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Bibliographic Data	
Authors	Ebadi S, Ansari NN, Naghdi S, and et al.
Title	The Effect Of Continuous Ultrasound On Chronic Non-Specific Low Back Pain: A Single Blind Placebo-Controlled Randomized Trial
PMID	23031570
Citation	BMC Musculoskeletal Disorders 2012, 13:192.
Other information if relevant	The trial was registered with the Netherlands Trial Registry NTR2251.

Methods	
Aim of study	To evaluate the effect of continuous ultrasound (US) combined with exercise therapy compared with placebo US combined with exercise therapy on the primary outcomes of function and pain for patients with non-specific chronic low back pain (NSCLBP).
Design	Assessor single-blinded randomized controlled trial

Participants	
Population from which participants are drawn	Participants were recruited from three university hospitals of the Tehran University of Medical Sciences in Tehran, Iran.
Setting (location and type of facility)	This study took place at three university hospitals of the Tehran University of Medical Sciences in Tehran, Iran.
Age	adults between the ages of 18 and 60 years, mean age 34.7 years
Sex	31 men, 19 women, total 50 at baseline
Total number of participants for whom outcome data were reported	At 4 and 8 weeks after baseline, 50 (100%) participants were analyzed using intention-to-treat analyses.
Inclusion criteria	Age between 18 and 60 years, and nonspecific chronic LBP of at least 3 months duration.
Exclusion criteria	1) having nerve root symptoms, 2) having systemic disease and specific conditions such as neoplasm, fractures, spondylolisthesis, spondylolysis, spinal stenosis, ankylosing spondylitis, previous low back surgery, 3) taking medication for specific psychological problems, and 4) being pregnant.
Other information if relevant	Groups were comparable on most baseline sociodemographic, clinical symptom characteristics, and outcome measure scores except for endurance time. Possible effect of endurance time at baseline was measured by evaluating the effect of adding this variable to the model using analysis of covariance (ANCOVA) which resulted in no change in the statistical significance of the Time or Group effects. The mean duration of pain for all participants was 7.0 years.

Intervention Groups

Group 1	
Group name	Intervention group = Continuous US plus semi-supervised exercise.
Number in group	25 at baseline
Description of intervention	Continuous US (non-stop for the entire treatment) was applied with a frequency of 1 MHz and an intensity of 1.5 W/cm^2. Slow circular movements were applied using the transducer head over the painful paravertebral low back region. The average local exposure time was planned to be one minute for each 5 cm^2 area, since the effective radiating area of the transducer head was 5 cm^2.
Duration of treatment period	10 sessions of treatment, three times a week, every other day for 4 weeks
Co-interventions if reported	The semi-supervised exercise program included posterior pelvic tilts, sit-ups, bridging, quadruped exercises, and posterior hip and knee muscles stretching. Patients were instructed to perform 2 to 3 stretches (of all muscles) per day and hold the stretch for 20 seconds unless it hurts. Stretches were to be performed before the daily strengthening exercises. A warm-up of 15 minutes of walking was advised before exercising. Strengthening exercises started with 5 repetitions and progressed according to each patient's improvement, to 3 sets of 10 repetitions. Patients received a pamphlet describing exercises with figures. To emphasize correct performance of the exercises at home, all exercises were checked by the therapist at each treatment session. Patients were asked to maintain the daily home exercises for one month beyond the 4-week treatment period.
Additional information if relevant	Patients were requested not to take pain medications during the intervention period and not to participate in any other exercise or treatment program.

Group 2	
Group name	Control group = placebo US plus semi-supervised exercise.
Number in group	50 at baseline
Description of intervention	Placebo US was applied by moving the transducer head over the painful paravertebral low back region at the same rate and pressure as for the continuous US group. The US machine and the light-emitting diode which signaled that its power was connected were in view of the subject, but the dials which indicated the US were out of sight.
Duration of treatment period	10 sessions of treatment, three times a week, every other day for 4 weeks.
Co-interventions if reported	Subjects received the same semi-supervised exercise program as the intervention group which is described above.
Additional information if relevant	Patients were requested not to take pain medications during the intervention period and not to participate in any other exercise or treatment program.

Primary outcome	
Outcome name and criteria for definition	The primary outcomes were functional disability measured by the Persian version of the Functional Rating Index (FRI), and pain intensity measured during the last week on a 100 mm visual analogue scale (VAS).
Time points measured and/or reported	At baseline, after the final treatment session (after 4 weeks), and at follow-up one-month after treatment ended.
Differences between groups	Both groups demonstrated statistically significant ($p < .001$) and clinically meaningful improvements in function after the 4-week treatment period. At the 4 week follow-up, the intervention group reduced their FRI score from baseline by 17.4 points, and the control group reduced the FRI by 12.8 points. One month after the end of treatment, the improvements in function persisted. The minimum clinically important difference (MCID) for the FRI is 9 points. For between-group differences over time, there was no statistically significant difference in improvements in function (P=0.31). Both groups demonstrated statistically significant ($p < 0.001$) and clinically meaningful reductions in pain after the 4-week treatment period. At the 4 week follow-up, the intervention group reduced their VAS score from baseline by 20 points, and the control group reduced the VAS by 18.3 points. One month after the end of treatment, the reductions in pain persisted. The minimum clinically important difference (MCID) for the VAS is 16 points. No significant between-group difference was observed for reduction in pain (P = 0.98).
Additional information if relevant (adverse effects, no. tested at follow-up, adherence	One patient in each group dropped out after the 9th treatment session, because of personal reasons, so 24 in each group were tested after the 4-week treatment period. Three patients in the intervention group and 6 patients in the placebo group did not complete the follow-up measurement one-month after treatment ended because of travelling, complete improvement or other personal reasons. This left 21 for follow-up measurements one-month after treatment ended in the intervention group and 18 in the control group. The dropout rate was 22%. According to the authors, the self-reported compliance rate seemed high, but it was not checked and not reported in this article. All data were analyzed using intention-to-treat analyses.
Additional information if relevant	

Secondary outcomes	
Outcome name and criteria for definition	Secondary outcome measures were paravertebral muscle fatigue or endurance time during a Biering-Sorensen test using surface electromyography, and lumbar flexion and extension range of motion (ROM) using the Modified-Modified Schober Test (MMST).
Time points measured	At baseline, after the final treatment session (after 4 weeks), and at follow-up one-month after treatment ended.
Differences between groups	Both groups did not show statistically significant improvements in lumbar flexion and extension ROM, and endurance time after either follow-up compared to the baseline measurement. No significant between-group differences were observed for improvement in lumbar flexion range of motion (P = 0.23), lumbar extension range of motion (P = 0.21), and endurance time (P = 0.17).

Additional information if relevant	
Conclusions	
Key Conclusions Of Study Authors	- The results of this study showed that both FRI and VAS improved after 10 sessions of treatment and over time after 1 month in both groups. FRI improvement was significantly greater in the group receiving continuous US. - This single blind, placebo-controlled, randomized clinical trial showed that adding 1 MHz, 1.5 W/cm^2 US to a semi-supervised regimen of exercise had significantly beneficial effects on function, lumbar flexion and extension ROM, and endurance time in patients with non-specific chronic LBP. - As both groups in this study improved significantly regarding pain, it can be concluded that the treatment common to both groups, exercise and mechanical application of the ultrasound head, may have attributed to improvements in pain. - A significant difference in the improvement of FRI scores in favor of the continuous US group can be related to the thermal and mechanical effects of continuous US. - Although lumbar flexion and extension ROM did not reach statistical significance within groups after treatment, the amount of improvement in ROM was significantly greater in the continuous US group. - Future studies should include a third group with no US to explore the differential effects of each intervention on patients with non-specific chronic LBP.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	Randomization was performed using opaque sealed envelopes, which were prepared by a statistician using a computer generated randomization schedule.
Allocation concealment *(selection bias)*	Low	The treatment codes were sequentially numbered and sealed in opaque envelopes to conceal allocation from the study team. The allocation sequence was concealed.
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.
Incomplete outcome data *(attrition bias)*	High	The dropout rate was 22%. All participants lost to follow-up were included in the ITT analysis.
Selective outcome reporting? *(reporting bias)*	Low	The trial was registered with Netherlands Trial Registry.
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	Supported financially by the Research Deputy, Tehran University of Medical Sciences	
Possible conflicts of interest for study authors	No Conflicts.	
Notes:		

Comments by DOWC staff

- The findings of this study showed that 4 weeks of semi-supervised exercise, with either continuous ultrasound or placebo ultrasound, resulted in significant pain reduction and improved function in those with chronic non-specific low back pain. Both groups demonstrated improved clinically meaningful outcomes in pain reduction and improved function.

- This study suggests that continuous ultrasound confers little additional benefit when added to semi-supervised exercise for chronic non-specific low back pain. Continuous ultrasound is no better than placebo ultrasound.

- The authors state in their conclusions that ultrasound has beneficial effects on function, but they do not say that US is better than placebo US. This is a true statement.

- I disagree with the authors when they claim that functional improvement was significantly greater in the continuous ultrasound group than in the placebo ultrasound group. Their results for time X group interaction on function says otherwise which was not significant (P = 0.31).

- The main effect of "time X group" is an important variable and represents the change scores between groups or the between group differences over time. "Time X group" is how you compare improvements between groups. The authors seemed to ignore the important non-significant "time X group" results in favor of the less important, but significant "group" results which may indicate some selective outcome reporting.

- The lack of finding a difference between groups for pain and function could be due to an inadequate sample size after dropouts that was not large enough to detect differences.

- Study strengths included the use of an RCT design, equal balancing of the control group to the intervention group in format and time (control of performance bias), trial registration, defined primary outcomes, an intention-to-treat analysis, and high compliance to treatment.

- The study lacked data and tables that showed improvements with change scores and standard deviations.
- Adverse effects were not addressed, and compliance with home exercises and attendance at treatment sessions was not reported.

- The main limitations of the study were lack of blinding of providers and patients, a small sample size, a high drop-out rate of 22%, and a short follow-up only one month after the end of treatment.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☐ Adequate ☒ Inadequate	This inadequate quality study does not support an evidence statement that ultrasound with exercise is better for either pain reduction or functional improvement than placebo ultrasound with exercise.
If inadequate, main reasons for recommending that the article not be cited as evidence	- Continuous ultrasound is no better than placebo ultrasound.

Additional references if relevant
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