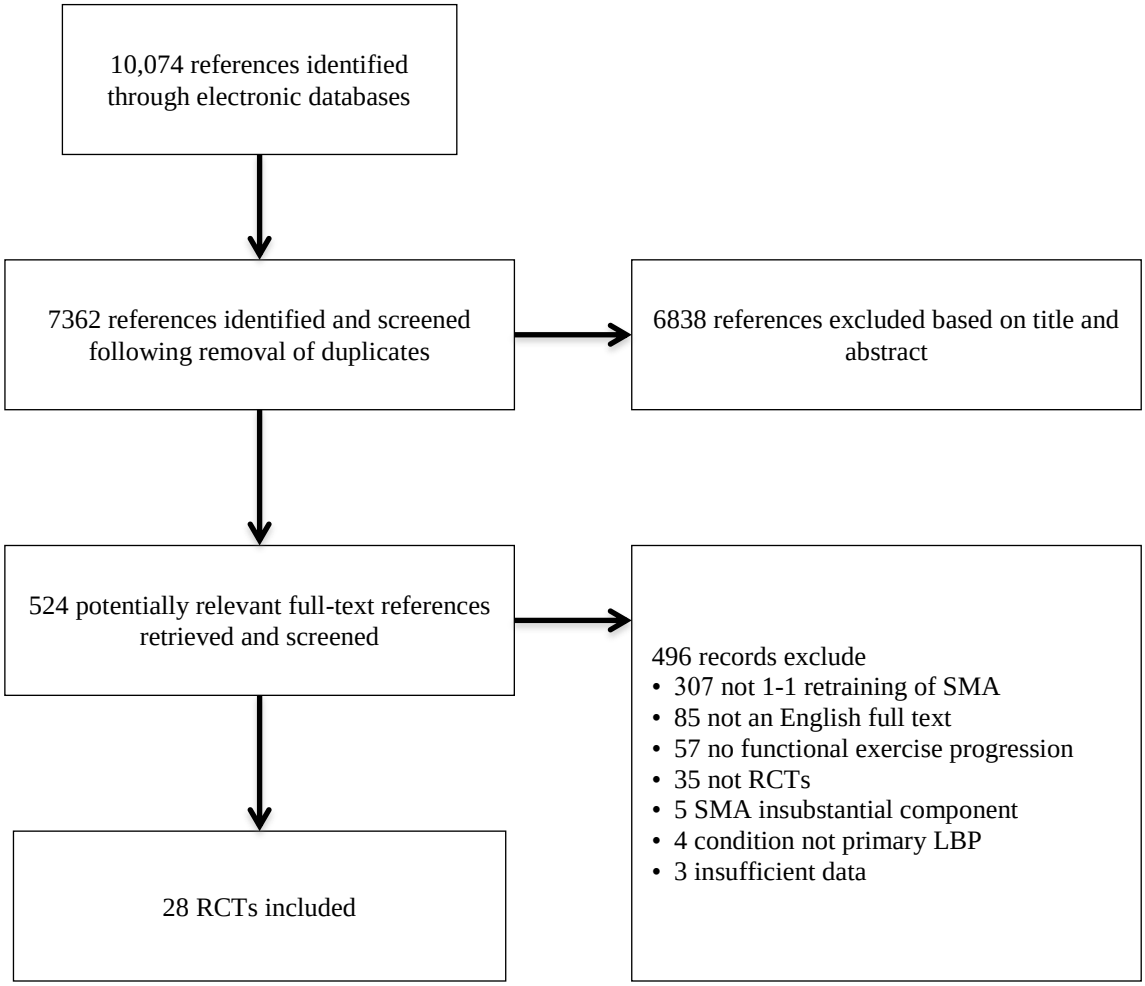
Overall quality of evidence was assessed using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach. Quality of evidence for each comparison was downgraded by one level in the presence of study limitations (less than 75% of trials scoring 6 or more on PEDro scale), inconsistency of results (due to more than 25% of trials showing conflicting results in clinically significant direction and/or effect), indirectness (due to limited applicability of the population or intervention) and imprecision of results (sparse data of <400 participants per comparison or data from a single trial).[4,24,27] The GRADE quality of evidence for each comparison and outcome was determined based on the following definitions:

- High-quality evidence where further research is very unlikely to change confidence in the estimate of effect. All domains are met
- Moderate-quality evidence where further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate. One of the domains is not met
- Low-quality evidence where further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate. Two of the domains are not met
- Very-low-quality evidence where any estimate of effect is very uncertain. Three or more of the domains are not met

RESULTS

Figure 1 outlines the number of trials considered at each stage of the selection process. The search strategy identified 7363 individual citations after removal of duplicates, with 525 full text papers retrieved and 28 trials finally included. Sample sizes ranged from 20 to 300 participants (mean of 82.9) with a combined total of 2323 participants.

Figure 1: Flow of studies



The characteristics of the included trials are described in Table 2. Of the 28 trials 6 were conducted in Europe,[9,45,49,59,60] two in North America,[40,47] five in Australia,[11,16,22,41,54] and 15 in other countries.[2,3,8,31,33,34,37,50,56-58,62,63,66,69,70] The mean duration of symptoms reported across 19 of the included trials was 4.3 years with 1 trial sampling participants with acute LBP (<6 weeks),[58] 25 trials persistent

LBP[2,3,8,9,11,16,22,31,33,37,40,41,47,50,54,56,57,59,60,62,63,66,69] and 3 sampling people with LBP of a mixed duration.[34,45,70] The mean baseline pain

201 **Table 2: Characteristics of trials**

RCT	PEDro Score	Sample size	Mean Age (years)	Mean Symptom duration	Study Comparisons (Group allocation)	Treatment sessions	Outcome Measures	Follow up	Adverse Effects
Ali et al 2013	5	30	38.4	unknown	SMA Flexion-extension based exercises (Exercise)	18	VAS ODQ	6 weeks	Nil
Areeudomwong et al 2012	6	20	39	44.2 months	SMA Trunk stretches; heat (MMP)	20	NRS RMDQ	10 weeks	Nil
Cai et al 2017	6	84	27.3	65.4 weeks	SMA Lumbar extensor exercises (Exercise – comparison data pooled) Lower limb exercises (Exercise – comparison data pooled)	16	NRS PSFS	3, 6 months	Nil
Cairns et al 2006	7	97	38.7	99.5 months	SMA + Manual therapy; exercise Manual therapy; exercise (MMP)	12	NRS ODI	6, 12 months	Nil
Costa et al 2009	9	154	53.7	331.5 weeks	SMA Detuned shortwave diathermy and ultrasound (Placebo)	12	NRS PSFS	2, 6, 12 months	Nil
Ferreira et al 2007	8	240	53.6	52 months	SMA General group exercise (Exercise) Spinal manipulation (Manual therapy)	12	VAS RMDQ	6, 12 months	Nil
Ford et al 2016	7	300	44.1	15.3 weeks	SMA + individualised physiotherapy + Advice Advice (Advice)	10 2	NRS ODI WA	5, 10, 26, 52 weeks	Nil
Hosseinifar et al 2013	5	30	38.3	unknown	SMA Flexion-extension based exercises (Exercise)	18	VAS FRI	6 weeks	Nil
Ibrahim et al 2018	8	30	49.6	64.5 months	SMA + Advice Advice (Advice)	12	NRS ODI	6 weeks	Nil
Inani et al 2013	5	30	30.4	unknown	SMA Stretching; trunk strengthening (Exercise)	48	VAS ODI	3 months	Nil
Kachanathu et al 2012	4	30	20.5	unknown	SMA Flexion-extension strengthening (Exercise)	32	VAS ODI	8 weeks	Nil
Lomond et al 2014	5	38	40.7	unknown	SMA Trunk strengthening; endurance training (Exercise)	10 weeks	NPI ODI	11 weeks, 6 months	Nil
Macedo et al 2012	8	172	49.2	87.4 months	SMA Graded activity; cognitive behavioural therapy (Exercise + CBT)	14	NRS RMDQ	2, 6, 12 months	mild reported (19 SMA, 17

									comparison)
Mannion et al 2007	7	159	64.9	116.8 months	SMA Advice to keep active (Minimal intervention) Multi-modal physiotherapy*	24	NRS RMDQ	2, 5, 12, 24 months	Nil
Miller et al 2005	5	29	47	26.2 months	SMA McKenzie exercises (McKenzie)	6 weeks	NRS FSQ	6 weeks	Nil
Niemisto et al 2003	8	196	37	6 years	SMA + Manipulation + Physician consultation Physician advice (Advice)	162	VAS ODI WA	5, 12 months 5, 12 months 12 months	Nil
Noormohammadpour et al 2018	7	20	42.3	16.2 months	SMA Participants on waiting list (Minimal Intervention)	80	VAS RMDQ	8 weeks	Nil
O'Sullivan et al 1997	7	42	31	28.5 months	SMA Physician consultation (CMM)	10	NRS ODI	3, 6, 30 months	Nil
Puntumetakul et al 2013	8	42	44.8	45.8 months	SMA Trunk stretches; heat (MMP)	20	NRS RMDQ	10, 14, 22 weeks	Nil
Puntumetakul et al 2018	6	38	38.8	8.4 weeks	SMA Ultrasound; heat (MMP)	14	NRS RMDQ	4, 7, 11 weeks	Nil
Rabin et al 2014	6	105	38.5	63.4 days	SMA Manual therapy; stretching (MMP)	12	NRS ODI	8 weeks	Nil
Rasmussen-Barr et al 2003	5	47	38	unknown	SMA Manual therapy	6	VAS ODI	6 weeks, 3, 12 months	Nil
Rasmussen-Barr et al 2009	7	71	38.5	10 years	SMA Daily walking (Exercise)	82	VAS ODI	8 weeks, 6, 12, 36 months	Nil
Salamat et al 2017	4	24	36	unknown	SMA Movement control; muscle relaxation (Exercise)	8	NRS ODI	4 weeks	Nil
Salavati et al 2016	5	40	31.3	40.4 months	SMA Ultrasound; interferential therapy; infrared radiation; exercise (MMP)	12	VAS ODI	4 weeks	2 SMA dropouts due to worse pain
Srivastav et al 2018	5	30	unknown	unknown	SMA + Ultrasound; stretching; strengthening Ultrasound; stretching; strengthening (MMP)	30	NRS ODI	6 weeks	Nil
Waseem et al 2019	7	120	46.0	unknown	SMA Superficial muscles of the spine exercise (Exercise)	6	ODI	6 weeks	Nil
Ye et al	6	63	23.9	unknown	SMA	36	VAS	3 and 12	Nil

2015	Stretching; spinal flexion and extension strengthening (Exercise)	ODI	months	

*Intervention excluded due to SMA being a substantial component of comparison treatment

VAS=Visual Analog Scale, ODQ=Oswestry Disability Questionnaire, NRS=Numerical Rating Scale, RMDQ=Roland Morris Disability Questionnaire, PSFS=Patient Specific Functional Scale, FRI=Functional Rating Index, NPI=Numerical Pain Index, FSQ=Functional Status questionnaire, SMA=Specific muscle activation, WA=Work absenteeism, CBT=Cognitive Behavioural Therapy, FU=Follow Up, CMM=Conservative Medical Management, MMP=Multi-modal Physiotherapy

scores reported across trials were for back/overall pain 5.1/10 (range 2.2 to 7.0) and leg pain 5.7/10 (range 4.6 to 6.6). 15 trials included some participants with a positive neurological sign.[2,3,9,11,16,22,31,37,43,45,49,54,62,70] The mean number of planned treatment sessions was 15.6 (range 4 to 48).

Table 3 describes the study limitations of included studies. Nineteen out of 28 trials (64%) scored 6 or more on the PEDro scale. Only 3 (10%) of trials reported participant blinding, 0 (0%) reported therapist blinding and 14 (50%) assessor blinding. Thirteen (46%) of trials reported adequate concealed allocation and 17 (61%) described an intention to treat analysis.

Table 3: Study limitations

	PEDro Score											
Trial	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**Total**
Ali 2013	□	□	-	□	-	-	□	-	-	□	□	5
Areeudomwong 2012	□	□	□	-	-	-	□	-	□	□	□	6
Cairns 2006	□	□	-	□	□	-	□	-	□	□	□	7
Cai 2017	□	□	-	□	-	-	□	□	-	□	□	6
Costa 2009	□	□	□	□	□	-	□	□	□	□	□	9
Ferreira 2007	□	□	□	□	-	-	□	□	□	□	□	8
Ford 2016	□	□	□	□	-	-	-	□	□	□	□	7
Hosseinifar 2013	□	□	-	□	-	-	□	-	-	□	□	5
Ibrahim 2018	□	□	□	□	-	-	□	□	□	□	□	8
Inani 2013	□	□	-	□	-	-	-	□	-	□	□	5
Kachanathu 2012	□	□	-	□	-	-	-	-	-	□	□	4
Lomond 2014	-	□	-	□	-	-	-	-	□	□	□	5
Macedo 2012	□	□	□	□	-	-	□	□	□	□	□	8
Mannion 2007	□	□	□	□	-	-	-	□	□	□	□	7
Miller 2005	□	□	-	-	-	-	-	□	-	□	□	4
Niemisto 2003	□	□	□	□	-	-	□	□	□	□	□	8
Noormohammadpour 2018	□	□	□	□	-	-	□	-	□	□	□	7
O'Sullivan 1997	□	□	□	□	-	-	□	□	-	□	□	7
Puntumetakul 2013	□	□	□	□	-	-	□	□	□	□	□	8
Puntumetakul 2018	□	□	-	□	-	-	□	□	-	□	□	6
Rabin 2014	□	□	□	□	-	-	-	-	□	□	□	6
Rasmussen-Barr 2009	□	□	□	□	-	-	-	□	□	□	□	7
Rasmussen-Barr 2003	□	□	-	□	-	-	-	□	-	□	□	5
Salamat 2017	□	□	-	□	-	-	-	-	-	□	□	4
Salavati 2016	□	□	-	□	-	-	-	□	-	□	□	5
Srivastav 2018	□	□	-	□	-	-	-	□	□	□	□	6
Waseem 2019	□	□	□	□	□	-	-	□	-	-	□	7
Ye 2015	□	□	-	□	-	-	-	□	□	□	□	6
Totals (28)	27	28	13	26	3	0	14	19	17	27	28	

There were minor adverse effects noted in two trials.[42,63]

Trials were grouped based on comparison treatment where there was considered to be within group clinical homogeneity. Based on I^2 scores and as required, forest plot visual inspection, all comparisons were deemed suitable for meta-analysis. The mean differences, treatment effect sizes, and associated 95%

CIs for the individual trials are presented for each comparison (Supplementary material 2). The potential for publication bias cannot be ruled out given that few trials contributed to most funnel plots, some of which contained a small trial with moderate-to-large effects favouring SMA.

An evaluation of the GRADE quality of the evidence was made for each comparison and outcome (Supplementary material 2). In some trials, follow-up data were collected at multiple time points within the predetermined time periods. In such cases data were included from the follow-up time point closest to 6-weeks (short term) and 6-months (intermediate term). When multiple outcome measures of the same domain were used (e.g. Oswestry and Roland Morris) the measure with greatest consistency with the other trials in the comparison (or across the review in cases of a tie) was chosen.

SMA compared to exercise

Eleven trials compared SMA with exercise (Supplementary material 2).[2,8,17,31,34,36,40,60,62,69,70] None of the trials had co-interventions in addition to SMA unless provided to both groups.

There was low quality evidence (inconsistency, imprecision) from the meta-analysis showing a small long-term effect (SMD 0.4, CI 0.0 to 0.8) on overall/back pain favouring SMA over other types of exercise.

There was low quality evidence (trial limitations, inconsistency) from the meta-analysis showing moderate short term (SMD 0.5, CI 0.2 to 0.9) and moderate long-term (SMD 0.6, CI 0.0 to 1.3) effects on activity limitation favouring SMA.

There was very low to moderate quality evidence (trial limitations, inconsistency, imprecision) showing no statistically significant short term or intermediate term effects on back/overall pain, or on leg pain across all time points. There were no outcome data on work participation or recurrence.

SMA compared to manual therapy

Two trials compared SMA with manual therapy (Supplementary material 2).[16,59] None of the trials had co-interventions in addition to SMA unless provided to both groups. There was very low to low quality

evidence (trial limitations, inconsistency, imprecision) from the meta-analysis of no significant between-group differences on pain or activity limitation at any time point. There were no outcome data on work participation or recurrence.

SMA compared to conservative medical management

One trial compared SMA with CMM (Supplementary material 2).[53] This trial[53] reported that a proportion of the participants in the comparison group also undertook regular swimming, walking or gym exercise as well as attending other treatment providers for pain relieving modalities as well as other exercises. However, we classed the comparison treatment as that intended to be provided at randomization (medical management).

There was moderate quality evidence (imprecision) from the meta-analysis showing large short (SMD 1.3, CI 0.6 to 2.0), intermediate (SMD 1.2, CI 0.5 to 1.9) and long (SMD 1.3, CI 0.5 to 2.0) term effects on overall/back pain favouring SMA.

There was moderate quality evidence (imprecision) showing a moderate intermediate (SMD 0.7, CI 0.1 to 1.4) and large long (SMD 0.8, CI 0.1 to 1.6) term effects on activity limitation favouring SMA.

There was moderate quality evidence (imprecision) showing no statistically significant effects on short term activity limitation. There were no outcome data on recurrence.

SMA and advice compared to advice alone

Three trials compared SMA and advice to advice alone (Supplementary material 2).[22,33,49] Of these, one trial[22] involved SMA provided with cointerventions (individualised physiotherapy).

There was moderate to high quality evidence (imprecision) from the meta-analysis showing moderate short (SMD 0.7, CI 0.4 to 0.9), moderate intermediate (SMD 0.5, CI 0.3 to 0.6) and small long term (SMD 0.3, CI 0.1 to 0.5) effects on overall/back pain favouring SMA. There was moderate quality evidence (imprecision) showing moderate short (SMD 0.5 CI 0.3 to 0.8) and moderate intermediate (SMD 0.5, CI 0.3 to 0.7) effects on leg pain favouring SMA. There was high quality evidence showing a

small intermediate (SMD 0.4, CI 0.2 to 0.6) and small long term (SMD 0.3, CI 0.1 to 0.5) effect on activity limitation favouring SMA.

There was high quality evidence showing a small long term (SMD 0.2, CI 0.0 to 0.4) effect on work participation favouring SMA.

There was moderate to high quality evidence (inconsistency and imprecision) showing no statistically significant effects on short term activity limitation as well as long term leg pain. There were no outcome data on recurrence.

SMA compared to multi-modal physiotherapy

Six trials compared SMA with MMP (Supplementary material 2).[3,56-58,63,66] None of the trials had co-interventions in addition to SMA.

There was low to moderate quality evidence (inconsistency and imprecision) from the meta-analysis showing large short (SMD 1.1, CI 0.4 to 1.8) and large intermediate (SMD 2.5, CI 1.6 to 3.3) term effects on overall/back pain favouring SMA.

There was low quality evidence (inconsistency and imprecision) showing large short term (SMD 1.2, CI 0.5 to 1.9) effects on activity limitation favouring SMA.

There was low to moderate quality evidence (inconsistency, imprecision) showing no statistically significant effects on overall/back pain or activity limitation at all other time points. There were no outcome data on work participation or recurrence.

SMA compared to placebo

One trial[11] compared SMA in the absence of cointerventions with placebo (Supplementary material 2).

There was moderate quality evidence (imprecision) from this trial showing small short term (SMD 0.4, CI 0.1 to 0.7) and moderate long term (SMD 0.5, CI 0.2 to 0.8) effects on overall/back pain favouring SMA.

There was moderate quality evidence (imprecision) showing a small short term (SMD 0.4, CI 0.1 to 0.7) effect on activity limitation favouring SMA.

There was moderate quality evidence (imprecision) showing no statistically significant effects on intermediate term overall/back pain. There were no outcome data on work participation or recurrence.

SMA compared to minimal intervention

Two trials compared SMA to minimal intervention.[45,50] There was moderate quality evidence (imprecision) showing no statistically significant effects on any outcome at any time point. There were no outcome data on work participation or recurrence.

Other single study comparisons

One trial[47] compared SMA in the absence of cointerventions with the McKenzie approach (Supplementary material 2) showing low quality evidence (trial limitations and imprecision) of no significant between-group differences on any outcome.

One trial[41] compared SMA with exercise including a cognitive behavioural approach (Supplementary material 2). There were no co-interventions in addition to SMA apart from ergonomic and pain education provided to both groups. There was moderate quality evidence (imprecision) of no significant between-group differences on any outcome or time point.

DISCUSSION

This systematic review included 28 trials that evaluated the effectiveness of SMA on pain, activity limitation and work participation. No studies were found investigating recurrence as an outcome. Analyses were conducted on SMA versus nine comparison group treatments being manual therapy, the McKenzie approach, exercise, exercise plus a cognitive behavioural approach, multimodal physiotherapy (MMP), advice, conventional medical management (CMM), placebo, and minimal intervention. For these outcomes low to high quality evidence was found supporting the effectiveness of SMA compared with exercise (short and long term), CMM (at all timepoints), advice (at all timepoints), MMP (short and intermediate term) and placebo (short and long term) for combinations of overall/back pain, activity

limitation and work participation. There were however a number of outcomes and timepoints where low to moderate quality evidence was found suggesting no between-group differences in these comparisons. Low to moderate quality evidence was also found of no between-group differences of SMA compared to minimal intervention, exercise including a cognitive behavioural approach, the McKenzie approach and manual therapy for overall/back pain and activity limitation.

Previous systematic reviews have reached variable conclusions on the effectiveness of SMA. One review found results that SMA is effective compared to other treatments.[7] Three other reviews concluded that SMA was effective compared to minimal intervention but no more effective than any other treatment including exercise due in part to small effects lower than the Minimal Clinically Important Difference being observed.[42,64,65] Our review did not include in the minimal intervention comparison, treatments recommended in guidelines such as advice or placebo, both of which are likely to have larger treatment effects than no or minimal intervention. Our results have some similarities to one of these previous systematic reviews,[7] however we used a more rigorous approach to synthesising the literature including analyses using the GRADE approach and meta-analysis using random effects in the presence of inconsistency. Our systematic review is also the first requiring all trials to evaluate SMA in accordance with the original descriptions of the method including functional progression. This is important because SMA is less likely to correct unhelpful motor control strategies during activities of daily living unless correct activation is initially practiced and then progressed into function.[61] Another key difference with other recent systematic reviews[42,64] is our inclusion of trials that treated people with purported specific LBP such as spondylolisthesis or disc herniation with associated radiculopathy. The hypothesised mechanisms of SMA have clear potential to improve such causes of LBP[1,20,21] and hence excluding these studies risks underestimating the true effectiveness of SMA for the broad population with LBP which encompasses specific and non-specific presentations. Finally, our review searched databases for an additional four years compared to the most recent previous review,[64] identifying a number of new trials.

Interpreting clinical importance in systematic reviews is complex.[14,15,18] Using the Minimally Clinically Important Difference to estimate clinical importance on group data is inconsistent with the original intentions and validated purpose of this measure.[15] A more appropriate metric of clinical importance is an effect size of 0.5 or larger[51] and in this systematic review such effects were demonstrated in SMA

compared to exercise, CMM, advice and MMP with standardised mean differences ranging from 0.5 to 2.5. Clinical importance of RCT findings should also consider responder analyses, consistency of results, benefits/risks in relation to the treatments and the population being evaluated.[14,15,18] In this review we did not report on responder analyses however minimal adverse events were described in included trials. As described in supplementary material 2, there were significant effects found across a range of comparisons. Between-group comparisons should also be interpreted in the context of large within-group improvements on all primary outcomes for both treatment groups in many of the included RCTs.[2,3,22,34,37,56,60,69,70]. These additional considerations strengthen the case for the clinical importance of the between-group differences reported in this systematic review.

We included studies involving participants with LBP of all durations based on literature suggesting natural history is more complex than the traditional acute/chronic dichotomy. First time onset LBP represents only 19% of acute cases[68] and the trajectory of LBP is typically recurrent or persistent with varying levels of severity.[12,35] In addition, there are hypothesised mechanisms of effect in SMA for people with both acute LBP (such as overcoming reflex inhibition of the local/deep muscles of the spine) as well as more persistent LBP (addressing unhelpful motor control patterns and restoring normal muscle size and connective tissue structure).[29]

Advice is recommended in all clinical guidelines as first line treatment for LBP.[55] For persistent LBP, advice is recommended alongside exercise and cognitive behavioural approaches.[23] While guidelines do not favour a particular type of exercise, our review found SMA to be more effective than other types of treatment including exercise and advice. These findings make a case to support the use of SMA as a first line exercise approach for managing LBP.

Limitations

Systematic reviews are most valuable when meta-analyses are conducted[28] and by grouping according to comparison treatment as well as having strict eligibility criteria on the descriptions of the treatment provided, clinical homogeneity was demonstrated. Consistent with other systematic reviews on SMA,[64] meta-analyses were conducted where reasonable clinical and statistical homogeneity was determined. In the event of higher levels of statistical heterogeneity, the quality of evidence was downgraded for

inconsistency. However, given there was substantial statistical heterogeneity present in some comparisons, the meta-analysis results should be interpreted with caution. This is particularly the case in the MMP comparison where large effects were shown in trials of small sample size. Replication of trials where large effects were demonstrated has the potential of reducing the heterogeneity and inconsistency of the results. Further trials for comparisons where non-significant effects were reported could also alter the evidence base considerably, as some of the trials in this review reporting non-significant results, but moderate to large effects, were potentially underpowered.

An additional limitation of this review was the exclusion of RCTs not published in English due to limited resources and funding. Despite some evidence stating that excluding non-English trials does not affect estimates of effectiveness in systematic reviews[48] the impact of this limitation on the results is uncertain.

CONCLUSION

The provision of SMA for patients with LBP is a commonly used treatment approach with significant evidence supporting potential mechanisms of effect. Low to high quality evidence was found supporting the effectiveness of SMA compared to other exercise, CMM, advice, MMP and placebo across most but not all outcomes and timepoints. Where significant results were demonstrated, the between-group differences were in many comparisons clinically important based on contemporary definitions and an effect size of 0.5 or more. On the basis of this systematic review, practitioners should consider SMA as a treatment component in their patients with LBP.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Figure legends

Figure 1: Flow of studies