

Combination of exercise and advice was slightly better than placebo for subacute low back pain

Synopsis

Summary of: Pengel LHM, Refshauge KM, Maher CG, Nicolas MK, Herbert RD, McNair P (2007). Physiotherapist-directed exercise, advice, or both for subacute low back pain: a randomized trial. *Annals of Internal Medicine* 146: 787–796. [Prepared by Gro Jamtvedt and Kåre Birger Hagen, CAP Editors.]

Question: What is the effectiveness of physiotherapist-directed exercise, advice, or both for subacute low back pain? **Design:** Randomised controlled trial. **Setting:** 7 university hospitals and primary care clinics in Australia and New Zealand. **Patients:** 259 persons with non-specific, subacute low back pain lasting for at least 6 weeks, but no longer than 12 weeks. **Interventions:** Participants were randomised to four groups: exercise and advice, exercise and sham advice, sham exercise and advice, or sham exercise and sham advice. 12 exercise or sham exercise sessions were delivered over 6 weeks. The exercise program included an individualised, progressive, submaximal program of aerobic exercise, stretches, functional activities, activities to build speed, endurance and co-ordination, and trunk and limb-strengthening exercises. Participants also received a home exercise program. The sham exercise intervention consisted of sham shortwave diathermy and sham pulsed ultrasound. In weeks 1, 2 and 4 participants received

advice or sham advice. Advice sessions aimed to encourage a graded return to normal activities. During the sham advice sessions the patients talked about their problems but received no advice. Participants were not informed whether their group allocation was active or sham for either intervention. **Outcomes:** Primary outcomes were average pain over the last week (0 to 10 scale), global perceived effect (–5 to 5 scale) and function (Patient Specific Functional Scale, 0 to 10) at 6 weeks and 12 months. **Results:** The effect of exercise (the adjusted difference in outcomes between exercise and sham exercise groups) at 6 weeks was –0.8 points (95% CI –1.3 to –0.3 points) on the pain scale and 0.5 points (95% CI 0.1 to 1.0 points) on the global perceived effect scale. The effect of advice at 6 weeks was –0.7 points (95% CI –1.2 to –0.2 points) on the pain scale and 0.8 points (95% CI 0.3 to 1.2 points) on the global perceived effect scale. The effect of advice on the function scale was significant at 6 weeks and 12 months. For pain, function, and global perceived effect, the effect of combined treatments was larger than the effect of exercise or advice alone. **Conclusion:** Physiotherapy-directed exercise and advice was slightly more effective than placebo at 6 weeks. The effect was greatest when the interventions were combined. At 12 months a small effect on participant-reported function was still reported.

Commentary

This trial is a highly-needed and well-conducted study which highlights a core question in clinical practice with low back pain (LBP) patients: should patients with subacute LBP have advice only, exercises only, or a combination of both? The results are in line with previous studies in subacute LBP concluding that advice and exercise each have beneficial effects. They add important new knowledge to the field, however, by demonstrating that combined exercise and advice is substantially more effective than either intervention alone.

The enhanced effect of combining a cognitive intervention with an exercise intervention may be explained by the complex nature of LBP and the fact that most patients get a nonspecific diagnosis. Hence, combining interventions with different fundamental mechanisms of action (cognitive or exercise) may increase the odds of targeting patients' underlying problems. Additionally, although the underlying mechanisms of action theoretically differ between a cognitive intervention and exercise, the interventions obviously have the potential to complement and heighten each other. A previous study has shown that combining cognitive intervention and exercises, ensuring a good link between the information given and the content of the exercise, can challenge the effect of spinal surgery (Brox 2003).

In the present study, potential placebo effects were controlled for by providing sham advice and sham exercise. The fact that the same clinicians provided both the real advice and the sham advice may have introduced a bias. The equivalent problem probably did not occur for the distinction between exercise and sham exercise, because the sham exercise involved a totally different practical procedure. However, the distinction between advice and sham advice would have been much more challenging. Furthermore, to present sham exercises by providing ultrasound and electrotherapy may be questioned. Would not patients with LBP know the difference between exercises and passive treatment modalities? In our opinion, this may have led to a nocebo effect for this particular intervention.

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References

Brox JI et al (2003) *Spine* 28: 1913–1921.