A. F. Bendix
T. Bendix
C. Hæstrup
E. Busch

A prospective, randomized 5-year follow-up study of functional restoration in chronic low back pain patients

Abstract A functional restoration (FR) program, dealing with a combination of intensive physical and ergonomic training, psychological pain management, and patient education, was tested in two randomized, parallel group studies. In one of these patients following the FR program were compared with a non-treated control group (project A), and in the other with patients on two less intensive treatment programs (project B). A total of 238 chronic low back pain patients participated in the two studies, 106 entering project A and 132 project B. Patients from the two projects were comparable except that the patients in project A were recruited from all over the country, whereas patients in project B all were living in and around Copenhagen. Thirteen patients never started any treatment, and 20 patients (9%) dropped out during the treatment period. Of the 207 who completed treatment, 89% returned a mailed questionnaire 5 years later. This was the case for 55% of the drop-outs. The questions referred to work situation, pain level, activities of daily living, days of sick leave, contact with health care professionals, physical activity, use of medication, and a subjective overall assessment. The results show that in project A the treated group reported significantly fewer contacts with the health care system and significantly fewer days of sick leave over the 5-year follow-up period compared to the control group. In all other parameters, including work ability, there was no statistically significant difference between the two groups. In project B, patients treated in the FR program did significantly better in most measured parameters, except in leg pain, use of pain medication and sport activity, where no significant differences were found between groups. The overall result shows a positive long-term effect of the FR program, but it also shows the necessity of testing a given treatment in different projects and designs, among other things due to statistical variations.

Key words Chronic low back pain · Functional restoration · Rehabilitation · Intensive multidisciplinary treatment

A. F. Bendix · T. Bendix · C. Hæstrup
E. Busch
Copenhagen Back Center,
Rigshospitalet, University Hospital,
Copenhagen, Denmark

A. F. Bendix (✉)
Skelstedet 28, DK-2950 Vedbæk,
Denmark
Tel./Fax +45-42-89 42 52;
e-mail: tomane@post4.tele.dk

Introduction

The functional restoration (FR) approach to patients with disabling chronic low back pain (CLBP) was first described by Mayer and his group from Productive Rehabilitation Institute of Dallas for Ergonomics (PRIDE) in Texas in 1985 [24]. The whole concept was later described in detail by the same group [23]. The philosophy of the FR program is to restore the patients' physical, psychosocial, and socioeconomic situation by focusing on active functioning. It is important to state that the FR program is designed for that small fraction of CLBP patients whose biomechanical dysfunction, physical decondition-

ing, and psychosocial stressors have led to chronic disuse-induced deconditioning syndrome, as clearly stated by Gatchel et al. [14] and Hazard [16]. For most patients FR marks the final attempt to improve their situation, having tried most other conservative treatments without results. FR involves modalities not generally considered as part of conservative treatment for CLBP. For the physical part it starts from the concept of reversing the deconditioning, where disuse and immobilization has had deleterious effects on joint mobility, muscle strength and endurance, and cardiovascular fitness. The physical restoration therefore involves intensive, physical training and work hardening with absolutely no passive modalities included. The other major part of the FR concerns the psychosocial and socioeconomic factors that usually accompany disability from chronic pain. The program focuses on identifying each patient's disability behavior and functional barriers and designing appropriate coping strategies to overcome these barriers.

FR programs that are similar to or modifications of the PRIDE program have been described and tested in several studies during the past 10 years [1, 3–6, 9, 11–13, 15, 17,18, 20, 21, 25, 27, 28]. In all studies, the aim has been to evaluate outcome from multidisciplinary programs for patients with chronic low back pain. However, patient selection, program content, and project designs vary between studies, all of which contribute to the varying outcome results. Only some studies were properly randomized [1, 3–6, 18, 27]. The follow-up period for most of the studies is 2 years or less, with a few having 2½–3 years of follow-up [19, 26], and a few even longer [13, 20].

At the Copenhagen Back Center, an FR program, very similar to the PRIDE model, was tested against control groups of no treatment or less intensive treatments in two randomized studies, and outcomes after 4 months [5, 6], 1 year [4], and 2 years [3] have previously been presented. The aim of this present study was to evaluate the long-term outcome following 5 years of participation in an FR program for patients with chronic, disabling low back pain.

Materials and methods

Project design

Two parallel studies, both prospective and randomized, were carried out as illustrated in Fig 1. The block randomization, following the minimization principle [31], aimed to assign patients in equal numbers to the different groups, using the following parameters: age, sex, pain level, scores for activities of daily living (ADL), days of sick leave during the previous 3 years, and number of cigarettes smoked per day.

The actual FR program and the two alternative treatment programs have been described in detail earlier [5–7]. Only a brief summary will be given here. The FR program, being the same in the two projects, runs for 3 weeks, 8 h every week day, followed by 6-h 1 day a week for the following 3 weeks. The daily schedule is outlined in Table 1.

In project A patients on the FR program were tested against a control group where no treatment was offered at the Back Center. In project B three groups were included, with those on the FR program being compared with patients undergoing pure physical training as well as with those on a combination of physical training and psychological support. The two latter groups received treatment twice a week for 6 weeks. Total hours of treatment in the four treatment groups were: 135 h in A1 and B1 and 24 h in B2 and B3. All patients were treated in groups of six to eight by the same staff, guided by the same basic philosophy.

Before entering a project, all patients underwent a thorough medical examination by a physician, and on the 1st day in a treatment program the patients were physically tested by physio- and occupational therapists and psychologically assessed by a clinical psychologist.

The analyses of the results were performed by a person who had not been involved in the treatment of the patients.

Patient population

Project A included 106 and project B 132 patients, who all met the following inclusion criteria: age 18–59 years, threatened job situation, defined as not being able to work or being absent from work unacceptably often due to low back trouble of at least 6 months' duration, evidence of severe personality disorder or psychosis precluding participation in group treatment, and ability to read and write Danish. Excluded were people with actual/clinically relevant disc herniation, surgery treatment options for this or other back pathology, pregnancy, cancer, clinically relevant fractures, unstable spondylolisthesis, and those on a social pension. Due to the
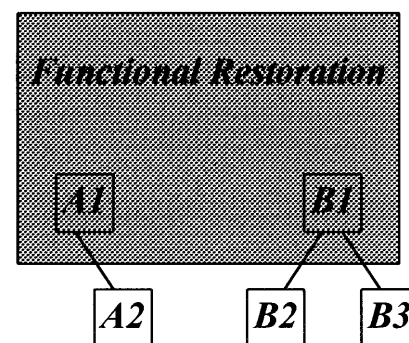

Fig. 1 Organization of the two projects

Table 1 Daily schedule for the functional restoration (FR) program

Time	Subject	Teacher/trainer
08.00–09.00	Aerobics	Physical therapists (PT)
09.00–10.00	Weight training	PT
10.00–11.30	Work simulation	Occupational therapists (OT)
11.30–12.00	Lunch	
12.00–12.30	Relaxation	Clinical psychologists (CP)
12.30–13.30	Psychological group	CP
13.30–14.00	Stretching	PT
14.00–15.00	Theoretical class	MD, PT, OT, CP, Rehab specialist, nutricianist, social worker
15.00–16.00	Recreational activities	PT, OT

practical fact that patients randomized to B2 and B3 had to live close to the Back Center, all patients in project B were recruited from the Copenhagen area. Patients allocated to project A were recruited from all over the country. Patients living outside Copenhagen, randomized to the intensive program in project A, stayed at a hotel or with friends during the 3 weeks, whereas all Copenhagen-area patients stayed in their homes.

Figure 2 illustrates the number of patients randomized to each group, the number of drop-outs and graduates and the number followed up. The 13 'never started' patients either got jobs while waiting for treatment, never showed up, were disappointed about results of randomization, or refused to participate for various psychosocial reasons. Two patients were, about 1½ years after having completed B2, enrolled in another project at the Back Center, and are therefore excluded from this 5-year study. The 20 drop-outs (9%) were defined as such if they had participated in less than two-thirds of the total treatment time. The reasons for drop-out were: unacceptable increase in back pain or pain anywhere else, dissatisfaction with the randomization result, new job shortly after treatment start, various psychosocial problems, various medical illnesses, finding the program too hard. For the graduates 89% and for the drop outs 55% participated in the 5-year follow-up, after several communications from the Back Center.

Selected basic demographic patient characteristics are listed in Table 2. Due to a shortcoming in the randomization, significantly more of the follow-up patients from A1 were in a position of being to work initially as compared to A2. There was also a tendency for patients from B3 to have a lower contact with the workforce than patients from B1 and B2. In all other parameters, there were no differences between groups. Concerning diagnosis, about half the patients (47%) were classified as 'non-specific lumbago ± sciatica,' 20% as 'chronic sciatica caused by previous disc herniation' (88% of these had undergone surgery), 15% as 'segmental pain,' i.e., pain from disc and/or facet joints, 5% as 'thoraco-lumbar Scheuermann disease,' and the remaining 13% as 'miscellaneous,' i.e., muscle tension, psychological, stable spondylolisthesis, etc. As CLBP is a multi-factorial condition, no patient could be diagnosed purely on symptomatic pathology, but rather on a combination of physical and psychosocial factors. Figure 3 illustrates that all our patient population had a smaller or greater component of organic pathology and behavioral issues as reasons for pain perception.

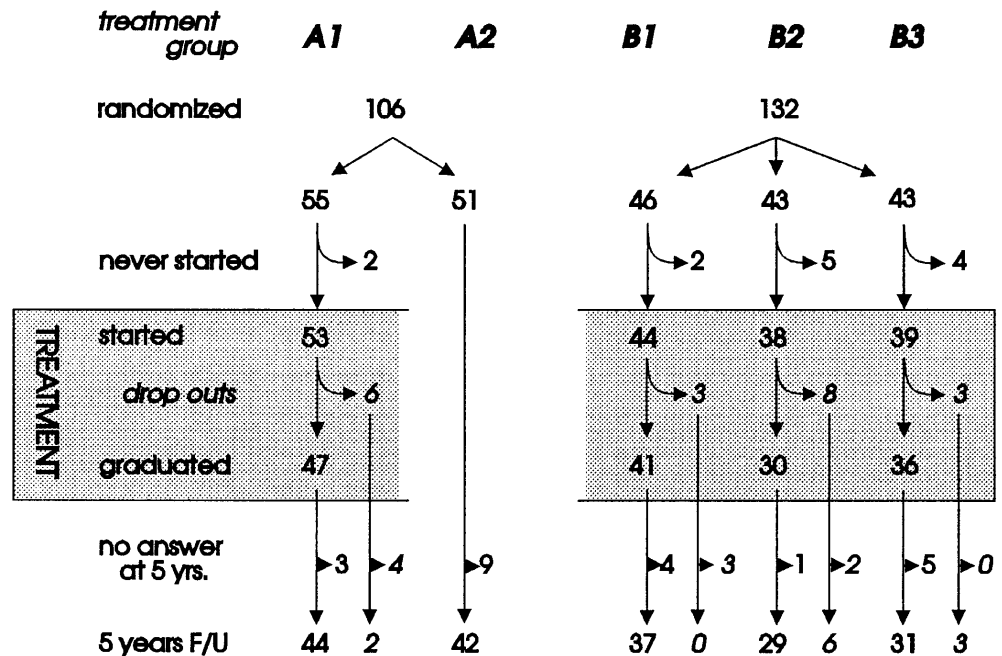**Fig. 2** Patient flow charts for projects A and B

Table 2 Initial median values for patients participating in the 5-year follow-up. In project A, the analyses were done on all patients, including the drop-outs. In project B, data were analyzed without the drop-outs (*ADL* Activities of Daily Living)

|	Project A			Project B			
	A1 (*n* = 46)	A2 (*n* = 42)	*P*	B1 (*n* = 37)	B2 (*n* = 29)	B3 (*n* = 31)	*P*
Age	42	41	0.7	41	45	42	0.2
Men:women	15:31	13:29	0.9	11:26	7:22	8:23	0.9
Working or applying for work (%)	39	17	0.02	38	45	16	0.05
Days of sick leave in previous 3 years	345	367	1.0	289	301	450	0.3
Back pain (0–10)	6	6	0.7	5	5	6	0.4
Leg pain (0–10)	4.5	5	0.7	3	3	3	0.9
ADL (0–30)	17	16	0.5	16	14	15	0.8
Smokers (%)	54	57	0.8	68	72	61	0.7
Perscription pain medication (%)	72	62	0.3	62	72	48	0.2
Sport activity (%)	33	33	1.0	35	31	19	0.4
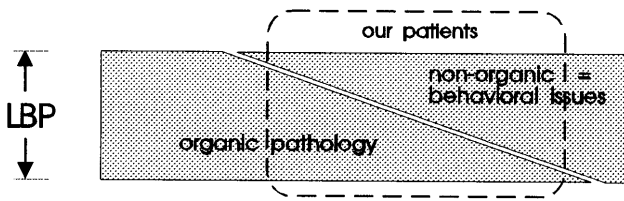
Fig. 3 Reasons for low back pain are multifactorial. A few cases can be explained purely by organic pathology or purely by behavioral issues, but in the majority of cases, a smaller or greater component of both is present. This was also the case with the patients in this project, who are all located somewhere in the dotted box

Follow-up

All patients initially participating in either project A or B were mailed a questionnaire about 5 years later. The exact 5-year period was defined as: the first Monday after 3 weeks of treatment, irrespective of treatment duration, plus 5 years. For project A, each patient in the control group was, at time of randomization, matched, according to time interval from randomization to treatment start, with one from the treated group. The median time for the actual period was 4.8 years (range 4.3–5.3 years) for project A, and 4.8 years (range 4.2–5.3 years) for project B.

The mailed questionnaire included a number of questions about the person's work situation, use of the health care system, days of sick leave due to low back pain, pain and disability levels, prescription medication for back pain, sports activity, and subjective overall assessment.

As there was no possibility of dropping out of the control group in project A, data were analyzed together for all patients, graduates and drop-outs, who returned the questionnaire. When doing so, we avoided comparing the best patients from A1 with all the controls. In project B there were drop-outs in all three groups, and data were analyzed with and without the drop-outs. The presented data are without the drop-outs, who are presented separately in the drop-out section.

Statistical methods

For the comparison between groups at time zero as well as at 5 years, Mann-Whitney (project A) and Kruskal-Wallis (project B) tests were performed. For the variables 'Δ working,' where tests were done on the differences between before the program and 5 years after, a χ^2 test was applied in the following way: the number of persons within each treatment group who reported themselves working before the program as well as 5 years later, did not participate in the analysis. Only the increase in number of people deemed able to work at 5 years compared to baseline joined a χ^2 row along with the persons who were still not able to work. The corresponding values for the alternative treatment group(s) were

subsequently added. To elucidate change over time, the Wilcoxon test for paired differences was used for the comparison of data taken within groups at time zero and at 5 years, respectively. The level of significance was defined as 5%.

The drop-out analyses, comparing different groups, were all carried out using Mann-Whitney tests.

Results

Work status

The 5-year questionnaire contained several questions concerning the person's actual working situation. Depending on the answers, each person was classified into one of three categories: (1) those deemed able to work, i.e., actually working, unemployed but seeking work, in rehabilitation paid work, or in education, (2) those who were sick listed, or (3) those with a pension application pending or pension obtained. Table 3 summarizes the results.

Category 1: working, unemployed, in education

In project A, no difference in overall contact with the labor force was seen between the two groups ($P = 0.1$). In project B the significant difference between groups ($P = 0.007$) indicated that B1 was different from B2 ($P = 0.02$) and B3 ($P = 0.004$), whereas B2 and B3 did not differ much ($P = 0.6$). As work situation at baseline was uneven across groups, it is of interest to compare the differences in number of people who were part of the workforce before treatment with the figures for 5 years later. In the treated group in project A, an increase of 11% was seen as compared to a 34% increase in A2. This difference just obtained statistical significance in favor of A2 ($P = 0.05$). In contrast, in project B there was a significant difference between the three groups ($P = 0.001$), with patients in B1 being significantly more able to work than those in B2 ($P = 0.0006$) and B3 ($P = 0.03$). B2 and B3 just obtained a significant difference ($P = 0.05$) in favor of B3. Some of the people who were working before entering the projects were no longer part of the workforce 5 years later. This was the case for five participants from A1, two from A2, two from B1, eight from B2, and three from B3. All these people had obtained or applied for a pension.

Table 3 Work status at 5-year follow-up. Δ working indicates the increase in the percentace of patients able to work from before entering the projects until 5 years later

	Project A			Project B			
	A1 (*n* = 46)	A2 (*n* = 42)	*P*	B1 (*n* = 37)	B2 (*n* = 29)	B3 (*n* = 31)	*P*
Working/seeking work (%)	50	51	0.1	68	38	32	0.007
Δ Working (%)	11	34	0.05	30	0	23	0.001
Sick listed (%)	2	0	–	3	3	0	–
Pension (%)	48	51	0.6	29	59	68	0.005

Category 2: sick listed

Only a very few persons in either project were sick listed after 5 years. The number is so small that statistics have no meaning.

Category 3: pension – 'application pending' and 'obtained'

In project A no difference was seen between the two groups ($P = 0.6$). In project B there was a significant difference between groups ($P = 0.005$) in favor of B1, where significantly fewer people were on pensions compared to B2 ($P = 0.02$) and B3 ($P = 0.002$).

LBP in daily living

Responses to the questions about how back pain influenced a person's daily life as regards daily activities, pain, medication etc. are summarized in Tables 4 and 5.

Activities of daily living (ADL)

A 15-question section about how LBP influenced daily activities, e.g., tying shoe laces, brushing teeth, watering flowers etc., previously evaluated by Manniche et al. [22], was used in the questionnaire. Each question was scored 0 (no problem), 1 (might be a problem), or 2 (is a problem), giving a maximum of 30 points. Patients in the two

groups in project A showed no statistically significant difference ($P = 0.2$), whereas patients in the three groups in project B were different in favor of those in B1 ($P = 0.02$), who differed significantly from those in B2 and B3 ($P = 0.01$ and 0.03 respectively), who did not differ much ($P = 0.6$).As seen from Table 5, the FR groups in both projects reported significantly lower scores at the end of the 5-year period, indicating a lower disability level ($P = 0.001$ in A and $P = 0.0008$ in B) as compared to the other groups, where no significant difference over time was seen.

Back pain

Back pain was measured with a box scale ranging from 0 through 10, indicating average pain level over the past 14 days. In none of the projects was any significant difference obtained between groups ($P = 1.0$ in A and 0.3 in B). In both groups in project A, however, back pain was significantly reduced within groups when comparing pain levels before entering the projects with those at 5-year follow-up ($P = 0.01$ in both). In project B, no significant changes were observed.

Leg pain

Using a similar box scale as for back pain, no significant changes were observed in any of the projects, either when comparing groups at 5 years, or when comparing within groups over time.

Table 4 Data from the 5-year follow-up

	Project A			Project B			
	A1 (n = 46)	A2 (n = 42)	P	B1 (n = 37)	B2 (n = 29)	B3 (n = 31)	P
ADL (0–30)	12	16	0.2	8	14	16	0.02
Back pain (0–10)	5	5	1.0	4	5	6	0.3
Leg pain (0–10)	4	5	0.6	3	4	4	0.07
Prescription medications (0–10)	3	4	0.7	0	4	4	0.009
Sport activity (SA) (%)	72	83	0.2	87	86	65	0.08
Days of SA/week	2	3	0.2	3	2	3	0.5
Overall assessment (1–5)	2	3	0.1	2	3	3	0.004

Table 5 Changes in ADL, back pain, leg pain, and sport activity during the 5-year follow-up period (*0 before entering the projects, 5 at 5-year follow-up*)

	A1		A2		B1		B2		B3	
	0→5 (n = 46)	P	0→5 (n = 42)	P	0→5 (n = 37)	P	0→5 (n = 29)	P	0→5 (n = 31)	P
ADL (0–30)	17 →12	0.001	16→16	0.3	16→ 8	0.0008	14→14	0.9	15→16	0.8
Back pain (0–10)	6 → 5	0.01	6→ 5	0.01	5→ 4	0.07	5→ 5	0.9	6→ 6	0.5
Leg pain (0–10)	4.5→ 4	0.3	5→ 5	0.3	3→ 3	0.7	3→ 4	0.5	3→ 4	0.1
Sport activity (%)	33 →72	0.0004	33→83	0.0002	35→87	0.0003	31→86	0.0007	19→65	0.001

Prescription medication for back pain

Depending on the kind and amount of pain medication, each patient was classified into one of five groups: (1) no medication = 0 points, (2) non-steroidal medication ≤ 4 days/week = 2 points, (3) non-steroidal medication > 4 days/week = 4 points, (4) morphine ≤ 4 days/weeks = 8 points, and (5) morphine > 4 day/week = 10. In project A, the two groups did not differ significantly at 5 years, whereas in project B the three groups were significantly different ($P = 0.009$), with patient in B1 consuming significantly less medication than those in B2 ($P = 0.002$), but not significantly less than those in B3 ($P = 0.1$).

Sport activity

All five groups in the two projects reported a fairly high level of participation, between 72% and 87%, in sport activities 2–3 days a week, but with no significant differences between the groups. In all groups, significantly more people had become physically active in the follow-up period as compared to before entering the projects, as seen from Table 5.

Overall assessment

To assess 'quality of life' in relation to low back pain at 5 years compared to baseline, each participant was asked to mark whether this was: (1) much better, (2) better, (3) unchanged, (4) worse, or (5) much worse. In project A, no significant difference between the two groups was seen ($P = 0.1$). In project B, there was a significant difference between groups ($P = 0.004$), with B1 participants reporting significantly better life quality than B2 ($P = 0.007$) and B3 ($P = 0.003$) participants, who did not differ ($P = 1.0$).

Continued sick leave and search for a cure

To visualize the participants' needs for staying in a 'patient' role – being unable to go to work or to handle the back problem themselves – they were asked about number of days' sick leave due to LBP and about their use of the health care system. (Table 6).

Days of sick leave

Sick leave was asked about in relation to low back pain, so sick days due to other illnesses were not included. All participants who were classified in work status category (3), were not included in this parameter, as one can not have sick days while on a pension. No statistically significant difference was found between the groups in any of the projects (A: $P = 0.4$, B: $P = 0.2$).

Utilization of the health care system

Patients were asked to record all contacts with family doctors, physical therapists, chiropractors etc. Hospitalization due to back pain was also registered. No difference was found either between the two groups in project A ($P = 0.1$) or between the groups in project B ($P = 0.2$). There was a tendency in both projects for the FR program groups to be less hospitalized with and without back surgery than the other groups.

Drop outs

To analyze drop-outs in these projects we decided to address the following three questions:

1. 'Did the patients who dropped out of a treatment program show any different characteristics in baseline data to patients who graduated?' This question is relevant, as it may help to predict which patients should not be referred to an FR program because they are likely to drop out. As seen from Table 7, the drop-outs tended to be younger, less likely to be working/seeking work, and with significantly more days sick leave due to back pain as compared to those who completed the program ($P = 0.02$). The drop-outs were also significantly less active in sports than the graduates ($P = 0.03$) and a trend was seen for more of the drop-outs to be smokers.

2. 'Did the patients in project A who participated in the 5-year follow-up differ in initial data from patients who did not respond to the 5-year follow-up?' There was a tendency, as outlined in Table 8, for those who did not join

Table 6 Data from the 5-year follow-up. (Days of sick leave applies only to the patients in each group not on or seeking a pension: A1, $n = 24$; A2, $n = 21$; B1, $n = 27$; B2, $n = 14$; B3, $n = 12$)

	Project A			Project B			
	A1 ($n = 46$)	A2 ($n = 42$)	P	B1 ($n = 37$)	B2 ($n = 29$)	B3 ($n = 31$)	P
Days of sick leave (median)	10	50	0.4	13	88	11	0.2
Contacts with health care system (median)	16	48	0.1	15	24	10	0.2
Hospitalized due to LBP (%)	22	38	0.09	22	24	23	1.0
Back surgery (%)	7	12	0.4	5	10	10	0.7

Table 7 Drop-out analysis: comparison of baseline data for patients who graduated from the two projects and patients who dropped out

	Graduates (n = 205)	Drop-outs (n = 20)	P
Age	42	38	0.1
Men:women	57:148	6:14	0.8
Working or applying for work (%)	30	10	0.06
Days of sick leave in previous 3 years	360	545	0.02
Back pain (0–10)	6	6	0.3
Leg pain (0–10)	4	4	0.9
ADL (0–30)	16	17	0.3
Smokers (%)	61	80	0.1
Prescription medication (%)	64	70	0.6
Sport activity (%)	32	10	0.03

the 5-year follow-up to be younger, more out of work, with more days sick leave, and reporting a lower level of sport activity, as compared to the follow-up groups. The differences did not, however, obtain statistical significance, except in the case of smoking in A1, where signif-

icantly more non-participants were smokers compared to participants (P = 0.02).

3. 'Does a high number of drop-outs from a treatment group (as in B2) affect the overall conclusions drawn on graduates participating in the follow-up?' This is important, as many studies draw conclusions from the group of patients who graduate from a program and respond to the follow-up communication. However, that is definitely the part of the patient population that responded best to the treatment, and it seems necessary also to take the above-mentioned question into consideration. Analyses were done by comparing baseline data from follow-up-graduates to baseline data from drop-outs and non-follow-up graduates in each group in project B (Table 9). Here too we saw a tendency for a lower likelihood that the drop-outs/non-follow-ups had been working, that they had taken more days of sick leave, and that they smoked more, but none of the differences were significant. This tendency was highest in B2, where the drop-out rate was highest, and the drop-outs also tended to have been less active in sports in this group.

Table 8 Drop-out analysis in project A: comparison of baseline data for patients who participated in the 5-year follow-up (+F-U-5) and patients who did not (–F-U-5)

	A1			A2		
	+F-U-5 (n = 46)	–F-U-5 (n = 7)	P	+F-U-5 (n = 42)	–F-U-5 (n = 9)	P
Age	42	35	0.1	41	36	0.7
Men:women	15:31	0:7	0.07	13:29	2:7	0.6
Working/seeking work (%)	39	14	0.2	17	10	0.6
Days of sick leave in previous 3 years	345	708	0.1	367	745	0.2
Back pain (0–10)	6	6	0.6	6	6	0.8
Leg pain (0–10)	4.5	4	0.5	5	4	0.9
ADL (0–30)	17	18	0.8	16	18	0.4
Smokers (%)	54	100	0.02	57	45	0.5
Prescription medication (%)	72	71	1.0	62	68	0.8
Sport activity (%)	33	29	0.8	32	25	0.7

Table 9 Drop-out analysis: initial values for patients in each group in project B. (*G+FU* participants who graduated and participated in the 5-year follow-up, *DO–FU* participants who either dropped out from treatment or did not participate in the 5-year follow-up)

	B1			B2			B3		
	G+FU (n = 37)	DO–FU (n = 7)	P	G+FU (n = 29)	DO–FU (n = 9)	P	G+FU (n = 31)	DO–FU (n = 8)	P
Age	41	44	0.8	45	41	0.09	42	42	0.6
Men:women	11:26	0:7	0.1	7:22	4:5	0.2	8:23	3:5	0.5
Working/seeking work (%)	38	29	0.6	45	11	0.07	16	13	0.8
Days of sick leave (previous 3 yrs)	289	570	0.3	301	549	0.03	450	341	0.5
Back pain (0–10)	5	5	0.05	5	6	0.3	6	7	0.2
Leg pain (0–10)	3	3	0.8	3	3	0.6	3	4	0.5
ADL (0–30)	16	19	0.06	14	14	0.5	15	17	0.5
Smokers (%)	68	71	0.8	72	89	0.3	61	63	1.0
Perscription pain medication (%)	62	86	0.2	72	78	0.8	48	50	0.9
Sport activity (%)	35	43	0.7	31	22	0.6	19	25	0.8

Discussion

At the Copenhagen Back Center, outcomes from an FR program for patients with CLBP have now been tested in two randomized, prospective studies with different follow-up terms: 4 months [5,6], 1 year [4], 2 years [3], and 5 years, as presented here. Results after 4 months and 1 year were very positive in both projects, showing that patients treated with FR were doing significantly better in terms of living a more active and less disabled life, including higher rates of return to work, fewer days of sick leave, fewer contacts with the health care system, and coping better in daily activities than those in control groups with no treatment or treatment in less intensive programs. At 2 years, the effect in favor of FR was still significant for most parameters in project B, but had faded out for some important parameters in project A. At the 5-year follow-up, almost all participants were either deemed able to work or were on a pension – very few were still sick listed. The number of pensions had increased in the period 2 through 5 years in both projects. In project A this increase was mostly due to the fact that the sick-listed patients had obtained pensions, whereas in project B some of the persons deemed able to work at 2 years reported being on pension after 5 years. This was the case for 30% of participants from each of the two less intensive programs, but only for 15% of participants treated in the FR program. Altogether, the positive effects of the FR program in project B seem to last even 5 years after participation, whereas the effects of the other project were almost eliminated after 2 years.

Our results correspond in many ways to those reported by Gallon in a 4- to 6-year follow-up study [13], although that program cannot be directly compared with ours, as the contents are different. The Finnish study by Härkäpää et al. [18] also showed very positive results 3 months after a multidisciplinary program that was quite different from the original FR program. After 1 year the effect had faded out in many of the measured parameters [19], and one of the interesting findings in their study was that a refresher program 1½ years after the primary program was found to improve physical functions more effectively than did the first program [19, 26]. Similar findings are also reported by Lanes et al. [20], who followed CLBP patients up to 9 years after treatment in a multidisciplinary program. They conclude from their study that the time factor is essential in getting patients back to work, and that periodic refresher training may be a good 'booster shot'. The fact that the good results in our projects after 1 year had faded out in one project after 2 years may reflect the importance of having reinforcing factors continuously present. During the FR program, patients experienced a new, more positive quality of life and learned to change an abnormal illness behavior into a more healthy behavior. It is likely that the reinforcing factors will decline over time, and our results may have been affected if a refresher program was offered after maybe 1–1½ years.

Reasons for the different results in the two projects can be viewed in different ways. First of all, the importance of carrying out different clinical controlled and randomized studies when testing a specific treatment is essential. Statistical variations and other unknown factors in research may be a major issue. Secondly, although patient populations in the two projects had the same inclusion and exclusion criteria, one factor was different: home address. The fact that the majority of patients from project A were recruited from rural areas of Denmark and the majority of the B patients from the City of Copenhagen may reflect differences in the socioeconomic conditions and in social culture in different parts of the country. The unemployment rate is not equal in all parts of the country, and a person's attitude towards returning to work may be influenced by the possibility of getting a job. There may also be differences in people's pain perception and coping strategies depending on what part of the country they live in. This was, however, not the case in another study from our Back Center, showing no differences in ability to work between two groups of Copenhagen patients treated with either FR or pure physical training [8]. A third explanation could be the fact that a randomized study almost always will disappoint patients in one of the groups. In project A, patients randomized to the control group were often disappointed about not getting any treatment. This disappointment could turn into a kind of anger towards the study, and they could report better results at the follow-up because they want to signal that they can manage without the treatment they never received. In project B, many of the patients randomized to groups 2 and 3 were also disappointed and their motivation for treatment may have been very low, reflecting poorer outcome results for these groups.

The attitude and empathy of the professional team of physicians, physio- and occupational therapists, clinical psychologists and counsellors are significant factors in every treatment, including FR. To compare results in different studies, it is crucial that the staffs are comparable as has been stated by Gatchel et al. [14]. With different cultures in different countries, it may be difficult to directly compare attitudes, and this could explain part of the difference in outcome results from the United States and Europe. Concerning the present two studies, the same professional team from the Copenhagen Back Center was involved in both projects to eliminate this risk.

The importance of getting low back pain patients out of a patient role and back to an active life style before they get too chronically disabled, has often been stressed [2, 10, 21, 28–30]. Results from analysis of the drop-outs and the non-responders in our study seem to support this. When looking at baseline data on these patients, they tended to be younger people with more days of sick leave and poor contact with the workforce as compared to people who responded to treatment and follow-up. Further studies should be carried out on this topic to draw final conclusions.

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