Spine

SPINE Volume 46, Number 6, pp 347–355

RANDOMIZED TRIAL

Early Occupational Intervention for People with Low Back Pain in Physically Demanding Jobs: 1-year Follow-up Results of the Randomized Controlled GOBACK Trial

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Study Design. Randomized controlled trial with 1-year follow up.

Objective. The aim of this study was to assess whether people with low back pain (LBP) and self-reported physically demanding jobs, benefit from an occupational medicine intervention, in addition to a single hospital consultation and a magnetic resonance imaging, at 1 year of follow-up. Secondly, to examine whether the positive health effects, found in both groups at 6 months, persist at 1-year follow-up.

Summary of Background Data. The prevalence of LBP is high in the working population, resulting in a substantial social and economic burden. Although there are many guidelines available on the management of LBP, including multidisciplinary biopsychosocial rehabilitation, they provide limited guidance on the occupational medicine aspects.

Methods. As reported previously, 305 participants with LBP and self-reported physically demanding jobs were enrolled in the randomized controlled study and randomly allocated to clinical care with additional occupational medicine intervention or clinical care alone. Data were collected at baseline, 6 months, and 1 year. Outcomes included in the present 1-year follow-up study are changes in neuropathic pain (painDETECT questionnaire), severity of pain (0–10 numerical rating scale), disability (Roland Morris Disability Questionnaire), fear-avoidance beliefs (FABQ), physical, and mental quality of life (short-form 36).

Results. The study showed no effect of an occupational intervention on neuropathic pain, fear-avoidance beliefs, physical and mental quality of life nor disability measured after 1 year. The positive effects found at 6 months in both groups, remained at 1-year follow-up.

Conclusion. The results suggest that a thorough clinical consultation, with focus on explaining the cause of pain and instructions to stay active, can promote long-lasting physical and mental health in individuals with LBP. Therefore, additional occupational interventions could focus on altering occupational obstacles on a structural level.

Key words: 1-year follow-up, disability, fear avoidance beliefs, low back pain, mental health-related quality of life, neuropathic pain, occupational medicine, pain, physical health-related quality of life, physically demanding jobs, workplace intervention, workplace visits.

Level of Evidence: 2

Spine 2021;46:347–355

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Acknowledgment date: July 13, 2020. First revision date: September 8, 2020. Acceptance date: September 10, 2020.

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

The Danish Working Environment Research fund and the Parker Institute funds were received in support of this work. Bispebjerg and Frederiksberg Hospital is supported by a core grant from the Oak Foundation (OCAY-18-774-OFIL).

No relevant financial activities outside the submitted work.

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DOI: 10.1097/BRS.0000000000003793

Low back pain (LBP) has a lifetime prevalence ranging between 38% and 84%,[1] affecting a considerable part of the working population,[2] thus resulting in a substantial social and economic burden.[3,4] Studies have

shown that 16% of workers with LBP report sick leave due to their back pain.[5] Most LBP episodes are self-limiting, and the patients typically recover within few weeks.[6] Ongoing discomfort for >3 months increases the risk of a chronic condition which may be aggravated by nociceptive and neuropathic components.[7]

Although the specific cause of LBP is rarely known, studies have shown that high physical workload, such as heavy lifting, bending and twisting of the back, and awkward postures, are risk factors for LBP.[8,9] However, it can be difficult to assess the workload on an individual level, since people with musculoskeletal disorders have a tendency of overestimating their workload exposures.[10,11]

Biopsychosocial rehabilitation models have proven effective on the management of LBP. A recent Cochrane review concluded that multidisciplinary biopsychosocial rehabilitation for subacute LBP resulted in less pain and reduced disability, increased possibility of return-to-work, and reduced days on sick leave at follow-up.[12] There are many guidelines on the management of LBP. However, they provide limited guidance on the occupational medicine aspects. Therefore, well-conducted randomized controlled trials (RCTs) on interventions with an occupational medicine consultation, work-related evaluations, and work-place visits are needed.

This is the 1-year follow-up study of the GOBACK trial, an RCT, which investigated the effect of an occupational intervention, added to a single hospital consultation (*i.e.*, clinical examination and magnetic resonance imaging [MRI])[13] in people with LBP. At 6 months, the trial showed no significant difference between the treatment groups in terms of sick leave, but both groups showed improvements from baseline in pain, fear-avoidance beliefs, physical quality of life, and disability.[14]

At www.clinicaltrials.gov, it is registered that duration of self-assessed sick leave due to LBP would be evaluated at 1 year (NCT02015572). However, due to limited staff and financial resources, it was only possible to collect weekly assessments of sick leave the first 6 months. The decision was taken before publishing the protocol, but was further supported by the fact that the overall self-assessed sick leave found at 6 months was very low.[14]

The objective of the 1-year follow-up was to investigate the additional effect of the occupational intervention on the secondary outcomes (pain, fear-avoidance beliefs, physical quality of life, and disability) after 1 year. As an exploratory objective we also evaluated whether the positive health effects (independent of groups) found at 6 months were long-lasting.[14]

MATERIALS AND METHODS

Setting and Participants

The GOBACK trial was a single-center, open-label, parallel-group randomized controlled trial with a superiority design. The study protocol has been published elsewhere.[13] It was approved by the Science Ethics Committee (H-3-2013-161) and the Danish Data Protection Agency (DPA: 2014-41-2673) and registered on ClinicalTrials.gov: NCT02015572.

Eligible participants were aged between 18 and 65 years, had a current episode of 2 to 4 weeks of LBP and a self-reported physically demanding job. In addition, they had to express concerns about their ability to continue working (minimum 30 hours/week). Exclusion criteria were pregnancy, severe somatic or psychiatric disease, cancer or metastatic disease, treatment or referral to outside providers (*e.g.*, surgery) or contraindications for having MRI.

Participants were randomly assigned to clinical care (*i.e.*, clinical examination and MRI) with additional occupational medicine (intervention) or clinical care alone (control). Data were collected at baseline (baseline questionnaires, baseline clinical examination, and MRI), at 6 months (questionnaires, clinical examination, and registration of accumulated sick leave in full days due to LBP) and after 1 year (questionnaires, clinical examination, MRI).

All questionnaire outcomes were collected on touch screens and blinded for the assessors and the personnel performing the intervention. These patient-reported outcome measures included information on demographic and personal data, general health information, history of work-related factors, and sick leave. The clinical examination was performed by a qualified physician, who also reviewed health-related answers to questionnaires.

Intervention

The GOBACK trial aimed to investigate the effect of an early additional occupational medicine intervention.[13] Therefore, all participants received a clinical examination, an MRI with a thorough explanation of the result from the MRI, and individualized recommendations regarding active lifestyle and work life.

The additional occupational medicine intervention lasted for 3 months and included: an initial consultation, a midway consultation, and a final consultation. An initial consultation is with a specialist in occupational medicine (OP) wherein a systematic, occupational-oriented interview was conducted followed by an occupational intervention plan. If considered relevant by the OP and acceptable by the participant, an optional workplace visit with the aim to provide and gain information and give recommendations about, for example, job rotations, need for ergonomic initiatives, adjustments of work tasks, or personal assistance, was arranged. The participant and the supervisor at the workplace were responsible for implementing the agreed plan. At the initial consultation, a physiotherapist further designed a plan for 3 × 45 minute self-administrated physical activity a week. A midway consultation (after 6 weeks) is with an OP focusing on retention at/return to work. A final consultation (at 12 weeks) is with an OP evaluating the intervention and providing further guidance for the participant. A detailed description of the intervention can be found in the protocol article.[13]

Outcomes At 1 Year

Outcomes assessing pain included the painDETECT questionnaire (PDQ)[7] to identify neuropathic components and a 0 to 10 numerical rating scale (NRS)[15] to detect severity of pain. To detect back pain-related disability the 24-item Roland Morris Disability Questionnaire (RMDQ)[16] was used, whereas the Fear-Avoidance Beliefs Questionnaire (FABQ) for physical activity and work[17] evaluated fear avoidance behavior. The Short Form Health Survey (SF-36) questionnaire graded physical and mental health-related quality of life (HRQoL).[18]

Sample Size and Statistical Analysis

A prespecified sample-size calculation can be found elsewhere.[13,14] The primary analyses are based on complete cases but were also performed on the intention-to-treat (ITT) population using multiple imputation for missing data. Baseline characteristics are reported as descriptive statistics stratified per randomized group. All *P* values and 95% confidence intervals are two-sided. We did not apply explicit adjustments for test-multiplicity. Differences between the randomized groups, in outcomes from baseline to 1 year, were analyzed using two-sample *t* tests on the ITT population, as well as all complete cases and further as a per-protocol analysis (*i.e.*, restricted to participants who received a workplace visit as part of the occupational intervention). In sensitivity analyses, dropouts and potential effect modification by baseline characteristics were analyzed. The statistical analyses were carried out using SAS Studio (version 3.8).

RESULTS

The study ran from March 7, 2014 to December 17, 2016. As illustrated in Figure 1, of 573 potentially eligible participants, 326 were enrolled for baseline assessment. Of these, 305 participants were randomized to the study: 153 participants to the 3-month occupational intervention in addition to a single hospital consultation and 152 participants to a single hospital consultation alone (control). During the 1-year period, 52 participants dropped out (17% of the total participants, 26 in each group). Thirty-five participants gave no reason for dropping out, 10 mentioned lack of time due to work responsibilities, four were not able to continue due to serious health problems such as cancer, and three gave other explanations for not wanting to continue. A total of 253 participants, 127 in the intervention group and 126 in the control group, completed the questionnaires for 1-year follow-up (Figure 1). The mean age was 46.4 years (SD 10), and, as expected due to the inclusion criteria, more men than women (32%) were enrolled (Table 1).

All participants in the occupational intervention group attended the initial and the midway consultation. A workplace visit took place in 40 cases (27.2%), although it was considered relevant for 55 participants (35.9%). A fear of being dismissed from work was the main reason for declining a workplace visit. Six of the participants who had a workplace visit dropped out of the study between 6-month and 1-year follow-up.

As presented in Table 2, we found no support to any statistically significant differences between the groups in change of outcomes (pain [PDQ, NRS], fear-avoidance beliefs [FABQ], physical or mental quality of life [SF-36-PCS and MCS, respectively] and disability [RMDQ]) from baseline to 1-year follow-up. As judged by the precision around the estimates it is unlikely a type-2 error (*e.g.*, the 95% confidence interval around SF36-PCS estimate, ranging from −4.52 to 0.97). The per-protocol analysis restricted to participants who had workplace visits, showed no statistically significant beneficial effect of the intervention compared to the control group in any of the outcomes (Table 3).

Evaluating the average change (independent of groups) after 1 year, the positive effects on outcomes found at 6 months remained at 1-year follow-up in both groups (Table 4, illustrated in Figure 2).

When analyzing the dropouts, we found that they had a statistically significant lower level of pain and neuropathic pain and better mental health at baseline compared to non-dropouts. We also found the dropouts less affected by disability and fear avoidance beliefs at work, although this was not statistically significant.

DISCUSSION

This is the 1-year follow-up study of the GOBACK trial, with the aim to evaluate whether individuals with LBP, in physically demanding jobs, benefit when adding a 3-month early occupational intervention to a single hospital consultation (*i.e.*, clinical examination, an MRI, and recommendations to stay active and continue working). No statistically significant additional improvement in pain, neuropathic pain, disability, fear avoidance beliefs, and HRQoL was found after 1 year when comparing the groups. Improvements of outcomes established at 6 months remained after 1 year in both groups.

These findings indicate that a thorough clinical consultation, with focus on explaining the cause of pain and instructions to stay active, can promote long-lasting physical and mental health in individuals with LBP. This is in accordance with previous studies, which emphasize that biopsychosocial models such as the Fear Avoidance Beliefs can add to the patient's understanding of LBP.[19–22] The Fear Avoidance Beliefs model explains how catastrophizing thinking may lead to fear of physical activities and work, and therefore avoidance of these activities.[19,23] The effect of high fear avoidance beliefs is widely examined, and it is argued that higher levels of fear avoidance beliefs are related to more persistent disability and difficulty of returning to full work status.[24–26] This is in line with the findings of this study, were we found persisting improvement of fear-avoidance beliefs and reduced disability after 1 year.

In contrast to what we anticipated; the additional occupational intervention did not result in a longer lasting add-on effect in any of the outcomes. A possible explanation is

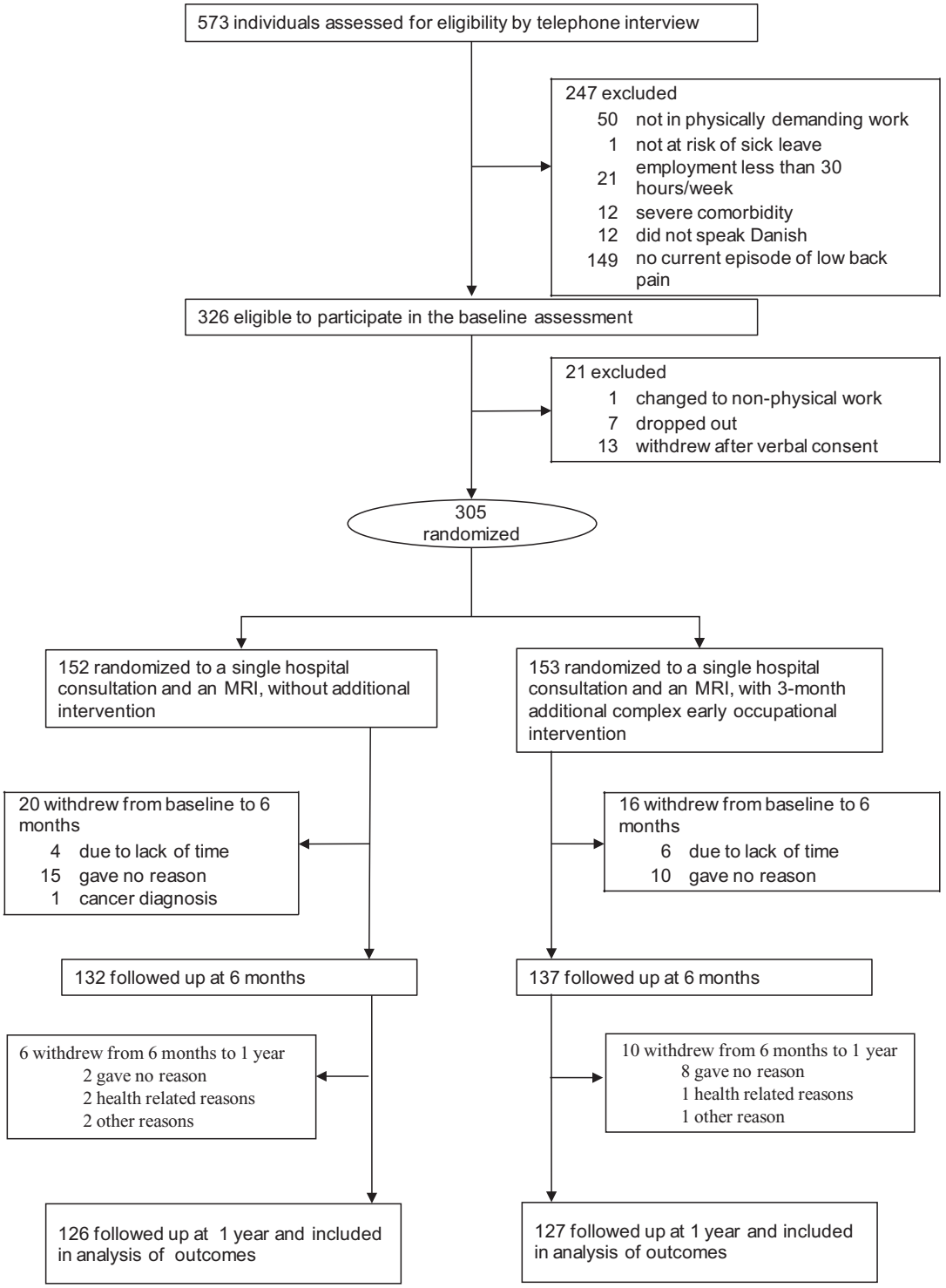

Figure 1. Flow of participants through the trial.

that the additional intervention had limited opportunity to change the participants' working conditions. Some participants had jobs that were physically demanding in their nature, where a significant decrease in physical labor was unrealistic. Furthermore, it could be speculated whether the recommendations in the occupational intervention were implemented, as many participants were employed in large companies, with weak incentives to establish those individual changes in the work environment, recommended by the OP's and physiotherapists. In addition, very few (n = 34) participants had workplace visits, which impeded the opportunity of involving the employers. However, in the analysis, restricted to the group who received workplace visits, we did not find a difference between the randomized

TABLE 1. Baseline Characteristics for All Participants Included in the 1-year Follow-up. Presented Stratified by "No Occupational Intervention" and "Additional Occupational Intervention"

Characteristics	All Participants, (n = 253)	No Occupational Intervention, (n = 126)	Additional Occupational Intervention, (n = 127)
Female sex, no. (%)	81 (32%)	41 (32.5%)	40 (31.5%)
Age, y	46.4 (10)	46.7 (10.2)	46.1 (9.9)
Current smoker, no. (%)	83 (33%)	46 (36.5%)	37 (29.1%)
BMI, kg/m^2	26.9 (4.3)	26.7 (4.3)	27.2 (4.2)
>9 y education, no. (%)	176 (70%)	95 (75.4%)	81 (63.8%)
NRS pain intensity	5.4 (1.9)	5.3 (2.0)	5.6 (1.9)
PDQ score for neuropathic pain	11.1 (6.1)	11.4 (6.26)	10.9 (5.9)
RMDQ score for disability	48.8 (22.4)	50.1 (22.1)	47.6 (22.7)
FABQ score for physical activity	14.6 (5.0)	14.6 (4.9)	14.6 (5.1)
FABQ score for work	24.7 (7.4)	24.5 (7.3)	24.9 (7.5)
SF-36 physical component summary	38.1 (8.0)	38.0 (7.7)	38.3 (8.0)
SF-36 mental component summary	49.0 (10.7)	48.7 (11.2)	49.3 (10.2)

() unless otherwise stated.

Data are given as mean (±SD) unless otherwise stated. For the NRS for pain, scores range from 0 to 10, with higher scores indicating more pain. For the PDQ, scores range from 0 to 30, with higher scores indicating more neuropathic pain. For the RMDQ, scores range from 0 to 100 after converting from a 24-item scale to a 23-item scale, with higher scores indicating greater disability. For the FABQ subscale for physical activity, the scores range from 0 to 24, with higher scores indicating greater fear-avoidance beliefs towards physical activities, and for the subscale for work, the scores range from 0 to 42, with higher scores indicating greater fear-avoidance beliefs towards work. For the SF-36 physical component summary, the scores range from 0 to 100, with higher scores indicating better physical function, and for the mental composite summary, the scores range from 0 to 100, with higher scores indicating better mental health. FABQ, Fear-Avoidance Beliefs Questionnaire; NRS, numeric rating scale; PDQ, painDETECT questionnaire; RMDQ, Roland–Morris Disability Questionnaire; Roland–Morris Disability Questionnaire; SF-36, Short Form Health Survey.

groups after 1 year. As a result of these findings, we believe that future studies could investigate the effect of structural changes instead of focusing on the individual.

There is a risk that the lack of difference between the groups and the improved outcomes in general could be caused by the self-limiting nature of acute LBP.[4] Nonetheless, in the present study, 74% of the participants were characterized as having chronic LBP at baseline,[14] a group wherein only about 40% recover within 12 months.[4,27,28]

TABLE 2. Changes in Outcomes After a Single Hospital Consultation With or Without an Additional Intervention in Individuals With Physically Demanding Jobs

Outcome	Change From Baseline to 1-year Follow-up		Comparison	
	No Occupational Intervention (*n* = 126)	Additional Occupational Intervention (*n* = 127)	Mean Difference Between Groups (95% CI)	*P*
PDQ score for neuropathic pain	−2.10 (−2.97 to −1.23)	−1.18 (−2.12 to −0.24)	0.92 (−0.35 to 2.10)	0.42
NRS pain intensity	−0.98 (−1.42 to −0.55)	−1.12 (−1.51 to −0.73)	−0.13 (−0.71 to 0.44)	0.65
RMDQ score for disability	−12.80 (−17.07 to −8.53)	−10.82 (−14.92 to −6.72)	1.98 (−3.91 to 7.88)	0.51
FABQ score for physical activity	−2.95 (−3.94 to −1.96)	−2.35 (−3.29 to −1.41)	0.60 (−0.76 to 1.95)	0.39
FABQ score for work	−3.21 (−4.72 to −1.71)	−2.96 (−4.49 to −1.43)	0.25 (−1.88 to 2.38)	0.81
SF-36 physical component summary	4.58 (2.94 to 6.22)	4.82 (3.26 to 6.38)	0.24 (−2.01 to 2.49)	0.83
SF-36 mental component summary	3.38 (1.46 to 5.31)	1.61 (−0.37 to 3.58)	1.77 (−4.52 to 0.97)	0.20

Data for change from baseline to 1-year follow-up are expressed as the difference in means with 95% confidence intervals. Outcomes are given as mean change in the 1 year from baseline, and the comparison is given as the mean difference between groups in change from baseline. For the PDQ, scores range from 0 to 30, with higher scores indicating more neuropathic pain. For the NRS for pain, scores range from 0 to 10, with higher scores indicating more pain. For the RMDQ, scores range from 0 to 100 after converting from a 24-item scale to a 23-item scale, with higher scores indicating greater disability. For the FABQ subscale for physical activity, the scores range from 0 to 24, with higher scores indicating greater fear-avoidance beliefs towards physical activities, and for the subscale for work, the scores range from 0 to 42, with higher scores indicating greater fear-avoidance beliefs towards work. For the SF-36 physical component summary, the scores range from 0 to 100, with higher scores indicating better physical function, and for the mental composite summary, the scores range from 0 to 100, with higher scores indicating better mental health. CI indicates confidence interval; FABQ, Fear-Avoidance Beliefs Questionnaire; NRS, numeric rating scale; PDQ, painDETECT questionnaire; RMDQ, Roland–Morris Disability Questionnaire; Roland–Morris Disability Questionnaire; SF-36, Short Form Health Survey.

TABLE 3. Per Protocol Analyses Restricted to Participants Who Received a Workplace Visit as a Part of the Occupational Intervention With Outcome Data Available After 12 Months

Outcome	Change From Baseline to 1-y Follow-up		Comparison	
	No Occupational Intervention ($n=126$)	Additional Occupational Intervention With Workplace Visit ($n=34$)	Mean Difference Between Groups (95% CI)	*P*
PDQ score for neuropathic pain	−2.10 (−2.97 to −1.23)	−1.91 (−4.09 to −0.26)	0.19 (−1.81 to 2.19)	0.85
NRS pain intensity	−0.98 (−1.42 to −0.55)	−1.00 (−1.80 to −0.20)	−0.02 (−0.94 to 0.90)	0.97
RMDQ score for disability	−12.80 (−17.07 to −8.53)	−14.32 (−17.07 to −8.53)	−1.52 (−10.54 to 7.50)	0.74
FABQ score for physical activity	−2.95 (−3.94 to −1.96)	−2.12 (−3.98 to −0.26)	0.83 (−1.28 to 2.95)	0.44
FABQ score for work	−3.21 (−4.72 to −1.71)	−1.47 (−4.29 to 1.35)	1.74 (−1.47 to 4.96)	0.28
SF-36 physical component summary	4.58 (2.94 to 6.22)	5.80 (2.16 to 9.43)	1.22 (−2.42 to 4.86)	0.51
SF-36 mental component summary	3.38 (1.46 to 5.31)	1.27 (−2.40 to 4.95)	−2.11 (−6.24 to 2.03)	0.32

Data for change from baseline to 1-year follow-up are expressed as the difference in means with 95% confidence intervals. Outcomes are given as mean change in the 1 year from baseline, and the comparison is given as the mean difference between groups in change from baseline. For the PDQ, scores range from 0 to 30, with higher scores indicating more neuropathic pain. For the NRS for pain, scores range from 0 to 10, with higher scores indicating more pain. For the RMDQ, scores range from 0 to 100 after converting from a 24-item scale to a 23-item scale, with higher scores indicating greater disability. For the FABQ subscale for physical activity, the scores range from 0 to 24, with higher scores indicating greater fear-avoidance beliefs towards physical activities, and for the subscale for work, the scores range from 0 to 42, with higher scores indicating greater fear-avoidance beliefs towards work. For the SF-36 physical component summary, the scores range from 0 to 100, with higher scores indicating better physical function, and for the mental composite summary, the scores range from 0 to 100, with higher scores indicating better mental health. CI indicates confidence interval; FABQ, Fear-Avoidance Beliefs Questionnaire; NRS, numeric rating scale; PDQ, painDETECT questionnaire; RMDQ, Roland–Morris Disability Questionnaire; Roland–Morris Disability Questionnaire; SF-36, Short Form Health Survey.

Our results contrast with several other studies focusing on multidisciplinary biopsychosocial rehabilitation for LBP.[1,29–31] Two recent Cochrane reviews stated that patients treated with multidisciplinary biopsychosocial rehabilitation experience less pain and disability compared to those receiving usual care.[12,29] In the present study, the treatment in the control group included MRI, which is not standard in the management of patients with nonspecific LBP, and therefore, the results of our study are not fully comparable to daily practice and the results in the Cochrane reviews.

TABLE 4. Mean Change for All Participants in Outcomes From Baseline to 6-month and 1-year Follow-up

Outcome	All Participants, Baseline ($n=253$)	Mean Change From Baseline to 6 mo (95% CI)	*P*	Mean Change From Baseline to 1 y (95% CI)	*P*
PDQ score for neuropathic pain	11.15 (6.06)	1.92 (1.25 to 2.60)	<0.001	1.64 (1.00 to 2.28)	<0.001
NRS pain intensity	5.45 (1.92)	1.11 (0.85 to 1.37)	<0.001	1.05 (0.76 to 1.34)	<0.001
RMDQ score for disability	48.84 (22.37)	11.50 (8.89 to 14.11)	<0.001	11.80 (8.86 to 14.75)	<0.001
FABQ score for physical activity	14.59 (5.02)	2.46 (1.82 to 3.09)	<0.001	2.65 (1.97 to 3.33)	<0.001
FABQ score for work	24.70 (7.38)	2.94 (2.00 to 3.88)	<0.001	3.09 (2.02 to 4.15)	<0.001
SF-36 physical component summary	38.11 (8.01)	−4.46 (−5.49 to −3.44)	<0.001	−4.70 (−5.82 to −3.58)	<0.001
SF-36 mental component summary	49.03 (10.65)	−1.62 (−3.08 to −0.17)	0.029	−2.49 (−3.86 to −1.12)	<0.001

Data for characteristics for low back pain are given as mean (SD). The comparison is given as the mean difference (95% CI) between the participants at baseline and 6-month and 1-year follow-up, respectively. For the PDQ, scores range from 0 to 30, with higher scores indicating more neuropathic pain. For the NRS for pain, scores range from 0 to 10, with higher scores indicating more pain. For the RMDQ, scores range from 0 to 100 after converting from a 24-item scale to a 23-item scale, with higher scores indicating greater disability. For the FABQ subscale for physical activity, the scores range from 0 to 24, with higher scores indicating greater fear-avoidance beliefs towards physical activities, and for the subscale for work, the scores range from 0 to 42, with higher scores indicating greater fear-avoidance beliefs towards work. For the SF-36 physical component summary, the scores range from 0 to 100, with higher scores indicating better physical function, and for the mental composite summary, the scores range from 0 to 100, with higher scores indicating better mental health. CI indicates confidence interval; FABQ, Fear-Avoidance Beliefs Questionnaire; NRS, numeric rating scale; PDQ, painDETECT questionnaire; RMDQ, Roland–Morris Disability Questionnaire; Roland–Morris Disability Questionnaire; SF-36, Short Form Health Survey.

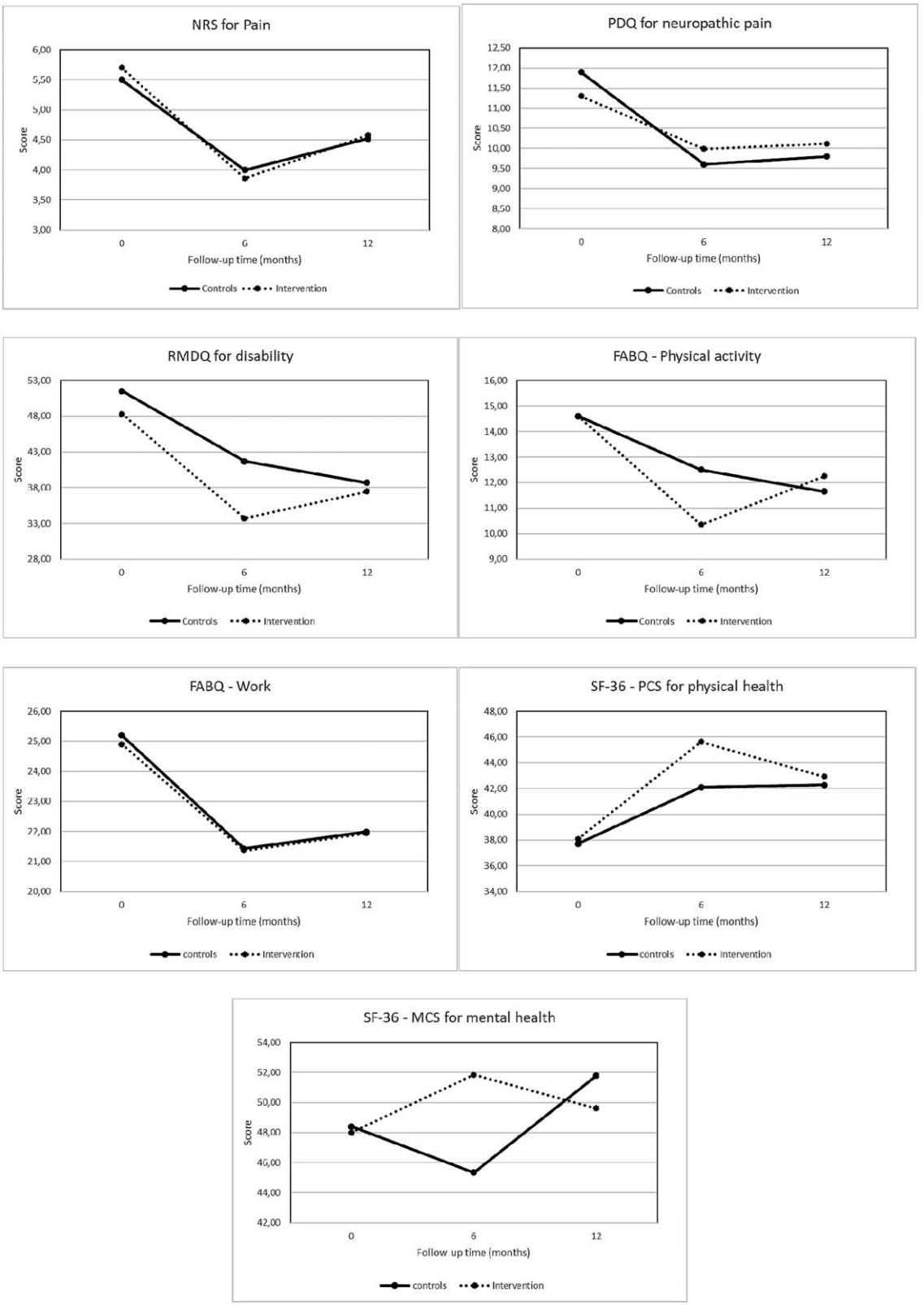

Figure 2. Changes in scores for each outcome at 6-month and 1-year follow-up.

The outcomes in the trial were chosen to reflect different aspects of LBP and are also widely used in related studies, but for most of the outcomes, it is hard to find agreements on clinically relevant changes, for example, a cut-off in FABQ-PA of >14 for elevated fear avoidance has been suggested.[32] In our population both groups scored on average above this level at baseline and decreased below this level at 1-year of follow-up, indicating a clinically relevant change.

For RMDQ, other studies have reported a clinically relevant change as 4 to 5 points,[33,34] a change which we found on average in each randomized group. However, the Danish translation of the international scale[35] with conversion to a 0 to100 scale[36] was used in the present study; thus, these numbers are not directly transferable. For NRS 1 to 2 points is considered to be a minimal important change.[34] We found a progress of approximately 1 point on average from baseline to 1-year follow-up in both groups.

Clinically relevant improvement for SF-36-PCS and SF-36-MCS has not yet been defined.[37] However, the average scores at baseline for SF-36-PCS and SF-36-MCS for all participants (38.1 *vs.* 49.0) were lower than the SF-36-PCS in the U.S. norm population (49.22 *vs.* 53.78),[38] indicating that the GOBACK population had affected physical and mental HRQoL, and at 1-year follow-up the gaps were reduced (42.81 *vs.* 51.52).

We have previously reported a poor association between self-reported physical demands at work, and objectively physical demands at work.[11] In this study, only 60% reported to have manual labor.[14] Consequently, 40% may have reported their job as physically demanding due to their back problem, more than actual high physical workload, which makes it difficult to generalize our results.

The participants, who dropped out, generally had more favorable scores for all outcomes at baseline. This may have affected the overall results, but since the number of dropouts was equal in both groups, and the groups were homogenous, it is reasonable to assume it had very low impact when evaluating the effect of the intervention.

Strengths/Limitations

The strengths of this study are the randomized clinical trial design, blinded assessment, and the low number of dropouts. The questionnaires were answered on a validated touch screen blinded for the personnel involved in the intervention, registering data directly in the dedicated database.

One limitation to this study is that accumulated sick leave was not measured after 6 months, which limited comparison with the 6-month follow-up. However, the outcomes evaluated in the present follow-up study were aspects associated with LBP, such as pain, disability, and psychosocial obstacles, which are highly relevant in long-term follow-up studies.

It is established practice to report results from RCTs from analyses based on the ITT population. Instead, we chose to report the results from the analyses based on complete cases, as the results were identical.

Another limitation could be that the additional occupational intervention focused on the individual participant, with limited involvement of the workplaces, partially caused by the small number of workplace visits. This made it difficult to implement changes in the working conditions. Furthermore, the fact that we used self-reported physically demanding jobs instead of objectively demanding jobs, may represent a limitation. A considerable number of the participants may have overrated the physical demands in their job tasks, thus diluting the effect of the occupational intervention.

CONCLUSION

The results from this follow-up study suggest that a thorough clinical consultation, with focus on explaining the cause of pain and instructions to stay active, can promote long-lasting clinically relevant physical and mental health improvements in individuals with LBP. An additional occupational intervention focusing on the individual did not result in larger or more persistent improvements. We suggest that future studies could focus on altering occupational obstacles on a structural level.

➢ Key Points

- ❑ The study showed no significant add-on effect from an additional occupational intervention at 1-year follow-up.
- ❑ Participants in the group receiving a thorough clinical consultation and an MRI, as well as the participants also receiving an additional occupational intervention had persistent improvements in pain, fear-avoidance beliefs, HRQoL, and disability from baseline to 1 year.
- ❑ A thorough clinical consultation, with focus on explaining the cause of pain and instructions to stay active, seems to promote long-lasting physical and mental health in individuals with LBP.

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