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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| In a 53-year-old female with chronic low back pain, are stabilization exercises more effective than massage for reducing the severity of pain? |

**AUTHOR**

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**CLINICAL SCENARIO**

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| The patient is a 53-year-old female presenting to the clinic with a primary complaint of chronic low back pain (CLBP). The patient has previously visited the clinic for the same diagnosis. She reports low back pain for the last six months with no history of trauma. The patient regularly takes anti-inflammatory medication to help control the pain but this only provides temporary relief. The patient has been unsuccessful with heat, electrical stimulation, and positional/postural education. Non-specific chronic low back pain is common in the aging population with a lifetime prevalence of 84%.12  With the growing elderly population, many physical therapy settings will likely service patients with a similar presentation.12 Exploring the efficacy of stabilization exercises and alternative interventions such as massage may give providers additional tools to apply to patients with non-specific CLBP that are not progressing in therapy.  |

**SUMMARY OF SEARCH**

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| * A total of 10 studies were selected that met inclusion/exclusion criteria, including seven randomized controlled trials (RCTs) and three systematic reviews with meta-analyses (MA). Three studies, two systematic reviews and one RCT were identified as the “best evidence” based on their relevance to the clinical question and methodological quality. These studies were reviewed and are discussed below.
* Results from a RCT report that spinal stabilization exercises demonstrate greater efficacy than massage therapy in the short-term.4 However, a systematic review reports that exercise is not an effective intervention for CLBP.10 Results from a systematic review report that massage is effective at reducing CLBP intensity in the short-term versus no intervention.6 For individuals with non-specific CLBP, neither intervention is effective in the long-term.4,6,10
* In future research, RCTs with large sample sizes and methodological rigor should compare exercise and massage on chronic low back pain. Addressing type, duration, magnitude and frequency of each applied therapy is also needed to determine the most effective and specific intervention.
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**CLINICAL BOTTOM LINE**

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| Current “best evidence” suggests that spinal stabilization exercises and manual therapy may be used to reduce CLBP intensity in the short-term. Additionally, spinal stabilization exercises may be more effective at controlling pain compared to manual therapy in the short-term. Based on current evidence, neither intervention is effective in the long-term. Results should be interpreted with caution as statistical significance varied across trials and clinical significance of these findings remains unclear.  |

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| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| FemaleWomenAging  | Stabilization Core strengtheningExercise\*Physical therapyPhysiotherapy  | Massage Soft tissue massageSoft tissue mobilization | Low back painLumbar painLumbago  |

**Final search strategy:**

Cochrane Library Search Strategy

1. female OR women OR aging – 543,213
2. low back pain OR lumbar pain OR lumbago OR LBP – 9,117
3. stabilization OR core strengthening – 2,746
4. exercis\* OR physical therapy OR physiotherapy – 73,414
5. massage OR soft tissue massage OR soft tissue mobilization – 2.603
6. #1 AND #2 AND #3 AND #4 AND #5 - 45

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| Cochrane Library PubMed CINHAL  | 4547415179661 | Omitted “female OR women OR aging” Omit comparison “massage OR soft tissue massage OR soft tissue mobilization” + Mesh terms for “low back pain OR lumbar pain OR lumbago OR LBP” + limited to meta-analysis, systematic reviews and RCTs +English Omit “stabilization OR core strengthening” and “exercise OR physical therapy OR physiotherapy” Mesh terms for “low back pain OR lumbar pain OR lumbago OR LBP” + limited to meta-analysis, systematic reviews and RCTs + English Omitted “female OR women OR aging” Omit comparison “massage OR soft tissue massage OR soft tissue mobilization” + MJ for “low back pain OR lumbar pain OR lumbago OR LBP”Omit “stabilization OR core strengthening” and “exercise OR physical therapy OR physiotherapy” + MJ for “low back pain OR lumbar pain OR lumbago OR LBP” |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * Systematic reviews, randomized controlled trials, controlled trials, uncontrolled trials
* Published up to September 2015
* Published in English
* Interventions that included either stabilization exercises or massage
* Studies involving the treatment of chronic low back pain
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| **Exclusion Criteria** |
| * Studies that involved participants with neurological or cardiopulmonary conditions
* Case studies or case series, abstracts, conference proceedings, letters to the editor, dissertations, expert opinion papers, narrative review articles
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**RESULTS OF SEARCH**

A total of ten relevant studies were identified and are listed below. Quality of evidence was assessed using the Jadad for RCTs and AMSTAR for systematic reviews.

**Summary of articles retrieved that met inclusion and exclusion criteria**

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| **Author (Year)** | **Study quality score** | **Level of Evidence** | **Study design** |
| Andrusaitis et al (2011) | Jadad – 4 | 2b | RCT |
| **Furlan et al (2015)** | AMSTAR - 10 | 1a | SR with MA |
| **Van Middle Koop (2011)** | AMSTAR - 11 | 1a | SR |
| Smith et al (2014) | AMSTAR – 8 | 1a | SR with MA |
| Kankaanpaa et a (1999) | Jadad – 3 | 2b | RCT |
| Cairns et al (2006)  | Jadad - 4 | 2b | RCT |
| **Goldby et al (2006)** | Jadad - 5 | 1b | RCT |
| Cherkin et al (2011) | Jadad - 4 | 2b | RCT |
| Moussouli et al (2014)  | Jadad - 2 | 2b | RCT |
| Franca et al (2010)  | Jadad – 4 | 2b | RCT |

**BEST EVIDENCE**

The following 3 studies were identified as the ‘best’ evidence and selected for critical appraisal. Reasons for selecting these studies were:

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| * Massage for low-back pain, Furlan et al (2015)
* A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain, van Middelkoop et al (2011)
* A randomized controlled trial investigating the efficiency of musculoskeletal physiotherapy on chronic low back disorder, Goldby et al (2006)

These studies were of higher level of evidence and presented with the least bias as evidenced by AMSTAR and Jadad scores. Additionally, each systematic review addresses each intervention (stabilization exercise vs. massage) individually and the selected RCT compares these two interventions. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of Massage for low-back pain by Furlan et al (2015)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The purpose of this systematic review with meta-analysis was to assess the short-term and long-term effects of massage therapy on non-mechanical low back pain and back specific functional status. |
| **Study Design** |
| * The study is a systematic review with meta-analysis that utilized data from eligible randomized controlled trials.
* *Search Strategy:* Literature searches were conducted in MEDLINE, EMBASE, CINAHL, CENTRAL, LILACS, Index to Chiropractic Literature, and Proquest Dissertation Abstracts until July 2014. PubMed was searched until August 2014. Reference lists of all included studies were also searched. No language restrictions were used. All search strategies were included in the systematic review.
* *Selection Criteria:* Only RCTs of adults (at least 18 years old) with non-specific LBP undergoing massage interventions were included in the analysis. LBP was classified as acute (<4 weeks), sub-acute (4-12 weeks) or chronic (>12 weeks). “Massage was defined as soft-tissue manipulation using the hands or a mechanical device.”6(pg.1) Two authors independently screened abstracts to determine if studies met inclusion criteria; a third review author handled disagreements.
* *Data Collection:* The same two authors who selected included studies extracted data independently following Cochrane methodological procedures. A third author was consulted on disagreements. Extracted data was double-checked by each author. The following data was extracted: “methods of patient recruitment, age of patients, country, ethnicity, work status, number of patients included in each RCT, length of LBP episode, causes of LBP, previous surgery, types of interventions, number of sessions, types of outcomes measures, timing of outcome assessment, funding for the study, statistical analyses and the authors’ conclusions about the effectiveness of the interventions.”6(pg.8)
* *Quality of Evidence:* Two authors independently assessed the risk of bias using the guidelines recommended by the CBN group and the Cochrane Handbook for Systematic Review of Intervention. The Grades of Recommendation, Assessment, Development and Evaluation (GRADE) was used to evaluate the quality of evidence for each included study.
* *Measuring Treatment Effect:* Continuous data with identical outcome measures were reported as weighted mean differences (WMD). Continuous data with different outcome measures were reported as standardized mean differences (SMD).
* *Test for Heterogeneity*: A random-effects model was used for all meta-analyses.
* *Publication Bias:* Funnel plots were used to assess publication bias.
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| **Setting** |
| Included studies performed interventions at university departments of physical therapy, health maintenance organizations, massage therapy offices, hospitals, rehabilitation facilities, and outpatient clinics. |
| **Participants** |
| * 25 RCTs (n = 3,096) performed in 13 different countries were included in this systematic review. Six of these RCTs were excluded from meta-analysis because they either compared massage techniques or did not report mean or standard deviation values.
* All participants were older than 18 years and had non-specific LBP. LBP was defined “as pain localized from the costal margin or 12th rib to the inferior gluteal fold.”6(pg.7) Additionally, LBP was classified as acute (< 4 weeks), sub-acute (4-12 weeks) or chronic (>12 weeks).
* Participants were similar at baseline with exceptions of pain duration, previous treatments, and age. Demographic information for individual studies were reported but mean demographic information was not reported.
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| **Intervention Investigated** |
| *Control* |
| * Comparison groups were defined as inactive controls (sham therapy, waiting lists or no treatment) or active controls (manipulation, mobilization, TENS, acupuncture, traction, relaxation, physical therapy, exercises or self-care education). Specific information about control interventions varied between studies.
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| *Experimental* |
| * Massage interventions applied varied from trial to trial. The majority of studies applied massage with hands; three studies used a mechanical device.
* Types of massage interventions included Swedish massage, deep-tissue massage, trigger and pressure point, and Thai massage.
* Frequency of treatments ranged from one to three times per week with individual treatment sessions lasting 10 minutes to one hour. The length of the intervention period was one day to five months.
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| **Outcome Measures** (Primary and Secondary) |
| * *Primary Outcomes:* Pain and back-specific functional status were the primary variables of interest. Pain and back-specific functional status were assessed in the short-term (≤ six months) and long-term (> 6 months). Sub-acute LBP (4 -12 weeks) and chronic LBP (>12 weeks) data were analysed together. Acute LBP (<4 weeks) was analysed separately. Outcomes were compared between the massage intervention group and inactive or active controls. Data about adverse effects was also extracted.
* *Secondary Outcomes:* Secondary outcome measures included “overall improvement, patient satisfaction, quality of life and work-related status.”6(pg.7) Data was extracted but analysis was not reported on these measures.
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| **Main Findings** |
| Because this systematic review with meta-analysis involved many statistical comparisons, only the primary comparison of massage versus inactive (sham therapy, waiting lists or no treatment) and active (manipulation, mobilization, TENS, acupuncture, traction, relaxation, physical therapy, exercises or self-care education) controls for sub-acute LBP + chronic LBP on pain outcomes are reported in this appraisal as they relate to the clinical question. *Inactive Controls** Seven studies (n = 761) provided data for pain in the short-term for massage versus inactive controls. Pooled standard mean difference (SMD) was -0.75 [95% CI -0.90, -0.60], p < 0.00001, I2 = 0%. These findings indicated that massage might be more effective at reducing pain in those with sub-acute or chronic LBP compared to inactive controls in the short-term.
* Three trials ( n = 615) reported data for pain in the long-term for massage versus inactive controls. Pooled SMD was 0.02 [95% CI -0.15, 0.18], p = 0.82, I2 = 0%. The results suggest that massage may not be more effective at reducing pain in those with sub-acute or chronic LBP compared to inactive controls in the long-term.

*Active Controls* * 12 trials (n = 964) assessed pain in the short-term for massage versus active controls. Pooled SMD was -0.37 [95% CI -0.62, -0.13] p = 0.003, I2 = 68%.
* Five studies reported data for pain in the long-term for massage versus active controls. Pooled SMD was -0.04 [95% CI -0.80, -0.01], p = 0.05, I2 = 86%.
* The small effect sizes observed in these meta-analyses suggest that massage may not be effective at reducing sub-acute and chronic LBP in the short- or long-term compared to active controls.
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| **Original Authors’ Conclusions** |
| Meta-analyses revealed significant differences in pain when comparing massage to inactive controls at short-term follow-up. These differences were also observed when comparing massage to active controls at both short- and long-term follow-up. However, the authors have “very little confidence” that massage is effective at treating LBP.6(pg.20) The authors attribute this conclusion to the low quality of included studies, small effect sizes and high heterogeneity. |
| **Critical Appraisal** |
| **Validity** |
| * AMSTAR analysis revealed a score of 11/11.
* A strength of this review was that all included studies were randomized clinical trials individually assessed by two authors. Additionally, various databases (i.e. PubMed, MEDLINE, EMBASE, CINAHL, CENTRAL, LILACS, Index to Chiropractic Literature, and Proquest Dissertation Abstracts) were searched to produce the included studies.
* To account for heterogeneity in treatment design across included studies, primary outcome measures were reported as SMD.
* A random-effects model was used as recommended by the CBN Editorial Board.
* Funnel plots for all included trials did not indicate publication bias or systematic review heterogeneity.
* Systematic data was compared to previous reviews and included 12 new RCTs.
* Comparison groups (active vs. inactive controls) were grouped together which could have biased outcomes.
* This review assessed massage as one entity though there were differences in massage technique, duration, number of treatment sessions, etc.
* Authors grouped sub-acute and chronic LBP together, which may have biased outcomes as individuals in each population may respond differently to massage interventions.
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| **Interpretation of Results** |
| Based on this recent systematic review with meta-analysis, massage may be effective in the short-term compared to inactive controls but does not show promise for the long-term in patients with sub-acute or chronic LBP. In the short-term compared to inactive controls, statistical significance was observed indicating that the differences in pain after treatment due to chance is small. Additionally, the large effect size suggests that these differences may be of great enough magnitude to be clinically important. In the long-term compared to inactive controls, poor statistical significance and small effect size indicate that differences observed were likely due to chance and that these differences were not clinically meaningful. Additionally, massage is not effective for LBP when compared to active controls for both short- and long-term. Though results were statistically significant for each follow-up, small to moderate effect sizes indicate that results are not important clinically. Differences in massage techniques are a significant limitation to this study as it is possible that different techniques may uniquely affect pain outcomes.  |

**(2) Description and appraisal of A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain by van Middelkoop et al. (2011)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The purpose of this systematic review with meta-analysis was to determine the effectiveness of physical and rehabilitation interventions such as exercise and massage on chronic low back pain (LBP). Effectiveness of other therapies such as back school, transcutaneous electrical nerve stimulation, low-level laser therapy, patient education, behavioural treatment, traction, multidisciplinary rehabilitation, lumbar supports, and heat/cold therapy were also explored.  |
| **Study Design** |
| * The study is a systematic review with meta-analysis that utilized data from eligible randomized controlled trials.
* *Search Strategy:* Literature searches were conducted in MEDLINE, EMBASE, CINAHL, CENTRAL, and PEDro until December 2008. Additionally, Cochrane reviews of the 11 aforementioned interventions were screened. Searches were limited to English, Dutch and German. Specific search terms were not provided.
* *Selection Criteria:* Three authors independently screened abstracts to determine if they met inclusion criteria. Those that fulfilled inclusion criteria then underwent a full text screen independently by two authors. A third author was consulted on disagreements.
* *Data Collection:* Two authors extracted data independently. Data pooled included study characteristics (number of participants, gender, age, setting, and duration of complaints), intervention characteristics (type, frequency, duration, co-interventions and control interventions), and outcome characteristics (outcome measures, instruments and scores). However, these were not explicitly presented in the review.
* *Quality of Evidence:* GRADE was used to evaluate the quality of evidence for each included study. Risk of bias was assessed using the Cochrane Back Review Group 11-item criteria list. Two reviewers assessed risk of bias and disagreements were discussed at a consensus meeting. Studies that fulfilled at least six of the 11 criteria were considered to have a low risk of bias.
* *Publication Bias:* Funnel plots were used to assess publication bias.
* *Test for Heterogeneity*: A Chi-square test was used to assess heterogeneity.
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| **Setting** |
| A location of each included study was not explicitly stated in this review. Subgroups of studies were completed in inpatient and outpatient rehabilitation facilities. |
| **Participants** |
| * In this systematic review with meta-analysis, 83 RCTs yielded a total of 8,816 participants. The majority of participants were included in the exercise studies, n = 3,957.
* Only six of the 83 RCTs, directly address the clinical question. For this reason, these six studies comparing exercise to no treatment were included in this appraisal. Five RCTs examined the effect of exercise on pain intensity immediately following treatment. Two RCTs examined the effect of exercise on pain intensity at 6-month follow-up. Smeets et al (2006) reported results for both time frames. RCTs in this systematic review with meta-analysis comparing exercise to massage were excluded from the appraisal because massage interventions were paired with other modalities such as ultrasound and laser therapy. The clinical question focuses on the effectiveness of massage as a single intervention.
* Participants (n = 405) in the included six studies were between the ages of 18 and 70 and the majority of patients were female. No specific data was reported comparing baseline demographics.
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| **Intervention Investigated** |
| *Control* |
| * Participants did not receive any exercise intervention during the treatment period. Participants were considered waiting list controls and received treatment after the study was completed.
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| *Experimental* |
| * Exercise therapy was defined as a series of specific movements designed to improve physical health. In the included studies, lumbar extension exercises, aerobic exercises, light resistance exercises and Pilates were applied. Duration, magnitude and frequency of exercises varied among groups. For example, in the Smeets et al (2006) RCT, those in the exercise group completed aerobic training with dynamic-static strengthening exercises. Aerobic training was completed on a stationary bicycle and included a 5-minute warm-up, 20 minutes of cycling at 65 to 80% of maximum heart rate, and a 5-minute cool down. Following aerobic training, participants performed three dynamic-static exercises at 70% their one-repetition maximum. Participants performed 3 x 15-18 repetitions “of leg extension while sitting on knees and hands, trunk lifting and lifting both legs while lying prone.”10(7:5). This intervention was applied three times a week for 10 weeks.
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| **Outcome Measures** (Primary and Secondary) |
| Eighty-three studies were included in the systematic review. Only six RCTs directly addressed the clinical question, which studied the effects of exercise on low back pain intensity.* *Primary Outcomes:* Pain intensity and physical function status were the primary outcome measures. Because the clinical question specifically addresses pain intensity, physical function status was excluded.
* Of the six included RCTs in this appraisal, pain intensity was reported immediately after treatment for five studies and at 6-month follow-up for two studies. The Smeets et al (2006) RCT reported pain intensity for both time frames. Pain outcome measures varied across studies. The West Haven-Yale Multidimensional Pain Inventory, McGill Pain Questionnaire, Borg CR-10 Scale, and Visual Analog Scale for Pain were utilized. The frequency at which pain outcomes were taken in each study was not reported.
* For the RCTs that studied physical function status, the Sickness Impact Profile (SIP), Roland-Morris Disability Questionnaire (RDQ), Oswestry Low Back Disability Questionnaire and SF-12 were used.
* *Secondary Outcomes:* No secondary outcomes were reported.
 |
| **Main Findings** |
| * Because pain outcomes were continuous data and varied across different studies, all pain outcome measures were pooled together and results were reported as weighted mean differences (WMD).
* The pooled sample revealed an overall mean difference for pain intensity immediately following treatment of -4.51 [-9.49, 0.47] at a 95% confidence interval (CI) for exercise vs. no intervention. The overall effect reflected a p value of 0.08. Results for the test of heterogeneity showed I2 = 27% with a p-value of 0.24.
* The pooled sample revealed an overall mean difference for pain intensity at 6-month follow-up of -16.46 [-44.48, 11.57] at a 95% CI for exercise vs. no intervention. The overall effect reflected a p value of 0.25. Results for the test of heterogeneity showed I2 = 93% with a p-value of 0.0002.
* Overall, there were no differences between groups receiving exercise and no treatment immediately after intervention or at 6-month follow-up. Individual studies did show a trend favouring exercise over no treatment immediately following intervention (Risch 1993) and at 6-month follow-up (Alexander 2001).
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| **Original Authors’ Conclusions** |
| * Results depict no statistically significant difference in pain reduction when participants engage in exercise compared to individuals that do not undergo treatment. However, due to the conflicting effectiveness of exercise of individual studies and lack of quality evidence, the authors conclude that exercise can be used as a conservative treatment for CLBP.
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| **Critical Appraisal** |
| **Validity** |
| * AMSTAR analysis revealed a score of 10/11.
* A strength of this review was that all included studies were randomized clinical trials individually assessed by two authors. Additionally, various databases (i.e. MEDLINE, EMBASE, CINAHL, CENTRAL, and PEDro) were searched to produce the included studies. Each study’s level of evidence was assessed using the 11-items recommended by the Cochrane Back Review Group (CBRG).
* Of the six included studies in this appraisal, only one RCT (Smeets 2006) was classified as having a low risk for bias, meeting nine of the suggested 11 CBRG criteria for internal validity. The remaining studies failed to report or had poor randomization, compliance, dropout rates and/or intention-to-treat analysis.
* In all included studies, participants and researchers administering the exercise interventions were not blinded and as such could have influenced the outcomes.
* Heterogeneity analysis showed moderate concern for heterogeneity I2 = 27% (P = 0.24) for exercise vs. no treatment immediately following intervention. Heterogeneity analysis showed considerable concern for heterogeneity I2 = 93% (P = 0.0002) for exercise vs. no treatment six months following intervention.
* Heterogeneity may be attributed to the difference in exercise interventions and the risk of bias in individual studies.
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| **Interpretation of Results** |
| Data for the meta-analyses were derived from six RCTs in which the level of evidence was low for all studies except one. Individual studies (Risch 1993 and Smeets 2006) depict trends favouring exercise over no intervention. Overall, however, results from the meta-analyses suggest that exercise is not superior to no intervention in reducing pain outcomes in patients with chronic low back pain immediately after treatment and at 6-month follow-up. This is supported by an overall mean difference and effect of -4.51 [-9.49, 0.47] and p = 0.08; -16.46 [-44.48, 11.57] and p = 0.25, respectively. Given the poor statistical and clinical significance, results should be interpreted with caution. |

**(3) Description and appraisal of A randomized controlled trial investigating the efficiency of musculoskeletal physiotherapy on chronic low back disorder by Goldby et al. (2006).**

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| **Aim/Objective of the Study/Systematic Review:** |
| The purpose of the randomized controlled trial was to determine the effectiveness of spinal stabilization exercises and manual therapy on chronic low back disorder. Chronic low back disorder is characterized by low back pain and disability. |
| **Study Design** |
| * Single-blinded randomized controlled trial.
* Primary care providers or hospital consultants recruited participants already receiving treatment for CLBP during March 1998 until November 1999. Follow-up data was collected until November 2001.
* “Numbers for the study were calculated based on a clinically relevant difference of 30% between groups at a power of 90%, for a level of significance of P < 0.05.”4(pg.1085)
* A researcher screened participants. A research assistant, blinded to group allocation, collected demographic and outcome measure data. Eighteen physiotherapists whose treatments were guided by the researcher performed therapy interventions.
* Before being allocated to treatment groups, participants were stratified based on patient age, gender, and anatomic site of referral. Age was separated into older or younger than 40 years, gender was classified as male or female, and anatomic site of referral was stratified to either the buttock, thigh or below the knee. From this process, a (2 x 2 x3) 12 strata randomization was created whose blocks of random numbers were computer-generated.
* After stratification, participants were randomly allocated to a spinal stabilization (40%), manual therapy (40%) or education/control (20%) group.
* Outcome measures were collected at baseline, 3-month, 6-month, 12-month and 24-month follow-ups.
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| **Setting** |
| All interventions were performed at two of St. George’s Hospital physiotherapy clinics in London, England.  |
| **Participants** |
| * 346 individuals with non-mechanical CLBP were initially recruited for the RCT.
* 10% were lost during three to 12-month follow-up. 50% were lost between the 12 to 24-month follow-up. As such, data analysis for demographic and clinical data was only reported up until 1-year follow-up.
* Participants were either withdrawn or dropped from the trial because of poor attendance (attended ≤ 1 treatment session), misfiling of data, or accidental prescription of spinal stability exercises in the manual therapy group.
* A carry forward analysis was used to account for the high drop out rate in the education/control group (only 28 of 40 participants were retained at 1-year follow-up).
* After accounting for dropouts, 213 individuals completed the study.
* Participants were similar at baseline for the following measured variables; age, gender, mean length of chronic low back pain, employment, ethnicity and medication use.
* Attendance varied among treatment groups. The spinal stabilization group attended 7.6(± 2.9) and the manual therapy group attended 5.3 (± 2.1).
* Mean age of participants was 42 years old. 68% were female. The average length of chronic low back pain was 11.72 years.
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| **Intervention Investigated** |
| *Control* |
| * Participants were provided a “Back in Action” educational booklet for home use. The “Back in Action” booklet has demonstrated to be ineffective in treating individuals with CLBP.
* Participants attended Back School, a three-hour group question and answer session. “The class covered anatomy, biomechanics and lifting, pathologies, and advice on education, exercise and general fitness.”4(pg.1085)
* Information on who led Back School was not indicated.
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| *Experimental* |
| *Spinal Stabilization Group** Participants attended 10, 1-hour group sessions over 10 weeks.
* The same two physiotherapists led all sessions.
* During each session, participants rotated between exercise stations. Exercises targeted the tranversus abdominis, multifidus, the pelvic floor and diaphragm muscles. The magnitude, duration, and frequency of exercises were not provided.
* Before and after each session, participants watched a video on how muscles contribute to the stability of the spine.
* Participants completed Back School at the end of the 10 weeks.

*Manual Therapy Group** Physiotherapists provided manual therapy interventions though specific techniques were not mentioned.
* Participants completed up to 10 manual therapy sessions at the discretion of their treating physiotherapist.
* Physiotherapists were restricted from prescribing exercises for the muscles targeted in the spinal stabilization group.
* Participants completed Back School at the end of the intervention.
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| **Outcome Measures** (Primary and Secondary) |
| The research assistant at baseline and at all follow-up visits completed all outcome measures.*Primary Outcomes** Pain: Intensity was graded on the 0-100 numerical grading scale (NRS) for the back and leg. A pain diagram was used to record the site of pain.

*Secondary Outcomes** Disability, Handicap, and Impairment: The Oswestry Disability Index was used to assess disability. Scores are reported as a percentage. The Low-Back Outcome Scale was used to measure handicap. Possible scores are between 0 and 65 where a higher score indicates a better patient status. Lumbar flexion range and a timed walking test were used to assess impairment.
* Quality of Life and Dysfunction: The Nottingham Health Profile was used to measure quality of life. Possible scores are between 0 and 100 where a higher score indicates greater perceived distress. A dysfunction score was developed via a primary component analysis. The dysfunction score was created from the NRS for back and leg pain, Oswestry Disability Index and Nottingham Health Profile outcomes.
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| **Main Findings** |
| * Because the clinical question relates to low back pain intensity, results for other outcomes were excluded from this appraisal.
* Within group results demonstrated significant reductions (P < 0.001) in low back pain for both the spinal stabilization and manual therapy groups at all follow-up sessions. There were no significant reductions in low back pain for the control/education group.
* Mean scores for back pain NRS (0-100), standard deviations and standard errors were reported in the RCT. Relative mean differences with a 95% CI were manually calculated, comparing the spinal stabilization group to the manual therapy group.
* There was a significant difference between low back pain favouring the spinal stabilization group at baseline and 6-month follow up; -9.92 [-18.26, -1.48] and -14.00 [-23.38, -4.72], respectively. 22.59
* Calculated mean differences between the spinal stabilization and manual therapy groups for 3-month and 12-month follow-ups were -6.57 [-15.29, 2.15] and -5.94 [-15.58, 3.70], respectively.
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| **Original Authors’ Conclusions** |
| The authors report that spinal stabilization exercises or manual therapy can significantly reduce CLBP up to 12-months after treatment. A spinal stabilization program applied over 10-weeks is more effective than manual therapy at reducing CLBP intensity months after treatment is stopped. As such, authors conclude that spinal stabilization rehabilitation can be used to reduce chronic low back pain intensity.  |
| **Critical Appraisal** |
| **Validity** |
| * JADAD analysis revealed a score of 5/5.
* The research assistant collecting demographic and outcome data was blinded to participant group allocation.
* Participants and physiotherapists were not blinded to the interventions and may have biased the outcomes.
* Study investigators attempted to recruit a number of participants such that a 30% between groups for each outcome measure represented a clinically significant difference. This was done at a power of 90% and P < 0.05. However, this was not observed with any comparison for pain intensity suggesting that the study may have been underpowered for the NRS outcome.
* A carry forward analysis was used to address the high drop out rate in the control/education group.
* Participants in the manual therapy group did not receive the same number of intervention sessions as those in the spinal stabilization group, which could have introduced bias.
* Authors reported reasons with associated number of participants that dropped from the study.
* Participants were recruited by physicians/consultants treating individuals with CLBP and as such excluded individuals in the population not currently seeking treatment for CLBP.
* Specific information about exercise interventions was not provided making it difficult to replicate the study.
* Participants in the manual therapy group were allowed to continue with their physiotherapy treatments as long as exercises were not targeting the muscles under study in the spinal stabilization group, therefore making it difficult to determine if manual therapy is effective alone.
 |
| **Interpretation of Results** |
| Based on the evidence provided in this article, spinal stabilization exercises and manual therapy should be used with caution to treat individuals with CLBP. Because patients included in this study were already receiving treatment for CLBP, it is difficult to determine if significant improvements in pain were solely due to the applied interventions. Spinal stabilization exercises demonstrated significant differences when compared to manual therapy at 6-months post-treatment. However, since the spinal stabilization group was favoured at baseline, the efficacy of spinal stabilization over massage therapy should be interpreted carefully.  |

**EVIDENCE SYNTHESIS AND IMPLICATIONS**

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| Based on the “best evidence” reviewed in this appraisal, it is unclear whether spinal stabilization exercises or massage are clinically effective at improving pain intensity in those with CLBP. When drawing this conclusion, more weight was given to the systematic reviews compared to the included RCT. Current evidence reports conflicting findings. In a RCT completed by Goldby et al, investigators demonstrated that both exercise and manual therapy reduce CLBP intensity in the short-term but that exercise was more effective than massage. In a systematic review by van Middelkoop, researchers demonstrated that exercise was not effective at reducing CLBP intensity. In a systematic review completed by Furlan et al, authors demonstrated that massage was effective at reducing CLBP in the short-term versus inactive controls (sham therapy, waiting lists or no treatment) but not effective when compared to active controls (manipulation, mobilization, TENS, acupuncture, traction, relaxation, physical therapy, exercises or self-care education). Differences in findings can be attributed to a number of methodological insufficiencies. Each included study defined “chronic low back pain,” “short-term,” and “long-term” differently which made it difficult to truly compare results. Individual studies included in the systematic reviews were of low quality secondary to poor randomization, blinding, and compliance. The included RCT only considered individuals with CLBP currently seeking treatment. Additionally, individual studies varied in the type of exercises and massage interventions that were applied. This was a significant limitation across all included trials. Given the results presented in this appraisal, clinicians should use caution when solely applying these interventions in practice. However, though *overall* results were not clinically significant, individual studies did show trends favouring both exercise and massage for managing CLBP intensity in the short-term. As such incorporating lumbar extension exercises, aerobic exercises, light resistance exercises, deep-tissue massage and/or trigger and pressure point may help reduce pain in patients with CLBP. Therapists should use their clinical judgement, incorporating patient presentation and performing frequent evaluations, when applying these interventions. This approach may be utilized in the aforementioned clinical scenario. In future research, RCTs with large sample sizes and methodological rigor should compare the effectiveness of exercise and massage on CLBP intensity. Addressing type, duration, magnitude and frequency of each applied therapy is also needed to determine the most effective and specific intervention. Future studies should determine the effectiveness of each intervention alone and that of the interventions combined. Additionally, CLBP intensity should be assessed at both short-term and long-term follow-up. These time frames should be defined. Going forward, investigators should also agree upon what constitutes “chronic low back pain.” Specifics about pain duration and location of pain would make it easier to generalize findings.  |

**REFERENCES**

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| (1) Andrusaitis SF, Brech GC, Vitale GF, Greve JM. Trunk stabilization among women with chronic lower back pain: a randomized controlled, and blinded pilot study. *Clinics (Sa Paulo).* 2011;66(9). (2) Cairns MC, Foster NE, Wright C. Randomized controlled trial of specific spinal stabilization exercises and conventional physiotherapy for recurrent low back pain. *Spine (Phila Pa 1976).* 2006;31(19):E670-81.(3) Cherkin DC, Sherman KJ, Kahn J, Wellman R, Cook AJ, Johnson E, Erro J, Delaney K, Deyo RA. A comparison of the effects of 2 types of massage and usual care on chronic low back pain: a randomized, controlled trial. Ann *Intern Med.* 2011;155(1):1-9.(4) Goldby LJ, Moor AP, Doust J, Trew ME. A randomized controlled trial investigating the efficiency of musculoskeletal physiotherapy on chronic low back disorder. *Spine (Phila Pa 1976).* 2006;31(10):1083-93.(5) Franca FR, Burke TN, Hanada ES, Marques AP. Segmental stabilization and muscular strengthening in chronic low back pain: a comparative study. *Clinics (Sao Paulo).* 2010;64(10):1013-7.(6) Furlan AD, Giraldo M, Baskwill A, Irvin E, Imamura M. *Cochrane Database Syst Rev*. 2015;9:CD001929. [Epub ahead of print].(7) Kankaanpaa M, Taimela S, Airaksinen O, Hanninen O. The efficacy of active rehabilitation in chronic low back pain. Effect on pain intensity, self-experienced disability, and lumbar fatigability. *Spine (Phila Pa 1976).* 199;24(10):1034-42.(8) Moussouli M, Vlachopoulos SP, Kofotolis ND, Theodoraski Y, Malliou P, Kellis E. Effects of stabilization exercises on health-related quality of life in women with chronic low back pain. *J Phys Act Health*. 2014;11(7):1295-303. (9) Smith BE, Littlewood C, May S. An update of stabilisation exercises for low back pain: a systematic review with meta-analysis. BMB *Musculoskelet Disord*. 2014;15:416.(10) Smeets RJ, Vlaeyen JW, Hidding A, Kester AD, van der Heijden GJ, van Geel AC, Knottnerus JA. Active rehabilitation for chronic low back pain: cognitive-behavioral, physical, or both?First direct post-treatment results from a randomized controlled trial. *BMC Musculoskelet Disord.* 2006;7:5. (11) Van Middelkoop M, Rubinstein SM, Kuijpers T, Verhagen AP, Ostelo R, Koes BW, van Tulder MW. A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. *Eur Spine J.* 2011;20(1):19-39.(12) Violante FS, Mattioli S,Bonfigiloli R. Low-back pain. *Handb Clin Neurol*. 2014;131:397-410. |