Critique author	Linda Metzger

Bibliographic Data	
Authors	Gert Bronfort, Michele J. Maiers, Roni L. Evans, and et al.
Title	Supervised exercise, spinal manipulation, and home exercise for chronic low back pain(LBP): a randomized clinical trial
PMID	21622028
Citation	The Spine Journal 11 (2011) 585–598.
Other information if relevant	The trial was registered on ClinicalTrials.gov NCT00269347.

Methods	
Aim of study	To examine the relative short- and long-term efficacy of high dose, supervised low-tech trunk exercise and chiropractic spinal manipulative therapy (SMT) for the treatment of LBP of at least 6-week duration and to compare the two interventions to a short course of home exercise.
Design	Assessor single-blinded randomized controlled trial

Participants	
Population from which participants are drawn	Participants were recruited principally through local newspaper advertisements, community posters, and postcard mailings.
Setting (location and type of facility)	Individual homes and chiropractic clinics
Age	adults 18 years of age to 65 years, mean age 45.1 years
Sex	120 men, 181 women, total 301 at baseline
Total number of participants for whom outcome data were reported	At the co-primary endpoint of 12 weeks, 282 (94%) participants were analyzed using intention-to-treat analyses and at 52 weeks, 245 (81%) participants were analyzed. The number tested at follow-ups was not significantly different between groups.
Inclusion criteria	Individuals aged 18 to 65 years who had a primary complaint of mechanical LBP of at least 6-week duration with or without radiating pain to the lower extremity.
Exclusion criteria	Previous lumbar spine fusion surgery, progressive neurological deficits, aortic or peripheral vascular disease, pain scores of less than 3 (0–10 scale), pending or current litigation, or ongoing treatment for back pain by other health care providers.
Other information if relevant	Groups were comparable on most baseline sociodemographic, clinical symptom characteristics, and outcome measure scores. The median duration of back pain was 5 years in all 3 groups.

Intervention Groups

Group 1	
Group name	Supervised exercise therapy (SET) group
Number in group	100 at baseline

Description of intervention	The main focus of the program was on the low back and abdominal musculature and included dynamic trunk strengthening exercises (trunk extensions and leg extensions) and abdominal exercises using low-tech methods, including warm-up and stretching. High dose one on-one supervised exercises were individualized in terms of intensity (e.g. repetitions and difficulty) according to the patients' abilities. The program consisted of 20, 1-hour sessions (approximately twice per week) with exercises emphasizing a high number of repetitions (two to three sets of 15–30 repetitions for each exercise) and progressive increase in muscle load.
Duration of treatment period	12 weeks
Co-interventions if reported	none
Additional information if relevant	

Group 2	
Group name	Spinal manipulative therapy (SMT)
Number in group	100 at baseline
Description of intervention	Visits typically occurred 1 to 2 times per week and lasted 15 to 30 minutes, but the chiropractor determined the frequency and number of treatments for each participant. Short-lever, low-amplitude, high-velocity SMT was applied to specific areas of the low back and sacroiliac regions.
Duration of treatment period	12 weeks
Co-interventions if reported	A few minutes of soft-tissue massage, ice, or heat.
Additional information if relevant	

Group 3	
Group name	Home exercise and advice (HEA) group, control group
Number in group	101 at baseline
Description of intervention	Instructions for individualized self-care were provided during two, 1-hour sessions and included advice and instruction on the use of ice and heat, ergonomic recommendations for home and work, and demonstration of good lifting techniques. Simple, low-dose stretching and strengthening exercises, including lumbar extension, bridging, and abdominal crunches, were demonstrated and practiced with patient participation. A book and laminated cards describing these exercises were given and subjects were encouraged to perform them at home on a daily basis. One provider follow-up visit was made.
Duration of treatment period	12 weeks
Co-interventions if reported	none
Additional information if relevant	

Primary outcome	
Outcome name and criteria for definition	The primary outcome was typical level of patient rated back pain over the last week measured using a 0–10 numerical rating scale measured 12 and 52 weeks after baseline. The minimal clinically important difference (MCID) in pain between groups in both the short and long term was at least a medium effect size.
Time points measured and/or reported	Two baseline assessments and at 4, 12, 26, and 52 weeks after randomization by a blinded assessor.
Differences between groups	All three groups demonstrated improved clinically meaningful outcomes in back pain reduction over the 12-week treatment period. At the 12 week follow-up, the SET and SMT groups reduced their pain score from baseline by 2.5 points and the HEA group reduced it by 2.0 points. At the 52 week follow-up, pain reductions were similar to the 12 week scores with a slightly greater reduction in the HEA group. ITT-analyses at both the short- and long-term, showed no statistically significant or clinically meaningful differences in treatment effects between any of the 2 by 2 group comparisons for patient-rated pain outcomes.
Additional information if relevant (adverse effects, no. tested at follow-up, adherence	Ten participants reported side effects that were transient in nature and nonserious. Six of them required rescue pain medication. At the co-primary endpoint of 12 weeks, 282 (94%) participants were analyzed using intention-to-treat analyses and at 52 weeks, 245 (81%) participants were analyzed. The number tested at follow-ups was not significantly different between groups. Overall, adherence to study interventions was high with 96% of the SMT group, 86% of the SET group, and 96% of the HEA group attending the predefined compliance threshold (80% of their treatment visits). The average number of spinal manipulation treatments in the SMT group delivered by chiropractors was just over 16.
Additional information if relevant	The overall attrition rate was 19%, with no differences in attrition rates among treatment groups.

Secondary outcomes	
Outcome name and criteria for definition	The secondary outcome measures were: disability, general health status (SF-36), frequency of medication use, global improvement, and satisfaction. Several trunk performance measures were assessed.
Time points measured	Two baseline assessments and at 4, 12, 26, and 52 weeks after randomization by a blinded assessor.
Differences between groups	All three groups demonstrated improved outcomes over the 12-week treatment period. In the short and long-term, there were no statistically significant differences in treatment effects for any of the patient-rated individual outcomes between any of the 2 by 2 group comparisons, except for satisfaction, which was statistically significant ($p<0.01$. Those in the home exercise group were least satisfied, those in the SET group were most satisfied, and those in the spinal manipulation group were in between. In the overall test for differences between groups (MANCOVA), the small advantage of the supervised exercise group was significant after 12, 26 and 52 weeks of treatment when compared with the home exercise group ($p<0.01$).
Additional information if relevant	

Conclusions	
Key Conclusions Of Study Authors	- The results of this study reported that both the short- and long-term differences between groups for patient-rated pain, disability, global improvement, general health status, and medication use consistently favored the supervised exercise group over the two other groups, but the differences were relatively small and not statistically significant for those outcomes. - At Weeks 12, 26, and 52, there was a clear trend for a greater proportion of supervised exercise patients reported 50% or more improvement in all three outcome measures. - This study demonstrated that chronic LBP patients who received supervised trunk exercises were significantly more satisfied with their treatment and follow-up periods than chiropractic spinal manipulation and home exercise groups, and also experienced the greatest gains in trunk strength and endurance at the end of treatment. - Although the high-dose supervised exercise group demonstrated significantly greater gains in trunk strength and endurance, these gains did not translate into significantly better patient-rated outcomes when compared with the low-dose home exercise group. - The spinal manipulation and home exercise groups had very similar short- and long-term outcomes. - For all 3 treatment groups, outcomes improved during the 12 weeks of treatment. All three treatment regimens were associated with mean changes of 40% to 50% in pain and disability at 12 weeks and 12 months post-treatment, which is a magnitude of effect comparable to or larger than seen in similar trials. - Given the lack of clear superiority of one treatment over another for chronic LBP, individual treatment decisions will best be made by choosing from a variety of modestly effective treatment options, guided by patient preferences and expectations, the clinician's experience, and considerations regarding costs and risks. - Given that the 3 interventions compared in this trial showed somewhat similar outcomes, the costs of these treatments are of interest and may need to be addressed. - Given the multifactorial and biopsychosocial nature of chronic LBP, it is highly unlikely that a single therapeutic approach will be the optimal strategy for most patients. The conduct of additional trials that evaluate heterogeneous back pain populations and monotherapies are unlikely to lead to better strategies for the management of chronic LBP. - New technology is making it possible to measure the activity of central pain processing centers in the brain. New studies that consider these cortical effects of existing treatment regimens, in addition to new brain targeted treatments, might show a new area of promise for chronic LBP research.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	The project statistician generated a randomization list using randomly mixed permuted blocks of different sizes.
Allocation concealment *(selection bias)*	Low	The treatment codes were sequentially numbered and sealed in opaque envelopes to conceal allocation from the study team.
Blinding of participants and personnel *(performance bias)*	High	Because of the nature of the interventions, it was not possible to blind participants or treatment provider.The lack of blinding does not prejudice the conclusions.
Blinding of outcome assessment *(detection bias)*	Low	All outcome measures were obtained by an investigator who was unaware of group allocation. The allocation sequence was concealed from the assessor.
Incomplete outcome data *(attrition bias)*	Low	The follow-up rate at 12 weeks was 94% for all outcomes. All participants lost to follow-up were included in the ITT analysis.
Selective outcome reporting? *(reporting bias)*	Low	The trial was registered with clinicaltrials.gov
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	Not reported.	
Possible conflicts of interest for study authors	Three authors provided consulting, received royalties, and/or research and fellowship support from the several pharmaceutical or biomedical companies.	
Notes:		

Comments by DOWC staff

- The findings of this study showed that 12 weeks of supervised high-dose exercise, spinal manipulative therapy, or low-dose home exercise with advice are all equally effective for reducing pain in the short- and long-term (one year) in those who have chronic low back pain.

- The results support a beneficial effect of all 3 interventions on pain for treating chronic LBP. All three groups demonstrated improved clinically meaningful outcomes in back pain reduction over the 12-week treatment period. At the 12 week follow-up, the SET and SMT groups reduced their pain score from baseline by 2.5 points and the HEA group reduced it by 2.0 points.

- The results for the between group differences on the pain scale are not statistically significant and do not show any clinically meaningful differences between the 3 treatment regimens.

- Since the community recruited participants were not typically seeking or receiving care for their back pain problems, it is unclear whether the conclusions are generalized to those who are seeking care for their back pain.

- The participants in the SET and SMT groups had an additional fourteen or fifteen visits with their treatment providers compared with the control group (HEA) who only had 2 visits which results in a potential risk of attention bias. These non-specific effects of added provider attention in the SET and SMT groups could have influenced the results in favor of these treatment groups that would overestimate the treatment effect sizes.

- Study strengths included the use of an RCT design, a large sample size with adequate statistical power to detect clinically meaningful effects, trial registration, a pre-specified protocol, a defined primary outcome, design features known to minimize bias such as assessor blinding and concealed allocation, an intention-to-treat analysis, a low drop-out rate at 12 weeks, long-term follow-up beyond the end of treatment, and high compliance to treatment.

- The main limitations of the study were lack of blinding of providers and patients, numerous secondary outcomes, the high number of treatment providers, and unequal matching of the control group to the other 2 interventions in format and time.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This adequate quality study provides some evidence that 12 weeks of supervised high-dose exercise, spinal manipulative therapy, or low-dose home exercise with advice are all equally effective for reducing pain in the short- and long-term (one year) in those who have chronic low back pain.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant
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