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A multifaceted workplace intervention for low back pain in nurses' aides: a pragmatic stepped wedge cluster randomised controlled trial

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Abstract

This study established the effectiveness of a workplace multifaceted intervention consisting of participatory ergonomics, physical training, and cognitive–behavioural training (CBT) for low back pain (LBP). Between November 2012 and May 2014, we conducted a pragmatic stepped wedge cluster randomised controlled trial with 594 workers from eldercare workplaces (nursing homes and home care) randomised to 4 successive time periods, 3 months apart. The intervention lasted 12 weeks and consisted of 19 sessions in total (physical training [12 sessions], CBT [2 sessions], and participatory ergonomics [5 sessions]). Low back pain was the outcome and was measured as days, intensity (worst pain on a 0-10 numeric rank scale), and bothersomeness (days) by monthly text messages. Linear mixed models were used to estimate the intervention effect. Analyses were performed according to intention to treat, including all eligible randomised participants, and were adjusted for baseline values of the outcome. The linear mixed models yielded significant effects on LBP days of −0.8 (95% confidence interval [CI], −1.19 to −0.38), LBP intensity of −0.4 (95% CI, −0.60 to −0.26), and bothersomeness days of −0.5 (95% CI, −0.85 to −0.13) after the intervention compared with the control group. This study shows that a multifaceted intervention consisting of participatory ergonomics, physical training, and CBT can reduce LBP among workers in eldercare. Thus, multifaceted interventions may be relevant for improving LBP in a working population.

Keywords: Low back pain, Occupational health, Cognitive–behavioural training, Participatory ergonomics, Physical training, Randomised controlled trial

1. Introduction

Low back pain (LBP) is among the most prevalent, costly, and disabling health conditions,[13] and interventions preventing LBP at a population level are needed. Workplaces enable one to reach a mixed population including those with fewer resources, and this makes it an important arena for interventions to prevent LBP.

The risk of LBP is high if the physical work demands and functional capacity are not balanced.[24] Therefore, as primary prevention of LBP, many interventions aim at reducing the work demands by adapting the work tasks to the worker, eg, with participatory ergonomics. Participatory ergonomics is reported to have small positive effects on general musculoskeletal symptoms,[28] but evidence is scarce with respect to a preventive effect on LBP.[5] Other means of improving the balance of physical work demands and functional capacity is to enhance the physical capacity of the worker by physical training.[34] Physical training shows moderate evidence for reducing the severity of LBP,[2] but limited evidence of reducing new episodes of LBP.[22,35]

Besides these physical factors, poor social relations at work have also been associated with an increased risk of LBP[7] and psychosocial cognitive factors play a central role as LBP progresses to disability.[12,20,41] Cognitive–behavioural training (CBT) shows a moderate positive effect on LBP intensity among patients[40] and improves measures of coping such as catastrophizing and pain-related fear of physical activity among a working population.[17] This implies that psychosocial factors are likely to be important components for both primary and secondary prevention of LBP.

Based on the notion that LBP is multifactorial and involves physical and psychosocial factors,[2] recent Cochrane reviews and most clinical guidelines suggest multifaceted biopsychosocial interventions for prevention of LBP.[9,19] Despite recommendations of biopsychosocial interventions for LBP,[9,19] there have been few previous multifaceted workplace interventions.[35] Participatory ergonomics, physical training, and CBT are all elements that have shown a positive effect of limited or varying size on LBP[2,28,40] and could potentially constitute important components in a multifaceted intervention for LBP. As multifaceted interventions are often comprehensive in nature, challenging standard evaluation designs such as the parallel randomised controlled trial, alternative designs that are more flexible to the real-world setting have been suggested, eg, the stepped wedge

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design.[21] Advantages of this design are that it allows a relatively flexible implementation, permitting all willing workers to eventually participate in the trial, improves statistical power, and is randomised and controlled.[15,44]

In light of the demographic shift attributed to ageing of the baby boomer generation, significant demands will be placed upon the health care industry in the future.[14] Therefore, effective interventions for LBP among job groups belonging to the health care industry are needed. Our aim was to test the effectiveness of a 3-month multifaceted intervention consisting of participatory ergonomics, physical exercise, and CBT for LBP in a workplace with mainly nurses' aides in a stepped wedge cluster randomised controlled design.

2. Methods

We have reported the trial protocol previously.[26] Briefly, between November 2012 and May 2014, we conducted a pragmatic stepped wedge cluster randomised controlled trial with 4 groups. A stepped wedge design is a crossover study with repeated measurements, in which clusters cross over from control to the intervention at randomised time points.[23] The stepped wedge design enables comparisons within and between clusters, which improves statistical power and necessitates fewer clusters than a parallel cluster randomised controlled trial.[44]

2.1. Participants

Details regarding the recruitment procedures and reach of workplaces and workers have been reported elsewhere.[27] Briefly, we contacted a large municipality in Denmark regarding participation. Nine districts in the municipality were offered participation. Four of the 9 districts (44%) in the municipality adopted the project, and the 4 participating districts comprised 54 working teams. Eligible participants were nurses' aides, kitchen and cleaning personnel, as well as janitors (service workers) employed in elderly care either in nursing homes or in home care more than 20 hours a week and being 18 to 65 years of age. The exclusion criteria for the study were unwillingness to participate, long-term sickness absence (more than 2 consecutive weeks), or not being permanently employed. Written informed consent was obtained from the participants before randomisation.

The study was approved by the Danish Data Protection Agency and the Ethics Committee for the regional capital of Denmark (Journal number: H-4-2012-115) and was conducted in accordance with the Declaration of Helsinki. The trial has been registered as ISRCTN78113519 in the Current Controlled Trials Register.

2.2. Randomisation

The workers who volunteered for participation were randomised to 4 successive time periods, 3 months apart in the stepped wedge design. A balanced cluster randomisation was applied with strata formed by each of the 4 districts and clusters formed within each stratum based on working teams (N = 54). Each of the districts consists of a number of working teams (between 4 and 19) comprising a supervisor and workers who report to that supervisor. All grouped clusters (N = 21) belonging to a specific stratum were drawn from a deck of cards with each colour representing a step from 1 to 4 in the study. Researchers blinded to the identity of the strata and clusters conducted the randomisation.

2.3. Blinding

Because of the nature of the intervention, we were unable to mask participants or those providing the intervention to treatment assignment. However, the participants did not receive information about which group they were randomised to until shortly before crossing over from control to intervention. Moreover, data collection was performed by text messages, and those handling the data were blinded to the intervention allocation.

2.4. Intervention

The intervention lasted 3 months and integrated participatory ergonomics, physical training, and CBT[26] (**Fig. 1**). An ergonomic work group consisting of 5 to 7 workers and a trained local therapist was responsible for the participatory ergonomics process. Two 3-hour workshops and 2 after 1-hour evaluation meetings of the process were conducted for this group. At the two 1-hour evaluation meetings, the implementation of the solutions was evaluated and possible adjustments made. The participatory ergonomics process focused on prevention of physical exertion and pain through minimising risk factors for LBP at work and reducing or changing the work tasks perceived as physically demanding. Two 3-hour CBT workshops were conducted for all participants with a focus on modification of maladaptive pain behaviours and cognitive processes, and the therapist led the workshops. The physical training consisted of 12 weekly 1-hour sessions supervised by a therapist for all participants with the overall aim of introducing different types of physical activities: (1) body awareness and body postures, (2) strength and coordination training, and (3) general physical activity. To build supervisor support, the supervisors of the participating teams were invited for three 1-hour knowledge sharing meetings discussing barriers and facilitators for implementation of the intervention. Additionally, as part of the planning of the intervention and overseeing the implementation of the intervention, steering group meetings were planned before, during, and after the trial. The steering group consisted of a chairman (a manager of 1 of the 4 participating districts), the managers of each of the remaining 3 participating districts, a local project leader, 2 of the researchers, a local union representative (an employee), and a local working environment representative. Material about the process of the project and role expectations was sent to the participating workplaces. The intervention was scheduled in the working time of the participants and delivered by trained local therapists. The research team arranged 6 days of training and a written protocol describing all intervention activities and offered support throughout the study period for the therapists. Fidelity of the intervention delivery was checked through the following: (1) questionnaires for the therapists after each session measuring whether sessions were delivered as intended (measured as prespecified success criteria according to the protocol) and (2) observations of random sessions to check the self-rating of the success criteria obtained. This was performed as part of a process evaluation to determine intervention fidelity and was not used for further training and feedback for the therapists.

2.5. Outcomes

The primary outcome was LBP. As LBP has been measured in numerous ways, we used the results of a Delphi study that reached consensus about duration and severity of LBP as a minimal definition of LBP.[4] Therefore, LBP was measured as

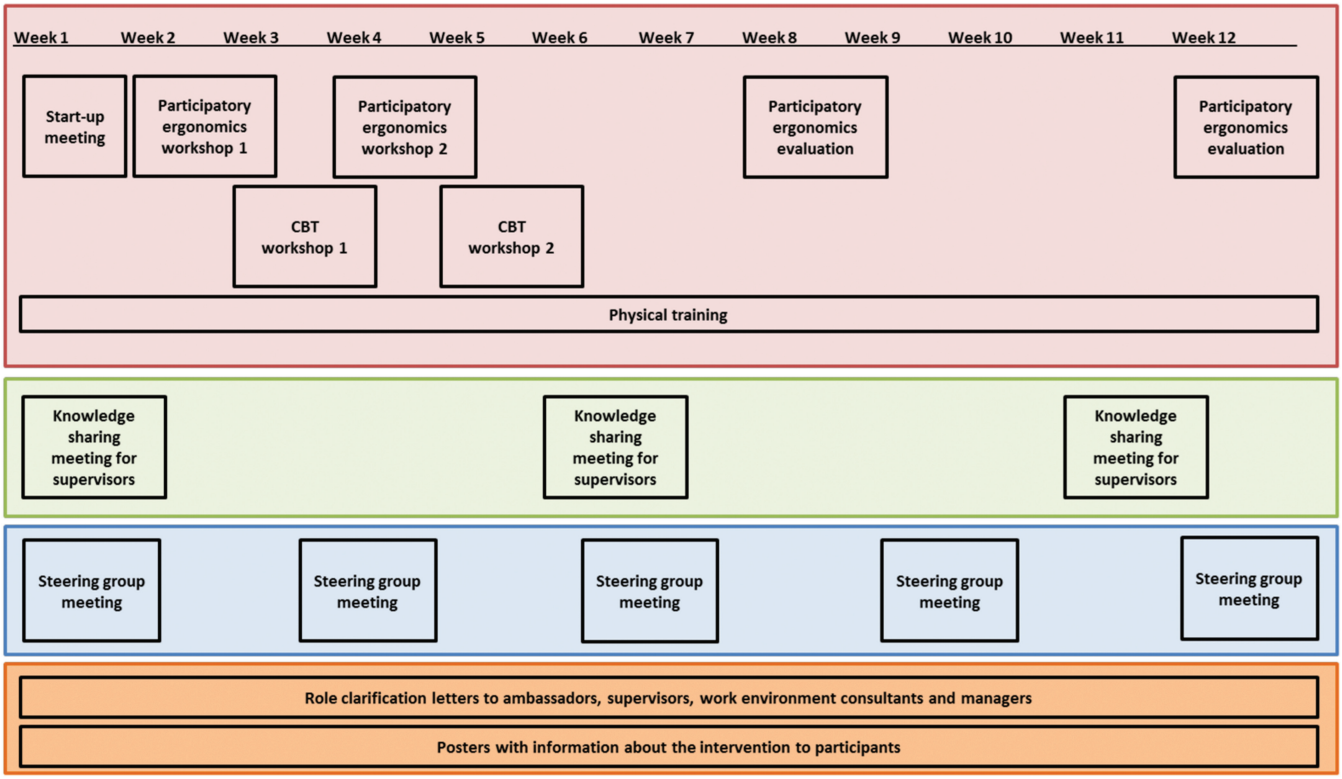

Figure 1. Overview of the 12 weeks of intervention. The intervention lasted 12 weeks and consisted of 19 sessions (participatory ergonomics [5 sessions], CBT [2 sessions], and physical training [12 sessions]) corresponding to 27 hours (participatory ergonomics [9 hours], CBT [6 hours], and physical training [12 hours]). For support of the intervention implementation, the supervisors of the participating teams were invited to 3 knowledge sharing meetings of 1-hour duration while their team were in the intervention, and steering group meetings were held frequently throughout the study period (with 5 meetings during the intervention). Moreover, letters about the process and role expectations were sent to the ambassadors, supervisors, work environment consultants, and managers, and posters with information about the intervention were supplied throughout the intervention period. CBT, cognitive–behavioural training.

days with LBP the preceding month (0-31 days). The severity was measured as LBP intensity, ie, worst pain the preceding month on a 0 to 10 numeric rank scale[43] (0 indicating no pain and 10 indicating worst imaginary pain) and the number of days with bothersomeness the preceding month (0-31 days). Pain intensity has been found to have a moderate correlation with more comprehensive disability measures such as Oswestry Disability Questionnaire ($r = 0.62$)[8] and a moderate-to-high correlation with Roland Morris Questionnaire ($r = 0.66$-0.70).[32] The bothersomeness of pain has been found to be valid as a single measure of the severity of LBP and is associated with disability, mental health, and work absence.[6] Data on LBP (days, pain intensity and bothersomeness) were collected monthly by text messages, giving a total of 15 measurements per participant for the trial period. This means that each participant received 3 to 4 text messages within each step (4 steps). The reason for the varying number of measurements was that during summer holidays and Christmas, there was a pause in the intervention. Therefore, the intervention period was prolonged to ensure that it was possible to conduct 12 weeks of intervention, but the data collection was still performed monthly.

From workplace registrations, we collected information about demographics and work-related factors. At baseline, the participants were asked to have their health measured and to answer a questionnaire for describing the baseline characteristics. The therapists registered participants' attendance in the activities at each session. Participants' appraisals of the intervention (satisfaction and relevance of the intervention) were measured by questionnaire after completion of 3 months of intervention. The questions were: "To which extent have you been satisfied with the project overall?" and "To which extent have you all in all, found the project relevant?" The response categories were on a 5-point Likert scale: "to a very large extent," "to a large extent," "some-what," "to a small extent," and "to a very small extent." The responses were dichotomised with the 2 first response categories indicating a positive response (satisfactory and relevant) and the 3 last response categories as a negative response (nonsatisfactory and not relevant).

Fidelity was measured in questionnaires for the therapists after each of the sessions as prespecified success criteria consisting of 55 questions on a 4-point Likert scale measuring the implementation of the protocol-defined activities within each session. The response categories were "not implemented," "partly implemented," "completely implemented," and "implemented more in depth." The last response category was included to contribute to the understanding of the implementation because more in-depth implementation of one theme may contribute to less implementation of another theme.[30] Moreover, the therapists' evaluation of the participants' maximal intensity during the physical training at a group level, measured by a scale ranging from 0 to 10, was included to measure to which extent the physical training fulfilled success criteria regarding intensity. For the success criteria, the questions on the 4-point Likert scale were scored as follows: the answers "completely implemented" and "implemented more in depth" were scored 100, "partly implemented" was scored 50, and "not implemented" was scored 0. The 0 to 10 scale concerning the participants' maximal intensity (0-10) in the physical training was scored 0 to 3 = 0, 4 to 5 = 50, 6 to 7 = 75,

and 8 to 10 = 100 based on an assumption of benefits from physical activity levels. The overall fidelity was scored as a mean of the success criteria for the sessions from 0% to 100%.

2.6. Sample size

We used the method described by Woertman et al.[44] for sample size calculation. The study was powered to detect a between-groups mean difference in the primary end point of 1 point in pain intensity,[26] which has been considered a relevant change in the workplace context in terms of risk of sickness absence.[11] The variance was set to 2.1 and α to 0.05, power to 0.8, and an intracluster correlation coefficient to 0.05. We calculated that we needed 65 participants in total. Giving that we had a workplace willing to offer the intervention to all workers, we chose to randomise all 594 who wanted to participate. Moreover, we expected to enrol both participants with and without pain, meaning that we needed a larger sample size to detect a difference in LBP intensity. Workplace studies often have a high dropout rate, and dropout could be as high as 50%. When conducting a stepped wedge design, the intervention period is prolonged. This can be an extra risk factor for a high dropout rate due to a high turnover rate or due to "fatigue" relating to waiting to receive the intervention. Moreover, there is a greater risk for organisational changes happening at the workplace during the study period, meaning that we could lose entire clusters in the evaluation.

2.7. Statistical analysis

For descriptive statistics, we used SPSS (IBM SPSS Statistics for Windows, Version 22.0, IBM Corp, Armonk, NY). For all other analyses, we used SAS version 9.3 (SAS Institute, Cary, NC, USA). We used Student *t* test for continuous variables and χ^2 for categorical variables to compare differences between those who completed the study (completers) and those who did not (noncompleters) and between responders with missing and nonmissing values.

Although the stepped wedge design has advantages in practical and logistic ways, which were crucial for the implementation of the intervention within the 54 teams, there is no consensus on analysing data from stepped wedge designs.[23] Mixed models account for significant influences of intercorrelation of repeated measures and enable comparison of the test conditions within and between groups. Therefore, we used linear mixed models to estimate the intervention effect, with treatment as independent categorical variable and random intercept for individual. The effect was analysed between 3 different groups corresponding to 3 different phases of the trial: (1) the control, (2) during the intervention, and (3) after the intervention corresponding to 3 months after implementation of the intervention. The main results will focus on the results after the intervention. The analyses were further adjusted for baseline values of LBP days, pain intensity, and bothersomeness, respectively, in a second model. Additionally, a sensitivity analysis on only nurses' aides was conducted. We used likelihood ratio tests to compare the models with and without a covariance structure. All analyses were performed according to intention to treat, including all eligible randomised participants without imputations because mixed models inherently account for missing values.[36]

3. Results

Figure 2 shows the flowchart of the trial. Of 1074 eligible workers from 54 teams, 594 wanted to participate and provided baseline data. In total, 21 clusters were randomised to 4 groups beginning the intervention at 4 different time points, with 5 clusters (126 participants) in group 1, 5 clusters (146 participants) in group 2, 5 clusters (158 participants) in group 3, and 6 clusters (164 participants) in group 4. Of the total randomised 594 participants, 8 participants were never included in the text message system (due to technical problems), giving a total study population for the analyses of 586. **Table 1** shows baseline characteristics of the entire study population and for the 4 groups separately. Mean age was 47 years, and 93% were women and 89% were nurses' aides. Mean number of clusters, teams, age, proportion of women, mean LBP days, pain intensity, and bothersomeness was similar among the 4 groups at baseline.

The completers ranged from 72% to 81% among the 4 groups with 452 (76%) of the total population completing the study, and no entire clusters or teams withdrew from the study. Among noncompleters, more were smokers and had lower job seniority compared with completers. Otherwise, there were no other significant differences in baseline characteristics. The most frequent reason for dropping out of the study was no longer being employed (53 participants, 37%). Among those answering less than 80% of the measurements, more were working evenings and nights, more were not born in Denmark, more experienced low social support from colleagues, more were smokers, and they had more LBP days (7.2 compared with 5.2), higher pain intensity (3.6 compared with 2.8), and higher bothersomeness (3.7 compared with 2.6) compared with those answering 80% or more of the measurements.

The intervention was delivered by 6 therapists (2 occupational therapists and 4 physiotherapists) with a mean of 11 years of experience after professional qualification. A total of 756 sessions (174 participatory ergonomics sessions, 80 CBT sessions, and 502 physical training sessions) were planned for the study period. Of the 756 planned sessions, 713 (94%) were conducted. For the remaining 43 (6%) sessions, the primary reasons for cancellations were due to few participants attending (26) or cancellations from therapists (8 sickness absence and 2 other work tasks interfering with the activity). In total, 12 steering group meetings were held throughout the study period; of those, 5 were held during the intervention. Moreover, all of the 12 planned knowledge sharing meetings for the 41 supervisors were held during the intervention period with an average participation rate of 52%. The core components of the intervention were delivered with a mean fidelity of 90%. There were no serious adverse events attributable to the intervention. The average participation rate for the entire intervention (27 hours) was 50%. Most participants were satisfied with the intervention (78%), and most participants also found the intervention relevant (80%).

Overall, the analyses were based on assessments from 586 participants (**Table 2**). The mean number of measurements for LBP days per participant was 11.5 (SD = 4.8), the mean number of measurements of pain intensity per participant was 11.6 (SD = 4.8), and the mean number of measurements for bothersomeness per participant was 11.5 (SD = 4.8). **Table 3** shows the results of the analyses of the effect of the multifaceted intervention on the 586 participants enrolled in the text message system. Effects were estimated with linear mixed models and were adjusted for significant influences of intercorrelation of repeated measurements. As the intracluster correlation (ICC) was low between the 4 overall cluster groups in the stepped wedge design (ICC = 0.007), adjustment for dependency of the individuals within the clusters was not necessary. The model was fitted with the best covariance

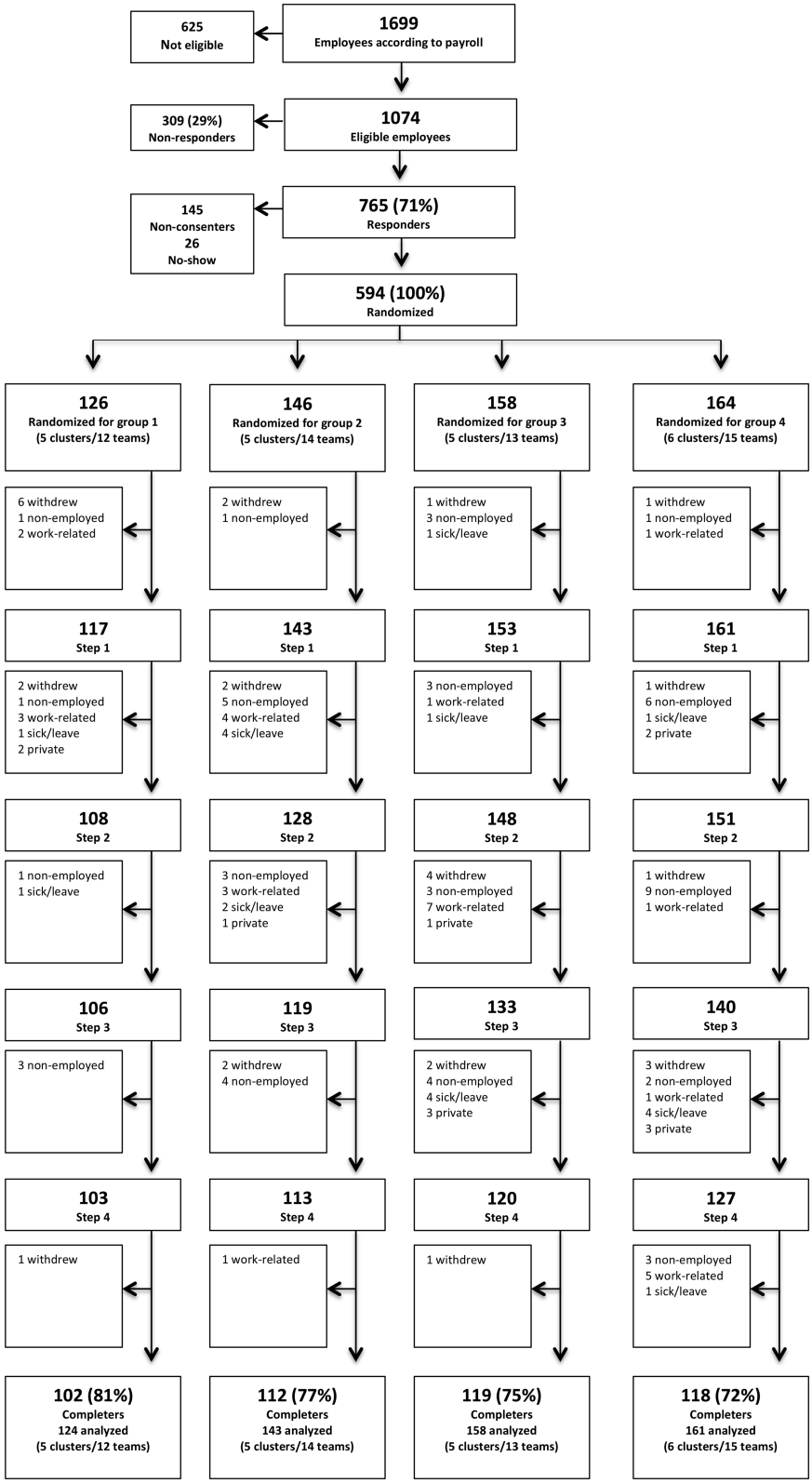

Figure 2. Trial profile. After assessing the payroll (n = 1699) for eligible participants, we excluded 625 who were not eligible (not belonging to the target job groups [ie, nurses' aides, kitchen and cleaning personnel, or janitors], no longer employed, long-term sick-listed, or not being permanently employed). Of the 1074 eligible employees, 594 were randomised in 4 groups in accordance with the stepped wedge design. Each of the 4 groups beginning the intervention at 4 time points 3 months apart consisted of 4 to 5 clusters and 12 to 15 working teams. The study comprised 4 steps, each lasting 3 months. Within each step, information about dropouts is given. The most frequent reason for dropping out of the study was no longer being employed (53 participants, 37%). Other reasons were due to time of the intervention activities interfering with their work tasks (31 participants, 22%), withdrawal of consent to participate (29 participants, 20%), sickness absence or leave (20 participants, 14%), and private reasons (10 participants, 7%). In the end, 586 participants were included in the analyses because 8 were never included in the text message system.

Table 1

Baseline characteristics.

	Total population (n = 594)	Group 1 (n = 126)	Group 2 (n = 146)	Group 3 (n = 158)	Group 4 (n = 164)
Age, y	47 (10.2)	48 (9.4)	46 (11.0)	46 (10.3)	47 (10.1)
Sex (female)	551 (93%)	117 (93%)	137 (94%)	144 (91%)	153 (93%)
Ethnicity (born in Denmark)	482 (86%)	111 (93%)	100 (76%)	136 (88%)	135 (86%)
LBP (0-31 d)	5.7 (7.68)	5.0 (7.29)	5.8 (8.15)	5.3 (7.14)	6.5 (8.06)
LBP intensity (0-10)	3.0 (2.94)	2.7 (2.95)	3.0 (2.70)	2.9 (2.94)	3.6 (3.07)
Bothersomeness (0-31 d)	3.2 (6.11)	3.1 (5.79)	4.0 (7.78)	2.5 (4.57)	3.4 (6.05)
LBP previous year, d					
0	123 (22%)	26 (22%)	24 (18%)	34 (22%)	39 (25%)
1-7	164 (29%)	42 (35%)	39 (30%)	47 (30%)	36 (23%)
8-30	136 (24%)	26 (22%)	38 (29%)	37 (24%)	35 (22%)
31-90	56 (10%)	9 (8%)	14 (11%)	17 (11%)	16 (10%)
>90	49 (9%)	12 (10%)	8 (6%)	11 (7%)	18 (12%)
Everyday	34 (6%)	4 (3%)	8 (6%)	9 (6%)	13 (8%)
Smokers	180 (32%)	38 (32%)	51 (39%)	42 (27%)	49 (31%)
Body mass index, kg/m^2	27 (5.8)	27 (5.6)	26 (5.9)	27 (5.9)	27 (5.9)
Job group (care workers)	527 (89%)	102 (81%)	138 (95%)	125 (79%)	162 (99%)
Job seniority, y					
0-1	68 (13%)	5 (4%)	17 (13%)	22 (16%)	24 (16%)
2-10	238 (45%)	50 (44%)	65 (51%)	63 (46%)	60 (40%)
>10	224 (42%)	60 (52%)	46 (36%)	51 (38%)	67 (44%)
Type of workplace					
Home care	283 (48%)	68 (54%)	67 (46%)	42 (27%)	106 (65%)
Nursing homes	241 (41%)	34 (27%)	71 (49%)	84 (53%)	52 (32%)
Unknown	70 (11%)	24 (19%)	8 (6%)	32 (20%)	6 (4%)
Work shift					
Day shift	454 (76%)	109 (87%)	122 (84%)	120 (76%)	103 (63%)
Evening/night	122 (21%)	14 (11%)	23 (16%)	29 (18%)	56 (34%)
Unknown	18 (3%)	3 (2%)	1 (1%)	9 (6%)	5 (3%)
Education					
Unskilled	37 (6%)	7 (6%)	8 (6%)	17 (11%)	5 (3%)
Low skilled	388 (65%)	83 (66%)	98 (67%)	81 (51%)	126 (77%)
High skilled	158 (27%)	35 (28%)	37 (25%)	55 (35%)	31 (19%)
Unknown	11 (2%)	1 (1%)	3 (2%)	5 (3%)	2 (1%)
Physical exertion during work (0-10)	6.4 (2.23)	6.6 (2.32)	6.5 (2.10)	6.2 (2.28)	6.5 (2.22)
Social support: colleagues (0-100)	79.1 (17.88)	80.8 (16.44)	76.7 (19.74)	80.0 (17.10)	78.8 (17.88)
Social support: supervisor (0-100)	78.3 (21.53)	78.5 (19.91)	75.3 (21.99)	80.5 (22.12)	78.5 (21.64)

Baseline characteristics of the total randomised population (N = 594) and of the 4 groups allocated for intervention at each step. Data are presented as mean (SD) or n (%).
LBP, low back pain.

structure (unstructured covariance). The analyses yielded significant effects on reduction of LBP days, pain intensity, and bothersomeness after the intervention compared with the control group. This corresponded to an effect after 3 months of intervention for LBP days of −0.8 (95% confidence interval [CI], −1.19 to −0.38), for pain intensity of −0.4 (95% CI, −0.60 to −0.26), and for bothersomeness of −0.5 (95% CI, −0.85 to −0.13). During the intervention, no statistically significant effect on LBP days, pain intensity, and bothersomeness was found, but the estimates showed a numerical reduction in all. The sensitivity analyses on nurses' aides showed similar estimates and *P* values as the analyses on the total population.

4. Discussion

Our study shows that a multifaceted intervention consisting of participatory ergonomics, physical training, and CBT can reduce LBP days, pain intensity, and bothersomeness in eldercare workplaces (nursing homes and home care) in a group of workers mainly made up of nurses' aides. In this study, we found a mean

Table 2

Summary of assessments for outcomes.

	Group 1 (n = 126)	Group 2 (n = 146)	Group 3 (n = 158)	Group 4 (n = 164)	Total (n = 594)
No. of participants	124	143	158	161	586
Maximum measurements throughout the study	1860	2145	2370	2415	8790
Measurements of LBP days	1488 (80%)	1619 (75%)	1881 (79%)	1850 (77%)	6838 (78%)
Measurements of LBP intensity	1494 (80%)	1621 (76%)	1880 (79%)	1853 (77%)	6848 (78%)
Bothersomeness	1489 (80%)	1621 (76%)	1880 (79%)	1833 (76%)	6823 (78%)

Data are presented as n (%). For each participant, a maximum of 15 measurements of LBP days, intensity, and bothersomeness were possible (1 text message each month throughout the 15 months of duration of the study). Of the total population of 594, 8 participants were never included in the text message system, giving a total study population of 586 participants and a maximum number of measurements throughout the study of 8790. The response rates for LBP days ranged between 75% and 80%, the response rates for intensity ranged between 76% and 80%, and the response rates for bothersomeness ranged between 76% and 80%.
LBP, low back pain.

Table 3

Results of the effect of the multifaceted intervention on LBP days, intensity, and bothersomeness.

	Model 1			Model 2		
	Regression coefficient (SE)	95% CI	*P*	Regression coefficient (SE)	95% CI	*P*
LBP days						
Control		Reference category			Reference category	
During	−0.3 (0.2)	−0.70 to 0.03	0.07	−0.3 (0.2)	−0.64 to 0.07	0.12
After	−0.9 (0.2)	−1.31 to −0.49	<0.0001	−0.8 (0.2)	−1.19 to −0.38	0.0001
LBP intensity (0-1)						
Control		Reference category			Reference category	
During	−0.1 (0.1)	−0.23 to 0.10	0.47	−0.01 (0.1)	−0.18 to 0.15	0.87
After	−0.5 (0.1)	−0.64 to −0.29	<0.0001	−0.4 (0.1)	−0.60 to −0.26	<0.0001
Bothersomeness, d						
Control		Reference category			Reference category	
During	−0.3 (0.2)	−0.62 to 0.05	0.09	−0.3 (0.2)	−0.63 to 0.04	0.08
After	−0.5 (0.2)	−0.84 to −0.11	0.01	−0.5 (0.2)	−0.85 to −0.13	0.01

The effects of the multifaceted intervention on LBP days, intensity, and bothersomeness for the 586 participants randomised to the intervention. The results are presented as model 1 (crude model) and model 2 (model adjusted for baseline values of LBP days, intensity, and bothersomeness, respectively). The results presented are the analyses of the difference between groups. The control group is the reference category.
CI, confidence interval; LBP, low back pain.

reduction in pain days of 0.8. As the duration of LBP is a significant risk factor for sickness absence,[37] a reduction in pain days could potentially be beneficial for both the workers and workplaces. With respect to pain intensity, the average changes were relatively small (−0.4). However, another study on nurses' aides shows that relatively small changes in pain intensity can decrease their risk of long-term sickness absence.[1] After the intervention, there was an effect of the intervention with a reduction in number of days of bothersomeness of 0.5 days. A higher degree of bothersomeness was found to be associated with increased risk of being absent from work or consulting health care professionals 6 months later.[6] Previous intervention studies in the health care setting and in the general community setting found contradictory results on bothersomeness.[10,33] Similar to a study investigating the effect of thai chi exercises,[10] we found that our intervention was effective in both reducing pain intensity and bothersomeness. Thus, the effects of the multifaceted intervention with a reduction in LBP days and pain intensity as well as a reduction in bothersomeness all constitute important aspects of pain with high impact for the participants to maintain their functioning at work, eg, work ability, productivity, and quality of life.

Several reviews have examined the effectiveness of workplace interventions for LBP.[3,22,35,39] However, multifaceted interventions for LBP have seldom been conducted in the workplace setting, and methodological problems (ie, small sample sizes, lack of control groups, and inadequate description of the interventions) may have contributed to their inconclusive results.[35] Previously, biopsychosocial workplace multifaceted intervention studies have targeted reduction of sickness absence and therefore aimed at workers already on sickness absence[16,31,38] or have consisted of rehabilitation studies of patients with chronic pain.[18] There are conflicts in results regarding the effect of such interventions on sickness absence.[31,38] More recently, a study in the secondary health care investigated the effect of counselling addressing workplace barriers and physical activity among workers with LBP, independently of their sickness absence status. This study found effects on sickness absence and pain in general, but no effect on specific measures of LBP (pain intensity and Roland Morris Disability Questionnaire).[16]

In contrast to other studies showing effect among workers with pain,[35,42] we were able to reduce LBP in a mixed population including both participants with and without LBP. As workers present with different levels of LBP (some might have LBP and others do not have LBP), it is particularly important that a workplace intervention be widely applicable and aim at both primary and secondary prevention of LBP. The use of a multifaceted intervention increases the likelihood that the intervention fits all workers' need because one worker might benefit from one component of an intervention and another worker benefit from another component of an intervention. However, it is also likely that a worker might need several components of the biopsychosocial intervention for prevention of LBP. Thus, multifaceted interventions may be relevant for entire working populations and not only for workers already experiencing pain. The finding of this study that one can achieve a reduction in LBP among the entire workplace is in agreement with the population strategy of shifting the whole distribution of LBP in a workplace population in a favourable direction.[29] However, as the workers present with different levels of LBP, the benefits they might get from the intervention might be different, meaning that those with higher levels of pain might receive greater benefit from the intervention.

4.1. Strengths and limitations of the study

This trial has several strengths: (1) the stepped wedge design allowing relatively flexible implementation and enabling all workers invited to eventually participate in the trial; (2) the large number of participating working teams and workers increasing the generalisability and power of the study; (3) use of frequent measures of LBP providing more valid measures of the fluctuating LBP; (4) the intervention was delivered by local trained therapists with potential of leveraging local knowledge and sustainability; (5) the high fidelity of the intervention (90%); and (6) the absence of strict exclusion criteria for participation in the trial, which may increase generalisability and make it more applicable to the real-life setting. Previously, we have reported that we reached a fairly representative group of the target population with respect to demographic factors and health.[27] However, we cannot disregard a potential selection bias, as there are still approximately 30% of the eligible participants in whom we lack information on.

Some limitations of our study are worth noting. First, small differences were observed between noncompleters and completers at baseline in smoking and job seniority, and among those answering more or less than 80% of the measurements, small differences were observed in work shift, ethnicity, social support at work, smoking, and LBP. Moreover, there was also a difference in dropout among the 4 groups with a higher

dropout in the groups beginning the intervention at a later time point. This can potentially cause a small selection bias towards a more healthy population being followed up. Moreover, the intervention included mainly nurses' aides from eldercare workplaces (nursing homes and home care). Thus, the results are perhaps not generalisable for other occupational groups. A potential criticism is the low participation rate (50%) in this study. However, this participation rate likely reflects how such an intervention would be delivered in real life, and therefore the results are likely to reflect what can be generally expected at the workplace. Another limitation of this study is that it consists of several integrated components in a way that does not allow for separate evaluation of the effect of each individual component. Moreover, because of the need for frequent repeated measures of LBP, we used a single measures of LBP instead of more comprehensive clinical measures,[25] which make comparisons with other studies difficult. Finally, the multifaceted intervention, by its nature, most likely requires more resources (costs) and is inherently more complex to deliver. It is therefore critical to determine whether the additional resources and effort required are cost effective in the longer run. Future studies should investigate how to implement cost-effective multifaceted interventions for LBP at the workplace.

5. Conclusions

A workplace multifaceted intervention consisting of participatory ergonomics, physical training, and CBT was effective in reducing LBP days, pain intensity, and bothersomeness among workers in eldercare workplaces. Thus, multifaceted interventions delivered at the workplace may be relevant for improving LBP in working populations.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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