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Effectiveness of Workplace Active Rest Program on low back pain in office workers: a stepped-wedge cluster randomized controlled trial

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Effectiveness of Workplace Active Rest Program on low back pain in office workers: a stepped-wedge cluster randomized controlled trial

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ABSTRACT

Objectives: This study aimed to investigate the effectiveness of Workplace Active Rest Program (WARP) on chronic low back pain (LBP) in office workers.

Design: This study conducted a closed cohort stepped-wedge cluster randomized trial. The total duration of the study was 16 weeks (4 weeks for each step). Sequence allocation was randomized, but no one was blinded.

Setting: This study was conducted in 3 offices in a Japanese electronics company.

Participants: We recruited 29 office workers with LBP greater than 3 months. LBP due to specific injury or disease was excluded. The median age was 38 years, and 26 (90%) were male. All participants completed the study.

Interventions: In the intervention phase, participants performed WARP comprising frequent stand-up and individualized brief exercise/physical activity during work. Physical therapists held LBP workshop and developed tailor-made programs before introducing WARP. We instructed participants to perform WARP at 5 timings during work. In the control phase, participants stayed as usual.

Primary and secondary outcome measures: Primary outcome was pain intensity of LBP assessed using Brief Pain Inventory. Secondary outcomes were work productivity loss measured using Work Limitations Questionnaire, LBP disability assessed using Roland-Morris Disability Questionnaire, psychosocial subscale assessed using STarT Back Screening tool, and physical activity measured

using triaxial accelerometers. These outcomes were collected at baseline and 4-month follow-up evaluation.

Results: In the intention-to-treat analysis, WARP did not show any significant effects on pain intensity (β, 0.01; 95% confidence interval, -0.50, 0.52) and secondary outcomes. The median adherence for WARP was 28.6% (interquartile range, 16.8, 41.1), which was equal to 1.43 times per day. No adverse effect was observed.

Conclusions: The present study was unable to confirm the effectiveness of active rest in improving LBP. Hence, a further study needs to investigate its effectiveness.

Trial registration: UMIN Clinical Trials Registry (UMIN000033210)

Strengths and limitations of this study

- This study is the first pragmatic trial conducted in the real-world setting that investigates the feasibility and effectiveness of active rest.
- All participants completed Workplace Active Rest Program.
- However, adherence to WARP was lower than we expected.
- Because recruited office workers had relatively mild LBP, we were unable to confirm whether WARP is effective in office workers with severe LBP.

INTRODUCTION

Low back pain (LBP) is a prevalent health problem in office workers[1,2] and is the leading cause of decreasing healthy life expectancy worldwide[3]. Moreover, LBP results in a large socioeconomic burden due to work productivity loss and medical expenses[4,5]. In terms of both individual and social impact, LBP among office workers is the crucial problems, which should be tackled.

Office workers are those workers who stay in prolonged sitting position during most of their working time[6,7]. Prolonged sitting is one of the causes of LBP, which is also due to several factors such as increased disc pressure[8], decreased trunk mobility[9], and less posture variation[10]. Although the previous studies have investigated the effectiveness of ergonomic intervention and back support, these are considered ineffective in improving LBP[11,12]. Recently, the use of standing desk has been shown to be effective in improving LBP[13], but it has the following limitations: it requires a lot of space and is costly. Therefore, easy-to-use solutions are required in the workplace.

Active rest (taking a break with exercise/physical activity in the workplace) could possibly improve LBP because it has the following characteristics: (1) sedentary break by standing up, which can prevent prolonged sitting, and (2) exercise/physical activity, which is recommended in the LBP guidelines[14,15]. A previous study showed that office-based stretching (10–15 minutes/session, 3 times/week) was effective in reducing the occurrence of musculoskeletal discomfort when compared with no intervention [16]. However, in our study, we developed a shorter exercise program involving frequent sessions (a few minutes per session, 5 times/day, except on weekends) because we aimed to

promote frequent standing to break the habit of prolonged sitting. Although a positive effect of active rest on LBP was shown in the laboratory study[17], its effectiveness in the real-world setting is still unknown. We hypothesized that there is a difference in the effectiveness between laboratory and real-world setting. Thus, the present study aimed to investigate the effectiveness of Workplace Active Rest Program (WARP) on chronic LBP and work productivity loss in office workers in the real-world setting.

METHODS

Study design

The present study was conducted according to the extension of the Consolidated Standards of Reporting Trials 2010 Statement for stepped-wedge cluster randomized controlled trial (SW-CRT)[18]. We used a closed cohort SW-CRT involving the randomization of clusters to different sequences. SW-CRT is a crossover design with repeated measurement, in which clusters switch from control to intervention condition. SW-CRT is a suitable study design if we assume that the intervention will do more good than harm, hence making it unethical to withhold the intervention from a control group. Thus, because it is morally acceptable and beneficial for participant recruitment, we introduced the SW-CRT design [19]. Moreover, this is the pragmatic design, which increases statistical power and decreases needed clusters compared to those in parallel CRT[20]. The present clinical trial was registered with UMIN Clinical Trials Registry (identifier: UMIN000033210).

As Figure 1 shows, we conducted the present study in 3 offices (clusters) in a Japanese electronics company. We set 3 sequences, where an office switched to the intervention condition one by one. The total duration of the study was 16 weeks (4 weeks for each step). Evaluation was conducted at baseline and 4 points during the last week of each step. Because of a closed cohort design, participants assessed in different periods were the same participants.

Patient and public involvement

Office workers with LBP were not involved in developing the research question, but we consulted them about the design of the study (especially the intervention program) in terms of feasibility and applicability by joining the employees' health committee. During the trial, they helped us to hold LBP workshop by arranging a room and equipment. We asked them to assess the burden of the intervention before they joined the study. We already disseminated the results of our study to participants and reported them at the employees' health committee.

Participants' recruitment

We recruited 29 participants from 3 offices of a Japanese electronics company in July 2018. Three offices were separated from one another. First, participants were approached by the public health nurse working in this company. When they were interested in the study, the public health nurse introduced them to us. Subsequently, researchers explained the study to the participants, and participants provided informed consent for inclusion in the study.

Office workers were eligible for the present study if they have the following characteristics: (1) are full-time workers and (2) engaged in desk work greater than 4 hours/daily working time (self-reported)[21] and (3) had LBP greater than 3 months. The location of LBP was defined as pain between the 12th rib and inferior gluteal folds[22]. Exclusion criteria were as follows: (1) LBP caused

by fracture and trauma injuries, infectious diseases, and internal organ disorders and (2) difficulty participating in the study due to medical or surgical disease. Cluster-level eligibility criteria were as follows: (1) an office where most workers were engaged in desk work and (2) supervisors granting permission in the performance of the study.

This study was approved by the Ethics Committee of Kobe University Graduate School of Health Sciences. All participants provided written informed consent for inclusion in the study.

Randomization and blinding

Offices were randomly assigned to one of the 3 successive sequences (one office per sequence) after all clusters and participants were recruited. A researcher who was not involved in the recruitment performed random allocation using computer-generated random numbers and coded information about offices. To prevent contamination, both clusters and participants were not informed of the time the intervention started and the detailed program of the intervention until 2 weeks before the intervention started. We also asked the participants exposed to the intervention not to disclose the program content to other workers. Due to the nature of the present study, participants, intervenient, and outcome assessors (self-reported) could not be blinded. Data analyst was not also blinded to group allocation.

Intervention

In the intervention phase, we offered WARP in two parts below. First, we held the LBP workshop (group), followed by the introduction of active rest in the workplace. LBP workshop was held when the group moved from the control phase to the intervention phase.

The purposes of LBP workshop were as follows: to allow the participants to understand LBP and sedentary behavior, develop customized exercise program, and explain how WARP is performed after the workshop. LBP workshop was held at company's gymnastics room after work for 90 minutes by two or three physical therapists (PTs) (PTs with expertise in LBP, at least 3 or more experience years) including the primary researcher (YT). To avoid inconsistency on workshop contents in PTs, we discussed and agreed with its contents before workshop. We disseminated leaflets about the contents of LBP workshop to the participants. First, we gave lecture on the following: (1) LBP causes and interventions using a biopsychosocial model and (2) the impact of sedentary behavior (SB) on health (death, noncommunicable diseases, and LBP). Second, evaluation was performed using a physical examination and an interview sheet (a brief file was described in Supplementary Figure 1). We evaluated trunk flexion and extension (comfortable direction), static trunk posture (sagittal plane, lordosis/kyphosis), Thomas test (flexibility of the iliopsoas muscle)[23], finger-floor distance test (spine and hip joint movement), and one-finger test (positive result indicates sacroiliac joint pain)[24] and asked if the participants felt painful sensations when sitting or standing. Third, individualized

exercise programs were developed based on the results of the evaluation. Some exercises were recommended based on the results on the physical examination and interview sheets (Supplementary Figures 1–2). We prepared 6 types of exercise focusing on spine and hip stretch and training, which can improve spine and hip joint mobility and decrease lumbar disc pressure (trunk extension exercise, stretching of the iliopsoas and hamstrings, abdominal oblique, erector spinae muscles, thoracolumbar fascia). We selected these exercises because these can be briefly performed by the participants when they stand up. We let them perform the recommended exercises during workshop after they had seen the demonstration. If participants had difficulty in performing the exercise, we individually helped them.

At the end of workshop, we explained to the participants how and when WARP is performed. Participants were instructed to perform WARP at 5 timings (just before the work starts, AM break, lunch break, PM break, after the work is finished). Because a chime ringed at these 5 timings, we asked them to stand up and perform their exercises for a few minutes after the chime ringed. We also recommended them to perform WARP other than the 5 fixed timings. However, the participants were not required to perform the program. We explained the content of WARP and introduced some brief exercises to other workers in the same office. It enables participants to easily perform exercise at workplace because they understand what they do. Additionally, to determine if problems occurred after performing WARP, researchers visited each office once a month.

Control

When the participants were in the control phase, we did not perform any intervention to the participants (usual work).

Primary outcome

Primary outcome was LBP intensity. We used the pain intensity subscale of Brief Pain Inventory (BPI), which is well-validated and reliable among patients with noncancer pain including LBP[25,26]. Participants rated their pain intensity at "worst," "least," "average," and "now" during the last 24 hours using 11-point Numerical Rating Scale (NRS), ranging from 0 (no pain) to 10 (worst imaginable pain). Finally, the mean of these four items was used as a BPI score. A Japanese version of BPI has a good validity and reliability[27].

Secondary outcome

The Roland-Morris Disability Questionnaire (RDQ) is a validated 24-item questionnaire that assesses the disability due to LBP such as "I change position frequently to try and get my back comfortable."[28,29]. Each item is scored either 0 or 1, with all scores summed to a total between 0 and 24 (a higher score indicates a greater disability level).

The STarT Back Screening tool is a validated screening tool that predicts the future disability level[30,31]. We used 5-item psychosocial subscale of the STarT Back Screening tool including fear of movement, depressive symptom, catastrophic attitude, anxiety, and pain distress. Score ranged from 0 to 5 (a higher score indicates a higher possibility for future disability level).

The Work Limitations Questionnaire (WLQ) is a validated 25-item questionnaire that evaluates work productivity loss due to physical/psychological issues[32,33]. The WLQ is composed of the following 4 subscales: (1) Time Management (the difficulty in performing a job tasks in a timely manner and in scheduling tasks), (2) Mental-Interpersonal Demands (the difficulty in performing cognitive job tasks and in interacting with colleagues), (3) Physical Demands (the ability to perform job tasks involving body strength, movement, endurance, coordination, and flexibility), and (4) Output Demands (work quantity and quality reduction and timeliness of completed work). Additionally, "Not applicable" was also provided as a response option and treated as a missing value. All subscales scores were converted to percentage, 0% (least limited) to 100% (most limited). Work productivity loss (%) was calculated from the weighed sum of the 4 subscale scores using a validated algorithm ranging from 0% to 24.9%. A higher score indicates a higher level of work productivity loss.

To measure physical activity and sedentary behavior, we distributed triaxial accelerometers (Active style Pro HJA-750C, Omron Healthcare Co., Ltd.) to the participants during each step. Details of the accelerometer measurement procedure were described elsewhere[34,35]. Participants were

instructed to wear triaxial accelerometers on their waist during only working time for 5 days. Data were recorded in 60-second epoch. In addition to the number of steps, time spent in moderate-to-vigorous physical activity (MVPA, 3.0 ≤ Metabolic equivalent; METs), light physical activity (1.5 < METs < 3.0), and SB (METs ≤ 1.5) were calculated using R version 3.5.2. Days with at least 4 hours of wearing time or 75% of working hours were considered a valid day[36], and we included the data with at least 1 valid day in the analysis. Non-wear time was defined as a period with continuous zero count lasting over 60 minutes.

Other measurements

We collected demographic data such as age, sex, height, weight, and body mass index. Participants were asked whether they were ever diagnosed with the following conditions: lumbar disc herniation, lumbar canal stenosis, lumbar compression fracture, trauma, spinal metastasis, fibromyalgia, rheumatoid arthritis, and infectious spondylitis. Participants also reported the status of their analgesic administration (none, rarely, sometimes, often, and always), consultation on orthopedic clinics, or alternative medicine for LBP (none, once, twice, three times, four times, and greater than five), sleep quality (very good, fairly good, fairly bad, and very bad), and other musculoskeletal pain including neck, shoulder, elbow, wrist, hip, knee, and foot (NRS). At the final follow-up evaluation (T4 evaluation of Figure 1), participants answered about their satisfaction (satisfied very much, satisfied,

normal, dissatisfied, dissatisfied very much) and free opinion about WARP.

Adherence

To evaluate adherence for WARP, we asked participants to keep diaries whether they performed WARP or not in each 5 timing. Adherence is calculated 100% if they performed WARP at all 5 timings during the whole intervention phase. Because WARP is a program at the workplace, we did not include holidays when assessing adherence.

Sample size

We calculated the sample size using formula specific for stepped-wedge design[20]. Primary outcome difference and standard deviation were set as 2.0 and 2.5, respectively[37]. The following assumed parameters were used: cluster size=10, intracluster correlation coefficient=0.05, the number of step=3, the number of baseline measurement=1, measurement after each step=1, two-sided α-level=0.05, and β=80%. To detect 2-point difference in primary outcome, a total of 22 participants were needed, and, actually, 29 participants joined the present study.

Statistical analysis

For the characteristics of participants, categorical variables were presented as frequency and

percentage and continuous variables as mean ± SD (standard deviations). If distributions of the continuous variables were skewed, data were presented as median (range or interquartile range [IQR]).

We performed both intention-to-treat (ITT) analysis and per-protocol analysis to investigate both the effectiveness and efficacy of WARP. Primary analysis was ITT analysis because this study aimed to investigate pragmatic effectiveness of WARP in the real-world setting. For ITT analysis, we performed the linear mixed effect model, setting the intervention as the fixed effect, individual and office as the random effect, and calendar time as the confounding factor. For per-protocol analysis, we also performed the linear mixed effect model after excluding participants whose adherence to WARP was median (28.6%) or less.

All statistical analyses were performed using Stata/IC 15.1 software (StataCorp). $P < 0.05$ was considered to be statistically significant.

RESULTS

We recruited 29 office workers from 3 offices in July (Figure 2). As planned, Office A performed the intervention in the first period (August), Office B in the second period (September), and Office C in the third period (October). All participants continued WARP until the end (no dropout) of the study. Twenty-eight participants completed the baseline and each follow-up evaluation (T1–T4). Only one participant did not answer T3 evaluation, but answered other evaluations.

The median age was 38 years, and 26 (90%) were male (Table 1). The median pain intensity assessed using BPI was 2.0 (IQR, 0.8, 2.2), and the median score of RDQ was 1.0 (0.0, 2.0). Only two participants performed the clinic or alternative care, and only one participant often received analgesic medication. The median proportion of sedentary time was 79.6% (68.1, 84.1). The median productivity loss estimated by WLQ was 2.2% (0.8, 5.9). Regarding the difference of characteristics in 3 offices, participants were younger in Office C than in other offices. Pain intensity was lighter in Office B than in other offices.

Table 1. Characteristics of participants

	All	Office A	Office B	Office C
N	29	8	8	13
Age, median (IQR)	38.0 (28.0, 45.0)	43.5 (37.0, 46.5)	41.5 (29.5, 46.0)	32.0 (27.0, 38.0)
Sex				
Male	26 (90%)	6 (75%)	7 (88%)	13 (100%)
Female	3 (10%)	2 (25%)	1 (13%)	0 (0%)
BMI, median (IQR)	21.9 (20.2, 24.6)	20.9 (19.9, 23.8)	21.5 (20.2, 24.3)	22.6 (21.5, 24.6)
Lumbar disc herniation	2 (7%)	0 (0%)	1 (13%)	1 (8%)
Lumbar canal stenosis	2 (7%)	0 (0%)	1 (13%)	1 (8%)
Pain intensity, median (IQR)	2.0 (0.8, 2.2)	1.9 (1.1, 3.0)	0.5 (0.2, 2.1)	2.0 (1.2, 2.5)
RDQ, median (IQR)	1.0 (0.0, 2.0)	1.0 (0.0, 1.5)	0.5 (0.0, 1.0)	1.0 (0.0, 2.0)
STarT Back, median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)	0.0 (0.0, 1.0)
Medicine				
None	23 (79%)	5 (62%)	7 (88%)	11 (85%)
Rarely	3 (10%)	2 (25%)	0 (0%)	1 (8%)
Sometimes	2 (7%)	1 (12%)	1 (13%)	0 (0%)
Often	1 (3%)	0 (0%)	0 (0%)	1 (8%)
Always	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Seek for clinic care	2 (7%)	0 (0%)	1 (13%)	1 (8%)
Seek for alternative care	2 (7%)	2 (25%)	0 (0%)	0 (0%)
Physical activity, median (IQR)				
Time spent for Sedentary (%)	79.6 (68.1, 84.1)	74.1 (58.5, 80.0)	78.9 (63.5, 84.9)	81.6 (73.5, 85.2)

Time spent for LPA (%)	16.3 (12.6, 24.4)	19.4 (15.5, 32.9)	17.2 (12.3, 27.9)	13.4 (11.0, 19.2)
Time spent for MVPA (%)	4.5 (2.9, 7.1)	5.6 (3.5, 10.1)	3.9 (2.2, 5.9)	4.1 (3.0, 6.3)
Step	4763.4 (3553.1, 6228.4)	4763.4 (3962.9, 8457.4)	4569.5 (3495.1, 6228.4)	4593.9 (3624.5, 5636.6)
Wearing time (minutes)	708.4 (666.3, 757.1)	682.7 (635.4, 744.4)	757.0 (666.4, 847.3)	707.1 (692.2, 743.5)
Other musculoskeletal pain				
Neck	17 (59%)	4 (50%)	8 (62%)	9 (69%)
Shoulder	18 (62%)	4 (50%)	8 (62%)	9 (69%)
Elbow	3 (10%)	0 (0%)	2 (15%)	1 (8%)
Hand	4 (14%)	1 (12%)	2 (15%)	1 (8%)
Hip	4 (14%)	1 (12%)	1 (8%)	2 (15%)
Knee	7 (24%)	2 (25%)	5 (38%)	1 (8%)
Foot	7 (24%)	3 (38%)	2 (15%)	2 (15%)
Sleep quality				
Good	15 (52%)	5 (62%)	7 (54%)	6 (46%)
Bad	14 (48%)	3 (38%)	6 (46%)	7 (54%)
Productivity loss, mean (IQR)	2.2 (0.8, 5.9)	1.8 (1.2, 2.5)	2.8 (0.8, 5.1)	2.2 (1.3, 6.9)
Time management, median (IQR)	0.0 (0.0, 15.0)	0.0 (0.0, 5.0)	0.0 (0.0, 10.0)	0.0 (0.0, 15.0)
Physical demand, median (IQR)	0.0 (0.0, 10.0)	2.5 (0.0, 25.0)	0.0 (0.0, 0.0)	0.0 (0.0, 10.0)
Mental-interpersonal demand, median (IQR)	8.3 (0.0, 16.7)	5.6 (1.4, 9.7)	11.1 (2.8, 18.1)	11.1 (0.0, 22.2)
Output demand, median (IQR)	10.0 (0.0, 25.0)	7.5 (0.0, 17.5)	13.1 (0.0, 30.0)	10.0 (0.0, 30.0)

IQR, interquartile range; SD, standard deviation; RDQ, Roland-Morris Disability Questionnaire; STarT Back, STarT Back Screening Tool; LPA, Low physical activity; MVPA, Moderate-vigorous physical activity

271

The median adherence for WARP was 28.6% (16.8, 41.1), which is equal to 1.43 times per day (Figure 3). Participants with higher adherence had relatively higher pain intensity, disability due to LBP, and higher work productivity loss (Supplementary Table 1) compared to those with lower adherence. Furthermore, low adherence was related to longer duration of WARP (adherence, Office A < B < C).

For ITT analysis with adjustment for time effects, pain intensity did not improve better in the intervention phase compared to the control phase (β, 0.01; 95% confidence interval, -0.50, 0.52) (Table 2). Regarding secondary outcomes, no significant improvement was observed. For per-protocol analysis with adjustment for time effects (n=14), Time Management Demands, and Mental-Interpersonal Demands (WLQ subscale), MVPA improved better in the intervention phase compared to the control phase. RDQ, productivity loss, and step significantly improved better in the intervention phase compared to the control phase. Calendar time had significant or marginal significant positive effects on primary and secondary outcomes. Any adverse effects were not reported in the present study.

Table 2. Intervention effect on each outcome

	ITT analysis (n=29)					Per-protocol analysis (n=14)				
	β	95% CI			*p* -value	*β*	95% CI			*p* -value
Pain intensity	0.01	-0.50	to	0.52	0.965	-0.16	-0.90	to	0.58	0.680
RDQ total score	-0.59	-1.26	to	0.08	0.085	-0.86	-1.63	to	0.39	0.177
WLQ			to					to		
Productivity loss (%)	-1.04	-2.70	to	0.61	0.218	-2.31	-4.77	to	0.17	0.068
Time management demands	-5.48	-13.71	to	2.74	0.191	-10.28	-21.04	to	-0.07	0.048
Mental-interpersonal demands	-5.31	-11.10	to	0.48	0.072	-10.48	-20.56	to	-0.41	0.041
Physical demands	1.23	-2.78	to	5.25	0.548	1.92	-4.86	to	7.71	0.515
Output demands	-1.05	-8.61	to	6.52	0.786	-9.34	-21.88	to	3.19	0.144
Physical activity										
Time spent for Sedentary (%)	-0.95	-4.58	to	2.67	0.607	-1.80	-6.62	to	3.03	0.466
Time spent for LPA (%)	0.92	-1.96	to	3.81	0.531	-0.02	-4.73	to	3.68	0.990
Time spent for MVPA (%)	0.15	-1.17	to	1.48	0.820	1.88	0.03	to	3.72	0.046
Step	146.80	-850.72	to	1144.33	0.773	889.44	-511.34	to	2290.21	0.213
STarT Back total score	-0.20	-0.57	to	0.18	0.306	-0.41	-1.08	to	0.27	0.235

All models were adjusted with time effect, participants with less than 28.6% (median) or median for adherence were excluded from per-protocol analysis, ITT, intention-to-treat; RDQ, Roland-Morris Disability Questionnaire; WLQ, Work Limitations Questionnaire; LPA, Low physical activity; MVPA, Moderate-vigorous physical activity

For participants' satisfaction for WARP, 4 (14%) were very satisfied, 10 (34%) were satisfied, and 15 (52%) were normal. No one was unsatisfied for WARP. As regards positive comments, some said that "I understood my back pain could be improved, and exercise was easy to perform," "It was nice to know effective stretch," "I feel my back pain is gradually improved,," "I could be careful for prolonged sitting," "I want to make use of personalized exercise," "Back pain was gradually improved," "I could consider problems and methods for solving back pain," and "It was nice to undertake an exercise instruction from professionals." As regards negative comments, some said that "Not enough follow-up other than questionnaire," "Regular feedback based on follow-up data can motivate us to perform this program, but actually no feedback in this program," "There were few people doing exercise around me, so it was hard to do exercise," and "I wanted to know exercise during sitting."

DISCUSSION

In summary, ITT analysis showed that WARP did not have significant positive effects on LBP intensity and other secondary outcomes such as LBP disability or work productivity. The median adherence of WARP was 28.6% (1.43 times/day), which was significantly lower than we expected. Per-protocol analysis revealed that WARP was not associated with LBP outcomes, but WARP had significant positive effects on some subscales of work productivity (Time Management Demands, Mental-Interpersonal Demands) and MVPA.

Although a recent systematic review investigated the current evidence of active rest, they concluded that there was low-quality evidence for conflicting effectiveness on LBP[38]. Studies included in the systematic review were conducted in the laboratory setting or healthy subjects without LBP. Therefore, this is the first randomized controlled trial that investigates the effectiveness of active rest on LBP and work productivity in the real-world setting. However, we were not able to demonstrate the significant positive effective of WARP on LBP. While the present study evaluated the effect of short and frequent office-based exercises (a few minutes per session, 5 times/day, except weekends) on LBP symptom reduction, a previous study showed the effect of long and less frequent office-based exercises (10–15 minutes per session, 3 times/week) on LBP symptom reduction [16]. These differences between the two study designs should be considered when interpreting the results of our study.

We have two potential explanations about the negative results of our studies. First, it might be due to low adherence of WARP, which could diminish its efficacy. Although we considered some strategies to keep adherence (e.g., introducing WARP to all workers other than the participants of this study in the same office, ringing the chime to inform them of WARP timing, and tailor-made exercise program), these might be insufficient to improve adherence. The previous studies suggested supervised exercise and group-based exercise[39]. However, there were no strict supervision or group-based exercise in our study because we tried to investigate the effectiveness of pragmatic easy-to-use solution. Moreover, lower adherence for workplace exercise was influenced by poorer psychosocial work environment (e.g., influence at work, work pace, quantitative demands, interpersonal relations) and lower exercise self-efficacy[40]. A further study should be conducted to perform such strategies to improve adherence, but simplicity and acceptance from employee and employer should be considered in terms of practical use. Second potential explanation of negative results is that the participants in our study had lower level of LBP intensity at baseline, which leads to low motivation for WARP and floor effect. Actually, participants with lower LBP intensity had lower adherence than those with high LBP intensity. We considered the floor effect owing to the mild pain by specifically recruiting workers with back pain (NRS was 3 or higher). However, a time lag between the recruitment and baseline assessments due to coordinating the schedule of LBP workshop might have led to a decrease in pain levels at the time the study was actually conducted. Future studies should focus on

the fluctuations of outcome variables between recruitment and baseline assessments.

Regarding per-protocol analysis, unstandardized coefficients of most outcome parameters were significantly positive compared to those of ITT analysis. A previous study reported that active rest (10-minute fitness program at lunch break) has positive effects on vigor, interpersonal stress, and physical activity[41]. Although the results of the per-protocol analysis should be carefully interpreted owing to selection bias and an underpowered analysis, these results indicate that WARP could have positive effects if its adherence was ideally kept."

Several limitations should be considered in interpreting the results of our study. First, adherence of the program was very low, which might lead to the underestimation on the potential efficacy of WARP. Second, severity level of LBP was relatively mild in this population, which might cause floor effect especially for BPI and RDQ. We should have set the inclusion criteria about the severity level of LBP to eliminate the floor effect. Otherwise, if mild LBP is common in the working population compared to primary care, we should focus on the incidence or recurrent incidence of LBP in terms of primary prevention. Finally, owing to the limited number of workplace settings and types included within one company, the results of the study should not be considered to be generalizable to other workplace settings.

We were unable to conclude that active rest is effective for LBP and productivity loss from the results of the present study. However, the present study provided valuable information for

conducting similar research, though the strategies implemented in this study might be insufficient for maintaining adherence. In the future, we need to study its effectiveness with high adherence or among workers with higher level of LBP intensity.

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Author Contributions

All authors have contributed to the conception and design of the study. Y Tsuboi has conducted recruitment, intervention, data collection, and data analysis. Y Tsuboi has written the first draft of the article, and all coauthors have revised it and agreed to the final paper.

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Competing Interests

None declared.

Patient consent for publication

Not required.

Data sharing statement

Data, STATA code for statistical analyses, and R code for data processing of accelerometers are available upon reasonable request.

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Figure Legends

Figure 1. Diagram of stepped-wedge cluster randomized controlled trial design

Figure 2. Flowchart for stepped-wedge cluster randomized trial

Figure 3. Adherence of intervention among each step and office

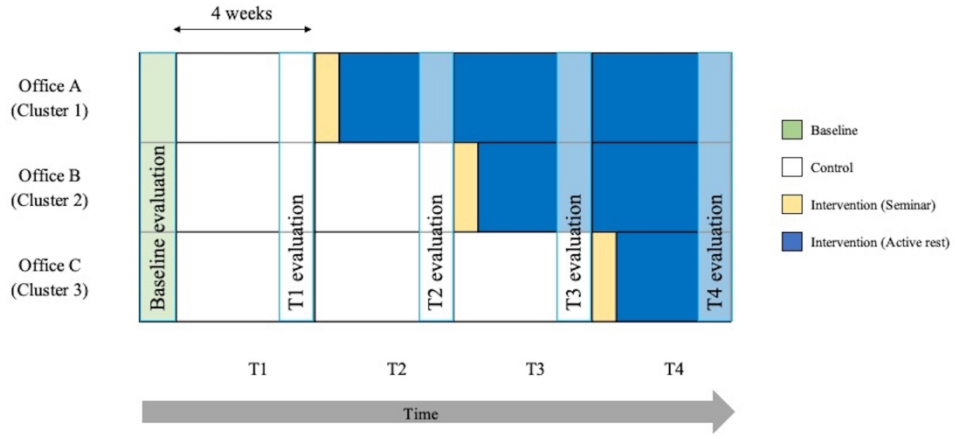

Fig.1. Diagram of stepped wedge cluster randomized controlled trial design

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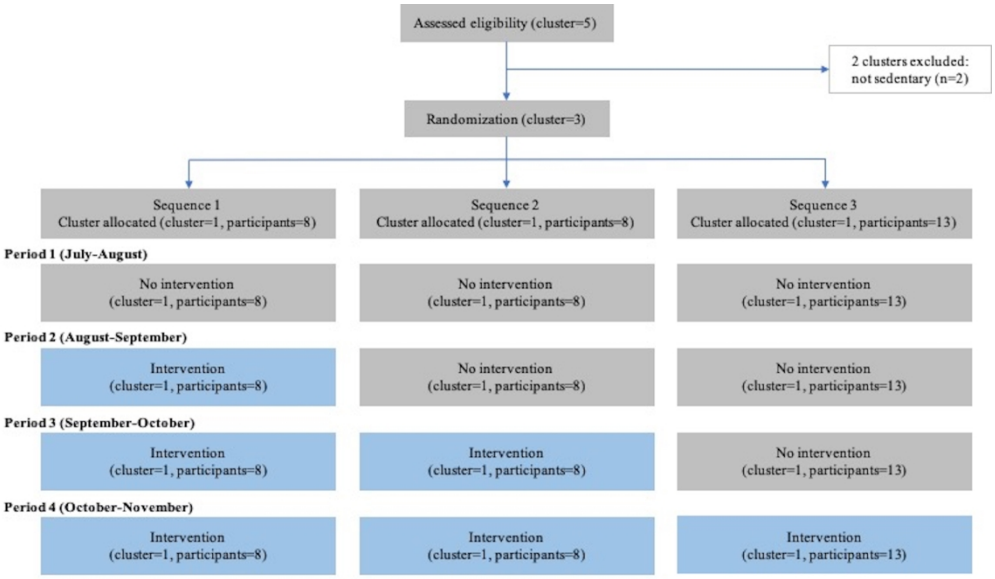
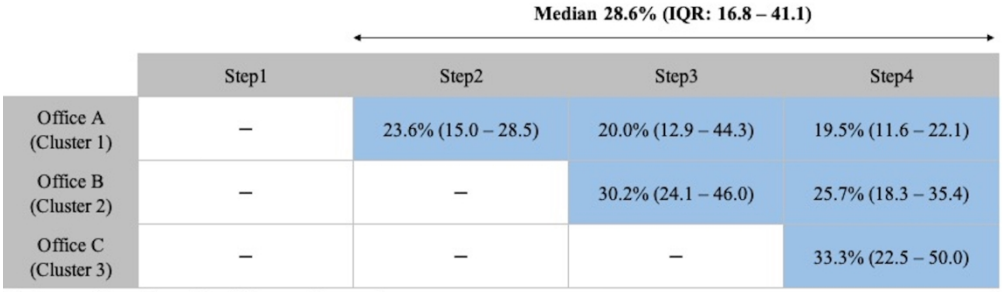


Figure 2. Flowchart for stepped wedge cluster randomized trial

267x169mm (300 x 300 DPI)



Data were shown in median (Interquartile range)

Figure 3. Adherence of intervention among each step and office

288x106mm (300 x 300 DPI)

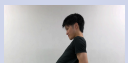
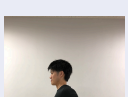
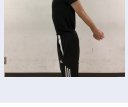
Supplementary figure 1

Check Sheet of Evaluation

No.	Question	Answer	Recommended Exercise
Q1	Which makes your low back comfortable after repeating 10 times? Forward bending or Backward bending?	Forward bending	❷, ❺
		Backward bending	❶
Q2	Check your spine alignment (Evaluated by PT)	Kyphosis	❶
		Neutral	—
		Lordosis	❷, ❺
Q3	Thomas test	Negative result	—
		Positive result	❷
Q4	Finger-Floor Distance test	Reached floor	—
		Did not reach floor	Qualitative check by PT ( )
Q5	Which makes you feel low back pain more? Sitting or Standing	座位	❶, ❸, ❹
		立位	❷, ❸, ❺

Supplementary figure 2

My Exercise Program

✓	No.	Exercise Name	Picture
	❶	Back Extension Stretch	
	❷	Iliopsoas Stretch	
	❸	Trunk Twist Stretch	
	❹	Lateral Trunk Stretch	
	❺	Trunk Bending Stretch	
	❻	Chest Stretch	

Supplementary table 1. Comparison of characteristics stratified by adherence

	Adherence >= median	Adherence < median	*p*-value
N	15	14	
Age, median (IQR)	38.0 (27.0, 45.0)	36.5 (31.0, 46.0)	0.73
Sex			0.58
Male	13 (87%)	13 (93%)	
Female	2 (13%)	1 (7%)	
BMI, median (IQR)	21.7 (20.2, 26.3)	22.2 (19.8, 24.2)	0.57
Lumbar disc herniation	2 (13%)	1 (7%)	
Lumbar canal stenosis	1 (7%)	1 (7%)	
Pain intensity, median (IQR)	2.0 (1.0, 2.5)	1.6 (0.5, 2.2)	0.42
RDQ, median (IQR)	1.0 (0.0, 2.0)	0.5 (0.0, 1.0)	0.71
STarT Back, median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	0.39
Medicine			0.22
None	13 (87%)	10 (71%)	
Rarely	0 (0%)	3 (21%)	
Sometimes	1 (7%)	1 (7%)	
Often	1 (7%)	0 (0%)	
Always	0 (0%)	0 (0%)	
Seek for clinic care	1 (7%)	1 (7%)	0.96
Seek for alternative care	1 (7%)	1 (7%)	0.96
Physical activity			
Sedentary time (%)	79.4 (65.8, 84.2)	80.2 (70.5, 81.8)	0.94
Low physical activity (%)	16.5 (12.0, 25.1)	16.2 (13.2, 22.2)	0.91
Moderate-vigorous physical activity (%)	4.1 (2.9, 6.7)	4.6 (3.5, 7.5)	0.73
Step	4518.2 (3407.6, 5896.8)	5056.0 (4117.5, 7159.2)	0.39
Wearing time (minutes)	701.6 (632.8, 759.4)	712.2 (696.8, 754.6)	0.60
Other musculoskeletal pain			
Neck	6 (43%)	11 (73%)	0.03
Shoulder	7 (50%)	11 (73%)	0.59
Elbow	1 (7%)	2 (14%)	0.23
Hand	2 (13%)	2 (14%)	0.13
Hip	3 (21%)	1 (7%)	0.31
Knee	5 (36%)	2 (14%)	0.22
Foot	5 (36%)	2 (14%)	0.41
Sleep quality			0.57

Good	8 (57%)	7 (47%)	
Bad	6 (43%)	8 (53%)	
Productivity Loss, mean (IQR)	3.0 (1.2, 6.9)	1.8 (0.4, 2.6)	0.39
Time Management, median (IQR)	0.0 (0.0, 15.0)	0.0 (0.0, 5.0)	0.55
Physical Demand, median (IQR)	0.0 (0.0, 8.3)	0.0 (0.0, 16.7)	0.54
Mental-Interpersonal Demand, median (IQR)	13.9 (0.0, 22.2)	6.9 (0.0, 11.1)	0.32
Output Demand, median (IQR)	20.0 (0.0, 40.0)	5.0 (0.0, 15.0)	0.22

IQR: Interquartile Range, SD: Standard Deviation, RDQ: Roland-Morris Disability Questionnaire, STarT Back: STarT Back Screening Tool

Table 3 | Checklist of information to include when reporting a stepped wedge cluster randomised trial (SW-CRT)

Topic	Item no	Checklist item	Page no
Title and abstract			
	1a	Identification as a SW-CRT in the title.	1
	1b	Structured summary of trial design, methods, results, and conclusions (see separate SW-CRT checklist for abstracts).	2
Introduction			
Background and objectives	2a	Scientific background. Rationale for using a cluster design and rationale for using a stepped wedge design.	4,6
	2b	Specific objectives or hypotheses.	5
Methods			
Trial design	3a	Description and diagram of trial design including definition of cluster, number of sequences, number of clusters randomised to each sequence, number of periods, duration of time between each step, and whether the participants assessed in different periods are the same people, different people, or a mixture.	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons.	not applicable
Participants	4a	Eligibility criteria for clusters and participants.	7-8
	4b	Settings and locations where the data were collected.	6
Interventions	5	The intervention and control conditions with sufficient details to allow replication, including whether the intervention was maintained or repeated, and whether it was delivered at the cluster level, the individual participant level, or both.	9-11
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed.	11-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons.	not applicable
Sample size	7a	How sample size was determined. Method of calculation and relevant parameters with sufficient detail so the calculation can be replicated. Assumptions made about correlations between outcomes of participants from the same cluster. (see separate checklist for SW-CRT sample size items).	14
	7b	When applicable, explanation of any interim analyses and stopping guidelines.	not applicable
Randomisation			
Sequence generation	8a	Method used to generate the random allocation to the sequences of treatments.	8
	8b	Type of randomisation; details of any constrained randomisation or stratification, if used.	8
Allocation concealment mechanism	9	Specification that allocation was based on clusters; description of any methods used to conceal the allocation from the clusters until after recruitment.	8
Implementation	10a	Who generated the randomisation schedule, who enrolled clusters, and who assigned clusters to sequences.	8
	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling; continuous recruitment or ascertainment; or recruitment at a fixed point in time), including who recruited or identified participants.	8
	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions.	8
Blinding	11a	If done, who was blinded after assignment to sequences (eg, cluster level participants, individual level participants, those assessing outcomes) and how.	8
	11b	If relevant, description of the similarity of treatments.	not applicable
Statistical methods	12a	Statistical methods used to compare treatment conditions for primary and secondary outcomes including how time effects, clustering and repeated measures were taken into account.	15
	12b	Methods for additional analyses, such as subgroup analyses, sensitivity analyses, and adjusted analyses.	15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each treatment condition or allocated sequence, the numbers of clusters and participants who were assessed for eligibility, were randomly assigned, received intended treatments, and were analysed for the primary outcome (see separate SW-CRT flow chart).	images file
	13b	For each treatment condition or allocated sequence, losses and exclusions for both clusters and participants with reasons.	images file
Recruitment	14a	Dates defining the steps, initiation of intervention, and deviations from planned dates. Dates defining recruitment and follow-up for participants.	16
	14b	Why the trial ended or was stopped.	not applicable
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each treatment condition or allocated sequence.	16
Numbers analysed	16	The number of observations and clusters included in each analysis for each treatment condition and whether the analysis was according to the allocated schedule.	17-18
Outcomes and estimation	17a	For each primary and secondary outcome, results for each treatment condition, and the estimated effect size and its precision (such as 95% confidence interval); any correlations (or covariances) and time effects estimated in the analysis.	19-20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended.	not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory.	not applicable
Harms	19	Important harms or unintended effects in each treatment condition (for specific guidance see CONSORT for harms).	19
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses.	24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings. Generalisability to clusters or individual participants, or both (as relevant).	24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	22-24
Other information			
Registration	23	Registration number and name of trial registry.	6
Protocol	24	Where the full trial protocol can be accessed, if available.	not applicable
Funding	25	Sources of funding and other support (such as supply of drugs), and the role of funders.	26
Research ethics review	26	Whether the study was approved by a research ethics committee, with identification of the review committee(s). Justification for any waiver or modification of informed consent requirements.	8

This table can be downloaded as a separate document in supplementary materials 3; page numbers can be added electronically to the PDF document.

BMJ Open

Effectiveness of Workplace Active Rest Program on low back pain in office workers: a stepped-wedge cluster randomized controlled trial

Journal:	*BMJ Open*
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Title page

1) Title of the article

Effectiveness of Workplace Active Rest Program on low back pain in office workers: a stepped-wedge cluster randomized controlled trial

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ABSTRACT

Objectives: This study aimed to investigate the effectiveness of Workplace Active Rest Program (WARP) on chronic low back pain (LBP) in office workers.

Design: This study conducted a closed cohort stepped-wedge cluster randomized trial. The total duration of the study was 16 weeks (4 weeks for each step). Sequence allocation was randomized, but no one was blinded.

Setting: This study was conducted in 3 offices in a Japanese electronics company.

Participants: We recruited 29 office workers with LBP greater than 3 months. LBP due to specific injury or disease was excluded. The median age was 38 years, and 26 (90%) were male. All participants completed the study.

Interventions: In the intervention phase, participants performed WARP comprising frequent stand-up and individualized brief exercise/physical activity during work. Physical therapists held LBP workshop and developed tailor-made programs before introducing WARP. We instructed participants to perform WARP at 5 timings during work. In the control phase, participants stayed as usual.

Primary and secondary outcome measures: Primary outcome was pain intensity of LBP assessed using Brief Pain Inventory. Secondary outcomes were work productivity loss measured using Work Limitations Questionnaire, LBP disability assessed using Roland-Morris Disability Questionnaire,

psychosocial subscale assessed using STarT Back Screening tool, and physical activity measured using triaxial accelerometers. These outcomes were collected at baseline and 4-month follow-up evaluation.

Results: In the intention-to-treat analysis, WARP did not show any significant effects on pain intensity (β, 0.01; 95% confidence interval, -0.50, 0.52) and secondary outcomes. The median adherence for WARP was 28.6% (interquartile range, 16.8, 41.1), which was equal to 1.43 times per day. No adverse effect was observed.

Conclusions: The present study was unable to confirm the effectiveness of active rest in improving LBP. Hence, a further study needs to investigate its effectiveness.

Trial registration: UMIN Clinical Trials Registry (UMIN000033210)

Strengths and limitations of this study

- This study is the first pragmatic trial conducted in the real-world setting that investigates the feasibility and effectiveness of active rest.
- All participants completed Workplace Active Rest Program.
- However, adherence to WARP was lower than we expected.
- Because recruited office workers had relatively mild LBP, we were unable to confirm whether WARP is effective in office workers with severe LBP.

INTRODUCTION

Low back pain (LBP) is a prevalent health problem in office workers[1,2] and is the leading cause of decreasing healthy life expectancy worldwide[3]. Moreover, LBP results in a large socioeconomic burden due to work productivity loss and medical expenses[4,5]. In terms of both individual and social impact, LBP among office workers is the crucial problems, which should be tackled.

Office workers are those workers who stay in prolonged sitting position during most of their working time[6,7]. Prolonged sitting is one of the causes of LBP, which is also due to several factors such as increased disc pressure[8], decreased trunk mobility[9], and less posture variation[10]. Although the previous studies have investigated the effectiveness of ergonomic intervention and back support, these are considered ineffective in improving LBP[11,12]. Recently, the use of standing desk has been shown to be effective in improving LBP[13], but it has the following limitations: it requires a lot of space and is costly. Therefore, easy-to-use solutions are required in the workplace.

Active rest (taking a break with exercise/physical activity in the workplace) could possibly improve LBP because it has the following characteristics: (1) sedentary break by standing up, which can prevent prolonged sitting, and (2) exercise/physical activity, which is recommended in the LBP guidelines[14,15]. A previous study showed that office-based stretching (10–15 minutes/session, 3 times/week) was effective in reducing the occurrence of musculoskeletal discomfort when compared

with no intervention [16]. However, in our study, we developed a shorter exercise program involving frequent sessions (a few minutes per session, 5 times/day, except on weekends) because we aimed to promote frequent standing to break the habit of prolonged sitting. Although a positive effect of active rest on LBP was shown in the laboratory study[17], its effectiveness in the real-world setting is still unknown. We hypothesized that there is a difference in the effectiveness between laboratory and real-world setting. Thus, the present study aimed to investigate the effectiveness of Workplace Active Rest Program (WARP) on chronic LBP and work productivity loss in office workers in the real-world setting.

METHODS

Study design

The present study was conducted according to the extension of the Consolidated Standards of Reporting Trials 2010 Statement for stepped-wedge cluster randomized controlled trial (SW-CRT)[18]. We used a closed cohort SW-CRT involving the randomization of clusters to different sequences. SW-CRT is a crossover design with repeated measurement, in which clusters switch from control to intervention condition. SW-CRT is a suitable study design if we assume that the intervention will do more good than harm, hence making it unethical to withhold the intervention from a control group. Thus, because it is morally acceptable and beneficial for participant recruitment, we introduced the SW-CRT design [19]. Moreover, this is the pragmatic design, which increases statistical power and decreases needed clusters compared to those in parallel CRT[20]. The present clinical trial was registered with UMIN Clinical Trials Registry (identifier: UMIN000033210).

As Figure 1 shows, we conducted the present study in 3 offices (clusters) in a Japanese electronics company. We set 3 sequences, where an office switched from control condition to the intervention condition one by one. The total duration of the study was 16 weeks (4 weeks for each step). Evaluation was conducted at baseline and 4 points during the last week of each step. Because of a closed cohort design, participants assessed in different periods were the same participants.

Patient and public involvement

Office workers with LBP were not involved in developing the research question, but we consulted them about the design of the study (especially the intervention program) in terms of feasibility and applicability by joining the employees' health committee. During the trial, they helped us to hold LBP workshop by arranging a room and equipment. We asked them to assess the burden of the intervention before they joined the study. We already disseminated the results of our study to participants and reported them at the employees' health committee.

Participants' recruitment

We recruited 29 participants from 3 offices of a Japanese electronics company in July 2018. Three offices were separated from one another. First, participants were approached by the public health nurse working in this company. When they were interested in the study, the public health nurse introduced them to us. Subsequently, researchers explained the study to the participants, and participants provided informed consent for inclusion in the study.

Office workers were eligible for the present study if they have the following characteristics: (1) are full-time workers (All workers worked in the same day shifts) and (2) engaged in desk work greater than 4 hours/daily working time (self-reported)[21] and (3) had LBP

greater than 3 months. The location of LBP was defined as pain between the 12th rib and inferior gluteal folds[22]. Exclusion criteria were as follows: (1) LBP caused by fracture and trauma injuries, infectious diseases, and internal organ disorders and (2) difficulty participating in the study due to medical or surgical disease. Cluster-level eligibility criteria were as follows: (1) an office where most workers were engaged in desk work and (2) supervisors granting permission in the performance of the study. Whereas Office A was administrative office, Office B and C were development offices.

This study was approved by the Ethics Committee of Kobe University Graduate School of Health Sciences. All participants provided written informed consent for inclusion in the study.

Randomization and blinding

Offices were randomly assigned to one of the 3 successive sequences (one office per sequence) after all clusters and participants were recruited. A researcher who was not involved in the recruitment performed random allocation using computer-generated random numbers and coded information about offices. To prevent contamination, both clusters and participants were not informed of the time the intervention started and the detailed program of the intervention until 2 weeks before the intervention started. We also asked the participants exposed to the intervention not to disclose the program content to other workers. Due to the nature of the present study, participants, intervenient,

and outcome assessors (self-reported) could not be blinded. Data analyst was not also blinded to group allocation.

Intervention

In the intervention phase, we offered WARP in two parts below. First, we held the LBP workshop (group), followed by the introduction of active rest in the workplace. LBP workshop was held when the group moved from the control phase to the intervention phase.

The purposes of LBP workshop were as follows: to allow the participants to understand LBP and sedentary behavior, develop customized exercise program, and explain how WARP is performed after the workshop. LBP workshop was held at company's gymnastics room after work for 90 minutes by two or three physical therapists (PTs) (PTs with expertise in LBP, at least 3 or more experience years) including the primary researcher (YT). To avoid inconsistency on workshop contents in PTs, we discussed and agreed with its contents before workshop. We disseminated leaflets about the contents of LBP workshop to the participants. First, we gave lecture on the following: (1) LBP causes and interventions using a biopsychosocial model and (2) the impact of sedentary behavior (SB) on health (death, noncommunicable diseases, and LBP). Second, evaluation was performed using a physical examination and an interview sheet (a brief file was described in Supplementary Figure 1). We evaluated trunk flexion and extension (comfortable direction), static

trunk posture (sagittal plane, lordosis/kyphosis), Thomas test (flexibility of the iliopsoas muscle)[23], finger-floor distance test (spine and hip joint movement), and one-finger test (positive result indicates sacroiliac joint pain)[24] and asked if the participants felt painful sensations when sitting or standing. Third, individualized exercise programs were developed based on the results of the evaluation. Some exercises were recommended based on the results on the physical examination and interview sheets (Supplementary Figures 1–2). We prepared 6 types of exercise focusing on spine and hip stretch and training, which can improve spine and hip joint mobility and decrease lumbar disc pressure (trunk extension exercise, stretching of the iliopsoas and hamstrings, abdominal oblique, erector spinae muscles, thoracolumbar fascia). We selected these exercises because these can be briefly performed by the participants when they stand up. We let them perform the recommended exercises during workshop after they had seen the demonstration. If participants had difficulty in performing the exercise, we individually helped them.

At the end of workshop, we explained to the participants how and when WARP is performed. Participants were instructed to perform WARP at 5 timings (just before the work starts, AM break, lunch break, PM break, after the work is finished). Because a chime ringed at these 5 timings, we asked them to stand up and perform their exercises for a few minutes after the chime ringed. We also recommended them to perform WARP other than the 5 fixed timings. However, the participants were not required to perform the program. We explained the content of WARP and

introduced some brief exercises to other workers in the same office. It enables participants to easily perform exercise at workplace because they understand what they do. Additionally, to determine if problems occurred after performing WARP, researchers visited each office once a month.

Control

When the participants were in the control phase, we did not perform any intervention to the participants (usual work).

Primary outcome

Primary outcome was LBP intensity. We used the pain intensity subscale of Brief Pain Inventory (BPI), which is well-validated and reliable among patients with noncancer pain including LBP[25,26]. BPI consists of 4 questions rating pain intensity separately at "worst," "least," "average," and "now" during the last 24 hours using 11-point Numerical Rating Scale (NRS), ranging from 0 (no pain) to 10 (worst imaginable pain). Finally, the mean of these four items was used as a BPI score (BPI score = [worst + least + average + now]/4). A Japanese version of BPI has a good validity and reliability[27].

At the moment of trial registration, although we had planned to evaluate weekly LBP intensity, we changed to monthly evaluation. This is because weekly evaluation was not feasible at

this company in terms of responders' burden for answering questionnaires.

Secondary outcome

The Roland-Morris Disability Questionnaire (RDQ) is a validated 24-item questionnaire that assesses the disability due to LBP such as "I change position frequently to try and get my back comfortable."[28,29]. Each item is scored either 0 or 1, with all scores summed to a total between 0 and 24 (a higher score indicates a greater disability level).

The STarT Back Screening tool is a validated screening tool that predicts the future disability level[30,31]. We used 5-item psychosocial subscale of the STarT Back Screening tool including fear of movement, depressive symptom, catastrophic attitude, anxiety, and pain distress. Score ranged from 0 to 5 (a higher score indicates a higher possibility for future disability level).

The Work Limitations Questionnaire (WLQ) is a validated 25-item questionnaire that evaluates work productivity loss due to physical/psychological issues[32,33]. The WLQ is composed of the following 4 subscales: (1) Time Management (the difficulty in performing a job tasks in a timely manner and in scheduling tasks), (2) Mental-Interpersonal Demands (the difficulty in performing cognitive job tasks and in interacting with colleagues), (3) Physical Demands (the ability to perform job tasks involving body strength, movement, endurance, coordination, and flexibility), and (4) Output Demands (work quantity and quality reduction and timeliness of completed work).

Additionally, “Not applicable” was also provided as a response option and treated as a missing value. All subscales scores were converted to percentage, 0% (least limited) to 100% (most limited). Work productivity loss (%) was calculated from the weighed sum of the 4 subscale scores using a validated algorithm ranging from 0% to 24.9%. A higher score indicates a higher level of work productivity loss.

To measure physical activity and sedentary behavior, we distributed triaxial accelerometers (Active style Pro HJA-750C, Omron Healthcare Co., Ltd.) to the participants during each step. Details of the accelerometer measurement procedure were described elsewhere[34,35]. Participants were instructed to wear triaxial accelerometers on their waist during only working time for 5 days. Data were recorded in 60-second epoch. In addition to the number of steps, time spent in moderate-to-vigorous physical activity (MVPA, 3.0 ≤ Metabolic equivalent; METs), light physical activity (1.5 < METs < 3.0), and SB (METs ≤ 1.5) were calculated using R version 3.5.2. Days with at least 4 hours of wearing time or 75% of working hours were considered a valid day[36], and we included the data with at least 1 valid day in the analysis. Non-wear time was defined as a period with continuous zero count lasting over 60 minutes.

Other measurements

We collected demographic data such as age, sex, height, weight, and body mass index. Participants

were asked whether they were ever diagnosed with the following conditions: lumbar disc herniation, lumbar canal stenosis, lumbar compression fracture, trauma, spinal metastasis, fibromyalgia, rheumatoid arthritis, and infectious spondylitis. Participants also reported the status of their analgesic administration (none, rarely, sometimes, often, and always), consultation on orthopedic clinics, or alternative medicine for LBP (none, once, twice, three times, four times, and greater than five), sleep quality (very good, fairly good, fairly bad, and very bad), and other musculoskeletal pain including neck, shoulder, elbow, wrist, hip, knee, and foot (NRS). At the final follow-up evaluation (T4 evaluation of Figure 1), participants answered about their satisfaction (satisfied very much, satisfied, normal, dissatisfied, dissatisfied very much) and free opinion about WARP.

Adherence

To evaluate adherence for WARP, we asked participants to keep diaries whether they performed WARP or not in each 5 timing. Adherence is calculated 100% if they performed WARP at all 5 timings during the whole intervention phase. Because WARP is a program at the workplace, we did not include holidays when assessing adherence.

Sample size

We calculated the sample size using formula specific for stepped-wedge design[20]. Primary

outcome difference and standard deviation were set as 2.0 and 2.5, respectively[37]. The following assumed parameters were used: cluster size=10, intracluster correlation coefficient=0.05, the number of step=3, the number of baseline measurement=1, measurement after each step=1, two-sided α-level=0.05, and β=80%. To detect 2-point difference in primary outcome, a total of 22 participants were needed. Considering drop out, we estimated 30 participants as required sample size, and 29 participants actually joined the present study.

Statistical analysis

For the characteristics of participants, categorical variables were presented as frequency and percentage and continuous variables as mean ± SD (standard deviations). If distributions of the continuous variables were skewed, data were presented as median (range or interquartile range [IQR]).

We performed both intention-to-treat (ITT) analysis and per-protocol analysis to investigate both the effectiveness and efficacy of WARP. Primary analysis was ITT analysis because this study aimed to investigate pragmatic effectiveness of WARP in the real-world setting. For ITT analysis, we performed the linear mixed effect model, setting the intervention as the fixed effect, individual and office as the random effect, and calendar time as the confounding factor. For per-protocol analysis, we also performed the linear mixed effect model after excluding participants

whose adherence to WARP was median (28.6%) or less. Unstandardized coefficients and 95% confidence intervals were calculated.

All statistical analyses were performed using Stata/IC 15.1 software (StataCorp). $P < 0.05$ was considered to be statistically significant.

RESULTS

We recruited 29 office workers from 3 offices in July (Figure 2). As planned, Office A performed the intervention in the first period (August), Office B in the second period (September), and Office C in the third period (October). All participants continued WARP until the end (no dropout) of the study. Twenty-eight participants completed the baseline and each follow-up evaluation (T1–T4). Only one participant did not answer T3 evaluation, but answered other evaluations.

The median age was 38 years, and 26 (90%) were male (Table 1). The median pain intensity assessed using BPI was 2.0 (IQR, 0.8, 2.2), and the median score of RDQ was 1.0 (0.0, 2.0). Only two participants performed the clinic or alternative care, and only one participant often received analgesic medication. The median proportion of sedentary time was 79.6% (68.1, 84.1). The median productivity loss estimated by WLQ was 2.2% (0.8, 5.9). Regarding the difference of characteristics in 3 offices, participants were younger in Office C than in other offices. Pain intensity was lighter in Office B than in other offices.

Table 1. Characteristics of participants

	All	Office A	Office B	Office C
N	29	8	8	13
Age, median (IQR)	38.0 (28.0, 45.0)	43.5 (37.0, 46.5)	41.5 (29.5, 46.0)	32.0 (27.0, 38.0)
Sex				
Male	26 (90%)	6 (75%)	7 (88%)	13 (100%)
Female	3 (10%)	2 (25%)	1 (13%)	0 (0%)
BMI, median (IQR)	21.9 (20.2, 24.6)	20.9 (19.9, 23.8)	21.5 (20.2, 24.3)	22.6 (21.5, 24.6)
Lumbar disc herniation	2 (7%)	0 (0%)	1 (13%)	1 (8%)
Lumbar canal stenosis	2 (7%)	0 (0%)	1 (13%)	1 (8%)
Pain intensity, median (IQR)	2.0 (0.8, 2.2)	1.9 (1.1, 3.0)	0.5 (0.2, 2.1)	2.0 (1.2, 2.5)
RDQ, median (IQR)	1.0 (0.0, 2.0)	1.0 (0.0, 1.5)	0.5 (0.0, 1.0)	1.0 (0.0, 2.0)
STarT Back, median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)	0.0 (0.0, 1.0)
Medicine				
None	23 (79%)	5 (62%)	7 (88%)	11 (85%)
Rarely	3 (10%)	2 (25%)	0 (0%)	1 (8%)
Sometimes	2 (7%)	1 (12%)	1 (13%)	0 (0%)
Often	1 (3%)	0 (0%)	0 (0%)	1 (8%)
Always	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Seek for clinic care	2 (7%)	0 (0%)	1 (13%)	1 (8%)
Seek for alternative care	2 (7%)	2 (25%)	0 (0%)	0 (0%)
Physical activity, median (IQR)				
Time spent for Sedentary (%)	79.6 (68.1, 84.1)	74.1 (58.5, 80.0)	78.9 (63.5, 84.9)	81.6 (73.5, 85.2)

Time spent for LPA (%)	16.3 (12.6, 24.4)	19.4 (15.5, 32.9)	17.2 (12.3, 27.9)	13.4 (11.0, 19.2)
Time spent for MVPA (%)	4.5 (2.9, 7.1)	5.6 (3.5, 10.1)	3.9 (2.2, 5.9)	4.1 (3.0, 6.3)
Step	4763.4 (3553.1, 6228.4)	4763.4 (3962.9, 8457.4)	4569.5 (3495.1, 6228.4)	4593.9 (3624.5, 5636.6)
Wearing time (minutes)	708.4 (666.3, 757.1)	682.7 (635.4, 744.4)	757.0 (666.4, 847.3)	707.1 (692.2, 743.5)
Other musculoskeletal pain				
Neck	17 (59%)	4 (50%)	4 (31%)	9 (69%)
Shoulder	18 (62%)	4 (50%)	5 (38%)	9 (69%)
Elbow	3 (10%)	0 (0%)	2 (15%)	1 (8%)
Hand	4 (14%)	1 (12%)	2 (15%)	1 (8%)
Hip	4 (14%)	1 (12%)	1 (8%)	2 (15%)
Knee	7 (24%)	2 (25%)	4 (31%)	1 (8%)
Foot	7 (24%)	3 (38%)	2 (15%)	2 (15%)
Sleep quality				
Good	15 (52%)	5 (62%)	7 (54%)	6 (46%)
Bad	14 (48%)	3 (38%)	6 (46%)	7 (54%)
Productivity loss, mean (IQR)	2.2 (0.8, 5.9)	1.8 (1.2, 2.5)	2.8 (0.8, 5.1)	2.2 (1.3, 6.9)
Time management, median (IQR)	0.0 (0.0, 15.0)	0.0 (0.0, 5.0)	0.0 (0.0, 10.0)	0.0 (0.0, 15.0)
Physical demand, median (IQR)	0.0 (0.0, 10.0)	2.5 (0.0, 25.0)	0.0 (0.0, 0.0)	0.0 (0.0, 10.0)
Mental-interpersonal demand, median (IQR)	8.3 (0.0, 16.7)	5.6 (1.4, 9.7)	11.1 (2.8, 18.1)	11.1 (0.0, 22.2)
Output demand, median (IQR)	10.0 (0.0, 25.0)	7.5 (0.0, 17.5)	13.1 (0.0, 30.0)	10.0 (0.0, 30.0)

IQR, interquartile range; SD, standard deviation; RDQ, Roland-Morris Disability Questionnaire; STarT Back, STarT Back Screening Tool; LPA, Low physical activity; MVPA, Moderate-vigorous physical activity

284

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The median adherence for WARP was 28.6% (16.8, 41.1), which is equal to 1.43 times per day (Figure 3). Participants with higher adherence had relatively higher pain intensity, disability due to LBP, and higher work productivity loss (Supplementary Table 1) compared to those with lower adherence. Furthermore, low adherence was related to longer duration of WARP (adherence, Office A < B < C).

For ITT analysis with adjustment for time effects, pain intensity did not improve better in the intervention phase compared to the control phase (β, 0.01; 95% confidence interval, -0.50, 0.52) (Table 2). Regarding secondary outcomes, no significant improvement was observed. For per-protocol analysis with adjustment for time effects (n=14), Time Management Demands, and Mental-Interpersonal Demands (WLQ subscale), MVPA improved better in the intervention phase compared to the control phase. RDQ, productivity loss, and step significantly improved better in the intervention phase compared to the control phase. Calendar time had significant or marginal significant positive effects on primary and secondary outcomes. Any adverse effects were not reported in the present study.

Table 2. Intervention effect on each outcome

	ITT analysis (n=29)					Per-protocol analysis (n=14)				
	β	95% CI			p -value	β	95% CI			p -value
Pain intensity	0.01	-0.50	to	0.52	0.965	-0.16	-0.90	to	0.58	0.680
RDQ total score	-0.59	-1.26	to	0.08	0.085	-0.86	-2.[illegible]	to	0.39	0.177
WLQ			to					to		
Productivity loss (%)	-1.04	-2.70	to	0.61	0.218	-2.31	-4.[illegible]	to	0.17	0.068
Time management demands	-5.48	-13.71	to	2.74	0.191	-10.28	-20.[illegible]	to	-0.07	0.048
Mental-interpersonal demands	-5.31	-11.10	to	0.48	0.072	-10.48	-20.[illegible]	to	-0.41	0.041
Physical demands	1.23	-2.78	to	5.25	0.548	1.92	-3.[illegible]	to	7.71	0.515
Output demands	-1.05	-8.61	to	6.52	0.786	-9.34	-21.[illegible]	to	3.19	0.144
Physical activity										
Time spent for Sedentary (%)	-0.95	-4.58	to	2.67	0.607	-1.80	-6.[illegible]	to	3.03	0.466
Time spent for LPA (%)	0.92	-1.96	to	3.81	0.531	-0.02	-3.[illegible]	to	3.68	0.990
Time spent for MVPA (%)	0.15	-1.17	to	1.48	0.820	1.88	0.[illegible]	to	3.72	0.046
Step	146.80	-850.72	to	1144.33	0.773	889.44	-51[illegible]	to	2290.21	0.213
STarT Back total score	-0.20	-0.57	to	0.18	0.306	-0.41	-1.[illegible]	to	0.27	0.235

All models were adjusted with time effect, participants with less than 28.6% (median) or median for adherence were excluded from per-protocol analysis, ITT, intention-to-treat; RDQ, Roland-Morris Disability Questionnaire; WLQ, Work Limitations Questionnaire; LPA,Low physical activity; MVPA, Moderate-vigorous physical activity

For participants' satisfaction for WARP, 4 (14%) were very satisfied, 10 (34%) were satisfied, and 15 (52%) were normal. No one was unsatisfied for WARP. As regards positive comments, some said that "I understood my back pain could be improved, and exercise was easy to perform," "It was nice to know effective stretch," "I feel my back pain is gradually improved,," "I could be careful for prolonged sitting," "I want to make use of personalized exercise," "Back pain was gradually improved," "I could consider problems and methods for solving back pain," and "It was nice to undertake an exercise instruction from professionals." As regards negative comments, some said that "Not enough follow-up other than questionnaire," "Regular feedback based on follow-up data can motivate us to perform this program, but actually no feedback in this program," "There were few people doing exercise around me, so it was hard to do exercise," and "I wanted to know exercise during sitting."

DISCUSSION

In summary, ITT analysis showed that WARP did not have significant positive effects on LBP intensity and other secondary outcomes such as LBP disability or work productivity. The median adherence of WARP was 28.6% (1.43 times/day), which was significantly lower than we expected. Per-protocol analysis revealed that WARP was not associated with LBP outcomes, but WARP had significant positive effects on some subscales of work productivity (Time Management Demands, Mental-Interpersonal Demands) and MVPA.

Although a recent systematic review investigated the current evidence of active rest, they concluded that there was low-quality evidence for conflicting effectiveness on LBP[38]. Studies included in the systematic review were conducted in the laboratory setting or healthy subjects without LBP. Therefore, this is the first randomized controlled trial that investigates the effectiveness of active rest on LBP and work productivity in the real-world setting. However, we were not able to demonstrate the significant positive effective of WARP on LBP. While the present study evaluated the effect of short and frequent office-based exercises (a few minutes per session, 5 times/day, except weekends) on LBP symptom reduction, a previous study showed the effect of long and less frequent office-based exercises (10–15 minutes per session, 3 times/week) on LBP symptom reduction [16]. These differences between the two study designs should be considered when interpreting the results of our study.

We have two potential explanations about the negative results of our studies. First, it might be due to low adherence of WARP, which could diminish its efficacy. Although we considered some strategies to keep adherence (e.g., introducing WARP to all workers other than the participants of this study in the same office, ringing the chime to inform them of WARP timing, and tailor-made exercise program), these might be insufficient to improve adherence. The previous studies suggested supervised exercise and group-based exercise[39]. However, there were no strict supervision or group-based exercise in our study because we tried to investigate the effectiveness of pragmatic easy-to-use solution. Moreover, lower adherence for workplace exercise was influenced by poorer psychosocial work environment (e.g., influence at work, work pace, quantitative demands, interpersonal relations) and lower exercise self-efficacy[40]. A further study should be conducted to perform such strategies to improve adherence, but simplicity and acceptance from employee and employer should be considered in terms of practical use. Second potential explanation of negative results is that the participants in our study had lower level of LBP intensity at baseline, which leads to low motivation for WARP and floor effect. Actually, participants with lower LBP intensity had lower adherence than those with high LBP intensity. We considered the floor effect owing to the mild pain by specifically recruiting workers with back pain (NRS was 3 or higher). However, a time lag between the recruitment and baseline assessments due to coordinating the schedule of LBP workshop might have led to a decrease in pain levels at the time the study was actually conducted.

Future studies should focus on the fluctuations of outcome variables between recruitment and baseline assessments.

Regarding per-protocol analysis, unstandardized coefficients of most outcome parameters were significantly positive compared to those of ITT analysis. A previous study reported that active rest (10-minute fitness program at lunch break) has positive effects on vigor, interpersonal stress, and physical activity[41]. Although the results of the per-protocol analysis should be carefully interpreted owing to selection bias and an underpowered analysis, these results indicate that WARP could have positive effects if its adherence was ideally kept."

Several limitations should be considered in interpreting the results of our study. First, adherence of the program was very low, which might lead to the underestimation on the potential efficacy of WARP. Second, severity level of LBP was relatively mild in this population, which might cause floor effect especially for BPI and RDQ. We should have set the inclusion criteria about the severity level of LBP to eliminate the floor effect. Otherwise, if mild LBP is common in the working population compared to primary care, we should focus on the incidence or recurrent incidence of LBP in terms of primary prevention. Finally, owing to the limited number of workplace settings and types included within one company, the results of the study should not be considered to be generalizable to other workplace settings.

We were unable to conclude that active rest is effective for LBP and productivity loss from

the results of the present study. However, the present study provided valuable information for conducting similar research, though the strategies implemented in this study might be insufficient for maintaining adherence. In the future, we need to study its effectiveness with high adherence or among workers with higher level of LBP intensity.

Acknowledgment

We would like to thank all participants who willingly joined in our study. We also gratefully acknowledge the public health nurse, Ms. Sato, who helped us in the recruitment and data collection. We appreciate the advice of Prof. Omori from the Clinical & Translational Research Center of Kobe University Hospital regarding our research protocol.

Author Contributions

Y Tsuboi, T Oka, K Nakatsuka, T Isa, and R Ono have contributed to the conception and design of the study. Y Tsuboi, K Nakatsuka, and T Isa has conducted recruitment, intervention, data collection, and data analysis. Y Tsuboi has written the first draft of the article, and T Oka, K Nakatsuka, T Isa, and R Ono have revised it and agreed to the final paper.

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Competing Interests

None declared.

Patient consent for publication

Not required.

Ethics statement

The study was approved by the Ethics Committee of Kobe University Graduate School of Health Sciences (No.718).

Data sharing statement

Data, STATA code for statistical analyses, and R code for data processing of accelerometers are available upon reasonable request.

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Figure Legends

Figure 1. Diagram of stepped-wedge cluster randomized controlled trial design

Figure 2. Flowchart for stepped-wedge cluster randomized trial

Figure 3. Adherence of intervention among each step and office

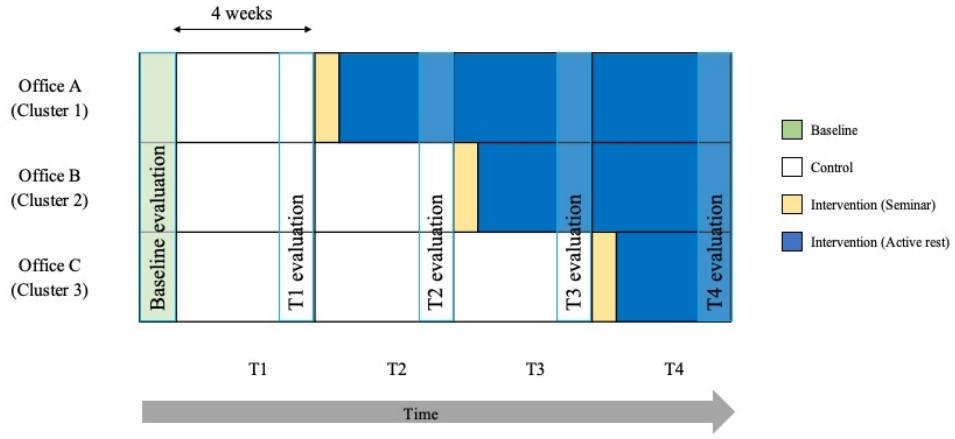


Fig.1. Diagram of stepped wedge cluster randomized controlled trial design

302x155mm (72 x 72 DPI)

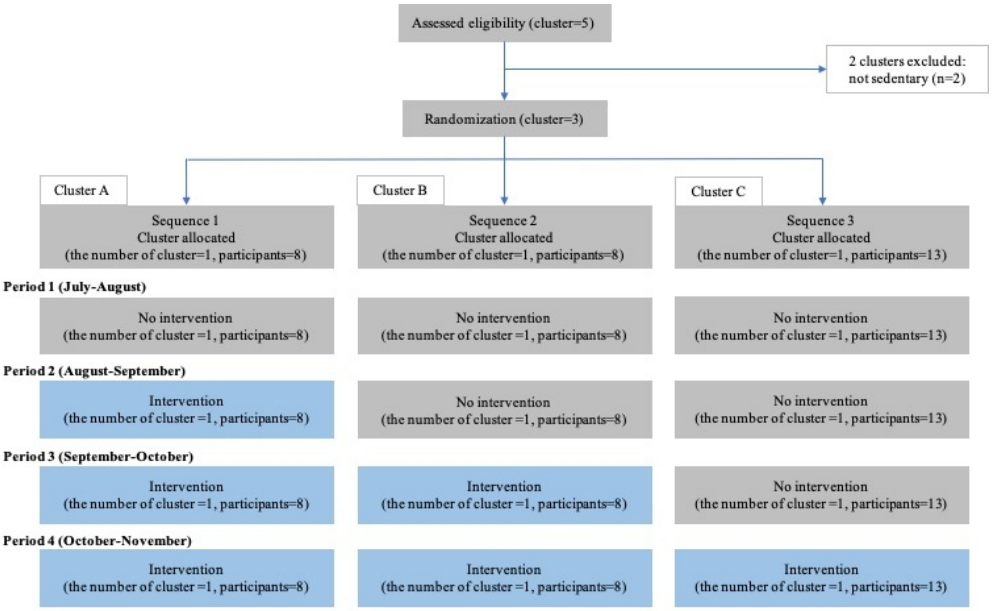
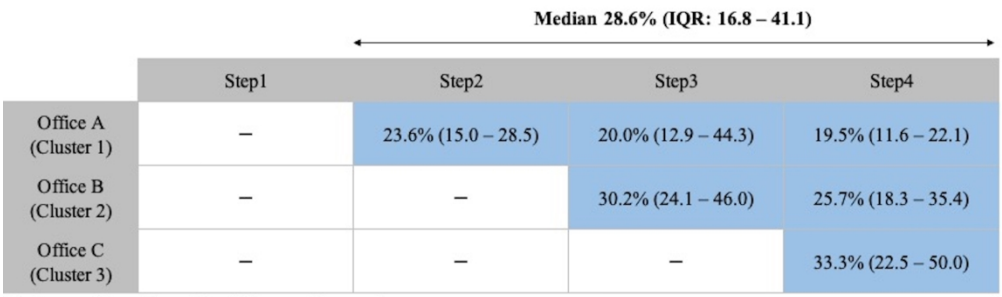


Figure 2. Flowchart for stepped wedge cluster randomized trial

267x178mm (72 x 72 DPI)



Data were shown in median (Interquartile range)

Figure 3. Adherence of intervention among each step and office

288x106mm (300 x 300 DPI)

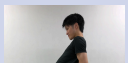
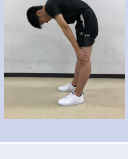
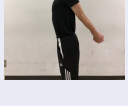
Supplementary figure 1

Check Sheet of Evaluation

No.	Question	Answer	Recommended Exercise
Q1	Which makes your low back comfortable after repeating 10 times? Forward bending or Backward bending?	Forward bending	❷, ❺
		Backward bending	❶
Q2	Check your spine alignment (Evaluated by PT)	Kyphosis	❶
		Neutral	—
		Lordosis	❷, ❺
Q3	Thomas test	Negative result	—
		Positive result	❷
Q4	Finger-Floor Distance test	Reached floor	—
		Did not reach floor	Qualitative check by PT ( )
Q5	Which makes you feel low back pain more? Sitting or Standing	座位	❶, ❸, ❹
		立位	❷, ❸, ❺

Supplementary figure 2

My Exercise Program

✓	No.	Exercise Name	Picture
	❶	Back Extension Stretch	
	❷	Iliopsoas Stretch	
	❸	Trunk Twist Stretch	
	❹	Lateral Trunk Stretch	
	❺	Trunk Bending Stretch	
	❻	Chest Stretch	

Supplementary table 1. Comparison of characteristics stratified by adherence

	Adherence >= median	Adherence < median	*p*-value
N	15	14	
Age, median (IQR)	38.0 (27.0, 45.0)	36.5 (31.0, 46.0)	0.73
Sex			0.58
Male	13 (87%)	13 (93%)	
Female	2 (13%)	1 (7%)	
BMI, median (IQR)	21.7 (20.2, 26.3)	22.2 (19.8, 24.2)	0.57
Lumbar disc herniation	2 (13%)	1 (7%)	
Lumbar canal stenosis	1 (7%)	1 (7%)	
Pain intensity, median (IQR)	2.0 (1.0, 2.5)	1.6 (0.5, 2.2)	0.42
RDQ, median (IQR)	1.0 (0.0, 2.0)	0.5 (0.0, 1.0)	0.71
STarT Back, median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	0.39
Medicine			0.22
None	13 (87%)	10 (71%)	
Rarely	0 (0%)	3 (21%)	
Sometimes	1 (7%)	1 (7%)	
Often	1 (7%)	0 (0%)	
Always	0 (0%)	0 (0%)	
Seek for clinic care	1 (7%)	1 (7%)	0.96
Seek for alternative care	1 (7%)	1 (7%)	0.96
Physical activity			
Sedentary time (%)	79.4 (65.8, 84.2)	80.2 (70.5, 81.8)	0.94
Low physical activity (%)	16.5 (12.0, 25.1)	16.2 (13.2, 22.2)	0.91
Moderate-vigorous physical activity (%)	4.1 (2.9, 6.7)	4.6 (3.5, 7.5)	0.73
Step	4518.2 (3407.6, 5896.8)	5056.0 (4117.5, 7159.2)	0.39
Wearing time (minutes)	701.6 (632.8, 759.4)	712.2 (696.8, 754.6)	0.60
Other musculoskeletal pain			
Neck	6 (43%)	11 (73%)	0.03
Shoulder	7 (50%)	11 (73%)	0.59
Elbow	1 (7%)	2 (14%)	0.23
Hand	2 (13%)	2 (14%)	0.13
Hip	3 (21%)	1 (7%)	0.31
Knee	5 (36%)	2 (14%)	0.22
Foot	5 (36%)	2 (14%)	0.41
Sleep quality			0.57

Good	8 (57%)	7 (47%)	
Bad	6 (43%)	8 (53%)	
Productivity Loss, mean (IQR)	3.0 (1.2, 6.9)	1.8 (0.4, 2.6)	0.39
Time Management, median (IQR)	0.0 (0.0, 15.0)	0.0 (0.0, 5.0)	0.55
Physical Demand, median (IQR)	0.0 (0.0, 8.3)	0.0 (0.0, 16.7)	0.54
Mental-Interpersonal Demand, median (IQR)	13.9 (0.0, 22.2)	6.9 (0.0, 11.1)	0.32
Output Demand, median (IQR)	20.0 (0.0, 40.0)	5.0 (0.0, 15.0)	0.22

IQR: Interquartile Range, SD: Standard Deviation, RDQ: Roland-Morris Disability Questionnaire, STarT Back: STarT Back Screening Tool

Table 3 | Checklist of information to include when reporting a stepped wedge cluster randomised trial (SW-CRT)

Topic	Item no	Checklist item	Page no
Title and abstract			
	1a	Identification as a SW-CRT in the title.	1
	1b	Structured summary of trial design, methods, results, and conclusions (see separate SW-CRT checklist for abstracts).	2
Introduction			
Background and objectives	2a	Scientific background. Rationale for using a cluster design and rationale for using a stepped wedge design.	4,6
	2b	Specific objectives or hypotheses.	5
Methods			
Trial design	3a	Description and diagram of trial design including definition of cluster, number of sequences, number of clusters randomised to each sequence, number of periods, duration of time between each step, and whether the participants assessed in different periods are the same people, different people, or a mixture.	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons.	not applicable
Participants	4a	Eligibility criteria for clusters and participants.	7-8
	4b	Settings and locations where the data were collected.	6
Interventions	5	The intervention and control conditions with sufficient details to allow replication, including whether the intervention was maintained or repeated, and whether it was delivered at the cluster level, the individual participant level, or both.	9-11
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed.	11-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons.	not applicable
Sample size	7a	How sample size was determined. Method of calculation and relevant parameters with sufficient detail so the calculation can be replicated. Assumptions made about correlations between outcomes of participants from the same cluster. (see separate checklist for SW-CRT sample size items).	14
	7b	When applicable, explanation of any interim analyses and stopping guidelines.	not applicable
Randomisation			
Sequence generation	8a	Method used to generate the random allocation to the sequences of treatments.	8
	8b	Type of randomisation; details of any constrained randomisation or stratification, if used.	8
Allocation concealment mechanism	9	Specification that allocation was based on clusters; description of any methods used to conceal the allocation from the clusters until after recruitment.	8
Implementation	10a	Who generated the randomisation schedule, who enrolled clusters, and who assigned clusters to sequences.	8
	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling; continuous recruitment or ascertainment; or recruitment at a fixed point in time), including who recruited or identified participants.	8
	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions.	8
Blinding	11a	If done, who was blinded after assignment to sequences (eg, cluster level participants, individual level participants, those assessing outcomes) and how.	8
	11b	If relevant, description of the similarity of treatments.	not applicable
Statistical methods	12a	Statistical methods used to compare treatment conditions for primary and secondary outcomes including how time effects, clustering and repeated measures were taken into account.	15
	12b	Methods for additional analyses, such as subgroup analyses, sensitivity analyses, and adjusted analyses.	15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each treatment condition or allocated sequence, the numbers of clusters and participants who were assessed for eligibility, were randomly assigned, received intended treatments, and were analysed for the primary outcome (see separate SW-CRT flow chart).	images file
	13b	For each treatment condition or allocated sequence, losses and exclusions for both clusters and participants with reasons.	images file
Recruitment	14a	Dates defining the steps, initiation of intervention, and deviations from planned dates. Dates defining recruitment and follow-up for participants.	16
	14b	Why the trial ended or was stopped.	not applicable
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each treatment condition or allocated sequence.	16
Numbers analysed	16	The number of observations and clusters included in each analysis for each treatment condition and whether the analysis was according to the allocated schedule.	17-18
Outcomes and estimation	17a	For each primary and secondary outcome, results for each treatment condition, and the estimated effect size and its precision (such as 95% confidence interval); any correlations (or covariances) and time effects estimated in the analysis.	19-20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended.	not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory.	not applicable
Harms	19	Important harms or unintended effects in each treatment condition (for specific guidance see CONSORT for harms).	19
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses.	24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings. Generalisability to clusters or individual participants, or both (as relevant).	24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	22-24
Other information			
Registration	23	Registration number and name of trial registry.	6
Protocol	24	Where the full trial protocol can be accessed, if available.	not applicable
Funding	25	Sources of funding and other support (such as supply of drugs), and the role of funders.	26
Research ethics review	26	Whether the study was approved by a research ethics committee, with identification of the review committee(s). Justification for any waiver or modification of informed consent requirements.	8

This table can be downloaded as a separate document in supplementary materials 3; page numbers can be added electronically to the PDF document.

BMJ Open

Effectiveness of Workplace Active Rest Program on low back pain in office workers: a stepped-wedge cluster randomized controlled trial

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Title page

1) Title of the article

Effectiveness of Workplace Active Rest Program on low back pain in office workers: a stepped-wedge cluster randomized controlled trial

2) Full name, postal address, e-mail and telephone number of the corresponding author & Full name, department, institution, city and country of all co-authors

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ABSTRACT

Objectives: This study aimed to investigate the effectiveness of Workplace Active Rest Program (WARP) on chronic low back pain (LBP) in office workers.

Design: This study conducted a closed cohort stepped-wedge cluster randomized trial. The total duration of the study was 16 weeks (4 weeks for each step). Sequence allocation was randomized, but no one was blinded.

Setting: This study was conducted in 3 offices in a Japanese electronics company. One office was for administrative department, the others are for engineering department.

Participants: We recruited 29 office workers with LBP greater than 3 months. LBP due to specific injury or disease was excluded. The median age was 38 years, and 26 (90%) were male. All participants completed the study.

Interventions: In the intervention phase, participants performed WARP comprising frequent stand-up and individualized brief exercise/physical activity during work. Physical therapists held LBP workshop and developed tailor-made programs before introducing WARP. We instructed participants to perform WARP at 5 timings during work. Control phase was set before intervention, and participants stayed as usual.

Primary and secondary outcome measures: Primary outcome was pain intensity of LBP assessed using Brief Pain Inventory. Secondary outcomes were work productivity loss measured using Work

Limitations Questionnaire, LBP disability assessed using Roland-Morris Disability Questionnaire, psychosocial subscale assessed using STarT Back Screening tool, and physical activity measured using triaxial accelerometers. These outcomes were collected at baseline and 4-month follow-up evaluation.

Results: In the intention-to-treat analysis, WARP did not show any significant effects on pain intensity (β, 0.01; 95% confidence interval, -0.50, 0.52) and secondary outcomes. The median adherence for WARP was 28.6% (interquartile range, 16.8, 41.1), which was equal to 1.43 times per day. No adverse effect was observed.

Conclusions: The present study was unable to confirm the effectiveness of active rest in improving LBP. Hence, a further study needs to investigate its effectiveness.

Trial registration: UMIN Clinical Trials Registry (UMIN000033210)

Strengths and limitations of this study

- This study is the first pragmatic trial conducted in the real-world setting that investigates the feasibility and effectiveness of active rest.
- All participants completed Workplace Active Rest Program.
- However, adherence to WARP was lower than we expected.

- Because recruited office workers had relatively mild LBP, we were unable to confirm whether WARP is effective in office workers with severe LBP.

INTRODUCTION

Low back pain (LBP) is a prevalent health problem in office workers[1,2] and is the leading cause of decreasing healthy life expectancy worldwide[3]. Moreover, LBP results in a large socioeconomic burden due to work productivity loss and medical expenses[4,5]. In terms of both individual and social impact, LBP among office workers is the crucial problems, which should be tackled.

Office workers are those workers who stay in prolonged sitting position during most of their working time[6,7]. Prolonged sitting is one of the causes of LBP, which is also due to several factors such as increased disc pressure[8], decreased trunk mobility[9], and less posture variation[10]. Although the previous studies have investigated the effectiveness of ergonomic intervention and back support, these are considered ineffective in improving LBP[11,12]. Recently, the use of standing desk has been shown to be effective in improving LBP[13], but it has the following limitations: it requires a lot of space and is costly. Therefore, easy-to-use solutions are required in the workplace.

Active rest (taking a break with exercise/physical activity in the workplace) could possibly improve LBP because it has the following characteristics: (1) sedentary break by standing up, which can prevent prolonged sitting, and (2) exercise/physical activity, which is recommended in the LBP

guidelines[14,15]. A previous study showed that office-based stretching (10–15 minutes/session, 3 times/week) was effective in reducing the occurrence of musculoskeletal discomfort when compared with no intervention [16]. However, in our study, we developed a shorter exercise program involving frequent sessions (a few minutes per session, 5 times/day, except on weekends) because we aimed to promote frequent standing to break the habit of prolonged sitting. Although a positive effect of active rest on LBP was shown in the laboratory study[17], its effectiveness in the real-world setting is still unknown. We hypothesized that there is a difference in the effectiveness between laboratory and real-world setting. Thus, the present study aimed to investigate the effectiveness of Workplace Active Rest Program (WARP) on chronic LBP and work productivity loss in office workers in the real-world setting.

METHODS

Study design

The present study was conducted according to the extension of the Consolidated Standards of Reporting Trials 2010 Statement for stepped-wedge cluster randomized controlled trial (SW-CRT)[18]. We used a closed cohort SW-CRT involving the randomization of clusters to different sequences. SW-CRT is a crossover design with repeated measurement, in which clusters switch from control to intervention condition. SW-CRT is a suitable study design if we assume that the intervention will do more good than harm, hence making it unethical to withhold the intervention from a control group. Thus, because it is morally acceptable and beneficial for participant recruitment, we introduced the SW-CRT design [19]. Moreover, this is the pragmatic design, which increases statistical power and decreases needed clusters compared to those in parallel CRT[20]. The present clinical trial was registered with UMIN Clinical Trials Registry (identifier: UMIN000033210).

As Figure 1 shows, we conducted the present study in 3 offices (clusters) in a Japanese electronics company. We set 3 sequences, where an office switched from control condition to the intervention condition one by one. The total duration of the study was 16 weeks (4 weeks for each step). Evaluation was conducted at baseline and 4 points during the last week of each step. Because of a closed cohort design, participants assessed in different periods were the same participants.

Patient and public involvement

Office workers with LBP were not involved in developing the research question, but we consulted them about the design of the study (especially the intervention program) in terms of feasibility and applicability by joining the employees' health committee. During the trial, they helped us to hold LBP workshop by arranging a room and equipment. We asked them to assess the burden of the intervention before they joined the study. We already disseminated the results of our study to participants and reported them at the employees' health committee.

Participants' recruitment

We recruited 29 participants from 3 offices of a Japanese electronics company in July 2018. Three offices were separated from one another. First, participants were approached by the public health nurse working in this company. When they were interested in the study, the public health nurse introduced them to us. Subsequently, researchers explained the study to the participants, and participants provided informed consent for inclusion in the study.

Office workers were eligible for the present study if they have the following characteristics: (1) are full-time workers (All workers worked in the same day shifts) and (2) engaged in desk work greater than 4 hours/daily working time (self-reported)[21] and (3) had LBP

greater than 3 months. The location of LBP was defined as pain between the 12th rib and inferior gluteal folds[22]. Exclusion criteria were as follows: (1) LBP caused by fracture and trauma injuries, infectious diseases, and internal organ disorders and (2) difficulty participating in the study due to medical or surgical disease. Cluster-level eligibility criteria were as follows: (1) an office where most workers were engaged in desk work and (2) supervisors granting permission in the performance of the study. Whereas Office A was for administrative department, Office B and C were for engineering department.

This study was approved by the Ethics Committee of Kobe University Graduate School of Health Sciences. All participants provided written informed consent for inclusion in the study.

Randomization and blinding

Offices were randomly assigned to one of the 3 successive sequences (one office per sequence) after all clusters and participants were recruited. A researcher who was not involved in the recruitment performed random allocation using computer-generated random numbers and coded information about offices. To prevent contamination, both clusters and participants were not informed of the time the intervention started and the detailed program of the intervention until 2 weeks before the intervention started. We also asked the participants exposed to the intervention not to disclose the program content to other workers. Due to the nature of the present study, participants, intervenient,

and outcome assessors (self-reported) could not be blinded. Data analyst was not also blinded to group allocation.

Intervention

In the intervention phase, we offered WARP in two parts below. First, we held the LBP workshop (group), followed by the introduction of active rest in the workplace. LBP workshop was held when the group moved from the control phase to the intervention phase.

The purposes of LBP workshop were as follows: to allow the participants to understand LBP and sedentary behavior, develop customized exercise program, and explain how WARP is performed after the workshop. LBP workshop was held at company's gymnastics room after work for 90 minutes by two or three physical therapists (PTs) (PTs with expertise in LBP, at least 3 or more experience years) including the primary researcher (YT). To avoid inconsistency on workshop contents in PTs, we discussed and agreed with its contents before workshop. We disseminated leaflets about the contents of LBP workshop to the participants. First, we gave lecture on the following: (1) LBP causes and interventions using a biopsychosocial model and (2) the impact of sedentary behavior (SB) on health (death, noncommunicable diseases, and LBP). Second, evaluation was performed using a physical examination and an interview sheet (a brief file was described in Supplementary Figure 1). We evaluated trunk flexion and extension (comfortable direction), static

trunk posture (sagittal plane, lordosis/kyphosis), Thomas test (flexibility of the iliopsoas muscle)[23], finger-floor distance test (spine and hip joint movement), and one-finger test (positive result indicates sacroiliac joint pain)[24] and asked if the participants felt painful sensations when sitting or standing. Third, individualized exercise programs were developed based on the results of the evaluation. Some exercises were recommended based on the results on the physical examination and interview sheets (Supplementary Figures 1–2). We prepared 6 types of exercise focusing on spine and hip stretch and training, which can improve spine and hip joint mobility and decrease lumbar disc pressure (trunk extension exercise, stretching of the iliopsoas and hamstrings, abdominal oblique, erector spinae muscles, thoracolumbar fascia). We selected these exercises because these can be briefly performed by the participants when they stand up. We let them perform the recommended exercises during workshop after they had seen the demonstration. If participants had difficulty in performing the exercise, we individually helped them.

At the end of workshop, we explained to the participants how and when WARP is performed. Participants were instructed to perform WARP at 5 timings (just before the work starts, AM break, lunch break, PM break, after the work is finished). Because a chime ringed at these 5 timings, we asked them to stand up and perform their exercises for a few minutes after the chime ringed. We also recommended them to perform WARP other than the 5 fixed timings. However, the participants were not required to perform the program. We explained the content of WARP and

introduced some brief exercises to other workers in the same office. It enables participants to easily perform exercise at workplace because they understand what they do. Additionally, to determine if problems occurred after performing WARP, researchers visited each office once a month.

Control

When the participants were in the control phase, we did not perform any intervention to the participants (usual work).

Primary outcome

Primary outcome was LBP intensity. We used the pain intensity subscale of Brief Pain Inventory (BPI), which is well-validated and reliable among patients with noncancer pain including LBP[25,26]. BPI consists of 4 questions rating pain intensity separately at "worst," "least," "average," and "now" during the last 24 hours using 11-point Numerical Rating Scale (NRS), ranging from 0 (no pain) to 10 (worst imaginable pain). Finally, the mean of these four items was used as a BPI score (BPI score = [worst + least + average + now]/4). A Japanese version of BPI has a good validity and reliability[27].

At the moment of trial registration, although we had planned to evaluate weekly LBP intensity, we changed to once in 4 weeks evaluation. This is because weekly evaluation was not

feasible at this company in terms of responders' burden for answering questionnaires.

Secondary outcome

The Roland-Morris Disability Questionnaire (RDQ) is a validated 24-item questionnaire that assesses the disability due to LBP such as "I change position frequently to try and get my back comfortable."[28,29]. Each item is scored either 0 or 1, with all scores summed to a total between 0 and 24 (a higher score indicates a greater disability level).

The STarT Back Screening tool is a validated screening tool that predicts the future disability level[30,31]. We used 5-item psychosocial subscale of the STarT Back Screening tool including fear of movement, depressive symptom, catastrophic attitude, anxiety, and pain distress. Score ranged from 0 to 5 (a higher score indicates a higher possibility for future disability level).

The Work Limitations Questionnaire (WLQ) is a validated 25-item questionnaire that evaluates work productivity loss due to physical/psychological issues[32,33]. The WLQ is composed of the following 4 subscales: (1) Time Management (the difficulty in performing a job tasks in a timely manner and in scheduling tasks), (2) Mental-Interpersonal Demands (the difficulty in performing cognitive job tasks and in interacting with colleagues), (3) Physical Demands (the ability to perform job tasks involving body strength, movement, endurance, coordination, and flexibility), and (4) Output Demands (work quantity and quality reduction and timeliness of completed work).

Additionally, “Not applicable” was also provided as a response option and treated as a missing value. All subscales scores were converted to percentage, 0% (least limited) to 100% (most limited). Work productivity loss (%) was calculated from the weighed sum of the 4 subscale scores using a validated algorithm ranging from 0% to 24.9%. A higher score indicates a higher level of work productivity loss.

To measure physical activity and sedentary behavior, we distributed triaxial accelerometers (Active style Pro HJA-750C, Omron Healthcare Co., Ltd.) to the participants during each step. Details of the accelerometer measurement procedure were described elsewhere[34,35]. Participants were instructed to wear triaxial accelerometers on their waist during only working time for 5 days. Data were recorded in 60-second epoch. In addition to the number of steps, time spent in moderate-to-vigorous physical activity (MVPA, 3.0 ≤ Metabolic equivalent; METs), light physical activity (1.5 < METs < 3.0), and SB (METs ≤ 1.5) were calculated using R version 3.5.2. Days with at least 4 hours of wearing time or 75% of working hours were considered a valid day[36], and we included the data with at least 1 valid day in the analysis. Non-wear time was defined as a period with continuous zero count lasting over 60 minutes.

Other measurements

We collected demographic data such as age, sex, height, weight, and body mass index. Participants

were asked whether they were ever diagnosed with the following conditions: lumbar disc herniation, lumbar canal stenosis, lumbar compression fracture, trauma, spinal metastasis, fibromyalgia, rheumatoid arthritis, and infectious spondylitis. Participants also reported the status of their analgesic administration (none, rarely, sometimes, often, and always), consultation on orthopedic clinics, or alternative medicine for LBP (none, once, twice, three times, four times, and greater than five), sleep quality (very good, fairly good, fairly bad, and very bad), and other musculoskeletal pain including neck, shoulder, elbow, wrist, hip, knee, and foot (NRS). At the final follow-up evaluation (T4 evaluation of Figure 1), participants answered about their satisfaction (satisfied very much, satisfied, normal, dissatisfied, dissatisfied very much) and free opinion about WARP.

Adherence

To evaluate adherence for WARP, we asked participants to keep diaries whether they performed WARP or not in each 5 timing. Adherence is calculated 100% if they performed WARP at all 5 timings during the whole intervention phase. Because WARP is a program at the workplace, we did not include holidays when assessing adherence.

Sample size

We calculated the sample size using formula specific for stepped-wedge design[20]. Primary

outcome difference and standard deviation were set as 2.0 and 2.5, respectively[37]. The following assumed parameters were used: cluster size=10, intracluster correlation coefficient=0.05, the number of step=3, the number of baseline measurement=1, measurement after each step=1, two-sided α-level=0.05, and β=80%. To detect 2-point difference in primary outcome, a total of 22 participants were needed. Considering drop out, we estimated 30 participants as required sample size, and 29 participants actually joined the present study. Although we set cluster size as 10 before recruitment, actual size of two clusters were 8. We conservatively performed sample size calculation by changing some parameters. However, required sample size is not changed (22 participants) even if it is 8 participants. Therefore, this difference would not affect the results of our study.

Statistical analysis

For the characteristics of participants, categorical variables were presented as frequency and percentage and continuous variables as mean ± SD (standard deviations). If distributions of the continuous variables were skewed, data were presented as median (range or interquartile range [IQR]).

We performed both intention-to-treat (ITT) analysis and per-protocol analysis to investigate both the effectiveness and efficacy of WARP. Primary analysis was ITT analysis because this study aimed to investigate pragmatic effectiveness of WARP in the real-world setting.

Regarding ITT analysis, we performed the linear mixed effect model for all outcomes, setting the intervention as the fixed effect, individual and office as the random effect, and calendar time as the confounding factor. Regarding per-protocol analysis, we also performed the linear mixed effect model for all outcomes after excluding participants whose adherence to WARP was median (28.6%) or less. Unstandardized coefficients and 95% confidence intervals were calculated.

All statistical analyses were performed using Stata/IC 15.1 software (StataCorp). $P < 0.05$ was considered to be statistically significant.

RESULTS

We recruited 29 office workers from 3 offices in July (Figure 2). As planned, Office A performed the intervention in the first period (August), Office B in the second period (September), and Office C in the third period (October). All participants continued WARP until the end (no dropout) of the study. Twenty-eight participants completed the baseline and each follow-up evaluation (T1–T4). Only one participant did not answer T3 evaluation, but answered other evaluations.

The median age was 38 years, and 26 (90%) were male (Table 1). The median pain intensity assessed using BPI was 2.0 (IQR, 0.8, 2.2), and the median score of RDQ was 1.0 (0.0, 2.0). Only two participants performed the clinic or alternative care, and only one participant often received analgesic medication. The median proportion of sedentary time was 79.6% (68.1, 84.1). The median productivity loss estimated by WLQ was 2.2% (0.8, 5.9). Regarding the difference of characteristics in 3 offices, participants were younger in Office C than in other offices. Pain intensity was lighter in Office B than in other offices.

Table 1. Characteristics of participants

	All	Office A	Office B	Office C
N	29	8	8	13
Age, median (IQR)	38.0 (28.0, 45.0)	43.5 (37.0, 46.5)	41.5 (29.5, 46.0)	32.0 (27.0, 38.0)
Sex				
Male	26 (90%)	6 (75%)	7 (88%)	13 (100%)
Female	3 (10%)	2 (25%)	1 (13%)	0 (0%)
BMI, median (IQR)	21.9 (20.2, 24.6)	20.9 (19.9, 23.8)	21.5 (20.2, 24.3)	22.6 (21.5, 24.6)
Lumbar disc herniation	2 (7%)	0 (0%)	1 (13%)	1 (8%)
Lumbar canal stenosis	2 (7%)	0 (0%)	1 (13%)	1 (8%)
Pain intensity, median (IQR)	2.0 (0.8, 2.2)	1.9 (1.1, 3.0)	0.5 (0.2, 2.1)	2.0 (1.2, 2.5)
RDQ, median (IQR)	1.0 (0.0, 2.0)	1.0 (0.0, 1.5)	0.5 (0.0, 1.0)	1.0 (0.0, 2.0)
STarT Back, median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)	0.0 (0.0, 1.0)
Medicine				
None	23 (79%)	5 (62%)	7 (88%)	11 (85%)
Rarely	3 (10%)	2 (25%)	0 (0%)	1 (8%)
Sometimes	2 (7%)	1 (12%)	1 (13%)	0 (0%)
Often	1 (3%)	0 (0%)	0 (0%)	1 (8%)
Always	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Seek for clinic care	2 (7%)	0 (0%)	1 (13%)	1 (8%)
Seek for alternative care	2 (7%)	2 (25%)	0 (0%)	0 (0%)
Physical activity, median (IQR)				
Time spent for Sedentary (%)	79.6 (68.1, 84.1)	74.1 (58.5, 80.0)	78.9 (63.5, 84.9)	81.6 (73.5, 85.2)

Time spent for LPA (%)	16.3 (12.6, 24.4)	19.4 (15.5, 32.9)	17.2 (12.3, 27.9)	13.4 (11.0, 19.2)
Time spent for MVPA (%)	4.5 (2.9, 7.1)	5.6 (3.5, 10.1)	3.9 (2.2, 5.9)	4.1 (3.0, 6.3)
Step	4763.4 (3553.1, 6228.4)	4763.4 (3962.9, 8457.4)	4569.5 (3495.1, 6228.4)	4593.9 (3624.5, 5636.6)
Wearing time (minutes)	708.4 (666.3, 757.1)	682.7 (635.4, 744.4)	757.0 (666.4, 847.3)	707.1 (692.2, 743.5)
Other musculoskeletal pain				
Neck	17 (59%)	4 (50%)	8 (62%)	9 (69%)
Shoulder	18 (62%)	4 (50%)	8 (62%)	9 (69%)
Elbow	3 (10%)	0 (0%)	2 (15%)	1 (8%)
Hand	4 (14%)	1 (12%)	2 (15%)	1 (8%)
Hip	4 (14%)	1 (12%)	1 (8%)	2 (15%)
Knee	7 (24%)	2 (25%)	4 (31%)	1 (8%)
Foot	7 (24%)	3 (38%)	2 (15%)	2 (15%)
Sleep quality				
Good	15 (52%)	5 (62%)	7 (54%)	6 (46%)
Bad	14 (48%)	3 (38%)	6 (46%)	7 (54%)
Productivity loss, mean (IQR)	2.2 (0.8, 5.9)	1.8 (1.2, 2.5)	2.8 (0.8, 5.1)	2.2 (1.3, 6.9)
Time management, median (IQR)	0.0 (0.0, 15.0)	0.0 (0.0, 5.0)	0.0 (0.0, 10.0)	0.0 (0.0, 15.0)
Physical demand, median (IQR)	0.0 (0.0, 10.0)	2.5 (0.0, 25.0)	0.0 (0.0, 0.0)	0.0 (0.0, 10.0)
Mental-interpersonal demand, median (IQR)	8.3 (0.0, 16.7)	5.6 (1.4, 9.7)	11.1 (2.8, 18.1)	11.1 (0.0, 22.2)
Output demand, median (IQR)	10.0 (0.0, 25.0)	7.5 (0.0, 17.5)	13.1 (0.0, 30.0)	10.0 (0.0, 30.0)

IQR, interquartile range; SD, standard deviation; RDQ, Roland-Morris Disability Questionnaire; STarT Back, STarT Back Screening Tool; LPA, Low physical activity; MVPA, Moderate-vigorous physical activity

288

The median adherence for WARP was 28.6% (16.8, 41.1), which is equal to 1.43 times per day (Figure 3). Participants with higher adherence had relatively higher pain intensity, disability due to LBP, and higher work productivity loss (Supplementary Table 1) compared to those with lower adherence. Furthermore, low adherence was related to longer duration of WARP (adherence, Office A < B < C).

For ITT analysis with adjustment for time effects, pain intensity did not improve better in the intervention phase compared to the control phase (β, 0.01; 95% confidence interval, -0.50, 0.52) (Table 2). Regarding secondary outcomes, no significant improvement was observed. For per-protocol analysis with adjustment for time effects (n=14), Time Management Demands, and Mental-Interpersonal Demands (WLQ subscale), MVPA improved better in the intervention phase compared to the control phase. RDQ, productivity loss, and step significantly improved better in the intervention phase compared to the control phase. Calendar time had significant or marginal significant positive effects on primary and secondary outcomes. Any adverse effects were not reported in the present study.

Table 2. Intervention effect on each outcome

	ITT analysis (n=29)					Per-protocol analysis (n=14)				
	β	95% CI			p -value	β	95% CI			p -value
Pain intensity	0.01	-0.50	to	0.52	0.965	-0.16	-0.90	to	0.58	0.680
RDQ total score	-0.59	-1.26	to	0.08	0.085	-0.86	-2.[illegible]	to	0.39	0.177
WLQ			to					to		
Productivity loss (%)	-1.04	-2.70	to	0.61	0.218	-2.31	-4.[illegible]	to	0.17	0.068
Time management demands	-5.48	-13.71	to	2.74	0.191	-10.28	-20.[illegible]	to	-0.07	0.048
Mental-interpersonal demands	-5.31	-11.10	to	0.48	0.072	-10.48	-20.[illegible]	to	-0.41	0.041
Physical demands	1.23	-2.78	to	5.25	0.548	1.92	-3.[illegible]	to	7.71	0.515
Output demands	-1.05	-8.61	to	6.52	0.786	-9.34	-21.[illegible]	to	3.19	0.144
Physical activity										
Time spent for Sedentary (%)	-0.95	-4.58	to	2.67	0.607	-1.80	-6.[illegible]	to	3.03	0.466
Time spent for LPA (%)	0.92	-1.96	to	3.81	0.531	-0.02	-3.[illegible]	to	3.68	0.990
Time spent for MVPA (%)	0.15	-1.17	to	1.48	0.820	1.88	0.[illegible]	to	3.72	0.046
Step	146.80	-850.72	to	1144.33	0.773	889.44	-51[illegible]34	to	2290.21	0.213
STarT Back total score	-0.20	-0.57	to	0.18	0.306	-0.41	-1.[illegible]	to	0.27	0.235

All models were adjusted with time effect, participants with less than 28.6% (median) or median for adherence were excluded from per-protocol analysis.

All outcomes were measured at 5 time points (once in 4 weeks). ITT, intention-to-treat; RDQ, Roland-Morris Disability Questionnaire; WLQ, Work Limitations Questionnaire; LPA, Low physical activity; MVPA, Moderate-vigorous physical activity

For participants' satisfaction for WARP, 4 (14%) were very satisfied, 10 (34%) were satisfied, and 15 (52%) were normal. No one was unsatisfied for WARP. As regards positive comments, some said that "I understood my back pain could be improved, and exercise was easy to perform," "It was nice to know effective stretch," "I feel my back pain is gradually improved,," "I could be careful for prolonged sitting," "I want to make use of personalized exercise," "Back pain was gradually improved," "I could consider problems and methods for solving back pain," and "It was nice to undertake an exercise instruction from professionals." As regards negative comments, some said that "Not enough follow-up other than questionnaire," "Regular feedback based on follow-up data can motivate us to perform this program, but actually no feedback in this program," "There were few people doing exercise around me, so it was hard to do exercise," and "I wanted to know exercise during sitting."

DISCUSSION

In summary, ITT analysis showed that WARP did not have significant positive effects on LBP intensity and other secondary outcomes such as LBP disability or work productivity. The median adherence of WARP was 28.6% (1.43 times/day), which was significantly lower than we expected. Per-protocol analysis revealed that WARP was not associated with LBP outcomes, but WARP had significant positive effects on some subscales of work productivity (Time Management Demands, Mental-Interpersonal Demands) and MVPA.

Although a recent systematic review investigated the current evidence of active rest, they concluded that there was low-quality evidence for conflicting effectiveness on LBP[38]. Studies included in the systematic review were conducted in the laboratory setting or healthy subjects without LBP. Therefore, this is the first randomized controlled trial that investigates the effectiveness of active rest on LBP and work productivity in the real-world setting. However, we were not able to demonstrate the significant positive effective of WARP on LBP. While the present study evaluated the effect of short and frequent office-based exercises (a few minutes per session, 5 times/day, except weekends) on LBP symptom reduction, a previous study showed the effect of long and less frequent office-based exercises (10–15 minutes per session, 3 times/week) on LBP symptom reduction [16]. These differences between the two study designs should be considered when interpreting the results of our study.

We have two potential explanations about the negative results of our studies. First, it might be due to low adherence of WARP, which could diminish its efficacy. Although we considered some strategies to keep adherence (e.g., introducing WARP to all workers other than the participants of this study in the same office, ringing the chime to inform them of WARP timing, and tailor-made exercise program), these might be insufficient to improve adherence. The previous studies suggested supervised exercise and group-based exercise[39]. However, there were no strict supervision or group-based exercise in our study because we tried to investigate the effectiveness of pragmatic easy-to-use solution. Moreover, lower adherence for workplace exercise was influenced by poorer psychosocial work environment (e.g., influence at work, work pace, quantitative demands, interpersonal relations) and lower exercise self-efficacy[40]. A further study should be conducted to perform such strategies to improve adherence, but simplicity and acceptance from employee and employer should be considered in terms of practical use. Second potential explanation of negative results is that the participants in our study had lower level of LBP intensity at baseline, which leads to low motivation for WARP and floor effect. Actually, participants with lower LBP intensity had lower adherence than those with high LBP intensity. We considered the floor effect owing to the mild pain by specifically recruiting workers with back pain (NRS was 3 or higher). However, a time lag between the recruitment and baseline assessments due to coordinating the schedule of LBP workshop might have led to a decrease in pain levels at the time the study was actually conducted.

Future studies should focus on the fluctuations of outcome variables between recruitment and baseline assessments.

Regarding per-protocol analysis, unstandardized coefficients of most outcome parameters were significantly positive compared to those of ITT analysis. A previous study reported that active rest (10-minute fitness program at lunch break) has positive effects on vigor, interpersonal stress, and physical activity[41]. Although the results of the per-protocol analysis should be carefully interpreted owing to selection bias and an underpowered analysis, these results indicate that WARP could have positive effects if its adherence was ideally kept."

Several limitations should be considered in interpreting the results of our study. First, adherence of the program was very low, which might lead to the underestimation on the potential efficacy of WARP. Second, severity level of LBP was relatively mild in this population, which might cause floor effect especially for BPI and RDQ. We should have set the inclusion criteria about the severity level of LBP to eliminate the floor effect. Otherwise, if mild LBP is common in the working population compared to primary care, we should focus on the incidence or recurrent incidence of LBP in terms of primary prevention. Finally, owing to the limited number of workplace settings and types included within one company, the results of the study should not be considered to be generalizable to other workplace settings.

We were unable to conclude that active rest is effective for LBP and productivity loss from

the results of the present study. However, the present study provided valuable information for conducting similar research, though the strategies implemented in this study might be insufficient for maintaining adherence. In the future, we need to study its effectiveness with high adherence or among workers with higher level of LBP intensity.

Acknowledgment

We would like to thank all participants who willingly joined in our study. We also gratefully acknowledge the public health nurse, Ms. Sato, who helped us in the recruitment and data collection. We appreciate the advice of Prof. Omori from the Clinical & Translational Research Center of Kobe University Hospital regarding our research protocol.

Author Contributions

Y Tsuboi, T Oka, K Nakatsuka, T Isa, and R Ono have contributed to the conception and design of the study. Y Tsuboi, K Nakatsuka, and T Isa has conducted recruitment, intervention, data collection, and data analysis. Y Tsuboi has written the first draft of the article, and T Oka, K Nakatsuka, T Isa, and R Ono have revised it and agreed to the final paper.

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Competing Interests

None declared.

Patient consent for publication

Not required.

Ethics statement

The study was approved by the Ethics Committee of Kobe University Graduate School of Health Sciences (No.718).

Data sharing statement

Data, STATA code for statistical analyses, and R code for data processing of accelerometers are available upon reasonable request.

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Figure Legends

Figure 1. Diagram of stepped-wedge cluster randomized controlled trial design

Figure 2. Flowchart for stepped-wedge cluster randomized trial

Figure 3. Adherence of intervention among each step and office

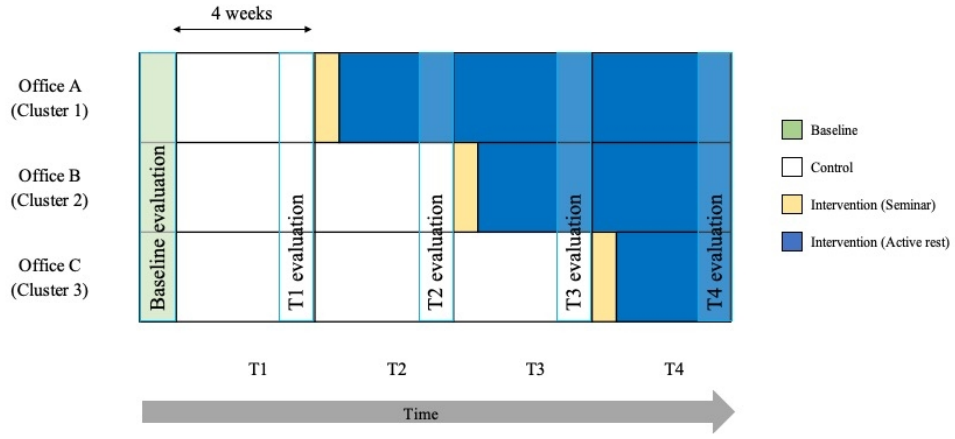


Fig.1. Diagram of stepped wedge cluster randomized controlled trial design

302x155mm (72 x 72 DPI)

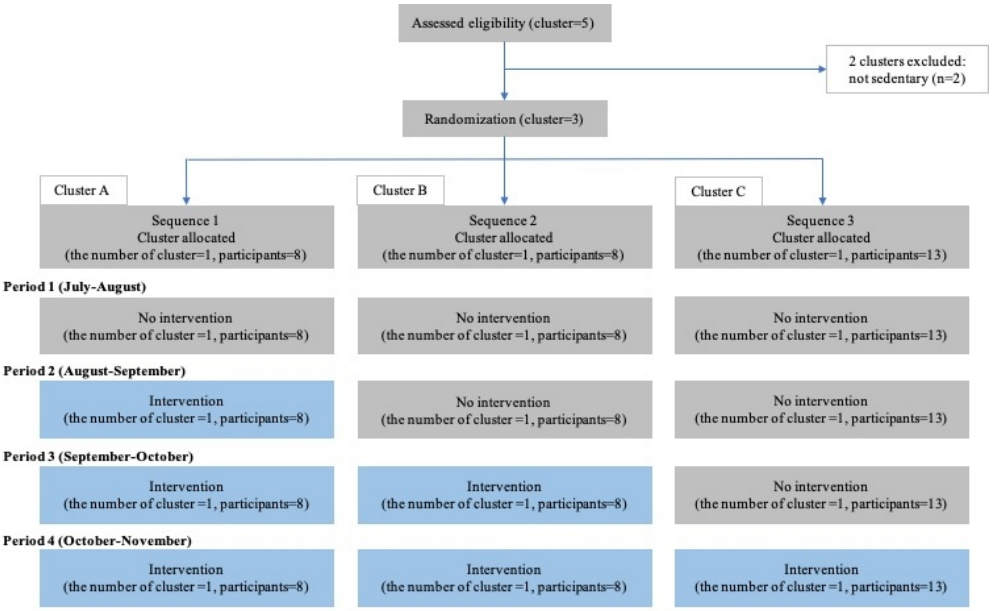
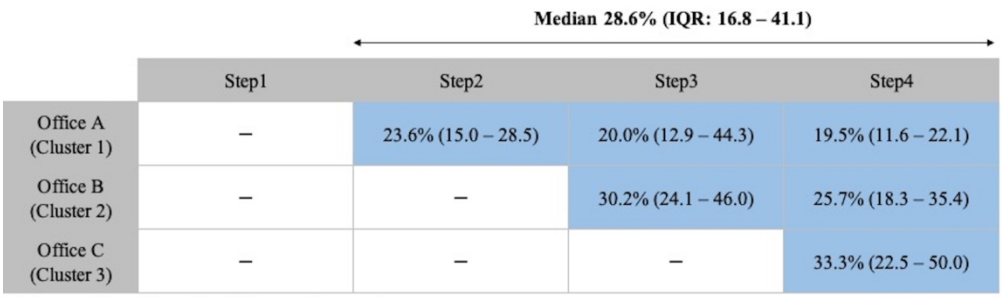


Figure 2. Flowchart for stepped wedge cluster randomized trial

267x178mm (72 x 72 DPI)



Data were shown in median (Interquartile range)

Figure 3. Adherence of intervention among each step and office

288x106mm (300 x 300 DPI)

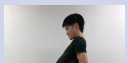
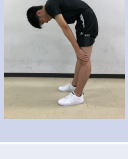
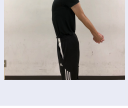
Supplementary figure 1

Check Sheet of Evaluation

No.	Question	Answer	Recommended Exercise
Q1	Which makes your low back comfortable after repeating 10 times? Forward bending or Backward bending?	Forward bending	❷, ❺
		Backward bending	❶
Q2	Check your spine alignment (Evaluated by PT)	Kyphosis	❶
		Neutral	—
		Lordosis	❷, ❺
Q3	Thomas test	Negative result	—
		Positive result	❷
Q4	Finger-Floor Distance test	Reached floor	—
		Did not reach floor	Qualitative check by PT ( )
Q5	Which makes you feel low back pain more? Sitting or Standing	座位	❶, ❸, ❹
		立位	❷, ❸, ❺

Supplementary figure 2

My Exercise Program

✓	No.	Exercise Name	Picture
	❶	Back Extension Stretch	
	❷	Iliopsoas Stretch	
	❸	Trunk Twist Stretch	
	❹	Lateral Trunk Stretch	
	❺	Trunk Bending Stretch	
	❻	Chest Stretch	

Supplementary table 1. Comparison of characteristics stratified by adherence

	Adherence >= median	Adherence < median	*p*-value
N	15	14	
Age, median (IQR)	38.0 (27.0, 45.0)	36.5 (31.0, 46.0)	0.73
Sex			0.58
Male	13 (87%)	13 (93%)	
Female	2 (13%)	1 (7%)	
BMI, median (IQR)	21.7 (20.2, 26.3)	22.2 (19.8, 24.2)	0.57
Lumbar disc herniation	2 (13%)	1 (7%)	
Lumbar canal stenosis	1 (7%)	1 (7%)	
Pain intensity, median (IQR)	2.0 (1.0, 2.5)	1.6 (0.5, 2.2)	0.42
RDQ, median (IQR)	1.0 (0.0, 2.0)	0.5 (0.0, 1.0)	0.71
STarT Back, median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	0.39
Medicine			0.22
None	13 (87%)	10 (71%)	
Rarely	0 (0%)	3 (21%)	
Sometimes	1 (7%)	1 (7%)	
Often	1 (7%)	0 (0%)	
Always	0 (0%)	0 (0%)	
Seek for clinic care	1 (7%)	1 (7%)	0.96
Seek for alternative care	1 (7%)	1 (7%)	0.96
Physical activity			
Sedentary time (%)	79.4 (65.8, 84.2)	80.2 (70.5, 81.8)	0.94
Low physical activity (%)	16.5 (12.0, 25.1)	16.2 (13.2, 22.2)	0.91
Moderate-vigorous physical activity (%)	4.1 (2.9, 6.7)	4.6 (3.5, 7.5)	0.73
Step	4518.2 (3407.6, 5896.8)	5056.0 (4117.5, 7159.2)	0.39
Wearing time (minutes)	701.6 (632.8, 759.4)	712.2 (696.8, 754.6)	0.60
Other musculoskeletal pain			
Neck	6 (43%)	11 (73%)	0.03
Shoulder	7 (50%)	11 (73%)	0.59
Elbow	1 (7%)	2 (14%)	0.23
Hand	2 (13%)	2 (14%)	0.13
Hip	3 (21%)	1 (7%)	0.31
Knee	5 (36%)	2 (14%)	0.22
Foot	5 (36%)	2 (14%)	0.41
Sleep quality			0.57

Good	8 (57%)	7 (47%)	
Bad	6 (43%)	8 (53%)	
Productivity Loss, mean (IQR)	3.0 (1.2, 6.9)	1.8 (0.4, 2.6)	0.39
Time Management, median (IQR)	0.0 (0.0, 15.0)	0.0 (0.0, 5.0)	0.55
Physical Demand, median (IQR)	0.0 (0.0, 8.3)	0.0 (0.0, 16.7)	0.54
Mental-Interpersonal Demand, median (IQR)	13.9 (0.0, 22.2)	6.9 (0.0, 11.1)	0.32
Output Demand, median (IQR)	20.0 (0.0, 40.0)	5.0 (0.0, 15.0)	0.22

IQR: Interquartile Range, SD: Standard Deviation, RDQ: Roland-Morris Disability Questionnaire, STarT Back: STarT Back Screening Tool

Table 3 | Checklist of information to include when reporting a stepped wedge cluster randomised trial (SW-CRT)

Topic	Item no	Checklist item	Page no
Title and abstract			
	1a	Identification as a SW-CRT in the title.	1
	1b	Structured summary of trial design, methods, results, and conclusions (see separate SW-CRT checklist for abstracts).	2
Introduction			
Background and objectives	2a	Scientific background. Rationale for using a cluster design and rationale for using a stepped wedge design.	4,6
	2b	Specific objectives or hypotheses.	5
Methods			
Trial design	3a	Description and diagram of trial design including definition of cluster, number of sequences, number of clusters randomised to each sequence, number of periods, duration of time between each step, and whether the participants assessed in different periods are the same people, different people, or a mixture.	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons.	not applicable
Participants	4a	Eligibility criteria for clusters and participants.	7-8
	4b	Settings and locations where the data were collected.	6
Interventions	5	The intervention and control conditions with sufficient details to allow replication, including whether the intervention was maintained or repeated, and whether it was delivered at the cluster level, the individual participant level, or both.	9-11
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed.	11-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons.	not applicable
Sample size	7a	How sample size was determined. Method of calculation and relevant parameters with sufficient detail so the calculation can be replicated. Assumptions made about correlations between outcomes of participants from the same cluster. (see separate checklist for SW-CRT sample size items).	14
	7b	When applicable, explanation of any interim analyses and stopping guidelines.	not applicable
Randomisation			
Sequence generation	8a	Method used to generate the random allocation to the sequences of treatments.	8
	8b	Type of randomisation; details of any constrained randomisation or stratification, if used.	8
Allocation concealment mechanism	9	Specification that allocation was based on clusters; description of any methods used to conceal the allocation from the clusters until after recruitment.	8
Implementation	10a	Who generated the randomisation schedule, who enrolled clusters, and who assigned clusters to sequences.	8
	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling; continuous recruitment or ascertainment; or recruitment at a fixed point in time), including who recruited or identified participants.	8
	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions.	8
Blinding	11a	If done, who was blinded after assignment to sequences (eg, cluster level participants, individual level participants, those assessing outcomes) and how.	8
	11b	If relevant, description of the similarity of treatments.	not applicable
Statistical methods	12a	Statistical methods used to compare treatment conditions for primary and secondary outcomes including how time effects, clustering and repeated measures were taken into account.	15
	12b	Methods for additional analyses, such as subgroup analyses, sensitivity analyses, and adjusted analyses.	15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each treatment condition or allocated sequence, the numbers of clusters and participants who were assessed for eligibility, were randomly assigned, received intended treatments, and were analysed for the primary outcome (see separate SW-CRT flow chart).	images file
	13b	For each treatment condition or allocated sequence, losses and exclusions for both clusters and participants with reasons.	images file
Recruitment	14a	Dates defining the steps, initiation of intervention, and deviations from planned dates. Dates defining recruitment and follow-up for participants.	16
	14b	Why the trial ended or was stopped.	not applicable
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each treatment condition or allocated sequence.	16
Numbers analysed	16	The number of observations and clusters included in each analysis for each treatment condition and whether the analysis was according to the allocated schedule.	17-18
Outcomes and estimation	17a	For each primary and secondary outcome, results for each treatment condition, and the estimated effect size and its precision (such as 95% confidence interval); any correlations (or covariances) and time effects estimated in the analysis.	19-20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended.	not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory.	not applicable
Harms	19	Important harms or unintended effects in each treatment condition (for specific guidance see CONSORT for harms).	19
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses.	24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings. Generalisability to clusters or individual participants, or both (as relevant).	24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	22-24
Other information			
Registration	23	Registration number and name of trial registry.	6
Protocol	24	Where the full trial protocol can be accessed, if available.	not applicable
Funding	25	Sources of funding and other support (such as supply of drugs), and the role of funders.	26
Research ethics review	26	Whether the study was approved by a research ethics committee, with identification of the review committee(s). Justification for any waiver or modification of informed consent requirements.	8

This table can be downloaded as a separate document in supplementary materials 3; page numbers can be added electronically to the PDF document.