

CASE STUDY

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Do Patients With Chronic Low Back Pain Benefit From Early Intervention Regarding Absence From Work?

A Randomized, Controlled, Single-Center Pilot Study

Anja Davis Norbye, PT, MSc,* Aina Vedvik Omdal, PT, BSc,* Marit Eikrem Nygaard, PT, MSc,*
Ulla Romild, Dr. Scient,[†] Guttorm Eldøen, MD,* and Rune Midgard, MD, PhD^{*,‡}

Study Design. A randomized, controlled, single-center pilot study.

Objective. The aim of this study was to investigate the feasibility of running a trial to explore if early intervention in individuals with chronic low back pain (CLBP) would lead to an early return to work (RTW) and reduce sick leave during 12 months of follow-up compared with patients on a 3-month waiting list.

Summary of Background Data. Back pain is the reason for numerous absent days from work. In Norway, the government initiated a priority program, *Earlier Return to Work (ERTW)*, to reduce work absences through early intervention. However, no proper evaluation has been performed on populations with CLBP. There is no consensus on how RTW should be measured. Only a few studies have examined how waiting time affects RTW.

Methods. Fifty-eight patients were included in the study. The group with early intervention was examined within 2 weeks, and the group on the waiting list was examined after 12 weeks. The intervention was identical in both groups and consisted of an outpatient, intensive back school. The data were obtained by

questionnaire after 3, 6, and 12 months. The primary outcome was absence from work.

Results. The sample size in a full-scale study must comprise at least 382 patients on the basis of the assumptions in the pilot. In the pilot study, early intervention directly compared with an ordinary waiting list did not significantly affect the number of sick leave days after 12 months of follow-up.

Conclusion. A prerequisite for launching a full-scale clinical trial is a redesign of the intervention, an improvement of procedures concerning inclusion and randomization, and finally a more precise definition of RTW.

Key words: chronic low back pain, fear avoidance, function, multidisciplinary back School, pain, randomized controlled trial, return to work.

Level of Evidence: 3

Spine 2016;41:E1257–E1264

Musculoskeletal disorders are the most common reason for work absences in Norway.¹ Sixty to eighty percent of Norwegians report experiencing back pain on one or more occasions.² As a result, low back pain has a large economic impact on society and leads to substantial work absences in Norway.³ Eighty-five percent of indirect costs related to low back pain result from work absences.⁴ Thus, in 2007, Norwegian authorities initiated a priority program called *Earlier Return to Work (ERTW)*. The aim of this initiative was to ensure that people absent from work and individuals who were at risk of needing sick leave were offered early intervention (EI) and subsequent treatment.⁵ To date, evaluations of the total effect of this program have not been convincing.⁶ No assessment of the subpopulation of people with chronic low back pain (CLBP) has been adequately performed, although several studies have emphasized that EI should be implemented to ensure early return to work (RTW).^{7,8}

Research concerning sick leave in populations with low back pain has found that a longer absence from work decreases the probability of RTW.^{7,9} Therefore, it is important to reduce the length of sick leave. In this study, we

From the *Department of Neurology, Molde Hospital, Møre and Romsdal Health Trust, Molde, Norway; [†]Swedish National Institute of Public Health, Ostersund, Sweden; and [‡]Unit for Applied Clinical Research, Norwegian University of Science and Technology, Trondheim, Norway.

Acknowledgment date: February 22, 2016. First revision date: May 24, 2016. Second revision date: June 27, 2016. Acceptance date: July 16, 2016.

The manuscript submitted does not contain information about medical device (s)/drug (s).

No funds were received in support of this work.

No relevant financial activities outside the submitted work.

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Address correspondence and reprint requests to Anja Davis Norbye, PT, MSc, Department of Neurology, Molde Hospital, 6407 Molde, Norway; E-mail: anja.margrete.davis.norbye@helse-mr.no

DOI: 10.1097/BRS.0000000000001878

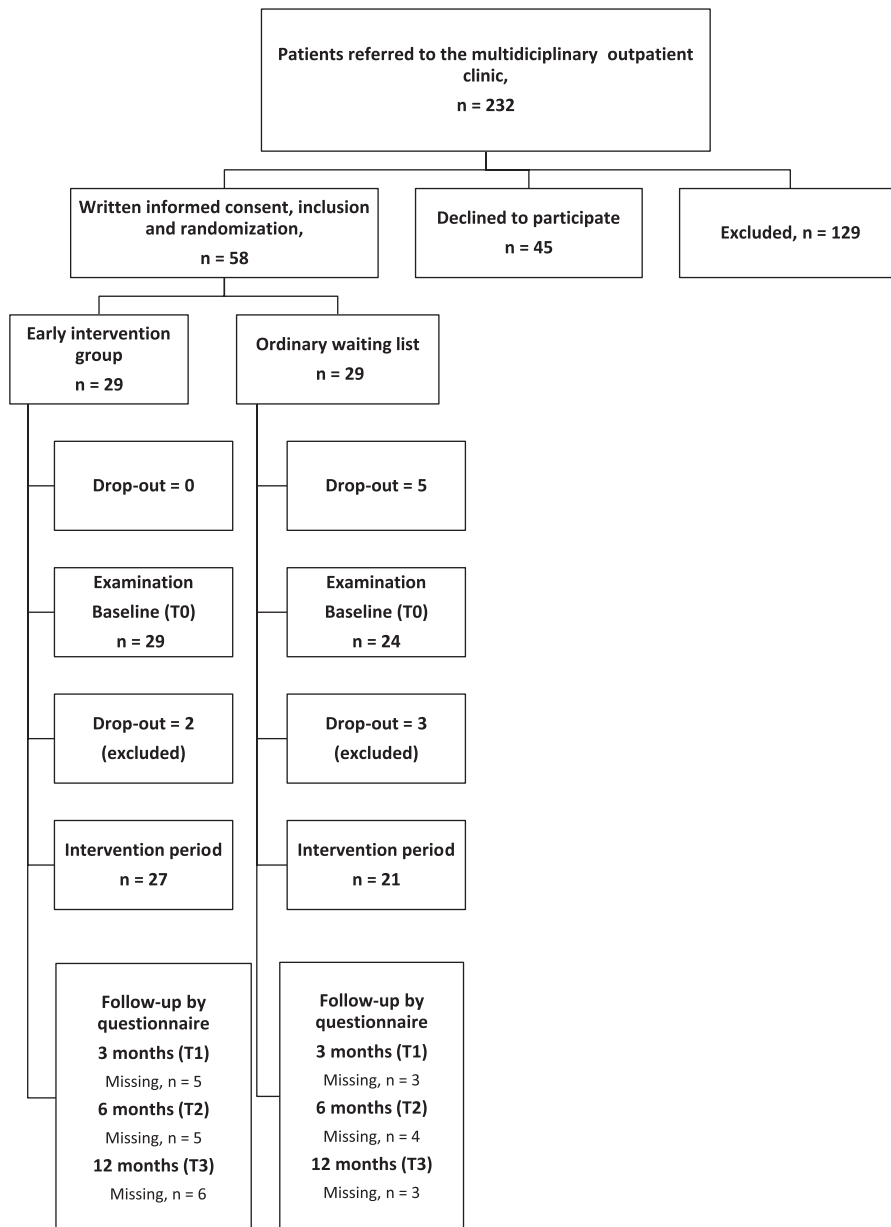


Figure 1. Flow chart of the study—Design, procedures, intervention sequences, and data collection.

sought to examine if EI for people with CLBP would lead to an early RTW and minimize sick leave during 12 months of follow-up compared with patients on a 3-month waiting list (WL). We initially designed a pilot study to address the feasibility of a full-scale trial. We asked: Is the present pilot study design feasible to inform a large-scale study investigating if EI in patients with CLBP reduces absence from work?

MATERIALS AND METHODS

Study Population

Participants were recruited from the patient population referred to the multidisciplinary clinic for low back pain at the Department of Neurology, Molde Hospital. These

patients were referred from general practitioners (GPs) and hospitals in Møre and Romsdal County from September 2013 to January 2014. We received a total of 232 referrals and included 58 patients for further intervention. All participants signed a written consent form. We excluded 129 patients because they met the predefined exclusion criteria, and 45 patients declined to participate. Ten patients withdrew their consent during the intervention and follow-up period and were excluded from the analyses (Figure 1). Criteria for inclusion and exclusion in the study are listed in Table 1.

The study administered questionnaires in Norwegian only; thus, the patients with an inadequate understanding of the written Norwegian language were excluded. The ethics committee for medical research in Eastern Norway (REK Sør Øst) approved the study.

TABLE 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Age 18–67 yrs inclusive	Age below 18 or over 67 yrs
Chronic low-back pain as main clinical problem	Main clinical problem localized in the thoracic or cervical spine
Employed part-time or full time	Out of work, not working, or on disability pension
On sick leave or in the risk of ending in sick leave	On sick leave for reasons other than low back pain
Have an adequate understanding of written Norwegian language	If malignancy was suspected based on referral application
	Low understanding of written Norwegian language

Randomization Procedure

Patients were selected for the study on the basis of the information in the referral application. Patients who met the inclusion criteria received an information leaflet and a consent form by mail. After 5 days, the physiotherapist called the patient and gave additional information about the study. After return of the written consent, we randomized the patient to either the EI group or the WL group.

The population was randomized into two arms; examination in the EI group was completed within 12 working days, while patients randomized to the WL group were examined after 90 days. We accepted a variation of ± 3 days. The waiting period was calculated from the date of randomization. Baseline was considered to be the date of examination, and participants completed a baseline questionnaire. The number of days on sick leave was registered from baseline.

All patients were block randomized in groups of 10 through a web-based randomization program. The participants were not stratified by age or gender. The researchers did not have access to the randomization key.

Intervention

All patients underwent the same intervention. Each participant took part in 20 sessions in the multidisciplinary clinic (Table 2) and was absent from work during participation in the back school.

An experienced physiotherapist examined the patients. The examination was partly standardized, although both patient history and examination were individualized.

At 3, 6, and 12 months after baseline, the patients received a questionnaire. By completing 12 months of follow-up, the participants completed their participation in the study.

Feasibility

During and after the study, we critically scrutinized our methods and procedures to pinpoint critical steps suitable for improvement in a full-scale trial.^{10,11}

Outcome Measures

The primary outcome was sick leave and RTW after 1 year of follow-up. Secondary outcomes included changes in pain,

TABLE 2. Elements and Duration of the Intervention at the Back School

Intervention	Duration, Hours, and Minutes	
Examination by a physiotherapist, including standardized instruction and guidance of physical activity, natural history of pain, and how to cope with the pain	2 h	
Two one-to-one controls with the physiotherapist	1 h	20 min
Participation in two indoor training groups	3 h	
Participation in a back school for low-back pain, starting 1 month after the examination, comprising		
Lessons and group discussions (L)	L = 11 h	
Indoor training (T)	T = 20 h	
Hydrotherapy (H)	H = 3 h	
Outdoor walks (O)	O = 4 h	30 min
Two one-to-one controls with the physiotherapist	1 h	20 min
Participation in two indoor training groups	3 h	
Participation in a follow-up day after the back school, within 2 months after finished course		
Contains lessons and group discussions (L)	L = 1 h	30 min
Indoor training (T)	T = 2 h	
Hydrotherapy (H)	H = 1 h	
Total intervention contact	53 h	40 min

TABLE 3. Sick Leave Results

Days	Waiting List Group	Early Intervention Group	P*
In total from baseline	75 (SD: 50)	111 (SD: 122)	0.211
In total, from baseline, related to LBP	63 (SD: 54)	86 (SD: 92)	0.367
In total, part-time sick leave converted to days	56 (SD: 42)	88 (SD: 101)	0.235
In total, part-time sick leave converted days, related to LBP	47 (SD: 44)	70 (SD: 83)	0.319

*All analyses were tested using Student *t* test.
LBP indicates low back pain.

function, and thoughts and beliefs concerning their back pain.

Sick Leave

The primary outcome was based on self-reports from the patients. Participants were instructed to register all absences from work from baseline until the follow-up was complete. Start dates and end dates for work, part time or full time, were recorded. They also recorded if sick leave during the follow-up was because of low back pain.

The patients received a diary at baseline to continuously record their sick leave data. Full-time RTW was recorded as one and part-time RTW recorded with decimals of one.

Secondary outcome measures were low back pain, measured using a validated Norwegian version of the 11-point Pain Intensity-Numerical Rating Scale (PI-NRS)¹²; disability and function, measured using the Oswestry Disability Index (ODI)¹³; and mindset, measured using the Fear-Avoidance Beliefs Questionnaire.¹⁴

Statistical Analyses

Baseline measures were tested using Pearson Chi-square test or Fisher exact test for dichotomous variables; the Mann-Whitney *U* test for categorical variables; and Student *t* test for continuous variables. Changes in primary outcomes were tested using Student *t* test, and the results were verified using the Mann-Whitney *U* test. Results for secondary outcomes were tested using analysis of variance (ANOVA) for repeated measurements. The IBM SPSS Statistics 22, SPSS Inc. 2013, Chicago, USA statistical package was used for all statistical analyses.

We have calculated the sample size in a main full-scale study based on the results from this small-scale pilot study and the assumption that days on sick leave would be 23 days less among persons with CLBP who receive EI compared with persons on an ordinary WL taking into account the variation as expressed in the standard deviation (SD) (Table 3).

RESULTS

Descriptive

We enrolled 58 patients with CLBP into the study out of 232 potentially eligible persons referred to the multidisciplinary outpatient clinic (Figure 1). After randomization, 29 patients were assigned to each group. Five patients withdrew their

consent after randomization, all from the WL group. Two patients from the EI group and three from the WL group were excluded after the examination, four because of the exclusion criteria and one because of an injury that made participation in the intervention impossible. Altogether, 48 patients completed the study: 27 in the EI group and 21 in the WL group.

The intervention groups were initially well balanced by age and gender. After randomization and drop-out, the distribution by gender was slightly skewed (Table 4).

The EI group was examined at 12 days after randomization, whereas the WL group was examined at 91 days after randomization. At baseline, the level of pain was the same in both groups. At the start of intervention, 56.3% of subjects were on sick leave, including 16 in the EI group and 11 in the WL group. One patient became unemployed during the follow-up period; two participants underwent surgery for sciatica, and one participant was referred to the clinic for a new examination. For the other participants, the protocol was followed during the follow-up year. Eight subjects were lost to follow-up.

After the treatment period, nine participants in each group had absences from work, and after completing the follow-up period, six from the EI group were on sick leave, three because of back pain and three related to other afflictions. In the WL group, four were on sick leave; only one was on sick leave because of CLBP.

Feasibility

Applications received by the outpatient clinic were of heterogeneous quality. Therefore, clarifications by phone calls to the referring GP were frequently required; such calls postponed the inclusion of patients into the study. Primarily due to this delay, the time from receiving an application to randomization could reach 3 weeks.

The elements and the duration of the intervention were extensive and time-consuming, both for participants and physiotherapists, and greatly impacted total capacity at the multidisciplinary clinic.

Sick leave was measured by self-reports in a continuously updated diary. For employed participants, RTW should coincide with the end of sick leave. However, for unemployed participants, this relationship may not hold. We did not establish a formal cooperation with the Norwegian Labour and Welfare Administration (NAV) that administers sickness benefits, work assessment allowances, and unemployment benefits.

TABLE 4. Demographic and Clinical Baseline Characteristics

	Waiting List Group (N = 21)	Early Intervention Group (N = 27)	P
Age (mean, SD) [‡]	41 (13)	41 (11)	0.954
Sex, women [†]	8 (38.1%)	15 (55.6%)	0.230
Married/live with significant other [†]	12 (57%)	21 (78%)	0.310
Educational level [§]	Completed upper secondary school: 17 (81.0%); Completed higher education: 4 (19%)	Completed upper secondary school: 16 (59.2%); Completed higher education: 11 (40.8%)	0.010
Duration of pain [§]	No pain: 0 (0%); Less than 3 months: 2 (10%); 3–12 months: 7 (33%); 1–2 years: 4 (19%); >2 years: 8 (38%)	No pain: 1 (4%); Less than 3 months: 9 (33%); 3–12 months: 10 (37%); 1–2 years: 1 (4%); >2 years: 6 (22%)	0.021
Pain (mean, SD) [‡] ; (1) In rest; (2) In activity	1) 4.6 (1.8); 2) 5.4 (1.5)	(1) 4.8 (2.1); 2) 5.3 (2.3)	(1) 0.786; (2) 0.864
ODI (mean, SD) [‡]	25.3 (SD: 8.6)	25.6 (12.2)	0.923
FABQ (mean, SD) [‡] ; 1) PA; 2) Work	1) 13.5 (3.8); 2) 10.8 (4.7)	(1) 19.4 (9.1); (2) 18.8 (10.6)	(1) 0.036*; (2) 0.846
Comorbidity: No [¶]	90.5%	92.6%	0.594
Days after randomization to intervention (mean, SD) [‡]	91 (SD: 4.6)	12 (SD: 4.5)	0.085
Days of sick-leave before baseline [‡]	160 (SD: 77)	93 (SD: 88)	0.085

*Significant below 0.05 level.
[†]Pearson Chi-square.
[‡]Student's T-test.
[§]Mann-Whitney U test.
[¶]Fisher exact test.

On the basis of the pilot study assumptions, the observed sick leave interval between early and ordinary intervention and the calculated SDs, the total required sample size in a full-scale trial would be 382 participants, given the likely skewed distribution of the examined metrics.

Primary Outcome

Our primary outcome was the difference in days on sick leave between the two groups after 12 months of follow-up. We reached complete follow-up with 36 patients (75%). EI did not lead to fewer days of sick leave (Table 3). In contrast, the WL group exhibited slightly better results than the EI group. However, none of the results were significant, and the confidence intervals were wide. The analyses were repeated using Mann-Whitney U test, which showed the same tendencies. We did not observe significant differences in sick leave between the groups before baseline.

Secondary Outcomes

All secondary outcomes (Figure 2A–E) support the findings regarding sick leave. Both groups had similar values at baseline (T0) and exhibited the same progression at T1, T2, and T3. None of the between-group analyses produced significant results (Table 5, <http://links.lww.com/BRS/B207>).

DISCUSSION

The main conclusion to be drawn from this small-scale pilot study is that we need to redesign the intervention before launching a full-scale study. The applied intervention represents a major effort that placed strain on both the multidisciplinary clinic, particularly the study physiotherapists, and the participating patients. The comprehensive and long-lasting intervention could also potentially have contributed to increased sick leave duration because participation required individuals to be physically present during the day. An intervention that is better structured and less time-consuming must be designed and implemented in a full-scale trial.

A more effectively integrated inclusion and randomization procedure is required. Thus, the invitation to GPs to refer patients with CLBP to the multidisciplinary clinic should preferably include a compact and structured application form that collects mandatory information, such as the duration of low back pain, employment status, the imminent risk of ending up on sick leave, and whether the patient is already on part-time or full sick leave. A structured interview by phone at randomization might also ensure better data quality at study onset. An early assessment of accurate information relevant to the study might shorten the time to inclusion and speed the randomization procedure.

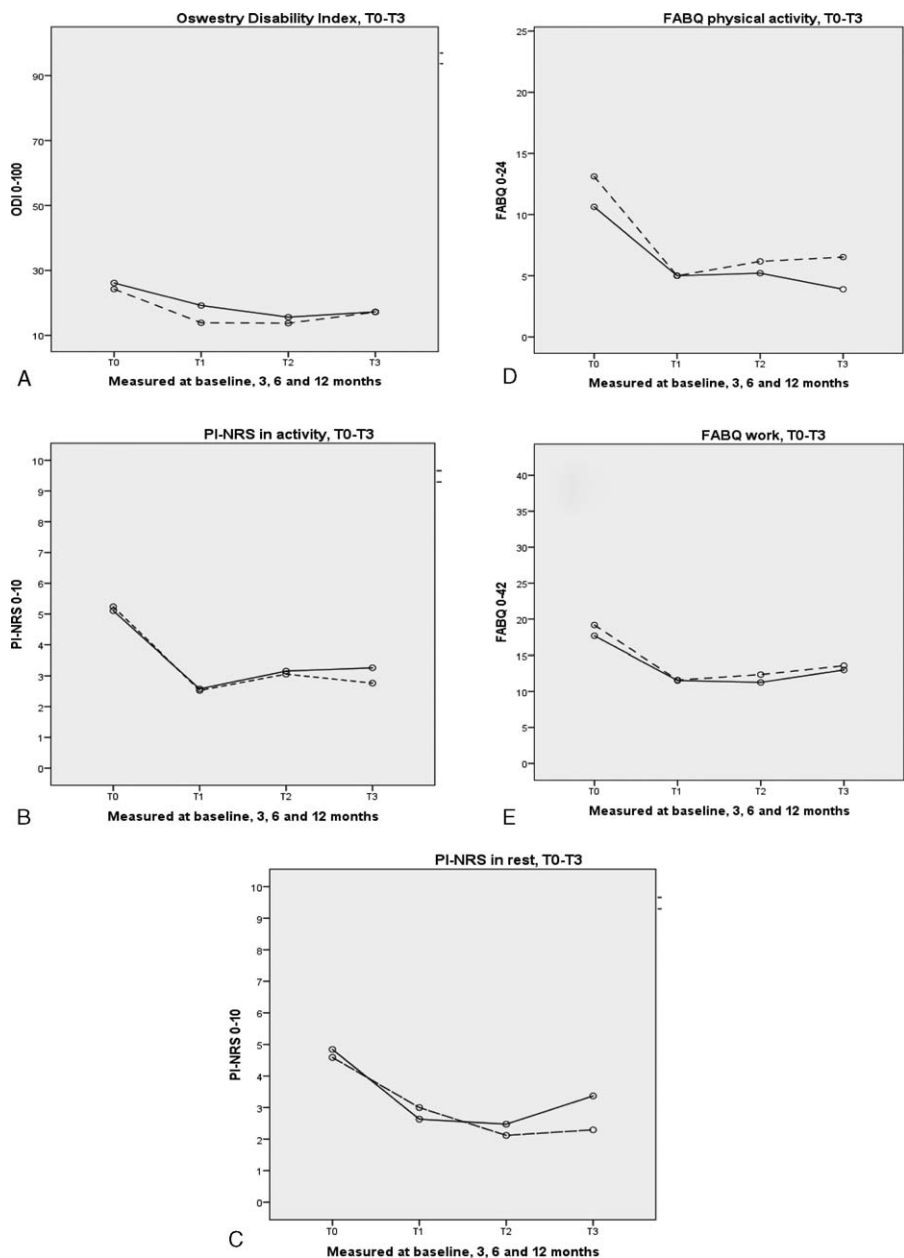


Figure 2. Secondary outcomes. (A) Oswestry Disability Index (ODI); (B, C) Pain Intensity—Numerical Rating scale (PI-NRS) in activity and rest; (D, E) Fear Avoidance Beliefs Questionnaire (FABQ) in physical activity and at work. Stippled line = waiting list; drawn line = early intervention.

Eventually, this approach will lead to clearer distinctions between the EI group and the ordinary WL group.

A more precise definition of RTW, such as a definition that specifies the number of days that an employee must be continuously present at work to qualify as a true RTW, must also be included in an upcoming trial. A clearly defined and preferably standardized measure for RTW is required when sick leave is not applicable, although RTW and sick leave are regarded as interchangeable in Norway. A formal cooperation with NAV might not only reduce loss to follow-up but also better ensure data quality regarding sick leave and could thereby improve the quality of a larger study.

In this pilot study, we found that EI did not lead to earlier RTW. Specifically, EI directly compared with the ordinary WL did not significantly affect the number of sick leave days

after 12 months of follow-up. Few studies have examined how waiting time affects RTW; instead, most research on this topic has focused on how different treatments affect RTW.^{8,15–20}

The tendency observed in our results corroborates a Norwegian governmental report⁶ that found a reduction of only 4 days in sick leave when patients received earlier treatment. Our results at 12 months of follow-up are also comparable with the median duration before RTW in an intervention study treating patients with neck pain and low back pain.²¹

Ten participants (25%) were still absent from work after 12 months. In addition to the reported general improvement in both groups, as in this study, the Norwegian sickness benefit system may influence these results and thus influence

the rate of RTW. If one is absent from work for more than 12 months in Norway, sick leave with full pay is altered to 66% coverage of income. Such an economic incentive may increase the motivation to RTW full-time. The Norwegian sick leave system²¹ may also have an impact on a “safe” economical sick leave situation during the first year that might influence motivation to RTW.

We chose to obtain sick leave information by self-report. However, self-reported sick leave may reduce the validity of the results²²; research has identified a degree of underrepresentation in self-reported information relative to database information, particularly if the information in question is obtained after the relevant absence period.²³ Nonetheless, a Swedish study concluded that self-reporting was sufficient for clinical trials.²³ We sought to improve on typical self-reporting by creating a leaflet to encourage continuous registration instead of only at follow-up time points. One weakness of utilizing national databases to obtain sick leave information is that the reasons for taking sick leave are not adequately registered in these databases.^{20,24} It is known that CLBP has a fluctuating course; thus, we chose to register part-time sick leave, which provided us with a more nuanced picture than that obtained by research that only distinguishes between full-time work and full-time sick leave.^{17,25,26}

Baseline characteristics were similar in both groups, demonstrating that the WL group remained stable during the waiting period. Nevertheless, it is notable that although we did not record clinical function at randomization, the WL group exhibited more rapid improvement than the EI group with respect to function and RTW.

The waiting time did not influence functional improvement, as demonstrated by the fact that the ODI scores in the WL group and the EI group were quite similar both clinically and statistically (Table 5, <http://links.lww.com/BRS/B207>). One recent study supports our findings in a population experiencing acute low back pain,²⁷ showing no significant differences in improvement of function, pain, or fear-avoidance beliefs in an EI group compared with usual care after 1 year.

Our treatment could be defined as a multidisciplinary treatment,^{15,28} which is recommended when RTW is the primary outcome.^{28,29} However, the ultimate intensity of multidisciplinary treatment remains under discussion.^{8,19,28} One recent study reported²⁰ that both brief and multidisciplinary treatments were effective, although in different subgroups. In those without work-related yellow flags,⁴ the brief intervention was sufficient, while approximately one-third of the group showed better outcomes as a result of participating in multidisciplinary treatment. With the high overall job satisfaction in both our groups, the intervention may have been somewhat too intensive. Treatment aiming at work participation rather than physical improvement is also debated when measuring RTW. However, several recent studies have found that work-specific interventions are not preferable when RTW is the main outcome.^{21,24,30}

The strength of this study is a long-term follow-up period, which made it possible to register subsequent relapses and the process of RTW over a period of time, a process described as long and complex.³¹ We have taken into account the importance of part-time sick leave, which resulted in more nuances for the RTW process and how the patients experience CLBP over a period of time; this is considered the strength of self-reports.⁷ We achieved complete follow-up in 75% of the patients, which is considered good when using self-reporting measurements.

We chose an open study design because blinding proved impossible. To ensure ample detachment, the randomization was performed by an independent institution. The randomization key was withheld from the researchers until publication.

The CLBP population is characterized by different influencing factors that contribute to the further development of disability and to RTW.¹⁶ Research examining sick leave in this group is challenging. In our planned full-scale study, we intend to include a larger population to increase the reliability of our results. Health economic outcome measures may also be included in this full-scale study.

➤ Key Points

- We performed a randomized, controlled, single-center pilot study to assess the feasibility of a full-scale study.
- We assessed persons with chronic low back pain attending a comprehensive back school program.
- We learned from the pilot study that the sample size must include at least 382 patients.
- A redesign of the intervention combined with improved inclusion and randomization procedures and a more stringent definition of return to work is mandatory before launching a full-scale trial.

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