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RANDOMIZED TRIAL

The Effect of Work-Focused Rehabilitation Among Patients With Neck and Back Pain

A Randomized Controlled Trial

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Study Design. Multicenter randomized trial with patients listed as sick for 1 to 12 months due to neck or back pain and referred to secondary care.

Objective. To compare the return-to-work (RTW) rate among patients offered work-focused rehabilitation or multidisciplinary rehabilitation.

Summary of Background Data. A growing number of studies have focused on the RTW processes associated with patients with back pain. Many studies have combined a workplace focus with multidisciplinary treatments; however, this focus has not been evaluated in Norway among patients with neck and back pain thus far.

Methods. A total of 405 patients who were referred to the spine clinics at 2 university hospitals in Norway were randomly assigned into work-focused and control intervention groups. The existing treatments at each hospital were used as the control interventions, which entailed either a comprehensive multidisciplinary intervention or a brief multidisciplinary intervention. The RTW rates and proportions were compared at 12 months.

Results. During the first 12 months after inclusion, 142 (70%) participants in the work-focused rehabilitation group and 152 (75%) participants in the control group returned to work. The median time to RTW was 161 days in the work-focused group and 158 days in the control group. A comparison of the work-focused and control interventions revealed a relative RTW probability (hazard ratio) of 0.94 (95% confidence interval = 0.75–1.17) after adjusting for age, sex, and education.

Conclusion. The results suggest that a focus on the workplace in specialist care does not substantially alter the RTW rate compared with standard multidisciplinary treatments.

Key words: low back pain, neck pain, multidisciplinary rehabilitation, work-focused rehabilitation, return to work, sick leave, Norway, patients, workplace, specialist care, outpatients.

Level of Evidence: 2

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Neck pain (NP) and low back pain (LBP) are among the most common disorders causing work absence and disability.[1,2] According to European guidelines, exercise and cognitive intervention reduce pain and improve functioning among patients with LBP.[3] However, these treatment modalities have had an insufficient effect on work-related disability.[4] Clinical, personal, and workplace factors might contribute to disability.[5] During the last decade, several models focusing on the return-to-work (RTW) process have been developed.[6–8] The models are characterized by the early identification of obstacles to the RTW process, combined with multidisciplinary interventions.[9,10]

Multidisciplinary treatment for LBP has a long tradition in Norway.[11–13] Both brief rehabilitation programs[11,13] and more comprehensive rehabilitation programs based on the models used in trials comparing rehabilitation with surgery[12,14] are offered.

The effectiveness of RTW interventions depends on the characteristics of the participants included as well as the setting and social context. The personal and medical factors of the patients can also influence their ability to RTW.[15] Most RTW interventions are applied within primary care and

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occupational settings.[7,8] Only a few studies have been conducted in the context of specialized care,[16,17] despite the major economic burden and individual experiences associated with these patients.[18]

The primary aim of this study was to evaluate if an RTW-focused intervention compared with multidisciplinary intervention would reduce the number of days needed before a sustainable RTW among sick-listed patients with NP and LBP in specialist health care. Second, we also wanted to evaluate whether sex, age, education, pain level, and disability influenced the effect of RTW-focused intervention.

MATERIALS AND METHODS

Design

This study was a multicenter prospective randomized controlled trial. Sick-listed patients referred to the neck and back outpatient clinics at St. Olavs Hospital, Trondheim, Norway, and Oslo University Hospital, Ulleval, Norway, were included and followed for 1 year. The participants were allocated to work-focused or control interventions.

Participants

All referred patients underwent a standardized medical examination to assess their eligibility for inclusion. To be included in the study, patients must have been between 18 and 60 years of age, employed, and have a sick-leave duration between 4 weeks and 12 months. The exclusion criteria were need for surgical treatment; cauda equina syndrome; symptomatic spinal deformities; osteoporosis with fractures; inflammatory rheumatic diseases; pregnancy; legal labor disputes; insufficient Norwegian language skills; cardiac, pulmonary, or metabolic disease with functional restrictions; and *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition)–diagnosed mental disorders.

Procedures and Interventions

Both work-focused and control interventions occurred at the neck and back clinics of their respective hospitals. All participants received a standard clinical examination from a physician. Relevant imaging was evaluated, and patients were informed about the findings and that the origin of pain is often difficult to visualize *via* imaging. Patients were reassured that daily activities, physical exercise, or work would not hurt or damage their necks or backs. Emphasis was placed on removing fear-avoidance beliefs, restoring activity level, and enhancing self-care and coping. At the time of this study, the neck and back clinic at St. Olavs Hospital used a comprehensive multidisciplinary intervention, whereas the neck and back clinic at Oslo University Hospital used a brief model; both programs were used as control interventions (Table 1).

The procedures mentioned in the previous text were also followed for the work-focused intervention; however, additional focus was placed on the RTW process (Table 1). The patients received individual appointments with the caseworker during the first days of treatment. Work histories, family lives, and obstacles to RTW were discussed. The caseworkers contacted participants' employers by phone in most cases (unless the patient refused) to inform them of the program and inquire about possible temporary modifications at work. The patients created a RTW schedule together with the caseworker and the multidisciplinary team. The patients and the caseworkers also discussed relevant issues for a meeting with the employer. The caseworker offered the patients assistance at this meeting, if requested. If sick-leave compensation was an issue, the caseworkers contacted municipal social services. The medical records and RTW schedules were sent to participants and their general physicians, who managed the patients' sick-leave certificates.

Primary Outcome

RTW was defined as the first 5-week period after random assignment that the patient did not receive sickness benefits, a work assessment allowance pension, or a disability pension from the Norwegian Labour and Welfare Administration. The 5-week duration was chosen because of the Norwegian holiday, which lasts 5 weeks. RTW was designated when patients receiving a partial disability pension prior to inclusion returned to their partial disability status.

TABLE 1. The Contents of Work-Focused and Control Interventions

	Work-Focused Intervention		Control Intervention	
	Oslo	Trondheim	Oslo	Trondheim
Team	Multidisciplinary Health Care Professionals			
	Caseworker	Caseworker		
Total duration of intervention, wk	3	3	3	3
Sessions with physiotherapist	7	7	1–2	17
Lectures	4	5	0	8
Group discussions	0	3	0	4
No. of appointments with a medical specialist	2	2	1	2
No. of appointments with a caseworker	2 (−3)	2	0	0

Baseline Variables

Demographics, education, and profession were recorded. Intensity of pain during activity during the past week was reported on an 11-point numeric rating scale, in the range from 0 (no pain) to 10 (worst possible pain).[19] Both neck/arm pain and back/leg pain were reported, and the highest pain rating of the 2 was used in the analyses. The Oswestry Disability Index[20,21] and neck disability index[22,23] are composed of 10 items in the range from 0 to 5. The summed score is presented as a percentage, where 0% represents no disability and 100% represents maximum disability. For participants reporting disability due to both NP and LBP, the highest disability score was used in the analyses and referred to as the disability index score. Emotional distress during the previous 14 days was measured using the Hopkins Symptom Checklist 10. These 10 items were scored from 1 (not at all) to 4 (very much), and the mean was calculated and reported.[24,25] The Waddell Fear-Avoidance Belief Questionnaire (FABQ) was used to measure fear-avoidance beliefs, where each item was scored on a 7-point Likert scale in the range from 0 (strongly disagree) to 6 (strongly agree). The 7-item FABQ about Work subscale ranges from 0 to 42, and the 4-item FABQ about Physical Activity subscale ranges from 0 to 24.[26,27] High scores denote strong fear-avoidance beliefs.

Sample Size

The sample size was calculated prior to the study on the basis of the relative probability (hazard ratio; HR) of returning to work found in previous studies.[7,17] An HR of 1.7 was assumed. Given a power (1-β) of at least 0.8 and a significance level of $\alpha = 0.05$, we determined that at least 157 patients were needed for the primary outcome. We also expected a 10% attrition rate during the interventions and another 30% to not respond to the questionnaires sent at 4 and 12 months; hence, a sample size of at least 224 patients was needed at inclusion.

Randomization

Patients were informed about the study, and they provided their informed consent prior to randomization. An independent statistician generated a random block sequence stratified by hospital. The first clinical examination was double-blinded because this protocol was performed prior to randomization. After randomization, it was not possible to blind either the treatment team or participants. However, the investigators did not have access to the allocation code in the data files for each patient until the analyses were performed.

Statistical Methods

We used a survival analysis (Kaplan-Meier) to investigate the length of sickness absence and the Breslow test to compare the intervention group with the standard care group. First, we analyzed each hospital separately. As no significant differences between the interventions were found, we subsequently merged the data from the 2 hospitals into joint analyses. A Cox proportional hazards regression model was used to calculate the HR for RTW rates between the 2 treatment groups. Crude and adjusted HR was calculated for all participants included in the study (adjusting for age, sex, and education). We formed subgroups by sex, education above or below university level, and by median split of the variables; age, pain intensity, disability scores. A survival analysis and comparison of the interventions (Breslow test) inside each subgroup were performed. All analyses were performed according to the intention-to-treat principle. A significance threshold of $P < 0.05$ was adopted. Statistical analyses were performed using PASW Statistics, version 18 (IBM SPSS; IBM Corporation, Armonk, NY).

RESULTS

Participant Flow

Between August 2009 and August 2011, 3961 patients were screened for eligibility. The major reasons for ineligibility were not being listed as sick (50%), unemployed (26%), having a disorder suitable for surgery (7%), and lacking Norwegian language skills (6%). A total of 723 patients were eligible; of these patients, 310 declined to participate, usually due to distance from the hospital or because they were receiving other treatments. The remaining 413 patients were included in the study. Seven patients were excluded shortly after randomization due to not being listed as sick (n = 3), unemployment (n = 1), the need for surgical evaluation (n = 1), pregnancy (n = 1), or language issues (n = 1). One participant withdrew his consent, leaving 405 participants (Figure 1).

Noncompliance

Nine patients in the work-focused group and 17 in the control group dropped out immediately after randomization. We considered participants compliant if they met and attended at least half of the offered treatment sessions. Eleven patients were considered noncompliant in the work-focused group, and 8 in the control group. However, all 405 participants were included in the analyses. The baseline characteristics were similar between the 2 intervention groups (Table 2).

Return to Work

The analyses showed that 142 (70%) participants in the work-focused group and 152 (75%) participants in the control group returned to work within the first 12 months after inclusion. The median time before RTW was 161 days for the work-focused group and 158 days for the control group (Figure 2); this difference was not significant (Breslow test, $P = 0.45$). When comparing work-focused with control intervention, the unadjusted HR was 0.91 (95% confidence interval, 0.73–1.13), and the adjusted HR was 0.94 (95% confidence interval, 0.75–1.17). No significant differences were found in the separate site analyses (Table 3). We also compared the survival analysis at the 2 sites for the control interventions and the work-focused interventions separately, and no significant differences were found (control intervention;

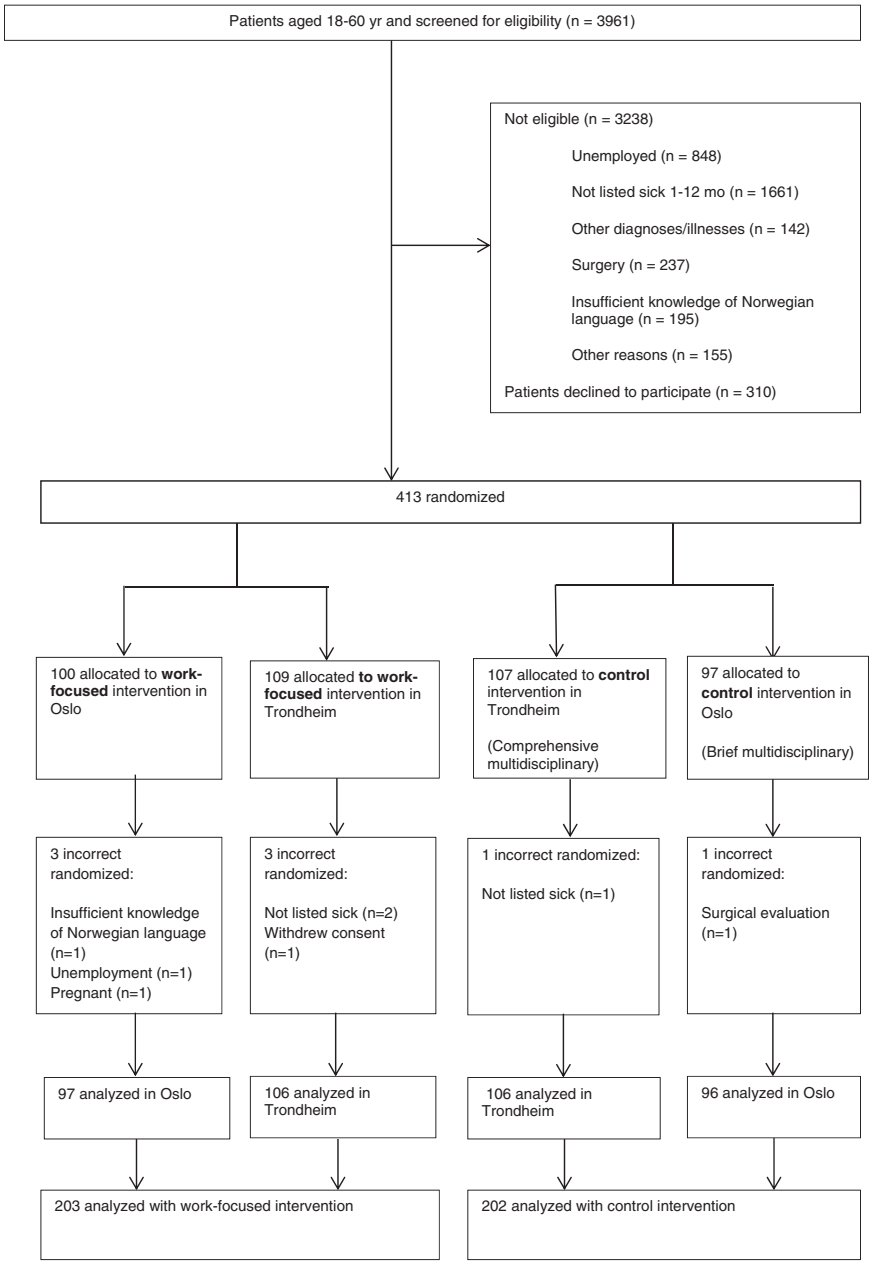

Figure 1. Patient flow chart.

Breslow test, $P = 0.87$ and work-focused intervention; Breslow test, $P = 0.15$).

The different subgroup analyses showed that the median time before RTW was significantly briefer in the control group than in the work-focused group (132 *vs.* 177 d, $P = 0.03$) within the subgroup "age above 41 years." No further significant differences were found in the other subgroup analyses. The median total sick-leave days at the 12-month follow-up evaluation were 117 days for the work-focused group and 107 days for the control group.

DISCUSSION

This study found that a work-focused intervention did not have additional effects on the RTW rate compared with a control intervention.

Comparison With Other Studies

This study documented a similar RTW percentage at a 12-month follow-up assessment as found in previous Norwegian studies of multidisciplinary interventions targeting sick-listed patients with subacute back pain.[11,13,28] However, the control groups in primary care previously achieved lower RTW rates.[11,13]

Studies in Canada and the Netherlands[7,8,17] have demonstrated positive effect on RTW of workplace-interventions compared with usual care. However, Loisel[29] requested that future RTW research should focus on intervention development rather than comparisons with usual care because the latter is "clearly known to be ineffective." Accordingly, this study used both brief and comprehensive multidisciplinary rehabilitation (which is the recommended treatment for patients with

TABLE 2. Baseline Characteristics

Variable	Control	N	Work-Focused Intervention	N
Females, no. (%)	98 (48.5)	202	90 (44.3)	203
Age, mean (SD), yr	41.0 (10.0)	202	40.2 (9.7)	203
Norwegian mother tongue, n (%)	153 (76.5)	200	162 (79.8)	203
Married or living with partner, n (%)	143 (71.5)	200	141 (69.5)	203
Having children, n (%)	150 (75.4)	199	152 (74.9)	203
Education, n (%)				
Primary school	34 (17.1)	199	30 (14.8)	203
Vocational high school/general secondary school	105 (52.8)	199	123 (60.6)	203
College/university <4 yr	36 (18.1)	199	32 (15.8)	203
College/university >4 yr	24 (12.1)	199	18 (8.9)	203
Occupational categories, n (%)				
Low-skilled blue-collar job	32 (15.9)	201	37 (18.2)	203
High-skilled blue-collar job	41 (20.4)	201	46 (22.7)	203
Low-skilled white-collar job	75 (37.3)	201	64 (31.5)	203
High-skilled white-collar job	53 (26.4)	201	56 (27.6)	203
Smoker, n (%)	59 (29.9)	197	59 (29.5)	200
BMI, mean (SD), kg/m^2	27.1 (5.0)	163	26.9 (4.7)	176
Physical activity during 1 wk: Sedentary patients, n (%)	25 (12.9)	194	24 (12.0)	200
NRS pain in activity, mean (SD)	6.2 (2.2)	190	6.1 (2.3)	194
ODI/NDI score, mean (SD)	38.2 (12.9)	199	38.6 (13.7)	200
HSCL-10, mean (SD)	1.95 (0.6)	197	2.04 (0.6)	196
BQ-PA, mean (SD)	13.8 (5.7)	195	13.8 (5.6)	197
FABQ-W, mean (SD)	26.7 (10.1)	194	28.6 (9.8)	194
Off-work period before inclusion, last episode, median (interquartile range), d	115 (71–189)	202	109 (69–168)	203

BMI indicates body mass index; NRS, numeric rating scale; ODI, Oswestry Disability Index; NDI, neck disability index; HSCL, Hopkins Symptom Checklist; FABQ-PA, fear-avoidance belief questionnaire physical activity; FABQ-W, fear-avoidance belief questionnaire work; SD, standard deviation.

chronic LBP) as a control intervention. Approximately identical effects of work-focused and control interventions have also been demonstrated in Denmark.[16]

The median number of weeks before RTW in this study was 23. With an exception,[11] this time frame is considerably longer than that of previous studies.[7,8,16,17] However, most of these studies have examined participants with subacute LBP recruited from primary care. With a typical sick leave of 4 months prior to entering the study, our sample frequently exhibited chronic neck and back pain; hence, they had a higher risk of prolonged disability and sick leave.[18] Loisel *et al*[10] found a mean program duration of 13.8 weeks before RTW among patients with chronic musculoskeletal disorders. However, 22% of study participants were discharged before program completion because RTW was not deemed to be attainable. Thus, these results are not directly comparable with those of our study. In the Netherlands, Lambeek *et al*[17] demonstrated positive effects of integrated care for patients with chronic LBP recruited from secondary care. The median time before RTW was 13 weeks in the intervention group and 30 weeks in the usual care group. This intervention was scheduled for a maximum of 12 weeks and implemented outside the hospital. It included workplace visits from specially trained occupational therapists, a graded activity program delivered by regional physiotherapists, and a care manager who was responsible for co-ordination and communication among patients' caretakers.

In contrast, our intervention lasted 3 to 4 weeks. Work was the primary focus, and the employees were supported in creating their schedule for RTW. However, we did not have the authority to directly intervene at the workplace. Furthermore, following the 3-to-4-week intervention, it was

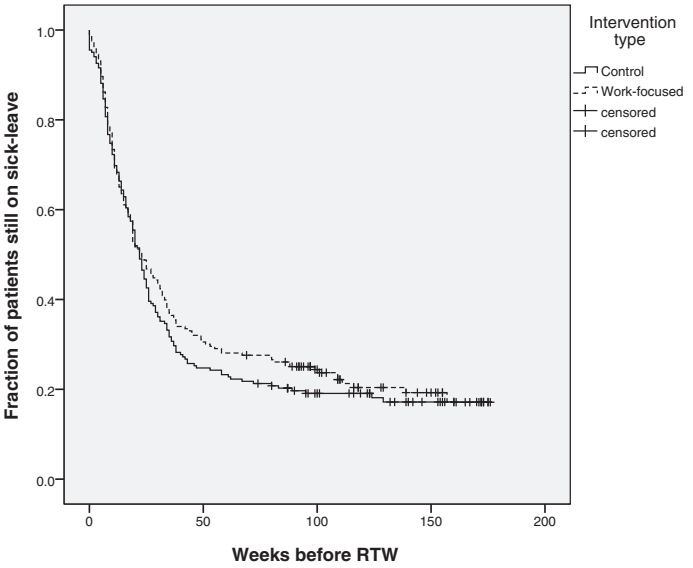

Figure 2. Survival plot from the Kaplan-Meier analysis showing the percentage of participants who returned to work during the follow-up period for both intervention groups.

the general physician who managed sick leave according to regulations in Norway. The degree to which the RTW schedule was followed in primary care should be investigated in future work.

The compensation system, health care system, and the working environment are important with regard to prolonged absences due to illness,[29,30] and these factors complicate direct comparisons of the RTW intervention effects between Norway and non-Scandinavian countries. Thus, the fact that Norway[31] has a low unemployment rate and provides full wages for the first year of sick leave might influence the effectiveness of work-focused interventions. However, with a median sick leave of 23 weeks before RTW for both groups, one might question the effectiveness of both work-focused and control interventions among this population.

This study found that participants older than 41 years benefitted more from the control intervention than the work-focused intervention. The varying effects of RTW interventions with regard to age and sex are shown.[32,33] However, no significant association between sociodemographic factors and the RTW rate is found.[34] These findings most likely vary across populations and social contexts.

Strength and Limitations

The strengths of this study are its randomized design, large sample size, complete follow-up data achieved by the use of national databases, and intention-to-treat analysis.

Surely, the use of 2 locations is a strength to the study. Yet, because of different existing treatment facilities at the 2 hospitals, it was not feasible to obtain similar control intervention in the study. As the similar effectiveness of these treatment programs is shown in,[16,33] this is assumed to increase the external validity of our results. In addition, even the work-focused interventions vary in implementation. However, the RTW process and the use of caseworker were the main focus

TABLE 3. Outcome for the 2 Sites; Trondheim and Oslo

	Trondheim		Oslo	
	Control	Work-Focused Intervention	Control	Work-Focused Intervention
Patients with RTW within 12 mo, n (%)	80 (75)	69 (65)	72 (75)	73 (75)
Kaplan-Meier				
Median no. of days until RTW	157	176	158	150
Breslow test *P*	0.178		0.750	
Cox proportional hazards regression model				
Unadjusted				
HR	0.78		1.08	
95% CI	0.57–1.06		0.79–1.47	
P	0.11		0.63	
Adjusted for age, sex, and educational level				
HR	0.76		1.15	
95% CI	0.56–1.04		0.84–1.57	
P	0.085		0.40	

RTW rate indicates return-to-work; HR, hazard ratio; CI, confidence interval.

of the work-focused intervention, and we put emphasis on this implementation to be alike. However, this is a limitation that certainly makes it more difficult to interpret the comparisons.

Another limitation might be that both the control and intervention groups received thorough clinical examinations in specialist care. These examinations might have been sufficiently reassuring for some patients, thereby impeding the detection of RTW differences.

Our analyses defined RTW as working for at least 5 weeks. Although other studies have used 4-week periods,[8,16,17] our choice was based on the Norwegian holiday, which lasts 5 weeks.

Clinical Value

The results of this study suggest that focusing on the workplace in specialist care does not result in additional effects with regard to the RTW rate. Palmer *et al*[35] systematically reviewed the effectiveness of community- and workplace-based interventions to reduce sickness absence and job loss. They concluded that most interventions are beneficial, but the effects were small, especially among large and high-quality studies. In addition, no intervention is clearly superior to another; however, effort-intensive interventions are less effective than simple programs.

Consequently, multidisciplinary work-focused treatment programs should most likely not be implemented for all patients with LBP and NP. This idea is supported by Haldorsen *et al*[36] and Stapelfeldt *et al*,[34] who found different effects with regard to the RTW rate using subgroup analyses based on a prognosis score instrument or psychosocial job factors.

CONCLUSION

The results of this study suggest that specialist health care focusing on the workplace does not result in additional effects with regard to the RTW rate compared with standard multidisciplinary treatments.

➢ Key Points

- ❑ A work-focused intervention did not have additional effects compared with a standard multidisciplinary intervention regarding the RTW rate among sick-listed patients for neck and back pain.
- ❑ During the first 12 months after inclusion, 73% of the participants had returned to work.
- ❑ The majority of the participants had chronic neck or back pain, and the median number of weeks before RTW in this study was 23 for both work-focused and control interventions.

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Authors Kjersti Myhre, MD, and Gunn Hege Marchand, MD, contributed equally to this work; therefore, both should be regarded as first authors.

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