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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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1 Title page

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3 **1) Title of the article**

4 Effectiveness of Workplace Active Rest Program on low back pain in office workers: a stepped-
5 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](https://clinicaltrials.gov/ct2/show/study?term=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

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6 78 promote frequent standing to break the habit of prolonged sitting. Although a positive effect of
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9 79 active rest on LBP was shown in the laboratory study[17], its effectiveness in the real-world setting
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12 80 is still unknown. We hypothesized that there is a difference in the effectiveness between laboratory
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15 81 and real-world setting. Thus, the present study aimed to investigate the effectiveness of Workplace
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18 82 Active Rest Program (WARP) on chronic LBP and work productivity loss in office workers in the
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21 83 real-world setting.
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84 **METHODS**

85 **Study design**

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

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

102 Patient and public involvement

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

109

110 Participants' recruitment

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

116 Office workers were eligible for the present study if they have the following characteristics:

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

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

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

126

127 **Randomization and blinding**

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

137

138 Intervention

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

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

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

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

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9 175 **Control**
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12 176 When the participants were in the control phase, we did not perform any intervention to the participants
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21 179 **Primary outcome**
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24 180 Primary outcome was LBP intensity. We used the pain intensity subscale of Brief Pain Inventory (BPI),
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26 181 which is well-validated and reliable among patients with noncancer pain including LBP[25,26].
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29 182 Participants rated their pain intensity at “worst,” “least,” “average,” and “now” during the last 24 hours
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31 183 using 11-point Numerical Rating Scale (NRS), ranging from 0 (no pain) to 10 (worst imaginable pain).
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34 184 Finally, the mean of these four items was used as a BPI score. A Japanese version of BPI has a good
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36 185 validity and reliability[27].
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44 187 **Secondary outcome**
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47 188 The Roland-Morris Disability Questionnaire (RDQ) is a validated 24-item questionnaire that assesses
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49 189 the disability due to LBP such as “I change position frequently to try and get my back
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51 190 comfortable.”[28,29]. Each item is scored either 0 or 1, with all scores summed to a total between 0
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54 191 and 24 (a higher score indicates a greater disability level).
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192 The STarT Back Screening tool is a validated screening tool that predicts the future
193 disability level[30,31]. We used 5-item psychosocial subscale of the STarT Back Screening tool
194 including fear of movement, depressive symptom, catastrophic attitude, anxiety, and pain distress.
195 Score ranged from 0 to 5 (a higher score indicates a higher possibility for future disability level).

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

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

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

217

218 **Other measurements**

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

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

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230 **Adherence**

231 To evaluate adherence for WARP, we asked participants to keep diaries whether they performed

232 WARP or not in each 5 timing. Adherence is calculated 100% if they performed WARP at all 5 timings

233 during the whole intervention phase. Because WARP is a program at the workplace, we did not include

234 holidays when assessing adherence.

235

236 **Sample size**

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

238 difference and standard deviation were set as 2.0 and 2.5, respectively[37]. The following assumed

239 parameters were used: cluster size=10, intraclass correlation coefficient=0.05, the number of step=3,

240 the number of baseline measurement=1, measurement after each step=1, two-sided α -level=0.05, and

241 β =80%. To detect 2-point difference in primary outcome, a total of 22 participants were needed, and,

242 actually, 29 participants joined the present study.

243

244 **Statistical analysis**

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

percentage and continuous variables as mean \pm 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.

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258 **RESULTS**

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

264 The median age was 38 years, and 26 (90%) were male (Table 1). The median pain
265 intensity assessed using BPI was 2.0 (IQR, 0.8, 2.2), and the median score of RDQ was 1.0 (0.0,
266 2.0). Only two participants performed the clinic or alternative care, and only one participant often
267 received analgesic medication. The median proportion of sedentary time was 79.6% (68.1, 84.1).
268 The median productivity loss estimated by WLQ was 2.2% (0.8, 5.9). Regarding the difference of
269 characteristics in 3 offices, participants were younger in Office C than in other offices. Pain intensity
270 was lighter in Office B than in other offices.

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Table 1. Characteristics of participants

	All	Office A	Office B	Office C
N	29	8	29	13
Age, median (IQR)	38.0 (28.0, 45.0)	43.5 (37.0, 46.5)	41.5 (29.0, 46.0)	32.0 (27.0, 38.0)
Sex				
Male	26 (90%)	6 (75%)	26 (90%)	13 (100%)
Female	3 (10%)	2 (25%)	3 (10%)	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%)	2 (7%)	1 (8%)
Lumbar canal stenosis	2 (7%)	0 (0%)	1 (4%)	1 (8%)
Pain intensity, median (IQR)	2.0 (0.8, 2.2)	1.9 (1.1, 3.0)	0.0 (0.0, 2.1)	2.0 (1.2, 2.5)
RDQ, median (IQR)	1.0 (0.0, 2.0)	1.0 (0.0, 1.5)	0.0 (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%)	18 (62%)	11 (85%)
Rarely	3 (10%)	2 (25%)	0 (0%)	1 (8%)
Sometimes	2 (7%)	1 (12%)	1 (4%)	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 (4%)	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 (63.0, 84.9)	81.6 (73.5, 85.2)

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4	Time spent for LPA (%)	16.3 (12.6, 24.4)	19.4 (15.5, 32.9)	17.2 (12.1, 27.9)
5	Time spent for MVPA (%)	4.5 (2.9, 7.1)	5.6 (3.5, 10.1)	3.1 (2.0, 5.9)
6	Step	4763.4 (3553.1, 6228.4)	4763.4 (3962.9, 8457.4)	4569.5 (4911, 6228.4)
7	Wearing time (minutes)	708.4 (666.3, 757.1)	682.7 (635.4, 744.4)	757.0 (666.4, 847.3)
8	Other musculoskeletal pain			
9	Neck	17 (59%)	4 (50%)	9 (69%)
10	Shoulder	18 (62%)	4 (50%)	9 (69%)
11	Elbow	3 (10%)	0 (0%)	1 (8%)
12	Hand	4 (14%)	1 (12%)	1 (8%)
13	Hip	4 (14%)	1 (12%)	2 (15%)
14	Knee	7 (24%)	2 (25%)	1 (8%)
15	Foot	7 (24%)	3 (38%)	2 (15%)
16	Sleep quality			
17	Good	15 (52%)	5 (62%)	6 (46%)
18	Bad	14 (48%)	3 (38%)	7 (54%)
19	Productivity loss, mean (IQR)	2.2 (0.8, 5.9)	1.8 (1.2, 2.5)	2.1 (0.5, 5.1)
20	Time management, median (IQR)	0.0 (0.0, 15.0)	0.0 (0.0, 5.0)	0.0 (0.0, 10.0)
21	Physical demand, median (IQR)	0.0 (0.0, 10.0)	2.5 (0.0, 25.0)	0.0 (0.0, 0.0)
22	Mental-interpersonal demand, median (IQR)	8.3 (0.0, 16.7)	5.6 (1.4, 9.7)	11.1 (2.3, 18.1)
23	Output demand, median (IQR)	10.0 (0.0, 25.0)	7.5 (0.0, 17.5)	13.1 (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

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

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

Table 2. Intervention effect on each outcome

	ITT analysis (n=29)					Per-protocol analysis (n=14)				
	β	95% CI		<i>p</i> -value		β	95% CI		<i>p</i> -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	-1.50	to	0.39	0.177
WLQ			to					to		
Productivity loss (%)	-1.04	-2.70	to	0.61	0.218	-2.31	-4.00	to	0.17	0.068
Time management demands	-5.48	-13.71	to	2.74	0.191	-10.28	-18.51	to	-0.07	0.048
Mental-interpersonal demands	-5.31	-11.10	to	0.48	0.072	-10.48	-16.26	to	-0.41	0.041
Physical demands	1.23	-2.78	to	5.25	0.548	1.92	-3.86	to	7.71	0.515
Output demands	-1.05	-8.61	to	6.52	0.786	-9.34	-17.88	to	3.19	0.144
Physical activity										
Time spent for Sedentary (%)	-0.95	-4.58	to	2.67	0.607	-1.80	-6.22	to	3.03	0.466
Time spent for LPA (%)	0.92	-1.96	to	3.81	0.531	-0.02	-3.73	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	-511.3	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

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

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299 **DISCUSSION**

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

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

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

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335 the fluctuations of outcome variables between recruitment and baseline assessments.

336 Regarding per-protocol analysis, unstandardized coefficients of most outcome parameters

337 were significantly positive compared to those of ITT analysis. A previous study reported that active

338 rest (10-minute fitness program at lunch break) has positive effects on vigor, interpersonal stress, and

339 physical activity[41]. Although the results of the per-protocol analysis should be carefully interpreted

340 owing to selection bias and an underpowered analysis, these results indicate that WARP could have

341 positive effects if its adherence was ideally kept.”

342 Several limitations should be considered in interpreting the results of our study. First,

343 adherence of the program was very low, which might lead to the underestimation on the potential

344 efficacy of WARP. Second, severity level of LBP was relatively mild in this population, which might

345 cause floor effect especially for BPI and RDQ. We should have set the inclusion criteria about the

346 severity level of LBP to eliminate the floor effect. Otherwise, if mild LBP is common in the working

347 population compared to primary care, we should focus on the incidence or recurrent incidence of LBP

348 in terms of primary prevention. Finally, owing to the limited number of workplace settings and types

349 included within one company, the results of the study should not be considered to be generalizable to

350 other workplace settings.

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

352 the results of the present study. However, the present study provided valuable information for

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

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362 University Hospital regarding our research protocol.

364 **Author Contributions**

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

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372 **Competing Interests**

373 None declared.

375 **Patient consent for publication**

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376 Not required.

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378 **Data sharing statement**

379 Data, STATA code for statistical analyses, and R code for data processing of accelerometers are

380 available upon reasonable request.

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495 Figure Legends

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

497 Figure 2. Flowchart for stepped-wedge cluster randomized trial

498 Figure 3. Adherence of intervention among each step and office

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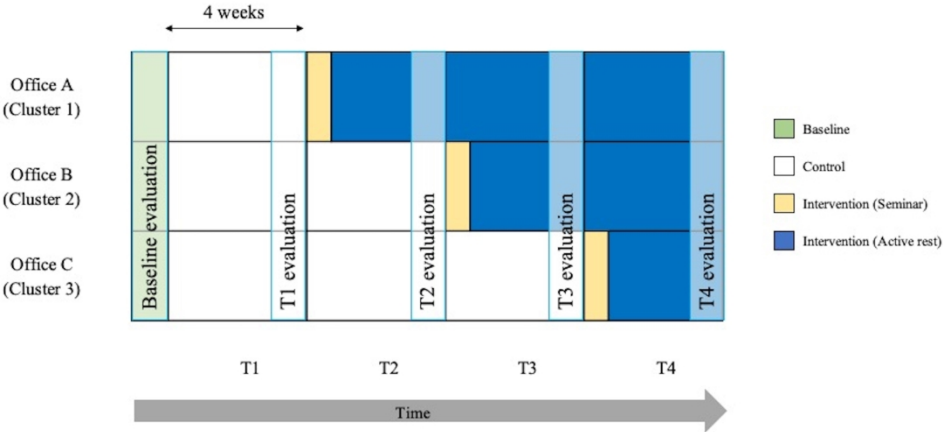


Fig.1. Diagram of stepped wedge cluster randomized controlled trial design

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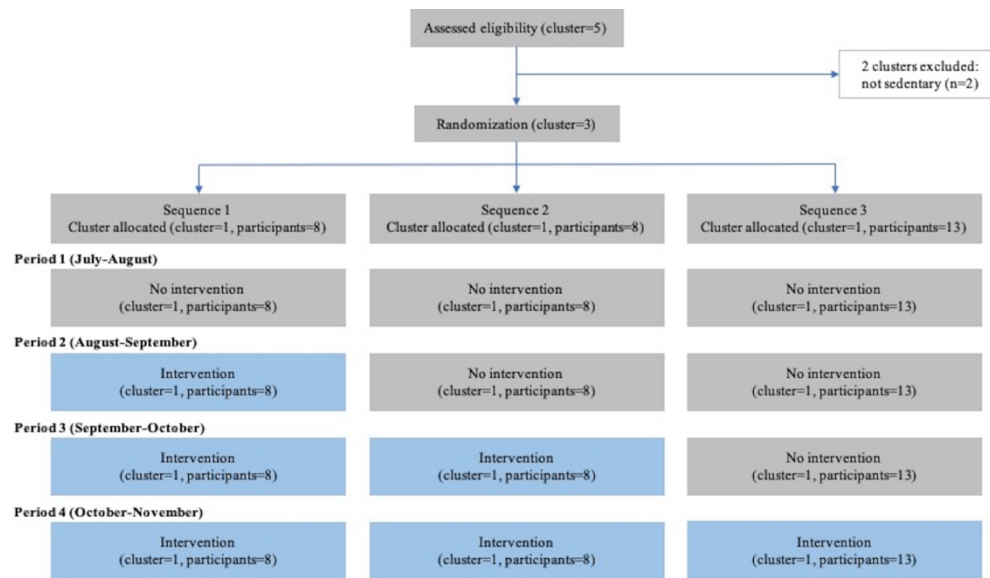
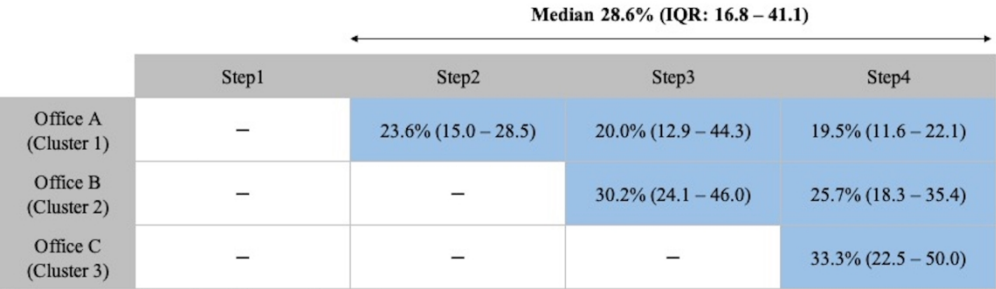


Figure 2. Flowchart for stepped wedge cluster randomized trial

267x169mm (300 x 300 DPI)



Data were shown in median (Interquartile range)

Figure 3. Adherence of intervention among each step and office


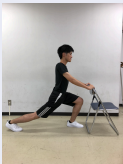




288x106mm (300 x 300 DPI)

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	②, ⑤
	Forward bending or Backward bending?	Backward bending	①
Q2	Check your spine alignment (Evaluated by PT)	Kyphosis	①
		Neutral	—
		Lordosis	②, ⑤
Q3	Thomas test	Negative result	—
		Positive result	②
Q4	Finger-Floor Distance test	Reached floor	—
		Did not reach floor	Qualitative check by PT ()
Q5	Which makes you feel low back pain more?	座位	①, ③, ④
	Sitting or Standing	立位	②, ③, ⑤

Supplementary figure 2

My Exercise Program			
✓	No.	Exercise Name	Picture
	①	Back Extension Stretch	
	②	Iliopsoas Stretch	
	③	Trunk Twist Stretch	
	④	Lateral Trunk Stretch	
	⑤	Trunk Bending Stretch	
	⑥	Chest Stretch	

Supplementary table 1. Comparison of characteristics stratified by adherence

	Adherence \geq median	Adherence $<$ median	<i>p</i> -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

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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

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RESEARCH METHODS AND REPORTING

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
Blinding	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions.	8
	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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1 Title page

2

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7 2) Full name, postal address, e-mail and telephone number of the corresponding author

8 & 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.

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](https://clinicaltrials.gov/ct2/show/study?term=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.

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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

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6 78 with no intervention [16]. However, in our study, we developed a shorter exercise program involving
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9 79 frequent sessions (a few minutes per session, 5 times/day, except on weekends) because we aimed to
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12 80 promote frequent standing to break the habit of prolonged sitting. Although a positive effect of
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15 81 active rest on LBP was shown in the laboratory study[17], its effectiveness in the real-world setting
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18 82 is still unknown. We hypothesized that there is a difference in the effectiveness between laboratory
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21 83 and real-world setting. Thus, the present study aimed to investigate the effectiveness of Workplace
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24 84 Active Rest Program (WARP) on chronic LBP and work productivity loss in office workers in the
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27 85 real-world setting.
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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.

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105 **Patient and public involvement**

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

112

113 **Participants' recruitment**

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

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

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

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

131

132 **Randomization and blinding**

133 Offices were randomly assigned to one of the 3 successive sequences (one office per sequence) after
134 all clusters and participants were recruited. A researcher who was not involved in the recruitment
135 performed random allocation using computer-generated random numbers and coded information
136 about offices. To prevent contamination, both clusters and participants were not informed of the time
137 the intervention started and the detailed program of the intervention until 2 weeks before the
138 intervention started. We also asked the participants exposed to the intervention not to disclose the
139 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.

142

143 **Intervention**

144 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.

147 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

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

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

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

179

180 **Control**

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

183

184 **Primary outcome**

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

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

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194 this company in terms of responders’ burden for answering questionnaires.

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196 **Secondary outcome**

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

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

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

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

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

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228 Other measurements

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

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

239

240 **Adherence**

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

245

246 **Sample size**

247 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 \pm 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

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

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

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271 RESULTS

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

277 The median age was 38 years, and 26 (90%) were male (Table 1). The median pain
278 intensity assessed using BPI was 2.0 (IQR, 0.8, 2.2), and the median score of RDQ was 1.0 (0.0,
279 2.0). Only two participants performed the clinic or alternative care, and only one participant often
280 received analgesic medication. The median proportion of sedentary time was 79.6% (68.1, 84.1).
281 The median productivity loss estimated by WLQ was 2.2% (0.8, 5.9). Regarding the difference of
282 characteristics in 3 offices, participants were younger in Office C than in other offices. Pain intensity
283 was lighter in Office B than in other offices.

Table 1. Characteristics of participants

	All	Office A	Office B	Office C
N	29	8	29	13
Age, median (IQR)	38.0 (28.0, 45.0)	43.5 (37.0, 46.5)	41.5 (29.0, 46.0)	32.0 (27.0, 38.0)
Sex				
Male	26 (90%)	6 (75%)	26 (90%)	13 (100%)
Female	3 (10%)	2 (25%)	3 (10%)	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%)	2 (7%)	1 (8%)
Lumbar canal stenosis	2 (7%)	0 (0%)	2 (7%)	1 (8%)
Pain intensity, median (IQR)	2.0 (0.8, 2.2)	1.9 (1.1, 3.0)	0.0 (0.0, 2.1)	2.0 (1.2, 2.5)
RDQ, median (IQR)	1.0 (0.0, 2.0)	1.0 (0.0, 1.5)	0.0 (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%)	23 (79%)	11 (85%)
Rarely	3 (10%)	2 (25%)	3 (10%)	1 (8%)
Sometimes	2 (7%)	1 (12%)	2 (7%)	0 (0%)
Often	1 (3%)	0 (0%)	1 (3%)	1 (8%)
Always	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Seek for clinic care	2 (7%)	0 (0%)	2 (7%)	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 (63.0, 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 (12.1, 27.9)	13.4 (11.0, 19.2)
Time spent for MVPA (%)	4.5 (2.9, 7.1)	5.6 (3.5, 10.1)	3.1 (2.0, 5.9)	4.1 (3.0, 6.3)
Step	4763.4 (3553.1, 6228.4)	4763.4 (3962.9, 8457.4)	4569.5 (4911, 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%)	17 (59%)	9 (69%)
Shoulder	18 (62%)	4 (50%)	17 (59%)	9 (69%)
Elbow	3 (10%)	0 (0%)	1 (4%)	1 (8%)
Hand	4 (14%)	1 (12%)	1 (4%)	1 (8%)
Hip	4 (14%)	1 (12%)	1 (4%)	2 (15%)
Knee	7 (24%)	2 (25%)	1 (4%)	1 (8%)
Foot	7 (24%)	3 (38%)	1 (4%)	2 (15%)
Sleep quality				
Good	15 (52%)	5 (62%)	15 (52%)	6 (46%)
Bad	14 (48%)	3 (38%)	15 (52%)	7 (54%)
Productivity loss, mean (IQR)	2.2 (0.8, 5.9)	1.8 (1.2, 2.5)	2.1 (0.5, 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 (2.3, 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

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

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

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Table 2. Intervention effect on each outcome

	ITT analysis (n=29)					Per protocol analysis (n=14)				
	β	95% CI		<i>p</i> -value		β	95% CI		<i>p</i> -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	-2.00	to	0.39	0.177
WLQ			to					to		
Productivity loss (%)	-1.04	-2.70	to	0.61	0.218	-2.31	-4.00	to	0.17	0.068
Time management demands	-5.48	-13.71	to	2.74	0.191	-10.28	-20.00	to	-0.07	0.048
Mental-interpersonal demands	-5.31	-11.10	to	0.48	0.072	-10.48	-20.00	to	-0.41	0.041
Physical demands	1.23	-2.78	to	5.25	0.548	1.92	-3.66	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	-6.42	to	3.03	0.466
Time spent for LPA (%)	0.92	-1.96	to	3.81	0.531	-0.02	-3.73	to	3.68	0.990
Time spent for MVPA (%)	0.15	-1.17	to	1.48	0.820	1.88	0.33	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	-1.18	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

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

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

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

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

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

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

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

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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.

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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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515	Figure Legends
516	Figure 1. Diagram of stepped-wedge cluster randomized controlled trial design
517	Figure 2. Flowchart for stepped-wedge cluster randomized trial
518	Figure 3. Adherence of intervention among each step and office
519	

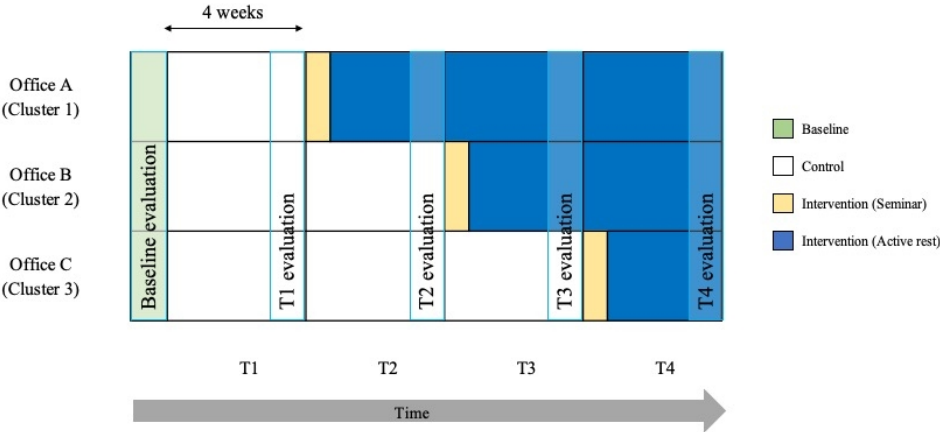


Fig.1. Diagram of stepped wedge cluster randomized controlled trial design

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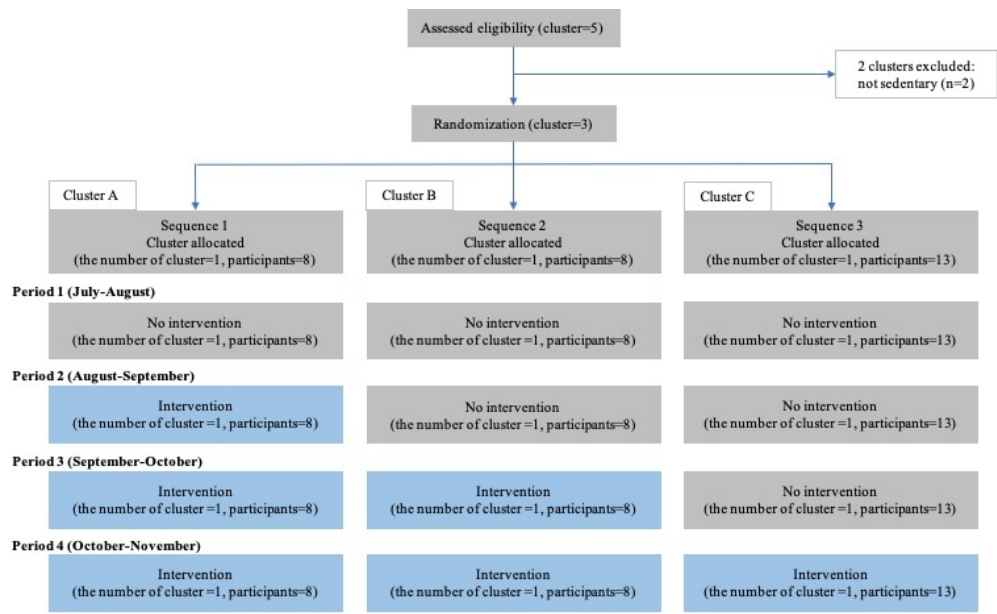


Figure 2. Flowchart for stepped wedge cluster randomized trial

267x178mm (72 x 72 DPI)

Median 28.6% (IQR: 16.8 – 41.1)

	Step1	Step2	Step3	Step4
Office A (Cluster 1)	—	23.6% (15.0 – 28.5)	20.0% (12.9 – 44.3)	19.5% (11.6 – 22.1)
Office B (Cluster 2)	—	—	30.2% (24.1 – 46.0)	25.7% (18.3 – 35.4)
Office C (Cluster 3)	—	—	—	33.3% (22.5 – 50.0)

Data were shown in median (Interquartile range)


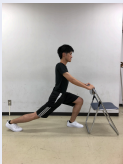




Figure 3. Adherence of intervention among each step and office

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	②, ⑤
	Forward bending or Backward bending?	Backward bending	①
Q2	Check your spine alignment (Evaluated by PT)	Kyphosis	①
		Neutral	—
		Lordosis	②, ⑤
Q3	Thomas test	Negative result	—
		Positive result	②
Q4	Finger-Floor Distance test	Reached floor	—
		Did not reach floor	Qualitative check by PT ()
Q5	Which makes you feel low back pain more?	座位	①, ③, ④
	Sitting or Standing	立位	②, ③, ⑤

Supplementary figure 2

My Exercise Program			
✓	No.	Exercise Name	Picture
	①	Back Extension Stretch	
	②	Iliopsoas Stretch	
	③	Trunk Twist Stretch	
	④	Lateral Trunk Stretch	
	⑤	Trunk Bending Stretch	
	⑥	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
Blinding	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions.	8
	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
	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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1 Title page

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3 1) Title of the article

4 Effectiveness of Workplace Active Rest Program on low back pain in office workers: a
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7 2) Full name, postal address, e-mail and telephone number of the corresponding author

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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](https://clinicaltrials.gov/ct2/show/study?term=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.

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➤ 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

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6 77 guidelines[14,15]. A previous study showed that office-based stretching (10–15 minutes/session, 3
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9 78 times/week) was effective in reducing the occurrence of musculoskeletal discomfort when compared
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12 79 with no intervention [16]. However, in our study, we developed a shorter exercise program involving
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15 80 frequent sessions (a few minutes per session, 5 times/day, except on weekends) because we aimed to
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18 81 promote frequent standing to break the habit of prolonged sitting. Although a positive effect of
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21 82 active rest on LBP was shown in the laboratory study[17], its effectiveness in the real-world setting
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24 83 is still unknown. We hypothesized that there is a difference in the effectiveness between laboratory
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27 84 and real-world setting. Thus, the present study aimed to investigate the effectiveness of Workplace
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30 85 Active Rest Program (WARP) on chronic LBP and work productivity loss in office workers in the
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33 86 real-world setting.
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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.

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106 Patient and public involvement

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

113

114 Participants' recruitment

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

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

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

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

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133 **Randomization and blinding**

134 Offices were randomly assigned to one of the 3 successive sequences (one office per sequence) after
135 all clusters and participants were recruited. A researcher who was not involved in the recruitment
136 performed random allocation using computer-generated random numbers and coded information
137 about offices. To prevent contamination, both clusters and participants were not informed of the time
138 the intervention started and the detailed program of the intervention until 2 weeks before the
139 intervention started. We also asked the participants exposed to the intervention not to disclose the
140 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.

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144 **Intervention**

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

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

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

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

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

180

181 **Control**

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

184

185 **Primary outcome**

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

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

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

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197 **Secondary outcome**

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

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

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

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

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

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229 Other measurements

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

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

240

241 **Adherence**

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

246

247 **Sample size**

248 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 \pm 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.

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

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

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Erasmus Hogeschool

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	29	13
Age, median (IQR)	38.0 (28.0, 45.0)	43.5 (37.0, 46.5)	41.5 (29.0, 46.0)	32.0 (27.0, 38.0)
Sex				
Male	26 (90%)	6 (75%)	26 (90%)	13 (100%)
Female	3 (10%)	2 (25%)	3 (10%)	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%)	2 (7%)	1 (8%)
Lumbar canal stenosis	2 (7%)	0 (0%)	2 (7%)	1 (8%)
Pain intensity, median (IQR)	2.0 (0.8, 2.2)	1.9 (1.1, 3.0)	0.0 (0.0, 2.1)	2.0 (1.2, 2.5)
RDQ, median (IQR)	1.0 (0.0, 2.0)	1.0 (0.0, 1.5)	0.0 (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%)	23 (79%)	11 (85%)
Rarely	3 (10%)	2 (25%)	3 (10%)	1 (8%)
Sometimes	2 (7%)	1 (12%)	2 (7%)	0 (0%)
Often	1 (3%)	0 (0%)	1 (3%)	1 (8%)
Always	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Seek for clinic care	2 (7%)	0 (0%)	2 (7%)	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 (63.0, 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 (12.1, 27.9)	13.4 (11.0, 19.2)
Time spent for MVPA (%)	4.5 (2.9, 7.1)	5.6 (3.5, 10.1)	3.1 (2.0, 5.9)	4.1 (3.0, 6.3)
Step	4763.4 (3553.1, 6228.4)	4763.4 (3962.9, 8457.4)	4569.5 (4911, 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%)	17 (59%)	9 (69%)
Shoulder	18 (62%)	4 (50%)	17 (59%)	9 (69%)
Elbow	3 (10%)	0 (0%)	1 (4%)	1 (8%)
Hand	4 (14%)	1 (12%)	1 (4%)	1 (8%)
Hip	4 (14%)	1 (12%)	1 (4%)	2 (15%)
Knee	7 (24%)	2 (25%)	1 (4%)	1 (8%)
Foot	7 (24%)	3 (38%)	1 (4%)	2 (15%)
Sleep quality				
Good	15 (52%)	5 (62%)	17 (59%)	6 (46%)
Bad	14 (48%)	3 (38%)	12 (44%)	7 (54%)
Productivity loss, mean (IQR)	2.2 (0.8, 5.9)	1.8 (1.2, 2.5)	2.1 (0.5, 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 (2.3, 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

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

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

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Table 2. Intervention effect on each outcome

	ITT analysis (n=29)					Per protocol analysis (n=14)				
	β	95% CI		<i>p</i> -value		β	95% CI		<i>p</i> -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	-2.00	to	0.39	0.177
WLQ			to					to		
Productivity loss (%)	-1.04	-2.70	to	0.61	0.218	-2.31	-4.00	to	0.17	0.068
Time management demands	-5.48	-13.71	to	2.74	0.191	-10.28	-20.00	to	-0.07	0.048
Mental-interpersonal demands	-5.31	-11.10	to	0.48	0.072	-10.48	-20.00	to	-0.41	0.041
Physical demands	1.23	-2.78	to	5.25	0.548	1.92	-3.66	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	-6.42	to	3.03	0.466
Time spent for LPA (%)	0.92	-1.96	to	3.81	0.531	-0.02	-3.73	to	3.68	0.990
Time spent for MVPA (%)	0.15	-1.17	to	1.48	0.820	1.88	0.33	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	-1.18	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

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

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

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

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

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

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

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

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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.

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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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519	Figure Legends
520	Figure 1. Diagram of stepped-wedge cluster randomized controlled trial design
521	Figure 2. Flowchart for stepped-wedge cluster randomized trial
522	Figure 3. Adherence of intervention among each step and office
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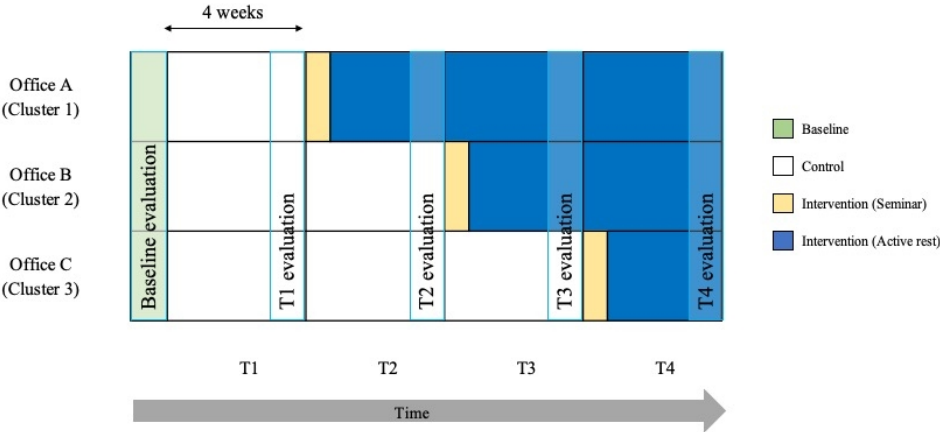


Fig.1. Diagram of stepped wedge cluster randomized controlled trial design

302x155mm (72 x 72 DPI)

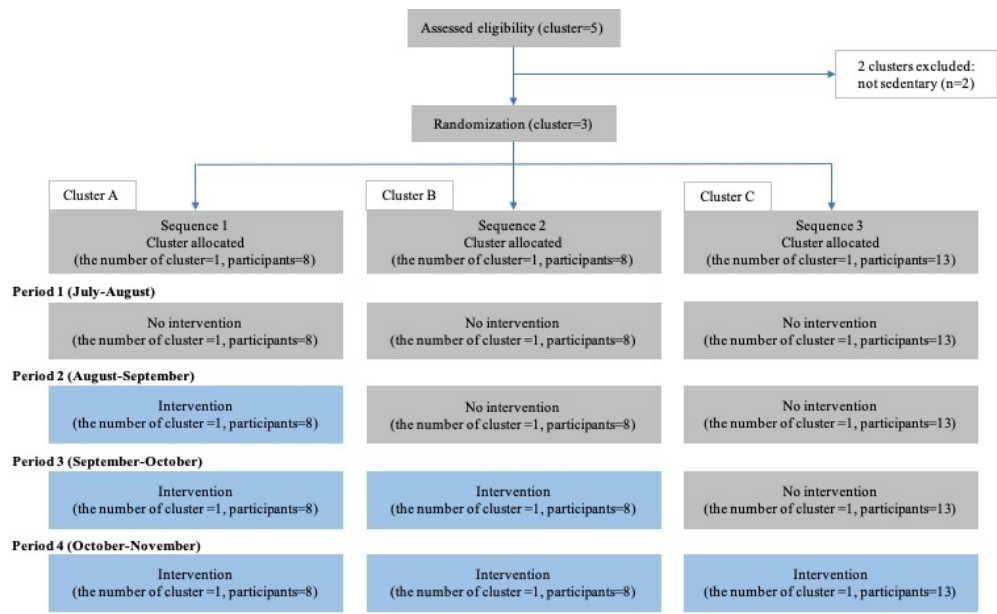


Figure 2. Flowchart for stepped wedge cluster randomized trial

267x178mm (72 x 72 DPI)

Median 28.6% (IQR: 16.8 – 41.1)

	Step1	Step2	Step3	Step4
Office A (Cluster 1)	—	23.6% (15.0 – 28.5)	20.0% (12.9 – 44.3)	19.5% (11.6 – 22.1)
Office B (Cluster 2)	—	—	30.2% (24.1 – 46.0)	25.7% (18.3 – 35.4)
Office C (Cluster 3)	—	—	—	33.3% (22.5 – 50.0)

Data were shown in median (Interquartile range)


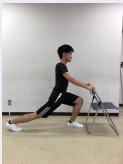




Figure 3. Adherence of intervention among each step and office

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	②, ⑤
	Forward bending or Backward bending?	Backward bending	①
Q2	Check your spine alignment (Evaluated by PT)	Kyphosis	①
		Neutral	—
		Lordosis	②, ⑤
Q3	Thomas test	Negative result	—
		Positive result	②
Q4	Finger-Floor Distance test	Reached floor	—
		Did not reach floor	Qualitative check by PT ()
Q5	Which makes you feel low back pain more?	座位	①, ③, ④
	Sitting or Standing	立位	②, ③, ⑤

Supplementary figure 2

My Exercise Program			
✓	No.	Exercise Name	Picture
	①	Back Extension Stretch	
	②	Iliopsoas Stretch	
	③	Trunk Twist Stretch	
	④	Lateral Trunk Stretch	
	⑤	Trunk Bending Stretch	
	⑥	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
Blinding	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions.	8
	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.