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Reduction of sick leave by a workplace educational low back pain intervention: A cluster randomized controlled trial

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Abstract

Aims: To investigate whether a workplace educational back pain intervention has an effect on sick leave at individual level and to identify possible predictors of the intervention effect.

Methods: Work-units in two municipalities were cluster-randomized to (1) educational meetings and peer support (45 units), (2) educational meetings, peer support, and access to an outpatient clinic if needed (48 units) or (3) control (42 units). Both intervention groups had educational meetings with information about back pain based on a "non-injury model". A "peer advisor" was selected among their colleagues. Outcome was days of sick leave at individual level at 3, 6, 9 and 12 months, adjusting for previous sick leave at unit level. Due to similar effect on sick leave the two intervention groups were merged (n=646) and compared to controls (n=211). Predictors were different levels of belief in back pain myths, pain-related fear, helplessness/hopelessness, and low back pain.

Results: The intervention group had significantly less days of sick leave at 3 months (4.9 days, p=.001) and at 6 months (4.4 days, p=.016) follow-up, compared to the control group. At three months, a low level of pain-related fear was the only predictor for intervention effect (8.0 less days of sick leave, p< .001).

Conclusions: A workplace educational back pain intervention had an effect on sick leave up to six months. Low score on pain-related fear was a predictor of the intervention effect.

Trial registration ClinicalTrials.gov, registration number: NCT00741650

Key words: work intervention; health education; health communication; psychological adaption; helplessness; hopelessness; low back pain; sick leave

Introduction

Neck and low back pain (LBP) are the most common complaints related to long-term sick leave and disability in Norway [1], and LBP is globally related to more disability than any other condition [2]. Despite great research effort, the evidence regarding prevention of LBP is scarce [3]. It seems difficult to prevent low back pain, but research has shown that it is possible to prevent the consequences of low back pain, such as sick leave, fear of movement or injury and inactivity [3]. Therefore, it is important to prevent these negative consequences of LBP [3].

Brief interventions based on a *"Non-Injury Model"* (NIM) with the aim to prevent consequences of LBP have shown success in increasing return to work (RTW) in clinical populations [4-6], and in reducing sick leave among employees [7, 8]. NIM is proposed by Indahl [4], and is in line with the European guidelines for the prevention of LBP [3]. According to NIM, the spine is considered to be a strong structure and pain is seldom a sign of an injury or disease caused by strain, but rather a functional disturbance [4]. Interventions based on NIM are effective regarding RTW among LBP patients for a substantial proportion of the participants [3-6]. More information concerning possible predictors for effect of such interventions in preventing sick leave will provide valuable knowledge for future interventions.

For those who are already on sick leave due to LBP, fear avoidance beliefs, low internal health locus of control, and negative expectancy of recovery are negative predictors for RTW [6, 9, 10]. Fear avoidance beliefs are associated with sick leave, even when controlling for LBP, previous sick leave, age and work environmental factors [11]. However, evidence from non-clinical populations is scarce, and it is therefore of interest to explore if beliefs and expectancies are valid as predictors of remaining at work in a non-patient population.

In the current study, we have explored this issue in a sample of Norwegian employees who participated in atWork, a cluster randomized controlled trial of a workplace intervention based on NIM. The aim with atWork was to prevent and manage negative consequences of LBP in a population of municipal employees, and it proved to be effective in reducing sick leave at group level at one year-follow up [8]. The current study contributes with longitudinal individual-level data on sick leave among employees who participated in atWork, consenting to gather individual data.

Changing misconceptions about low back pain and enable the employees to cope with back and neck pain at the workplace, is the core of atWork. The Cognitive Activation Theory of Stress (CATS) [12] is therefore an important theoretical framework for the intervention. CATS defines coping, which is essential for health, as the acquired expectancy that most or all responses lead to a positive result. Hopelessness (negative response outcome expectancy) and helplessness (no response outcome expectancy) on the other hand, are associated with sustained activation, which may have major implications for health [12].

The aim of the current study was to investigate the effect of atWork on sick leave at individual level, and to investigate whether belief in back pain myths, pain-related fear, helplessness/hopelessness, and LBP predict the effect of the atWork intervention.

Materials and Methods

Participants and procedure

In the period 2008-2010, all employees in two Norwegian municipalities were invited to participate in the atWork intervention. It was estimated to be around 3500 employees in total in the two municipalities at the initiation of the study. The effect of the intervention on sick leave at unit level and details of procedure and interventions are published elsewhere [8]. Since the intervention was carried out in workplace units, a cluster-randomized design was

chosen. 125 work units (clusters) in the municipalities were randomized into three groups: (1) educational meetings and peer support, (2) educational meetings, peer support and access to an outpatient clinic, or (3) control group that received treatment as usual (Figure 1). Randomization of whole units, stratified according to sectors (i.e., schools, nursing homes etc.) was done at Uni Health using computer generated, random numbers. Due to the nature of the intervention, it was not possible to blind participants of their allocation.

All employees who were randomized to any of the intervention groups received 2-4 educational meetings at the workplace. At these meetings evidence-based information about LBP based on NIM and the European guidelines for LBP was presented [6, 7]. At each work unit, a peer advisor was selected among the employees. The peer advisor was a colleague who received a brief education regarding back pain, and should assist colleagues with information and support to increase their likelihood to stay at work. Additionally, in the intervention group with access to an outpatient clinic, the peer advisor could, if needed, directly refer the employee to the clinic.

The control group did not receive any intervention. Both the control group and the intervention groups were free to receive treatment as usual from GPs and the remaining Norwegian health care system.

At baseline, 1746 employees responded to the questionnaire, giving a response rate of approximately 50%. Together with the baseline questionnaire, the participants received a consent form where we asked them for permission to collect register data on sick leave from NAV. Only data from employees providing such consent are included in this study (n=795). Furthermore, participants with missing data on workplace unit (n=94) were excluded, as this information was necessary to know which group the participants were randomized to. The two intervention groups were combined into a single intervention group, because few workers went to the outpatient clinic, and the result from either intervention was similar on

sick leave. Consequently, 646 (mean age = 44.2 years (SD = 10.81), 86% females) constituted the intervention group, and 211 (mean age = 43.1 years (SD = 11.62), 88.2% females) the control group (Figure 1).

INSERT FIGURE 1 HERE

Ethics

The study followed the Helsinki declaration, and was approved by the Norwegian Regional Ethics Committee in Western Norway (REK vest, ID 6.2008.117). The Norwegian Social Science Data Services recommended the study (NSD, ID 18997), as well as the privacy authority at the Oslo University Hospital (Rikshospitalet, ID 08/2421).

Instruments

Outcome variable. *Sick leave* was measured at individual level by individual registry data from the Norwegian Labour and Welfare Administration (NAV). In Norway the employer pays the first 16 calendar days of a sick leave period. After the 16 days period, NAV covers the disbursement with sick leave benefits equal to 100% of past earning. The available data were based on the sickness payment database from NAV. In cases where the employees were sick listed for more than 16 days, these 16 days were also included in the data material. In the present study the number of days on sick leave was calculated for the 12 months both prior to and after the intervention.

Predictor variables. All predictor variables were measured at baseline.

Low Back Pain (LBP) was measured by a single item from the Subjective Health Complaints (SHC) inventory [13], asking if the participants had experienced LBP in the last 30 days. The item was rated on a four-point scale from 0 = “no complaints” to 3 = “serious complaints”. The item was dichotomized to 0 (no or some complaints) and 1 (much or severe complaints).

Attitudes and beliefs regarding LBP were measured by two items from Deyo's "back pain myths" [14]. Originally, Deyo [14, 15] proposed seven myths that represent misconceptions regarding LBP. Two of these myths were explored in the current study, as these are specifically addressed in atWork [8], in addition to being the most prevalent in the general population [15]: 1) "Most back pain is caused by injury and heavy lifting" (Myth lifting) and 2) "Everyone with back pain should have a spine X-ray" (Myth X-ray). The items were rated on a five-point scale from 1 = "totally disagree" to 5 = "totally agree". The items were dichotomized to 0 = "totally disagree", "disagree", "neither disagree nor agree", and 1 = "agree" and "totally agree".

Pain related fear was measured by the Tampa Scale for Kinesiophobia (TSK). The scale consists of 13 items measuring fear of back (re)injury due to movement [16, 17], rated on a four-point scale from 1 = "totally disagree" to 4 = "totally agree". The scale was dichotomized based on the mean value for the sum-score (mean = 25.4) into 0 = low (below the mean) and 1 = high (above the mean).

Helplessness and Hopelessness were measured by six items from the Theoretically Originated Measure of the Cognitive Activation Theory of Stress (TomCats) [18], designed to measure response outcome expectancies in CATS [12]. The scale consists of three factors, representing the three response outcome expectancies in CATS. In the current study, helplessness and hopelessness were treated as one single factor based on factor analysis from a previous publication from the same sample [19]. Examples of statements are: "I really don't have any control over the most important issues in my life" (helplessness), and "all my attempts at making things better just make them worse" (hopelessness). All items were rated on a five-point scale from 1 ="not true at all" to 5 ="completely true". The scale was dichotomized based on the mean value (mean = 10.2) into 0 = low (below the mean) and 1 = high (above the mean).

Statistical analyses

Differences between the intervention and the control group at baseline on the predictor variables were tested with independent-samples t-tests.

Means, standard deviations, and percent of participants on sick leave in three-month periods one year before and the year after the intervention were calculated. Means and 95% confidence intervals were calculated for sick leave days stratified by the predictors (high/low) in the intervention and control group the year after the intervention.

Sick leave days in three-month periods the year after the intervention were analyzed using generalized estimating equations (GEE) [20]. Using this approach, corrections for the clustered nature of the data were accounted for [21]. The analyses were based on least squares estimators and identity link function. Standard errors were calculated based on a robust variance estimator, corrected for clustering of data. Differences in days of sick leave the year preceding the intervention were adjusted for in the analyses to control for differences in initial sick leave between the intervention and control group. No further variables were adjusted for in the analyses. Adjustment for clustering was done at unit level, i.e. on workplace department.

For differences in effect on days of sick leave between intervention and control group, adjusted mean difference scores and 95% confidence intervals with corresponding *p*-values were calculated. Six models including the interaction effect of days of sick leave for the dichotomized (high/low) predictors and intervention were conducted to test if there were statistically significant differences between the intervention and control group regarding the effect of the predictors on sick leave. There was one for the total effect, and five for each of the predictors. Selection of the predictors was based on the theoretical framework of the atWork intervention, i.e. the non-injury model and CATS. The interaction terms were

composed by dummy variables for the predictors and dummy variables for the time dimension. Each model included four interactions terms based on the four time periods; 0-3, 3-6, 6-9, and 9-12 months.

For significant results, stratified analyses of the predictors were conducted to calculate the effect within the two categories (high/low).

The statistical analyses were performed using SPSS® version 21.0 (IBM Corporation, Armonk NY, USA) for Windows. *p*-values lower than 5 % (0.05) were considered statistically significant.

Results

Descriptive statistics

There were no statistical significant differences at baseline between the intervention and control group in the predictor variables (Table1).

The prevalence of days of sick leave the year before the intervention differed between the intervention and the control group (Table 2). Mean scores for overall sick leave days, stratified by high and low baseline scores on the predictor variables in the intervention and control group are presented in Table 3.

INSERT TABLE 1 HERE

INSERT TABLE 2 HERE

INSERT TABLE 3 HERE

The effect of the atWork intervention on sick leave

The adjusted analyses showed a statistically significant effect of the intervention on days of sick leave the first six months subsequent to the intervention (Table 4). Employees in the

intervention group had on average an effect of 4.9 less days of sick leave the first three months and 4.4 less days of sick leave the next three months after participating in the intervention, compared to the control group (See Table 2 for means and SD; Table 4). When calculating the difference between the groups based on estimated and adjusted means, the difference in change was 45.6% the first three months, and 41.4% the next three months. There was no statistically significant effect of the intervention on days of sick leave subsequent to the first six months (Table 4).

The effect of the intervention on sick leave within different levels of beliefs, expectancies and low back pain

There was a statistically significant effect of the intervention on days of sick leave for the different levels of pain-related fear measured at baseline the first three months (Table 4). Thus, stratified analyses of this predictor were conducted to calculate the effect within the two categories (high/low). The adjusted mean difference between the intervention and control group on low pain-related fear the three first months was -8.03 (95% CI: -12.88 – -3.17, $p <$ .001), indicating that employees in the intervention group with low (≤ 25.4) scores had on average an effect of 8.03 less days of sick leave the first three months after participating in the intervention, compared to the control group (See Table 3 for means and 95% CI). When calculating the difference between the intervention and control group within the low levels of pain-related fear, the difference in change was 67.8% the first three months. There was no statistically significant effect of the intervention for the levels of pain-related fear subsequent to the first three months.

There were no statistically significant differences in effect of the intervention between individuals with high and low scores on the other predictor variables (back pain myths, helplessness/hopelessness and low back pain) (Table 4). Thus, stratified analyses of these predictors to calculate the effect within the two categories were not conducted.

INSERT TABLE 4 HERE

Discussion

The main aim of this study was to investigate if there was an effect of atWork on sick leave, and to identify baseline characteristics with the participants that could contribute to this effect. There was an effect on sick leave the first six months subsequent to the intervention.

This is in line with, but expands on the findings by Odeen et al. [8] by showing individual effects among those consenting to gather individual data and also showing exactly when during the first year the effect occurred. Our result regarding the short-term effect is also in accordance with a previous similar intervention study among LBP patients [5]. However, effects on RTW are found for up to five years in a clinical population [6]. In a clinical setting the message is tailored to fit the individual need, which might result in a stronger effect than in the atWork study designed to reach all employees present at work. Still, the effect of atWork on sick leave is important, since population-based preventive interventions often requires long-term implementation for an effect to occur [22].

In the current study, low scores on pain-related fear predicted effect of the intervention. The result is in accordance with a recent systematic review of back pain interventions showing that high fear-avoidance beliefs at baseline were associated with poor treatment outcomes in terms of more pain and/or disability and less RTW [10]. Also in line with the present study, Staal et al. [23] found that workers with scores equal to or above the median on fear avoidance beliefs at baseline return to work more slowly after participating in a graded activity intervention than those with scores below the median.

While expectancies are generalized, pain-related fear represents specific beliefs regarding fear of movement or (re)injury when in pain, which might explain why pain-related fear was the only significant predictor in this study. In a previous qualitative study, participants in an

educational intervention similar to atWork, emphasized trust in the professionals and improved understanding as important aspects contributing to their coping with the complaints [24]. Strong pain-related fear can hamper confidence in the professionals and the information they receive from the intervention. Furthermore, the non-injury model might be more conceivable for employees with low pain-related fear. For employees with low or moderate scores on pain-related fear, atWork might provide the reassurance they need to be able to stay at work despite pain. Employees with strong and deep-rooted pain-related fear may need something else, e.g. more extensive, multidisciplinary treatments than what was provided in atWork, or an intervention targeting pain related fears, including performance of practical tasks. Cognitive behavior therapy (CBT) has shown to be effective in reducing avoidance, catastrophizing, and disabling beliefs among LBP patients [25], but might also have a negative effect on disability for individuals with low scores on fear avoidance [26].

Strengths and limitations

A major strength of the current study is that the outcome is measured by registry data on sick leave that are considered highly accurate and thus reduce the risk of measurement errors. The sample is relatively large, and due to the sample diversity regarding workplace size and work tasks, the possibility of group specific effects and localization effects are reduced. The high predominance of women in the sample (87.2%) is representative for the municipality sector in Norway [27]. A further strength of the study is that all unit types (e.g. kindergartens, nursing homes etc.) were represented in the sample, and there was no systematic dropout from any unit types on responses to the questionnaire.

The current study contributes to increase knowledge concerning the effect of a work place based low-cost and low-threshold sick leave intervention. Municipal employees have relatively high sickness absence compared with employees in private and state-level public

sector [28]. This study addresses one of the sectors with the highest rates of long-term sick leave.

A limitation of this study is the lack of a published protocol. The low response rate of approximately 50% might increase the risk of non-response bias and limit the validity of the findings. It would have been relevant to investigate whether men and women have different effect of the intervention, but the low number of men in the study could not justify such analyses. Caution should be made when generalizing to private sector employees and to men.

In cases where the employee is sick listed for 16 days or less, the sick leave is not registered in NAV, and thereby missed in this study. Although we were most interested in the long-term sick leave due to its negative consequences both for the individual and the society, it would have been interesting to also see how the intervention affected the short-term sick leave. Due to data protection issues, information about which diagnoses the individuals were sick listed for was not available. However, there is a high degree of comorbidity in subjective health complaints [29], and huge variation regarding which diagnosis the general practitioner choose when presented for the same patient [30], making the specific diagnoses less relevant in this setting.

A further limitation of the current study is that we cannot exclude the possibility of confounding variables as the unit of randomization was different from the unit of analysis. However, adjustment for sick leave the year before the intervention and for clustering of the data within the unit of randomization justifies the analyses. Some of the sub groups were small. This results in wide confidence intervals, which also indicates low power for these analyses.

Implications

Knowledge on individuals who benefit from work place interventions is important for authorities regarding whom to focus in such interventions. Still, excluding workers with high levels of pain-related fear seems unrealistic as well as unethical. The intervention has a preventive approach towards all employees present at work. More knowledge of characteristics about individuals with high scores on pain-related fear, and why they do not respond to interventions such as atWork is needed. Furthermore, future studies should explore mediational effects, i.e. whether expectancies and beliefs change as a result of the intervention, and if these changes predict effect on sick leave.

Conclusions

The atWork intervention had an effect on days of sick leave at individual level the first six months subsequent to the intervention, and low levels of pain related fear predicted the effect. There were no differences in effect of the intervention between individuals with high and low scores on helplessness and hopelessness, belief in the back pain myths and low back pain. Since the effect of atWork on sick leave was limited to the first six months, indicating a need for repetition of the intervention message, the educational part of atWork should be tested in primary health care, and considered implemented as a part of regular practice in primary care if the results are positive.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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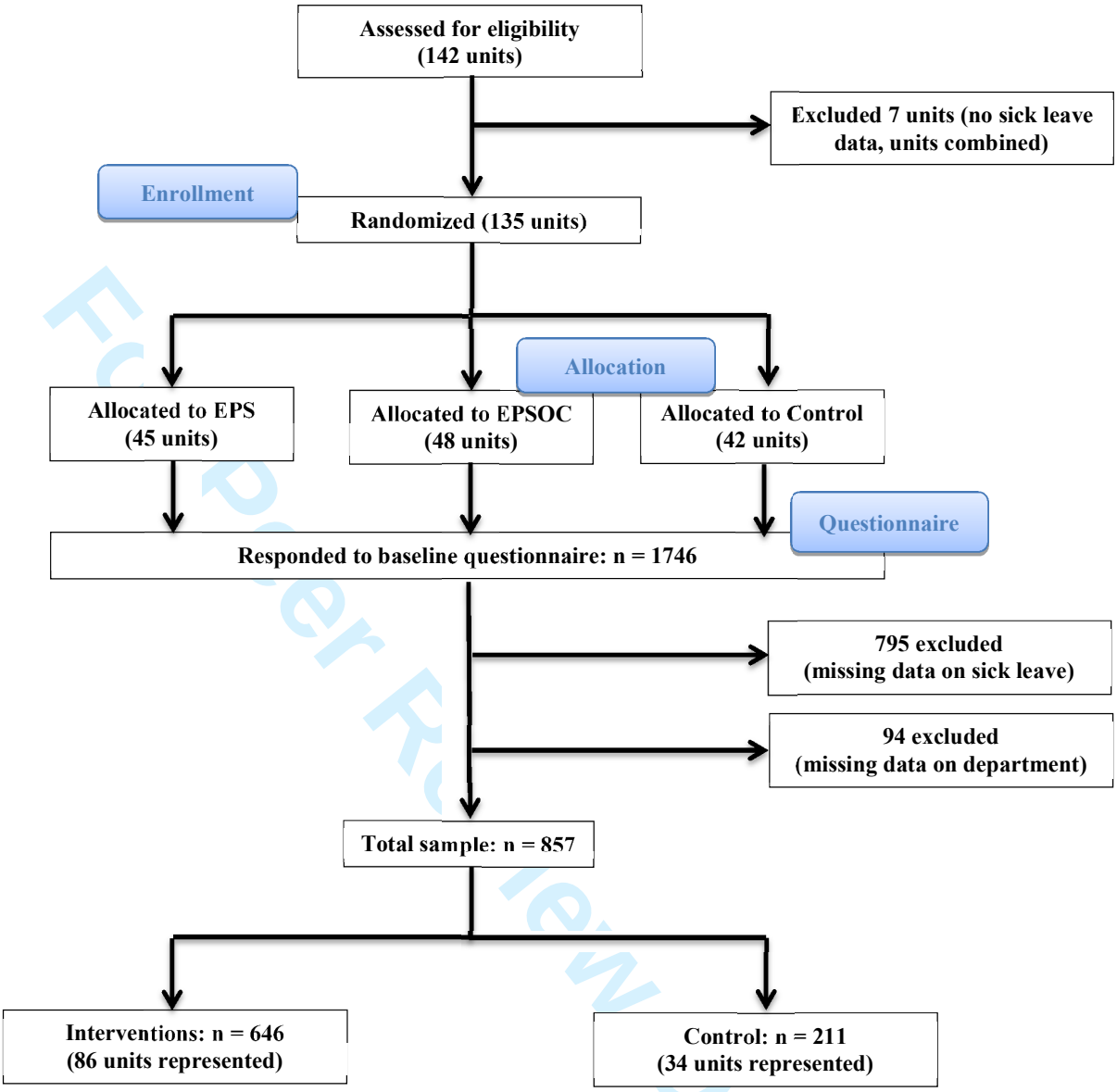

Figure 1. Flow chart of participants: EPS = Education and Peer Support. EPSOC = Education, Peer Support and Outpatient Clinic.

Table 1: Number, percentages, means and standard deviations (SD) in the intervention and control group for the predictor variables: Low back pain, Deyo's myths (myth lifting, myth X-ray), pain-related fear, and helplessness/hopelessness. Differences between groups at baseline tested with independent-samples *t*-tests.

	Intervention	Control	Intervention	Control	*t*-value	*p*-value
	n (%)	*n* (%)	Mean (SD)	Mean (SD)		
Low back pain (0-3)[a]	635	206	0.96 (0.9)	1.10 (40.9)	-1.76	.079
Low	434 (68.3)	128 (62.1)				
High	201 (31.7)	78 (37.9)				
Myth lifting (1-5)[b]	620	206	3.26 (0.9)	3.22 (1.1)	0.46	.645
Low	408 (65.8)	125 (60.7)				
High	212 (34.2)	81 (39.3)				
Myth X-ray (1-5)[b]	614	203	3.05 (1.1)	3.04 (1.2)	0.03	.976
Low	134 (66.4)	134 (66.0)				
High	206 (33.6)	69 (34.0)				
Pain-related fear (13-46)[c]	623	207	25.36 (6.2)	25.47 (5.8)	-0.23	.816
Low	331 (53.1)	108 (52.2)				
High	292 (46.9)	99 (47.8)				
Helplessness/hopelessness (6-30)[d]	628	205	10.32 (3.6)	10.01 (3.5)	1.06	.289
Low	363 (57.8)	127 (62.0)				
High	265 (42.2)	78 (38.0)				

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Table 2. Mean and standard deviation (SD) of sick leave days in blocks of three months the year before and after the intervention, and percent of participants on sick leave for one or more days during the three months periods.

	Months 12-9	Months 9-6	Months 6-3	Months 3-0	Months 0-3	Months 3-6	Months 6-9	Months 9-12
Intervention (n = 646)								
Mean (SD)	9.26 (23.1)	8.66 (22.6)	8.96 (23.7)	7.18 (21.1)	6.51 (18.3)	9.26 (23.7)	10.50 (24.8)	9.63 (23.3)
% on sick leave	19.2	18.4	16.6	15.9	16.9	17.0	21.2	20.3
Control (n = 211)								
Mean (SD)	6.48 (19.9)	6.52 (18.9)	4.39 (15.5)	8.01 (22.6)	9.28 (23.8)	11.45 (27.3)	8.51 (23.1)	7.37 (20.5)
% on sick leave	14.2	14.2	10.9	15.2	18.5	19.9	17.5	19.0
Total (n = 857)								
Mean (SD)	8.58 (22.4)	8.13 (21.8)	7.84 (22.1)	7.38 (21.5)	7.19 (19.8)	9.80 (24.6)	10.01 (24.4)	9.08 (22.7)
% on sick leave	18.0	17.4	15.2	15.8	17.3	17.7	20.3	20.0

Table 3: Unadjusted mean scores and 95% CI for sick leave days stratified by high and low baseline scores on low back pain, Deyo's myths (myth lifting, myth X-ray), pain-related fear, and helplessness/hopelessness in the intervention and control group.

		Intervention	Control
		Mean (95% CI)	**Mean (95% CI)**
Low back pain_low[a]	0-3	5.93 (4.33 - 7.54)	8.02 (4.03 - 12.02)
	3-6	7.50 (5.48 - 9.51)	9.63 (5.17 - 14.10)
	6-9	7.52 (5.55 - 9.50)	8.34 (4.44 - 12.24)
	9-12	6.29 (4.56 - 8.01)	5.30 (2.35 - 8.25)
Low back pain_high	0-3	8.08 (5.16 - 10.98)	10.22 (5.06 - 15.37)
	3-6	13.48 (9.60 - 17.36)	13.99 (7.51 - 20.46)
	6-9	17.33 (13.07 - 21.60)	9.33 (3.91 - 14.75)
	9-12	16.70 (12.53 - 20.87)	11.04 (5.48 - 16.60)
Myth lifting_low[b]	0-3	6.50 (4.70-8.29)	10.33 (5.92 - 14.74)
	3-6	9.74 (7.44 - 12.03)	11.93 (6.90 - 14.74)
	6-9	10.12 (7.78 - 12.45)	9.27 (5.07 - 13.47)
	9-12	9.49 (7.26 - 11.72)	6.12 (3.03 - 9.21)
Myth lifting_high	0-3	7.12 (4.60 - 9.65)	7.14 (2.80 - 11.46)
	3-6	9.48 (6.12 - 12.85)	9.77 (4.42 - 15.11)
	6-9	12.34 (8.67 - 16.00)	7.86 (3.05 - 12.68)
	9-12	10.70 (7.34 - 14.07)	9.77 (4.45 - 15.07)
Myth X-ray_low[b]	0-3	5.98 (4.28 - 7.68)	8.92 (4.98 - 12.87)
	3-6	8.22 (6.07 - 10.37)	10.22 (5.77 - 14.68)
	6-9	8.80 (6.59 - 11.02)	6.87 (3.41 - 10.32)
	9-12	7.60 (5.56 - 9.63)	6.40 (3.25 - 9.56)
Myth X-ray_high	0-3	8.24 (5.41 - 11.06)	8.45 (3.34 - 13.55)
	3-6	12.18 (8.48 - 15.88)	10.94 (4.73 - 17.16)
	6-9	15.13 (11.15 - 19.13)	10.83 (4.61 - 17.04)
	9-12	14.51 (10.68 - 18.34)	9.93 (4.21 - 15.64)
Pain-related fear_low[c]	0-3	5.03 (3.39 - 6.66)	10.52 (5.68 - 15.35)
	3-6	9.62 (7.05 - 12.19)	11.84 (6.55 - 17.13)
	6-9	10.17 (7.61 - 12.74)	8.71 (4.21 - 13.22)
	9-12	8.76 (6.36 - 11.17)	7.06 (3.17 - 10.94)
Pain-related fear_high	0-3	8.14 (5.68 - 10.59)	7.40 (3.43 - 11.38)
	3-6	9.27 (6.54 - 12.01)	10.60 (5.43 - 15.76)
	6-9	11.23 (8.22 - 14.23)	8.32 (3.92 - 12.73)
	9-12	10.89 (8.06 - 13.72)	8.02 (3.96 - 12.08)
Helplessness/hopelessness_low[d]	0-3	4.36 (2.88 - 5.84)	6.70 (3.22 - 10.18)
	3-6	7.92 (5.68 - 10.16)	9.67 (5.40 - 13.94)
	6-9	9.07 (6.66 - 11.48)	6.24 (2.59 - 9.88)
	9-12	8.09 (5.90 - 10.29)	5.24 (2.26 - 8.23)
Helplessness/hopelessness_high	0-3	9.56 (6.84 - 12.28)	13.63 (7.29 - 19.97)
	3-6	11.07 (7.93 - 14.21)	14.90 (7.90 - 21.89)
	6-9	12.63 (9.43 - 15.84)	12.42 (6.62 - 18.23)
	9-12	11.52 (8.45 - 14.59)	10.86 (5.38 - 16.34)

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Table 4: Adjusted mean difference with 95% CI for the intervention and control group in effect on days of sick leave, and for the interaction effect of days of sick leave for the two levels (high/low) of low back pain, Deyo's myths (myth lifting, myth X-ray), pain-related fear, and helplessness/hopelessness, with intervention. Differences between groups were tested with generalized estimating equations (GEE) adjusted for days of sick leave the year preceding the intervention and workplace department (unit).

	Months	Mean diff (95% CI)	*p*-value
Intervention vs Control	0-3	-4.94 (-7.79 - -2.08)	.001
	3-6	-4.36 (-7.90 - -0.82)	.016
	6-9	-0.18 (-3.69 - 3.33)	.922
	9-12	-0.94 (-3.61 - 3.80)	.961
Low back pain (low vs high)[a]	0-3	-1.24 (-8.16 - 5.68)	.725
	3-6	0.43 (-7.56 - 8.43)	.915
	6-9	7.63 (-0.30 - 15.55)	.059
	9-12	3.48 (-4.86 - 11.83)	.413
Myth lifting (low vs high)[b]	0-3	4.47 (-2.37 - 11.32)	.200
	3-6	2.56 (-7.36 - 12.48)	.612
	6-9	4.28 (-4.47 - 13.04)	.338
	9-12	-1.78 (-9.21 - 5.65)	.639
Myth X-ray (low vs high)[b]	0-3	1.58 (-6.55 - 9.72)	.703
	3-6	2.09 (-7.84 - 12.02)	.679
	6-9	1.22 (-8.27 - 10.72)	.801
	9-12	2.24 (-6.23 - 11.10)	.621
Pain-related fear (low vs high)[c]	0-3	7.58 (0.24 - 14.91)	.043
	3-6	2.25 (-9.05 - 13.55)	.696
	6-9	2.79 (-6.39 - 11.97)	.551
	9-12	2.51 (-4.53 - 9.56)	.485
Helplessness/hopelessness (low vs high)[d]	0-3	-3.05 (-10.45 - 4.35)	.419
	3-6	-3.40 (-12.96 - 6.15)	.485
	6-9	-3.95 (-12.20 - 4.30)	.348
	9-12	-3.51 (-10.10 - 3.09)	.297

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Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	4
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	4
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	4, 5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	4
	4b	Settings and locations where the data were collected		
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	6

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	
	7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		**5**
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	5
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	4, 5

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		
	11b	If relevant, description of the similarity of interventions		
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		**8**
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Reported in flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Reported in flow diagram
Recruitment	14a	Dates defining the periods of recruitment and follow-up		**4**
	14b	Why the trial ended or was stopped		
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	Table 1 and 2

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Reported in flow diagram
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		**9,10**
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		**12**
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		**10-13**
Other information				
Registration	23	Registration number and		**2**

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	**13**

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.