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Bibliographic Data	
Authors	Gatti R, Faccendini S, Tettamanti A, and et al.
Title	Efficacy of Trunk Balance Exercises for Individuals With Chronic Low Back Pain: A Randomized Clinical Trial
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Other information if relevant	

Methods	
Aim of study	To determine the efficacy of trunk balance exercises for individuals with chronic low back pain.
Design	Single-blind randomized clinical trial

Participants	
Population from which participants are drawn	Ambulatory individuals with a history of chronic low back pain (CLBP) were recruited by their primary care doctors they had visited concerning their CLBP in Milan, Italy.
Setting (location and type of facility)	The study was conducted at the Rehabilitation Service of San Raffaele Hospital, Milan.
Age	Adults between18 and 65 years, mean age 57.8 years
Sex	51 females, 28 males
Total number of participants for whom outcome data were reported	The number of participants assessed was 79.
Inclusion criteria	Ages 18 to 65 years, low back pain, with or without referred pain in the lower limbs, present for at least 3 months and associated with a lumbar pathology that involves the intervertebral disc, the vertebrae, or the spinal nerve roots.
Exclusion criteria	Inflammatory arthritis, indications for surgical intervention, contraindications to exercise, and the presence of neurological diseases.
Other information if relevant	Baseline pain and disability did not differ between groups.

Intervention Groups

Group 1	
Group name	Intervention group: Trunk balance exercises
Number in group	34
Description of intervention	Fifteen minutes of trunk balance exercises were completed in small groups of 4 to 6 people supervised by the same physiotherapist. The exercises were introduced in order of increasing difficulty, tailored to the ability of each participant, and each of 6 exercises was performed for 2 to 3 minutes. Exercises progressed in difficulty to make them more challenging by changing the support base, closing their eyes, or moving their heads or arms. Exercises included single limb kneeling, sitting on the edge of a table, and kneeling on a pillow with head raised.

Duration of treatment period	The intervention consisted of 2 sessions per week, each lasting 60 minutes, for a total of 10 treatments over 5 consecutive weeks.
Co-interventions if reported	Standard trunk flexibility exercises consisting of 15 minutes of walking on a treadmill and 30 minutes of flexibility exercises for the spine and lower limbs performing 10 repetitions for each of 11 exercises. The stretching exercises, primarily for the hip musculature, were performed with each stretching position maintained for 1 minute, followed by a 30-second rest.
Additional information if relevant	33 participants completed the study.

Group 2	
Group name	Control group
Number in group	45
Description of intervention	Fifteen minutes of strengthening exercises for the limbs and trunk were completed in small groups of 4 to 6 people supervised by the same physiotherapist. These exercises were performed with a load of 50% of the maximal voluntary contraction (MVC) and targeted the quadriceps, hamstrings, and latissimus dorsi. Abdominal strengthening was also performed.
Duration of treatment period	The intervention consisted of 2 sessions per week, each lasting 60 minutes, for a total of 10 treatments over 5 consecutive weeks.
Co-interventions if reported	Same standard trunk flexibility exercises as the intervention group consisting of 15 minutes of walking on a treadmill and 30 minutes of flexibility exercises for the spine and lower limbs performing 10 repetitions for each of 11 exercises. The stretching exercises, primarily for the hip musculature, were performed with each stretching position maintained for 1 minute, followed by a 30-second rest.
Additional information if relevant	38 participants completed the study.

Primary outcomes	
Outcome name and criteria for definition	1. Pain intensity (estimated using a visual analogue scale [VAS] on a scale ranging from 0 to 100. MCID = 35 points. 2. Disability evaluated using the Roland and Morris Questionnaire [RMQ] on a scale ranging from 0 to 24. MCID =3.5 points 3. Quality of life measured with the mental and physical components of the 12-Item Short-Form Health Survey [SF- 12]. MCID= 5.2 pts. Improvement in the SF- 12 is indicated by an increase in score.
Time points measured and/or reported	Assessments were conducted at baseline before the first treatment session and one week after the final session by an assessor blinded to study group assignment.

Differences between groups	1. For within group results, patients in the intervention group showed a significant reduction of 14.8 points in their mean VAS score at the 6 week assessment (*P*= 0.001). The reduction in VAS score was only 5.6 points (*P* = .115) for the control group. For between group results, decrease in pain intensity was not significantly different between the 2 groups (*P* = .165; mean difference, 9.2 pts. 95% CI: –2.5, 20.9). 2. For within group results, the RMQ score from pre-intervention to post-intervention, decreased by an average of 3.4 points (*P*<.001) for the experimental group and 1.3 points (*P* = .005) for the control group. For between group results, the improvement in RMQ score was significantly greater and clinically significant for the intervention group (*P* = .011; mean difference, 2.1; 95% CI: 0.7, 3.6). The statistically significant improvement in RMQ score reached the MCID for 19 participants in the intervention group and 14 in the control group (RR, 1.79; 95% CI: 1.05, 3.04; *P* = .04). 3. For within group results, the SF-12 physical component score increased an average of 5.5 points (*P*<.001) for the intervention group and 2.3 points (*P* = .032) for the control group. For between group results, the increase in the physical component score was significantly and clinically different between the 2 groups (*P* = .048; mean difference, 3.2; 95% CI: 0.1, 5.8). 4. For within group results, the SF-12 mental component score increased an average of 3.6 points (*P*=0.098) for the intervention group and decreased 0.6 points (*P* = 0.310) for the control group. For between group results, the improvement in the mental component score was not significantly different between the 2 groups (*P* = 0.202; mean difference, 3.0; 95% CI: -1.12, 7.12).
Additional information if relevant	There were no statistically significant differences between the 2 groups in baseline demographics or outcome measures. Follow-up rates were excellent, with one drop-out in the intervention group and 7 withdrawals in the control group. Intention-to-treat analysis was conducted.

Secondary outcomes	
Outcome name and criteria for definition	Painful positions, changes in medication usage, and presence of referred pain in the lower limbs. The number of participants who improved or worsened for each secondary outcome was calculated.
Time points measured	Assessments were conducted at baseline before the first treatment session and one week after the final session by an assessor blinded to study group assignment.

Differences between groups	1. Twenty-eight participants in the intervention group had an improvement in their painful positions, while 6 remained unchanged or worsened. In the control group, 27 improved and 18 remained unchanged or worsened. The difference between the 2 groups was statistically significant, with a relative risk (RR) of 1.37 (95% CI: 1.03, 1.83). 2. Five of the 8 participants in the intervention group who took pain medication prior to the study reduced their use of pain medication after the intervention, while the use of pain medication was unchanged or increased for the other 3 participants. In the control group, 5 of 16 participants who took pain medication decreased their use and the remaining 11 did not change or increase their use of pain medication. The RR between groups was not significant (RR, 2.00; 95% CI: 0.81, 4.94; *P* = .20). 3. Twenty-four participants in the intervention group and 27 in the control group had referred pain in their lower extremities at the beginning of the treatment period. In the intervention group, 13 improved and 11 remained unchanged or were worse, while 8 improved and 19 remained unchanged or were worse in the control group. The RR between groups was not significant (RR, 1.83; 95% CI: 0.92, 3.64; *P* = .08).
Additional information if relevant	
Conclusions	
Key conclusions of study authors	- Trunk balance exercises combined with flexibility exercises, compared to the combination of muscle-strengthening exercises of the limbs and trunk and flexibility exercises, appear to be more effective in reducing disability, and also led to improvements in function on the physical component of the quality of life health survey in patients with chronic low back pain. - This study showed that the significant and clinically meaningful improvements in RMQ and in the physical component of the SF-12 scores, which include items such as going up stairs and vocational activities, suggest that challenging balance exercises in this population have a potential impact on reducing disability. - Improvement in the VAS pain score was not different between the 2 groups. It is noted that the low score at baseline might have precluded the ability to identify a difference between groups, by limiting the possible magnitude of improvement for either group. - For the secondary outcome variable, “painful positions,” a statistically significant effect in favor of the intervention group was found. Greater improvement in this secondary outcome, although also related to pain, may reflect a more functional aspect of daily living related to disability. - The use of trunk balance training should be considered as part of a rehabilitation program for chronic low back pain.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	Randomized assignment was conducted by the project coordinator to ensure that the 2 research assistants responsible for outcome assessments were blinded to treatment group assignment.
Allocation concealment *(selection bias)*	Low	Assignment to treatment group was determined by a computer-generated randomization list.
Blinding of participants and personnel *(performance bias)*	High	Patients were aware of which group they were in, and it was not possible to blind them. The lack of blinding does not prejudice the conclusions.
Blinding of outcome assessment *(detection bias)*	Low	All outcome assessments were collected by an assessor blinded to intervention assignment.
Incomplete outcome data *(attrition bias)*	Low	Participant follow-up was excellent with few drop-outs. Results of all outcomes were reported.
Selective outcome reporting? *(reporting bias)*	Low	The trial was not registered with clinicaltrials.gov
Other bias		

Sponsorship if reported		
Study funding sources if reported	Not reported. This research was conducted by staff at 2 universities, one in Italy and one in Switzerland.	
Possible conflicts of interest for study authors	None declared.	
Notes:		

Comments by DOWC staff

- The results of this study support that trunk balance exercises combined with flexibility exercises are more effective than a combination of strength and flexibility exercises in reducing disability and improving physical function in patients with chronic low back pain. Between-group differences were statistically significant and these improvements were small, but clinically meaningful.
- Trunk balance exercises are easily learned by chronic pain patients, do not necessitate any special equipment, and can be performed independently at home after a period of supervised training, according to individual requirements. This is important because a home exercise program can be effective for patients who are motivated.
- One strength of the study was the specificity of the intervention for each patient where adjusting the difficulty of the motor skills exercises to maintain and then intensify the exercise workout for each individual contributed to the good results of the study.
- Additional strengths of the study included an active control group, a control group that received equal attention, adequate randomization, generalizability of the findings, and functional outcomes.
- The low rate of drop-outs in both groups is indicative of well tolerated interventions.
- Since the outcomes were all self-reported by the patients, and the patients could not be blinded to the intervention, the results are prone to information bias.
- It is difficult to attribute the results of the study to either the combination of the entire exercise program (trunk balance + flexibility) or simply the trunk balance training component.
- Limitations of the study included no clinical trial registration, no prior sample size analysis, 4 designated primary outcomes, and no long-term follow-up beyond the termination of the intervention period (6 weeks).
- A larger sample size for the study could have resulted in significantly greater improvements in the VAS scale for the intervention group, further reinforcing the effectiveness of this intervention in individuals with chronic LBP.
- This study did not include follow-up beyond the period of treatment, so long-term effectiveness of the exercise program is not known.
- The authors failed to address any adverse effects of any of the exercises.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This study is adequate for some evidence that trunk balance exercises combined with flexibility exercises are more effective than a combination of strength and flexibility exercises in reducing disability and improving physical function in patients with chronic low back pain.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant