

## **Abstract**

**Background.** 2.7 million patients present to US EDs annually for management of low back pain (LBP). Despite optimal medical therapy, 48% remain functionally impaired 3 months later. We performed a systematic review to address the following question: among patients with non-chronic LBP, does spinal manipulation, massage, exercise, or yoga, when combined with standard medical therapy, improve pain and functional outcomes more than standard medical therapy alone.

**Methods.** We used published searches to identify relevant studies, supplemented with our own updated search. Studies were culled from the Cochrane Register of Controlled Trials, Medline, EMBASE, CINAHL and the Index to Chiropractic Literature. Our goal was to identify randomized studies that included patients with non-radicular LBP of <12 weeks duration that compared the complementary therapy to usual care, sham therapy, or to interventions known not to be efficacious, while providing all patients with standard analgesics. The outcomes of interest were improvement in pain scores or measures of functionality.

**Results.** We identified two RCTs in which chiropractic manipulation + medical therapy failed to show benefit versus medical therapy alone. We identified four RCTS in which exercise therapy + medical therapy failed to show benefit versus medical therapy alone. We did not identify any eligible studies of yoga or massage therapy.

**Conclusions.** In conclusion, for patients with non-chronic, non-radicular low back pain, available evidence does not support the use of spinal manipulation or exercise therapy in addition to standard medical therapy. There is insufficient evidence to determine if yoga or massage is beneficial.

## Background

Low back pain (LBP) is a very common reason for an emergency department (ED) visit, resulting in 2.7 million visits to US EDs annually.(1) Among an unselected ED LBP population, outcomes are generally poor; more than 50% of these patients report persistent pain and functional impairment three months later. (2)Even among patients with acute, new onset LBP, 20-25% of patients report persistent pain and functional impairment at the three month mark.(3) Medical therapy for LBP is of only modest benefit. Adding a skeletal muscle relaxant or an opioid to standard therapy with a non-steroidal anti-inflammatory drug does not improve three month outcomes.(3) A variety of complementary or alternative therapies may be useful for patients with LBP. Chiropractic manipulation, massage, exercise therapy and yoga are commonly recommended for patients with LBP. However, published data on these therapeutic modalities have been gathered in heterogeneous populations using differing methodologies thus making interpretation difficult for emergency physicians. (4-7)The goal of this work is to clarify the role of these four types of complementary therapies for ED patients with non-radicular, non-chronic LBP who are treated with appropriate medical therapy. Specifically, we reviewed the published literature systematically to determine whether chiropractic manipulation, massage, exercise therapy or yoga, when added to typical medical care, would improve short or long-term pain and functional outcomes more than typical medical care alone among patients with non-chronic low back pain.

## Methods

**Overview.** This is a “piggy-back” systematic review of the published literature to determine whether spinal manipulation, massage, exercise therapy, or yoga, when combined with standard care, are more effective in improving pain and functionality scores than standard care alone among ED patients with acute or sub-acute low back pain. To answer our question of interest, we extracted relevant data from four previously published high-quality systematic reviews on each of these four topics (manipulation, massage, exercise, yoga), and then supplemented the published systematic reviews with our own updated literature search.

**Selection criteria.** We included randomized studies of patients with acute or sub-acute non-radicular low back pain. For the purpose of this analysis, we defined acute as LBP duration of less than one month and sub-acute LBP as at least one month in duration but less than three months. Because patients with radicular LBP may be treated differently than patients without radicular symptoms, we excluded studies in which the majority of patients had radicular symptoms, sciatica, or known spinal pathology. Because our research question involves improving upon rather than replacing standard medical therapy, we only included randomized studies in which, by protocol, all patients were treated with a standard medical therapy, which we defined as a non-steroidal anti-inflammatory agent, acetaminophen, a skeletal muscle relaxant, an opioid, or a benzodiazepine. Thus, all patients included in this analysis received standard care with or without a complementary therapy. Finally, because we sought evidence of efficacy, we only included studies in which the complementary modality was compared to no care, an inactive control, such as a sham therapy, or a therapy known to be ineffective.

**Search Strategy.** We identified updated high quality systematic reviews on each of the four complementary therapies of interest.(4-7) However, these reviews were not tailored to our specific goal: to identify complementary therapies that are useful adjuvants to standard medical therapy among patients with non-chronic, non-radicular LBP. Rather than repeating the search, we relied upon the studies identified in each of these reviews, but then further winnowed the identified studies to meet our selection criteria. To determine whether or not a particular RCT included by the published author group was eligible for our study, two of us reviewed the study in detail and independently determined whether or not the original RCT was eligible for our study. Our original plan was to resolve disagreement through discussion, though that was not necessary as both reviewers agreed on all studies.

To identify relevant studies published subsequent to the searches performed in each of these systematic reviews, we updated the search as follows. We searched Medline and Cochrane Central using the original authors’ search strategy encompassing the time from the original search date until May, 2016. For this updated search, one author identified potentially eligible studies. Final eligibility was determined by discussion.

When data were missing or unclear, we attempted to contact study authors.

**Outcomes of interest.** The primary outcomes of interest for this analysis were improvement in LBP or LBP related functional impairment. Pain assessments were typically performed using patient rating scales such as a visual analog scale (VAS) or a numerical rating scale for pain (NRS). LBP-related functional impairment was measured using disease specific instruments such as the Oswestry Disability Index.

**Bias.** For studies identified by the original systematic review, we report the assessment of bias originally reported. For studies identified in our updated search, we used the Cochrane assessment of bias instrument.

Analysis. We had hoped to identify a sufficient number of similar studies so that the results could be aggregated. This was not the case. Therefore, we report the results for individual studies and summarize results qualitatively.

## Results

We identified two RCTs of spinal manipulation, four of exercise therapy and none for either yoga or massage that met our search criteria. (Figure 1)

### *Spinal manipulation*

Of twenty studies on spinal manipulation identified in the initial review, we excluded all but two (Table 2a). Four studies compared different types of manipulation to each other and thus did not have an inactive control. The remaining fourteen studies did not administer standard medical therapy to all patients.

Our updated search identified 195 new unique references. None of these met our selection criteria. Reasons for exclusion are detailed in Figure 1a.

The two studies that met our selection criteria are discussed below (Table 1).

#### Hancock et al. (8)

This study enrolled 240 patients with back pain duration of less than six weeks who presented to a general practitioner in Sydney, Australia. Patients were randomized to one of four groups: diclofenac 50mg, twice daily + sham therapy; placebo tablets + spinal manipulation; both diclofenac and spinal manipulation; or placebo tablets + sham therapy. All patients received a prescription for acetaminophen 1 gram four times daily and general LBP advise from their GP. Manipulation consisted of mobilization techniques and high velocity thrusts, adapted to the patient's clinical presentation. Each patient received two or three treatment sessions per week for four weeks to a maximum of 12 treatments. The primary outcome, number of days to sustained pain freedom, did not differ among the groups. Similarly, secondary outcomes, which included measures of pain, functional impairment, and patient perceptions, did not differ meaningfully between any of the groups.

#### Juni et al. (9)

This study randomized 104 Swiss ED or general practice patients with back pain duration of less than four weeks to standard care with or without spinal manipulation. Standard care consisted of acetaminophen, diclofenac, and dihydrocodeine, as well as typical LBP advise. Manipulation treatment consisted of high velocity low amplitude thrusts, spinal mobilization, and muscle energy techniques. Patients received a maximum of five sessions of therapy over the course of two weeks. There were no statistically significant differences between the groups with regard to pain scores or analgesic use.

### *Yoga*

Of eleven studies on yoga identified in the initial review, all eleven included only patients with chronic low back pain, and were therefore excluded from this analysis. (Table 2b)

Our updated search identified 57 new unique references. None of these met our selection criteria. Reasons for exclusion are detailed in Figure 1b.

### *Massage*

Of sixteen studies identified by the initial review, none were eligible for this analysis. Eight of the studies included chronic pain patients. Five of the studies compared different types of massage (no inactive control), or compared massage to other active treatment modalities. Two studies did not provide standard medication to all participants, and one study did not perform just massage, but combined massage with other complementary therapies. (Table 2c)

Our updated search identified 308 new unique references. None of these met our selection criteria. Reasons for exclusion are detailed in Figure 1c.

### *Exercise therapy*

Of sixty-one studies on exercise therapy identified in the original systematic review, three were eligible for this analysis. (Table 2d) Forty-five of the excluded studies enrolled patients with chronic LBP. Among the remaining studies, two had no comparator group, and eleven did not administer analgesics to each experimental group.

Our updated search identified 1341 new unique references. Only one of these met our selection criteria. Reasons for exclusion are detailed in Figure 1d.

The four studies that met our selection criteria are discussed below. (Table 1)

#### Hides et al. (10)

This study enrolled 41 ED patients with LBP lasting less than three weeks and randomized them to standard treatment or standard treatment plus exercise therapy. Standard treatment consisted of advice and prescription of minor analgesics. The exercise therapy was aimed at strengthening the spinal musculature. Patients were taught how to perform isometric multifidus contractions while contracting deep abdominal muscles. There were no statistically significant differences between the groups with regard to pain or functional impairment up to 4 weeks after enrollment.

#### Faas et al. (11)

This study enrolled 473 patients who presented to a Dutch GP with LBP of 3 weeks duration or less. All patients were provided with acetaminophen and general LBP advice and were randomized into one of three groups. The exercise therapy group was instructed by a physical therapist during 20 minute sessions, twice per week, for five weeks. During these sessions, patients were taught eight exercises and seven pieces of advice for daily living. A second group received sham therapy, while the final group received only the medication. There were no differences among the groups with regard to frequency of pain recurrences, use of medical resources, or markers of overall health.

#### Gilbert et al. (12)

This study enrolled 270 patients with new onset LBP who presented to a Canadian family practitioner. Patients were randomized to one of four groups: bed rest + physical therapy, bed rest alone, physical therapy alone, or neither of these. All participants received simple analgesics, NSAIDs, or muscle relaxants. Patients were stratified based on medication received. Patients assigned to physical therapy were instructed on how to perform isometric flexion exercises and was instructed to repeat the exercises at home three times daily. Patients assigned to bed rest were told to stay in bed for four days. There were no significant differences between the groups with regard to pain or overall improvement. Patients who received physical therapy stopped taking medication sooner, while those assigned to bed rest took longer to resume normal activities.

#### Machado et al. (13)

This study randomized 146 Australian general practice patients with LBP duration less than six weeks to first-line care or to first-line care plus McKenzie therapy. First-line care consisted of advice to remain active, reassurance, and acetaminophen. The McKenzie method uses a standardized diagnostic approach to assign specific exercises that presumably are of most benefit to individual patients with LBP. Patients

were provided with up to six sessions over three weeks. There were no differences in pain or functional outcomes at one or three weeks post enrollment.

## Discussion

Low back pain is a common problem that emergency physicians treat on a daily basis. In this systematic review of the published literature, we sought evidence to determine whether emergency physicians should encourage patients with acute or sub-acute non-radicular LBP to seek out complementary therapy in addition to standard medical therapy. We identified evidence to suggest that neither chiropractic manipulation nor exercise therapy is of benefit for these patients. Insufficient evidence exists to determine whether yoga and massage therapy should be offered.

Up to one third of patients with acute, non-traumatic, non-radicular LBP report persistent pain and functional impairment three months after an ED visit.(3) Non-steroidal anti-inflammatory drugs are the most common treatment for LBP, but are often inadequate in that, for many patients, they do not completely relieve LBP and related functional impairment.(3) Emergency physicians commonly prescribe opioids or skeletal muscle relaxants in addition to NSAIDs,(1) a practice that exposes patients to additional side effects without efficacy benefits.(3) Thus, there is a need for non-medical therapies.

In this analysis, we excluded studies in which patients were not provided with standard medical therapy. Thus, we do not address the role of complementary therapy among patients who cannot tolerate or do not like standard medical therapy. Similarly, we excluded studies of patients with chronic or radicular pain.

While generally speaking, neither chiropractic manipulation nor exercise therapy appear to benefit patients with non-chronic back pain, there are other plausible explanations for our findings. It may be that there is a subset of patients with acute LBP who may benefit—for example, it may be that self-motivated patients are more likely to benefit from exercise therapy. Outcomes after chiropractic manipulation may depend on the relationship between the chiropractor and the patient or on the efforts or technique of the individual chiropractor. It is also possible that certain exercise modalities are better than others. However, to our reading, there have not been either chiropractic techniques or exercise modalities that have clearly demonstrated benefit over other techniques or modalities.

We were not able to identify sufficient evidence to determine whether yoga or massage offer benefit to these patients. Other forms of complementary and alternative treatments such as acupuncture, individual stretching exercises, and meditation were beyond the scope of our review and may provide some benefit to select patients.

Unfortunately, this systematic review leaves emergency physicians with fewer available tools to help their patients with non-chronic back pain. Other than NSAIDs or skeletal muscle relaxants, each of which may offer modest benefit,(14, 15) no other therapies have an evidence base to support common use. Fortunately, for most patients, acute LBP improves over time. (3) Patients should be counseled that tincture of time works as well as just about anything else.

## Conclusion

In conclusion, for patients with acute or sub-acute, non-radicular low back pain, available evidence does not support the use of spinal manipulation or exercise therapy in addition to standard medical therapy. There is insufficient evidence to determine if yoga or massage is beneficial.



## References

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## Tables and Figures

Table 1. Six RCTs included in this review

Table 2. Reasons for exclusion among studies included in published systematic review

Figure 1a. Flow diagram. Spinal manipulation therapy

Figure 1b. Flow diagram. Yoga

Figure 1c. Flow diagram. Massage

Figure 1d. Flow diagram. Exercise therapy

Table 1. Six RCTs included in this review

Author, year, modality	Setting, sample size	Study quality	Intervention	Control	Medication	Short-term outcome	Long-term outcome
Juni et al., 2009, spinal manipulation	ED and GP, Bern, 104	Low risk of bias	SMT + standard care. SMT initiated within 24 hours of randomization. Up to five sessions in two weeks (median 3). Techniques: high velocity, low amplitude thrusts; spinal mobilizations and muscle energy techniques	Standard care: rapid return to activities; avoidance of bed rest	acetaminophen, diclofenac, dihydrocodeine	At 14 days, no difference between groups in pain scores, analgesics consumption, and measures of functional impairment	At 6 months, no difference in pain levels or analgesic requirements
Hancock et al., 2007, spinal manipulation	University of Sydney, 239	Low risk of bias	SMT + standard care. SMT: two or three sessions per week over four weeks. (max 12 treatments). Techniques: high velocity thrusts targeted at areas of pain	Standard care and sham SMT. Sham: low frequency ultrasound wave treatment Standard care: medication usage instructions	diclofenac	At one and two weeks, there were no significant differences between the groups in regards to time until recovery.	Through twelve weeks, there were no statistically significant differences between groups.
Gilbert et al., 1985, exercise therapy	McMaster University, Canada, 252	High risk of bias	PT + standard care. Patients given session with a physical therapist who taught an exercise regimen to be continued at home (three times a day). Patients	Standard care: analgesics prescription	Physician's discretion. Patients stratified by minor or major analgesics (Minor: muscle relaxants or <8 aspirins/day Major:	No statistically significant differences in pain or functional impairment at 6 or 12 weeks.	At 1 year, patients in active group reported less ability to perform daily life activities than other groups. Other categories

			received 1-2 sessions. Patients also provided education on pain management.		NSAIDs, $\geq 8$ aspirins/day)		had no significant differences, but overall trends showed that the active group performed worse than the control.
Faas et al., 1993, exercise therapy	40 different Dutch GPs, 473	Moderate risk of bias	PT + standard care. Sessions 20 minutes, twice a week for 5 weeks led by a physiotherapist. Patients were advised on how to move in ways that limit pain. Patients were advised to continue the exercises at home daily.	Sham therapy + standard care or standard care alone. Sham therapy consisted of low dose ultrasonography sessions, twice a week for five weeks.	Acetaminophen	At two and four weeks, there were no significant differences between groups in regards to pain, functionality, overall markers of health	At one year, there were no significant differences between the groups in regards to recurrence, functionality, overall markers of health.
Hides et al., 1996, exercise therapy	University of Queensland, Brisbane, 39	Moderate risk of bias	PT + standard care. Sessions aimed at strengthening the multifidus muscle.	Standard care: advice given on pain management, patients were advised to take off work and to take brief bed rest.	Minor analgesics including aspirin, acetaminophen, NSAIDs, opioids, diazepam	No significant differences between groups in regards to pain or functionality outcomes through the first four weeks.	At ten weeks, there were no significant differences between the groups in any outcome measure.
Machado et.al., 2010, exercise therapy	27 primary care practices, Sydney, 146	Moderate risk of bias	PT + standard care. McKenzie based treatment approach. PT	Standard care: Advise to remain active, reassurance	Acetaminophen	No significant differences between groups in regards to	Not reported

			within 48 hours of presentation. Up to six session in 3 weeks.			pain or functionality outcomes through the first four weeks.	
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SMT= spinal manipulation therapy PT= physical therapy

Table 2. Reasons for exclusion

2a. Spinal manipulation therapy. Reasons for exclusion

Author, year	Reason for exclusion
Bergquist-Ullman and Larsson, 1977	Standard medical therapy not provided
Brennan et al., 2006	No inactive control group
Cherkin et al., 1998	Standard medical therapy not provided
Childs et al., 2004	Standard medical therapy not provided
Cleland et al., 2009	No inactive control group
Cramer et al., 1993	Standard medical therapy not provided
Farrell and Twomey, 1982	Standard medical therapy not provided
Glover et al., 1974	Standard medical therapy not provided
Hadler et al., 1987	No inactive control group
Hallegraeff et al., 2009	Standard medical therapy not provided
Hoehler, et al., 1981	Standard medical therapy not provided
Hoiriis et al., 2002	Standard medical therapy not provided
MacDonald and Bell, 1989	Standard medical therapy not provided
Postacchini, et al., 1988	Standard medical therapy not provided
Rasmussen, 1979	Standard medical therapy not provided
Seferlis, et al., 1998	Standard medical therapy not provided
Shargren, et. al., 1997	Standard medical therapy not provided
Sutlive et al., 2009	No inactive control group

Table 2b. Yoga. Reasons for exclusion

Author, year	Reason for exclusion
Cox et al., 2010	Chronic LBP
Galantino et al., 2004	Chronic LBP
Pushpika et al., 2010	Chronic LBP
Saper et al., 2009	Chronic LBP
Sherman et al., 2005	Chronic LBP
Sherman et al., 2011	Chronic LBP
Tekur et al., 2008	Chronic LBP
Tekuret al., 2010	Chronic LBP
Tilbrook et al., 2011	Chronic LBP
Williams et al., 2005	Chronic LBP
Williams et al., 2009	Chronic LBP

Table 2c. Massage. Reasons for exclusion

Author, year	Reasons
Chatchawan et al., 2005	No inactive control
Cherkin et al., 2001	Chronic LBP
Farasyn et al., 2006	Standard medical therapy not provided
Field et al., 2007	Chronic LBP
Franke et al., 2000	Chronic LBP
Geisser et al., 2005	Chronic LBP
Hernandez-Reif et al., 2000	Chronic LBP
Konrad et al., 1992	No inactive control
Li-Chen Hsieh et al., 2004	Chronic LBP

Li-Chen Hsieh et al., 2006	Chronic LBP
Mackawan et al., 2007	No inactive control
Melzack et al., 1983	No inactive control
Poole et al., 2007	Chronic LBP
Pope et al., 1994	No inactive control
Preyde, 2000	Standard medical therapy not provided
Yip and Tse, 2004	Active group received several treatments

Table 2d. Exercise therapy. Reasons for exclusion

Author, year	Reasons
Alexandre, et al., 2001	Chronic LBP
Aure et al., 2003	Chronic LBP
Bendix et al., 1995	Chronic LBP
Bendix, et al., 2000	Chronic LBP
Bentsen et al., 1997	Chronic LBP
Bronfort et al., 1996	Chronic LBP
Buswell, 1982	Chronic LBP
Calmels, et al., 2004	Chronic LBP
Cherkin et al., 1998	Standard medical therapy not provided
Chok et al., 1999	Standard medical therapy not provided
Dalichau and Scheele, 2000	Chronic LBP
Davies et al., 1979	Chronic LBP
Delitto et al., 1993	No inactive control
Descarreaux et al., 2002	Chronic LBP
Deyo et al., 1990	Chronic LBP
Elnagger et al., 1991	Chronic LBP
Farrell and Twomey, 1982	No inactive control
Frost et al., 2004	Chronic LBP
Galantino et al., 2004	Chronic LBP
Gur et al., 2003	Chronic LBP
Hansen et al., 1993	Chronic LBP
Hemmilä, et al., 1997	Chronic LBP
Hildebrandt et al., 2000	Chronic LBP
Johannsen, et al., 1995	Chronic LBP
Jousset et al., 2004	Chronic LBP
Kankaanpää et al., 1999	Chronic LBP
Kendall and Jenkins, 1968	Chronic LBP
Kuukkanen and Mälkiä, 2000	Chronic LBP
Lidström and Zachrisson, 1970	Chronic LBP
Lie and Frey, 1999	Chronic LBP
Lindström et al., 1992	Standard medical therapy not provided
Ljunggren et. al, 1997	Chronic LBP
Lønn et al., 1999	Chronic LBP
Malmivaara et al., 1995	Standard medical therapy not provided
Manniche et al., 1988	Chronic LBP
Mannion et al., 1999	Chronic LBP
Mofett et al., 1999	Standard medical therapy not provided

Moseley, 2002	Chronic LBP
Niemistö et al., 2003	Chronic LBP
Petersen et al., 2002	Chronic LBP
Preyde, 2000	Chronic LBP
Rasmussen-Barr et al., 2003	Chronic LBP
Risch et al., 1993	Chronic LBP
Rittweger, et al., 2002	Chronic LBP
Seferlis et al., 1998	Standard medical therapy not provided
Soukup et al., 1999	Chronic LBP
Staal et al., 2004	Standard medical therapy not provided
Stankovic and Johnell, 1990	Standard medical therapy not provided
Storheim, 2003	Standard medical therapy not provided
Torstensen et al., 1998	Chronic LBP
Tritilanunt and Wajanavisit, 2001	Chronic LBP
Turner et al., 1990	Chronic LBP
Underwood, 1998	Standard medical therapy not provided
Waterworth and Hunter, 1985	Standard medical therapy not provided
Yelland et al., 2004	Chronic LBP
Yeung et al., 2003	Chronic LBP
Yozbatiran et al., 2004	Chronic LBP
Zylbergold and Piper, 1981	Chronic LBP



Figure 1a. Flow diagram. Spinal manipulation therapy

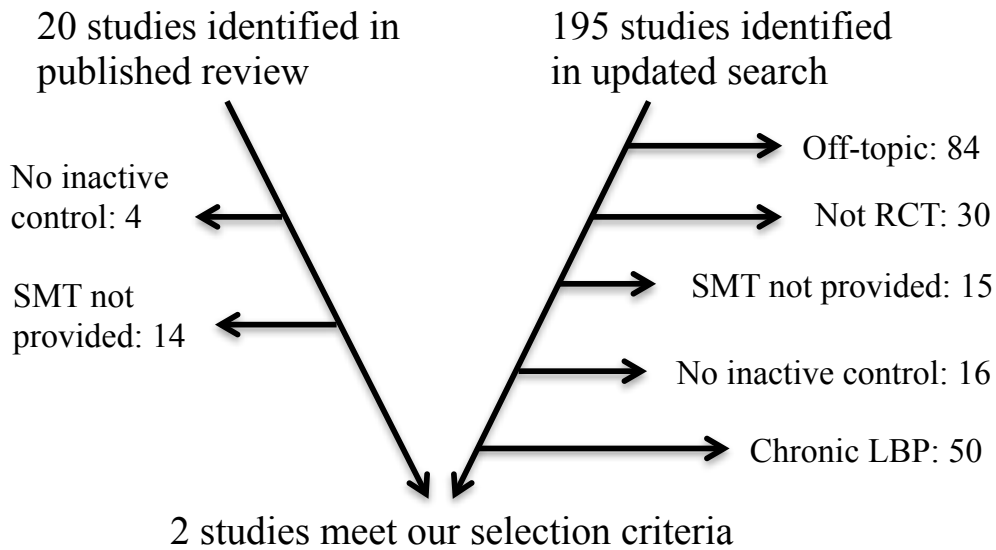


Figure 1b. Flow diagram. Yoga

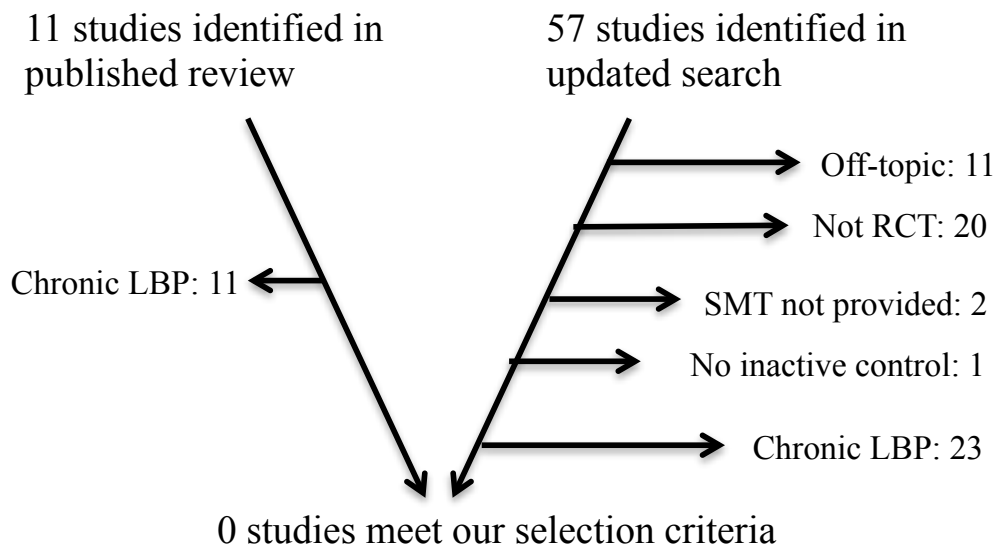


Figure 1c. Flow diagram. Massage

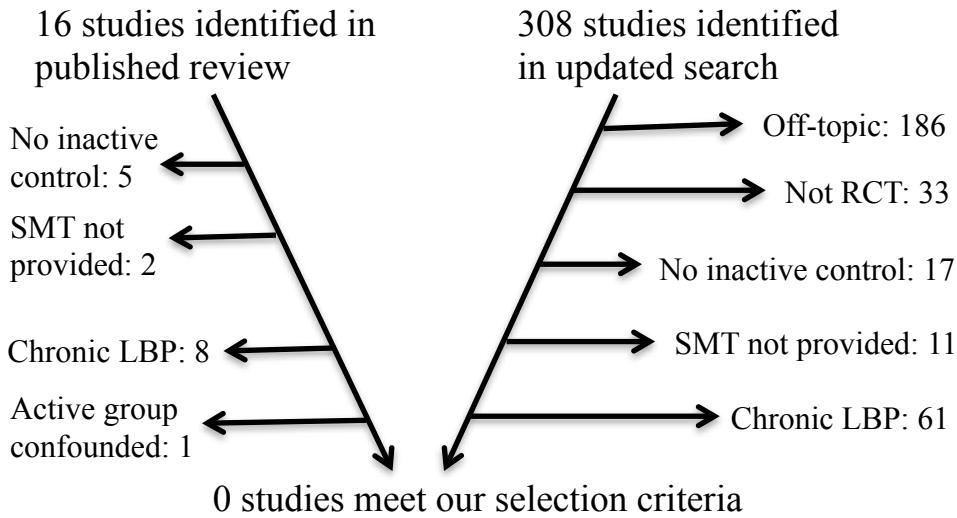
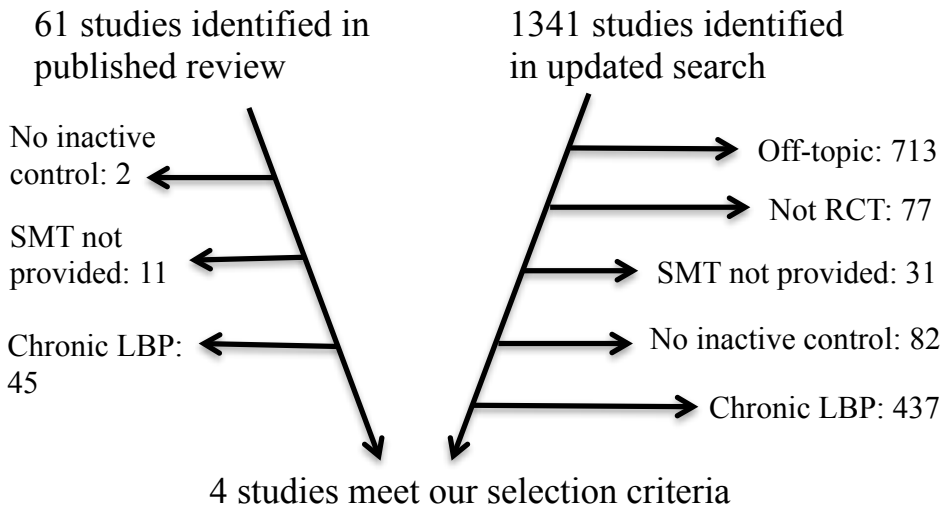


Figure 1d. Flow diagram. Exercise therap



SMT= standard medical therapy. Off-topic= did not meet selection criteria. Not RCT= systematic review, cohort study or some other non-randomized comparison