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Bibliographic Data	
Authors	Roni Evans, Gert Bronfort, Craig Schulz , and et al.
Title	Supervised Exercise With and Without Spinal Manipulation Performs Similarly and Better Than Home Exercise for Chronic Neck Pain
PMID	22024905
Citation	SPINE 2012 Volume 37, Number 11, pp 903–914.
Other information if relevant	The trial was registered on ClinicalTrials.gov NCT00269360.

Methods	
Aim of study	To evaluate the relative effectiveness of 3 treatment approaches to chronic neck pain, 1) high-dose supervised exercise combined with spinal manipulation, 2) high-dose supervised exercise alone, 3) and low dose home exercise and advice for chronic neck pain.
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 mass mailings in the Minneapolis/St. Paul, Minnesota area.
Setting (location and type of facility)	This study took place at the Wolfe-Harris Center for Clinical Studies at Northwestern Health Sciences University in Bloomington, Minnesota.
Age	adults 18 years of age to 65 years, mean age 46.3 years
Sex	75 men, 195 women, total 270 at baseline
Total number of participants for whom outcome data were reported	At 12 weeks, 237 (88%) participants were analyzed using intention-to-treat analyses and at 52 weeks, 199 (74%) participants were analyzed. The number tested at follow-ups was not significantly different between groups.
Inclusion criteria	18 to 65 years of age, primary complaint of mechanical, nonspecific neck pain (equivalent to grades I and II), pain duration of 12 weeks or more, and neck pain score of 3 or greater (0–10 scale).
Exclusion criteria	Previous cervical spine surgery, neck pain referred from peripheral joints or viscera, progressive neurological deficits, existing cardiac disease requiring medical treatment, blood clotting disorders, diffuse idiopathic hyperostosis, inflammatory or destructive tissue changes of the cervical spine, significant infectious disease or other severe disabling health problems, substance abuse, pregnant or nursing women, pending or current litigation, or ongoing treatment of neck pain by other health care providers.
Other information if relevant	Groups were comparable on most baseline sociodemographic, clinical symptom characteristics, and outcome measure scores. Differences between groups were noted for age, duration, and frequency of symptoms. These variables were factored in as covariates in the statistical analyses. The mean duration of neck pain was 9.4 years and was moderate in severity (5.6).

Intervention Groups

Group 1	
Group name	Supervised exercise therapy (ET) group
Number in group	89 at baseline
Description of intervention	The main focus of the program was neck (neck extension, flexion, and rotation) and upper body strengthening 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	Supervised exercise therapy combined with spinal manipulative therapy (ET+SMT)
Number in group	91 at baseline
Description of intervention	20 sessions of ET (as described above) preceded by a 15- to 20-minute session of spinal manipulation therapy (SMT) by a licensed chiropractor. Visits typically occurred 1 to 2 times per week, but the chiropractor determined the frequency and number of treatments for each participant. Focused mainly on manual SMT to the cervical and thoracic spines using low-amplitude, high-velocity SMT applied to specific joints of interest.
Duration of treatment period	12 weeks
Co-interventions if reported	A few minutes of soft-tissue massage
Additional information if relevant	

Group 3	
Group name	Home exercise and advice (HEA) group, control group
Number in group	90 at baseline

Description of intervention	Instructions for individualized self-care were provided during two, 1-hour sessions and included advice and instruction on simple low-dose stretching and strengthening exercises, including self-mobilization of the neck and shoulder joints, neck retraction, extension, flexion, rotation, and lateral bending motions, as well as scapular retraction, with no resistance, and ergonomic and posture recommendations for home and work, and demonstration of good lifting techniques. 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 neck pain measured using a 0–10 numerical rating scale. The minimal clinically important difference (MCID) in pain between groups was an eight percentage point difference.
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 neck pain reduction over the 12-week treatment period. At the 12 week follow-up, the ET+SMT group reduced their pain score from baseline by 3.3 points, the ET group reduced by 3.1 points, and the HEA group reduced it by 1.9 points. At 12 weeks, significant between-group differences were noted in favor of the ET + SMT and ET groups compared with HEA for pain ($P \leq 0.001$), but there was no significant difference between the ET+SMT and ET groups. The differences in patient rated pain between ET + SMT and HEA was 1.3 points ($P < 0.001$), and ET and HEA was 1.1 points ($P = 0.001$) at 12 weeks. At the 52 week follow-up, pain reductions did not persist in the ET+SMT and ET groups, but the reduction in the HEA group was identical to their reduction at 12 weeks. At 52 weeks, the advantage of the ET + SMT and ET groups compared with HEA disappeared, with no significant between-group differences for pain observed for all 3 groups.
Additional information if relevant (adverse effects, no. tested at follow-up, adherence	A greater number of patients in the 2 supervised exercise groups (65%–74% at 12 weeks and 51%–57% at 52 weeks) experienced the prespecified 2.5-point reduction in pain, compared with home exercise (42% at 12 wk and 41% at 52 wk). Side effects were more frequently reported in the 2 supervised exercise groups (ET + SMT = 90/91, ET = 86/89, HEA = 30/90; $P < 0.001$) and included muscle soreness, upper extremity symptoms, headache, back pain, jaw pain, nausea, and dizziness. Four of them required rescue pain medication. All but one was classified as mild and expected. At 12 weeks, 237 (88%) participants were analyzed using intention-to-treat analyses and at 52 weeks, 199 (74%) participants were analyzed. The number tested at follow-ups was not significantly different between groups.

Additional information if relevant	Overall, 92% of study participants attended at least 80% of their treatment visits (ET + SMT = 89%; ET= 92%; HEA = 98%).

Secondary outcomes	
Outcome name and criteria for definition	The secondary outcome measures were: disability (Neck Disability index), general health status (SF-36), frequency of medication use, global perceived effect, and satisfaction.
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. At 12 weeks, significant between-group differences were noted in favor of the ET + SMT and ET groups compared with HEA for global perceived effect, and satisfaction ($P \leq 0.001$). The ET + SMT group also demonstrated a significantly greater reduction in disability than the HEA group ($P = 0.001$). No significant differences between groups were observed for the other self-report measures in the short term. At 52 weeks, no significant between-group differences were observed for the secondary outcomes except for satisfaction.
Additional information if relevant	

Conclusions	
Key Conclusions Of Study Authors	- This study found that 12 weeks of high-dose supervised strengthening exercise with or without manipulation results in greater pain reduction, greater global perceived effect, and more satisfaction than low dose home mobilization exercise and advice for chronic neck pain in the short term. - The 2 supervised exercise groups were not significantly different from one another in terms of any of the patient-rated outcomes, suggesting that spinal manipulation confers little additional benefit when added to supervised exercise for chronic neck pain. - In this study, the between-group differences for pain between the 2 supervised exercise groups and home exercise were 11 to 13 percentage points at week 12, which translates into large effect size differences (0.8–0.9). These group differences diminished to 3 to 6 percentage points by week 26 and 2 to 3 percentage points at week 52, which translates to small effect sizes (0.2–0.4). - Patients in all 3 groups had greater expectations of improvement for supervised exercise than for home exercise and this was likely due to obvious differences in dose and supervision. - The results of qualitative interviews suggest that personal attention played an important role in the supervised exercise groups. - The observed between-group differences in some of the blinded strength measures in favor of the 2 supervised exercise groups (consistent with patient self-report measures) suggest that at least some of the demonstrated effects may be attributable to the high-dose strengthening exercise program. - Side effects were more frequently reported in the 2 supervised exercise groups. This was expected because of the dose and intensity of the exercise treatment. - The clinical and baseline characteristics of this study population are similar to those observed in other studies including primary care settings, which enhances the generalizability of the findings. - From a societal or payer's perspective, the benefits of frequent, supervised exercise, with or without manipulation, may not outweigh the associated time, effort, side effects, and costs when compared with a home exercise program. So a low-dose home exercise program may be a prudent first line of therapy for people with chronic neck pain, which, if unsuccessful, could be followed by more aggressive, high-dose supervised exercise. - Future studies are needed to investigate individual preferences related to supervised and home exercise programs and their relationship to outcomes. Careful consideration should be given to choosing the most appropriate exercise program for individual patients taking into account side effects, preferences, and costs.

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 88% 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	Supported by a grant award to Northwestern Health Sciences University by the U.S. Department of Health and Human Services, Health Resources and Services Administration, R18HP10013. The researchers of the study operate independently of the funding agency. The funding agency played no role in the study.	
Possible conflicts of interest for study authors	No Conflicts.	
Notes:		

Comments by DOWC staff

- The findings of this study showed that 12 weeks of supervised high-dose exercise, with or without spinal manipulative therapy, resulted in significantly greater pain reduction compared to low-dose home exercise with advice in the short-term (12 weeks) in those who have chronic neck pain.

- The results support a beneficial effect of all 3 interventions for treating chronic neck pain. All three groups demonstrated improved clinically meaningful outcomes in neck pain reduction over the 12-week treatment period. At the 12 week follow-up, all 3 groups reduced their neck pain score from baseline; the ET group reduced by 3.1 points, the ET + SMT group reduced by 3.3 points, and the HEA group reduced it by 1.9 points.

- Overall, similar proportions of patients in the 2 supervised exercise groups reported clinically meaningful improvements of at least 2.5 points on the patient-rated pain scale (ET + SMT =74% and ET = 65% at 12 weeks, ET + SMT = 51% and ET = 57% at 52 weeks). Noteworthy, however, is the sizeable proportion of the home exercise group (41%–42%) who experienced meaningful improvements in pain in both the short term and the long term. This may be due to the fact that the HEA group learned how to perform their exercises at home, and so it was somewhat easier for them to continue with their exercises into the long-term, since they produced some benefit. The 2 supervised groups never learned how to conduct their exercises at home, being perhaps less likely to perform their exercises into the long-term beyond the supervised sessions.

- The participants in the ET 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 ET and SMT groups could have influenced the results in favor of these treatment groups that would overestimate the treatment effect sizes.

- Since the authors did not measure patients' long-term adherence with exercise, it is not known whether that may have affected the long-term (52 weeks) outcomes. It would have been useful to measure exercise adherence in the long-term and perform a sensitivity analysis comparing those who were adherent versus those who were not.

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

- 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, 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, 20 sessions 1-2 times per week, with or without spinal manipulative therapy, resulted in significantly greater pain reduction in the short-term (12 weeks) compared to low-dose home exercise with advice in people with chronic neck pain. Disability reduction was alos significantly greater. However the low dose group had only 2 visits with a provider which would generally be expected to diminish the outcome measurements. The effect decreased by one year.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant
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