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The Effect of McKenzie Therapy as Compared With That of Intensive Strengthening Training for the Treatment of Patients With Subacute or Chronic Low Back Pain: A Randomized Controlled Trial

[Randomized Trial]

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Abstract[^]

Study Design. A randomized controlled comparative trial with an 8-month follow-up period was conducted.

Objective. To compare the effect of the McKenzie treatment method with that of intensive dynamic strengthening training in patients with subacute or chronic low back pain.

Summary of Background Data. Randomized studies indicate that the efficacy of the McKenzie method in the treatment of patients with acute or subacute low back pain is debatable. Currently, no randomized studies examining the effects of this method for patients with chronic low back pain have been published.

Methods. For this study, 260 consecutive patients with low back pain and at least 8 weeks duration of symptoms (85% of the patients had more than 3 months duration of symptoms) were randomized into two groups: Group A was treated with the McKenzie method (n = 132), and Group B was treated with intensive dynamic strengthening training (n = 128). The treatment period for both groups was 8 weeks at an outpatient clinic, followed by 2 months of self-training at home. Treatment results were recorded at the end of the treatment period at the clinic, then 2 and 8 months after. In both groups, 30% of the patients were lost to follow-up evaluation. An intention-to-treat analysis of the main effect variables, disability, and pain was performed for all the patients included in the study. A supplementary analysis of the 180 patients who completed the full treatment program also was undertaken.

Results. Intention-to-treat analysis showed a tendency toward a difference in reduction of disability in favor of the McKenzie group at the 2-month follow-up assessment ($P = 0.04$), but no differences at the end of treatment and at the 8-

month follow-up evaluation. No differences in reduction of pain were observed at any time between the groups. The supplementary analysis of the patients who had completed the full intervention showed a tendency toward a difference in favor of the McKenzie method in reduction of pain at the end of treatment ($P = 0.02$). This difference reached statistical significance at the 2-month follow-up assessment ($P = 0.01$), but no difference was found after 8 months. The supplementary analysis showed no differences between the groups with regard to reduction of disability.

Conclusion. The McKenzie method and intensive dynamic strengthening training seem to be equally effective in the treatment of patients with subacute or chronic low back pain.

Disability related to low back pain (LBP) is a major problem in the Western World. Its prevalence in Denmark and United Kingdom is approximately 15% to 30%, and the lifetime prevalence is 60% to 80%. [6,8](#) Back pain is the second leading reason why primary care consultation is sought. [10](#)

Among LBP patients presenting at a primary health setting, approximately 30% are pain free 1 month later, and 60% are pain free 3 months after the initial visit. However, at least 60% will experience one or more recurrences in the following year, and 20–25% will continue to report a substantial impact on their ability to carry out their day to day activities. [9,23,25](#)

Two recent consensus reports on the treatment of patients with chronic low back pain (CLBP) recommend back training programs as effective treatment for reduction of disability and improvement of physical function. [2,21](#) The latest published systematic review from the Cochrane Collaboration concluded that there is strong evidence showing exercise therapy to be more effective than usual care by general practitioners, and that exercise therapy and conventional physiotherapy (comprising a combination of hot packs, massage, traction, mobilization, short-wave diathermy, ultrasound, stretching, flexibility and coordination exercises, and electrotherapy) are equally effective for the treatment of CLBP. However, the authors concluded that it still is unclear whether exercise therapy is more effective than inactive treatment (consisting of semihot packs and light traction, hot packs and rest, detuned ultrasound and detuned short-wave diathermy) for CLBP. It also remains unclear whether any specific type of exercises (flexion, extension, or strengthening exercises) is more effective than another. [24](#)

Exercise therapy by the McKenzie method is a popular treatment for LBP among physical therapists, [3,12](#) although no sound randomized controlled trials have been published to support the effectiveness of the method. [24](#) The objective of this study was to test the effectiveness of the McKenzie method, as compared with that of intensive dynamic strengthening training, a widely recommended treatment method, for CLBP patients.

Materials and Methods[^]_—

Subjects.[^]_—

For this study, 749 consecutive patients with subacute or chronic LBP who attended a hospital clinic

for rheumatology in Copenhagen, Denmark, were considered for inclusion. The criteria for inclusion were LBP with or without leg pain for more than 8 weeks, age of 18 to 60 years, and a radiograph, CT scan, or MRI taken within the preceding 2 years.

The study excluded 30 patients free of symptoms on the day of inclusion and 58 patients who had received treatment by the McKenzie method or strengthening training in the past. Patients were excluded if an initial examination by a rheumatologist found clinical evidence of an affected nerve root (*i.e.*, dermatomal distribution of symptoms or signs of diminished sensibility, muscle strength, or reflexes) ($n = 70$), severe osteoporosis ($n = 3$), spondylolisthesis ($n = 24$), fracture ($n = 4$), or referred pain from viscera ($n = 1$). Furthermore, patients were excluded if the examining rheumatologist judged the patient to be in a social or psychological crisis, and therefore needing a combination of various treatment approaches ($n = 56$). Other exclusion criteria were another disease ($n = 50$), pregnancy ($n = 4$), and inability to understand Danish ($n = 76$). Another 103 patients declined to participate before randomization.

After signing their informed consent, 270 patients were randomized to McKenzie treatment and strengthening training (135 patients in each group). However, 10 patients (3 in the McKenzie group and 7 in the training group) never appeared for treatment and were excluded from the analysis ([Table 1](#)). In all, 260 patients participated in the trial: 132 in the McKenzie group and 128 in the training group.

Table 1. Patients Included ITT = intention to treat analysis; LOCF = last observation carried forward.

Management Allocation and Treatment.[△]

Randomization was carried out by a computer-generated list of random numbers using sealed envelopes that contained the assignment of patients to either the McKenzie group or the strengthening training group. Blinding of the physical therapists performing the interventions was not possible. However, for both interventions, therapist preference bias was minimized by choosing therapists who strongly believed in the treatments they performed.

McKenzie treatment was planned individually after an initial physical assessment according to the principles described by Robin McKenzie. [20](#) In short, treatment consisted of self-mobilizing repeated movements or sustained positions performed in specific movement directions, the application of manual overpressure, and/or mobilization by the therapist. [20](#) Initial assessment and treatment lasted 1 hour, and subsequent treatments lasted typically half an hour. Intervals between treatments were at the discretion of the physical therapist. All seven therapists performing the treatment had completed the course program A to D arranged by the McKenzie Institute International, and six of the therapists attended and passed a credential examination on the method during the period of this study, from August 1996 to December 1998.

The strengthening training was carried out in groups of six patients under the guidance of a physical therapist. Sessions began with a period of 5 to 10 minutes on a stationary bike. This was followed by low-intensity, warm-up exercises for approximately 10 minutes, comprising 10 repetitions of low-resistance exercises for the lumbopelvic muscles in flexion, extension, and rotation. After that, an intensive dynamic back strengthening training program was performed in flexion and extension. This training program was chosen because it has shown excellent outcome in CLBP patients, as compared with treatment using inactive physical methods or low-intensity physical training. [17](#)

This program has become a common treatment for patients with CLBP in Denmark. It has been described in detail elsewhere. [18](#) Four strengthening exercises were performed in a series of 10 repetitions with a 1-minute rest between the series. The number of repetitions was graded individually. The initial dosage typically was a total of 50 repetitions, whereas the dosage during the treatment period of 8 weeks was increased gradually to 100 repetitions. At the conclusion of each session, the patients performed 10 minutes of stretching exercises for the trunk and hip muscles. The training sessions lasted from 60 to 90 minutes and were performed twice a week. Missed sessions to a maximum of 30% were accepted. All physical therapists guiding the patients' performance of exercises had several years of experience in this type of group strengthening training.

In both treatment groups, the patients received a maximum of 15 treatments for a period of 8 weeks. They were instructed to continue self-administered exercises at home or at a fitness center for a minimum of 2 months after completion of the treatment at the clinic. Because most of the patients had long-lasting LBP, this period of self-administered exercises was expected to be necessary for the patients to experience the full effect of the intervention. If a patient was totally free of symptoms some time before the maximum of 15 treatments was reached, he or she was allowed to continue with self-administered exercises from that time. Patients were encouraged not to seek any other kind of physical treatment during the 2-month period of self-administered exercises. Time consumption for each of the treatment groups was calculated according to the number of treatment sessions and minutes per session spent with each patient reported by the therapists.

Outcome Measurements.[△]

The effects of treatment on perceived pain, disability, return to work, use of pain medication, and the patients own perception of change in back-related quality of life were recorded. The main outcome variables were measures of self-reported disability and pain, which were assessed by a questionnaire included in Manniche's Low Back Pain Rating Scale, which had previously been validated. [16](#) This questionnaire was chosen because it was the only one validated in the Danish language, and because it allowed comparisons with the original published results from the training program used in the current study. [17](#) The disability scale comprised scores for 15 items on the impact on activities of daily living and social life. The results were expressed on a total score ranging from 0% (no difficulties) to 100% (highest score on difficulties on all items). Back pain and leg pain intensities were measured separately. Back and leg pain intensity scales 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 past 2 weeks. This 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).

Return to work was measured by an item in the questionnaire for which the patients registered whether they were on sick leave at the moment because of LBP. Use of over-the-counter (OTC) pain medication was measured by an item in the questionnaire for which patients registered whether they had used OTC pain medication within the past 2 weeks because of LBP. The patients' own perception of global change in back-related quality of life was measured by the choice they registered on a 5-point scale (much better, better, no change, worse, much worse) at the follow-up assessment.

The number of subjects seeking care for LBP during 2- and 8-month follow-up periods was measured by the patients' report of whether they had visited a general practitioner because of a back problem during the preceding 2 and 6 months. In Denmark, the general practitioner is by far the most common health care provider seen by persons with LBP. [1](#)

Follow-up assessment was carried out at the end of treatment at the clinic, then at 2 and 8 months afterward. This assessment was performed by postal questionnaire. If no response was received in 3 weeks, a second questionnaire was mailed. After 3 more weeks, telephone calls were placed to all the nonresponding subjects. If contact was established, subjects were asked to answer the questions over the telephone.

Statistical Analysis.[^](#)

The authors calculated that 84 participants per group would be required to detect a difference of 25% on the main outcome variable with 90% power and a 5% risk of Type 1 error in a single comparison. However, multiple comparisons were performed, and the authors chose to be more restrictive by defining statistical significance at a *P* value of 0.01 or less.

Intention-to-treat analysis was performed on all the participants in the study. Patients indicating withdrawal from treatment for reasons other than their reaction to the treatment to which they had been randomized (dropout Type A) were given the baseline registration for the missing data points at the follow-up assessments. Patients indicating withdrawal because of negative or positive results of the treatment to which they were randomized (dropout Type B or C) were given, respectively, the worst or median score registered for patients who had completed treatment in their treatment group. If a patient's value was missing on the main outcome variables at the 2- and 8-month follow-up assessments, the value from the last available observation (end of treatment or 2-month follow-up assessment) was carried forward. The mean or median was used as an index of localization, and standard deviation or 10% percentiles served as an index of dispersion.

Comparison of unpaired categorical variables was performed by means of the $[\chi]^2$ test. Different strata of discrete and continuous variables were compared using the Mann–Whitney *U* test.

Results[^](#)

Material[^]

The background characteristics for the two groups in the study were the same except that more patients in the strengthening training group had pain distribution below the knee ($P = 0.01$) ([Table 2](#)). Because the duration of symptoms was more than 3 months in 85% of the patients, the majority were considered chronic. For the 80 patients (31%) who withdrew during the treatment period, the following baseline characteristic differed significantly from those of the patients who completed the treatment: Relatively more patients among the withdrawals were smokers ($P = 0.006$) ([Table 3](#)).

Table 2. Baseline Characteristics of the Intention-To-Treat Population Only the following difference between the groups was statistically significant: More patients in the training group had pain distribution below the knee ($P = 0.01$). * Median value (10th and 90th percentiles). LBPRS = Low back pain rating scale.

Table 3. Baseline Characteristics of Withdrawals and Completed Only the following difference between the groups was statistically significant: relatively more patients among the group who withdrew during treatment were smokers ($P = 0.006$). * Median value (10th and 90th percentiles). LBPRS = low back pain rating scale; McK = McKenzie treatment; ST = strengthening training.

The reasons for withdrawal stated by the patients are presented in [Table 1](#). These reasons were as follows: Type A (inability to comply with the treatment schedule because of working hours or personal reasons, $n = 21$); Type B (increase of other problems [*e.g.*, headache or hip pain] [$n = 4$], referral to a neurosurgical department by the decision of a rheumatologist because of signs of a prolapsed disc [$n = 6$], a desire to change to another treatment [$n = 24$], dissatisfaction with treatment [$n = 8$], and finally, unexplained withdrawal [$n = 14$]); and Type C (satisfaction with achieved outcome, $n = 3$). A total of 13 patients (5%) had missing values at the 2- or 8-month follow-up assessment ([Table 1](#)). For these patients, the values from last available observation (end of treatment or 2-month follow-up assessment) were carried forward.

Outcomes[^]

Intention-to-treat analysis was performed on the main outcome variables: disability and pain. The data are presented in [Table 4](#). Neither disability nor pain intensity differed between the groups at baseline. After adjustment for baseline values, there was a trend toward greater reduction in the disability score favoring the McKenzie group at the 2-month follow-up assessment only ($P = 0.04$). Changes in back and leg pain intensities did not differ between the groups after treatment at the clinic ($P = 0.38$), at the 2-month follow-up assessment ($P = 0.41$), or at the 8-month follow-up assessment ($P = 0.83$).

Table 4. Intention-to-Treat Analysis Patient scores on main outcome variables. Median values (10th and 90th percentiles). **P* value refers to analysis of difference to baseline score. † Low back pain rating scale range 0–100%. ‡ Low back pain rating scale, range 0–60.

The median time for the treatment period in the McKenzie group was slightly shorter (median, 210 minutes; 10th and 90th percentile, respectively, 90 and 450 minutes) than in the training group (median, 225 minutes; 10th and 90th percentile, respectively, 45 and 255 minutes).

A supplementary analysis was performed on all outcome variables for the 180 patients who completed the intervention. The data are presented in [Table 5](#). No outcome variable differed between the groups at baseline. After adjustment for baseline values, the only statistically significant difference between the groups involved the changes in back and leg pain. The McKenzie group showed a greater reduction in pain intensity than the training group at the 2-month follow-up assessment ($P = 0.01$), but the differences were not significant at the end of treatment at the clinic ($P = 0.02$) or at the 8-month follow-up assessment ($P = 0.16$). There were no significant differences from the supplementary analysis at any follow-up assessment between the groups in change of disability, global change in back-related quality of life, number of patients using pain killers because of LBP, number of patients on sick leave, or number of patients visiting a general practitioner because of LBP.

Table 5. Patients Who Completed Intervention* Median value (10th and 90th percentiles). †*P* value refers to analysis of difference to baseline score LBP RS = low back pain rating scale.

Discussion[^]

The intention-to-treat analysis in the current study showed no statistically significant differences between McKenzie treatment and strengthening training with regard to change of disability at any follow-up assessment. A tendency was found, however, in favor of the McKenzie group 2 months after completion of treatment at the clinic. Pain scores were consistently lowest in the McKenzie group, but did not differ with statistical significance in comparison with the training group. The total amount of time spent with each patient was distributed almost equally between the groups.

No previous study has been published comparing McKenzie treatment with strengthening training for CLPB patients. However, several recent studies have provided evidence that treatment programs containing active exercises are equally effective in patients with CLBP, irrespective of the type of exercises compared. [4,5,15,19](#) One explanation might maintain that any type of intensive exercise program that manages to make the patients expand the limits to their physical functioning may provide the patients with a method for increasing the feeling of pain control, thus inhibiting negative pain

behavior relating to a CLBP problem.

Patients in this study were selected from a patient group normally considered suitable for strengthening training inasmuch as all patients with clinical signs of affected nerve root were excluded. A previous study indicated that especially this subgroup of patients may profit from McKenzie treatment, [11](#) leaving the possibility that the included patients may not have been equally suitable for both interventions. This assumption, however, needs to be examined in further studies. Given the outcomes of the current study, the equally distributed amount of time spent with each patient, the type of patients investigated, and the apparent difficulties in proving the effectiveness of a particular type of active exercises over that of others, it seems reasonable to conclude that the McKenzie treatment has some potential, as compared with strengthening training, in the treatment of nonspecific CLBP.

This conclusion is supported by the results from the supplementary analysis of the patients who completed the full intervention. A strong tendency in favor of the McKenzie treatment was found with regard to a change in back and leg pain at the end of treatment that reached a statistically significant difference at the 2-month follow-up assessment. At 8 months, the difference was no longer apparent.

In both analyses, all the trends and statistically significant differences in disability or pain exceeded the minimum criteria for clinical importance predefined in this study as a 25% difference between groups. In the intention-to-treat-analysis, the difference between groups in disability change at the 2-month follow-up assessment was 122%. In the supplementary analysis, the differences in change of pain between groups were 33% at end of treatment and 83% at the 2-month follow-up assessment.

For several reasons, the authors found it relevant also to present the supplementary analysis. First, patients who completed the full treatment program differed only regarding a few background characteristics known to influence prognosis from those who withdrew ([Table 3](#)). Therefore, they seemed still to be fairly representative of the total patient population originally included in the study. Second, it might be relevant to the clinician to get information on the outcome for patients who actually completed the full prescribed amount of treatment expected to be effective for CLBP.

One drawback of the study was the relatively high withdrawal rate of approximately 30% in both groups. However, this is not uncommon in studies of CLBP patients in an outpatient setting. [5,14,22](#)

In spite of the randomization procedure, some baseline characteristics were unequally distributed between the two treatments groups. More patients in the strengthening training group had pain distribution below the knee and a longer duration of symptoms. A *post hoc* analysis was performed (data not presented), which showed that the two baseline characteristics were not negatively associated with reduction of pain and disability at any follow-up assessment. On the contrary, the findings showed a statistically significant reduction of pain in favor of the patients with pain below the knee, as compared with the patients with pain above the knee. Thus, it appears that these differences in baseline characteristics did not contribute to poor outcome in the strengthening training group, as compared with the McKenzie group in the current study.

An intention-to-treat analysis may minimize bias arising from loss of patients that might contaminate the balance between treatment groups for factors known or not known to influence outcome. Furthermore, from a clinical perspective, it seems reasonable to include outcome information from all patients that have received treatment, irrespective of whether they have completed the full dose or not. For these reasons, the authors believed that it would be appropriate primarily to perform an intention-to-treat analysis, which included the available information on the reasons for withdrawal given by the patients. They assumed that patients who withdrew for practical or personal reasons not associated with treatment (dropout Type A) did not change, as compared with baseline measurements. This means that they ignored the general trend of improvement over time for these patients, but that they also ignored the possibility of deterioration. Patients who withdrew because of side effects, dissatisfaction with the treatment, or no given explanation (dropout Type B) were assumed to match an outcome corresponding to the worst score on the main outcome variables registered in the treatment group to which they were randomized. Patients who withdrew because of satisfaction with the degree of improvement attained (dropout Type C) were assumed to match an outcome corresponding to the median score of the main outcome variables registered in the treatment group to which they were randomized. These procedures follow the recommendations by Gillings and Koch. [13](#) The procedure for handling missing values during follow-up assessment (*i.e.*, carrying the last observation forward) is not regarded as introducing contamination into the analysis inasmuch as the number of missing values was small (5%).

In the current study, as in many other studies of CLBP, there was no untreated control group. Because of this, the possibility that nonspecific effects (*e.g.*, extra attention) might be responsible for improvement cannot be excluded. However, an attempt was made to distribute this possible source of bias evenly among treatment groups because all the therapists were dedicated to the type of treatment they were performing and the patients in both groups received the same amount of contact. Furthermore, the level of improvement in pain and disability in the training group among the 86 patients who completed the intervention is similar to that in the original study by Manniche et al [17](#) using this training program.

The current findings suggest that there is a need for a classification system highlighted by others [7](#) to increase researchers' ability to identify differences in treatments for LBP patients. In heterogeneous samples of nonspecific LBP patients, subgroups of patients for whom a specific treatment has been of benefit may be masked by subgroups for whom no demonstrable benefits occurred. Therefore, the aims of such a classification system would be to identify patient characteristics predictive of the effects of different types of treatments, and to distinguish clinically relevant subgroups for testing the hypotheses of treatment effectiveness.

The results from the intention-to-treat analysis need testing in future studies because, although weakened by a high withdrawal rate, they showed a tendency in favor of the McKenzie treatment at the 2-month follow-up assessment, at which time, the authors had expected the full effect of the interventions to be apparent. The credibility of the results in the current study is supported by the fact that both statistical analyses point in the same direction. However, the possibility that the difference in

disability scores resulted from random variation cannot be excluded because it is not supported by other results from the intention-to-treat analysis either at the end of treatment or at the 8-month follow-up assessment. Therefore, on the basis of the data, it appears that in managing patients with more than 8 weeks of low back pain, McKenzie treatment and intensive dynamic strengthening training are equally effective.

Key Points[^]

- * The effectiveness of the McKenzie treatment equaled that of intensive strengthening training, a widely recommended treatment for patients with chronic low back pain.
- * The intention-to-treat analysis showed no statistically significant differences between the McKenzie treatment and strengthening training in reduction of disability and pain at any follow-up assessment.
- * Analysis of patients completing the full treatment program at the clinic showed the McKenzie treatment to be superior to strengthening training only in reduction of pain intensity at the 2-month follow-up assessment.

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