Increasing Days at Work Using Function-Centered Rehabilitation in Nonacute Nonspecific Low Back Pain: A Randomized Controlled Trial

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ABSTRACT. Kool JP, Oesch PR, Bachmann S, Kneusel O, Dierkes JG, Russo M, de Bie RA, van den Brandt PA. Increasing days at work using function-centered rehabilitation in nonacute nonspecific low back pain: a randomized controlled trial. Arch Phys Med Rehabil 2005;86:857-64.

Objective: To evaluate the effect of function-centered compared with pain-centered inpatient rehabilitation in patients whose absence from work is due to chronic nonspecific low back pain (LBP).

Design: Single-blinded randomized controlled trial with follow-up assessments immediately after treatment and at 3 months.

Setting: Center for work rehabilitation in Switzerland.

Participants: Patients with more than 6 weeks of work absence due to chronic nonspecific LBP (N=174; 137 men, 37 women; mean age ± standard deviation, 42±8y; mean sick leave before study, 6.5mo).

Interventions: Function-centered treatment (FCT) (4h/d, 6d/wk, for 3wk) consisted of work simulation, strength, endurance, and cardiovascular training. Pain-centered treatment (PCT) (2.5h/d, 6d/wk, for 3wk) used a mini back school, individually selected passive and active mobilization, stretching, and low-intensity strength training.

Main Outcome Measures: The number of days at work in 3 months after treatment, self-efficacy, lifting capacity, pain, mobility, strength, and global perceived effect. Effect sizes (ESs) (Cohen *d*) were defined as small (ES range, 0.2–0.5), moderate (ES range, 0.5–0.8), and large (ES, >0.8).

Results: Groups were comparable at baseline. Moderate ESs for the FCT group versus PCT group were found for days at work (25.9d vs 15.8d, ES=.36, *P*=.029), self-efficacy (5.9 points vs –7.4 points, ES=.55, *P*=.003), and lifting capacity (2.3kg vs 0.2kg, ES=.54, *P*=.004).

Conclusions: Function-centered rehabilitation increases the number of work days, self-efficacy, and lifting capacity in patients with nonacute nonspecific LBP.

Key Words: Low back pain; Randomized controlled trial; Rehabilitation; Sick leave.

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CHRONIC LOW BACK PAIN (LBP) is a major health problem in Western Europe and North America. The total expenses of the Swiss Disability Insurance fund increased from SFr 4 billion (US $3.4 billion) in 1990 to SFr 10 billion (US $8.50 billion) in 2002. Compared with 10 other European Organization for Economic Cooperation and Development countries, Switzerland showed the highest rate of increase.[1] Musculoskeletal disorders, including LBP, were the primary diagnosis in 31% of all patients receiving disability pensions. Among musculoskeletal disorders, nonspecific disorders showed the largest increase, at 7.9%.[2] LBP is nonspecific in 85% of all patients.[3] Psychosocial factors reduce the success of purely medical treatment and thus have led to the development of multidisciplinary approaches.[4]

Meta-analyses show strong evidence that exercise[5,6] and multidisciplinary rehabilitation[7] reduce disability and pain in patients with nonacute LBP. Work absenteeism is reduced by exercise, in comparison with usual care.[8] Several investigators[6,9,10] found no evidence that favored 1 particular type of exercise over other types.

Exercise therapy in patients with LBP still relies on a biomedical model of disease that is focused mainly on somatic issues. Diagnosis of the underlying pathologic condition provides the basis for rational physical treatment of the illness. Pain intensity is used to determine the intensity of the exercises and leads to restrictive recommendations regarding activity and work.[11] This approach seems to increase behaviors such as taking pain-killers, seeking health care, stopping work, limping, guarding, and talking about pain.[12]

The biopsychosocial model, applied with patients with nonspecific LBP and other musculoskeletal disorders, emphasizes the role of psychologic factors such as personal beliefs, illness behavior, and fear avoidance, as well as social factors such as family, work, and the wider social network in the development and maintenance of symptoms.[4] Based on this model, work hardening[13] and functional restoration programs[14] were developed with the intent to overcome dysfunctional illness behavior and implement ergonomic and social interventions to facilitate return to work.

So far, it appears that the key to success in the treatment of nonspecific nonacute LBP is physical activity in any form, rather than through any specific activity.[9] It remains unclear whether applying the biopsychosocial model that primarily emphasizes activity is more effective in reducing work absenteeism than intensive treatment based on the biomedical model with its restrictive recommendations.

Our purpose in this study of patients with sick leave resulting from nonspecific nonacute LBP was to evaluate the effect of 3

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weeks of function-centered rehabilitation compared with pain-centered inpatient rehabilitation on the number of days at work in the first 3 months of follow-up. Secondary outcomes were self-efficacy, lifting capacity, pain, mobility, strength, and patient satisfaction.

METHODS

Design and Setting

We conducted a randomized controlled trial (RCT) to compare the effect of a function-centered treatment (FCT) versus a pain-centered treatment (PCT) in patients with nonacute nonspecific LBP. Patients were treated by 2 independent multidisciplinary teams in a rehabilitation center specializing in work rehabilitation in Valens, Switzerland. The primary outcome was the number of days at work after discharge. Secondary outcomes were the number of patients at work after 3 months, self-efficacy, lifting capacity, patient satisfaction, pain, and mobility. Included were patients seen between January 2000 and May 2003. Based on a power analysis before the study, we estimated that 90 patients were needed in each group to detect a difference of 10 days at work during the first 3 months of follow-up, with 80% power and α equal to .05. The study was approved by the ethics committee of the Canton of St Gallen. The objectives and the primary and secondary outcomes of the study, described in the outcome measurements section, were reported in an earlier publication.[15] Publication before a study is begun helps prevent post hoc changes in the reporting of the primary outcome, as well as publication bias.

Inclusion Criteria and Randomization

Patients were eligible for the study if they were between 20 and 55 years of age, had nonacute nonspecific LBP, and were referred to our center for inpatient rehabilitation. Not eligible were patients with specific LBP from nerve root compression, vertebral fracture, tumor, infection, inflammatory diseases, spondylolisthesis, spinal stenosis, and definite instability.[16] Two rheumatologists (SB, OK) determined the eligibility of patients.

Inclusion criteria were checked by 2 researchers (JPK, PRO). Patients were included if they had had at least 6 weeks of sick leave in the previous 6 months and were either employed or unemployed and looking for a job. Patients with cardiovascular, pulmonary, or psychiatric disease or some other comorbidity that would reduce working capacity were excluded. Based on the results of an earlier study, we used 4 predictive tests for nonreturn to work; patients with 2 or more positive predictive tests were excluded.[15,17] These tests were (1) preliminary cessation of a 3-minute step test, (2) preliminary cessation of the triceps-brachii pseudo strength test, (3) a positive Waddell signs result,[18] and (4) a momentary pain intensity of 9 or 10 on a numeric rating scale (NRS) rated from 0 to 10. All patients who met the inclusion criteria were told that 2 generally accepted treatments were currently used in the rehabilitation center, and that this study would evaluate whether 1 of the 2 treatments was more effective in reducing LBP-related disability. Patients were accepted if they understood German or Italian well enough to follow instructions during the physical assessment. Patients were excluded if they were unable to read the information about the study and the informed consent form, which was available in German, Italian, Serbo-Croatian, Albanian, Turkish, French, Spanish, and Portuguese. Patients who gave their written informed consent were divided into strata based on 2 predictive factors identified in a previous cohort study.[17] The 4 strata were defined by work status (unemployed, employed) and workload (1–2 or 3–5) according to the definition of the US Department of Labor: 1, sitting; 2, maximum load lifted 5 to 10kg; 3, maximum load lifted 10 to 25kg; 4, maximum load lifted 25 to 45kg; and 5, maximum load lifted greater than 45kg.[19] An independent and blinded research assistant performed concealed randomization within these 4 strata using a randomization schedule with blocks of 2 generated on a computer by an independent researcher.

Treatment

All patients were treated 6 days a week, and the length of stay (LOS) considered necessary was 3 weeks. Independent teams of therapists were responsible for the 2 different treatments. In both groups, a rheumatologist prescribed medications such as analgesics and nonsteroidal anti-inflammatory drugs and might also have applied local infiltrations. The physician of the rehabilitation center determined the working capacity after rehabilitation for all patients. Treatment after rehabilitation was at the discretion of the patient's primary physician. Table 1 lists important differences between the 2 treatments.

Function-Centered Treatment

All patients were treated by a rheumatologist, a physical and occupational therapist trained in ergonomics, a sports therapist, a social worker, and a nurse. If required, a psychologist offered counseling. The FCT was based on work hardening and functional restoration programs. The primary goal of the FCT group during its 4 hours of treatment a day was to increase work-related capacity. Treatment emphasized improving self-efficacy, defined as the patients' confidence in their ability to carry out normal activities of daily living (ADLs). The rheumatologist informed patients about the results of the imaging and other diagnostic procedures and about the benign character of nonspecific LBP. Patients were told that degenerative changes, if diagnosed, were within the normal range (eg, not causing pain in the majority of people). The therapist performed a work-related assessment that included a job profile describing the physical demands and an evaluation of job-relevant physical activities such as lifting and carrying loads, working in a bent position, or performing overhead activities. Treatment activities were chosen based on a patient's required capacities, as identified in the work-related assessment. Treatment consisted of work simulation, strength and endurance training through isokinetic exercise, cardiovascular training performed by walking and aqua-aerobics, sports therapy, and self-exercise. Patients were told that increasing activity might cause more pain because the body had to adjust to the activity again. All team members emphasized that patients should continue therapeutic activities even if their pain increased. The treatment protocol did not contain massage, hot packs, and other passive treatments because we did not believe that they facilitate an increase in activity and self-efficacy, nor has the research literature shown them to be effective.

Pain-Centered Treatment

All patients were treated by a rheumatologist, a physical therapist, and a nurse. If required, a psychologist or a social worker was consulted. The primary goal in the PCT group was to reduce pain. The secondary goal was to increase strength and decrease disability. The physical therapist examined the patients to identify painful movements and limitations in mobility, strength, and muscle length in the lumbar region and lower extremities. Treatment was for 2.5 hours a day and consisted of individually selected passive and active mobilization, stretch-

Table 1: Differences in Patient Information According to the Treatment Protocol Used in the 2 Groups

Treatment Information	FCT	PCT
Goals	Increase work-related capacity. Improve self-efficacy. Return to work.	Pain reduction. Strength and mobility training. Return to work.
Role of the treating team members	Coach patients. Determine goals with patients. Primary focus on improvement of function.	Treat patients to reduce pain, mobilize joints, and enhance relaxation. Increase pain-free movement.
Explanation of complaints	Loss of function contributes to pain. LBP-related complaints are nonspecific: there are no abnormal changes in the lumbar spine constituting a contraindication for work-related training.	LBP is explained by somatic findings such as disk degeneration, joint stiffness, and trigger points diagnosed in the clinical, imaging, and other examinations.
Treatment	Work simulation, strength, and endurance training, cardiovascular training.	Massage, relaxation, hot packs, and electrotherapy. Passive and active mobilization.
Advice if pain increases during activity or treatment	Pain is not an alarm sign for potential damage. Try to increase function even if pain increases.	Reduce intensity of exercise if pain increases. Avoid activities that increase pain. Use modalities and relaxation if pain increases.

ing, strength training, and a mini back school. Unlike with the FCT group, patients in the PCT group were told to stop activities when pain increased. Passive pain modulating treatments such as hot packs, electrotherapy, or massage were used daily. Low-intensity movement therapy in the pool and progressive muscle relaxation further enhanced relaxation. Progressive muscle relaxation used systematic contraction and relaxation of specific muscle groups. Patients were encouraged to incorporate relaxation techniques into daily living as a coping skill to reduce stress, muscle tension, and pain.[20,21]

Outcome Measurements

Days at work and other work-related outcomes were assessed with a questionnaire sent to employers and the patients' primary physicians, who were blinded to the patients' group assignments. Nonresponders received a reminder and, if necessary, a phone call from the blinded research assistant. A blinded research assistant (MR) recorded the work-related predictive factors and performed the physical measurements before and after rehabilitation. The research assistant was not involved in any patient treatment in the rehabilitation center. Assessments were performed in a separate room to prevent unmasking of the assessor. Patient questionnaires were used to assess self-efficacy, satisfaction with treatment, and pain.

We evaluated adherence to the treatment protocol because protocol deviations are a potential cause of insignificant results. The amount of treatment received was evaluated by recording the LOS and attendance at scheduled appointments. Therapists' and physicians' adherence to the treatment protocol for the 2 different concepts was assessed. Tape recordings of the verbal information given to patients were made on 25 consecutive occasions. Seven experts, who were blinded to the treatment, independently rated the information given to the patients. In addition to an overall rating, separate ratings were given for the formulated goals, information about the treatment plan, explanation of the source of the complaints, and advice about coping with pain. A score of more than 7.5 on a visual analog scale from 0 (not at all according to the treatment protocol) to 10 (perfectly according to the treatment protocol) was considered adequate adherence to the protocol.

Patients could not be blinded to treatment but every effort was taken to keep patients unaware of any expected advantage in effectiveness, a condition that is sometimes called naive. We recorded on a 7-point Likert scale overall satisfaction with treatment, satisfaction with the advice received, knowledge about the complaints, and the perceived possibilities to have an influence on the complaints. If the scores for satisfaction with treatment in the 2 groups were comparable, we considered the efforts to keep patients unaware or naive to have been successful.

Primary Outcome

The number of days at work was the primary outcome. Each calendar day within a period at work was counted, leading to a maximum of 90 days at work during the 3-month follow-up period. This method is insensitive to the fact that patients work on different days of the week. Because Switzerland does not have a central database that tracks sick leave, we assessed days at work with questionnaires sent to employers and primary physicians after 3 months. Inconsistencies were resolved through additional phone calls to the people involved. We also computed the proportion of patients at work after 3 months, an outcome that has been used in several other studies.[8]

Secondary Outcomes

Self-efficacy, defined as the patients' confidence in their ability to carry out normal ADLs, was assessed before and after treatment with the Performance Assessment and Capacity Testing (PACT) instrument.[22,23] The PACT consists of 50 daily activities done in varying sitting and standing postures. The activities are illustrated to reduce language-related difficulties. Patients are instructed to rate the degree of difficulty in performing these activities on a 5-point scale (1, unrestricted ability to perform the activity; 2, slightly limited; 3, moderately limited; 4, severely limited; 5, unable to perform the activity). The PACT includes a consistency check that indicates whether the patient understands the instructions. For patients who did not answer the questions consistently, the research assistant repeated the instructions.

Before and after rehabilitation, the maximum lifting capacity within security limits was assessed from floor to waist, from waist to crown, and horizontally at waist level. The research assistant was trained and experienced in this method and its reliability has been confirmed.[24-26]

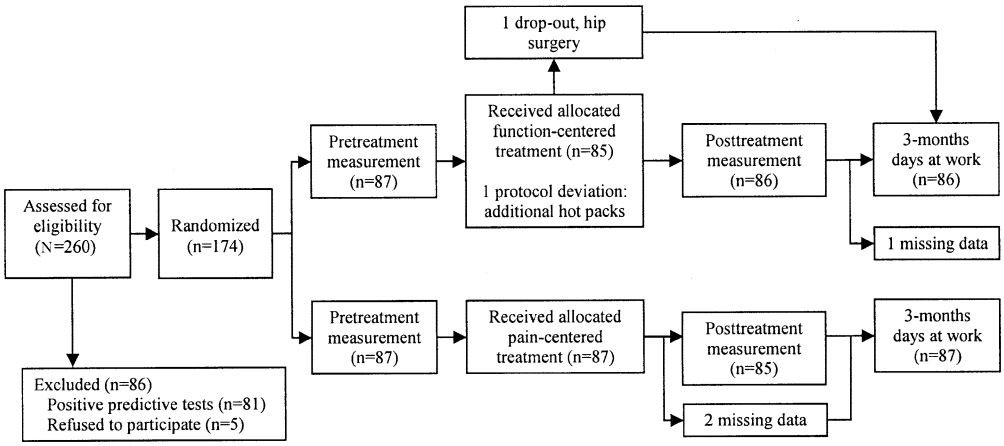

Fig 1. Flow chart of patients in the study.

The perceived effect was assessed after treatment and after 3 months with a questionnaire that encompassed physical capacity, general well-being, and overall improvement. We used a 7-point Likert scale.[27]

Momentary, maximal, and minimal pain in the last week was rated on an 11-point NRS ranging from 0 (no pain) to 10 (the worst pain I can imagine).[28] Pain measurements were taken before and after treatment and after 3 months.

Before and after treatment, the following physical measurements were performed. The finger-to-floor distance was used as a measure of active spinal and hip mobility in flexion.[29] Spinal mobility in extension was measured in degrees with an inclinometer.[30] Muscle performance was assessed by recording the maximum duration of isometric hip and trunk extension and flexion against gravity.[31,32]

Predictive Factors

Before treatment, we used a questionnaire to assess work satisfaction, using a 7-point Likert scale ranging from very satisfied to very unsatisfied.

Analysis

Analysis was performed by intention-to-treat. Between-group comparisons at baseline, after treatment, and at 3 months follow-up were performed with chi-square tests for categorical variables. Independent samples *t* tests were applied in continuous variables with a normal distribution and a Mann-Whitney *U* test was used with nonparametric continuous variables. We used the general linear method in repeated measurements of continuous variables and performed a subgroup analysis of days at work stratified for sex, nationality, age, workload, and unemployment, using univariate analysis of variance and Bonferroni adjustment for multiple post hoc comparisons.

Effect sizes (ESs) were computed for all outcomes. In continuous variables with a normal distribution, the Cohen *d* was computed by dividing the mean difference in change between the 2 groups by the standard deviation (SD) of the change in the control group. If results were analyzed with the general linear method, we derived the ES from η^2.[33] Positive values of ESs display desirable effects. ESs of .20 were considered small, .50 were regarded as moderate, and .80 were regarded as large.[34] Statistical analysis was performed with SPSS, version 11.5.[a] Alpha was set at .05.

RESULTS

Between January 1, 2000 and May 1, 2003, 260 eligible patients were referred to the rehabilitation center, and 174 participated in the study (fig 1). During the treatment phase, 1 patient in the FCT group dropped out because he was diagnosed with necrosis of the head of the femur and underwent surgery. The measurements after treatment were missed for 2 patients in the PCT group because of reductions in the LOS of 1 and 4 days that were not noticed by the research assistant.

The number of days at work was obtained for 99% of the patients. No data were available for 1 patient in the FCT group. The return rate of the 3-month follow-up questionnaires was 93% in patients, 84% in employers, and 82% in primary physicians. There was no difference in the return rates of the 2 treatment groups.

Table 2: Comparability of the Treatment Groups at Baseline

Variables	FCT Group (n=87)	PCT Group (n=87)
Age (y)	41.6±8.4	42.5±8.4
Sex (men/women)	69/18	68/19
Body mass index (kg/m^2)	26.7±4.2	27.2±4.0
Nationality		
Switzerland	38	35
Italy	17	11
Yugoslavia	11	16
Bosnia	5	6
Macedonia	5	5
Croatia	4	5
Spain, Portugal, Turkey	7	9
Unemployed	18 (21)	20 (23)
Heavy work: workload >25kg	68 (78)	68 (78)
No professional education	38 (44)	42 (48)
Days of sick leave during 2y before treatment	184±156	199±135
Self-efficacy (PACT)	110±39	102±42
Lifting capacity (kg)		
Floor-waist	15.8±5.4	15.6±7.3
Horizontal	20.4±7.6	18.9±7.8
Waist-shoulders	13.2±4.3	13.0±4.8
Pain (NRS range, 0–10)	5.5±2.0	5.7±2.2
Muscle performance (s)		
Extension hip/trunk	30.4±32.3	25.9±25.9
Flexion trunk	30.4±28.5	25.5±22.8
Finger-to-floor distance (cm)	22.8±13.5	26.7±15.1
Lumbar extension (deg)	12.1±7.6	10.6±6.5

NOTE. Values are mean ± SD, n, or n (%).

Table 3: Outcome After Treatment and 3 Months

Variables	FCT	n	PCT	n	ES	*P*
Days at work*	25.9±32.2	86	15.8±27.5	87	.36	.029†
Self-efficacy change‡ (PACT)	5.9±32.5	86	−7.4±4.4	85	.55	.003§
Lifting capacity change‡ (kg)						
Floor-waist	2.3±5.4	86	0.2±3.9	85	.54	.004§
Horizontal	1.7±5.9	86	−0.2±6.0	85	.32	.049§
Waist-shoulders	1.3±3.2	86	−0.2±3.7	85	.41	.006§
Perceived effect‡						
Physical capacity	4.1±2.1	86	2.9±1.7	85	.71	<.001
General well-being	4.0±2.1	86	3.1±1.9	85	.47	.005
Overall improvement	4.4±2.0	86	3.6±2.0	85	.40	.009
Pain change‡ (NRS range, 0–10)						
Post	−0.25±2.1	86	0.55±1.9	85	.42	.023§
3mo	0.35±2.1	86	0.89±1.9	85	.28	.094§
Muscle performance change‡ (s)						
Extension hip/trunk	8.6±26.2	86	2.5±24.9	85	.24	.121§
Flexion trunk	0.7±21.6	86	−1.9±18.4	85	.14	.398§
Finger-to-floor distance change‡ (cm)	−2.9±7.7	86	0.0±8.3	85	.44	.018§
Lumbar extension change‡ (deg)	−1.0±6.3	86	0.4±7.0	85	−.20	.166§

NOTE. Values are mean ± SD.
*Measurement after 3 months.
†Mann-Whitney *U* test.
‡Measurement after treatment.
§Mixed between-within subjects analysis of variance.

Baseline Comparability

Table 2 displays the baseline comparability of the 2 groups for the most important prognostic and outcome variables. There were no significant differences between the groups after randomization. Two patients in each group received a 50% disability allowance. There were 16 patients with litigation problems in the FCT group and 9 in the PCT group. Work satisfaction was slightly better in the FCT group (1.8±2.1 vs 2.4±2.9, $P=.134$).

Adherence to the Protocol

LOS was comparable in both groups, with 22.2±3.7 days in the FCT group and 22.3±3.8 days in the PCT group. All patients attended at least 90% of the scheduled treatments. One patient in the FCT group was not treated according to the protocol because she insisted on having hot packs and massage for pain relief.

Overall satisfaction with treatment, satisfaction with advice received, knowledge about the complaints, and the perceived possibilities of having an influence on the complaints were the same in the 2 groups, indicating that the effort to keep patients unaware of any expected treatment advantage was successful.

The expert ratings of the adherence to the 2 different treatment concepts were greater than 7.5. The average overall score for therapists and physicians was 8.8 in the FCT group and 8.9 in the PCT group.

Outcome Measurement

Table 3 shows the main results. There was a small to moderate ES favoring the FCT group for the primary and most of the secondary outcomes. More patients were at work in the FCT group than in the PCT group (47% vs 27%, ES=.15, $P=.037$), and the unemployment rate was slightly smaller in the FCT group (19% vs 24%, ES=.05, $P=.637$).

Subgroup comparisons for the number of days at work showed a significant negative effect of unemployment on work absenteeism without an interaction between unemployment and group. No effect was found for sex, age, workload, and nationality (Bonferroni adjustment, $\alpha=.01$).

Regarding the secondary outcomes after treatment, the FCT group had improved significantly more in self-efficacy, in all 3 tests for lifting capacity, and for the perceived effect. The moderate ESs for the perceived effect after rehabilitation were not maintained during the 3-month follow-up period. Pain intensity was significantly lower in the FCT group after treatment. During the 3-month follow-up, pain increased in both groups, but the difference in favor of the FCT group remained. No difference was found in back and hip extensor strength, trunk flexor strength, and spinal mobility.

Because the size of the study sample was considered sufficient to detect clinically relevant differences in the outcomes used, we did not perform a power analysis of nonsignificant results.

DISCUSSION

This is the first RCT in Switzerland to evaluate work-related rehabilitation in patients with LBP. Work absence was significantly reduced, and more patients had returned to work after 3 months. The ESs were small for work absence (.36), moderate for self-efficacy (.55), and small to moderate for lifting capacity (.32–.54), and pain intensity (.42). The PCT group did not achieve the goal of pain reduction. Pain intensity increased in this group and decreased in the FCT group. At the onset of the study, physicians and therapists criticized the FCT because they feared that encouraging the patients to move regardless of pain would lead to an increase in pain intensity. The pain reduction experienced by the FCT group supports the hypothesis that fear of pain may be more disabling than pain itself.[35]

Compared with other studies, our results are remarkable because 2 experimental treatments were compared, resulting in a relatively small treatment contrast. In a recent review,[8] only 1 of 9 comparisons between 2 experimental treatments showed a significant effect. The ES for work absence in this study is similar to the ES in 5 studies that compared intensive treatment

with usual care.[36-40] Usual care essentially consisted of treatment by a general practitioner who gave advice and prescribed medications.

The treatment duration in the FCT group in this study was 70 hours. Authors of a recent review[41] reported that only treatments with a duration of at least 100 hours were effective. That review, however, was limited to multidisciplinary rehabilitation. Other treatments using exercise or activity, with duration of 20 to 40 hours, have also been effective.[37,39,42] Previous studies in Switzerland either did not randomize patients[43] or lacked a control group.[15]

Excluding patients who will not benefit from treatment is essential to increasing the statistical power and efficiency of an RCT. Our positive results and the high follow-up rate were in part the result of excluding patients with positive predictive tests for nonreturn to work, as identified in a previous study.[17] In an attempt to evaluate whether exclusion was justified, we evaluated work absence by sending questionnaires and reminders to the first 40 excluded patients, who had also attended 3 weeks of rehabilitation. The nonresponse rate in this group was 30%, and only 1 patient had returned to work, which confirms the value of the predictive tests.

An important question is which treatment elements may have been essential to the effectiveness of the FCT. The program consisted of 4 hours of activity, 6 days a week, for 3 weeks. The FCT primarily focused on reducing work absence by improving work-related capacity and self-efficacy. Patients were encouraged to move even if their pain increased. One big challenge for the team members was to give consistent information. Patients were repeatedly assured that the spine was not seriously damaged and would benefit from intensive training. Work-related activities were used to improve functional capacity. Lifting capacity improved and pain intensity decreased in the FCT group despite the higher level of activity. However, it is questionable whether the moderate improvement in lifting capacity explains the increased number of work days, or whether self-efficacy is more important.

It would be helpful to identify the relative contributions of the different elements of the multidisciplinary rehabilitation to the treatment effect. As others have stated,[7] the answer to this question remains unknown.

In the health care systems of many countries, a 3-week inpatient intervention is not available. Some countries offer intensive outpatient programs that make it possible for patients to gradually resume work while receiving treatment. PCT may be considered unethical because it is not in accordance with current guidelines. The PCT applied light to moderate exercises and modalities were used to support treatment. The essential characteristic of the PCT was that pain reduction and the avoidance of pain was the primary goal. Despite the guidelines, PCTs are still more frequently used than FCTs.[11]

Blinding of patients is not possible for the type of treatments we evaluated. The excellent adherence to the treatment protocol and the comparable satisfaction with treatment in both groups indicate that we succeeded in keeping patients naive with regard to any expected treatment advantage.

Although the number of work days was increased significantly in the FCT group, the problem of LBP-related work absence and disability is obviously not solved. Considering the remaining amount of work absence, the effect of the FCT was small and disappointing. The investigated group, however, was characterized by histories of long-standing sick leave, heavy work, and low education, resulting in a limited possibility of reducing work demands. Return to work was additionally limited because less demanding jobs are scarce in the employment market. Only 2 patients found new jobs.

Measurement of the number of days at work was essential in this study. Its internal validity was increased by the nearly complete follow-up data for days at work. The reliability of work days' measurement was increased by sending questionnaires to both the primary physicians and the employers, who were blinded to the treatment group. Several previous studies obtained sick day totals from a national database for sick leave compensation. There is no such database in Switzerland. The questionnaires we used may introduce more random measurement error, but the advantage of our method is that the initial days of each period of sick leave are also covered, which increases the reliability of the ES estimate. Databases used in other studies did not cover the first 7[37] or 16 days[44,45] of each work absence. Many studies that reported sick days did not describe how work absence due to unemployment and work absence in patients receiving a full disability allowance were analyzed. To avoid the problem of these different types of work absence, we used days at work as the primary outcome.

Knowledge of the Swiss national languages was limited in more than 50% of the patients participating in our work rehabilitation program. Treatment was developed to be applicable to these patients. The key element of the FCT was activity offered as isokinetic and work-related training, walking, and sports therapy. This treatment did not require proficient verbal communication and could be applied to this group of patients, thus increasing the study's external validity.

The external validity of this study is further supported by the patient population, representative of patients in Switzerland with LBP who are at risk of permanently losing working capacity, becoming unemployed, or becoming dependent on a disability allowance. The majority of the patients were accustomed to heavy work, were born in other countries, were poorly educated, and had insufficient personal resources—particularly insufficient knowledge of the Swiss national languages. All of these factors made it difficult for them to participate successfully in vocational measures. Other studies[37,39,46,47] included only patients with proficient knowledge of the national language, which gave them a better perspective to participate in vocational measures and to find lighter work. Assessments in this study had to be either available in all required languages or be independent of language. The PACT self-efficacy assessment does not require proficient knowledge of language because it uses pictures of physical activities.

The cost effectiveness of the FCT needs further analysis. The average cost of 1 day of work absence is estimated to be €155 (US $213).[48] The savings during the first 3 months are €1550 (US $2130) per person and €135,000 (US $18,600) for the total FCT group. The costs of rehabilitation paid by health insurance are €220 (US $303) per day or €4900 (US $6749) per patient in the FCT and PCT groups. The 10 work-days benefit for the FCT group is considered relevant. For definitive conclusions, we plan a detailed analysis of cost effectiveness, including medical treatment in the first follow-up year and disability pensions. If the benefit for work absence in the FCT group is maintained until the 1-year follow-up, the experimental treatment may be cost effective.

The results of this single-center study should be confirmed in other centers for work rehabilitation.

CONCLUSIONS

Function-centered rehabilitation decreases work-related disability. Our ESs were small to moderate. The number of days at work during the 3 months of follow-up was 10 days higher in the FCT group, and the number of patients who returned to work was significantly larger. Self-efficacy, lifting capacity,

and pain intensity improved significantly in the FCT group. A subgroup analysis showed a significant negative effect of unemployment without an interaction between unemployment and group. The number of days at work did not depend on sex, age, workload, or nationality. FCT should be used in place of the still widely used PCT.

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