SPINE Volume 32, Number 26, pp 2948–2956
©2007, Lippincott Williams & Wilkins, Inc.

One-Year Follow-up Comparison of the Effectiveness of McKenzie Treatment and Strengthening Training for Patients With Chronic Low Back Pain

Outcome and Prognostic Factors

Tom Petersen, PT, PhD,* Kristian Larsen, PT, MPH,† and Soren Jacobsen, MD, DMSc‡

Study Design. A randomized controlled trial with multivariable analyses of prognostic factors.

Objective. To report the long-term outcome of McKenzie treatment compared with strengthening training. Further, to determine patient-related factors associated with poor outcome 14 months after completion of treatment.

Summary of Background Data. Exercise therapy is widely recommended for patients with chronic low back pain. However, reports vary considerably concerning characteristics of patients who will not respond to treatment. Knowledge of factors associated with poor outcome may assist identification of patients requiring special attention.

Methods. A total of 260 patients with chronic low back pain were included in a previously reported randomized controlled trial of McKenzie therapy *versus* strengthening training. Outcome variables were: functional status, pain level, work status, and use of healthcare services during follow-up. Also, factors associated with withdrawal during the intervention were sought identified. The following factors of possible prognostic significance were determined: levels of pain and disability, pain-distribution, duration of symptoms, smoking habits, leisure activities, workload, job satisfaction, treatment preference, outcome expectations, treatment modality received, compliance with home exercises during follow-up, and demographic variables such as age, gender, work status, and application for pension. Association between variables was examined by multiple logistic regression analysis and odds ratios.

Results. No differences in outcomes were found between the treatment groups at 14 months of follow-up. Low level of pain intensity and disability, sick leave at entry, low pretreatment expectations of future work ability, withdrawal during treatment, and discontinuance of exercises after the end of the treatment period were associated with poor outcome.

Conclusion. Poor long-term outcome of exercise therapy for chronic low back pain can be explained by a number of patient-related factors. Different prognostic factors were associated with different outcomes. These factors were more important in determining outcome than the exercise-programs studied.

Key words: randomized controlled trial, prognosis, explanatory value, chronic disease, low back pain, outcome, exercise therapy, exercises. **Spine 2007;32:2948–2956**

The most recent guidelines for the management of patients with chronic low back pain (CLBP) recommend supervised exercise therapy as a first-line treatment for the reduction of pain and disability.[1] However, no recommendations are given for the specific type of exercise to be used (strengthening/muscle conditioning, aerobic, McKenzie, flexion exercises, *etc.*).

Exercise therapy by the McKenzie method is a popular treatment for LBP among physical therapists.[2,3] However, only one randomized controlled trial by the present authors has been published to support the effectiveness of the method for patients with CLBP.[4] It was found that the McKenzie method and intensive dynamic strengthening training appeared to be equally effective in the treatment of patients with CLBP at 2 and 8 months of follow-up.

It is of great interest to identify risk factors associated with persisting problems after treatment. In research, this knowledge might be used to create more homogenous subgroups of patients before inclusion in randomized controlled trials for determining the efficacy of different treatment programs. In clinical practice, it is essential to identify prognostic factors for poor outcome and address these factors during treatment in order to choose the most effective treatment for individual patients.

The most recent systematic review of the literature on prognostic factors in patients with longstanding back pain (at least 12 weeks duration or recurrent episodes) concluded that consistent evidence for prediction of poor outcome following multidisciplinary rehabilitation or back school treatment was found only for high levels of pain intensity and for problems functioning at work.[5] However, this review summarized studies measuring outcome after a variety of follow-up periods (ranging from time of discharge to 30 months of follow-up) and included analyses using univariate as well as multivariable statistical methods. By means of multivariable sta-

From the *Back Center of Copenhagen, Copenhagen, Denmark; †Holstebro Hospital, Holstebro, Denmark; and ‡Department of Rheumatology, Copenhagen University Hospital, Rigshospitalet, Denmark.
Acknowledgment date: October 19, 2006. First revision date: March 21, 2007. Second revision date: June 6, 2007. Acceptance date: June 6, 2007.
Supported in part by grants from the Danish Physiotherapy Organization, Madsens Fund, and the Danish Rheumatism Association.
The manuscript submitted does not contain information about medical device(s)/drug(s).
Foundation and Professional Organizational funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.
Address correspondence and reprint requests to Tom Petersen, PT, PhD, Back Center of Copenhagen, Hans Knudsens Plads 3D, 2100 Copenhagen, Denmark; E-mail: tompet@mail.tele.dk

tistical methods that allow adjustment for other factors, several studies have aimed particularly at the identification of prognostic factors for the long-term outcome at the 12-month follow-up from exercise therapy in CLBP patients (at least 6 weeks in duration). Prognostic pretreatment variables that confer poor outcome include older age,[6,7] younger age,[8] female gender,[9] high level of disability,[8,10–12] high level of pain intensity,[7–11,13] high level of leg pain intensity,[7] not employed,[7,9,12] sick-listed,[7] high number of days on sick leave,[7,8,14] high number of prior practitioners visited,[6,15] negative expectations regarding return to work,[8,14] smoking,[7] participation in sports activities,[7] compensation involvement,[14,16] pending litigation,[6] short time in present job,[9] physically demanding job,[7,10] exposure to vibrations,[7] nonorganic signs,[13] high level of psychological problems,[8,9,11] high belief in chance control of disease,[11] low satisfaction with colleagues,[10] prior surgery,[6,9] lack of neurologic signs,[6] and low aerobic capacity or back muscle endurance.[7,13]

It appears that the results regarding age are contradictory. Furthermore, most of the reported associations are inconsistent with those of similarly designed studies that found no association between poor long-term outcome and age,[9,12,15,16] gender,[6,8,12,13,15,16] level of disability,[9,14–16] duration of disability,[6,9,14,15] level of pain intensity,[14–16] employment status,[15,16] sick listing,[6] number of days on sick leave,[6,13] level of workload,[6,13,15] compensation involvement,[6,12] nonorganic signs,[6] or level of psychologic problems.[10,12,16]

Thus, it seems difficult to draw firm conclusions from the existing body of literature. Several authors have pointed out that one of the explanations for this might be the fact that the best selection of individual predictors is "intervention specific," outcome specific, and time specific.[14,17–20]

The focus of this study was the effectiveness of the McKenzie method as compared with that of strengthening training 14 months after the completion of treatment. Furthermore, the purpose was to identify pretreatment variables associated with poor long-term outcome following physical exercise programs in CLBP patients by using a multivariable method of analyses. The following questions were addressed:

Is it possible to identify baseline variables associated with outcome measured on variables expressing different aspects of the patients' status at 14 months follow-up?

Are the identified variables more strongly associated with long-term outcome than the influence of the type of treatment?

Is it possible, on the basis of baseline variables, to explain which patients will withdraw from an exercise program?

■ Methods

Participants. A total of 260 consecutive patients referred to an outpatient rheumatology clinic in Copenhagen, Denmark, from August 1996 through December 1998, participated in a randomized controlled trial comparing mobilizing exercises by the McKenzie method and strengthening training. Criteria for inclusion and exclusion of patients are presented elsewhere.[4] Ethical approval was granted by Copenhagen Research Ethics Committee (file no. 01-147/96).

All patients had had chronic disabling LBP for a duration of at least 2 months. The randomization procedure allocated 132 patients to the McKenzie group and 128 to the strengthening-training group. Data from this trial were used for further analysis in the present work.

Treatments. McKenzie treatment was planned individually after an initial physical assessment according to previously described principles.[21] Strengthening training was carried out in groups of 6 patients under the guidance of a physical therapist. In both treatment groups, patients received a maximum of 15 treatments for a period of 8 weeks. Patients 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. They were encouraged not to seek any other kind of physical treatment for the 2-month period of self administered exercises. Detailed information on these programs and results at short-term follow-up have been published earlier.[4]

Data Collection. At baseline before randomization, all patients completed a questionnaire. Follow-up assessment was carried out 14 months after the completion of treatment by means of a postal questionnaire as earlier described.[4]

Potential Prognostic Variables. The baseline questionnaire was designed to gather information on: age, gender, work status, duration of symptoms, pain location, pain intensity,[22] level of disability,[22] workload,[23] participation in sports activities,[23] application for disability pension or pending litigation because of LBP, sick-listing because of LBP, relations to coworkers,[24] smoking, preference to treatment, and expectations for treatment outcome.[24] Continuation of exercises after completion of treatment, and allocation to the McKenzie or strengthening training group were also recorded.

Outcome Variables. Outcome at follow-up on levels of pain and disability, global status, work status, sick listing, and care seeking for LBP was recorded, as well as withdrawal during treatment.

Changes in functional disability and back/leg pain were measured on Low Back Rating Scale.[22] Poor outcome was defined as an improvement of $<15\%$ from baseline values.[25]

Global assessment of change was determined by the patient's answer on a 5-point verbal scale with the end points of "much better" and "much worse" to a question reading "Has the treatment made your quality of life . . . ." Poor outcome was defined as a score of "no change," "worse," or "much worse."

Work status was measured by an item in the questionnaire where the patients registered whether or not they were sick-listed from work at the moment because of LBP.

Care seeking for LBP during the 14-month follow-up was measured by the patients' reports of whether or not they had visited a healthcare practitioner because of a back problem during the preceding 6 months.

Analyses. Analyses were performed on 2 samples of patients. A total of 260 patients were originally included in the randomized study. At the 14-month follow-up, analyses were performed on outcome data reported by all respondents. An additional analysis was made on a subset of 180 patients that completed the full intervention ("completers").

All analyses were performed with the SPSS 12.0 (SPSS Inc., Chicago, IL) or Stata 7.0 (StataCorp, College Station, TX) software for Windows. Within-group changes on discrete and continuous variables were tested by Student paired *t* test and between-group comparisons were performed by means of Student unpaired *t* test. Comparison of unpaired categorical variables was performed by means of the χ^2 test. The level of statistical significance was chosen at $P < 0.05$.

Analyses of association between explanatory variables and outcome were performed using multiple logistic regression analyses with backward stepwise selection. A cutoff *P* value of 0.25 was used for the selection of explanatory variables to be entered into the model. At each step, a significance level of 0.05 or lower was specified for variables to remain in the model. The assumptions for logistic regression were fulfilled, *i.e.*, additivity on log scale, proportionality on logit scale, and no interaction effect. Due to lack of power in this randomized controlled trial only the following theory based combinations of variables were tested for possible interaction: 1) applying for pension or pending litigation and duration of symptoms/high disability score/on sick leave at entry/expecting problems at entry coping with future work tasks/older age/low expectations at entry to be working after 6 months/discontinuation of exercises during follow up/withdrawal during treatment; 2) high disability score and expecting problems at entry coping with future work tasks/low expectations at entry to be working after 6 months/high back and leg pain score; 3) on sick leave at entry and expecting problems at entry coping with future work tasks/low expectations at entry to be working after 6 months; and 4) expecting problems at entry coping with future work tasks and low expectations at entry to be working after 6 months.

Risk estimates expressed as odds ratios for all variables that remained in the model were examined. Also, receiver operating characteristic curves were established with the purpose of measuring the goodness-of-fit of the model. The area under the receiver operating characteristic curve is based on the association between sensitivity and specificity. It is considered a useful method to estimate the model's ability to discriminate between the outcomes of interest.[26] A value for the area under the curve of 0.5 would denote no explanatory value, whereas 1 of 1 would describe a perfect model.[27]

■ Results

Baseline characteristics for the 260 patients originally included in the study have been presented elsewhere.[4] Eighty-five percent of the patients had a duration of symptoms of more than 3 months (median duration, 11 months; interquartile range, 4–39 months); thus, the majority of patients were considered chronic. A total of 241 subjects (93%) of the original sample completed the 14-month follow-up assessment. Because of missing data for some variables, the numbers available for each analysis varied slightly. In the univariate analysis, we found an interaction between the explanatory variables on sick leave at entry and low expectations at entry to be working after 6 months that was significantly associated with the outcome variable pain. This association, however, did not remain in the final model. Tables 1 and 2 summarize results regarding prognostic factors of poor outcome.

Group Comparisons Regarding Outcome From Treatment at 1-Year Follow-up

At the 14-month follow-up, for the McKenzie group, mean change in disability level from baseline was 7 points (from 36.9 to 29.7 points; confidence interval [CI], 4.3–10.1, $P = 0.001$), and for pain, mean change from baseline was 5 points (from 21.4 to 15.9 points; CI, 2.9–7.9, $P = 0.001$). For the strengthening training group, mean disability change was 9 points (from 39.5 to 30.5 points; CI, 5.4–12.5, $P = 0.001$), and for pain, mean change was 8 points (from 22.1 to 14.3 points; CI, 5.7–9.9, $P = 0.001$).

There was no difference at 14 months between the groups in any of the primary outcomes: improvement in disability (mean difference of 2 points; CI, −6.3 to 2.3, $P = 0.44$) or improvement in pain (mean difference of 2 points, CI, −5.6 to 0.9, $P = 0.16$). No between-group differences were found in the secondary outcomes: number of patients on sick leave ($P = 0.35$) or number of patients seeking additional health care for back pain ($P = 0.61$).

Prognostic Factors for Poor Reduction of Disability and Pain

For all the patients who responded to questionnaires at the 14-month follow-up, 66% reported poor outcome on reduction of disability and 75% reported poor outcome on reduction of pain. In the analysis on all respondents, the baseline characteristics that were associated with poor reduction in disability were low expectations of future work ability and a low level of disability at baseline. Poor reduction in pain was explained by discontinuation of exercises during follow-up and a low level of pain at baseline. The subgroup analysis on the data from the completers showed the same results.

Prognostic Factors for Being on Sick Leave

A total of 11% of all respondents were sick-listed at 14 months follow-up. Being sick-listed was explained by being on sick leave at entry and by withdrawal during treatment. Analysis on completers displayed a different pattern of association, however. Being sick-listed was explained only by low expectations of work ability, whereas being on sick leave at entry showed no association.

Prognostic Factors for Use of Health Care

A total of 33% of the patients had sought care for back pain during follow-up. In the analysis on all respondents, a need for the use of health care during follow-up was explained by low expectations of future work ability and by a low level of pain. The analysis on completers showed the same results.

Prognostic Factors for Poor Global Assessment

Poor global assessment of change at 14 months was reported by a total of 35% of the patients who completed the full treatment. Global assessment of change was included only in the analysis on completers. The reason for this choice was that the question to be answered by the

Table 1. Analysis on All Respondents: Odds Ratios (95% Confidence Intervals) for Association Between Prognostic Variables and Withdrawal During Treatment or Poor Outcome at 14-Month Follow-up (Multiple Logistic Regression Analysis Using $P < 0.25$ as Criteria for Inclusion in the Model)

Prognostic Variable	Withdrawal During Treatment (N = 243)	Disability (N = 211)	Pain (N = 210)	Sick Listed (N = 206)	Health Care (N = 208)
Disability score above 37% at entry (N = 129)*	NS	0.2‡‡ (0.1–0.5)	NS	2.2 (0.7–6.9)	1.7 (0.9–3.3)
Back and leg pain score above 19 at entry (N = 122)†	1.7 (0.8–3.3)	0.5 (0.2–1.1)	0.07‡‡ (0.0–0.2)	0.5 (0.2–1.5)	0.5** (0.3–1.0)
Expecting problems at entry coping with future work tasks (N = 118)‖	NS	2.9†† (1.4–6.1)	1.8 (0.8–4.1)	NS	NS
Low expectations at entry to be working after 6 mo (N = 105)¶	1.9** (1.1–4.0)	NS	2.1 (0.9–4.9)	2.9 (0.9–9.0)	2.5†† (1.3–4.8)
On sick–leave at entry (N = 91)	1.6 (0.9–3.1)	0.5 (0.2–1.0)	NS	4.2** (1.4–13.0)	NS
Withdrawal during treatment (N = 80)		1.9 (0.9–4.2)	1.9 (0.8–4.8)	3.2** (1.0–9.8)	1.6 (0.8–3.1)
Discontinuation exercises during follow up (N = 130)		NS	2.5** (1.2–5.4)	0.4 (0.1–1.2)	NS
Applying for pension/litigation (N = 23)	1.9 (0.7–5.0)	3.6 (0.8–15.5)	NS	3.0 (0.8–11.6)	NS
Low job satisfaction (N = 111)#	NS	0.7 (0.3–1.3)	NS	0.5 (0.2–1.4)	0.6 (0.3–1.2)
Duration of symptoms >6 mo (N = 162)	2.2** (1.2–4.3)			NS	NS
Age >40 yr (N = 87)	0.5 (0.3–1.0)	1.9 (0.9–3.8)	NS	NS	NS
Gender (male) (N = 142)	NS	NS	NS	NS	NS
Smoking (N = 157)	2.2** (1.2–4.3)	NS	NS	NS	NS
Pain below the knee (N = 82)	0.6 (0.3–1.3)	2.1 (0.9–4.9)	NS	NS	NS
Heavy job tasks (N = 161)‡	NS	NS	NS	NS	NS
Low leisure activities (N = 205)‡	NS	NS	NS	NS	NS
Preferring other treatment (N = 81)§	NS	NS	NS	NS	NS
Type of treatment (strengthening training) (N = 132)	NS	NS	NS	NS	NS

*Scored on a 15–item disability scale from 0% (no difficulties) to 100% (highest score on difficulties on all items). High-/low-risk groups were formed above/equal to or below the median of 36.7% found in the sample.
†Scored on 2 × 3 separate 11 point box scales comprising the following items: LBP at the moment, the worst LBP within the last 2 wk, and the average level of LBP within the last 2 wk (total score of 0–60 points). High-/low-risk groups were formed above/equal to or below the median.
‡Measured on two 4-point Likert scales: ratings of usual participation in sport activities, 1 = none (high risk) through 4 = several times per week (low risk) and usual work load: 1 = sedentary work (low risk) and 4 = heavy materials handling and positional loading (high risk). Dichotomized into two groups with 2 points in each group.
§Measured at entry by responses to the following two questions: 1) "Do you have an opinion on whether one of the treatments would be the better to improve your back problem?" (Yes/No) 2) "If Yes: which treatment?" The reply to the question was rated as a risk factor in cases where the patients reported to prefer the treatment to which they were not allocated by later randomization.
‖Measured on an 11-point box scale (endpoints "No trouble at all" and "So much trouble that I won't be able to do my job at all"). Dichotomized into high-/low-risk groups according to scores above/below the cutoff point at the median of 3 found in the sample.
¶Measured on an 11-point box scale regarding certainty for being at work 6 mo after completion of treatment (endpoints "Not at all certain" and "Very certain"). Dichotomized into high-/low-risk groups according to scores above/equal to or below the cutoff point at the median of 9 found in the sample.
#Measured on an 11-point box scale regarding relations to coworkers (endpoints "Don't get along well at all" and "Get along very well"). Dichotomized into high-/low-risk groups according to scores above/below the cutoff point of the median of 1 found in the sample.
**Statistically significant at the 0.05 level.
††Statistically significant at the 0.01 level.
‡‡Statistically significant at the 0.001 level.
NS indicates not statistically significant at the 0.05 level or below.

patients read, "Has the treatment made your quality of life . . . ." We did not consider patients who did not complete treatment to be able to give a plausible answer to this question. Poor global assessment of change was explained by older age, discontinuation of exercises, and low level of pain.

Prognostic Factors for Withdrawal During Treatment

A total of 30% of the patients did not complete the full intervention. Withdrawal from treatment was explained by smoking, duration of symptoms, and low expectations of future work ability.

Table 2. Analysis on Patients Who Completed the Full Intervention: Odds Ratio (95% Confidence Interval) for Explanatory Power of Prognostic Variables Regarding Poor Outcome at 14-Month Follow-up (Multiple Logistic Regression Analysis Using $P < 0.25$ as Criteria for Inclusion in the Model)

Prognostic Variable	Disability (N = 158)	Pain (N = 157)	Global (N = 158)	Sick Listed (N = 153)	Health Care (N = 155)
Disability score above 37 at entry (N = 86)	0.2‡ (0.1–0.4)	1.8 (0.7–4.8)	NS	4.3 (0.9–19.7)	1.8 (0.8–4.0)
Back and leg pain score above 19 at entry (N = 80)	NS	0.06‡ (0.0–0.2)	0.3* (0.1–0.8)	NS	0.4* (0.2–0.8)
Expecting problems at entry coping with future work tasks (N = 75)	2.9* (1.2–7.0)	2.0 (0.7–5.5)	1.9 (0.9–4.2)	NS	NS
Low expectations at entry to be working after 6 mo (N = 63)	1.8 (0.8–4.3)	2.5 (0.9–7.0)	NS	6.5* (1.4–30.0)	2.2* (1.0–4.7)
On sick-leave at entry (N = 55)	0.5 (0.2–1.0)	0.5 (0.2–1.3)	NS	NS	NS
Discontinuation of exercises during follow up (N = 90)	NS	2.9* (1.2–7.3)	3.6** (1.6–8.3)	NS	0.6 (0.3–1.3)
Applying for pension/litigation (N = 12)	NS	NS	NS	NS	NS
Low job satisfaction (N = 75)	0.5 (0.2–1.0)	NS	NS	0.4 (0.9–1.7)	NS
Duration of symptoms more than 6 mo (N = 105)	NS	NS	NS	NS	NS
Age above 40 yr (N = 62)	NS	NS	4.8‡ (2.0–11.0)	NS	NS
Gender (male) (N = 93)	NS	NS	NS	NS	0.6 (0.3–1.2)
Smoking (N = 98)	NS	NS	0.5 (0.3–1.1)	NS	NS
Pain below the knee (N = 60)	2.0 (0.8–4.3)	NS	2.3 (0.9–5.7)	NS	NS
Heavy job tasks (N = 106)	NS	NS	NS	7.6 (0.9–66.0)	NS
Low leisure activities (N = 142)	NS	NS	0.5 (0.2–1.3)	NS	NS
Preferring other treatment at entry (N = 54)	NS	NS	NS	NS	NS
Type of treatment (strengthening training) (N = 86)	NS	NS	NS	NS	NS

*Statistically significant at the 0.05 level.
†Statistically significant at the 0.01 level.
‡Statistically significant at the 0.001 level.
NS indicates not statistically significant at the 0.05 level or below.

Prognostic Factors Across Outcome Measures

In the analysis on all respondents, the baseline variables that were the most consistently associated with poor outcome across several outcome measures were low levels of pain and low expectations of future work ability.

In the analysis on completers, the same results were found regarding low levels of pain and low expectations of future work ability in addition to discontinuation of exercises.

Goodness-of-Fit of the Model

Knowing the prevalence of a particular variable in a given sample of patients makes it possible to estimate how useful the combination of statistically significant baseline variables in the final model is at explaining the outcome for the individual patient.

As displayed in Table 3, it was possible by means of the variables included in the final model to explain rather well which patients were likely to experience poor outcome following exercise therapy. The positive explanatory values of combinations of variables were fairly consistent in both samples analyzed. The best explanation was obtained in the discrimination of patients who would/would not have poor reduction of pain. For example, given a prevalence of poor pain reduction of 72%

Table 3. The Explanatory Value of Variables That Remained in the Final Regression Model

Outcome	Prevalence of Poor Outcome	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Area Under the Curve
All respondents						
Withdrawal during treatment	30.1	68.9	60.4	43.2	81.6	0.70
Disability	66.0	62.9	78.9	85.4	51.9	0.76
Pain	74.6	73.3	79.3	91.3	50.0	0.84
Sick listed	11.4	70.0	75.8	23.7	95.9	0.84
Used health care	33.3	63.4	56.9	43.3	75.0	0.66
Completers						
Disability	63.2	63.0	79.3	84.0	55.4	0.75
Pain	71.8	74.3	77.3	89.4	54.0	0.84
Sick listed	8.4	70.0	76.2	17.1	97.3	0.85
Used health care	31.1	52.1	68.2	42.4	76.0	0.68
Global	35.1	70.2	62.4	51.3	78.8	0.74

in a sample of CLBP patients 14 months after the completion of a full treatment, it follows from Table 3 that, if they had a pretreatment pain score below 19 and a disability score below 37, were not on sick leave, had low expectations of future work ability, and did not continue to perform exercises, the clinician would be able to identify those who would experience poor reduction of pain with a positive explanatory value of 0.9, meaning that 90% of those would be true positives. Presence of the pretreatment variables would be able to discriminate those patients who would experience poor pain reduction from those who would not with an area under the receiver operating characteristic curve of 0.84, which is regarded as excellent discrimination.[27]

Discussion

One of the main issues of this study were to investigate whether it was possible to identify pretreatment variables associated with withdrawal from treatment and poor long-term outcome following physical exercise programs in CLBP patients. And, if so, whether these variables were more important than the type of exercise therapy provided. Based on the present results, the answer to both questions is yes.

The long-term effectiveness of McKenzie-therapy and strengthening training did not differ between treatment groups. Results were consistent across the analysis on all enrolled patients and the supplementary analysis on the subgroup of patients who completed the full intervention (data not presented). Neither did type of treatment have any influence on outcome in comparison with other prognostic factors. An explanation for these findings might be that LBP of some duration is a fluctuating condition and possible differences between treatments may be overshadowed by natural variation. Consequently, there is a high probability of recurrence of the LBP problem sooner or later, and various treatment methods might have a certain effect but none will be able to cure the problem. Another explanation of our negative findings might be the fact that any type of intensive exercise program that gives patients the experience of expanded limits to their physical functioning may provide them with a method that increases the feeling of control over the pain, thus inhibiting negative pain behavior related to the LBP problem. Previous studies have shown that treatment programs containing active exercises are equally effective for patients with subacute or chronic LBP, irrespective of the type of exercises that have been compared.[28–33]

The most substantial finding in this study is that for the main outcome variables, disability and pain, a strong association was found between pretreatment levels and long-term changes. Patients with low pretreatment scores on disability and pain had a 5 and 14 times reduced risk of poor reduction of disability and pain, respectively, compared with those with high pretreatment scores. Studies with a similar design as ours (sample of patients with CLBP, intervention with predominantly exercise therapy, outcome reported at 1-year follow-up, and analysis with multivariable or univariate methods) have shown the same association.[7,34,35] Whether this is explained by the phenomenon of regression toward the mean, a higher degree of motivation in the most severely disabled patients, or that the underlying mechanisms of exercise therapy worked the best in the most disabled patients is yet to be investigated. Two previous studies[14,36] found no association between pretreatment levels and long-term reduction of disability and pain, whereas several studies have reported a positive association between high pretreatment disability or pain scores and long-term incapacity for work in patients with CLBP treated with exercise therapy.[7,9,10,12,13,37–39]

Another striking finding is that the 2 variables related to the patients' pretreatment expectations regarding work capacity (expecting coping with future work tasks and low expectations to be working after 6 months) were associated with outcome regarding poor reduction of disability and use of healthcare services during the past 6 months. It is worth noting that expectations regarding working capacity are not merely another expression of level of disability in as much as only 64% of patients with low expectations of coping with future work tasks and 57% of patients with low expectations to be working after 6 months had high levels of disability. Also, results from other exercise studies have shown that low expectations regarding work capacity were associated with various long-term outcomes, such as non return to work, poor reduction of pain, or poor global assessment.[14,37]

The explanatory value of discontinuation of exercises after end of treatment for long-term pain reduction is supported by the findings of Manniche *et al*,[36] Bronfort *et al*,[40] and Taimela *et al*[41] It appears logical that, given the recurrent course of CLBP, it is necessary for the patient to continue the self-administration of disease-specific exercises for the purpose of secondary prophylaxis. One might speculate whether the causal association between the variables might be reverse and that the reason for discontinuation of exercises in fact is poor perceived benefit from exercises by the end of treatment. However, this notion is not supported by our data. About 50% of the patients who did not continue the exercises after the completion of the full intervention in our study reported good outcome regarding change in disability scores at end of treatment.

A strong association was found between being sick-listed at 14 months and being on sick leave at entry or withdrawal during treatment. Patients on sick leave at entry were 4 times more likely to be sick-listed at follow-up than those who were not on sick leave at entry. To our knowledge, the explanatory value of being on sick leave at entry has not been reported in other studies. The problem with most studies with a design similar to ours is that all patients were on sick leave at entry[13] or studies did not include sick leave as both an explanatory and outcome variable.[8–12,14–16] Two studies found no association between sick leave at entry and return to work at follow-up.[6,7] This difference in results might be attributed to the fact that a sample of patients relevant for the outcome variable return to work is not equivalent to those being relevant for the outcome variable being sick-listed. In addition to the number of patients on sick leave at entry, the latter sample also comprises patients who were working at entry. It was not possible to include return to work as an outcome variable in this study because of a low number of patients in the not returned to work category (18 patients). Being sick-listed was the only outcome variable at 14 months follow-up that was influenced by withdrawal during treatment. Also, Proctor *et al*[42] found noncompliance with treatment to be associated with a high risk of not returning to work in a population with chronic musculoskeletal disorders from various regions (50% with CLBP) 1 year after exercise therapy. Gatchel *et al*[43] found that CLBP patients who completed a rehabilitation intervention had better chances than the noncompliers for return to work 1 year after. According to our analysis on completers, being on sick leave at entry had no association to being sick-listed at follow-up. This might indicate that the exercise programs used in our study were effective in reducing the need for sick-listing in these patients once they completed the full intervention.

One third of the patients at follow-up reported the use of healthcare services during the past 6 months, which was explained by low level of pain and low expectations to be working after 6 months. Unexpectedly, patients with low pretreatment pain scores had twice the risk of having visited a healthcare provider because of LBP during follow-up compared with those with high pretreatment scores (Table 1). To our knowledge, no other studies have been published investigating CLBP patients' need for health care in a similar design. Overall, the 2 variables related to the patients' expectations regarding work capacity were among the few variables that were the most consistently associated with several outcomes. Our overall findings are supported by 2 previous studies in which low expectations regarding work ability predicted poor long-term outcome regarding reduction of pain intensity,[14] return to work,[14,37] and global assessment[14] following exercise therapy.

In the subgroup analysis on the data from the completers, patients above 40 years of age had a 5 times higher likelihood of reporting poor change in quality of life than patients with an age below 40 years. In previous exercise studies, older age has been found to have significant prognostic value for poor long-term outcome in patients with subacute or chronic LBP regarding quality of life,[44] pain,[44] disability,[44] return to work,[6,45] and pension obtained.[7] However, other studies have reported no influence on pain, disability,[12,14,16,36] or return to work.[9,14,15,46]

Application for pension or pending litigation did not reach a statistically significant association to any of the outcome variables. The presence of these characteristics at entry is an exclusion criterion in many outcome studies based on the notion that these patients will present with a lack of motivation towards getting better. Our results are not in line with those of exercise studies by Rainville *et al*[16] and Beissner *et al*[6] in patients with CLBP as well as Becker *et al*[34] in patients with chronic pain of various origins. This discrepancy might be explained by the fact that, in our sample, it is possible that the explanatory value of this variable is overpowered by that of the 2 variables regarding expectations for work ability. Although no statistically significant interaction effect was found, 78% and 70% of patients with an application for pension or pending litigation reported low expectations at entry regarding expecting problems coping with future work tasks and low expectations to be working after 6 months, respectively.

Is it possible to explain which patients will not complete an exercise program? In our study, duration of symptoms, low expectations of coping with future work tasks, and smoking were all associated with withdrawal during the intervention, although only a low positive explanatory value was found. The influence of the latter 2 variables is supported by the results of several similar studies.[7,8,37] However, a study by Rainville *et al*[16] found no association with either of these 2 variables and withdrawal. Smoking was found to be predictive of noncompletion of treatment and decrease in work retention at 1-year follow-up in a study by McGeary *et al.*[47] Proctor *et al*[42] reported smoking to be associated with noncompliance of exercise therapy in a population with chronic musculoskeletal disorders from various regions (50% with CLBP). Recently, the association between smoking in itself and first time or recurrent LBP has been challenged. The associations reported in the literature might be explained by physiologic mechanisms[48] or by the assumption that smokers have a certain risk-lifestyle.[49–52] Whether these considerations apply to patients with CLBP is nor clear. Although our method of analysis controlled for several potential confounders, it is obviously impossible to control for all possible extraneous factors that are linked to both smoking and CLBP.

Even though most of our findings are supported by previous studies predicting lack of success with exercise-oriented interventions for patients CLBP, some are in contradiction with other studies. This diversity might be explained by differences in treatment, patient characteristics, outcome measures used, and whether values were dichotomized or continuous. Thus, the need for standardization in these types of studies previously stated by others[20,53] must be emphasized.

Some limitations of this study must be acknowledged. We aimed at identifying factors associated with long-term outcome. Many baseline variables were included in this study as there were no specific hypotheses of any of the variables to be of particular importance. In some of the analyses, lack of statistical power resulted in confidence intervals of large magnitude. Although significant odds ratios were obtained, results from an explorative analysis strategy as the one we have chosen would need to be validated in future cohort studies.

An important strength in this study is the fact that we performed an analysis on all patients enrolled as well as a subgroup analysis on completers. Consistent findings in both analyses increased their credibility.

We think that our study sample is fairly representative of the patients with CLBP seen in primary care settings.

Generally, the discriminative values of the selected prognostic factors were high, which should encourage practitioners to use them when considering the application of exercise therapy to the individual patient. The practitioner might find our results helpful in motivating the patient with CLBP to an active approach to treatment. In essence, the message to the patient could be: "persons with similar characteristics as you have been found to have a poor prognosis. Can you mobilize the energy and discipline to reverse this trend? Do you have the ability to be an ice breaker?" Alternatively, the practitioner might be confirmed in his identification of patients that would need special attention or even to be referred to a multidisciplinary intervention.

■ Conclusion

The result of this study showing that expectations regarding future work ability seems to be a strongly associated with the lack of long-term success is consistent with those of several other similar studies. Regarding pretreatment levels of pain and disability, results form previous studies are not entirely conclusive. Smoking, duration of symptoms, and expectations regarding future work ability were associated with withdrawal. Only the value of smoking, however, is consistently supported by several previous studies.

For the researcher, our study confirms that different factors are associated with different outcomes. For the clinician, the prognostic factors presented should not be regarded as a screening tool to exclude patients from exercise treatment. Rather, the results provide information on particular characteristics of patients who might benefit from special attention toward those factors or from more extensive efforts (cognitive, behavioral, vocational) at reducing pain, perceived disability, and enhance ability to work.

■ Key Points

- McKenzie treatment and strengthening training were equally effective in the treatment of patients with chronic low back pain at the 14-month follow-up.
- Expectations regarding future work ability and pretreatment levels of pain appear to be the most consistently associated with the lack of long-term success of patients with chronic low back pain treated with exercise therapy.
- Different factors were associated with different outcomes.
- The associations found in the analysis on all patients included in the study were similar to those of the analysis on the subgroup of patients who completed the full intervention.
- The explanatory power of the interventions compared was not sufficient to outmatch the prognostic value of other variables.

References

1. COST Action B13. European guidelines for the management of chronic non-specific low back pain. 2004. European Commission Research Diractorate General. Low Back Pain: Guidelines for its Management. www.backpaineurope.org.
2. Battie MC, Cherkin DC, Dunn R, et al. Managing low back pain: attitudes and treatment preferences of physical therapists. *Phys Ther* 1994;74:219–26.
3. Foster NE, Thompson KA, Baxter GD, et al. Management of nonspecific low back pain by physiotherapists in Britain and Ireland: a descriptive questionnaire of current clinical practice. *Spine* 1999;24:1332–42.
4. Petersen T, Kryger P, Ekdahl C, et al. 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. *Spine* 2002;27:1702–9.
5. van der Hulst M, Vollenbroek-Hutten MM, Ijzerman MJ. A systematic review of sociodemographic, physical, and psychological predictors of multidisciplinary rehabilitation-or, back school treatment outcome in patients with chronic low back pain. *Spine* 2005;30:813–25.
6. Beissner KL, Saunders RL, McManis BG. Factors related to successful work hardening outcomes. *Phys Ther* 1996;76:1188–201.
7. Bendix AF, Bendix T, Haestrup C. Can it be predicted which patients with chronic low back pain should be offered tertiary rehabilitation in a functional restoration program? A search for demographic, socioeconomic, and physical predictors. *Spine* 1998;23:1775–83.
8. Carosella AM, Lackner JM, Feuerstein M. Factors associated with early discharge from a multidisciplinary work rehabilitation program for chronic low back pain. *Pain* 1994;57:69–76.
9. Polatin PB, Gatchel RJ, Barnes D, et al. A psychosociomedical prediction model of response to treatment by chronically disabled workers with low-back pain. *Spine* 1989;14:956–61.
10. Merkesdal S, Mau W. Prediction of costs-of-illness in patients with low back pain undergoing orthopedic outpatient rehabilitation. *Int J Rehabil Res* 2005;28:119–26.
11. Talo S, Puukka P, Rytokoski U, et al. Can treatment outcome of chronic low back pain be predicted? Psychological disease consequences clarifying the issue. *Clin J Pain* 1994;10:107–21.
12. Turner JA, Robinson J, McCreary CP. Chronic low back pain: predicting response to nonsurgical treatment. *Arch Phys Med Rehabil* 1983;64:560–3.
13. Kool JP, Oesch PR, de Bie RA. Predictive tests for non-return to work in patients with chronic low back pain. *Eur Spine J* 2002;11:258–66.
14. Hildebrandt J, Pfingsten M, Saur P, et al. Prediction of success from a multidisciplinary treatment program for chronic low back pain. *Spine* 1997;22:990–1001.
15. Gross DP, Battie MC. Predicting timely recovery and recurrence following multidisciplinary rehabilitation in patients with compensated low back pain. *Spine* 2005;30:235–40.
16. Rainville J, Sobel JB, Hartigan C, et al. The effect of compensation involvement on the reporting of pain and disability by patients referred for rehabilitation of chronic low back pain. *Spine* 1997;22:2016–24.
17. Hazard RG, Bendix A, Fenwick JW. Disability exaggeration as a predictor of functional restoration outcomes for patients with chronic low-back pain. *Spine* 1991;16:1062–7.
18. Kleinke CL, Spangler AS Jr. Predicting treatment outcome of chronic back pain patients in a multidisciplinary pain clinic: methodological issues and treatment implications. *Pain* 1988;33:41–8.
19. Tota-Faucette ME, Gil KM, Williams DA, et al. Predictors of response to pain management treatment: the role of family environment and changes in cognitive processes. *Clin J Pain* 1993;9:115–23.
20. Waddell G, Burton AK, Main CJ. *Screening to identify people at risk of long-term incapacity for work: A conceptual and scientific review.* 2003.

London: Royal Society of Medicine Press Ltd. Available at http://www.rsmpress.co.uk/bkwaddell2.htm.

21. McKenzie RA. *The Lumbar Spine: Mechanical Diagnosis and Therapy*. Waikanae, New Zealand: Spinal Publications; 1981.
22. Manniche C, Asmussen K, Lauritsen B, et al. Low Back Pain Rating scale: validation of a tool for assessment of low back pain. *Pain* 1994;57:317–26.
23. Kjoeller M, Rasmussen NK. *Questionnaire for the Danish Health and Morbidity Survey 1994*. Copenhagen: Danish Institute for Clinical Epidemiology; 1996.
24. Hazard RG, Haugh LD, Reid S, et al. Early prediction of chronic disability after occupational low back injury. *Spine* 1996;21:945–51.
25. Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions: overview and methodology. *Phys Ther* 2001; 81:1629–40.
26. Altman DG. *Practical Statistics for Medical Research*. London: Chapman & Hall; 1991.
27. Hosmer DW, Lemeshow S. *Applied Logistic Regression*, 2nd ed. New York: John Wiley and Sons; 2001:160–4.
28. Bendix T, Bendix A, Labriola M, et al. Functional restoration versus outpatient physical training in chronic low back pain: a randomized comparative study. *Spine* 2000;25:2494–500.
29. Bentsen H, Lindgarde F, Manthorpe R. The effect of dynamic strength back exercise and/or a home training program in 57-year-old women with chronic low back pain: results of a prospective randomized study with a 3-year follow-up period. *Spine* 1997;22:1494–500.
30. Johannsen F, Remvig L, Kryger P, et al. Exercises for chronic low back pain: a clinical trial. *J Orthop Sports Phys Ther* 1995;22:52–9.
31. Keel PJ, Wittig R, Deutschmann R, et al. Effectiveness of in-patient rehabilitation for sub-chronic and chronic low back pain by an integrative group treatment program (Swiss Multicentre Study). *Scand J Rehabil Med* 1998; 30:211–9.
32. Ljunggren AE, Weber H, Kogstad O, et al. Effect of exercise on sick leave due to low back pain: a randomized, comparative, long-term study. *Spine* 1997; 22:1610–6.
33. Mannion AF, Muntener M, Taimela S, et al. A randomized clinical trial of three active therapies for chronic low back pain. *Spine* 1999;24:2435–48.
34. Becker N, Hojsted J, Sjogren P, et al. Sociodemographic predictors of treatment outcome in chronic non-malignant pain patients: do patients receiving or applying for disability pension benefit from multidisciplinary pain treatment? *Pain* 1998;77:279–87.
35. Harkapaa K, Jarvikoski A, Mellin G, et al. Health locus of control beliefs and psychological distress as predictors for treatment outcome in low-back pain patients: results of a 3-month follow-up of a controlled intervention study. *Pain* 1991;46:35–41.
36. Manniche C, Lundberg E, Christensen I, et al. Intensive dynamic back exercises for chronic low back pain: a clinical trial. *Pain* 1991;47:53–63.
37. Barnes D, Smith D, Gatchel RJ, et al. Psychosocioeconomic predictors of treatment success/failure in chronic low-back pain patients. *Spine* 1989;14: 427–30.
38. Dolce JJ, Crocker MF, Doleys DM. Prediction of outcome among chronic pain patients. *Behav Res Ther* 1986;24:313–9.
39. Mannion AF, Junge A, Taimela S, et al. Active therapy for chronic low back pain: 3. Factors influencing self-rated disability and its change following therapy. *Spine* 2001;26:920–9.
40. Bronfort G, Goldsmith CH, Nelson CF, et al. Trunk exercise combined with spinal manipulative or NSAID therapy for chronic low back pain: a randomized, observer-blinded clinical trial. *J Manipulative Physiol Ther* 1996;19: 570–82.
41. Taimela S, Diederich C, Hubsch M, et al. The role of physical exercise and inactivity in pain recurrence and absenteeism from work after active outpatient rehabilitation for recurrent or chronic low back pain: a follow-up study. *Spine* 2000;25:1809–16.
42. Proctor TJ, Mayer TG, Theodore B, et al. Failure to complete a functional restoration program for chronic musculoskeletal disorders: a prospective 1-year outcome study. *Arch Phys Med Rehabil* 2005;86:1509–15.
43. Gatchel RJ, Mayer T, Dersh J, et al. The association of the SF-36 health status survey with 1-year socioeconomic outcomes in a chronically disabled spinal disorder population. *Spine* 1999;24:2162–70.
44. Karjalainen K, Malmivaara A, Mutanen P, et al. Outcome determinants of subacute low back pain. *Spine* 2003;28:2634–40.
45. Mayer T, Gatchel RJ, Evans T. Effect of age on outcomes of tertiary rehabilitation for chronic disabling spinal disorders. *Spine* 2001;26:1378–84.
46. Lacroix JM, Powell J, Lloyd GJ, et al. Low-back pain: factors of value in predicting outcome. *Spine* 1990;15:495–9.
47. McGeary DD, Mayer TG, Gatchel RJ, et al. Smoking status and psychosocioeconomic outcomes of functional restoration in patients with chronic spinal disability. *Spine J* 2004;4:170–5.
48. Iwahashi M, Matsuzaki H, Tokuhashi Y, et al. Mechanism of intervertebral disc degeneration caused by nicotine in rabbits to explicate intervertebral disc disorders caused by smoking. *Spine* 2002;27:1396–401.
49. Hagen KB, Tambs K, Bjerkedal T. A prospective cohort study of risk factors for disability retirement because of back pain in the general working population. *Spine* 2002;27:1790–6.
50. Kaila-Kangas L, Leino-Arjas P, Riihimaki H, et al. Smoking and overweight as predictors of hospitalization for back disorders. *Spine* 2003;28:1860–8.
51. Leboeuf-Yde C, Kyvik KO, Bruun NH. Low back pain and lifestyle: I. Smoking: information from a population-based sample of 29,424 twins. *Spine* 1998;23:2207–13.
52. Petersen M. Nonphysical factors that affect work hardening success: a retrospective study. *J Orthop Sports Phys Ther* 1995;22:238–46.
53. Pincus T, Burton AK, Vogel S, et al. A systematic review of psychological factors as predictors of chronicity/disability in prospective cohorts of low back pain. *Spine* 2002;27:E109–20.