

Long-Term Effect of a Combined Exercise and Motivational Program on the Level of Disability of Patients With Chronic Low Back Pain

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Study Design. A prospective clinical randomized controlled trial.

Objectives. To determine the long-term effect of a combined exercise and motivational program on the level of disability of patients with chronic and recurrent low back pain (LBP).

Summary of Background Data. There is agreement on the importance of exercise during the course of chronic LBP. However, it is well known that long-term adherence with exercises is particularly low.

Methods. A total of 93 patients with LBP were randomly assigned to the control group (standard exercise program) or the motivational group (combined exercise and motivational program). Follow-up assessments were performed at 3.5 weeks, 4 months, 12 months, and 5 years. Main outcome measures were disability scores, pain intensity, and working ability. In addition to classic statistics, the sophisticated linear partial credit model was used to test the effects of treatment on disability scores.

Results. In both groups, significant improvements in the disability scores were found at all points of follow-up assessment, however, the cumulative effect of the treatment in the motivational group was more than twice as much as in the control group. This result is in accordance with the increasing divergence in pain intensity between groups between 12 months and 5 years after intervention. A significant, positive long-term effect at the 5-year reassessment in working ability was only seen in the motivational group. All statistically significant results were confirmed by intention-to-treat analyses.

Conclusions. Regarding long-term efficacy, the combined exercise and motivation program was superior to the standard exercise program. Five years after the supervised combined exercise and motivational program, patients had significant improvements in disability, pain intensity, and working ability.

Key words: exercise, low back pain, long-term compliance, disability, working ability. *Spine* 2005;30:995–1000

During the last 15 years, numerous studies have concluded that exercise helps alleviate chronic low back pain (LBP).^{1–7}

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There have also been a number of reviews and evidence based medicine studies supporting this argument.^{8–10}

The success of these exercises is determined by several factors. Most clinicians contend that for positive results, the exercises must be tailored to the type and stage of the disorder,^{11–22} of the proper intensity, and performed with the correct technique.^{17,23–25} Likewise, full benefits can only be realized if the exercises are performed regularly and consistently, with patients attending all prescribed training sessions and maintaining the exercise regimen at home after active intervention has ended.^{13,26–28}

The problem of low compliance with exercise has been discussed repeatedly.^{29–33} Follow-up data suggest that from one third to two thirds of patients are noncompliant with exercise.³⁴ This result is particularly true regarding unsupervised exercising at home.^{32,33,35} Difficulty with compliance might be because patients are no longer motivated by their therapists and do not receive any feedback about their progress.^{29–37} There is little research that shows the clinical effectiveness of interventions intended to increase compliance.

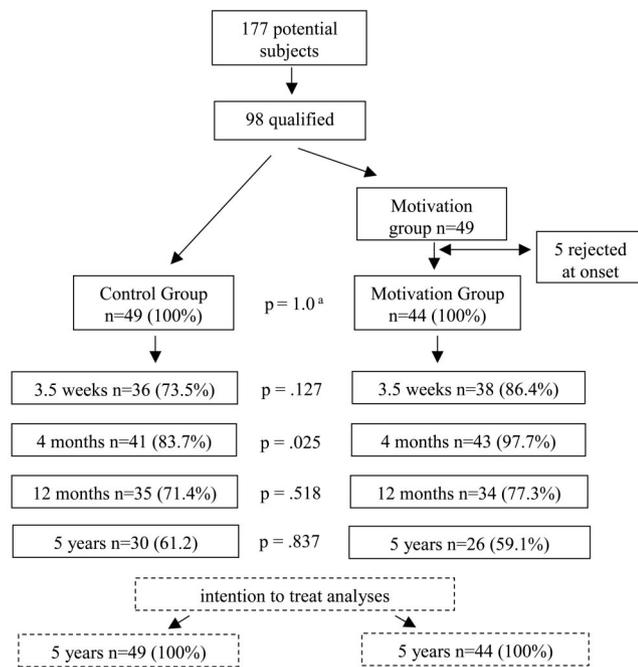
We have previously published the one-year results of the effect of a combined exercise and motivational program.³⁸ The purpose of the actual study was to evaluate the long-term effectiveness of the combined exercise and motivational program in patients with chronic and recurrent LBP. It studies the degree of subjective disability, pain intensity, and working ability at 5 years after intervention.

Materials and Methods

Sample Description. Consecutive patients who were referred to the outpatient department of our hospital in Vienna, Austria, for individual exercise treatment of LBP were included in the study. Enrollment required LBP fulfilling the topographic criteria as described by Kuorinka *et al*,³⁹ recurrent or chronic LBP of at least 4 months in duration, and patients between 20 and 60 years old.

Criteria for exclusion were: specific LBP, such as tumors, fractures, infections, acute lumbar radicular lesions, and spinal stenosis; 3 or more of 5 nonorganic physical signs⁴⁰; and patients involved in disability pension proceedings or private insurance litigation. Because a workers' compensation law does not exist in our country, patients who were comparable to the workers' compensation population (*i.e.*, people who are disabled from work related injuries) were not excluded. Informed consent was obtained from all patients.

Figure 1 shows recruitment and subject dropout information. After the initial screening, 98 of 177 patients fulfilled all inclusion and exclusion criteria. Five patients randomized to



^{a)} Comparison of the percentages of responders per follow-up (two sided p values).

Figure 1. Subject recruitment and dropout.

the motivational group were excluded immediately after randomization because 3 of them did not fulfill the criteria and were previously included by mistake, and the other 2 patients did not come to the first physical therapy session. Thus, the data from 93 patients were included in the baseline analysis. The *P* values indicate that the percentages of responders, except for the 4-month follow-up, do not differ significantly ($\alpha = 0.05$) between the groups (Figure 1). The average age of the entire patient sample was 44.12 years (standard deviation [SD], 10.66), and 46 (49%) were men.

Patients were randomly assigned to 2 groups with regimens that consisted of either the standard exercise program (control group) or a combined exercise and motivational program (motivational group). All patients were instructed individually by a physical therapist and were prescribed 10 treatment sessions of equal duration in both groups. Because the motivational program was part of the treatment sessions in the motivational group, it did not require any additional treatment time. From the first training session, patients were advised to exercise regularly at home, if possible daily, and to continue exercising after completion of the treatment program. The patients were not told that one purpose of the study was the measurement of their disability and compliance with exercise. The treatment sessions were directed by 8 physical therapists who were randomly allocated to one of the 2 treatment groups by casting lots.

At the beginning of the study, the 4 therapists assigned to the motivational group were given a detailed introduction concerning the motivational program. The therapists of the control group were not precluded from using their habitual motivational techniques. In both groups, patients were assessed on the day of randomization, on the day of the eighth treatment session (approximately 3.5 weeks after study entry), 4 months, 12 months, and 5 years after the beginning of the study. At study entry, the demographic data (*i.e.*, age, gender, body mass index), participation in any physical exercise program before the

training phase of this study, the patient's history of spinal surgery, and the original level of working ability were recorded.

Treatment Description

Exercise Program. The exercise program consisted of individual, submaximal gradually increased exercises. The treatment was directed toward improving spinal mobility, as well as trunk and lower limb muscle length, force, endurance and coordination, thereby restoring normal function. The protocol of the exercises has been described in detail elsewhere.⁴¹⁻⁴³ Each patient was prescribed a total of 10 training sessions. The level of compliance regarding the number of training sessions was significantly higher ($P = 0.001$) in the motivational group (mean = 9.64, SD = 1.06) compared to the control group (mean = 8.61, SD = 2.15). The training time per session was 25 minutes, and average training frequency was 2.3 (range 2-3) sessions per week. All patients were encouraged to be physically active and to continue exercising at home to help overcome fears about anticipated or actual pain that might contribute to the avoidance of physical activity.

Motivational Program. In addition to the standard exercise program, the motivational program implemented in the motivational group consisted of the following interventions:

1. Extensive counseling and information strategies were used to ensure that patients received clear instructions, emphasizing the importance of regular and consistent exercise for reducing the pain and likelihood of recurrent episodes. The therapist also tried to enhance each patient's internal locus of control by explaining that rehabilitation in large part depended on the patient's behavior. In addition, the therapist inquired about any problems the patient encountered and tried to solve them in mutual cooperation with the patient (*e.g.*, by tailoring the regimen to the patient's daily routine in terms of treatment time and duration).
2. Reinforcement techniques were used, with the therapist giving positive feedback and commending patients for their efforts. In cooperation with the patient, the therapist developed reward and punishment strategies (*e.g.*, saving up money for a special purpose), with particular attention placed on positive reinforcement (*i.e.*, rewards for exercise compliance).
3. The oral agreements between the patient and the therapist were reinforced in writing in the form of a "treatment contract." The terms of this agreement were negotiated individually with each patient. By signing the contract, the patients agreed to exercise regularly at the time and for the duration specified in the contract, and to gradually increase the intensity of the exercises.
4. Patients were asked to post the treatment contract in a prominent place at home to remind them of their exercises.
5. Finally, patients were involved more in their care by reporting all exercises they had performed in an exercise diary.

Main Assessment Measures

Disability. Assessment of the patient's history of disability was based on the low back outcome scale questionnaire devel-

oped by Greenough and Fraser.⁴⁴ This questionnaire includes 13 items dealing with the patient's perception of disability. The total score can vary from 0 (a great deal of disability) to 75 (no disability).

Pain. Pain intensity was assessed using the 101-point numerical rating scale.⁴⁵ Pain topography was recorded using the pain drawing method.⁴⁶ The cause of the pain (*e.g.*, injury, increased physical strain, nonphysiologic movement, stress, other reasons, no answer) was also documented.

Working Ability. Working ability was analyzed in terms of the following 4 categories: (1) patients who were able to return to their original level of occupational activity, (2) patients who were able to do lighter work, (3) patients with the capability to work part-time, and (4) patients unable to work because of their back disability.

Further Outcome Measures. Additionally, body mass index, the number of LBP episodes requiring treatment, and the use of health care were documented. Exercise compliance was measured by the number of years the patients reported to have performed regularly (at least 3 times weekly). More details about the treatment and assessment can be found in the article by Friedrich *et al*, reporting the 12-month results.³⁸

Statistical Analysis. Appropriate descriptive statistics were used to describe the study participants. Comparison of the 2 groups was performed with the χ^2 test, Student *t* test for independent means, or Mann-Whitney *U* test. Differences between the various points of assessments were analyzed using the Student *t* test for dependent means or the Wilcoxon matched pairs signed rank test.

To show the effects of treatment on the level of disability, the sophisticated multivariate linear partial credit model was used.^{47,48} The 13 items of the low back outcome scale were transformed into 3-answer categories to increase the size of the frequency of each category. The likelihood ratio test was used to determine the restricted model with the highest degree of generalizability that does not differ significantly from the quasi-saturated model. This restricted model permits generalization of effects across all 13 items. The 2 parameters entered in this model were: (1) the effect of the standard exercise therapy regimen, including spontaneous remission; and (2) the effect of the motivational program.

To control for the effect of dropouts in the follow-up studies, intention-to-treat analyses were calculated.⁴⁹ All important statistical tests were repeated by one or, if possible, 2 commonly feasible methods of intention-to-treat analysis using the last observed response ("carry forward"), respectively assuming that all missing responses were constant ("constant value") (*i.e.*, all of the dropout subjects showed no difference between the groups).

Although the interval nature of these measurements could not be documented, score and force measurements were added, and partly treated as interval level data. The level of significance for this study was chosen at $\alpha = .05$. All analyses were performed on a personal computer using the SPSS statistical package (SPSS, Inc., Chicago, Ill) and the LPCM-WIN Linear Partial-Credit Model (version 1.0, Assessment Systems Corp., St. Paul, MN).⁵⁰

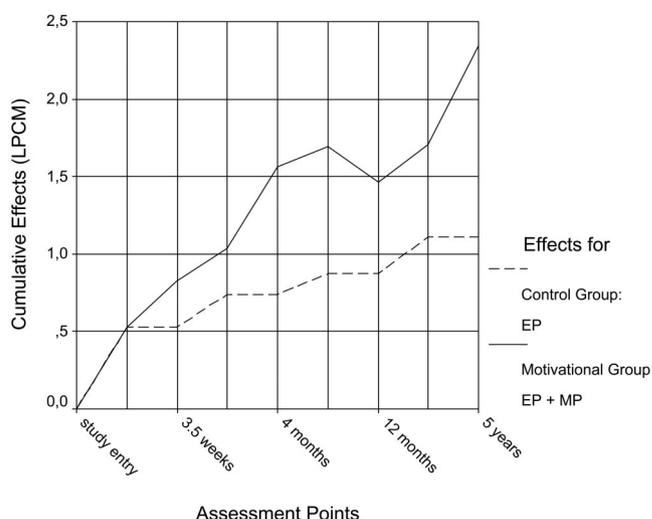


Figure 2. Independent cumulative effects of the exercise program (EP), including spontaneous remission, and the motivational program (MP) on the level of disability, determined with the Linear Partial-Credit Model (LPCM).

■ Results

Randomization

Figure 1 provides an overview of the number of patients from whom follow-up data were available and the sample sizes for the intention-to-treat analyses. There were no significant differences between the motivational and control groups on sociodemographic variables, pain histories, disability scores, and working ability data at study entry. This result is also true for the patients who remained in the study at the 5-year reassessment. There were no baseline differences in outcome measures among patients who remained in the study and those for whom follow-up data were not available at the 4-month, 12-month, and/or 5-year reassessments.

Disability

Between study entry and the 3.5-week follow-up, a significant effect of the exercise program was noticeable ($P < 0.001$) (Figure 2). During the further course of the study, the effects seen in both groups did not decrease below this level, so that the significant effect was maintained through all subsequent points of assessment. The dashed line shows the effect of the exercise program, including spontaneous remissions. The increase above this line shows the additional effect of the motivational program. Between 3.5 weeks and 4 months after study entry, a significant effect of the motivational program ($P = 0.003$) was observed, as seen in the steep increase of the continuous line (Figure 2). This significant effect was also observed between 12 months and 5 years after study entry ($P = 0.003$), so that the cumulative effect in the motivational group (effect parameter = 2.34) across all points of assessment was more than twice that in the control group (effect parameter = 1.11). The intention-to-treat analyses validate these significant results.

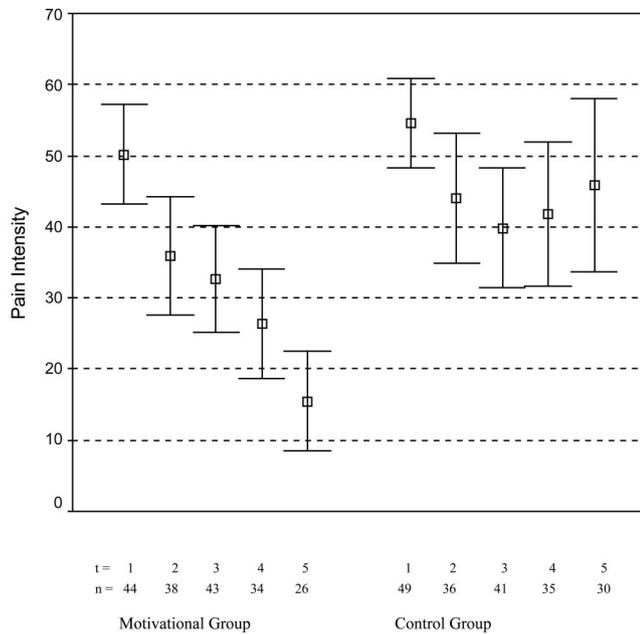


Figure 3. Pain intensity (independent data; mean and 95% confidence interval) at study entry (t₁), 3.5-week follow-up (t₂), 4-month follow-up (t₃), 12-month follow-up (t₄), and 5-year follow-up (t₅).

Pain Intensity

Different courses between study entry and the 5-year re-assessment of pain intensity between the motivational group and control group are shown in Figure 3. In the control group, a decrease in pain intensity is shown only from study entry to the 4-month follow-up, contrasted by a steady decrease in pain intensity in the motivational group from study entry to the 5-year reassessment. Random sampling for dependent data ($n = 41$) did not have a significant effect on these results. Mean values between the study entry and 5-year follow-up show a significant difference in the motivational group ($P < 0.001$) but not in the control group ($P = 0.155$). At the 5-year follow-up, significant differences in pain ratings favoring the motivational group were observed ($P = 0.001$). This result is true even under calculations of intention-to-treat analyses (“carry forward,” $P < 0.001$; “constant value,” $P < 0.001$).

Working Ability

Working ability did not increase immediately during exercise therapy (Figure 4). However, following a nonsignificant decrease in both groups, there has been a significant improvement in the motivational group between study entry and the 4-month follow-up, as well as between study entry and the 5-year follow-up ($P = 0.005$); no improvement was seen in the control group ($P = 0.599$). Random sampling for dependent data ($n = 41$) did not have a significant effect on these results. At the last point of assessment, a significant difference between the groups favoring the motivational group was found ($P = 0.005$), which is confirmed by the “constant value” method of intention-to-treat analyses ($P = 0.021$) but not confirmed by the “carry forward” method ($P = 0.064$).

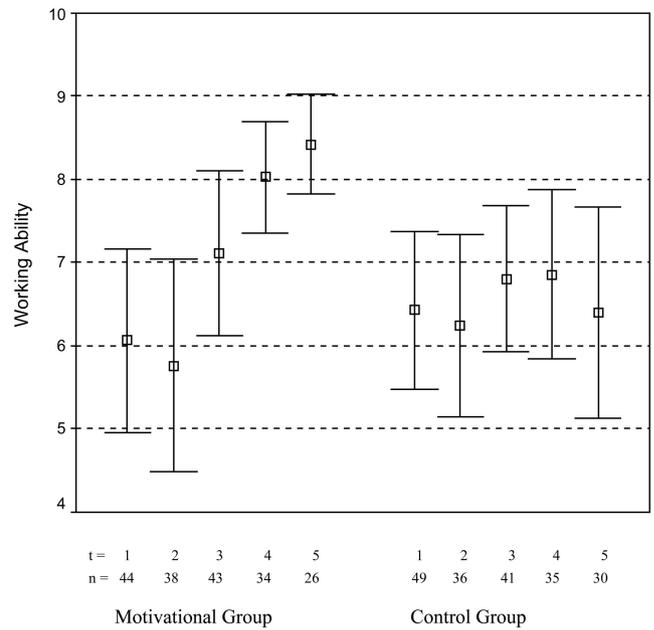


Figure 4. Working ability (independent data; mean and 95% confidence interval) at study entry (t₁), 3.5-week follow-up (t₂), 4-month follow-up (t₃), 12-month follow-up (t₄), and 5-year follow-up (t₅).

Further Outcome Measures

Differences between the motivational group and control group at 5-year follow-up in further outcome measures are shown in Table 1.

Discussion

Even when subjected to intention-to-treat analysis, the combined exercise and motivational program was shown to be significantly more effective than the standard exercise program, as measured by the decrease of disability and pain, and the increase in the degree of working ability. This conclusion holds according to the intention-to-treat analyses.

The disability score used in this study comprises a number of factors experienced by most patients as particularly distressful. In a study that investigated the predictors of treatment success in patients with chronic LBP undergoing a multimodal treatment, an improvement in the patient’s subjective perception of functional disability was the most powerful predictor of treatment outcome.⁵¹ Moreover, individual perceptions of physical functioning highly increase the chances of the patient returning to productive employment activity.

In our study, treatment in both groups was designed to modify types of behavior aimed at avoiding anticipated pain. It appears that the patients in the motivational group are more able to develop a sense of control over pain and to eliminate a pain avoidance mechanism. One likely explanation for the long-term effect of the combined exercise and motivational program is that it provided the patients with a set of tools that are readily retrievable, even after treatment termination, supporting them in dealing with the multifaceted psychosocial phe-

Table 1. Differences Between the Motivational and Control Groups at 5-Year Follow-up in Further Outcome Measures

	Motivational Group (n = 26)	Control Group (n = 30)	Difference P Value*
Sociodemographic and other baseline data			
Age (yrs)	47.5 (10.6)†	51.4 (10.9)†	0.180
Gender			
Male	13/23.2‡	18/32.1‡	0.453
Female	13/23.2‡	12/21.4‡	
Body Mass Index (kg/m ²)	25.7 (5.0)†	26.7 (4.3)†	0.414
No. of LBP episodes requiring therapy	1.75§	5.75§	0.016*¶
Use of health care			
Consulted a physician for LBP	22.3§	33.9§	0.315
Stayed at a health resort for LBP (no = 0/yes = 1)	0.18 (.39)†	0.50 (.51)†	0.025*
Compliance			
No. of years exercises were performed regularly	3.5 (2.0)†	4.4 (2.2)†	0.134

*Significance at $\alpha = .05$ for the appropriate statistic.

† Mean (SD).

‡ Count/percent.

§ Median.

¶ Intention-to-treat analysis ('constant value'): $P = 0.038$.

|| Intention-to-treat analysis ('constant value'): $P = 0.040$.

nomenon of chronic LBP. Moreover, the motivational program may contribute to treatment efficacy by helping patients perform the exercises correctly rather than by motivating them to exercise regularly and persistently.

Regarding compliance measured in the self-rated number of years exercises were performed regularly, no significant difference between the groups at 5-year follow-up was found. Interestingly, patients in the motivational group were not more committed to adopting the prescribed practices long-term than the patients in the control group. Patients in the control group even reported regular exercise for 1 year longer than the motivational group. Nevertheless, although the combined exercise and motivational program effectively reduced disability and pain levels, there was no complete chain of cause and effect between improved motivation, enhanced compliance as measured by the level of adherence with long-term exercise after treatment termination, and superior treatment outcome in terms of disability, pain intensity, and working ability. This result agrees with data that have shown that compliance is not necessarily associated with clinical outcome.³⁴ The observed result regarding compliance could be in line with the fact that reliable longitudinal measures to validate objectively adherence with exercise therapy recommendations do not exist. Numerous investigators have deplored the lack of valid and reliable measurement tools to assess the degree of patient compliance.⁵¹⁻⁵³ It could be that patients in the control group who reported less reduced disability and pain levels, compared to the patients of the motivational group, do not admit noncompliance, or they even overstate their level of compliance.

The high values of SD at the 5-year reassessment of the control group in pain intensity (control group SD = 32.59; motivational group SD = 17.29), as well as in the low back outcome scale (control group SD = 17.07; motivational group SD = 10.67) and working ability (control group SD 3.41; motivational group SD = 1.47) show the heterogeneous results of this group. People's

perceptions are very different; some feel very well, but more feel disabled.

Limitations of the Study

As mentioned previously, it is often not possible to validate objectively motivation and compliance with recommended self-care regimens. Because patients in litigation and with nonorganic signs were excluded, the results of the study may not be generalizable to the chronic LBP population as a whole. Furthermore the effect of the combined program may partly be unspecific because patients included in the combined program had more frequent therapeutic contacts (*i.e.*, patients in the motivation group on average attended 9.6 of the control group 8.6 treatment sessions).

Conclusions

Our study shows that a program combining conventional exercise therapy with motivation enhancing intervention strategies significantly reduced the long-term level of disability and pain, and increased the level of working ability in patients with chronic LBP. Further research should analyze which specific mechanisms lead to these results.

Key Points

- After 5 years of follow-up, a combined exercise and motivational program was more effective than a standard exercise program, as measured by self-reported disability, pain intensity, and working ability.
- Extensive counseling and information strategies, as well as reinforcement techniques seemed to be the important points of the motivational program to reach these positive results.

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