

EM Hay, R Mullis, M Lewis, K Vohora, CJ Main, P Watson, KS Dziedzic, J Sim, C Minns Lowe, PR Craft Comparison of physical treatments versus a brief pain-management programme for back pain in primary care: a randomized clinical trial in physiotherapy practice. Lancet 2005, 365: 2024-30.

Design: Randomized clinical trial

Population /sample size/setting:

- 402 patients (192 men, 210 women, mean age 40.6 years) with lower back pain were recruited from 28 general practices in the UK
- Eligibility criteria were all adults aged 18-64 years who consulted with general practitioners for the first or second time with an episode of non-specific low back pain (as defined by the UK Clinical Standards Advisory Group) of less than 12 week duration and who were able to give informed written consent.
- Exclusion criteria included clinical indicators of possible serious spinal or systematic disorders; long-term sick leave (> 12 weeks); a clinical diagnosis of osteoporosis or inflammatory arthritis; systematic steroid treatment for longer than 12 weeks; pregnancy, previous hip or back surgery or a fracture; abdominal surgery within the previous 3 months; and treatment by another health care professional for this episode of back pain.

Main outcome measures:

- Randomized to one of two interventions: pain management program of instruction (n=201) or to manual physical therapy (n=201).
- Pain management program consisted of a brief 2 day course of instruction consisting of explanations of pain mechanisms, a graded return to usual activities, problem-solving exercises, and individually tailored exercise focusing on general activity and spine mobility; no manual treatments were used.
 - o Program was designed to identify and address psychosocial risk factors for persistent or recurrent disability related to back pain.
- Manual PT consisted of up to six 20 minute sessions of articular mobilization, articular manipulation, and other soft tissue techniques, combined with exercises focusing on muscle strengthening back exercises and ergonomic advice.
 - o Manual therapy and the techniques used were standardized before the trial.
- Study nurses were unaware of treatment allocation, trial participants were unaware of study hypothesis, but treating physiotherapists were aware of study hypothesis.
- Outcomes were measured at baseline, 3 months, and 12 months
- The primary outcome was change in disability related to the back measured at 12 months on the self-completed Roland Morris Disability Questionnaire (RMDQ) 24 item scale.
 - o Some self-completed secondary outcomes were included: participants' overall assessment of change compared with baseline (6 point scale from completely

better to much worse), pain location, pain severity rating (0-100 on the VAS scale), nature of pain (McGill pain questionnaire), depression, somatic distress, fear of movement (Tampa scale of kinesiophobia from 17-68), and coping strategies, satisfaction with treatment (VAS scale 0-100), days off work, and co-interventions.

- Follow-up rate was 82% at 12 months for both groups
- 17% (33) assigned to the pain management program and 10% (20) assigned to the manual PT group did not attend for their treatment.
- The RMDQ change scores did not differ between groups at both 3 months and 12 months. No significant differences in outcome between the two treatment groups. Both groups reported decreased disability scores compared to baseline.
 - o Baseline RMDQ scores were 13.8 in the pain management program group and 13.3 in the manual PT group
 - o At 3 months the RMDQ scores were 6.0 in the pain management program group and 5.1 in the manual PT group. RMDQ scores decreased 7.8 and 8.1 points, respectively.
 - o At 12 months the RMDQ scores were 5.2 in the pain management program group and 4.4 in the manual PT group. RMDQ scores decreased 8.8 points total in both groups.
- Clinical outcome was the same, since the difference in scores between the 2 groups was below the clinically important threshold of 2 points at both 3 and 12 months of follow-up.
- For the secondary outcomes, no differences were noted between the 2 groups.
 - o Participants' overall self-assessment of improvement did not differ between groups at 12 months. 84% of participants in each group rated themselves as completely better, much better or better.
 - o Secondary outcomes for back pain or function and psychological measures were not different between the groups.
 - o Participants in the pain management program group made significantly fewer contacts with secondary care over 12 months than participants in the manual PT group ($p = 0.012$).

Authors' conclusions:

- The RMDQ change scores did not differ between groups at both 3 and 12 months of follow-up.
- Clinical outcome was the same at 3 months and 12 months for participants randomized to either a pain management program or to manual physical therapy.
- There were no significant differences in outcome between the two treatment groups in the primary outcome measure or any of the secondary outcome measures.

- Because of the higher than expected drop out rate resulting in smaller group sizes, the trial was underpowered to detect a 2 point difference in RMDQ change scores between groups.
- There is a need to develop and assess training programs and competency levels for practitioners who deliver pain management programs in primary care.
- Manual therapy is not essential as an initial treatment for patients with subacute low back pain. A pain management program can be delivered in fewer treatment sessions, resulting in fewer referrals to secondary care and might be an efficient first-line approach to care in primary care practice for patients with low back pain.

Comments:

- This is a well-designed and documented study.
- 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 obvious differing effects in the acute phase of LBP. Both interventions did show improvement in the first 3 months, but the improvements were similar for both interventions.
- It is possible that the pain management program method is advantageous in reducing the amount of “secondary” health care sought by participants, but the study was only designed to detect this as a secondary outcome, and the amount of “primary” health care sought by participants in this group did not show any similar reduction. Only 1% (2) of the pain management program participants and 7% (11) of the PT participants sought secondary health care. This reduction may only be a marginal clinically important lesser amount of health care.
- The RMDQ mean change scores measured at 12 months follow-up may have been susceptible to floor effects, since these scores were already quite low after 3-months follow-up. After 3 months follow-up, the RMDQ scores were already in the lowest quartile (6.0 and 5.1) of the 24 point scale. This may be why little improvement was observed at 12 months follow-up in both intervention groups, since they were close to the minimum possible score. The authors did not discuss floor effects, so perhaps they did not consider this as a limitation of the study analysis.
- It is not known whether either of these interventions is superior to no active intervention, since a “no treatment control group” was not included. Therefore, this study cannot be used as evidence one way or the other about the effectiveness of either intervention compared to “no treatment”.

Assessment:

Adequate for some evidence that a two day course of instruction in pain management is as effective as six sessions of manual physical therapy in reducing disability from nonspecific low back pain of less than 12 weeks duration.