
**Design:** Randomized clinical trial

**Reviewed (11-2-16):** No changes to conclusions

**Objective:** To compare the effects of the McKenzie method with those of spinal manipulation when used adjunctive to information and advice in a clinical subgroup of patients with low back pain of more than 6 weeks duration.

**Population /sample size/setting/interventions:**

- 350 participants (195 women, 155 men, mean age 37.5) with low back pain of more than 6 weeks duration who presented with centralization or peripheralization of symptoms with or without signs of nerve root involvement from a primary care specialist center in Copenhagen, Denmark. All participants were randomized to one of two interventions; 1) McKenzie method (n=175) performed by certified physical therapists, or 2) spinal manipulation (n=175) performed by chiropractors.
- The McKenzie treatment intervention consisted of an initial physical assessment followed by an individual treatment plan. Manual vertebral mobilization techniques including high velocity thrust were not allowed.
- The spinal manipulation intervention included a pretreatment physical assessment followed by all types of manual techniques including vertebral mobilization, self-manipulation, alternating lumbar flexion/extension movements, stretching, and high velocity thrust as well as myofascial trigger-point massage at the discretion of the chiropractor. Specific exercises in the directional preference were not allowed.
- In both treatment groups, patients were informed of their assessment results, the benign course of back pain, the importance of staying physically active, proper back care, and were provided “The Back Book”. A maximum of 15 treatments for 12 weeks were given. Patients were instructed to continue self-administered exercises and/or mobilizing at home for a minimum of 2 months after finishing the 12 weeks of treatment at the back center.
- Eligibility criteria included 1) low back pain with or without leg pain for more than 6 weeks, 2) adults aged 18 to 60 years of age, 3) able to speak and understand the Danish language, and 4) a presentation of clinical signs of disc-related symptoms (being centralization or peripheralization with repeated test movements (flexion, extension, gliding) under a McKenzie protocol done by a trained practitioner of the method.
- Exclusion criteria included being free of symptoms on the day of inclusion, demonstrated nonorganic signs, suspicion of serious pathology based on physical exam and/or MRI, application for disability pension, pending litigation, pregnancy, comorbidity, recent back surgery, language problems, communication problems, or abuse of drugs or alcohol.

**Main outcome measures:**

- Primary outcome measure was proportion of patients reporting treatment success at 2 months follow-up defined as a reduction of ≥ 5 points or a score below 5 points on the
Roland Morris Disability Questionnaire (RMDQ) which spanned 0 to 23 points. Secondary outcome measures were treatment success at other follow-ups, pain and disability reduction, global perceived effect, return to work, quality of life, days with reduced activity, satisfaction with treatment, and use of health care after treatment.

- Outcome measures were recorded at the end of the 12-week treatment period, and again at 2 and 12 months after treatment completion.
- Baseline characteristics were similar for the 2 groups except that more patients were on sick leave in the McKenzie group and this difference was statistically significant (P=0.039).
- Intention to treat analysis was performed on all participants.
- Centralization/peripheralization at the initial examination had no influence on the success rate in either group.
- Primary outcomes:
  - In both groups, more than half of the patients reported success at post-treatment and this success carried through at both 2 and 12 months follow-up post-treatment.
  - At the 2 month evaluation, 71% of the McKenzie group and 59% of the spinal manipulation group were recorded as successful and the between group difference of 12% was significant (P=0.018).
  - There were 36 (21%) withdrawals in the McKenzie group during treatment (28 related to lack of effect) and 55 (31%) withdrawals in the spinal manipulation group (43 related to lack of effect) and this difference was significant between the groups (P=0.021).
- Secondary outcomes:
  - In both groups, a 50% reduction in mean disability and pain was reported at post-treatment and this reduction carried through at both 2 and 12 months follow-up post-treatment.
  - At the 2 and 12 month evaluations, there was a tendency toward a greater reduction in disability scores favoring the McKenzie group (P=0.022 and P=0.030); Reduction in pain score was not significantly different between groups (P=0.309 and P=0.063).
  - At the end of treatment, there was a statistically significant difference of 13% in favor of the McKenzie group for global perceived effect (P=0.016).

Authors’ conclusions:

- Although both groups improved, the McKenzie method appeared to be more favorable in reducing disability.
- Although between-group differences were not particularly large at all follow-ups, the McKenzie method appeared to be the more favorable method of treatment.
- The difference in withdrawal rates was also in favor of the McKenzie group.
- The between group difference of 12% in patients reporting success was slightly below the predefined clinically important level of 15% and the difference in reduction of disability (1.5 points) was below the predefined 2.5 points.
- The generalizability of the results could be hampered by the fact that the clinicians in both treatment groups made decisions without standardization.
- It has previously been suggested that centralizers fare better than peripheralizers when treated with the McKenzie method; this study did not observe a treatment difference, and the prognostic value of centralization remains to be clarified by other research.
- It would be useful to explore clinical findings which identify patients likely to respond better to the McKenzie method or to spinal manipulation and to test the effects of combining the two treatments.

Comments:

- This is a well-designed and documented study.
- An attempt was made to distribute attention bias evenly between groups.
- A limitation of the study is a relatively high withdrawal rate during intervention (26%).
- Both trends and statistically significant differences in success and disability for the McKenzie method were below the minimum criteria for clinical importance predefined in this study.
- Blinding of the physical therapists performing the interventions was not possible. Both interventions were done by practitioners who were committed to the methods with which they treat patients; therefore, it is likely that biases arising from practitioner and patient expectations were minimized and are balanced between the groups, and that lack of blinding would have no clear direction of bias.
- At baseline, the McKenzie group had more patients on sick leave (37%) than the manipulation group (27%); this would be unlikely to bias the McKenzie group towards a better outcome of treatment.
- A lack of a nontreatment control group means that definitive conclusions cannot be drawn as to whether the results occurred due to the natural history of back pain, nonspecific effects, or the 2 treatment interventions of the study.
- The superiority of McKenzie treatment over manipulation is modest and could be different if a different sample were selected for study; however, the study has sufficiently high quality to support evidence that McKenzie is at least as effective as spinal manipulation for nonspecific back pain.
- Since both groups mobilized intervertebral spinal joints during the course of treatment and likely influenced the same pain mechanism, this may explain the modest difference between treatments in patients.
- Mean duration of symptoms for low back pain in the McKenzie group was 97 weeks and in the manipulation group the mean was 94 weeks. Essentially, this was a study of patients with chronic low back pain.

Assessment:

- This is a high quality study that is adequate for good evidence that a 12 week course of treatment in the McKenzie method is at most modestly more effective than spinal manipulation of similar duration in reducing disability in patients with persistent (more than 6 weeks duration, mean = 95 weeks) nonspecific low back pain, although a clinically relevant difference was not apparent. The McKenzie method should not be utilized if there is severe nerve root involvement with motor, sensory, or reflex abnormality.