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McKenzie Method of Mechanical Diagnosis and Therapy was slightly more effective than placebo for pain, but not for disability, in patients with chronic non-specific low back pain: a randomised placebo controlled trial with short and longer term follow-up

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ABSTRACT

Background The McKenzie Method of Mechanical Diagnosis and Therapy (MDT) is one of the exercise approaches recommended by low back pain (LBP) guidelines. We investigated the efficacy of MDT compared with placebo in patients with chronic LBP.

Methods This was a prospectively registered, two-arm randomised placebo controlled trial, with a blinded assessor. A total of 148 patients seeking care for chronic LBP were randomly allocated to either MDT (n=74) or placebo (n=74). Patients from both groups received 10 treatment sessions over 5 weeks. Patients from both groups also received an educational booklet. Clinical outcomes were obtained at the end of treatment (5 weeks) and 3, 6 and 12 months after randomisation. Primary outcomes were pain intensity and disability at the end of treatment (5 weeks). We also conducted a subgroup analysis to identify potential treatment effect modifiers that could predict a better response to MDT treatment.

Results The MDT group had greater improvements in pain intensity at the end of treatment (mean difference (MD) −1.00, 95% CI −2.09 to −0.01) but not for disability (MD −0.84, 95% CI −2.62 to 0.93). We did not detect between-group differences for any secondary outcomes, nor were any treatment effect modifiers identified. Patients did not report any adverse events.

Conclusion We found a small and likely not clinically relevant difference in pain intensity favouring the MDT method immediately at the end of 5 weeks of treatment but not for disability. No other difference was found for any of the primary or secondary outcomes at any follow-up times.

Trial registration number ClinicalTrials.gov (NCT02123394)

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BACKGROUND

Low back pain (LBP) is one of the most prevalent, costly and disabling health conditions worldwide.[1–3] Patients with chronic LBP (ie, with a duration of 12 weeks or more)[4] are even more likely to seek care[5–7] and use health services[8 9] than patients with acute LBP. Healthcare utilisation due to LBP has increased substantially over the past two decades,[10] with increasing use of surgery,[11] spinal injections,[12 13] opioid medications[14 15] and visits to physiotherapists.[16 17]

Current guidelines for chronic LBP recommend exercise as a treatment option.[10 18 19] Some evidence suggests it may be important to combine education with exercise.[20] The McKenzie Method of Mechanical Diagnosis and Therapy (MDT) prescribes repeated exercises in a specific direction, combined with an educational approach[21 22] and according to guidelines, it can benefit patients with chronic LBP in the short term.[10 19] MDT involves the assessment of symptomatic and mechanical responses to repeated movements and sustained positions.[21 22]Patients' responses to this assessment are used to classify them into three subgroups: derangement, dysfunction and postural.[21 22] The treatment is then tailored to this classification.[21 22] MDT aims to give patients the ability to self-manage their pain through the specific exercises and education provided.[21 22]

MDT has been widely investigated in patients with acute LBP, but not in patients with chronic LBP.[23–25] There are just three randomised clinical trials (RCTs), which compare MDT with other interventions in patients with chronic LBP.[23–25] One of these RCTs found that MDT reduced pain at 4 weeks compared with conventional physiotherapy[25] and another reported greater improvements in disability at 1 month compared with Back School method.[23] However, no differences were identified between MDT and an educational intervention.[24] No studies have compared MDT against a placebo treatment to identify its true efficacy. It also remains unclear if some characteristics of patients (effect modifiers) can modify the clinical response of patients treated with MDT.[26] We hypothesised that patients with clear centralisation, pain located below the knee, higher baseline pain intensity and younger patients would respond better to MDT than to placebo.[27 28] Therefore, the primary objective of this trial was to assess the efficacy of MDT in patients with chronic non-specific LBP at the end of a 5-week treatment programme. Our secondary objective was to assess the effect of the programme through to 12-month follow-up and to identify possible treatment effect modifiers for MDT.

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METHODS

Trial design

Prospectively registered, two-arm, placebo randomised controlled trial with a blinded assessor. All methodological steps of this study are described in detail in the published protocol.[29] There were no deviations from the registered protocol.[29]

Participants and recruitment

Participants were patients seeking care for chronic non-specific LBP (with a duration of at least 3 months)[4] in the physiotherapy clinic of the *Universidade Cidade de São Paulo* (São Paulo/Brazil) between May 2014 and July 2015. To be eligible, patients had to have a pain intensity of at least 3 points (measured on a 0–10 point Numerical Pain Rating Scale (NPRS)); aged between 18 and 80 years; and be able to read Portuguese. Patients with any contraindication to exercise,[30] ultrasound or shortwave therapy; evidence of nerve root compromise tested by a clinical neurological examination (with at least two of these signs: motor, reflex or sensory abnormalities); serious spinal pathology (eg, fracture, tumour, inflammatory and infectious diseases); serious cardiovascular and metabolic diseases; previous back surgery; or pregnancy were excluded.

Randomisation

A simple randomisation schedule was computer generated by one of the study investigators not directly involved with the assessment and treatment of patients. The allocation was concealed by using consecutive numbered, sealed and opaque envelopes. Before randomisation, all patients were assessed according to the MDT approach. This enabled the MDT assessment findings/classification to be explored as effect modifiers. The MDT assessment involved a medical history and physical examination.[21] The physical examination focuses on using repeated or sustained end-range loading strategies in standing or lying postures. Depending on the response of symptoms to these loading strategies, patients are classified as having derangement, dysfunction or postural syndrome.[21] Eligible patients were allocated to the treatment groups (MDT or placebo) by a physiotherapist who opened the next available numbered envelope prior to the first treatment session.

Blinding

At the end of the study, the assessor was asked whether the patients were allocated to the real treatment group or to the placebo group in order to measure blinding. Given the nature of the study it was not possible to blind the therapists to the interventions. We described the study to the patients as 'a comparison of two physiotherapy treatments, with one of the interventions being a placebo. Placebo means a treatment delivered at a non-therapeutic dose and patients were unlikely to distinguish between a real and a placebo treatment.'

Interventions

Patients from both groups received a 5-week treatment programme (10 treatment sessions, twice a week, for 30–40 min duration). All patients also received a translated version of 'The Back Book.'[31] The chief investigator of the study audited both interventions once every month. Patients were treated in an outpatient physiotherapy clinic by independent therapists to minimise possible preference bias of therapists. One therapist delivered the MDT treatment and two therapists delivered the placebo.

MDT group

The McKenzie Method of MDT prescribes repeated exercises in a specific direction, combined with an educational approach to treat patients with mechanical pain.[21 22] The participants allocated to this group were treated according to the principles of the MDT method[21 22] and the choice of therapeutic exercise was guided by the history, physical examination findings and classification into three syndromes/groups: (1) derangement syndrome, (2) dysfunction syndrome and (3) postural syndrome.[21 22] The exercises were individually progressed as indicated by reassessment.[22]

In the case of patients classified with derangement syndrome, the exercises were performed following the directional preference of movement, identified by relief of pain, centralisation of pain (pain referred to a peripheral location from the spine is progressively abolished) or abolishment of pain.[21 22] The directional preference movement can be spine flexion, spine extension or spine lateral shift.[21 22] Patients were instructed to do 10–15 repetitions of home exercises matching their directional preference, three to five times per day.

For patients classified with dysfunction syndrome, the selected directional movement for treatment was the one that produced pain at the end of range of motion, which returned to resting level after the patient returned to the initial/neutral position.[21 22] This treatment choice aimed to stretch shortened tissues. Patients were instructed to do 10–15 repetitions of exercise, three to five times per day into the painful or stiff direction. Patients with postural syndrome were treated by correcting sitting or other poor postures, since these patients only have pain in sustained end of range postures.[21 22] Furthermore, all patients in the MDT group also received a book of MDT educational advice called 'Treat Your Own Back.'[32] Descriptions of the exercises prescribed in this study were published previously.[23] Adherence to home exercises was monitored by means of a daily log that the patient filled in at home and brought to the therapist at each subsequent session. The care provider who treated patients in this group had 6 years of clinical experience as a physiotherapist and completed the Level A—Lumbar Spine Course, certified by the McKenzie Institute of Brazil, 3 years before the study started. Since then, the therapist had clinical experience using the method and also worked as the therapist on another MDT trial.[23]

Placebo group

Patients allocated to the placebo group were treated with detuned pulsed ultrasound (Ibramed^{R}) for 5 min with patients in side lying. They also received detuned short wave diathermy (Ibramed^{R}) in pulsed mode for 25 min (in a supine position). The devices were used with the internal cables disconnected to obtain the placebo effect. However, it was possible to handle them and adjust doses and alarms as if they were connected to simulate clinical practice as well as to increase the credibility of these devices to the patients. This type of placebo has been used successfully in previous trials with patients with LBP.[33–36] The care providers who treated patients in this group were physiotherapists, one with 3 years of clinical experience and the other with 9 years of experience.

Outcomes

Demographic and clinical characteristics (eg, marital status, educational status, medication, smoking and physical activity) and each patient's expectancy for improvement were assessed at baseline assessment.[37] Clinical outcomes were measured at the baseline assessment, at the end of treatment, and 3, 6 and

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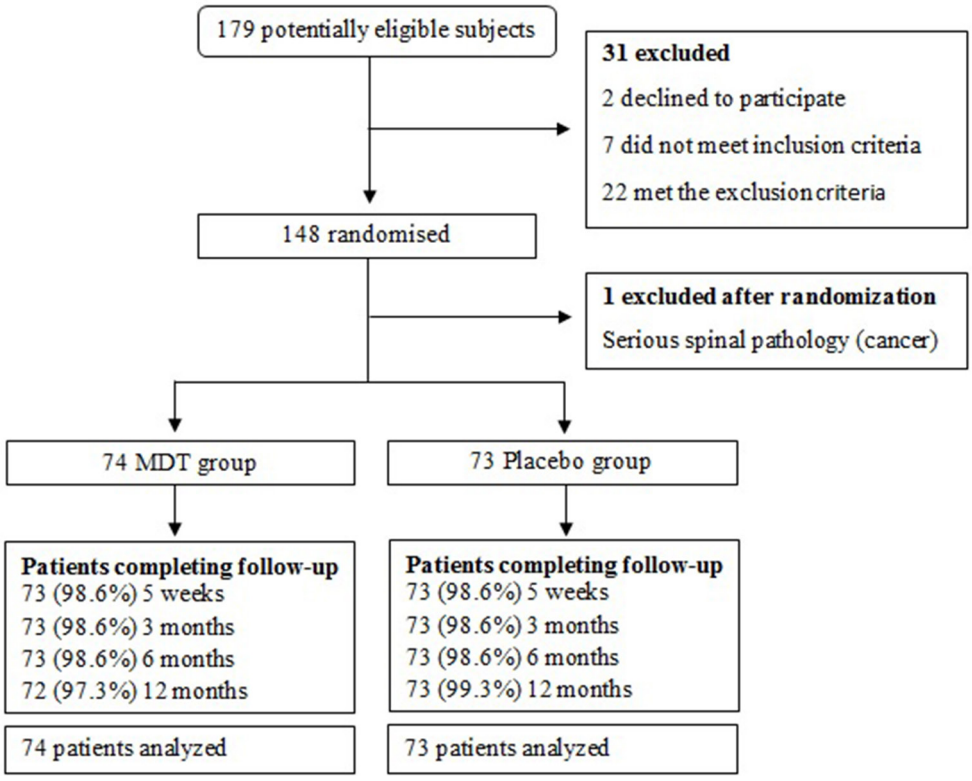

Figure 1 Flow diagram of the study. MDT, Mechanical Diagnosis and Therapy.

12 months after randomisation. The primary outcomes were pain intensity[38] and disability[39 40] at the end of treatment. The secondary outcomes were pain intensity and disability 3, 6 and 12 months after randomisation and function,[41 42] kinesiophobia,[43] and global impression of recovery[38] at the end of treatment and 3, 6 and 12 months after randomisation. All measurement tools were previously cross-culturally adapted into Brazilian-Portuguese and have had their measurement properties tested.[38 39 43]

Pain intensity was recorded as average pain intensity for the past 7 days on an 11-point NPRS scored from 0 (no pain) to 10 (worst possible pain).[38] Disability was assessed with the Roland Morris Disability Questionnaire (RMDQ), scored from 0 (no disability) to 24 (high disability).[39 40] Function was assessed with the Patient Specific Functional Scale (PSFS) using the average of three items scored from 0 (unable to perform) to 10 (able to perform at preinjury level).[41 42] Global perceived effect (GPE) was scored from −5 (vastly worse) to +5 (completely recovered).[38] Kinesiophobia was assessed by the Tampa Scale of Kinesiophobia, scored from 17 (no kinesiophobia) to 68 (high kinesiophobia).[43] Expectancy of improvement was assessed by a scale from 0 (no expectancy for improvement) to 10 (expectancy for the greatest possible improvement).[37]

Statistical analysis

A sample of 148 patients (74 per group) provided 80% power to detect a difference of 1 point in pain intensity measured by NPRS (estimated SD of 1.84 points)[33] and a difference of 4 points in disability measured by the RMDQ[39 40] (estimated SD of 4.9 points)[33] allowing for alpha level of 5% and loss to follow-up of 15%. The statistical analysis followed intention-to-treat principles.[44] The characteristics of the participants were presented using descriptive statistical tests. The between-group differences (effects of treatment) and their respective 95% CIs were calculated by constructing linear mixed models[45] using interaction terms of treatment groups versus time, all models were adjusted for baseline estimates.

We also conducted a subgroup analysis to identify potential treatment effect modifiers that could predict a better response to MDT treatment. This was calculated by linear regression models using change in pain and disability from baseline to 5 weeks as the dependent variables. Only patients classified as derangement syndrome (104/148, 70.7%) at baseline were included in this analysis as they received a similar treatment approach. We prospectively selected four potential effect modifiers for treatment after consideration of the theoretical rationale and consultation with an educator in the MDT approach (clear centralisation, pain below the knee, higher baseline pain intensity and younger age).[28] All four potential effect modifiers were investigated in separate models. Continuous effect modifiers (pain intensity and age) were dichotomised using a median split. Each model included terms for group, predictor and the interaction term (group × predictor). As this was an exploratory secondary analysis and likely underpowered we assessed both the statistical significance and the point estimates of the interaction term. We considered an interaction term of greater than 1 point on the NPRS or 3 points on the RMDQ to be potentially clinically important at 5 weeks of follow-up.[46] We used IBM SPSS V.19.0 for the analyses.

RESULTS

Recruitment and baseline data

From a total of 179 patients who were seeking care for LBP, 148 were considered eligible and were included in the study between May 2014 and June 2016. One participant was excluded after randomisation because he had a diagnosis of cancer during the period of treatment. As this patient was incorrectly included in the study he was excluded from the study and analyses. Therefore,

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Table 1 Demographic and clinical characteristics of the patients at baseline (n=148)

Variables	MDT (n=74)	Placebo (n=73)
Gender		
Female	58 (78.4)	54 (74.0)
Male	16 (21.6)	19 (26.0)
Age (years)	57.47 (12.16)	55.47 (13.65)
Duration of symptoms (months)*	36 (102.0)	48 (96.0)
Weight (kg)	73.73 (13.72)	77.90 (16.75)
Height (m)	1.61 (0.08)	1.62 (0.09)
Marital status		
Single	15 (20.3)	20 (27.4)
Married	44 (59.5)	32 (43.8)
Divorced	11 (14.9)	11 (15.1)
Widowed	4 (5.4)	10 (13.7)
Education status		
Elementary degree	36 (48.6)	43 (59.0)
High school	21 (28.4)	18 (24.7)
University	17 (23.0)	12 (16.4)
Use of medication	41 (55.4)	48 (65.8)
Physically active	20 (27)	23 (31.5)
Smoker	7 (9.5)	10 (13.9)
Recent low back pain episode	50 (67.6)	52 (71.2)
Pain intensity (0–10)	7.19 (1.81)	6.99 (1.73)
Disability (0–24)	13.28 (6.20)	14.32 (5.82)
Function (0–10)	4 (1.92)	3.92 (1.73)
Global perceived effect (−5 to +5)	−2.12 (3.0)	−1.92 (3.16)
Kinesiophobia (17–68)	50.18 (7.29)	53.33 (8.15)
Expectancy of improvement (0–10)	8.35 (2.0)	8.16 (1.85)
MDT classification		
Derangement	55 (74.3)	49 (67.1)
Dysfunction	3 (4.1)	11 (15.1)
Postural	5 (6.8)	3 (4.1)
Other	11 (14.9)	10 (13.7)

*Duration of symptoms is expressed as median (IQR).
Categorical variables are expressed as number (%), continuous variables are expressed as mean (SD).
MDT, Mechanical Diagnosis and Therapy.

the statistical analyses were conducted on the remaining 147 patients (figure 1). The characteristics of the patients at baseline are described in table 1. The baseline characteristics of both groups were similar for most variables, the only exception being kinesiophobia. Nevertheless, all treatment effects are adjusted for baseline estimates.

Most of the study participants were women, married, sedentary, overweight and the mean age was 56. Almost half of the patients used medication. Both groups began the treatment with moderate levels of pain intensity and disability. Treatment adherence was high and similar in the two groups. From a total of 10 sessions that could be completed the patients allocated to the MDT group attended a mean of 9.01 sessions (SD=2.39) compared with a mean of 9.23 sessions (SD=1.81) for patients allocated to the placebo group. There was no statistically significant difference between groups (p=0.53). Adherence to home exercises was monitored only for the MDT group by means of a daily log that the patient filled in at home and brought to the therapist at each subsequent session. From a total of 25 days that could be completed the patients attended a mean of 18.76 days (SD=8.51).

Primary and secondary outcomes and estimation/adverse events

Patients allocated to the MDT group had greater improvements in pain intensity (treatment effect −1.00, 95% CI −2.09 to −0.01) at the end of treatment (table 2). There was no statistically significant between-group difference for disability at the end of treatment. There was no statistically significant between-group difference for pain or disability at 3, 6 or 12 months. No between-group differences were observed for all remaining secondary outcomes. Patients did not report any adverse events.

Process measures

Patients were asked at every follow-up if they used other treatments during the period of the study (cointervention). The number of cointerventions used in both groups was similar (table 3). The main cointerventions were medication, conventional physiotherapy, massage, hydrotherapy, stretching, Pilates method and acupuncture. After the last follow-up (12 months), the assessor was asked whether the patients were allocated to the treatment group (MDT) or to the placebo group in order to measure blinding. The results showed that the assessor only guessed correctly 32% of the time in the MDT group and 28% of the time in placebo group, suggesting the assessor was successfully blinded to the treatment allocation.

Results of subgroup analysis

A total of 104 (70.7%) patients were classified as being in the derangement syndrome and were included in the secondary subgroup analysis. The results of the linear regression analyses for the outcomes of pain and disability are shown in tables 4 and 5, respectively. None of the interaction terms (clear centralisation, pain below the knee, high pain intensity and age younger than 54) for any of the outcomes were statistically significant and point estimates did not exceed prespecified thresholds for clinical importance.

DISCUSSION

This is the first randomised placebo controlled clinical trial to assess the efficacy of the McKenzie Method of MDT in patients with chronic non-specific LBP at 5 weeks, and 3, 6 and 12 months of follow-up. We observed within-group improvement for all outcomes at all follow-up times for both groups. The use of The Back Book in both groups may have contributed to these improvements. At 5 weeks of follow-up we observed that patients allocated to the MDT group had improvements for pain intensity, but not for disability compared with placebo group. No between-group differences were observed for any secondary outcomes. Finally, we did not detect any treatment effect modifiers.

Interpretation of principal findings

We observed a statistically significant difference for pain intensity at short term only. The mean effect was 1.00 point and the upper limit of the CI was 2.10 points on the 11-point NPRS, so this remains a small effect. A 2-point change is the minimal detectable change for the NPRS.[46] Therefore, we are confident in our conclusion that the mean effect of MDT compared with placebo in patients with chronic LBP is small and unlikely to have clinical importance. The potential benefits of treatment need to be weighed up against the cost and time involved for the 10 sessions of therapy. The effect size in the current study is similar to previous studies which compared exercises with no treatment,[20 47] placebo[20 33 48] or with other conservative treatment such as advice to stay active.[20 49] Studies investigating other

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Table 2 Unadjusted mean (SD) and adjusted mean difference and 95% CIs for the outcomes of the study (n=147)

	Unadjusted mean (SD)		McKenzie versus placebo	
Outcomes	**McKenzie**	**Placebo**	**Adjusted mean differences (95% CI)**	**p**
Pain intensity (0–10)				
Baseline	7.19 (1.81)	6.99 (1.73)		
5 weeks	3.32 (2.75)	4.18 (2.80)	−1.0 (−2.10 to −0.01)	0.04
3 months	3.95 (2.73)	4.70 (2.97)	−0.94 (−1.99 to 0.09)	0.07
6 months	4.47 (2.84)	5.03 (2.90)	−0.75 (−1.80 to 0.28)	0.15
12 months	5.08 (3.0)	4.85 (3.08)	−0.07 (−0.96 to 1.12)	0.88
Disability (0–24)				
Baseline	13.28 (6.20)	14.32 (5.82)		
5 weeks	7.97 (6.61)	9.92 (6.54)	−0.84 (−2.63 to 0.94)	0.35
3 months	7.97 (6.32)	9.85 (6.93)	−0.77 (−2.56 to 1.01)	0.39
6 months	8.33 (7.22)	9.89 (7.35)	−0.45 (−2.25 to 1.33)	0.61
12 months	7.72 (6.87)	8.48 (7.48)	0.52 (−1.27 to 2.32)	0.56
Function (0–10)				
Baseline	4 (1.92)	3.92 (1.73)		
5 weeks	6.99 (2.15)	6.65 (1.99)	−0.18 (−0.98 to 0.60)	0.63
3 months	6.59 (1.89)	5.97 (2.27)	−0.46 (−1.25 to 0.32)	0.24
6 months	6.17 (2.39)	5.93 (2.21)	−0.08 (−0.87 to 0.70)	0.82
12 months	5.54 (2.62)	6 (2.48)	0.66 (−0.13 to 1.45)	0.10
Global perceived effect (−5 to +5)				
Baseline	−2.12 (3.0)	−1.92 (3.16)		
5 weeks	2.90 (2.64)	2.53 (2.70)	0.56 (−0.52 to 1.64)	0.31
3 months	2.66 (2.37)	1.92 (3.05)	0.93 (−0.15 to 2.0)	0.09
6 months	2.10 (2.86)	1.63 (3.17)	0.65 (−0.43 to 1.74)	0.23
12 months	1.60 (3.0)	1.30 (3.18)	0.02 (−1.0 to 1.11)	0.95
Kinesiophobia (17–68)				
Baseline	50.18 (7.29)	53.33 (8.15)		
5 weeks	43.79 (8.46)	48.22 (10.20)	−1.28 (−4.32 to 1.75)	0.40
3 months	46.71 (9.45)	48.82 (10.63)	1.02 (−2.01 to 4.07)	0.50
6 months	46.48 (9.05)	47.28 (10.29)	2.25 (−0.79 to 5.30)	0.14
12 months	46.81 (12.08)	48.01 (11.34)	2.01 (−1.03 to 5.07)	0.19

Primary outcomes are highlighted in dark grey. Negative treatment effects favour McKenzie for the outcomes of pain intensity, disability and kinesiophobia. Positive scores for function and GPE. Pain intensity was measured by NPRS; disability by RMDQ; function by PSFS; GPE by Global Perceived Effect Scale; kinesiophobia by Tampa Scale of Kinesiophobia.

interventions for chronic LBP such as opioids[15 20] and non-steroidal anti-inflammatory drugs[50] also typically report similar small effects on pain.

We did not detect any treatment effect modifiers. A previous study from our research team suggested that older age may be an important effect modifier for patients with chronic LBP receiving MDT compared with Back School method.[28] Another trial comparing MDT with spinal manipulation[27] included six predictor variables: centralisation, age, below 40 years, duration of symptoms more than 1 year, leg pain, pain below the knee, signs of nerve root involvement and pain response. They concluded that it was not possible to detect any treatment effect modifiers. A limitation of all existing subgroup analyses in MDT trials (including our trial) is that these analyses were exploratory and underpowered to detect significant interactions. Larger trials with preplanned, powered analyses are needed to clarify this. The lack of findings in the subgroup analysis further questions whether the small effects we found for pain were a result of effects specific to MDT or simply due to any form of exercise.

Table 3 Proportion of cointerventions in both treatment groups (n=148)

Time points	McKenzie	Placebo
5 weeks	10 (13.5)	13 (17.8)
3 months	5 (6.8)	7 (9.6)
6 months	9 (12.2)	16 (21.9)
12 months	15 (20.3)	14 (19.2)

Variables are expressed as number (%).

Generalisability and strengths of the study

This study had good levels of internal and external validity. We included a number of features to minimise bias. The trial was prospectively registered and followed a published protocol without any changes during the study.[29] The outcome assessments for both intervention groups were measured at the same time and all the outcomes were reported as they were prospectively registered. We used true randomisation, concealed allocation, blinded assessment and an intention-to-treat analysis. We achieved excellent follow-up rates and treatment adherence in both groups. Use of a placebo design allows to control for possible confounders such as natural recovery, regression to mean, therapist bias and placebo effects.[51] We used a placebo treatment, which was quite different from the active MDT. In theory, this placebo allowed for some non-specific effects such as time with therapist and expectation.[51 52] As the groups were different in the amount of exercise, the placebo used

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Table 4 Results of effect modifier analyses for pain intensity at 5 weeks

Variables	Beta coefficient	p	95% CI
Clear centralisation			
Treatment	0.20	0.11	−0.36 to 3.18
Clear centraliser	−0.17	0.22	−3.0 to 0.72
Interaction: treatment × clear centraliser	−0.03	0.83	−2.86 to 2.34
Pain below the knee			
Treatment	0.24	0.01	0.28 to 3.02
Pain below the knee	0.19	0.22	−1.30 to 5.56
Interaction: treatment × pain below the knee	−0.23	0.15	−7.46 to 1.22
High pain intensity			
Treatment	0.40	0.02	0.43 to 5.04
High pain intensity	0.46	0.00	1.53 to 5.37
Interaction: treatment × high pain intensity	−0.30	0.13	−4.81 to 0.62
Age younger than 54 years			
Treatment	0.13	0.30	−0.81 to 2.59
Age younger than 54 years	−0.15	0.28	−2.93 to 0.86
Interaction: treatment × age younger than 54 years	0.12	0.44	−1.62 to 3.69

does not enable us to determine if any differences were a result of exercise generally or specifically due to mechanisms associated with the MDT approach.

Patients in both groups had a similar duration and number of treatment sessions to avoid attention control bias. We carefully monitored the home exercise programme of the MDT group.

Table 5 Results of effect modifier analyses for disability at 5 weeks

Variables	Beta coefficient	p	95% CI
Clear centralisation			
Treatment	−0.08	0.54	−3.58 to 1.91
Clear centraliser	−0.36	0.01	−6.74 to −0.94
Interaction: treatment × clear centraliser	0.20	0.21	−1.47 to 6.61
Pain below the knee			
Treatment	0.08	0.45	−1.36 to 3.03
Pain below the knee	0.03	0.82	−4.87 to 6.13
Interaction: treatment × pain below the knee	−0.09	0.58	−8.87 to 5.06
High pain intensity			
Treatment	0.02	0.91	−3.70 to 4.14
High pain intensity	−0.01	0.89	−3.48 to 3.06
Interaction: treatment × high pain intensity	0.05	0.81	−4.08 to 5.18
Age younger than 54 years			
Treatment	−0.05	0.69	−3.23 to 2.16
Age younger than 54 years	−0.14	0.32	−4.51 to 1.50
Interaction: treatment × age younger than 54 years	0.21	0.19	−1.42 to 7.00

Interaction terms provide the critical information for assessing whether effect modification exists.
Positive interactions mean that the direction of the effect was in favour of the study's hypothesis.
Negative interactions mean the effect was in the opposite direction to that hypothesised.

Another strength of our study was that our interventions were conducted by independent therapists whom were properly trained to perform the proposed interventions. This minimised the risk of possible preference bias of the therapist and cross contamination. The care provider who treated patients in the MDT group had completed the first level (Level A—Lumbar Spine Course certified by the McKenzie Institute of Brazil), thus she was appropriately trained and able to apply this method. This course is widely available in other countries such as the USA, European, Asia Pacific, Middle East and African countries. This widely available training can be very useful for clinicians worldwide in terms of standardisation; however, it is not possible to assume that treatment and patient response to MDT would be identical across different cultures. A very large previous study on MDT levels of training[53] with more than 20 000 patients concluded that patients with LBP treated by physical therapists who underwent any MDT training had better functional outcomes and fewer visits than those treated by physical therapist with no MDT training. However, this study also showed that the level of MDT training was not associated with better outcomes.[53] This means that just a fraction of training might be enough.

Limitations

Limitations of our study included not being able to blind therapists to the treatment allocation. Another limitation of our study is the difference of the treatment providers in terms of clinical experience. The therapist providing the MDT intervention had 6 years of experience as a physiotherapist while one therapist providing and placebo intervention had 3 years of experience and the other had 9 years of experience. Both treatments were audited by two senior authors (LOPC and LdCMC). We did not use a specific method to measure the treatment fidelity which can be considered a limitation of the study. Our study provided therapy twice a week for 5 weeks and recommendation to practice home exercises. We measured the adherence of home exercises of the MDT group by means of a self-reported daily log. It is still unclear if the same effect sizes in our study would be achieved by having a higher or lower frequency of intervention.

Registration and protocol

This study was approved by the Research Ethics Committee of the Universidade Cidade de São Paulo (#480754) and the patient consent was obtained. This study was also prospectively registered at ClinicalTrials.gov (NCT02123394). The study protocol for the study was previously published.[29]

CONCLUSION

We found a small and likely not clinically relevant difference in pain intensity favouring the McKenzie MDT method immediately at the end of a 5-week treatment period. No differences were observed for the primary outcome of disability or for any other secondary outcomes (ie, function, GPE and kinesiophobia) at any follow-up times.

What are the findings?

- The McKenzie Method of *Mechanical Diagnosis and Therapy* was slightly more effective than placebo for pain intensity but not for disability and only immediately at the end of treatment.

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How might it impact on clinical practice in the future?

- Patients with chronic low back pain treated by the McKenzie Method of *Mechanical Diagnosis and Therapy* may experience small improvements over and above placebo effects in terms of pain intensity at short-term follow-up. This small effect size is similar to other interventions such as opioids and non-steroidal anti-inflammatory drugs, however, with lower risk of harm.

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Contributors ANG was involved in setting the research question; trial design; literature search, writing protocol; data analysis and manuscript preparation assisted by LOPC, MJH and LdCMC. LOPC also contributed in securing funding assistance; randomisation schedule preparation; data interpretation and statistical analysis strategy. MJH also contributed to data interpretation and statistical analysis strategy. FSdS was the blind assessor and had full access to all of the data in the study. MOdA and GVFdOG were the therapists of placebo group. ANG was responsible for MDT treatment group. All coauthors reviewed the manuscript before submission.

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Competing interests The care provider who treated patients in the MDT group has completed first level McKenzie training, however has no involvement with the McKenzie Institute. This trial did not receive neither funding from McKenzie Institute nor any assistance in writing/analysing the results of this trial. Authors do not have any involvement with the McKenzie Institute. MJH, LOPC and ANG receive funding from International Mechanical Diagnosis and Therapy Research Foundation for the following studies on MDT: (1) Hancock MJ, Maher CG, Mota da Silva T, Clare H, Steffens D (2016). Secondary prevention of a recurrence of low back pain. (2) Hancock MJ, Garcia AN, Costa LdCM, Costa LOP (2014). Identifying patients with back pain who respond best to MDT. MJH is keynote speaker at the 2017 McKenzie conference and his travel costs will be paid.

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REFERENCES

1 Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. *Spine J* 2008;8:8–20.
2 Hoy D, Bain C, Williams G, *et al*. A systematic review of the global prevalence of low back pain. *Arthritis Rheum* 2012;64:2028–37.
3 GBD 2015 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet* 2016;388:1545–602.
4 Airaksinen O, Brox JI, Cedraschi C, *et al*. Chapter 4. european guidelines for the management of chronic nonspecific low back pain. *Eur Spine J* 2006;15 Suppl 2:s192–s300.
5 IJzelenberg W, Burdorf A. Patterns of care for low back pain in a working population. *Spine* 2004;29:1362–8.
6 Molano SM, Burdorf A, Elders LA. Factors associated with medical care-seeking due to low-back pain in scaffolders. *Am J Ind Med* 2001;40:275–81.
7 Mortimer M, Ahlberg G; MUSIC-Norrtälje Study Group. To seek or not to seek? Care-seeking behaviour among people with low-back pain. *Scand J Public Health* 2003;31:194–203.
8 Carey TS, Evans A, Hadler N, *et al*. Care-seeking among individuals with chronic low back pain. *Spine* 1995;20:312–7.
9 Von Korff M, Lin EH, Fenton JJ, *et al*. Frequency and priority of pain patients' health care use. *Clin J Pain* 2007;23:400–8.
10 Delitto A, George SZ, Van Dillen LR, *et al*. Low back pain. *J Orthop Sports Phys Ther* 2012;42:A1–A57.
11 Gray DT, Deyo RA, Kreuter W, *et al*. Population-based trends in volumes and rates of ambulatory lumbar spine surgery. *Spine* 2006;31:1957–63.
12 Carrino JA, Morrison WB, Parker L, *et al*. Spinal injection procedures: volume, provider distribution, and reimbursement in the U.S. medicare population from 1993 to 1999. *Radiology* 2002;225:723–9.
13 Friedly J, Chan L, Deyo R. Increases in lumbosacral injections in the Medicare population: 1994 to 2001. *Spine* 2007;32:1754–60.
14 Deyo RA, Von Korff M, Duhrkoop D. Opioids for low back pain. *BMJ* 2015;350:g6380.
15 Abdel Shaheed C, Maher CG, Williams KA, *et al*. Efficacy, tolerability, and Dose-Dependent effects of opioid analgesics for low back pain: a systematic review and Meta-analysis. *JAMA Intern Med* 2016;176:958-68.
16 Feuerstein M, Marcus SC, Huang GD. National trends in nonoperative care for nonspecific back pain. *Spine J* 2004;4:56–63.
17 Beattie PF, Silfies SP, Jordon M. The evolving role of physical therapists in the long-term management of chronic low back pain: longitudinal care using assisted self-management strategies. *Braz J Phys Ther* 2016;20:580–91.
18 Wong JJ, Côté P, Sutton DA, *et al*. Clinical practice guidelines for the noninvasive management of low back pain: a systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. *Eur J Pain* 2017;21:201–16.
19 Staal JB, Hendriks EJM, Heijmans M, *et al*. KNGF guideline: a clinical practice guideline for physical therapy in patients with low back pain. *Royal Dutch Society for Phys Ther* 2013:1–12.
20 Hayden JA, van Tulder MW, Malmivaara A, *et al*. Exercise therapy for treatment of non-specific low back pain. *Cochrane Database Syst Rev* 2005;3:CD000335.
21 McKenzie R, May S. The Lumbar Spine mechanical diagnosis & therapy vol I. *New Zealand: Spinal Publications* 2003.
22 McKenzie R, May S. The Lumbar Spine mechanical diagnosis & therapy vol II. *New Zealand: Spinal Publications* 2003.
23 Garcia AN, Costa LC, da Silva TM, *et al*. Effectiveness of back school versus McKenzie exercises in patients with chronic nonspecific low back pain: a randomized controlled trial. *Phys Ther* 2013;93:729–47.
24 Sorensen PH, Bendix T, Manniche C, *et al*. An educational approach based on a non-injury model compared with individual symptom-based physical training in chronic LBP. A pragmatic, randomised trial with a one-year follow-up. *BMC Musculoskelet Disord* 2010;11:1–13.
25 Sakai Y, Matsuyama Y, Nakamura H, *et al*. The effect of muscle relaxant on the paraspinal muscle blood flow: a randomized controlled trial in patients with chronic low back pain. *Spine* 2008;33:581–7.
26 van Middelkoop M, Rubinstein SM, Verhagen AP, *et al*. Exercise therapy for chronic nonspecific low-back pain. *Best Pract Res Clin Rheumatol* 2010;24:193–204.
27 Petersen T, Christensen R, Juhl C. Predicting a clinically important outcome in patients with low back pain following McKenzie therapy or spinal manipulation: a stratified analysis in a randomized controlled trial. *BMC Musculoskelet Disord* 2015;16:74.
28 Garcia AN, Costa LC, Hancock M, *et al*. Identifying patients with chronic low back Pain who respond best to mechanical diagnosis and therapy: secondary analysis of a Randomized Controlled Trial. *Phys Ther* 2016;96:623–30.
29 Garcia AN, Costa LC, Hancock MJ, *et al*. Efficacy of the McKenzie method in patients with chronic nonspecific low back pain: a protocol of randomized placebo-controlled trial. *Phys Ther* 2015;95:267–73.
30 Kenney LW, Humphrey RH, Mahler DA. *ACSM's Guidelines for exercise testing and prescription*: Williams & Walkins Baltimore, 1995.
31 Manchester MR, Glasgow GW, York JKM, *et al*. *The Back Book: TSO*, 2002.
32 McKenzie R. *Trate você mesmo a sua coluna*. Spinal Publication LTD, 1998.
33 Costa LO, Maher CG, Latimer J, *et al*. Motor control exercise for chronic low back pain: a randomized placebo-controlled trial. *Phys Ther* 2009;89:1275–86.
34 Balthazard P, de Goumoens P, Rivier G, *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 Musculoskelet Disord* 2012;13:162.
35 Kumar SP. Efficacy of segmental stabilization exercise for lumbar segmental instability in patients with mechanical low back pain: a randomized placebo controlled crossover study. *N Am J Med Sci* 2011;3:456–61.
36 Ebadi S, Ansari NN, Naghdi S, *et al*. The effect of continuous ultrasound on chronic non-specific low back pain: a single blind placebo-controlled randomized trial. *BMC Musculoskelet Disord* 2012;13:192.
37 Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry* 2000;31:73–86.
38 Costa LO, Maher CG, Latimer J, *et al*. Clinimetric testing of three self-report outcome measures for low back pain patients in Brazil: which one is the best? *Spine* 2008;33:2459–63.
39 Costa LO, Maher CG, Latimer J, *et al*. Psychometric characteristics of the Brazilian-Portuguese versions of the Functional Rating Index and the Roland Morris Disability Questionnaire. *Spine* 2007;32:1902–7.
40 Nusbaum L, Natour J, Ferraz MB, *et al*. Translation, adaptation and validation of the Roland-Morris questionnaire--Brazil Roland-Morris. *Braz J Med Biol Res* 2001;34:203–10.
41 Chatman AB, Hyams SP, Neel JM, *et al*. The Patient-Specific Functional Scale: measurement properties in patients with knee dysfunction. *Phys Ther* 1997;77:820–9.
42 Pengel LH, Refshauge KM, Maher CG. Responsiveness of pain, disability, and physical impairment outcomes in patients with low back pain. *Spine* 2004;29:879–83.
43 de Souza FS, Marinho CS, Siqueira FB, *et al*. Psychometric testing confirms that the Brazilian-Portuguese adaptations, the original versions of the Fear-Avoidance Beliefs Questionnaire, and the Tampa Scale of Kinesiophobia have similar measurement properties. *Spine* 2008;33:1028–33.

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44 Hollis S, Campbell F. What is meant by intention to treat analysis? survey of published randomised controlled trials. *BMJ* 1999;319:670–4.
45 Twisk JWR. *Applied Longitudinal Data analysis for Epidemiology: a Practical Guide*, 2003. ISBN: 0521819768, 9780511061608.
46 Ostelo RW, Deyo RA, Stratford P, *et al*. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine* 2008;33:90–4.
47 Alexandre NM, de Moraes MA, Corrêa Filho HR, *et al*. Evaluation of a program to reduce back pain in nursing personnel. *Rev Saude Publica* 2001;35:356–61.
48 Maher CG, Latimer J, Hodges PW, *et al*. The effect of motor control exercise versus placebo in patients with chronic low back pain [ACTRN012605000262606]. *BMC Musculoskelet Disord* 2005;6:54.
49 Miyamoto GC, Costa LO, Galvanin T, *et al*. Efficacy of the addition of modified pilates exercises to a minimal intervention in patients with chronic low back pain: a randomized controlled trial. *Phys Ther* 2013;93:310–20.
50 Enthoven WT, Roelofs PD, Deyo RA, *et al*. Non-steroidal anti-inflammatory drugs for chronic low back pain. *Cochrane Database Syst Rev* 2016;2:CD012087.
51 Machado LA, Kamper SJ, Herbert RD, *et al*. Imperfect placebos are common in low back pain trials: a systematic review of the literature. *Eur Spine J* 2008;17:889–904.
52 Hancock MJ, Maher CG, Latimer J, *et al*. Selecting an appropriate placebo for a trial of spinal manipulative therapy. *Aust J Physiother* 2006;52:135–8.
53 Deutscher D, Werneke MW, Gottlieb D, *et al*. Physical therapists' level of McKenzie education, functional outcomes, and utilization in patients with low back pain. *J Orthop Sports Phys Ther* 2014;44:925–36.

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McKenzie Method of Mechanical Diagnosis and Therapy was slightly more effective than placebo for pain, but not for disability, in patients with chronic non-specific low back pain: a randomised placebo controlled trial with short and longer term follow-up

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