

Paper III

***Motivating disability pensioners with back pain to return to work –
A Randomized Controlled Trial***

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Short title: Returning disability pensioners to work

J Rehabil Med

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Abstract

Objective: To investigate the outcome of a brief vocational-oriented intervention aiming to motivate disability pensioners with back pain to return to work.

Design: A randomised controlled trial was conducted.

Subjects: Participants (n=89) (mean age: 49 years, 65% women) who had received disability benefit for more than 1 year were randomised into an intervention group (education, reassurance, motivation, vocational counselling, n=45) and a control group (n=44).

Methods: Primary outcome measures were return to work or having entered a return to work process. Secondary outcome measures were life satisfaction, disability, fear avoidance behaviour and expectancy. Prognostic factors for having entered a return to work process were evaluated.

Results: The intervention had no statistically significant effect on return to work or having entered a return to work process at 1-year follow-up. Twice as many in the intervention group (n=10, 22%) had entered a return to work process compared to the controls (n=5, 11%). The number needed to treat was 9. Only minor differences in secondary outcome measures were demonstrated. Positive expectancy, better physical performance and less pain were related to return to work.

Conclusion: The effort of returning disability pensioners back to work by a brief vocational-oriented intervention may be of clinical relevance. The effect needs to be further explored in larger samples of disability pensioners.

Key words: randomized controlled trial, return to work, disability pensioners, low back pain, vocational-oriented rehabilitation

Introduction

Throughout the western world, disability pension (DP) has become an increasing economical and social concern (1-3). The financial consequences are huge, reaching € 5.2 billion by 2004 or 2.5 % of Gross National Product in Norway alone. In addition, loss of work due to disability puts a burden on each individual affecting economic security, social standing and self respect (4, 5).

Low back pain is one of the most common conditions leading to early retirement on medical grounds (6), representing 15% of all disability pensioners in Norway in 2004 (7). The chance of returning to work after sick leave due to back pain has been shown to steadily decrease over time (5, 8). Returning to work after becoming a disability pensioner is even more unlikely (7, 9). Still, disability pensioners might be considered a work power reserve with a considerable production potential. The possibility of returning disability pensioners back to work is an issue of great concern throughout the western world (10). During the last decade, the Norwegian government has made several efforts to reduce the increasing number of disability pensioners, by introducing economic incentives and by inviting disability pensioners to participate in projects aiming for a return to work (11).

Only few studies have examined the effect of rehabilitation programmes aiming to get disability pensioners with back pain to return to work (12, 13), while many intervention studies have addressed this issue in sick-listed workers still employed. Waddell & Burton (12) suggest that rehabilitation programmes should include health-related, personal or psychological and social or occupational dimensions according to a biopsychosocial model. In such a model, the identification of obstacles for a return to work is crucial. To our knowledge no prior randomised controlled studies have been conducted, addressing return to work in

disability pensioners. In a non-controlled setting, Watson et al. (13) conducted a study to investigate the effect of a vocational-oriented rehabilitation programme aiming to return disability pensioners with back pain to employment. In this programme, nearly 40% of those enrolled eventually became re-employed in the course of 6 weeks (12 sessions). The authors were unable to demonstrate predicting factors for a successful return to work except that long duration of unemployment was shown to be associated with failure to make positive progress towards work. However, their study did not include a control group, making general conclusions uncertain.

Predictors for returning to work have not yet been elucidated in disability pensioners with back pain. The pensioners have by definition at least 50 % reduced working ability to pain and physical limitations. In a previous study, pain and poor physical function were found to be negatively related to return to work in patients on long-term sick leave due to back pain (14). In a 2-year follow-up study of patients on sick leave due to back pain, low self-assessed work ability predicted longer time to return to work (15). A recent review of prognostic factors of a similar patient group conclude that psychological, social and economical factors are important for returning long-term sick-listed to work (16). A positive expectancy for outcome has also been shown to predict a return to work in these patients (17).

DP may be self-perpetuating even if the underlying condition improves. To stay out of the work market for a long time makes it difficult to re-enter. A vocational-oriented intervention offered on a voluntary basis might, however, be helpful to get into a process of returning to work. A randomised controlled study was designed to evaluate the effectiveness of a brief vocational-oriented intervention programme, the primary outcome being return to work or having entered a process of returning to work. We also wanted to evaluate the effect of the

programme on functioning, fear avoidance beliefs, life satisfaction and on belief in a return to work in the future. Furthermore, we wanted to examine whether physical performance, self-assessed work ability, emotional distress, fear avoidance beliefs and expectancy could predict return to work.

Materials and methods

Selection and recruitment

Eighty-nine individuals (65% women) receiving DP due to back pain participated in the study. Mean age was 49.0 years (SD=5.4) ranging from 36 to 56 years. Eligible for the study were all individuals on DP due to back pain in the county of Hordaland, Norway (n=431), being under 56 years of age and having received full disability benefit payment for more than one year (Fig. 1). The disability pensioners (n=431) were identified through the National Insurance Administration. All received written information about the project before they were invited to participate. It was emphasised that the primary goal of the study was to make a survey of functioning and health status in disability pensioners with chronic low back pain who had been out of work for some time, and secondly, based on these findings, conduct a brief vocational-oriented intervention. It was underscored that everyone was welcome to participate, whether they believed that they would eventually return to work or not. The study was approved by the Norwegian Ethics Committee for Medical Research, Health Region west and performed according to the Helsinki Declaration.

Design and randomisation

A randomised controlled trial was conducted. The participants were randomised into an intervention group (n=45) or a control group (n=44). The method of concealed random allocation was used. Simple randomisation was conducted by a computer-generated random

list. Blocks of ten were used to produce the list to ensure equal treatment numbers. No one in the clinical team was aware of the block size and could therefore not predict the group assignments. An independent assistant with no prior knowledge of the participants and with no involvement in the treatment performed the randomisation.

Procedure

A comprehensive questionnaire, part 1, was mailed to all participants. Before randomization, 70 of 89 participants underwent physical testing, and were thereafter asked to answer a second part of the questionnaire (Fig. 1). The questionnaire was mailed to the participants (n=19) who did not attend the physical testing. Based on the results of the physical testing, each participant received individual guidance of how to improve their physical fitness. Evaluation of physical functioning based on physical performance tests is not the focus of the present study. Only 29 of the participants (64%) in the intervention group completed the intervention programme (Fig. 1). Reasons given for dropping out were health complaints (n=3), lack of motivation (n=7), attending other rehabilitation programmes (n=4) or waiting for further medical treatment (n=2). Outcome was assessed by a follow-up questionnaire which was mailed to the participants one year after intervention and collected register data from the National Insurance Administration Offices.

Intervention

The intervention programme consisted of 2 sessions lasting for 3 h each, two or three days apart, and was organized in groups of 5 to 11 persons. The programme included 2 h lectures related to spinal problems, focusing on pain mechanisms and aiming to reduce fear avoidance beliefs related to activity and work. Another part of the programme involved 3 h motivational interviewing (18) aiming to help the participants to focus on their strength and capacity. They

were encouraged to identify barriers for returning to work and to look for possible solutions for a successful return to work. In addition, 1 h information by counsellors from the social insurance office and work office was provided, and accessible options for combining health-adjusted work and disability benefit were outlined. After the group sessions the participants were offered individual follow-up by a physician and a nurse including a medical examination and assessment of their work ability. Twenty-five of 29 participants accepted the offer. They were also given appropriate motivation to consider work again. The participants, who were motivated to try out for work after this intervention, were followed up by a counsellor from the work office, with the aim of entering specific work-related training.

Measures

Socio-demographic data were collected concerning age, marital status, years of education, years out of work, life style and sleep. Several self-report questionnaires dealing with pain and physical and mental functioning was filled in by the participants at baseline before the intervention and 1 year after, and performance data of physical tests were recorded at baseline.

Self-reported instruments

Numeric Rating Scale (NRS; scale 0-10) was used to assess present *pain intensity* (19).

Roland Morris Disability Questionnaire was used to assess disability in *daily function* (20).

Norwegian Functional Scale was used to assess *work related function* (21).

Work ability was rated on a 5-point ordinal scale by answering the question: "To what degree is your ability to perform your ordinary work reduced today?"

Fear Avoidance Beliefs Questionnaire was used to assess *fear avoidance beliefs* for physical activity and work (22).

Life satisfaction was assessed by Cantrils Ladder Scale, a 10-point vertical numeric rating scale (23).

Hopkins Symptom Checklist was used to assess *emotional distress*. A person is considered in need of treatment if the mean rating is ≥ 1.75 (24).

Expectation of return to work was rated on a 3-point scale by the question: "Do you believe that you will ever be able to return to work?" Answer categories were: "Yes", "No" or "Do not know".

Being in a return to work process was rated on a 3-point scale by the question: "Have you succeeded in returning to work?" Answer categories were: "Yes", "No" and "Still in the process".

Physical performance tests

Back Performance Scale is a physical performance measure, giving a sum score of 5 activities requiring *dynamic mobility of the trunk* (Sock test, Pick-up test, Roll-up test, Fingertip-to-floor test, Lift test) (25, 26).

Outcome

Primary outcome of the intervention programme was return to work measured by register data from the National Insurance Offices and self-report data of being in a process of return to work defined as being on educational course or being in work training at 1 year follow-up.

Return to work was defined as reduced disability benefit payment (less than 100%).

Secondary outcome measures were life satisfaction, daily and work-related functioning, fear avoidance for physical activity and work and belief in return to work.

Statistical analysis

Comparisons of change between intervention and control groups were examined by t-test for independent samples. Data was obtained from National Insurance Offices in the period from April 2004 to August 2005. Differences in disability benefit payments between intervention and control groups and between participants and non-attendees were examined by counting. Relative Risk (RR) for having entered a return to work process was calculated. Differences between participants and non-attendees were examined by independent samples t-test for continuous data and Chi-Square test for categorical data. Logistic regression analysis was used to identify possible predictors at baseline for having entered a process of returning to work (dependent variable) after 1 year. All variables were dichotomised using the median score as the split point. An exceptions was belief in return to work which was divided between “yes” in one group and “no and do not know” in the other. All potential predictors were examined using univariate logistic regression analysis. The potential predictors were also analysed by either adjusting for age and gender or group allocation.

Results

There were no differences between the intervention and the control groups in baseline characteristics (Table I).

Comparisons of participants and non-attendees

There were no statistically significant differences in gender ($\chi^2=2.7$, $p=0.10$), age ($t=-1.4$, $p=0.15$) and number of years out of work ($t=-0.29$, $p=0.77$) between those who participated in the study and those who did not ($n=342$).

Change in return to work status at 1 year follow-up

No significant differences in return to work were found between the intervention and the control groups. Reduction in disability benefit payment (less than 100%) during the study period was registered in 2 participants (4%) in the intervention group, and one of them had still reduced payment at 1-year follow-up (2%). In the control group 2 participants had reduced payment during the study period and also at 1-year follow-up (4.5%). The reductions ranged from 4 to 42%. After 1 year, 10 participants (22%) in the intervention group and 5 (11%) of the controls reported to have entered a process of returning to work (RR=1.96 (0.73-5.26). Power calculation demonstrated that this difference only gave a power of 19%. However, the Absolute Risk Reduction was 11, and number needed to treat was 9. Among the non-attendees, only 4 individuals (1%) had reduced disability benefit payment during the study period and at 1-year follow-up.

Change in secondary outcomes from baseline to 1-year follow-up

Only minimal changes in secondary outcomes were registered between groups from baseline to 1-year follow-up (Table II). An exception was life satisfaction which had improved significantly more in the control group. There was no difference between the groups in belief in returning to work ($F(3,68)=0.33$, $p=0.81$).

Predictors for being in a process of return to work

The disability pensioners who at baseline had positive expectancy, less pain and better physical performance were most likely to have entered a return to work process at 1 year follow-up (Table III). When adjusting for age and gender, odds ratio for fear avoidance for work was high and significant (OR=10.6, 95% CI=1.5-78.1), while pain (OR=5.5, 95% CI=1.1-13.6) and belief in returning to work (OR=10.5, 95% CI=2.4-44.5) showed higher

odds ratios. Physical performance showed unchanged odds ratios. When adjusting only for group allocation, the prognostic factors remained the same as for the univariate analysis.

Discussion

The main goal of this project was to investigate the effect of a brief vocational-oriented intervention, aiming to help disability pensioners with low back pain back to work. A higher percentage of those who participated in the study had reduced benefit payment during the study period compared to non-attendees. Two individuals in the intervention group as well as in the control group had reduced disability benefit payment during the study period. However, twice as many (n=10) in the intervention group were engaged in some “work-related” activity compared to the control group (n=5), although this difference was not statistically significant. We were not able to demonstrate effectiveness by the intervention on life satisfaction, functioning or fear avoidance behaviour.

To help disability pensioners becoming re-employed after years out of work is considered very difficult to achieve (7, 9, 27). Although the positive outcome from the vocational-oriented intervention was modest, it may still be of practical relevance. The economical advantage of re-employment is so great that only a small yield might be considered a success. The number needed to treat in our study was 9, meaning that 9 disability pensioners need to receive the intervention for each person having entered a return to work process. The power was only 20%, but the observed difference was less than the difference assumed for the sample size calculations.

It has been claimed that rehabilitation programmes should focus on identifying each individual’s barriers for returning to work, taking biological, personal/psychological and

environmental/social issues into consideration (12). In our study we did encourage all participants to focus on their strengths and capacities, but for people who have been out of work for years, these factors might take longer time to identify and realize. The intervention offered in our study was relatively brief and inexpensive. Brief intervention programmes have been demonstrated to be superior to more comprehensive programmes in employed patients sick-listed with back pain (28). In Watson's non-controlled study (13), all components of the intervention were exclusively directed toward return to work and to improvement of work ability which was interpreted as the main reason for success. Since we also included pensioners not motivated to return to work and our participants were not given individually adjusted work task training, our approach might have been too general and not focused enough. However, due to differences in designs and participants between Watson et al. (13) and our study, the results are not comparable.

Our intervention did not have any effect on function, belief in returning to work or fear avoidance beliefs. Only the control group reported improvement in life satisfaction 1 year after intervention, and the improvement was significantly higher compared to the intervention group. Being subjected to an active intervention and pulled out of the safety net that the DP represent, might be perceived as a stressful event and explain why the intervention group did not improve in life satisfaction.

Studies of this kind are often affected by self-selection and our study is no different. All disability pensioners that fulfilled the inclusion criteria were invited to the study, and only 18% believed that they would be able to return to work eventually, indicating that the prognosis was low for return to work for several of the pensioners. One might speculate that some of the pensioners invited into our study would hesitate to participate because they had

fear of being found fit for work, and thereby risk losing their disability benefit (29). Norway's relatively generous disability benefit gives most pensioners a satisfactory financial situation and might discourage return to work for a marginal improvement of income (30).

Timing of the intervention is proven to be important to succeed in returning patients with long lasting back pain to work. It is suggested that the intervention should take place between 2 and 3 months after the start of work absenteeism (31). It has been claimed that people who have been out of work for longer than 2 years are unlikely to ever return (5). The length of work absenteeism was also shown to predict return to work in disability pensioners with back pain in the study of Watson et al. (13). Those who had been unemployed for longer than a mean of 4 years were less likely to have made progress toward work compared with those who had been out of work for a mean of three years. The participants in our study had been out of work for a mean of 9.5 years.

The participants in our study had considerably reduced physical and mental functioning, and they reported high pain levels. In a previous study conducted on patients on long-term sick leave due to back pain, return to work was related to improved physical function and reduced pain. Improvement from baseline to 1-year follow-up evaluation on physical performance measures and also on reports of pain was greater in patients who had returned to work compared to those who had not (14). This is supported by results of our study, as the participants with less pain and less activity limitations were most likely to have entered a return to work process at 1 year follow-up. Due to few observations and a selected group of participants, these findings should be interpreted with caution. One might still question whether the intervention should have been complemented with physical or work-related training. Recently, functional capacity training was demonstrated to decrease work-related

disability in patients on sick leave due to back pain. Both increased work capacity and self-efficacy was suggested as explaining factors (33). However, a problem for many of the disability pensioners is that they previously have gone through considerable rehabilitation efforts, but despite of this have not been able to return to work.

Positive patient expectation is demonstrated to be of great importance in vocational-oriented interventions (32). The results of a systematic literature review have indicated that patients expect to hear an explanation of their pain, advice on back pain management, pain relief and sickness absence (17). Providers of vocational oriented programmes should know about these expectations and have a defined strategy on how to meet them. Our programme might not have given these issues sufficient consideration.

Excluding patients who are not likely to benefit from rehabilitation, is essential to increase the statistical power and efficiency of an RCT (33). Knowing predictors for return to work among disability pensioners is also important for public authorities when deciding who should be included in efforts helping them return to work. The cost effectiveness of rehabilitation aiming at return to work have been shown to improve when more than 2 out of 4 prognostic tests were positive (34). The modest result in favour of a return to work process in the present study might partly be due to the fact that all disability pensioners volunteering for the study were included, also those lacking belief in a return to work. The participants with a positive expectancy for returning to work were more likely to having entered a return to work process.

This is the first RCT study evaluating a vocational oriented programme for disability pensioners. Even if this study failed to demonstrate a significant effect on return to work, indication was provided that the intervention had some positive effect on the process of

returning disability pensioners to work. Whether the pensioners who entered the process eventually returned to work, is not known. Due to the vast economical implication of returning pensioners back to work, the study indicates that brief vocational-oriented programmes might still be of practical relevance. To select participants with a positive expectation, less pain and better physical performance may increase the success rate of rehabilitation efforts. A major limitation of findings in our study is the low number of participants. Whether our sample is representative for the whole population of back pain disability pensioners in Norway may be questioned. The present study should probably be considered a pilot and feasibility study, and a larger scale study is recommended. However, to motivate for participation in vocational-oriented studies seem to be a challenging task.

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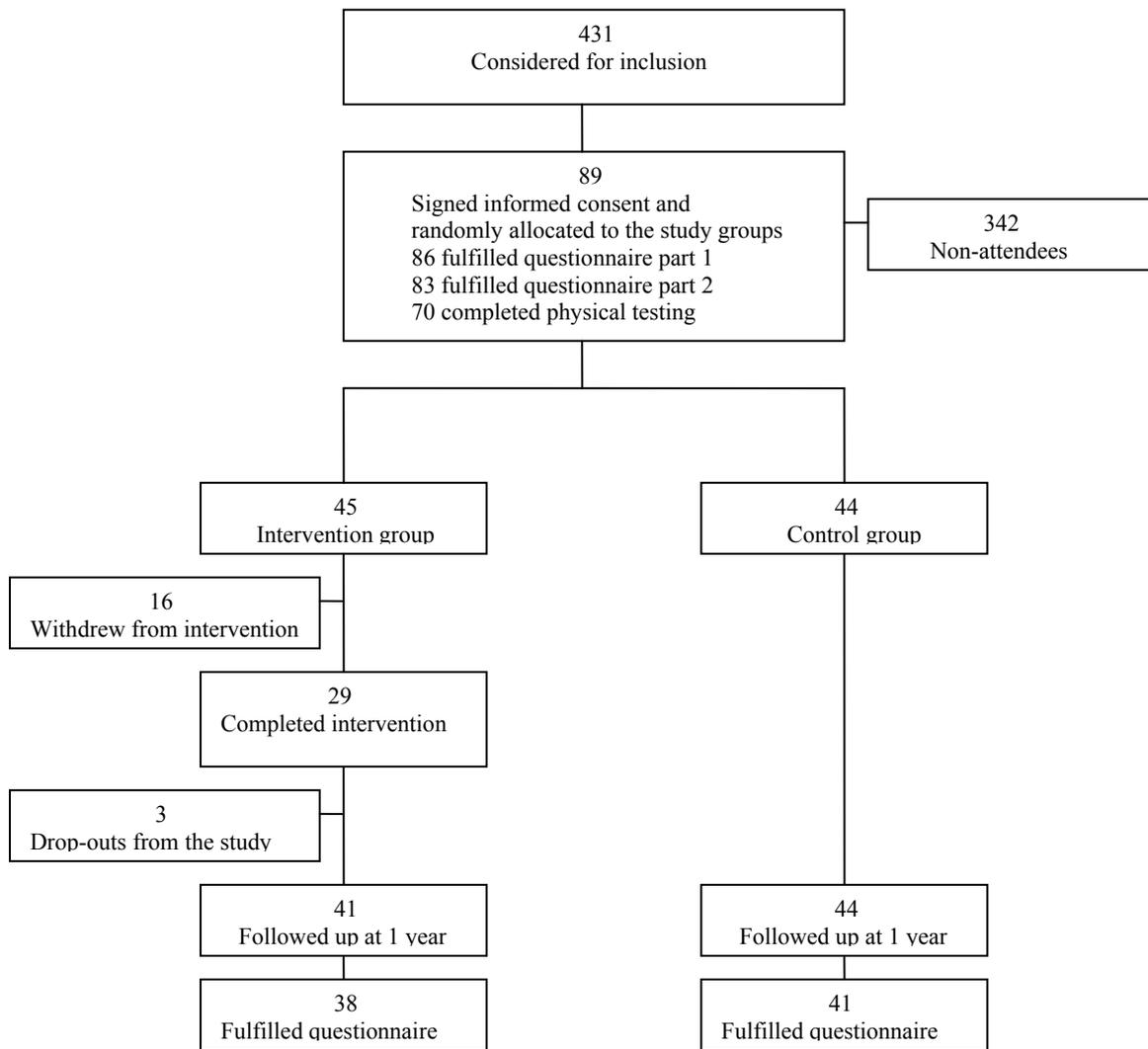


Fig 1. Recruitment and follow-up of study participants

Table I. *Baseline characteristics*

Variables	Intervention n=45	Control n=44
Age, yrs: mean (SD)	49.1 (6.4)	49.0 (4.5)
Gender, female: n (%)	26 (60.0)	30 (69.8)
Body Mass Index, kg/m ² : mean (SD)	25.1 (4.0)	26.1 (4.4)
Disability pension, years: mean (SD)	9.8 (4.8)	11.6 (5.8)
Years of education, years: mean (SD)	11.4 (2.5)	11.2 (2.2)
Highest education		
High school or less (≤ 12 years): n (%)	35 (85.4)	34 (81)
College/university (> 12 years): n (%)	6 (14.6)	8 (19)
Married: n (%)	25 (61)	31 (73.8)
Smokers: n (%)	26 (61.9)	24 (60)
Previous surgery: n (%)	21 (55.3)	22 (55)
Quality of sleep: n (%)		
Very good or good	8 (19)	7 (18)
Moderate	13 (32)	13 (32)
Bad or very bad	20 (49)	20 (50)
Work ability (1-5) ^a : mean (SD)	2.0 (0.9)	1.8 (0.9)
Physical performance tests		
Flexibility of the trunk, BPS (0-15) ^b : mean (SD)	7.3 (3.7)	7.4 (3.5)
Pain		
Numeric Rating Scale (1-10) ^b : mean (SD)	6.9 (1.6)	6.6 (1.9)
HSCL-25, total (1-4) ^b	1.9 (0.6)	1.8 (0.5)
Depression (1-4): mean (SD)	1.9 (0.8)	1.7 (0.6)
Anxiety (1-4): mean (SD)	1.6 (0.6)	1.6 (0.5)
Somatization (1-4): mean (SD)	2.2 (0.6)	2.0 (0.6)
HSCL ≥ 1.75 , n (%)	19 (47.5)	18 (47.4)

HSCL=Hopkins Symptom Checklist, BPS= Back Performance Scale,

^aHigh score indicates good health status, function or life satisfaction,

^bLow score indicates good function, * $p \leq 0.05$

Table II. Comparisons of changes in test measures from baseline to 1-year follow-up within and between groups

Variables	Intervention group (n=45)		Control group (n=44)		Group difference <i>p-values</i>
	Mean (SD)	Mean change (SD)	Mean (SD)	Mean change (SD)	
Life satisfaction (1-10) ^a					
Baseline	5.3 (1.9)		4.5 (1.6)		
1 year follow-up	5.3 (1.7)	0.1 (0.3)	5.4 (2.0)	0.9 (1.9)	0.05*
NFS (1-4) ^b					
Baseline	1.7 (0.4)		1.7 (0.4)		
1 year follow-up	1.7 (0.3)	0.0 (0.3)	1.6 (0.4)	0.1 (0.3)	0.19
RMQ (0-24) ^b					
Baseline	14.1 (3.5)		13.9 (4.6)		
1 year follow-up	14.1 (4.0)	0.1 (3.2)	13.9 (5.5)	0.1 (3.7)	0.99
FABQ-PA (0-24) ^b					
Baseline	14.9 (6.1)		13.9 (4.6)		
1 year follow-up	13.0 (5.9)	1.9 (5.3)	13.9 (5.5)	0.1 (6.6)	0.14
FABQ-W (0-42) ^b					
Baseline	30.8 (10.7)		32.2 (9.2)		
1 year follow-up	30.0 (10.2)	0.8 (9.1)	29.3 (12.0)	2.9 (7.7)	0.33

^aHigh score indicates good function, ^bLow score indicates good function

**p*<0.05 independent sample t-test, †*p*<0.05 paired sample t-test

NFS: Norwegian Functional Scale; RMQ: Roland Morris Disability Questionnaire; FABQ-PA: Fear Avoidance Beliefs Questionnaire - physical activity; FABQ-W: Fear Avoidance Beliefs - work

Table III. Odds ratios (OR) for having entered a return to work process (n=15) vs not being in a return to work process (n=64)

Variables studied	n	OR with 95% CI	
		non-adjusted	<i>P</i>
Demographic variables			
Age <50years	40	1.1 (0.4-3.5)	0.816
Male (33%)	29	2.1 (0.7-6.5)	0.213
Pain			
Pain ^b <7	34	3.3 (1.0-10.9)	0.047*
Psychological variables			
Fear avoidance for phys.activity ^b <14.8	38	1.3 (0.4-4.6)	0.673
Fear avoidance for work ^b <35	34	3.0 (0.7-12.4)	0.135
HSCL ^b <1.75	36	0.8 (0.2-2.7)	0.717
Belief in return to work	15	6.9 (1.9-24.8)	0.003*
Life satisfaction ^a ≥5	51	2.6 (0.7-10.0)	0.175
Physical performance and work ability			
Dynamic mob of the trunk (BPS ^b) > 7.5	33	5.9 (1.2-29.6)	0.032*
Work ability better than moderate	17	0.2 (0.0-1.5)	0.115

Note: Continuous variables were dichotomized using the median split, unless otherwise specified.

^aHigh score indicates good function, ^bLow score indicates good function,

HSCL: Hopkins Symptom Checklist; BPS: Back Performance Scale, **p* <0.05