

Machado L, Maher CG, et al. The effectiveness of the McKenzie method in addition to first-line care for acute low back pain: a randomized clinical trial. BMC Medicine 2010;8:10

Design: Randomized clinical trial

Population /sample size/setting:

- 146 patients (73 men, 73 women, mean age 46) treated for a new episode of nonspecific back pain in Australia and New Zealand
- Eligibility criteria were age 18 to 80, acute lumbar pain (between 12th rib and buttock crease) with or without leg pain, of less than 6 weeks duration, preceded by at least a 4 week period free of consultation with a health care practitioner for back pain
- Exclusion criteria were nerve root compromise, infection, fracture, spinal surgery in past 6 months, pregnancy, severe cardiovascular/metabolic disease

Main outcome measures:

- Randomized to one of two interventions: first-line care (n=73) or McKenzie method care (n=73)
 - o First-line care was provided by physicians who had received training in guideline-based care for LPB
 - The guidelines, similar in content, were either those of the American College of Physicians, the American Pain Society, the European guidelines, or the National Australian guidelines
 - o First-line care consisted of advice to remain active and avoid bed rest, reassurance of the favorable prognosis of acute LBP, and use of acetaminophen (but not NSAIDs) as needed; the patient was allowed to continue NSAIDs if already taking them
 - o McKenzie intervention consisted of first-line care measures, supplemented by consultation with credentialed McKenzie physical therapists, who classified the patients into one of three recognized McKenzie syndromes: derangement, dysfunction, and postural
 - Physical therapists were instructed to confine treatment to the principles in the McKenzie textbooks, and not to use other treatment modalities
 - The number of treatment sessions was up to the therapist, with a maximum of 6 sessions
 - Patients were encouraged to try the McKenzie exercises at home, and all of them received a copy of *Treat Your Own Back*, McKenzie's book for patients

- Intervention period lasted 3 weeks, during which patients were asked not to seek treatment outside what was being provided in the trial
- Primary outcomes were pain (scale from 0-10) at the 1 week mark, average pain in the first 7 days, and pain at the 3 week mark; also global perceived effect at 3 weeks (scale from -5, 'vastly worse' to +5 'completely recovered')
 - o Some secondary outcomes were considered: disability on the Roland Morris Disability Questionnaire, Function at 1 and 3 weeks on the Patient Specific Functional Scale, global perceived effect at 1 week, and persistent LBP at 3 months
- Patients recorded their self-assessed outcomes in a booklet, but the data were transcribed by a blinded researcher who entered the pain and global perceived effect data during a telephone follow-up call at the 1 week and 3 week points; the same researcher called the patients at 3 months to ascertain the presence of continuing LBP
- In the McKenzie group, 94% of patients were classified as having the derangement syndrome and 6% as having the dysfunction syndrome
 - o Adherence to home McKenzie exercise was 66% in the first week and 74% over the 3 week period
- Mean outcomes with respect to pain were similar between treatment groups; both groups reported pain relief compared to baseline
 - o Baseline mean pain was 6.6 in the McKenzie group and 6.3 in the first line care group
 - o At 3 weeks the pain scores were 2.0 in the McKenzie group and 2.3 in the first line care group
 - Although the McKenzie group had a lower pain score that was "statistically significant" compared to the control group, the difference at 3 weeks (0.7 points) was below the clinically important threshold of 1 point
 - o For the other outcomes, global perceived effect, disability, and function, the group differences were near zero
 - o At 3 months, similar proportions of patients continued to have at least some back pain, not being completely pain-free (53% of McKenzie group and 47% of control group)
 - o Fewer McKenzie patients sought additional back pain health care (such as NSAIDS and acupuncture) after the first 3 weeks; 7% of the McKenzie group and 26% of the control group had sought additional health care

Authors' conclusions:

- Patients with acute LBP generally recover quickly if they receive care which from physicians who are made familiar with evidence-based guidelines

- The addition of the McKenzie method to this guideline-based care adds little of clinical importance in the acute recovery phase
- It is possible that the McKenzie method is advantageous in reducing the amount of health care sought by LBP patients, but the study was not designed to detect this outcome, and effects in the first three weeks are trivial in size

Comments:

- The majority (66%) of patients had had LBP for less than 2 weeks at randomization, and less than half had leg pain
- Because of the high rate of recovery for acute LBP, it is to be expected that as long as patients avoid bed rest and try to remain active, other interventions are likely not to have effects which will be obvious in that acute phase of LBP
- Although the effect size, expressed as a group difference in pain scores, was trivial in size, the pain after 3 weeks was 2.0 in the McKenzie group and 2.3 in the control group
 - o When outcomes are measured on scales such as the 0-10 point pain scale reported here, they are susceptible to floor effects, in which there is very little room for improvement when scores are close to the minimum possible score
 - o There are analytical methods (Twisk 2009) which may be more suitable than traditional linear mixed models (used by the authors) when floor effects are likely to be observed in a clinical trial
 - It is not certain that the regression methods described by Twisk would actually perform better than the much more familiar methods used by the authors, but the omission of floor effects from the discussion section may mean that they did not consider it as a limitation of the study analysis
- Therefore, even though there was not a clinically important effect size on the primary outcome, the floor effect is likely to provide only partial information about the comparative effectiveness of various interventions
- Although it was not a primary outcome, the difference in health care utilization is less susceptible to floor and ceiling effects (no strict upper bound to the amount of health care sought), and here, the McKenzie group sought a clinically important lesser amount of health care (7% sought such care vs 26% in the control group)
- The study cannot therefore be used as evidence one way or the other about the effectiveness of the McKenzie method in the setting of acute LBP; it points to the desirability of studying the method in settings with longer durations of pain when differences in recovery may be easier to detect

Assessment: Inadequate as evidence for or against the McKenzie method for acute LBP (floor effects likely to limit the analysis of treatment effects, a non-primary outcome of health care

utilization suggesting a treatment difference which would be easier to detect in the acute care setting)

Reference:

Twisk J, Rijmen F. Longitudinal tobit regression: A new approach to analyze outcome variables with floor or ceiling effects. *J Clin Epidemiol* 2009; 62: 953-958