

**Balthazard P, de Goumoens P, et al. Manual therapy followed by specific active exercises versus a placebo followed by specific active exercises on the improvement of functional disability in patients with chronic non specific low back pain: a randomized controlled trial. BMC Musculoskeletal Disorders 2012, 13:162.**

Design: Randomized clinical trial

Population/sample size/setting:

- 42 patients (14 men, 28 women, mean age 43) treated for chronic low back pain at a university physical therapy department in Switzerland
- Eligibility criteria were age 20-65 with nonspecific LBP with or without lower extremity symptoms lasting 12-26 weeks, and the ability to continue usual medication
- Exclusion criteria were numerous, and included recent spinal fracture or surgery, nerve root motor or sensory deficits, neurogenic claudication, a score of 3/5 or more Waddell signs, opioid medications, psychiatric disorders, radiographic abnormalities other than degenerative changes, and several specific conditions leading to low back pain (neoplasia, infection, inflammation, visceral origin); sick leave from work over 6 months was also grounds for exclusion

Main outcome measures:

- Randomized to either manual therapy (MT, n=20) or sham therapy (ST, n=22)
- Both interventions involved visits to physical therapy 8 times over a period of 4 to 8 weeks, and each session included a protocol of active exercises
  - o Mobility exercises consisted of pelvic tilt and low back lateral flexion progressing from the supine position to sitting on a stable plane to sitting on a ball
  - o Passive stretching exercises consisted of lengthening erector spinae, hamstring, iliopsoas, rectus femoris, piriformis
  - o Motor control exercises commenced at the 4<sup>th</sup> session, and aimed at active recruitment of stabilizing trunk muscles, progressing from supine to sitting to standing position
  - o Strengthening exercises began at the 6<sup>th</sup> or 7<sup>th</sup> session in order to increase strength of superficial trunk muscles, done against external resistance
  - o Both groups were given the same set of home mobility exercises
- MT and ST were the group contrasts; ST consisted of detuned ultrasound for 5 to ten minutes at the beginning of each session followed by AE
- MT also was done for 5-10 minutes at the beginning of each session, followed by AE
  - o Passive accessory intervertebral was done by applying posterior-anterior pressure on painful vertebral segments with the patient lying prone
  - o Muscle energy techniques were done with the patient side-lying, with a hold-relaxed technique on the ilium

- High-velocity, low-amplitude manipulation was done on stiff vertebral segments with the patient side-lying
- VAS pain on a 10 point scale was measured immediately before and after the MT or ST component of each visit
- Principal outcome measures for the study were pain VAS and Oswestry disability, taken at baseline, after the 8<sup>th</sup> intervention visit, and followed up at 3 and 6 months after the end of treatment; these were administered by the same physical therapist who had administered the treatment sessions
  - VAS pain ratings at each evaluation were reported by each patient, both for current pain and for average pain in the 48 hours prior to each evaluation visit
  - Oswestry was administered at each evaluation visit
- Secondary outcomes included levels of fear/avoidance beliefs about work and physical activity, a test of erector spinae muscle endurance, and a test of abdominal muscle endurance
- The MT group received more immediate pain relief during the sessions than the ST group; the adjusted difference was 0.76 points
- The MT group also had an advantage over the ST group with respect to pain VAS during follow-up
  - The analysis of VAS was done in a way to use information from each longitudinal evaluation, and the effect of MT over ST was 1.24 points on the 10 point VAS scale
    - The p value for the difference was 0.032, which was greater than the prespecified value of 0.025 to declare statistical significance
  - The analysis of the Oswestry disability scores was done in the same manner, showing a treatment effect of MT of 7.14 points on a 50 point scale
    - The p value for the treatment effect was 0.013, less than the prespecified value of 0.025 for statistical significance
- The secondary outcomes did not differ significantly between MT and ST groups

Authors' conclusions:

- Manual therapy, followed immediately by active exercise, accelerates recovery from disability in chronic nonspecific low back pain
- MT has an immediate analgesic effect as well as a lasting effect; the immediate effect may facilitate the performance of the active exercises which were an integral part of each session and of the treatment program
- There may be limitations in the application of the results to other patient populations, since the study participants were recruited from a rheumatology clinic at a university hospital

Comments:

- The analysis appears to have taken appropriate measures to control Type I error, by partitioning the Type I error (set at 0.05) for the two main outcomes (0.025 for pain and 0.025 for the Oswestry disability)
- The follow-up evaluations were done by the same physical therapists who had administered the treatment sessions, raising the possibility that the evaluations are biased
  - o However this is not likely, because the secondary outcomes did not differ between the two groups
  - o The secondary outcomes would have been more sensitive to bias, because they involved performance of muscle activities, where there is a potential for a coaching and observer effect; the main outcomes, which were patient-reported, would have been less sensitive to lack of assessor blinding, and bias arising from this source is likely to have been adequately controlled
- An important exclusion was of patients with more than 6 months of sick leave from work
- Group comparisons are made for the main outcome measures, but there is no report of whether there was improvement within groups
  - o It is possible that there was some improvement within the sham treatment group, but such improvement cannot be determined from the information given
  - o A 15 point Oswestry improvement is conventionally considered to be clinically significant
    - The mean Oswestry for the ST group was 32 and the mean at 6 months was 26; not many patients are likely to have had a 15 point reduction
    - The mean Oswestry for the MT group was 30 and the mean 6 month score was 16; this does not mean that the average reduction was 14 points, but it is likely that some patients exceeded a 15 point reduction and others failed to reach a 15 point reduction
    - Numbers of patients in each group showing a 15 point reduction would have been more informative than the data reported by the authors, but almost certainly would have shown an advantage for the MT group
- Functional disability, which did reach statistical significance, is a more important outcome for workers' compensation than symptom reduction, which did not reach statistical significance

Assessment: Adequate for some evidence that manual therapy, followed by active exercises, may be effective for the reduction of disability from nonspecific low back pain lasting more than 12 weeks