

Storheim K, Brox J, Holm I, et al. Intensive Group Training versus Cognitive Intervention in Sub-Acute Low Back Pain: Short-Term Results of a Single-Blind Randomized Controlled Trial. J Rehabil Med 2003; 35:132-140.

Design: Randomized clinical trial

Reviewed (10-10-16): No changes to conclusions (LM)

Objective: To evaluate the short-term effect of physical exercise and a cognitive intervention in sub-acute low back pain.

Population /sample size/setting/interventions:

- 93 participants sick-listed from a permanent job for 8-12 weeks due to sub-acute non-specific low back pain who were recruited from the local National Insurance Offices and from general practitioner's in 2 counties in Norway. All participants were randomized to one of three interventions; 1) a physical exercise regime (n=30), 2) a cognitive intervention (n=34), or a control group (n=29).
- The physical exercise intervention consisted of an initial standard clinical exam followed by enrollment in a back training exercise group designed and led by experienced physical therapists focusing on increasing overall fitness, functional capacity, cardiovascular fitness, flexibility, body awareness, relaxation, and strength in the thighs, abdominal, and pelvic floor muscles. The exercise period was 15 weeks with at least 2 one-hour sessions per week, preferably 3. Patients started at the lowest intensity level and could enter into more advanced classes as they progressed.
- The cognitive intervention also consisted of an initial standard clinical exam followed by two 30 to 60 minute consultations with the physical medicine specialist and the physical therapist. The consultation included an explanation of pain mechanisms, and reassurance that it is safe to move. Also included were coping strategies and instruction and advice on using certain muscles and on the proper squat technique. No treatment was referred.
- Patients in the control group were treated by their general practitioner and had no restrictions of treatments or referrals.
- Eligibility criteria included sick-listed from a permanent job for 8-12 weeks due to non-specific LBP, 20-60 years of age, understanding Norwegian, accessibility to follow all 3-treatment alternatives, and conducting regular physical exercise less than 3 times per week for the last 6 months.
- Exclusion criteria included sciatic pain, spinal stenosis with neurological affection, spondylolysis or spondylolisthesis > grade 2, spinal fracture, tumor, or infection, abuse of drugs or alcohol, rheumatic diseases, back surgery, pregnancy, or diseases that might interfere with participation.

Main outcome measures:

- The primary outcome measures were pain (two VAS scales), disability (RMDQ), and sick-listing (number of working days lost in 18 weeks).
- Secondary outcome measures included self-efficacy beliefs for pain and function, fear-avoidance beliefs (Fear-Avoidance Belief Questionnaire, FABQ), emotional distress

(Hopkins Symptom Checklist, HSCL-25), generic health status (SF-36 Health Survey), and life satisfaction (Cantrils Ladder Scale).

- Outcome measures were recorded at 18 weeks.
- 17 (18.3%) participants withdrew prior to 18 weeks: 2 (5.9%) from the cognitive group, 9 (30%) from the exercise group, and 6 (20.7%) from the control group.
 - o The baseline values were carried forward for the reported analyses, so that the participants who withdrew were recorded as if they had the same pain and disability scores at the end of treatment that they had at the beginning.
 - o Dropouts were more likely to be men and more dropouts were living alone.
- Compared with the control group, the exercise group had a significant reduction in pain intensity of 28.7 points on a scale from 0 to 100 (P=0.04).
- Compared to the control group, the cognitive group had a significant reduction in disability of 1.9 points on the 24 point Roland-Morris scale (P=0.02).
- The exercise and cognitive groups did not differ in pain and disability improvements at the 18-week evaluation.
- Sick-listing showed no differences between the treatment groups.

Authors' conclusions:

- The cognitive group improved in disability, the exercise group improved in pain, but none of the interventions decreased sick leave time.
- The dropouts (9 of 30) in the exercise group may have left that analysis underpowered for comparison with the other groups.

Comments:

- This is a well-designed and documented study.
- The inclusion of a nontreatment control group is a strength of this study meaning that definitive conclusions can be drawn, since the results have definitely occurred due to the 2 treatment interventions of the study and are not due to the natural history of back pain.
- The attrition rate is high (38.7%) when both dropouts and those not adhering to the protocol are considered.
- The study is underpowered to observe clinically significant differences between treatment groups and within treatment groups.
- The dropouts in the exercise group were counted as if they had the same pain scores at the end of the study as at the beginning.
 - o This analysis assumes that the dropouts did not withdraw because of pain becoming greater with exercise; if they withdrew because of worsening pain with the particular exercise program, the authors' analysis will miss that development.
 - o The number of dropouts in the exercise group means that it is better not to draw conclusions about its effect on pain.
- The withdrawal rate in the cognitive group is low enough to be acceptable for purposes of the statistical analysis, and also can be regarded as an outcome of interest; if cognitive intervention is more acceptable than a vigorous exercise program for patients with low back pain, that has implications for decision-making in that population.
 - o The high dropout rate clouds the treatment effect only for the exercise group, not for the cognitive group.

- The cognitive group improved and showed a clinically relevant reduction in disability of 3.5 points on the 24 point Roland-Morris scale which exceeded the clinically relevant threshold of 2 points. The control group also improved and showed a reduction in disability of 1.6 points, but this reduction did not meet the criteria for clinically relevant. Even though the cognitive group met the clinically relevant threshold, there is still uncertainty about the magnitude of the difference between the cognitive group and the control group due to wide confidence intervals (-3.8 to -0.06).
- A slight confusion arises from the use of the phrase “positive change in pain intensity” for the exercise group; the numerical direction was negative, and this is evaluated by the authors as a good thing, a “positive development”.

Assessment:

- This study is adequate for some evidence that a cognitive intervention consisting of two hour-long consultations with a physical medicine specialist and a physical therapist produces short-term reductions in back disability.