

Comparison of Research Studies: Which Study Allows Stronger Conclusion About the Efficacy of a Non-surgical Intervention for LBP?

Study No. 1¹

OBJECTIVE: To evaluate effectiveness of an exercise program in a community setting for patients with low back pain to encourage a return to normal activities.

DESIGN: Patients randomized into either a progressive exercise program group or a group treated with usual primary care management. Patients' preferences for type of management were elicited independently of randomisation.

PARTICIPANTS: 187 patients aged 18-60 years with mechanical low back pain of 4 weeks to 6 months' duration. **INTERVENTIONS:** Exercise classes led by a physiotherapist that included strengthening exercises for all main muscle groups, stretching exercises, relaxation session, and brief education on back care. A cognitive-behavioural approach was used. **MAIN OUTCOME MEASURES:** Assessments of debilitating effects of back pain before and after intervention and at 6 months and 1 year later. Measures included Roland disability questionnaire, Aberdeen back pain scale, pain diaries, and use of healthcare services.

RESULTS: At 6 weeks after randomisation, the intervention group improved marginally more than the control group on the disability questionnaire and reported less distressing pain. At 6 months and 1 year, the intervention group showed significantly greater improvement in the disability questionnaire score (mean difference in changes 1.35, 95% confidence interval 0.13 to 2.57). At 1 year, the intervention group also showed significantly greater improvement in the Aberdeen back pain scale (4.44, 1.01 to 7.87) and reported only 378 days off work compared with 607 in the control group. The intervention group used fewer healthcare resources. Outcome was not influenced by patients' preferences.

CONCLUSIONS: The exercise class was more clinically effective than traditional general practitioner management, regardless of patient preference, and was cost effective

Study No. 2²

STUDY DESIGN: A comparison of treatment of 412 patients with chronic back pain at two separate centers using the same treatment protocols and outcome measures. Outcome was defined by specific strength testing; Short Form-36 scores at intake, discharge, and 1-year follow-up; self-appraisal of improvement at discharge and in a 1-year follow-up; and reuse of health care services after discharge. **OBJECTIVES:** To investigate the efficacy of standardized treatment methods using isolated lumbar strength testing and strengthening based on progressive protocols using specific equipment. Comparison of results should clarify the effect of the treatment center versus the efficacy of standardized protocols. **SUMMARY OF BACKGROUND DATA:** There has been little support in the scientific literature for exercise programs based on standardized protocols. The use of specialized equipment to achieve intense specific exercise also has been poorly supported. Overall health benefit has not often been related to specific improvement in strength. **METHODS:** More than 400 individuals with chronic back pain were evaluated at the initiation of treatment, discharge, and 1 year after discharge. Measures of efficacy were based on Short Form-36 scores, self-appraisal of improvement, and reuse of health care services after discharge. Study participants were patients with chronic back pain consecutively referred to each treatment site and underwritten by a variety of payers, including workers' compensation, Medicare, and private insurance. **RESULTS:** Overall response during the course of the program and at 1-year follow-up was similar between the two centers. Similar proportions of participants at each site demonstrated improvement in SF-36 scores, self-appraisal of improvement, and reuse of health care services. **CONCLUSIONS:** Standardized protocols using specific strength and measurement equipment can achieve similar benefits at different sites

STUDY 3³

This study was designed to evaluate the effects of early physical therapy intervention on treatment outcomes for workers with acute low back injuries. A total of 3867 cases were randomly selected from the database of a large occupational health care provider. Cases were assigned to either the early therapy intervention group or one of the two comparison groups on the basis of their delay to physical therapy. The treatment outcomes for the three groups were compared. The results showed that patients in the early therapy intervention had more favorable outcomes than the two comparison groups. Specifically, patients in the early intervention group had fewer physician visits, fewer restricted workdays, fewer days away from work, and shorter case duration. These results provide a strong indication for the effectiveness of early therapy intervention. The financial implications of the findings is discussed.

STUDY 4⁴

Fifty patients with an average age of 47 years received epidural steroid injections for lumbosacral radicular pain due to disk herniation or spinal stenosis. All patients had failed previous conservative treatment. Mean follow-up was 24 months (range: 12-36 months). Immediately after injection, all 50 patients reported various degrees of relief from leg and back pain. At the last follow-up examination, 68% of patients were asymptomatic, 20% had no change in preinjection radicular symptoms, and 12% had various degrees of relief. No significant correlation was found between pain relief, age, or number of injections. Early pain relief may be anticipated after epidural steroid injections in 80% of patients with radicular symptoms due to disk herniation or spinal stenosis.

STUDY 5⁵

PURPOSE: To review the use, complications, and efficacy of spinal manipulation as a treatment for low-back pain. **DATA IDENTIFICATION:** Articles were identified through a **MEDLINE** search, review of articles' bibliographies, and advice from expert orthopedists and chiropractors. **STUDY SELECTION:** All studies reporting use and complications of spinal manipulation and all controlled trials of the efficacy of spinal manipulation were analyzed. Fifty-eight articles, including 25 controlled trials, were retrieved. **DATA ANALYSIS:** Data on the use and complications of spinal manipulation were summarized. Controlled trials of efficacy were critically appraised for study quality. Data from nine studies were combined using the confidence profile method of meta-analysis to estimate the effect of spinal manipulation on patients' pain and functional outcomes.

RESULTS OF DATA SYNTHESIS: Chiropractors provide most of the manipulative therapy used in the United States for patients with low-back pain. Serious complications of lumbar manipulation, including paraplegia and death, have been reported. Although the occurrence rate of these complications is unknown, it is probably low. For patients with uncomplicated, acute low-back pain, the difference in probability of recovery at 3 weeks favoring treatment with spinal manipulation is 0.17 (for example, increase in recovery from 50% to 67%; 95% probability limits of estimate, 0.07 to 0.28). For patients with low-back pain and sciatic nerve irritation, the difference in probabilities of recovery at 4 weeks is 0.098 (probability limits, -0.016 to 0.209). **CONCLUSIONS:** Spinal manipulation is of short-term benefit in some patients, particularly those with uncomplicated, acute low-back pain. Data are insufficient concerning the efficacy of spinal manipulation for chronic low-back pain. [References: 65]

STUDY 6⁶

OBJECTIVE: To discuss the effects of an active care protocol that includes isolated lumbar spine strengthening on a chronic low back pain patient.

CLINICAL FEATURES: A 20-yr-old female college basketball player suffered from a 7-month history of debilitating low back and left leg pain. Four previous independent physicians expressed diagnostic and therapeutic uncertainty. Bone scan, MRI, nerve conduction study, electromyography, CT, discogram and laboratory evaluation had all failed to identify the etiology of the problem. The patient was forced to discontinue basketball and drop out of college as a result of her spinal problem. Treatment by her prior physicians consisted of analgesics and prolonged bedrest. **INTERVENTION and OUTCOMES:** The patient underwent a functional restoration program consisting of isolated lumbar extensor progressive resistance exercise (PRE) on a MedX lumbar instrument, PRE to ancillary musculature, progressive aerobic exercise, static stretching and proprioceptive exercises. She showed a 368% increase in average lumbar isometric strength, 41% increase in isolated lumbar sagittal plane range of motion and decrease in pain. The patient returned to school after 8 wk of care; at 18-month check-up, she remained asymptomatic. **CONCLUSION:** Functional restoration, even with uncertain diagnosis, can be effective in the resolution of chronic low back pain.

Reference List

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**RANK-ORDER STUDIES ACCORDING TO THEIR STRENGTH OF
EVIDENCE**

(1= highest level of evidence to 6 being the lowest level)

LEVEL OF EVIDENCE

ARTICLE/STUDY NUMBER