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RANDOMIZED TRIAL

The McKenzie Method Compared With Manipulation When Used Adjunctive to Information and Advice in Low Back Pain Patients Presenting With Centralization or Peripheralization

A Randomized Controlled Trial

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Study Design. Randomized controlled trial.

Objective. To compare the effects of the McKenzie method performed by certified therapists with spinal manipulation performed by chiropractors when used adjunctive to information and advice.

Summary of Background Data. Recent guidelines recommend a structured exercise program tailored to the individual patient as well as manual therapy for the treatment of persistent low back pain. There is presently insufficient evidence to recommend the use of specific decision methods tailoring specific therapies to clinical subgroups of patients in primary care.

Methods. A total of 350 patients suffering from low back pain with a duration of more than 6 weeks who presented with centralization or peripheralization of symptoms with or without signs of nerve root involvement, were enrolled in the trial. Main outcome was number of patients with treatment success defined as a reduction of at least 5 points or an absolute score below 5 points on the Roland Morris Questionnaire. Secondary outcomes were reduction in disability and pain, global perceived effect, general health, mental health, lost work time, and medical care utilization.

Results. Both treatment groups showed clinically meaningful improvements in this study. At 2 months follow-up, the McKenzie treatment was superior to manipulation with respect to the number of patients who reported success after treatment (71% and 59%, respectively) (odds ratio 0.58, 95% confidence interval [CI] 0.36 to 0.91, $P = 0.018$). The number needed to treat with the McKenzie method was 7 (95% CI 4 to 47). The McKenzie group showed improvement in level of disability compared to the manipulation group reaching a statistical significance at 2 and 12 months follow-up (mean difference 1.5, 95% CI 0.2 to 2.8, $P = 0.022$ and 1.5, 95% CI 0.2 to 2.9, $P = 0.030$, respectively). There was also a significant difference of 13% in number of patients reporting global perceived effect at end of treatment ($P = 0.016$). None of the other secondary outcomes showed statistically significant differences.

Conclusion. In patients with low back pain for more than 6 weeks presenting with centralization or peripheralization of symptoms, we found the McKenzie method to be slightly more effective than manipulation when used adjunctive to information and advice.

Key words: low back pain, chronic disease, McKenzie treatment, physical therapy, chiropractic manipulation, exercise. **Spine 2011;36:1999–2010**

Disability related to low back pain (LBP) is a major problem in the Western World.[1,2] About 60% to 65% of the Nordic population are likely to experience LBP during their lifetime and 45% to 55% of adults will experience pain within a 12-month period.[3] Studies from a variety of countries investigating the long-term course of LBP show that most patients will improve rapidly.[4] Further improvement is apparent until about 3 months. Thereafter, levels for pain, disability, and return to work remains almost constant. Six months after an episode of LBP, 60% to 70% of patients will have experienced relapses of pain and 16% will be sick-listed. As much as 62% will still be experiencing pain after 12 months.[4,5]

The most recent published consensus reports for the treatment of patients with persistent nonspecific low back pain (NSLBP) recommend a program that focuses on self-management after initial advice and information. These patients should also be offered a structured exercise program tailored to the individual patient and other methods such as manipulation.[6,7]

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Previous studies have compared the effect of the McKenzie method, also called Mechanical Diagnosis and Therapy (MDT), with that of manipulation in mixed populations of patients with acute and subacute symptoms of NSLBP and found no difference in outcome.[8,9]

Recently, the need for studies testing the effect of treatment strategies for diagnostic subgroups of patients with NSLBP in primary care has been emphasized[10–12] based on the hypothesis that subgrouping methods improve decision-making toward the most effective management strategies. Although initial data show promise, there is presently insufficient evidence to recommend the use of specific decision methods tailoring specific therapies in primary care.[7]

Three randomized studies have tested the effects of the McKenzie method *versus* spinal manipulation in a subgroup of patients with predominantly acute or subacute NSLBP that responded favorably to end range motions during physical examination.[13–15] The conclusions drawn from these studies were not in concurrence and they were limited by a low methodologic quality. To pursue the idea of subgrouping further, we wanted to focus on a more homogeneous clinical subgroup of patients by the inclusion of patients with NSLBP characterized by centralization or peripheralization of symptoms during physical examination. To control for the benign natural course of LBP in the early phases, patients with persistent pain were targeted. In addition, we wanted to increase the relevance of the study for daily practice by incorporating the latest recommendations regarding self-management in both the treatment arms.

The objective of this study was 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 LBP of more than 6 weeks duration.

MATERIALS AND METHODS

Patients

We recruited patients from September 2003 to May 2007 at a primary care specialist center in Copenhagen, Denmark. Patients were referred from primary care physicians for treatment of persistent LBP. Eligible patients were between 18 and 60 years of age, suffering from LBP with or without leg pain for a period of more than 6 weeks, able to speak and understand the Danish language, and with a presentation of clinical signs of disc-related symptoms. Signs of disc-related symptoms were identified during initial screening if the patient fulfilled the clinical criteria for centralization or peripheralization of symptoms with or without signs of nerve root involvement as defined by the Petersen/Laslett classification.[16] Centralization is defined as the abolition of symptoms in the most distal body area and peripheralization is defined as the production of symptoms in a more distal body area. These criteria have previously been found to have acceptable degree of intertester reliability (Kappa value 0.64) and construct validity (likelihood ratio 6.9) using a positive discography as reference standard.[17,18] Patients were excluded if they were free of symptoms at the day of inclusion, demonstrated positive nonorganic signs,[19] or if serious pathology was suspected based on physical examination and/or magnetic resonance imaging, that is, severe nerve root involvement (disabling back or leg pain in combination with progressive disturbances in sensibility, muscle strength, or reflexes), osteoporosis, severe spondylolisthesis, fracture, inflammatory arthritis, cancer, or referred pain from the viscera. Other exclusion criteria were application for disability pension, pending litigation, pregnancy, comorbidity, recent back surgery, language problems, or problems with communication including abuse of drugs or alcohol.

Treatment Allocation and Treatment

The initial screening was performed before randomization by a physical therapist with a diploma in the MDT examination system based on reliability studies.[17,20] The examiner was unaware of treatment assignment and the screening was conducted without talking about therapeutic possibilities.

After baseline measures were obtained, randomization was carried out by a computer-generated list of random numbers in blocks of 10 using sealed envelopes. A secretary who was not involved in the study prepared opaque, sequentially numbered envelopes indicating one of the two treatments. The practitioners performing the interventions had no knowledge of the results of the initial screening. Blinding of the practitioners in one group to the treatment given in the other group was not possible. For both interventions, however, practitioner preference bias was minimized by choosing therapists and chiropractors who strongly believed in the treatments that they performed.

The McKenzie treatment was planned individually after the therapist's pretreatment physical assessment.[21] Manual vertebral mobilization techniques including high velocity thrust were not allowed. An educational booklet describing self care[22] or a "lumbar roll" for correction of the seated position was sometimes provided to the patient at the discretion of the therapist. All three therapists performing the treatment had passed a credential examination in the McKenzie method.

In the spinal manipulation treatment, all types of manual techniques including vertebral mobilization and high velocity thrust as well as myofascial trigger-point massage were used. The choice of technique, or combination of techniques, was at the discretion of the chiropractor dependent of the results of their pretreatment physical assessment. General mobilizing exercises, that is, self-manipulation, alternating lumbar flexion/extension movements, and stretching, were allowed but not specific exercises in the directional preference. An inclined wedged pillow for correction of the seated position was available to the patients if the chiropractor believed this to be indicated. Spinal manipulation was performed by three chiropractors with several years of clinical experience in this type of treatment.

In both treatment groups, patients were informed thoroughly of the results of the physical assessment, the benign course of back pain, and the importance of remaining physically active. Guidance on proper back care was also

given. In addition, all patients were provided with a Danish version of "The Back Book," which previously has been shown to have beneficial effect on patients' beliefs about back pain.[23] A maximum of 15 treatments for a period of 12 weeks were given. If considered necessary by the treating clinician, instruction in stabilizing and strengthening home exercises was provided at the end of the treatment period. All patients were educated in an individual program of self-administered mobilizing, stretching, stabilizing, and/or strengthening exercises chosen by their physical therapist or chiropractor depended on the treatment goals. Patients were instructed to continue the exercises at home or at a gym for a minimum of 2 months after completion of the treatment at the back center. Because the patients suffered from persistent LBP we expected this period of self-administered exercises to be necessary for the patients to experience the full effect of the intervention. Patients were encouraged not to seek any other kind of treatment for the 2 months period of self-administered exercises.

Outcome Measures

The main outcome measure was proportion of patients reporting success at 2 months follow-up. Treatment success was defined as a reduction of at least 5 points or an absolute score below 5 points on the 23-item modified Roland Morris Disability Questionnaire (RMDQ).[24] A validated Danish version of RMDQ was used.[25] The definition of treatment success was based on the recommendations by others.[26,27]

Secondary outcome measures were treatment success at other follow-ups as well as measures of changes in RMDQ at all follow-ups.

Other outcome measures were changes in pain,[28] global perceived effect,[29] quality of life,[30] days with reduced activity,[31] return-to-work, satisfaction with treatment, and use of health care after the completion of treatment.

Follow-up assessment was carried out by a secretary blinded to treatment allocation at the end of treatment, after 2 months, and 1-year post-treatment.

Sample Size

We calculated that 169 participants per group would be required to detect a between-group difference of 15% (P_0 = 35%) in proportions of patients reporting success on the main outcome variable with 80% power and a 5% risk of type 1 error, or in total 380 patients allowing for 10% loss to follow-up. Recommendations regarding a minimum clinically important difference in proportions of patients with treatment success in this patient population are lacking. Therefore, the estimated 15% between-group difference was made by consensus among the practitioner who participated in the study when they were asked the question: what would you require the difference to be if it would make you consider using the results in clinical decision making?

STATISTICAL ANALYSES

Intention-to-treat analysis was performed on all participants in the study. The analysis plan was agreed in advance by the trial management group. A statistician who had no knowledge of the randomization code performed all analyses and interpretations of results were made by the whole trial management group blinded to treatment allocation.

In addition to the measure of treatment success defined as a absolute reduction of at least 5 points on RMDQ, we performed a sensitivity analysis using a relative minimal clinical important difference of 30% recommended by some authors.[32,33]

Most commonly, patients seek treatment when their symptoms are at their peak. Consequently symptoms can be expected to decrease toward its characteristic level when the next measure is performed.[34,35] The effect of this phenomenon, known as Regression to The Mean, can be reduced by taking serial measures and calculating the average value as the "true baseline." In this study, the true baseline score on the secondary outcome variable RMDQ was calculated as the mean from two measures taken over an average period of 16 days.

The between-group analyses on the dichotomous variables were performed based on the χ^2 test and calculation of odds ratios. Continuous or discrete variables were compared using the Student *t* test or Mann-Whitney *U* test. The mean or median was used as an index of localization, and standard deviation or 10% percentiles as an index of dispersion. Multivariate analyses were performed to examine the influence of the following baseline covariates on main and secondary outcomes: disability score, gender, radiating pain below the knee, on sick leave, and classified as reducible disc syndrome (centralization of symptoms). For the main dichotomous outcome, treatment success, a logistic regression analysis was used, and for the main continuous outcome, RMDQ, multiple regression analysis was used. A secondary analysis combining the three follow-up points was performed by means of repeated measures analysis of variance (ANOVA). Finally, interaction in $2 \times 2 \times 2$ tables was tested by the Breslow-Day Test with the last score carried forward for subjects with missing 2 months RMDQ scores.

RESULTS

After exclusion of otherwise ineligible patients, 574 patients were screened for a possible disc syndrome (Figure 1) and 307 (53%) of those showed centralization, labeled "educible Disc Syndrome" and 43 (7%) showed peripheralization, labeled "Irreducible Disc Syndrome" (Table 1). Baseline characteristics were similar for the two treatment groups except for the fact that statistically significant more patients were on sick leave in the McKenzie group (Table 1). This variable was included as a covariate in multivariate analyses. The Regression to The Mean analysis among all patients showed a minimal change in disability across two baseline measures (mean difference −0.49, 95% CI −0.81 to −0.17, P = 0.02).

The trial population had predominantly chronic LBP. The mean duration of symptoms in the treatment groups was 97 and 94 weeks, respectively. Mean disability level on the 23-item version of RMDQ was slightly higher than reported in a similar study population in primary care.[36]

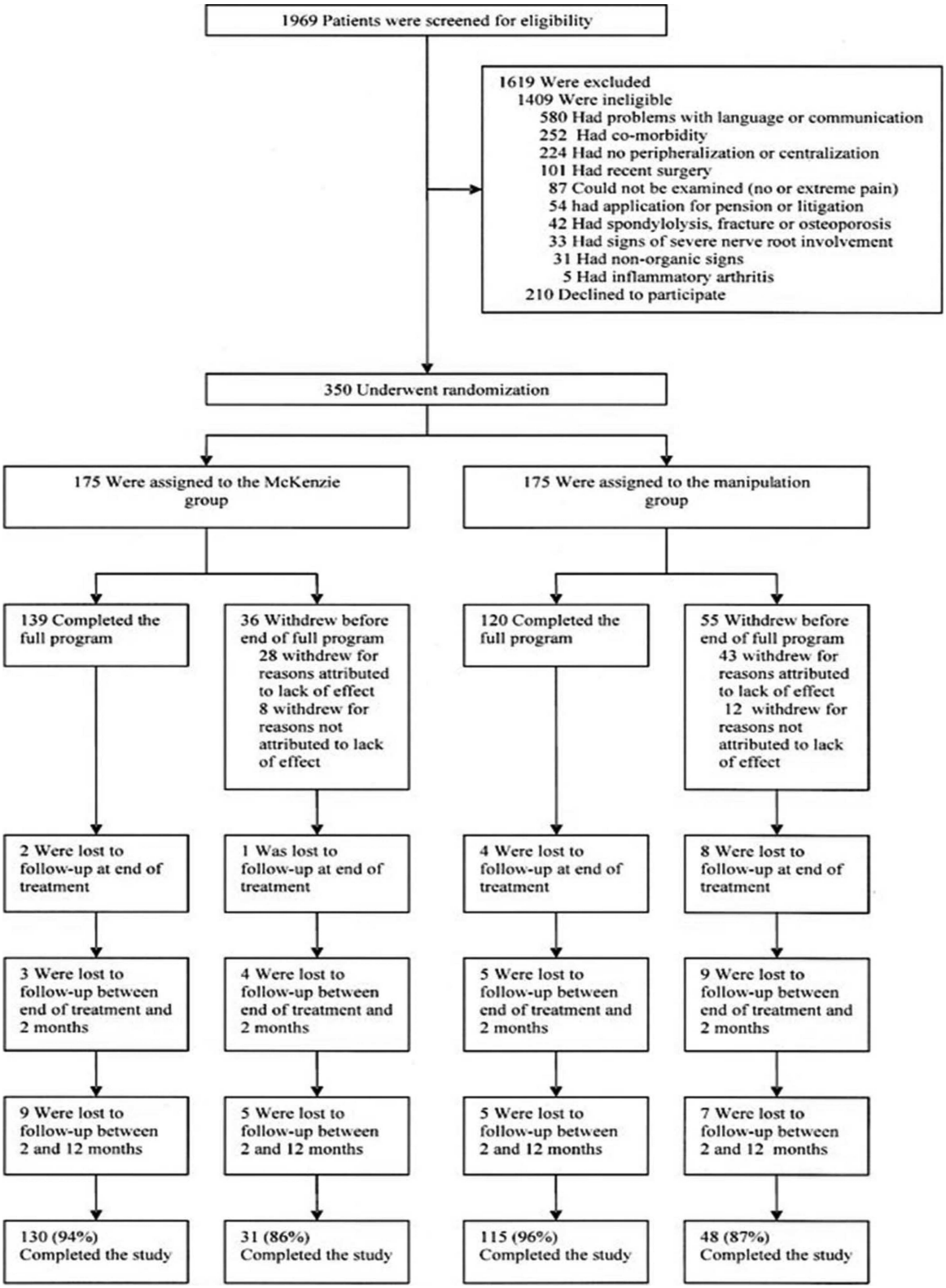

Figure 1. Flow of participants through the trial.

OUTCOMES

In both treatment groups, about half of the patients reported success and a reduction in mean disability above 50% at end of treatment (Table 3). These treatment responses were maintained at follow-up after 2 months and 1 year. A statistically significant larger proportion of patients withdrew or was excluded during treatment in the manipulation group, mainly for reasons likely to be related to lack of treatment effect (43 patients in the manipulation group *vs.* 28 in the McKenzie group) (Table 2).

TABLE 1. Comparison of Baseline Characteristics and Treatment Information for Patients in the Two Treatment Groups

Variable	McKenzie Group, n = 175	Manipulation group n = 175	*P*
Sex, number females	103 (59%)	92 (53%)	0.237
Age (yr)	38 (10.4)	37 (9.4)	0.623
Body mass index	25 (4.3)	26 (4.4)	0.424
Number of smokers	76 (43%)	75 (43%)	0.914
Work load, median (10%; 90% percentiles)*	5 (1;9)	4 (1;8)	0.165
Leisure activities, median (10%; 90% percentiles)†	1 (1;3)	2 (1;4)	0.926
Number on sick leave	65 (37%)	47 (27%)	0.039
Work absence duration in weeks	23 (47.9)	21(45.3)	0.938
Symptom duration in weeks	97 (230)	94 (181)	0.666
Number with symptoms below knee level	88 (50%)	102 (58%)	0.133
Number with signs of nerve root involvement‡	18 (10%)	18 (10%)	1.000
Number with reducible/irreducible disc syndrome§	151/24 (86%/14%)	156/19 (89%/11%)	0.416
Disability¶	13 (4.8)	13 (5.0)	0.746
Back and leg pain‖	30 (11.2)	29 (11.3)	0.746
General health**	67 (19.8)	65 (18.6)	0.291
Mental health††	65 (20.4)	65 (19.3)	0.581
Expectations to improvement, median (10%;90% percentiles)‡‡	8 (4.5;10)	7 (5;10)	0.507

Note: Values are means (standard deviations) unless stated otherwise.

**Measured on an 11-point box scale. 0 indicates very physically demanding; 10, not at all physically demanding.*

†Measured on a 4-point Likert scale rating usual participation in physical activities, 1 = no physical activities to 4 = high load activities several times per week.

‡Positive straight leg raise test of less than 60 degrees that reproduced leg pain and the detection of diminished reflex, sensory disturbances and/or muscle weakness in a myotomal or dermatomal pattern.

§Reducible disc syndrome indicates centralization of symptoms. Irreducible disc syndrome, peripheralization of symptoms. Classified during initial screening.

¶Average of two baseline measures. Scored on modified Roland Morris Disability Questionnaire (0–23 points).

‖The back and leg pain questionnaire included three separate 11-point box scales comprising the following items: LBP at the moment, the worst LBP within the past 2 weeks, and the average level of LBP within the last 2 weeks. These summed to a total score ranging from 0 points (no back or leg pain at all) to 60 points (worst possible back and leg pain on all items).

***Scored on Short Form 36 general health perceptions scale (0–100).*

††Scored on Short Form 36 mental health scale (0–100).

‡‡Scored after the second treatment on a 11-point box scale. 0 indicates I expect no improvement at all; 10, I am certain that I will improve.

Post-treatment

There was a statistically significant difference of 13% in favor of the McKenzie group regarding number of patients who reported global perceived effect at end of treatment (Table 3). The number needed to treat (NNT) with the McKenzie method was 8 (95% CI 4 to 40) meaning that for every 8 patients, one would have success with the McKenzie method who would not have achieved this response with manipulation. No other statistically significant differences were observed.

Follow-up at 2 Months

There was a statistically significant difference of 12% in favor of the McKenzie group regarding number of patients who reported treatment success at 2 months follow-up (Table 3). The NNT with the McKenzie method was 7 (95% CI 4 to 47).

The McKenzie group showed a reduction of 1.5 point (95% CI 0.2 to 2.8) in level of disability compared to the manipulation group. No other statistically significant differences were observed.

Follow-up at 12 Months

The McKenzie group showed a reduction 1.5 point (95% CI 0.2 to 2.9) in level of disability compared to the manipulation group (Table 3). No other statistically significant differences were observed.

TABLE 2. Comparison of Withdrawal Characteristics and Information Regarding Course of Treatment

Characteristic	McKenzie Group, n = 175	Manipulation Group, n = 175	*P* Values Difference (95% CI)
No. of withdrawals, any reason (n = 91, 26%)*	36	55	0.021
No. of withdrawals, reasons (1–10)			0.700
1. Referred for surgical evaluation	5	9	
2. Referred for diagnostics evaluation	1	4	
3. Referred for differential diagnostics	1	3	
4. Comorbidity	4	4	
5. Change in medication	1	0	
6. Transferred to other physical treatment	10	9	
7. Practical obstacles (working ours, etc.)	3	3	
8. Patient decision	10	18	
9. Problems with communication	0	1	
10. Other	1	4	
No. of withdrawals, reasons related (1,2,3,5,6,8)/unrelated (4,7,9,10) to lack of effect during treatment†	28/8	43/12	0.964
Treatment duration in days mean (SD)	67.5 (25.4)	60.5 (38.0)	0.044–7.0 (−0.2 to −13.8)
Treatments given mean (SD)	7.9 (3.5)	7.1 (3.9)	0.031–0.9 (−0.8 to −1.6)

**By decision from the study group.*

†Information gathered by the participating physical therapists, chiropractors, or doctors.

Follow-up from Baseline to 12 Months Follow-up

The results from a secondary analysis by means of repeated measurement ANOVA revealed a reduction from baseline to the three follow-ups in the McKenzie group of 6.5 (SD 5.9), 6.8 (SD 5.9), and 7.1 (SD 6.1) and in the manipulation group of 5.9 (SD 5.9), 5.3 (SD 6.0), and 5.5 (SD 6.5); F = 2.71, $P = 0.045$.

Supplementary Analyses

Neither the sensitivity analysis defining success as a 30% reduction in disability nor the analyses of covariance adjusting for five baseline variables changed the results markedly (Table 3).

Post Hoc Test for Interaction

Centralization/peripheralization at initial screening had no statistical significant influence on the association between treatment group and success rate (Table 4).

DISCUSSION

In both the McKenzie and the manipulation group, long-term improvements were observed. 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 sensitivity analysis showed that the results were robust and the between-group differences remained after adjustment for predefined prognostic variables. The difference in number of patients reporting success after treatment was slightly below the predefined clinical relevant level of 15% and furthermore the difference in reduction of disability was below the 2.5 points recommended by others.[26]

Number of patients with treatment success was chosen as the main outcome measure in this trial based on the belief that clinicians need to be able to tell patients what their chances are of obtaining a specific outcome. The reports of mean improvement are useful, but around every mean value there will be patients who fare better than the mean and those who fare worse. In our definition of treatment success, we used a strict definition of minimal clinical important difference on RMDQ in the upper end of the recommended interval from 2.5 to 5 points.[26] A lack of a nontreatment control group in this study means that conclusions cannot be drawn as to whether our results can be explained by the natural history of back pain or nonspecific effects such as extra attention. However, the long pretreatment duration of symptoms and the minimal change in disability across two baseline measures in the Regression to The Mean analysis suggest that the patient sample was in a stable condition and that an important improvement without intervention should not be expected. Furthermore, an attempt was made to distribute attention bias evenly between groups by securing that all practitioners were dedicated to the type of treatment they performed and the patients in both groups received the same amount of contact. A limitation of the study is a relatively high withdrawal rate during intervention. The withdrawal rate covers patients who decided to discontinue treatment

TABLE 3. Outcomes Post-treatment and at 2 and 12 Months Follow-up Post-treatment

Outcomes	McKenzie Group	Manipul. Group	Between-group Difference (95% CI), *P*	McKenzie Group	Manipulation Group	Between-group Difference (95% CI), *P*	McKenzie Group	Manipula-tion Group	Between-group Difference (95% CI), *P*
No with success/ total no. of patients* (n = 335 post-treatment, n = 329 at 2 months, n = 324 at 12 months)	116/172 (67%)	98/163 (60%)	0.73†† (−0.47 to 1.14) *P* = 0.163	120/168 (71%)	95/161 (59%)	0.58†† (0.36 to 0.91) *P* = 0.018	113/161 (70%)	101/163 (62%)	0.69†† (0.44 to 1.10) *P* = 0.119
Adjusted results† (n = 335 post-treatment, n = 329 at 2 months, n = 324 at 12 months)			0.74†† (0.47 to 1.18) *P* = 0.211			0.59†† (0.37 to 0.95) *P* = 0.028			0.7†† (0.44 to 1.12) *P* = 0.137
Sensitivity analysis: no with success/total no. of patients ‡ (n = 335 post-treatment, n = 329 at 2 months, n = 324 at 12 months)	120/172 (70%)	98/163 (60%)	0.65†† (0.42 to 1.03) *P* = 0.065	120/168 (71%)	98/161 (61%)	0.62†† (0.39 to 0.99) *P* = 0.044	116/161 (72%)	100/163 (61%)	0.62†† (0.39 to 0.98) *P* = 0.042
Reduction in disability§ (n = 335 post-treatment, n = 329 at 2 months, n = 322 at 12 months)	6.5 (5.6 to 7.4)	5.8 (5.0 to 6.7)	0.7 (−0.6 to 2.0) *P* = 0.268	6.7 (5.8 to 7.6)	5.2 (4.3 to 6.1)	1.5 (0.2 to 2.8) *P* = 0.022)	7.1 (6.1 to 8.0)	5.6 (4.6 to 6.6)	1.5 (0.2 to 2.9) *P* = 0.030
Adjusted results† (n = 335 post-treatment, n = 329 at 2 months, n = 322 at 12 months)			0.53 (−0.66 to 1.73) *P* = 0.381			1.4 (0.15 to 2.62) *P* = 0.028			1.4 (0.12 to 2.74) *P* = 0.033
Reduction in pain§ (n = 333 post-treatment, n = 326 at 2 months, n = 323 at 12 months)	15.3 (13.4 to 17.4)	13.8 (11.8 to 15.8)	1.6 (−1.2 to 4.4) *P* = 0.271	14.4 (12.4 to 16.4)	13.0 (11.1 to 14.9)	1.4 (−1.3 to 4.1) *P* = 0.309	15.0 (12.9 to 17.1)	12.2 (10.1 to 14.3)	2.8 (−0.2 to 5.8) *P* = 0.063
No still on sick leave/total no. on sick leave at baseline (n = 332 post-treatment, n = 329 at 2 months, n = 323 at 12 months)	30/65 (45%)	15/47 (32%)	*P* = 0.218	20/66 (30%)	14/47 (30%)	*P* = 0.930	14/66 (21%)	6/47 (13%)	*P* = 0.219

(*Continued*)

TABLE 3. (*Continued*)

Outcomes	McKenzie Group	Manipul. Group	Between-group Difference (95% CI), *P*	McKenzie Group	Manipulation Group	Between-group Difference (95% CI), *P*	McKenzie Group	Manipula-tion Group	Between-group Difference (95% CI), *P*
Days off work or school in past 4 wk¶ (n = 325 post-treatment, n = 323 at 2 months, n = 308 at 12 months)	5.1 (3.6 to 6.6)	4.4 (2.9 to 5.9)	0.7 (−1.4 to 2.8) *P* = 0.532	3.8 (2.4 to 5.1)	3.4 (2.1 to 4.7)	0.4 (−1.5 to 2.3) *P* = 0.703	3.2 (1.8 to 4.5)	1.9 (0.9 to 2.9)	1.3 (−0.4 to 2.9) *P* = 0.127
Days with reduced activity in past 4 wk¶ (n = 330 post-treatment, n = 328 at 2 months, n = 320 at 12 months)	7.0 (5.6 to 8.5)	7.3 (5.7 to 8.9)	0.25 (−2.4 to 1.9) *P* = 0.817	6.2 (4.7 to 7.6)	6.5 (5.1 to 8.0)	0.4 (−2.4 to 1.7) *P* = 0.726	5.4 (4.0 to 6.8)	5.6 (4.2 to 6.9)	−0.14 (−2.1 to 1.8) *P* = 0.887
SF-36: quality of life general health§ (n = 333 post-treatment, n = 321 at 2 months, n = 314 at 12 months)	72.1	69.5	2.6 (−1.6 to 6.8) *P* = 0.226	70.4	66.6	3.8 (−0.9 to 8.5) *P* = 0.111	69.5	65.3	4.2 (−0.8 to 9.2) *P* = 0.101
SF-36: quality of life mental§ (n = 334 post-treatment, n = 329 at 2 months, n = 324 at 12 months)	74.2	74.2	−0.03 (−4.3 to 4.3) *P* = 0.988	76.5	73.5	3.0 (−1.2 to 7.1) *P* = 0.162	76.2	73.8	2.5 (−1.9 to 6.9) *P* = 0.270
No with global perceived effect/total no. of patients‖ (n = 322 post-treatment)	81/169 (48%)	53/153 (35%)	*P* = 0.016	–	–	–	–	–	–
No satisfied with treatment/total no. of patients** (n = 336 post-treatment)	133/173 (77%)	133/163 (82%)	*P* = 0.287	–	–	–	–	–	–
No with contact to health care in past 2 months/total no. of patients (n = 330 at 2 months, n = 325 at 12 months)	–	–	–	60/170 (35%)	70/160 (44%)	*P* = 0.194	87/162 (54%)	89/163 (55%)	*P* = 0.556

(*Continued*)

TABLE 3. (*Continued*)

Outcomes	McKenzie Group	Manipul. Group	Between-group Difference (95% CI), *P*	McKenzie Group	Manipulation Group	Between-group Difference (95% CI), *P*	McKenzie Group	Manipulation Group	Between-group Difference (95% CI), *P*

Note: Values are mean change from baseline (95% confidence intervals) unless stated otherwise post-treatment 2 months follow-up 12 months follow-up.

**No. of patients with an absolute score below 5 points or at least 5 points reduction on Roland Morris.*

†outcomes adjusted for pretreatment variables: sex, disability-score, pain below knee, on sick leave, and classified as reducible disc syndrome.

‡No. of patients with a 30% reduction on Roland Morris.

§See Table 1 for definitions of scores.

§No. of days on The North American Spine Society Lumbar Spine Outcome Assessment Instrument.

¶No. of patients scoring completely cured_ or Much improved_ on a 6-point Likert scale (much worse, worsened, no change, improved, much improved, completely cured); 1 = worst, 6 = best.

***No. of patients scoring very satisfied_ or somewhat satisfied_ with treatment on a 5-point Likert scale (very dissatisfied, somewhat dissatisfied, neither satisfied nor dissatisfied, somewhat satisfied, very satisfied); 1 = worst, 5 = best.*

††Odds ratio (95% confidence interval) for success in the manipulation compared to the McKenzie group.

TABLE 4. *Post Hoc* Interaction Test

Variable	McKenzie	Manipulation	*P**
Centralizers	105/151 (70%)	92/156 (59%)	0.26
Peripheralizers	16/24 (67%)	7/19 (37%)	

Note: No. of patients with successful outcome at 2 months follow up stratified by treatment and centralization/peripheralization; N = 350.

**Breslow–Day Test for interaction between treatment and centralization/peripheralization with regard to successful outcome.*

No. of patients with success/total no. of patients.

during the course as well as patients that were excluded by decision of the practitioner. The majority withdrew or was excluded for reasons likely to be related to lack of treatment effect (43 patients in the manipulation group *vs.* 28 in the McKenzie group). The difference in withdrawal rate between groups supports the conclusion that the McKenzie treatment was the most suitable for our patient sample. A difference in proportions of this magnitude is not likely to be explained by an unequal distribution of candidates for The McKenzie method and Manipulation withdrawal/exclusion as an effect of randomization especially because the patients' expectations to improvement were similar in the groups. Most of these patients responded to follow-up questionnaires and were included in the intention-to-treat analysis. This procedure appears reasonable also from a clinical perspective, inasmuch as there was a large difference between groups in the number of patients withdrawing or already excluded after the first visit (16 patients in the manipulation group *vs.* 1 patient in the McKenzie group) (data not presented).

Unfortunately, the enrolment of patients had to be stopped before the planned sample size was reached due to a change in overall patient care politics by decision of the management of the Back Center Copenhagen. Although the study was slightly underpowered at long-term follow-up, the narrowness of confidence intervals suggests that type II error is unlikely.

This trial compared the effectiveness of treatments commonly used in primary care. However, the generalizability of our treatment results might be hampered by the fact that clinical decision making was performed without standardization by highly skilled clinicians.

What is new in this study is the inclusion of patients with persistent LBP and a changeable symptomatology, that is, both centralizers and peripheralizers during initial screening. Based on a randomized study it has been concluded that centralizers do better than noncentralizers when treated with the McKenzie method compared to other types of treatment.[37] However, the poor outcome reported among noncentralizers in that study might be related to patients with no change in symptoms during initial examination. In our *post hoc* analysis of interaction, centralization was not a treatment effect modifier. Also the value of centralization as a prognostic factor for outcome (regardless of treatment) shown in earlier studies[20] has been challenged by recent published data.[38,39] The question remains: are centralization and peripheralization prognostic factors regardless of treatment or are they treatment effect modifiers related to a specific treatment?

We used particularly strict criteria for centralization or peripheralization of symptoms[16] because these have demonstrated an association with positive discography.[18] We recognize that the diagnostic value of discography is controversial,[40] however, when performed with determination of a control disc, there appears to be no other means of directly challenging the intervertebral disc to detect if it is the source of LBP.[41] The majority of patients were classified as reducible disc syndromes based on the finding of centralization of symptoms from a distal to a more proximal body part. Although previous studies[37,42] have used more liberal definitions of centralization, results of those studies might indicate that such a subgroup of patients would profit the most from the McKenzie method. On the other hand, a recent review concluded that patients with signs of a possible lumbar disc disease with or without nerve involvement often undergo spinal manipulative treatment in practice and the hypothesis that high-velocity spinal manipulation may be effective in these patients is supported by current evidence.[43]

In our study, the number of patients with clinical signs of nerve root involvement was distributed evenly between treatment groups, but more patients in the manipulation group were referred to surgical evaluation for this reason (nine patients in the manipulation group *vs*. five in the McKenzie group) (Table 2). Although this small number of patients is not likely to influence the overall outcomes, this finding suggests that the McKenzie method should be recommended as the first choice for the treatment of these patients.

The within-group results of our study might indicate that the manipulative approach to patients with centralization of peripheralization of symptoms should be considered, if the McKenzie method fails to provide improvement.

The most apparent differences between the treatments compared in this study were as follows: treatment by the McKenzie method was mainly performed by patient generated force using repeated or static movements to end range of motion in a direction that relieves the patient's symptoms during physical examination, where as spinal manipulation was mainly performed by manually generated force using a single thrust movement with low amplitude in a direction of restricted movement as judged by clinical examination. Both treatment methods, however, intended to mobilize intervertebral spinal joints, and both were monitored by the patient's pain response during the course of treatment. Thus, both treatments are likely to influence the same pain mechanism. This might be one of the possible explanations for the relatively modest difference between treatments in our patients.

Evidence from randomized trials in clinical subgroups of patients comparable to ours have provided promising results in patients with predominantly acute and subacute LBP.[13,14,37,42] Those studies did not intent to suggest a possible pathoanatomical condition, but rather to delineate a subgroup of patients with increased chance of responding to a specific intervention. They have included a broader group of patients with a directional preference, that is, a favorable response to end range motion tests during physical examination regardless of whether the response was centralization or just an improvement in intensity of symptoms. The study by Long *et al*[37] with 2 weeks follow up found greater improvement by the McKenzie method when compared with general mobilizing and stretching exercises. The study by Browder *et al*[42] with 6 months follow-up suggests substantial benefit of the McKenzie method compared with lumbar strengthening exercises. Schenk *et al*[14] found greater improvement by the McKenzie method as compared with that of spinal manipulation, where as Erhard *et al*[13] reached the opposite conclusion. Both of the latter studies, however, were hampered by a low methodologic quality (small sample size, only short-term follow-up, and/or blinding of investigator uncertain). In addition, all of the four abovementioned studies are subjected to the risk of intervention bias inasmuch as the same practitioner performed both of the treatments compared. In a recent study, Kilpikoski *et al*[15] performed a secondary analysis of data from their earlier published trial[9] comparing the McKenzie method with manipulation. Only patients classified as centralizers were included. Although it suffered from small sample size, the study found a tendency in favor of the McKenzie method compared with manipulation that reached a statistical significance only in reduction of disability at 6 months follow-up.

Given the promising preliminary results in the literature and the improvement rate achieved in both our treatment groups, a future research area would be to explore clinical findings that identify which patients respond better to the McKenzie method or manipulation in patients with acute, subacute, or chronic LBP. Furthermore it seems worthwhile to test the effects of a combination of the two treatments as suggested by the results of a series of case reports.[44]

➢ Key Points

- ❑ The McKenzie-method and spinal manipulation are recommended treatments for patients with persistent nonspecific LBP. Preliminary evidence from low-quality studies comparing the two interventions is promising although results from those studies have only been reported in populations with acute or subacute low back and mainly for short-term outcomes.
- ❑ In patients with persistent LBP showing centralization or peripheralization of symptoms, this study found the McKenzie-method to be more effective than spinal manipulation when applied adjunctive to information and advice, although clinical relevance is questionable.
- ❑ The between-group differences in outcome were most apparent 2 and 12 months after the completion of treatment. However, differences were not particularly large.
- ❑ The results of this study support the value of a classification approach based on clinical examination findings in the management of patients with LBP in primary care.

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