

## RANDOMIZED TRIAL

# Multidisciplinary Intensive Functional Restoration Versus Outpatient Active Physiotherapy in Chronic Low Back Pain

## A Randomized Controlled Trial

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**Study Design.** Randomized parallel group comparative trial with a 1-year follow-up period.

**Objective.** To compare in a population of patients with chronic low back pain, the effectiveness of a functional restoration program (FRP), including intensive physical training and a multidisciplinary approach, with an outpatient active physiotherapy program at 1-year follow-up.

**Summary of Background Data.** Controlled studies conducted in the United States and in Northern Europe showed a benefit of FRPs, especially on return to work. Randomized studies have compared these programs with standard care. A previously reported study presented the effectiveness at 6 months of both functional restoration and active physiotherapy, with a significantly greater reduction of sick-leave days for functional restoration.

**Methods.** A total of 132 patients with low back pain were randomized to either FRP (68 patients) or active individual therapy (64 patients). One patient did not complete the FRP; 19 patients were lost to follow-up (4 in the FRP group and 15 in the active individual treatment group). The number of sick-leave days in 2 years before the program was similar in both groups ( $180 \pm 135.1$  days in active individual treatment vs.  $185 \pm 149.8$  days in FRP,  $P = 0.847$ ).

**Results.** In both groups, at 1-year follow-up, intensity of pain, flexibility, trunk muscle endurance, Dallas daily activities and work and leisure scores, and number of sick-leave days were significantly

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improved compared with baseline. The number of sick-leave days was significantly lower in the FRP group.

**Conclusion.** Both programs are efficient in reducing disability and sick-leave days. The FRP is significantly more effective in reducing sick-leave days. Further analysis is required to determine if this outweighs the difference in costs of both programs.

**Key words:** controlled randomized trial, functional restoration, low back pain, occupational therapy, physical therapy. **Spine 2011;36:2235–2242**

Management of chronic low back pain (LBP) remains a challenge in most industrial countries despite a considerable body of literature.<sup>1,2</sup> The interest of health care providers and researchers is in part due to the fact that chronic LBP, although in itself a common and benign disease, has, in 10% to 25% of the patients, a considerable impact on work ability. Because indirect health costs mainly due to sick-leave payments of these work-disabled patients account for most of the overall costs of LBP, the main outcome criterion of many studies is either return to work or the number of sick-leave days.<sup>3</sup> This would at best require long-term studies because LBP is known to be a lifelong disease with frequent relapses but few studies report longer than 1-year follow-up.<sup>4</sup>

One of the streams of research in this area has focused on the bio-psycho-social model of LBP and has aimed at designing programs that would combine interventions addressing physical deconditioning, pain-coping mechanisms, and workplace and health system barriers.<sup>5</sup> These programs have been developed in a number of different health care and worker compensation policy environments.<sup>6–14</sup> These studies have in general shown an effect on either return to work or reduction of the number of sick-leave days. These programs usually include flexibility strength and endurance training,<sup>15,16</sup> various behavioral interventions,<sup>14,17,18</sup> and sometimes workplace intervention and participatory ergonomics.<sup>5,19–22</sup>

Multidisciplinary interventions based on this bio-psycho-social model remain in most countries limited to secondary

health care facilities, frequently in a rehabilitation medicine environment, and treat a limited number of selected patients.

In parallel with the development of such programs, a significant shift has been observed in the recommendations for primary-care treatment of both acute and chronic LBP. Present European and American<sup>23,24</sup> recommendations include limiting, as much as possible, rest at the acute period and state that physical treatment, if performed, should focus on active exercises rather than on passive techniques such as massage and heat applications. These recommendations are based on evidence showing that activity does not result in increasing pain and that fear of movement is high in both patients and physicians,<sup>25-27</sup> which may lead some patients into a circle in which pain induces reduction of activity that induces physical deconditioning, reducing still more activity. There are presently limited data on the real-life implementation of these recommendations.<sup>28,29</sup>

A number of controlled trials have compared different types of interventions.<sup>14,17,30-34</sup> A recent review<sup>35</sup> summarizes the results of the available controlled trials evaluating the effectiveness of exercise on work disability and concludes that although exercise interventions do have a significant effect on work disability, no recommendations can be made as to the type of exercises that should be recommended. Other trials compare integrated-care models to standard care.<sup>35-37</sup> Most of these studies conclude that integrated or multidisciplinary care leads to better work ability outcome, but they include often limited data on the content of "standard care" and specially on whether the physical treatment provided in standard-care setting is or is not in line with present recommendations.

In our country, "standard care" for chronic LBP patients most often includes physical treatment, which is usually applied by independent private-practice physiotherapists. The exact content of the physiotherapy sessions varies a lot and there are limited data as to the effective implementation of recommendations for active exercises. Therefore, comparison of specific programs, implemented within rehabilitation facilities, by rehabilitation researchers, with "standard care" is at high risk of overestimating the effect of multidisciplinary care or intensive treatment and measuring, in fact, the superiority of exercise treatment *versus* passive techniques.

Thus, we designed a controlled randomized study that aimed at comparing the reduction in sick-leave duration achieved by a multidisciplinary program (FRP), based on the bio-psychosocial model, with what could be considered as evidence-based physical treatment in a primary-care environment<sup>23</sup> (active individual treatment, [AIT]).

Results at the end of the program and preliminary results at 6-month follow-up have been previously published.<sup>9,38</sup> End-of-program outcomes showed that physical outcome measures such as flexibility, strength, endurance, pain, and disability measures were improved in both programs, with significantly better results in the multidisciplinary intensive program. Preliminary results at 6 months showed that the number of sick leaves was significantly lower in the multidisciplinary intensive program. The objective of the present study is to report the outcomes of both programs at 1 year.

## MATERIALS AND METHODS

### Population

Patients were eligible for inclusion if they were referred to a multidisciplinary LBP clinic, in a level 1 hospital, between January 2000 and April 2003. They were evaluated consecutively and independently in this multidisciplinary clinic, by a physical medicine and rehabilitation specialist, an occupational medicine specialist, a psychologist, and an ergonomist. They were assessed on their medical and employment histories and had a standardized medical examination. The purpose of the study was explained. This study was approved by the local ethics committee.

The inclusion criteria were nonspecific chronic LBP for at least 3 months, age 18 to 50 years, on sick leave or at risk of work disability, presently engaged in a nonlimited work contract, and having given informed consent.

Exclusion criteria were LBP of specific origin (malignant, traumatic, infectious, or inflammatory LBP, acute sciatica, spondylolisthesis), recent spinal surgery (<4 months), cardiac or respiratory insufficiency (detected by stress tests), neurologic impairment, a psychiatric disorder precluding group therapy, and receiving disability pensions. A total of 132 patients (46 women and 86 men) were included and were randomized to either the AIT group (64 patients) or the FRP group (68 patients).

### Design

The study was designed as a prospective open clinical trial. Patients were randomized by an independent methodologist to one of the 2 rehabilitation programs, according to an eight-element permutation table. Patients were evaluated at baseline and after treatment by a physiotherapist who was not blinded but had not been involved in the treatment of the patient. Specific training for the testing procedure was provided.

### Interventions

Patients remained off work during the 5 weeks of treatment. No other cointerventions or treatments were allowed, except their medication prescribed at baseline.

The FRP was performed 6 hours a day, 5 days a week, during 5 weeks, in 2 rehabilitation centers. Patients were treated in groups of 6 to 8. Isotonic techniques were used for muscle strengthening, with resistance being increased weekly according to the individual patient's progress. Endurance training consisted of stepping, jogging, and cycling exercises. Occupational therapists supervised weightlifting activities and work-simulation workshops. At the end of the day, balneotherapy provided relaxation and proprioception exercises. Patients met with the physiatrist, who was the medical supervisor of the program every week and attended the weekly staff meeting. Frequent opportunities for informal meetings between the patients were provided, especially during meal times. An appointment with the psychologist was scheduled during week 1 and more often if required. Dietetic advice was provided in group session 3 times during the program. A contact was

made with the occupational physician and ergonomic advice on the workplace was provided.

The AIT was composed exclusively of ambulatory physiotherapy, 1 hour 3 times a week, during 5 weeks, and was provided by a private-practice physiotherapist, who had previously received information and training on this program. The program was in accordance with the international guidelines on rehabilitation for LBP patients and included only active and isotonic exercises. The first 2 weeks were focused on flexibility training and pain management. Strengthening exercises and functional training were then introduced. Patients were advised to perform home exercises for at least 50 minutes twice a week (these exercises could include stretching, jogging, and swimming).

### Data Collection and Outcome Measures

The number of sick-leave days in the year before treatment and after treatment was counted, and the reduction in the number of sick-leave days was the primary outcome measure. Days off-work for other reasons were not included in the count. The count relied on self-declaration by the worker and was checked by adding the number of days on the sick notes. The patients were also asked whether they worked full-time or part-time and whether their workstation had changed. Patients had a standardized assessment at the beginning (t0), at the end of the 5 weeks of treatment (t5), and at 12 months after treatment (t12).

Secondary outcome measures were trunk flexibility, assessed by the fingertip-to-floor distance in centimeters; and trunk muscle endurance, assessed by the Sorensen test (time of isometric contraction of extensor muscles, measured in seconds)<sup>39</sup> and the Ito test (time of isometric contraction of flexor muscles, in seconds).<sup>40</sup> Lifting capacity was evaluated by the Progressive Isoinertial Lifting Evaluation test (measured in kilograms).<sup>41</sup> The patient's level of pain during the last 24 hours was evaluated using a 10-cm visual analog scale. The Dallas Pain Questionnaire assessed the impact of pain on quality of life, with 4 items as follows scored from 0% to 100%: daily activities, work and leisure activities, anxiety and depression, and sociability. Patients were questioned on their subjective opinion: Had their physical fitness increased? Had they resumed sport and leisure activities? And did they feel able to return to work?

### Statistical Analysis

A preliminary study had shown that the standard deviation of the number of sick-leave days at the 1-year follow-up after FRP was 110.<sup>42</sup> With an estimation of 10% dropouts, a population of 54 patients in each group allowed detection of a difference of 60 days between the groups with a 95% probability ( $\alpha = 5\%$ ,  $\beta = 20\%$ ). Comparisons between groups were made by student *t* tests for quantitative data and by Pearson chi-square test for qualitative data. Evolution of the groups was assessed by paired *t* test for quantitative data and McNemar test for qualitative data. The level of significance was defined as 0.05. Analyses were performed with SPSS statistical software, version 11.5 (SPSS, Inc, Chicago, IL).

## RESULTS

Mean age was 39.8 years (range = 24–50 years). The basic characteristics of the 64 patients allocated to the AIT group and the 68 patients of the FRP group were evaluated. Pre-treatment characteristics have been previously described.<sup>9,38</sup> Baseline characteristics of both groups appear in Table 1. There was no significant difference between the 2 groups for any of the measures, except the fact that more patients had undergone spinal surgery in the FRP group (18.8% in AIT *vs.* 33.8% in FRP;  $P = 0.050$ ). A total of 51% patients were on sick leave before treatment. There was no difference between groups regarding the number of sick-leave days during the 2 years preceding treatment ( $180 \pm 135.1$  days in AIT *vs.*  $185 \pm 149.8$  days in FRP;  $P = 0.847$ ).

The patients' flow chart appears in Figure 1. One patient did not have the complete FRP because of a tibial fracture at home. At 1-year follow-up, 64 (94.1%) patients of the FRP group and 49 (76.5%) patients of the AIT group were evaluated.

### Analysis of the Lost to Follow-up Group

Nineteen (14.4%) patients were missing at 1-year follow-up, and they were more frequently included in AIT than in FRP (respectively, 15 of 64 patients *vs.* 4 of 68 patients;  $P = 0.006$ ). The lost to follow-up patients were more frequently on sick leave at inclusion (respectively, 48 of 133 patients *vs.* 15 of 19 patients;  $P = 0.005$ ) and their number of sick-leave days in the 2 years before treatment was more important (respectively,  $200.2 \pm 4.01$  days *vs.*  $179.3 \pm 137.7$  days;  $P = 0.001$ ).

At t5 (end of treatment), the endurance of trunk muscles was lower ( $132.6 \pm 52.2$  seconds *vs.*  $179.4 \pm 66.7$  seconds;  $P = 0.04$  for the Sorensen test and  $131.4 \pm 82.4$  seconds *vs.*  $173.5 \pm 73.3$  seconds;  $P = 0.02$  for the Ito test), and their Dallas scores were more important on daily activities ( $41.5 \pm 22.1\%$  *vs.*  $30.4 \pm 18.1\%$ ;  $P = 0.018$ ) and work and leisure activities ( $46.3 \pm 22.3\%$  *vs.*  $31.8 \pm 22.7\%$ ;  $P = 0.01$ ). All other criteria were not statistically different at t5.

### Effectiveness of the Interventions

Table 2 shows the difference between pretreatment and 1-year post-treatment values (t12–t0) for the different outcome measures. In both groups, the number of sick-leave days in the post-treatment year decreased significantly compared with the pretreatment year, with a higher reduction in FRP than in AIT ( $-101.2 \pm 126.5$  days *vs.*  $-79 \pm 143.9$  days;  $P < 0.001$ ). All physical and functional criteria were improved except for the Dallas anxiety and depression score and the Dallas sociability score in the AIT.

Outcome measures at 1 year in both groups are compared in Table 3. The number of sick-leave days during the year after treatment was more important in the AIT group ( $72.0 \pm 109.9$  days in AIT *vs.*  $37.3 \pm 67.8$  days in FRP;  $P = 0.042$ ), but there was no difference between groups on the number of patients who had returned to work. The rate of unemployment was not statistically different between groups (6.2% *vs.* 6.1%;  $P = 0.72$ ). There was no difference in physical outcome measures except for better results in FRP for trunk

**TABLE 1. Demographic and Clinical Characteristics at Baseline in a Randomized Clinical Trial Comparing Functional Restoration and Active Individual Therapy**

	Functional Restoration (n = 68)		Active Individual Therapy (n = 64)		P
	Mean or %	SD	Mean or %	SD	
Age (yr)	40.8	7.4	38.7	6.1	ns
Sex (% men)	67.6		62.5		ns
History of spinal surgery (%)	23.5		18.8		<0.05
No. of sick-leave days in the 2 yr before treatment	185	149	180	135	ns
Fingertip-to-floor distance (cm)	12.6	9.3	13.8	12.7	ns
Sorensen test (s)	97.7	50.7	84.8	53	ns
Ito test (s)	78.3	50.3	65.6	47.8	ns
Intensity of pain on visual analog scale (cm)	4.7	2.1	4.5	2.1	ns
Dallas daily activities (%)	51.8		51	23.3	ns
Dallas work and leisure (%)	51.9		58	27.7	ns
Dallas anxiety depression (%)	36.7		30.9	23.5	ns
Dallas social interaction (%)	30.7		27.4		ns

*Comparison of both groups at baseline using t test or chi-square test.*  
*ns indicates not significant.*

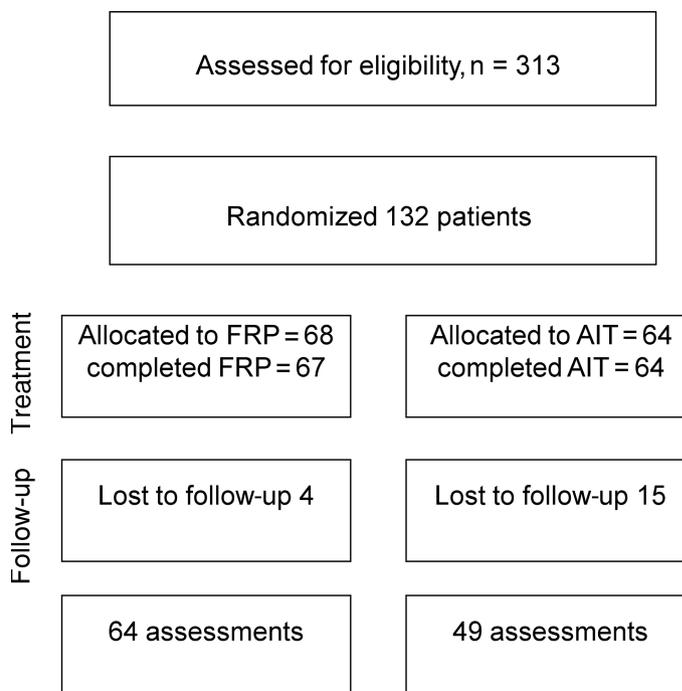
flexibility with the fingertip-to-floor distance. Dallas “work and leisure” and “sociability” subscores were significantly lower in the FRP group. More than 90% of patients felt able to work in both groups. More patients felt they had increased their physical fitness in the FRP group (84% *vs.* 66%; *P* = 0.02).

**DISCUSSION**

This study provides some information on the long-term results of both programs, and shows that in both cases, most of the outcome measures remain significantly improved at 1-year follow-up compared with baseline. This is the case for sick leaves, which account for a high proportion of the costs.

The main limitation of this study is the lost to follow-up rate. The outcome measures and specially the number of sick leaves were not available for these patients. Intention-to-treat analysis could not be performed. The absence of satisfactory prediction models of the outcome of LBP depending on baseline values makes assumptions as to the outcome of these patients difficult. The only strong assumption is that these patients, who were more disabled at baseline, would probably have had outcomes below the mean group value. The main outcome measure being the number of sick-leave days, carrying on the last value would not have reduced the bias. Thus the bias induced by these patients is probably an overestimation of the effect of the intervention in both groups. Because the number of these patients is also larger in the AIT group, this bias may be greater in this group and the between-group difference may have been underestimated. The overall lost to follow-up rate was 14%, which is lower than in most other studies.<sup>6,8</sup>

Better compliance to follow-up in the FRP group could be an effect of the multidisciplinary and intensive approach. Other authors have already shown that patients who do not complete the programs or are lost to follow-up tend to have longer sick leaves and specific psychological profiles.<sup>43</sup>



**Figure 1.** Patients’ flow chart throughout the study. AIT indicates active individual therapy; FRP, functional restoration program.

**TABLE 2. Evolution Between t0 and t12 (Difference t12 Value–t0 Value)**

	Functional Restoration				Active Individual Therapy			
	n	Mean or %	SD	P	n	Mean or %	SD	P
Reduction in the number of sick-leave days (posttreatment year–pretreatment year)	64	–101.2	126.5	<0.001	49	–79	143.9	<0.001
Fingertip-to-floor distance (cm)	64	–12.8	8.7	<0.001	49	–10.9	13.5	<0.001
Sorensen test (s)	63	+56.9	79.6	<0.001	48	+45.2	50.3	<0.001
Ito test (s)	63	+75.6	71.7	<0.001	48	+60.2	64.1	<0.001
Progressive Isoinertial Lifting Evaluation	56	+7.3	7.9	<0.001	41	+6	9.7	<0.001
Intensity of pain on visual analog scale (cm)	64	–1.7	2.6	<0.001	48	–1.0	2.3	<0.01
Dallas daily activities (%)	64	–20.3	18.1	<0.001	49	–10.4	23.3	<0.01
Dallas work and leisure (%)	63	–22.8	23.8	<0.001	49	–17.1	27.7	<0.001
Dallas anxiety depression (%)	63	–15.6	21.4	<0.001	49	–4.8	23.5	ns
Dallas social interaction (%)	63	–15.7	21.8	<0.001	49	–1.4	22.7	ns

Comparison between t0 and t12 using paired t test or McNemar test.  
ns indicates not significant.

Persistence at 1 year of improved physical and disability outcome measures has been found in a number of previous studies with intensive FRPs.<sup>11,14,33,44</sup> These programs are performed for in- or outpatients, often over several weeks and include several hours of physical activity per day.

Outpatient physical treatment has been less extensively studied despite the fact that it remains, at least in some countries, the main first-line treatment of LBP. In a recent review of randomized trials evaluating the effect of exercise on LBP, only 7 studies included interventions consisting in

**TABLE 3. One-Year Follow-up Data in Functional Restoration Program and Active Individual Treatment Groups**

	Functional Restoration			Active Individual Therapy			P
	n	Mean or %	SD	n	Mean or %	SD	
No. of sick leave days	64	37.3	67.8	49	72.0	109.9	0.042
Working at 1 yr	64	81.6		68	82.8		ns
Return to work (%)	64	93.8		48	85.4		ns
Full-time work (%)	64	79.7		47	70.2		ns
Same work station (%)	59	83.1		40	70.0		ns
Fingertip-to-floor distance (cm)	64	–0.6	10.2	49	3.7	12.7	0.047
Sorensen test (s)	63	153.7	65.3	48	133.7	58.0	ns
Ito test (s)	63	153.4	78.3	48	126.8	69.4	ns
Progressive Isoinertial Lifting Evaluation (kg)	58	27.4	11.2	44	27.3	9.7	ns
Intensity of pain on visual analog scale (cm)	64	2.9	2.4	48	3.5	2.3	ns
Dallas daily activities (%)	64	31.4	22.9	49	39.1	21.9	ns
Dallas work and leisure (%)	64	29.8	25.2	49	39.6	24.4	0.04
Dallas anxiety and depression (%)	64	21.9	23.6	49	25.5	24.1	ns
Dallas social interaction (%)	64	15.5	20.9	49	24.7	25.6	0.04
Increased physical fitness (%)	59	84.0		36	63.9		0.02
Sports and leisure activities (%)	60	80.0		40	70.0		ns
Ability to return to work (%)	59	93.2		36	91.7		ns

ns indicates not significant.

supervised exercises for less than 5 hours per week, available in a primary-care environment.<sup>6,9,11,30,38,45,46</sup> Our present results show that such interventions are effective on the long term and this should lead to further studies on the effective application of international recommendations for active exercises in LBP, and on the possible barriers. Further analysis of the cost effectiveness of such treatments should be undertaken.

Comparison of the results of both programs at 1-year follow-up allows further conclusions. Reduction of pain is similar in both groups and this is in accordance with most of the studies comparing low- and high-intensity programs.<sup>8</sup> At 1 year, the outcome measures that assess the physical component of deconditioning, especially the Sorensen and Ito tests and the Progressive Isoinertial Lifting Evaluation task did not differ significantly between groups. Flexibility is better in the FRP group, but the difference between 3.7 cm and -0.6 cm is not necessarily of clinical significance. These results differ from those obtained at the end of the treatment (t5) or at 6 months,<sup>9,38</sup> which had shown better results in the FRP group for trunk muscle endurance. This could indicate that although intensive programs lead to better end-of-treatment outcome measures, the long-term results do not depend crucially on the intensity of the initial training. This result would deserve further confirmation. The recent randomized trial by Dufour *et al*,<sup>8</sup> which has similarities with that in our study did not include measures of trunk muscle endurance.

It is highly probable that long-term physical outcomes are more closely related to changes in lifestyle and depend on the patient resuming sport and leisure activities, and this result was obtained in both groups. Low-intensity physical treatment seems to be sufficient to induce changes that will be maintained on the long term. Some authors have shown that “refreshing sessions” could enhance the effect of such programs.<sup>47</sup>

Disability measures and sick leaves remain significantly different between groups at 1 year. The Dallas “work and leisure” and “social interaction” subscores remained significantly better in the FRP group and the number of sick-leave days was lower. The possible bias due to the lost to follow-up could have underestimated this difference because these patients were more impaired at baseline and more often in the AIT group.

Further studies are necessary to determine whether these results compensate or not for the large difference in cost of both programs. Despite being a lot more intensive in the amount of physical training, the FRP does not modify the physical outcome at 1 year more than a less intensive program. Intensity is not the only difference between both programs. FRP includes a multidisciplinary approach, with occupational therapy interventions, and contacts with the workplace. It is led by secondary-care physicians and physiotherapists who are highly experienced in the management of chronic LBP, is organized for a group of patients, and probably includes some type of informal peer counseling effect. This is not the case in the AIT group. Thus, the significant between-group difference observed selectively in disability and participation measures could be interpreted as the effect of an “integrated care”

approach, despite the fact that this program is not as centered on workplace issues as models developed in Canada and the Netherlands.<sup>48–50</sup> Integrated-care models have been evaluated and compared with usual care, and have shown superiority in most studies.<sup>2,35</sup> This would also be congruent with recent reviews showing that physical deconditioning may not be as central in disability as thought a decade ago.<sup>51</sup>

Further studies are required to better define which components of treatment are crucial in modifying which of the outcome measures. Most of the present studies, including this work, compare programs that differ in the intensity of physical treatment, the care setting, and the existence or not of a multidisciplinary approach, and tend to show that “more is better.” Closer attention to the different outcome measures and specific design of further studies could confirm that “some is enough” in terms of long-term physical outcome measures but that an integrated-care model is necessary if the objective is to improve not only physical outcome measures but also disability measures and participation, which account for most of the costs and could be loosely related to physical condition.<sup>52</sup>

## CONCLUSION

One-year follow-up shows that both AIT and FRP improved not only on the long-term physical outcome measures but also on disability measures and sick-leave duration. The superiority of the intensive FRP on physical outcome, observed at the end of the treatment, was no longer statistically significant at 1 year. The disability measures and the number of sick-leave days remained statistically better in the FRP group at 1 year. This could indicate that the crucial difference between both treatments is the multidisciplinary approach rather than the intensity of the physical training.

## ➤ Key Points

- ❑ Multidisciplinary intensive functional restoration and less intensive outpatient physical therapy both reduce significantly the number of sick-leave days of chronic LBP patients at 1-year follow-up.
- ❑ Physical outcome measures such as trunk muscle endurance and disability outcome measures are also significantly improved in both programs.
- ❑ The reduction in the number of sick-leave days is significantly larger in the FRP.

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