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Effects of a multi-component workplace intervention programme with environmental changes on physical activity among Japanese white-collar employees: a protocol for a cluster randomized controlled trial

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Abstract

Introduction: Physical activity is one of the most important health behaviours as a determinant of physical and mental health. Although intervention strategies for promoting physical activity among workers are needed, evidence for the effectiveness of multi-level workplace interventions with environmental changes on the promotion of physical activity are still limited due to lack of cluster randomized controlled trials (cRCTs). The aim of this study is to investigate effects of a 3-month workplace intervention programme with environmental changes on the improvement in physical activity among Japanese white-collar employees.

Methods and analysis: This study will be a two-arm and parallel-group cluster (worksite) RCT. Japanese worksites and workers who are employed by the worksites will be recruited through health insurance associations and chambers of commerce. Worksites that meet the inclusion criteria will be randomly allocated to intervention or control groups. The intervention worksites will be offered the original intervention programme that consists of 13 contents with environmental changes. The control worksites will be able to get three times feedback of the assessment of the amount of physical activity, and basic occupational health service in each worksite. The primary outcome will be the total amount of physical activity measured by the Global Physical Activity Questionnaire at baseline, 3-months, and 6-months. Multi-level latent growth modelling (LGM) will be conducted to examine the effectiveness of the intervention programme.

Ethics and Dissemination: This study was ethically approved by the research ethics committee of the Graduate School of Medicine and Faculty of Medicine, The University of Tokyo, Japan (No. 10919). Results will be submitted and published in a scientific

peer-reviewed journal.

Trial Registration number: This study protocol is registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR, ID=UMIN000024069)

Article summary

Strengths and limitations of this study

－This study will be the first cluster RCT of the multi-component workplace intervention programme with environmental changes among white-collar employees, including the majority of the worksites in Japan, which are small-sized worksites.

－The findings will be generalisable because of the validated scale used for the standard operational definitions.

－The study will also be the first to investigate the effects of a multi-component workplace intervention both on physical activity and psychological distress.

－The shortage of our human and monetary resources could be a limitation causing selection bias, and impacting small sample size and high attrition rates.

－Another limitation is that all measurements (e.g., physical activity, psychological distress) are self-reported, causing potential measurement errors and informational bias.

Introduction

Physical activity is one of the most important health behaviours as a determinant of physical and mental health[1]. Promotion of physical activity is effective in reducing risks for coronary heart disease, type 2 diabetes, cancers, and all-cause mortality[2-4]. In addition, physical activity is effective for prevention and treatment of depression, anxiety, and improvement of health-related quality of life[5-8]. The benefits of promoting physical activity among the working population have also been demonstrated[9,10]. Moreover, although the evidence is still limited, significant associations between physical activity and improved work-related outcomes have been reported[11-13]. However, despite the importance in promoting physical activity, levels of physical activity in the population are usually low[14]. Modern changes in working styles, including technological advances, have resulted in a large increase in workers engaged in sedentary occupations[15]. Intervention strategies for promoting physical activity among workers are therefore needed.

Many systematic reviews have already been conducted for workplace intervention strategies to promote physical activity[16-27]. Recently Schröer *et al.*[18] conducted a meta-review of workplace health interventions for promoting healthy lifestyles, and concluded that physical activity among employees was increased by multi-component interventions. Some other systematic reviews suggested a similar strategy[19-21]. Multi-component interventions typically include both individual and environmental modifications, such as education[21,22], cognitive-behavioural and motivational approaches[22], counseling[21,23], involvement of families in interventions[19], provision of informational messages[24], using signs for stair-use[19,20,25,26] active commuting[18], implementing new policies encouraging physical activity[21,27], employer

incentives[24], and provision of facilities and equipment for physical activity[19-21,24]. An ecological model[28] is also proposed to describe that various multi-level factors such as intrapersonal, interpersonal, organizational, community, and public policy level factors, could influence specific health behaviours interactively, across different levels and domains. The model also implies that multi-level interventions may be effective in changing behaviour.

However, the quality of evidence for the effectiveness of a multi-level workplace intervention for the promotion of physical activity is still limited. Most studies that have investigated the effects of a stair-use intervention used time-series study designs[25,26]. Very few randomized controlled trials (RCTs) have been used to determine the effects of other components with environmental changes[21,27,28-31]. It was concluded that there was limited and low quality data for the evidence; thus, studies with more rigorous research designs are needed. However, conducting RCTs in a workplace is difficult because of employees' resistance to randomization and potential contamination[17]. In addition, because environmental modifications are conducted at worksite- or company-level, randomization at the individual level in a worksite cannot detect the effects of the workplace environment. Therefore, cluster RCTs (cRCTs) are needed to implement programme interventions using multi-level designs.

A systematic search was conducted to review previous cRCTs meeting the following criteria: participants were worksites and workers employed by a company/organization; intervention programmes included multiple components (two or more components) with environmental changes (programmes, organizational policies, and practice promoting internal physical environment, internal social environment, and external physical and social environments[32]) at the workplace; outcomes were

individual-level physical activity; randomization was conducted at the worksite- or company-level. We identified four cRCTs[33-36] meeting our inclusion criteria; three studies[33-35] were conducted in the US and one[36] in the UK. These studies had high quality of evidence; however, they had inconsistent results: two studies[33,34] reported significant effects resulting from the promotion of physical activity while the others[35,36] reported insignificant effects. In addition, operational definitions of the components of the workplace environment investigated were also different and poor. As only one study[34] quantitatively assessed workplace environment with the cRCT, the specific factors of workplace environment that influenced the behavioural changes among employees could not be detected. Furthermore, these studies targeted only a few companies and restricted areas. Participating worksites were predominantly large, and had many resources to support employees' healthy behaviours. However, 96.7% of worksites in Japan are small (≤ 50 employees)[37]. Further cRCTs are needed to produce more clear evidence and to be able to generalise the effectiveness of workplace interventions with environmental changes on the promotion of physical activity, including small-sized worksites.

Objectives

In this study, we aim to investigate the effects of a 3-month multi-level workplace intervention programme on improving the total amount of physical activity among Japanese white-collar employees. The workplace environments that we will target will be operationally defined using scores from a validated scale[38,39], measuring programmes, organizational policies, and practice promoting internal physical environments to promote physical activtiy[32]. The findings will be generalisable because future intervention programme will be developed according to the same scale.

Additionally, since we will include not only large-sized but also small-sized worksites as participants, findings from this study will be useful in informing all employers, occupational health staff members, and researchers. We will also examine the effects of the programme on enhancing self-regulation for physical activity as a psychological determinant for physical activity, and improving psychological distress and subjective health status as secondary health outcomes. We hypothesise that physical activity among employees, self-regulation for physical activity, psychological distress, and subjective health will be significantly improved in intervention worksites when compared with the control worksites.

Trial design

This study will be a two-arm, parallel-group cRCT. The randomization procedure will be conducted at the cluster (worksite) level. The worksites will be randomly assigned to an intervention or a control (treatment as usual, TAU) group; after completion of a baseline survey worksites will be randomized using a 1:1 ratio. The randomization will be: conducted stratified by worksite size (≤ 49, 50-299, and ≥ 300 employees); permuted-blocked (blocked size = 2); non-blinded. Measurements will be collected at the worksite and worker-level, and analysis for evaluating the efficacy of the intervention programme will be conducted at the worker-level taking into consideration the cluster (worksite) level effects. The study protocol was registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR, ID=UMIN000024069). This protocol was reported according to the SPIRIT guidelines[40].

Methods and analysis

Participants

This cRCT will include multi-level participants: worksites and workers who are employed by the worksites. As the intervention programme will include environmental modifications at the workplace, the cluster level is each worksite. There will be no inclusion and exclusion criteria for worksites; any Japanese worksites will be able to participate in the study if they interested in the promotion of physical activity. Workers will be considered for inclusion in this study if they are: workers employed by the included worksites; workers who are 18 years of age or older; white-collar workers (managerial, professional, technical, clerical, and other job types which require desk-work or sitting-work). There will be no exclusion criteria for workers enrolled in this study.

Procedure

Figure 1 shows a participant flow chart for this study. We will recruit more than a hundred worksites in the Kanto area through some of the health insurance associations and chambers of commerce in the area, using snowball sampling methods. The corresponding author (KW) will send invitations to these organizations, asking them to participate in the recruitment of the worksites. If they agree to assist, the corresponding author will also provide an explanation asking each worksite to participate in the study. In our previous study conducted using the same sampling methods in Kanto area, approximately half of the worksites agreed to join the study[41]. Therefore, this study is expected to recruit 50 or more worksites. After the worksite representatives' agree to partake in the study, nested workers will be recruited. An average cluster size will be approximately 20 workers. In this study, coordinators in each worksite will be appointed with whom we will discuss sampling methods for the workers. Some worksites will

recruit workers randomly, some will recruit workers using flyers, and the others will recruit workers in one of the departments. As the response rate of workers was 87.8% in our previous study, about 878 workers are expected to agree and join the study[41]. After the worksites and workers complete the baseline survey, the worksites will be allocated randomly to the intervention or control group. The intervention programme with environmental changes will last 3-months. The post surveys immediately after the completion of the intervention (3-month follow-up) and 6-month follow-up surveys will be conducted in both the intervention and control groups.

---------- Insert Figure 1 here ----------

Intervention programme

We developed an original intervention programme that consists of multi-component environmental changes based on a validated scale (the Environmental Assessment Tool, EAT)[38,39], good practices to promote physical activity among Japanese worksites, and a literature review. Table 1 shows contents of the intervention programme. The EAT, used to define the workplace environment to promote physical activity in this study, was tested in both the US and Japan, where its reliability and validity were confirmed[38,42]. Higher scores on the EAT indicate a more supportive environment for physical activity promotion and a more invested environment by employers[39]. The EAT consists of three subordinate scales[38]. Of these, variables for Physical Activity Assessment (PAA) and Organizational Characteristics and Support (OCS) can be determined and measured for promoting physical activity among employees. We referred eight items in the two subordinate scales to develop the

intervention programme: parking/bike, signs/bulletin boards/advertisements, shower/changing facilities, stairs/elevators, physical activity/fitness facilities, work rules, written policies, and health promotion programmes for physical activity, and weight management. Additionally, we conducted qualitative interviews for Japanese worksites in the Kanto area, to learn about good practices with environmental changes, already being conducted to promote physical activity. From the results, the 13 contents based on seven items of the EAT (Table 1) were considered feasible to conduct at Japanese workplace. Each operational definition of the environmental change was defined by the EAT scoring system. Finally, literature reviews were conducted to investigate rationales and functions of each item to promote physical activity among workers. Three possible functions for the items were ascertained from the literature[24,27,43]: building awareness and social norms around physical activity, enhancing accessibility for physical activity, and enhancing individual cognitive-behavioural skills. As our resources are limited, only seven contents (No.1-No. 7, Table 1) will be offered free of charge to the participating worksites. The other six contents (No. 8-No.13) will be optional, offered with co-funding or no funding from the research team. If the worksite is not feasible for conducting the specific items, only feasible contents will be conducted. For instance, prompts for stair-use (No. 4) cannot be enacted if the worksite is located in a single-storied building. Taking these conditions into account, we will discuss with the coordinators which and how many contents can be feasibly conducted at each worksite. Here details of the seven contents that will be offered in free are described

---------- Insert Table 1 here ----------

Intervention programme contents

1. Policy making and declaration

The effects of employers or worksite representatives making and declaring policy to encourage employees to be physically active have been discussed in previous studies[19,21,27]. Policies can be attractive for building awareness and social norms among employees. In this study, details of the recommended policies will be discussed by the research team and the coordinator and endorsed by the worksite representatives in each worksite. We will determine if the worksite has a *written* policy, and whether the policy has been posted or communicated to employees.

2. Posters detailing the programme contents and recommendations for physical activity

The incorporation of informational messages in health interventions, are also considered effective for building awareness and social norms[24]. In this study, two kinds of posters will be attached at three or more locations within worksites: information about the intervention programme contents and recommendations for participating in the programme and being physically active. We will determine the number of posters distributed in each workplace; more posters will be considered more effective.

3. Notification provided on intra-website/electronic bulletin board systems

In addition to the use of posters, notifications regarding the programme contents and recommendations for physical activity will also be conducted on an intra-website or a bulletin board system. Based on the results of the assessment investigating good practices among Japanese worksites, we determined that most of the worksites had their own electronic systems to share confidential information within worksites; however, they did not utilize them for physical activity promotion. We will measure whether the

worksite offers information via these electronic systems.

4. Prompts for stair-use at stairs and elevators

The effect of using signs for stair-use[19,20,25,26] for promoting physical activity has repeatedly been suggested on the literature as well. In addition, the qualitative interviews revealed that some Japanese worksites already took it into the good practice. This intervention programme will also include the prompts for stair-use to build awareness and social norms. We will determine whether *any* prompt for stair-use is displayed at stairs or elevators.

5. Exercise

Health promotion programmes at the workplace enhance the accessibility for physical activity among employees[24,43]. Based on the EAT, we determined whether or not *any* exercise programme was provided outside of working hours. No criterion is set for duration, frequency, and intensity of exercise. In this study, we will use the "radio physical fitness exercise[44]" as a standard exercise programme. It is the most popular exercise programme in Japan and most of Japanese people can used this in order to work out without instruction. Any other exercise programmes will be accepted based on discussion between the research team and the coordinators.

6. Individual competition of physical activity within the worksite

There will be a special programme held during the intervention period (3-months) during which participating employees will track their physical activity completed. Such programmes can be effective in enhancing accessibility for physical activity and for increasing self-monitoring by providing the actual opportunity for individuals to trace their own activity[45]. A website was newly developed by the corresponding author, which is password-locked and includes an individual

self-monitoring system. A password to access the website will be shared only among the employees in the intervention worksites. They will be able to log in their individual page after creating accounts, and to record the duration of physical activity per day in three strata: work-related, transport-related, and leisure-time. The recorded data can be checked at any time by both the individuals and the research team during the study. Those who completed more physical activity (ranked by the total amount of physical activity during the intervention programme) will get prizes sponsored by the employers; the worksites will discuss the winners and the prizes. We will measure whether or not employers held physical activity competitions.

7. Psychological education to increase self-regulation for physical activity

Self-regulation (goal setting, reinforcement, self-monitoring, corrective self-reaction, performance self-guidance, and preparation for individual outcome expectations)[46] has recently been indicated as a psychological determinant most strongly associated with physical activity [47]. In this study, a 60-minute single education seminar was developed, which consists of goal-setting and self-monitoring. The seminar will be held in a group-based style, and the participating employees will be instructed to gradually increase their time spent on physical activity by more than 10 minutes daily. Employees will be instructed to record their physical activity using digital devices (e.g., smart watches, smartphones, and the website used during this study). During the seminar, employees will also discuss the importance of remaining physically active despite high workloads. We will measure whether or not any psychological education is provided by the worksites, including components to enhance self-regulative strategies for physical activity among employees.

Intervention worksites

Worksites in the intervention group will be offered the intervention programme described above for 3-months. At the starting stage of the intervention, policies will be implemented and informational messages will be provided to employees (No. 1-No.4). The individual competition programme (No. 6) and the optional contents for facilitations (No. 8-No. 13) will also be started. The exercise programme (No. 5) and the psychological education (No. 7) will also be conducted in each worksite. In addition to the intervention programme, three-times feedback (baseline, 3-month, and 6-month follow-up surveys) of the assessment of the amount of physical activity, and basic occupational health service in each worksite will be offered as the TAU.

Control worksites

Worksites in the control group will be offered the three-times feedback and basic occupational health service as the TAU. Worksites and employees enrolled in the control group will be put on a waiting list to receive the same intervention programme with the intervention worksites after completing the 6-month follow-up survey.

Outcomes

All outcomes, including the primary and secondary outcomes (self-regulation for physical activity, psychological distress, and subjective health), will be measured at the baseline survey, and at the 3-month and 6-month follow-up surveys (Table 2).

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Physical activity

Physical activity will be measured using the Japanese version of Global Physical Activity Questionnaire (GPAQ v2)[48]. This scale is widely used and has demonstrated

reliability and validity. Metabolic equivalents (METs) will be used as a unit of physical activity intensity. This scale consists of three domain-specific physical activities in moderate-to-vigorous intensity per week: work-related; transportation; and leisure-time, and sitting time in a day. In the study, we will calculate the total amount of physical activity per week (METs-hours/week), according to the GPAQ analysis guide[49]. We will assume that physical activity is promoted for employees with higher levels of physical activity.

Self-regulation for physical activity

Self-regulation for physical activity will be measured using the Japanese version of the 12-item Physical Activity Self-Regulation scale (PASR-12)[50,51]. The internal consistency, convergent validity, and structural validity of the Japanese version of the PASR-12 have been confirmed in a previous study[51]. The PASR-12 asks the workers how frequently they utilized cognitive and behavioural methods for physical activity in the past 4-weeks (e.g., "I mentally kept track of my physical activity"). The PASR-12 consists of 12 items and six factors: self-monitoring; goal setting; eliciting social support; reinforcements; time management; relapse prevention. All items are rated on a five point Likert scale (1=Never to 5=Very Often). We will calculate individual 6-factor scores and total PASR-12 scores.

Psychological distress

Questions from the Brief Job Stress Questionnaire (BJSQ)[51] will be used to measure psychological distress at work in terms of vigor (three items, e.g., "I have been very active"), irritation (three items, e.g., "I have felt angry"), fatigue (three items, e.g., "I have felt extremely tired"), anxiety (three items, e.g., "I have felt tense"), and depression (six items, e.g., "I have felt depressed"). This scale has been widely used to

assess responses to stress in Japan and has demonstrated reliability and validity[53,54]. All items are rated on a 4-point Likert scale (1=Hardly to 4=Almost). In this study, we will calculate each factor and total scores. As vigor measures a positive aspect of psychological distress, vigor scores will be reverse-coded in calculating the total scores; higher scores indicate higher psychological distress.

Subjective health

Overall subjective health status will be measured using one question "Overall, how good is your health?" rated on 7-point Likert scale (1=Not very good to 7=Very good). Higher scores indicate better subjective health status.

Sample size calculation

The required sample size was calculated according to the guidelines in the Consolidated Standards of Reporting Trials (CONSORT) for cluster RCTs[55], taking into account intra-class correlations (ICC) of the outcomes nested by the worksites (Table 3). Sample sizes in cRCTs should be multiplied by design effect $(1+[m-1]\rho)$, where m is the average cluster size and ρ is ICC[56]. In our previous study[38], ICC for physical activity among Japanese employees was 0.009. In another study[57] 1.1% in the variance of leisure-time physical activity was found in working groups among employees. Therefore, the estimated ICC for the primary outcome in this study was set to 0.01 and cluster size was set to 20[58]. An effect size of the intervention programme for individual physical activity was estimated based on a previous meta-analysis[17] and a cRCT[34]. The former meta-analysis concluded standardized mean difference (d) of workplace interventions on physical activity was 0.21. Cohen's d of the cRCT was calculated using the reported descriptive statistics and the standardized Cohen's d for vigorous and moderate physical activity was 0.24. The required sample size ranges between 436 to

569 employees in each arm; thus, from 22 to 29 worksites they should be recruited, in the case of alpha error probability of 0.05 and a power (1-β) of 0.90, using G*Power version 3.1.9.2 (Table 3)[59,60].

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Randomization

Enrolled worksites which meet the inclusion criteria will be randomized to intervention or control groups. The randomization will be stratified into three strata based on worksite size (≤ 49, 50-299, and ≥ 300 employees) because the intervention effect might be different based on this factor; it has been proven that it is easier for large worksites to facilitate health and welfare systems[38]. Permuted-blocked randomization (blocked size = 2) will be adopted for equal randomization. The coordinators in the participating worksites will be notified of the result of the randomization. A stratified permuted-block random table will be created by an independent biostatistician. This table will be managed by another research assistant and will be blinded to the researchers (KW and NK).

Statistical analysis

Multi-level latent growth modelling (LGM)[34,61] using robust maximum likelihood estimation will be conducted as the main analysis to examine the effects of the intervention programme on the promotion of physical activity among white-collar employees (Figure 2). In this study, we will determine three-levels of information: repeated measures for employees at level 1, physical activity within employees at level 2, and workplace environment within worksites at level 3. However, because estimation

for the total amount of physical activity at baseline and changes of physical activity can be accounted for in latent variables in LGM, the number of hierarchical levels will be one less than the number of hierarchical levels in other multi-level modelling approach[61]. We will investigate the significance of the coefficient from a dummy variable for the intervention (control = 0, intervention = 1) compared to the linear slope of physical activity as the effect of the intervention programme. We will reference some model fit indices, such as chi square ($\chi 2$), comparative fit index (CFI), Tucker-Levis index (TLI), and root mean square error of approximation (RMSEA). We will consider that the model demonstrates good fit if CFI and TLI exceed 0.95 and RMSEA is less than 0.06[62]. Intention to treat (ITT) analysis using full information maximum likelihood (FIML) estimation will be conducted, including all employees who complete the baseline survey. When results of LGM are misspecification or improper solutions, we will consider conducting three-level mixed model analysis using the restricted maximum likelihood estimation (REML). Mplus version 7.4[63] for LGM and the PASW statistics version 18 (IBM SPSS software) for mixed model analysis will be used. Analyses for secondary outcomes (self-regulation for physical activity, psychological distress, and subjective health) will also be conducted using the same methods.

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Potential subgroup analyses will be conducted, stratified by worksite size, sex, job categories (e.g., manufacture, services, construction, transportation), and initial levels of physical activity or self-regulation.

Some mediation analyses will also be conducted using multi-level structural

equation modelling. We will model (1) the intervention dummy variable for physical activity, mediated by self-regulation for physical activity and (2) the intervention dummy variable for psychological distress and subjective health, mediated by physical activity.

Data monitoring

A Data Monitoring Committee (DMC) will be set up, consisting of the corresponding author (KW) and the coordinator in each worksite because human resources are limited. The DMC will be held every 3-months following the randomization in each worksite. The purpose of the meetings will be to review the participation rates and reasons for study dropout. The DMC will be independent from any sponsor and competing interest.

Ethics and dissemination

Ethical considerations

This study protocol was ethically approved by the research ethics committee of the Graduate School of Medicine and Faculty of Medicine at The University of Tokyo, Japan (No. 11230). We will obtain informed consent from all representatives of the worksites and all employees (Appendix 1, 2). The consent form will inform the worksites and employees that we guarantee protection of personal information, and that the data will be anonymous and only used for academic purposes. The surveyed data will be saved on a password-protected digital device (USB memory stick). The device will be stored in a research room at the Department of Mental Health in the Graduate School of Medicine at The University of Tokyo. The data will be stored as anonymous. Only the authors will have access to the final dataset. There is no competing interest.

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Dissemination of research findings

Results and Findings will be submitted and published in a scientific peer-reviewed journal according to the guidelines in the Consolidated Standards of Reporting Trials (CONSORT) for cluster RCTs[52]. Participants will be informed of conference presentations and publications.

Strengths and limitations

To the best of our knowledge, this study will be the first cRCT of a multi-component workplace intervention programme with environmental changes among Japanese white-collar employees. The study will include the majority of the worksites in Japan, including small-sized worksites. In addition, operational definitions and components of the intervention programme are developed based on a validated scale. The findings will be generalisable because future intervention programmes will be developed according to the same scale. The study will also be the first to investigate the effects of a multi-component workplace intervention both on physical activity and psychological distress.

This study is subject to several limitations. All measurements are self-reported; therefore, there will likely be measurement errors and information bias. Additionally, since there is a shortage in our human and monetary resources we will not be able to recruit worksites from large areas within Japan. Sampling method will not be at random for both the worksite- and the employee-level, possibly causing a selection bias. Furthermore, we will not be able to offer all of our interventions for free, potentially limiting the impact of our proposed interventions. Other possible limitations will be

small sample sizes and high attrition rates.

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Author's contributions

Kazuhiro Watanabe and Norito Kawakami have made substantial contributions to the conception and design, writing of and revision of the protocol for important intellectual content, and approving the final version of the protocol to be published. All authors will be involved in all of the study process (i.e., recruitment, assessment, intervention, and analysis).

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Competing interests

The authors have no conflicts of interest to declare.

Figure Legend

Figure 1. Participant flow chat

Figure 2. Latent growth modelling (LGM) for the study

Table 1. Contents of the intervention programme with environmental changes

No	Contents	Japanese EAT variables[38]	Operational definitions	Functions
1	Policy making and declaration	Written policies	Whether the worksite has a written policy statement supporting employee physical fitness and the policy is posted or otherwise communicated to employees	Employer policy support Building awareness and social norms
2	Posters detailing the programme contents and recommendations for physical activity	Signs/Bulletin boards/Advertisements	How many posters are displayed at the worksite	Informational messages Building awareness and social norms
3	Notifications provided on intra-website/electronic bulletin board systems	Signs/Bulletin boards/Advertisements	Whether the worksite inform the programme contents via an intra-website and/or an electronic bulletin board system	Informational messages Building awareness and social norms
4	Prompts for stair-use at stairs and elevators	Stairs/Elevator	Whether any prompt for stair-use is displayed at stairs or elevators	Informational messages Building awareness and social norms
5	Exercise	Health promotion programmes: physical activity	Whether any exercise programme is provided before office hours, at lunch time, or after office hours	Enhancing accessibility for physical activity
6	Individual competition of physical activity within the worksite	Health promotion programmes: physical activity	Whether any competition programme is provided by employers	Employer incentives Support for self-regulation Enhancing accessibility for physical activity
7	Psychological education to increase self-regulation for physical activity	Health promotion programmes: physical activity	Whether any education programme is provided that help employees enhance self-regulative strategies for physical activity	Behavioural-cognitive approach Increasing self-regulation for physical activity
8	Subsidization of a membership to offsite exercise facilities	Physical activity/Fitness facilities	Whether membership at offsite exercise facilities is subsidized by employers	Enhancing accessibility for physical activity

9	Providing onsite fitness facilities	Physical activity/Fitness facilities	Whether any aerobic and strength equipment are provided at the workplace, and whether four stations per 500 employees are provided at the worksite	Enhancing accessibility for physical activity
10	Providing bike rack spaces	Parking/Bike	Whether any bike rack space is provided at the worksite	Enhancing accessibility for physical activity
11	Providing changing facilities	Shower/Changing facilities	Whether any changing facility is provided at the worksite	Enhancing accessibility for physical activity
12	Providing shower facilities	Shower/Changing facilities	Whether any shower facility is provided at the worksite	Enhancing accessibility for physical activity
13	Contract for sponsorship with sports teams	Physical activity/Fitness facilities	Whether employers contract any sponsorship with any sports team	Employer support Building awareness and social norms

Abbreviations: EAT, Environmental Assessment Tool.

Table 2. Outcome measures

Measurement	Aim	Baseline	3-month follow-up	6-month follow-up
Primary outcome				
GPAQ v2	The amount of physical activity	×	×	×
Secondary outcomes				
PASR-12	Self-regulative strategies for physical activity	×	×	×
BJSQ	Severity of psychological distress	×	×	×
Subjective health	Overall subjective health status	×	×	×

Abbreviations: GPAQ, Global Physical Activity Questionnaire; BJSQ, Brief Job Stress Questionnaire; PASR, Physical Activity Self-Regulation.

Table 3. Sample size calculation for the cluster randomized controlled trial

Article	Mean change between groups	SD	Effect size (*d*)	Required sample size (each arm)[a]	Design effect	Required sample size for cluster RCT (each arm)	Required number of Worksites (each arm)
Conn *et al*. (2009)[17]	-	-	0.21	478	1.19	568.82	28.4
Dishman *et al.* (2010)[34]							
Vigorous physical activity	6.0	25.0	0.24	366	1.19	435.54	21.8
Moderate physical activity	3.3	13.9	0.24	366	1.19	435.54	21.8

a: $\alpha = 0.05$, $(1-\beta) = 0.90$, allocation ratio = 1:1.
Abbreviations: SD, standard deviation; RCT, randomized controlled trial.

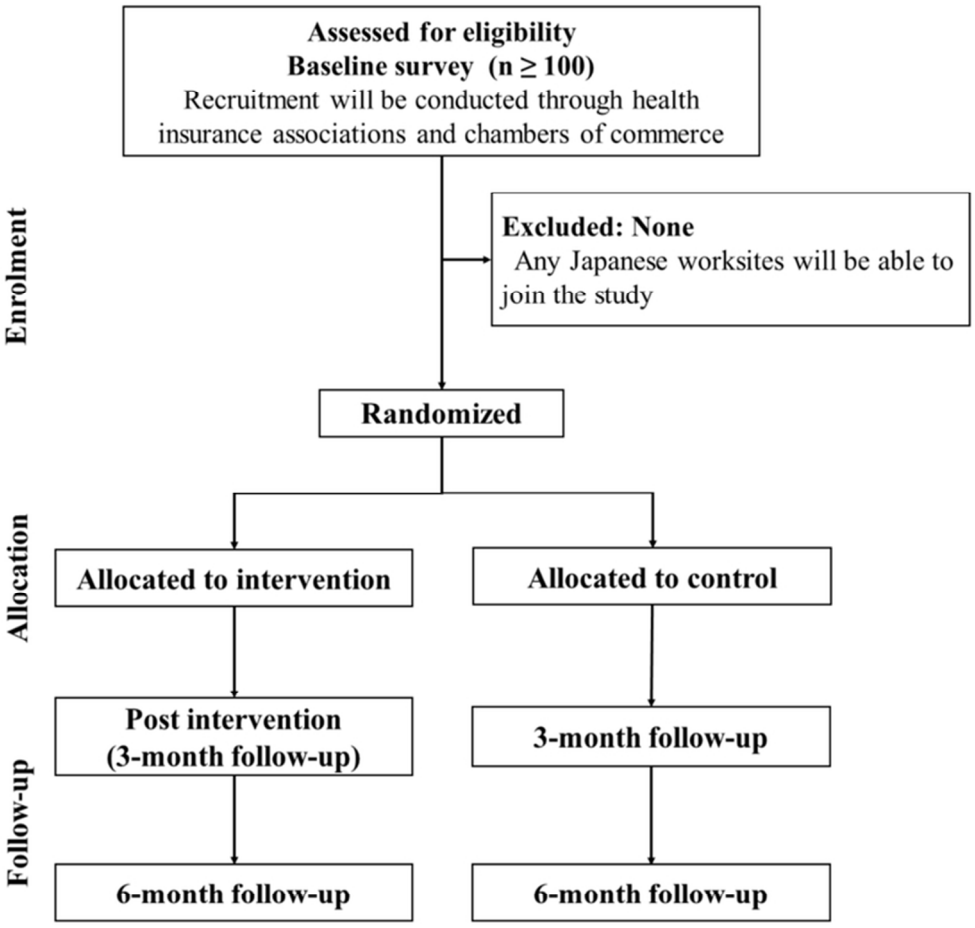

Figure 1. Participant flow chat

69x69mm (300 x 300 DPI)

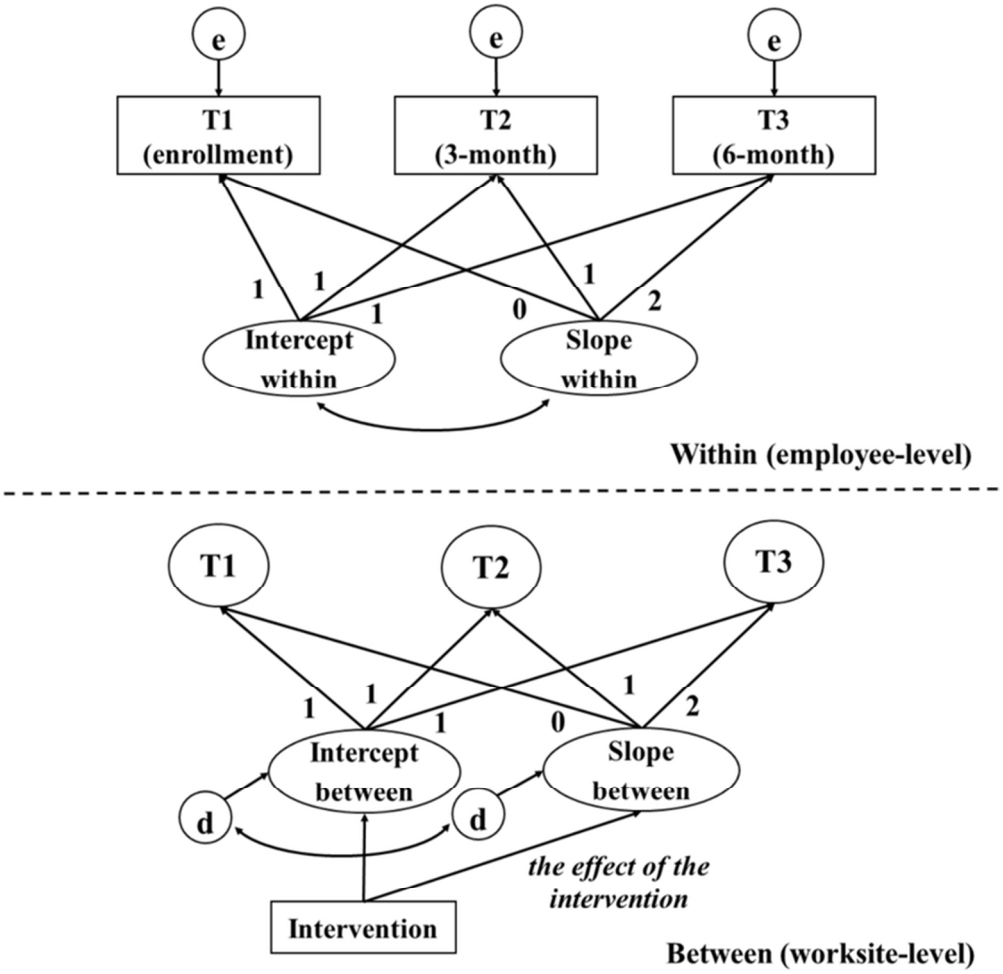

Figure 2. Latent growth modelling (LGM) for the study

69x69mm (300 x 300 DPI)

承　諾　書

東京大学医学系研究科長・医学部長　殿

研究課題「ホワイトカラー労働者の身体活動促進のための職場介入研究」

私は、上記研究への参加にあたり、説明文書の記載事項について、
連絡担当者　渡辺和広から説明を受け、これを十分理解しましたので、
事業所として上記研究に協力することを承諾いたします。

以下の項目について、説明を受け理解しました。

- ☐ この研究の概要について
- ☐ 研究協力の任意性と撤回の自由について
- ☐ 個人情報の保護について
- ☐ 研究結果の公表について
- ☐ 研究参加者にもたらされる利益及び不利益について
- ☐ 研究終了後の資料（試料）等の取扱方針について
- ☐ 事業所側の費用負担について
- ☐ その他について

平成　　年　　月　　日

事業所名 _____

代表者氏名（自署）_____

承　諾　撤　回　書

東京大学医学系研究科長・医学部長　殿

研究課題「ホワイトカラー労働者の身体活動促進のための職場介入研究」

私は、上記研究への事業所としての参加にあたり、説明文書の記載事項について説明を受け承諾しましたが、承諾の是非について再度検討した結果、承諾を撤回いたします。

平成　　年　　月　　日

事業所名 _____

代表者氏名（自署）_____

同　意　書

東京大学医学系研究科長・医学部長　殿

研究課題「ホワイトカラー労働者の身体活動促進のための職場介入研究」

私は、上記研究への参加にあたり、説明文書の記載事項について、連絡担当者　渡辺和広から説明を受け、これを十分理解しましたので本研究の研究参加者となることに同意いたします。

以下の項目について、説明を受け理解しました。

- □　この研究の概要について
- □　研究協力の任意性と撤回の自由について
- □　個人情報の保護について
- □　研究結果の公表について
- □　研究参加者にもたらされる利益及び不利益について
- □　研究終了後の資料（試料）等の取扱方針について
- □　あなたの費用負担について
- □　その他について

平成　　年　　月　　日

氏名（自署）＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

同　意　撤　回　書

東京大学医学系研究科長・医学部長　殿

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私は、上記研究への参加にあたり、説明文書の記載事項について説明を受け同意しましたが、同意の是非について再度検討した結果、同意を撤回いたします。

平成　　年　　月　　日

氏名（自署）＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Reported on page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p.3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	p.3
Funding	4	Sources and types of financial, material, and other support	p.19, 29
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p.1, 29
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	pp.4-6
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	pp.6-7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	p.7
Methods: Participants, interventions, and outcomes			

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	pp.7-9
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	p.7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	pp.9-14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p.18-19
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	pp.14-16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	pp.8-9, Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	p.16
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	pp.7-9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	pp.17

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	pp.17
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	pp.17
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	pp.17
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	pp.7-9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	pp.18-19
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	pp.18-19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	pp.17-18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	pp.18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	pp.17-18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	pp.18-19

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p.19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p.19-20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	p.19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	pp.19, 29
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	p.19
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	p.19-20
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A

Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Effects of a multi-component workplace intervention programme with environmental changes on physical activity among Japanese white-collar employees: a protocol for a cluster randomized controlled trial

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Effects of a multi-component workplace intervention programme with environmental changes on physical activity among Japanese white-collar employees: a protocol for a cluster randomized controlled trial

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Abstract

Introduction: Physical activity is one of the most important health behaviours as a determinant of physical and mental health. Although intervention strategies for promoting physical activity among workers are needed, evidence for the effectiveness of multi-level workplace interventions with environmental changes on the promotion of physical activity are still limited due to lack of cluster randomized controlled trials (cRCTs). The aim of this study is to investigate effects of a 3-month workplace intervention programme with environmental changes on the improvement in physical activity among Japanese white-collar employees.

Methods and analysis: This study will be a two-arm and parallel-group cluster (worksite) RCT. Japanese worksites and employees who are employed by the worksites will be recruited through health insurance associations and chambers of commerce. Worksites that meet the inclusion criteria will be randomly allocated to intervention or control groups. The intervention worksites will be offered the original intervention programme that consists of 13 contents with environmental changes. The control worksites will be able to get three times feedback of the assessment of the amount of physical activity, and basic occupational health service in each worksite. The primary outcome will be the total amount of physical activity measured by the Global Physical Activity Questionnaire at baseline, 3-months, and 6-months. Multi-level latent growth modelling (LGM) will be conducted to examine the effectiveness of the intervention programme.

Ethics and Dissemination: This study was ethically approved by the research ethics committee of the Graduate School of Medicine and Faculty of Medicine, The University of Tokyo, Japan (No. 11230). Results will be submitted and published in a scientific

peer-reviewed journal.

Trial Registration number: This study protocol is registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR, ID=UMIN000024069). Issue date: 1 Mar 2017, protocol amendment number: 03, author: K.W.

Introduction

Physical activity is one of the most important health behaviours as a determinant of physical and mental health[1]. Promotion of physical activity is effective in reducing risks for coronary heart disease, type 2 diabetes, cancers, and all-cause mortality[2-4]. In addition, physical activity is effective for prevention and treatment of depression, anxiety, and improvement of health-related quality of life[5-8]. The benefits of promoting physical activity among the working population have also been demonstrated[9,10]. Moreover, although the evidence is still limited, significant associations between physical activity and improved work-related outcomes have been reported[11-13]. However, despite the importance in promoting physical activity, levels of physical activity in the population are usually low[14]. Modern changes in working styles, including technological advances, have resulted in a large increase in workers engaged in sedentary occupations[15]. Intervention strategies for promoting physical activity among workers are therefore needed.

Many systematic reviews have already been conducted for workplace intervention strategies to promote physical activity[16-27]. Recently Schröer et al.[18] conducted a meta-review of workplace health interventions for promoting healthy lifestyles, and concluded that physical activity among employees was increased by multi-component interventions. Some other systematic reviews suggested a similar strategy[19-21]. Multi-component interventions typically include both individual and environmental modifications, such as education[21,22], cognitive-behavioural and motivational approaches[22], counseling[21,23], involvement of families in interventions[19], provision of informational messages[24], using signs for stair-use[19,20,25,26] active commuting[18], implementing new policies encouraging physical activity[21,27], employer

incentives[24], and provision of facilities and equipment for physical activity[19-21,24]. An ecological model[28] is also proposed to describe that various multi-level factors such as intrapersonal, interpersonal, organizational, community, and public policy level factors, could influence specific health behaviours interactively, across different levels and domains. The model also implies that multi-level interventions may be effective in changing behaviour.

However, the quality of evidence for the effectiveness of a multi-level workplace intervention for the promotion of physical activity is still limited. Most studies that have investigated the effects of a stair-use intervention used time-series study designs[25,26]. Very few randomized controlled trials (RCTs) have been used to determine the effects of other components with environmental changes[21,27,28-31]. It was concluded that there was limited and low quality data for the evidence; thus, studies with more rigorous research designs are needed. However, conducting RCTs in a workplace is difficult because of employees' resistance to randomization and potential contamination[17]. In addition, because environmental modifications are conducted at worksite- or company-level, randomization at the individual level in a worksite cannot detect the effects of the workplace environment. Therefore, cluster RCTs (cRCTs) are needed to implement programme interventions using multi-level designs.

A systematic search was conducted to review previous cRCTs meeting the following criteria: participants were worksites and workers employed by a company/organization; intervention programmes included multiple components (two or more components) with environmental changes (programmes, organizational policies, and practice promoting internal physical environment, internal social environment, and external physical and social environments[32]) at the workplace; outcomes were

individual-level physical activity; randomization was conducted at the worksite- or company-level. We identified four cRCTs[33-36] meeting our inclusion criteria; three studies[33-35] were conducted in the US and one[36] in the UK. These studies had high quality of evidence; however, they had inconsistent results: two studies[33,34] reported significant effects resulting from the promotion of physical activity while the others[35,36] reported insignificant effects. In addition, operational definitions of the components of the workplace environment investigated were also different and poor. As only one study[34] quantitatively assessed workplace environment with the cRCT, the specific factors of workplace environment that influenced the behavioural changes among employees could not be detected. Furthermore, these studies targeted only a few companies and restricted areas. Participating worksites were predominantly large, and had many resources to support employees' healthy behaviours. However, 96.7% of worksites in Japan are small (≤ 50 employees)[37]. Further cRCTs are needed to produce more clear evidence and to be able to generalise the effectiveness of workplace interventions with environmental changes on the promotion of physical activity, including small-sized worksites.

Objectives

In this study, we aim to investigate the effects of a 3-month multi-level workplace intervention programme on improving the total amount of physical activity among Japanese white-collar employees. The workplace environments that we will target will be operationally defined using scores from a validated scale[38,39], measuring programmes, organizational policies, and practice promoting internal physical environments to promote physical activtiy[32]. The findings will be generalisable because future intervention programme will be developed according to the same scale.

Additionally, since we will include not only large-sized but also small-sized worksites as participants, findings from this study will be useful in informing all employers, occupational health staff members, and researchers. We will also examine the effects of the programme on enhancing self-regulation for physical activity as a psychological determinant for physical activity[40-42], and improving psychological distress and subjective health status as secondary health outcomes. We hypothesise that physical activity among employees, self-regulation for physical activity, psychological distress, and subjective health will be significantly improved in intervention worksites when compared with the control worksites.

Trial design

This study will be a two-arm, parallel-group cRCT. The randomization procedure will be conducted at the cluster (worksite) level. The worksites will be randomly assigned to an intervention or a control (treatment as usual, TAU) group; after completion of a baseline survey worksites will be randomized using a 1:1 ratio. The randomization will be conducted stratified by worksite size (≤ 49, 50-299, and ≥ 300 employees); permuted-blocked (blocked size = 2); non-blinded. Measurements will be collected at the worksite and worker-level, and analysis for evaluating the efficacy of the intervention programme will be conducted at the worker-level taking into consideration the cluster (worksite) level effects. The study protocol was registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR, ID=UMIN000024069). This protocol was reported according to the SPIRIT guidelines[43].

Methods and analysis

Participants

This cRCT will include multi-level participants: worksites and employees who are employed by the worksites. As the intervention programme will include environmental modifications at the workplace, the cluster level is each worksite. There will be no inclusion and exclusion criteria for worksites; any Japanese worksites will be able to participate in the study if they are interested in the promotion of physical activity. Employees will be considered for inclusion in this study if they are: workers employed by the included worksites; workers who are 18 years of age or older; white-collar workers (managerial, professional, technical, clerical, and other job types which require desk-work or sitting-work). There will be no exclusion criteria for participants enrolled in this study.

Procedure

Figure 1 shows a participant flow chart for this study. We will recruit more than a hundred worksites in the Kanto area through some of the health insurance associations and chambers of commerce in the area, using snowball sampling methods. The corresponding author (KW) will send invitations to these organizations, asking them to participate in the recruitment of the worksites. If they agree to assist, the corresponding author will also provide an explanation asking each worksite to participate in the study. In our previous study conducted using the same sampling methods in Kanto area, approximately half of the worksites agreed to participate in the study[44]. Therefore, this study is expected to recruit 50 or more worksites. After the worksite representatives' agree to partake in the study, nested employees will be recruited. An average cluster size will be approximately 20 employees. In this study, coordinators in each worksite will be appointed with whom we will discuss sampling methods for the workers. Some

worksites will recruit workers randomly, some will recruit workers using flyers, and the others will recruit workers in one of the departments. As the response rate of workers was 87.8% in our previous study, about 878 workers are expected to agree and participate in the study[44]. After the worksites and employees complete the baseline survey, the worksites will be allocated randomly to the intervention or control group. The intervention programme with environmental changes will last 3-months. The post surveys immediately after the completion of the intervention (3-month follow-up) and 6-month follow-up surveys will be conducted in both the intervention and control groups.

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Intervention programme

We developed an original intervention programme that consists of multi-component environmental changes based on a validated scale (the Environmental Assessment Tool, EAT)[38,39], good practices to promote physical activity among Japanese worksites, and a literature review. Table 1 shows contents of the intervention programme. The EAT, used to define the workplace environment to promote physical activity in this study, was tested in both the US and Japan, where its reliability and validity were confirmed[38,45]. Higher scores on the EAT indicate a more supportive environment for physical activity promotion and a more invested environment by employers[39]. The EAT consists of three subordinate scales[38]. Of these, variables for Physical Activity Assessment (PAA) and Organizational Characteristics and Support (OCS) can be determined and measured for promoting physical activity among

employees. We referred eight items in the two subordinate scales to develop the intervention programme: parking/bike, signs/bulletin boards/advertisements, shower/changing facilities, stairs/elevators, physical activity/fitness facilities, work rules, written policies, and health promotion programmes for physical activity, and weight management. Additionally, we conducted qualitative interviews for Japanese worksites in the Kanto area, to learn about good practices with environmental changes, already being conducted to promote physical activity. From the results, the 13 elements based on seven items of the EAT (Table 1) were considered feasible to conduct at Japanese workplaces. Each operational definition of the environmental change was defined by the EAT scoring system. Finally, literature reviews were conducted to investigate rationales and functions of each item to promote physical activity among workers. Three possible functions for the items were ascertained from the literature[24,27,46]: building awareness and social norms around physical activity, enhancing accessibility for physical activity, and enhancing individual cognitive-behavioural skills. As our resources are limited, only seven elements (No.1-No. 7, Table 1) will be offered free of charge to the participating worksites. The other six elements (No. 8-No.13) will be optional, offered with co-funding or no funding from the research team. If the worksite is not feasible for conducting the specific items, only feasible contents will be conducted. For instance, prompts for stair-use (No. 4) cannot be enacted if the worksite is located in a single-storied building. Taking these conditions into account, we will discuss with the coordinators which and how many elements can be feasibly conducted at each worksite. Here details of the seven elements that will be offered in free are described

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Intervention programme elements

1. Policy making and declaration

The effects of employers or worksite representatives making and declaring policy to encourage employees to be physically active have been discussed in previous studies[19,21,27]. Policies can be attractive for building awareness and social norms among employees. In this study, details of the recommended policies will be discussed by the research team and the coordinator and endorsed by the worksite representatives in each worksite. We will determine if the worksite has a *written* policy, and whether the policy has been posted or communicated to employees.

2. Posters detailing the programme contents and recommendations for physical activity

The incorporation of informational messages in health interventions, are also considered effective for building awareness and social norms[24]. In this study, two kinds of posters will be attached at three or more locations within worksites: information about the intervention programme contents and recommendations for participating in the programme and being physically active. We will determine the number of posters distributed in each workplace; more posters will be considered more effective.

3. Notification provided on intra-website/electronic bulletin board systems

In addition to the use of posters, notifications regarding the programme contents and recommendations for physical activity will also be conducted on an intra-website or a bulletin board system. Based on the results of the assessment investigating good practices among Japanese worksites, we determined that most of the worksites had their own electronic systems to share confidential information within worksites; however,

they did not utilize them for physical activity promotion. We will measure whether the worksite offers information via these electronic systems.

4. Prompts for stair-use at stairs and elevators

The effect of using signs for stair-use[19,20,25,26] for promoting physical activity has repeatedly been suggested on the literature as well. In addition, the qualitative interviews revealed that some Japanese worksites already took it into the good practice. This intervention programme will also include the prompts for stair-use to build awareness and social norms. We will determine whether *any* prompt for stair-use is displayed at stairs or elevators.

5. Exercise

Health promotion programmes at the workplace enhance the accessibility for physical activity among employees[24,46]. Based on the EAT, we determined whether or not *any* exercise programme was provided outside of working hours. No criterion is set for duration, frequency, and intensity of exercise. In this study, we will use the "radio physical fitness exercise[47]" as a standard exercise programme. It is the most popular exercise programme in Japan and most of Japanese people can used this in order to work out without instruction. Any other exercise programmes will be accepted based on discussion between the research team and the coordinators.

6. Individual competition of physical activity within the worksite

There will be a special programme held during the intervention period (3-months) during which participating employees will track their physical activity completed. Such programmes can be effective in enhancing accessibility for physical activity and for increasing self-monitoring by providing the actual opportunity for individuals to trace their own activity[48]. A website was newly developed by the

corresponding author, which is password-locked and includes an individual self-monitoring system. A password to access the website will be shared only among the employees in the intervention worksites. They will be able to log in their individual page after creating accounts, and to record the self-reported duration of physical activity per day in three strata: work-related, transport-related, and leisure-time. The recorded data can be checked at any time by both the individuals and the research team during the study. Those who completed more physical activity (ranked by the total amount of physical activity during the intervention programme) will get prizes sponsored by the employers; the worksites will discuss the winners and the prizes. We will measure whether or not employers held physical activity competitions.

7. Psychological education to increase self-regulation for physical activity

Self-regulation (goal setting, reinforcement, self-monitoring, corrective self-reaction, performance self-guidance, and preparation for individual outcome expectations)[40] has recently been indicated as a psychological determinant most strongly associated with physical activity [41]. In this study, a 60-minute single education seminar was developed to enhance self-regulation for physical activity, which consists of goal-setting and self-monitoring. The seminar will be held in a group-based style, and the participating employees will be instructed to gradually increase their time spent on physical activity by more than 10 minutes daily. Employees will be instructed to record their physical activity using digital devices (e.g., smart watches, smartphones, and the website used during this study). During the seminar, employees will also discuss the importance of remaining physically active despite high workloads. We will measure whether or not any psychological education is provided by the worksites, including components to enhance self-regulative strategies for physical activity among employees.

Intervention worksites

Worksites in the intervention group will be offered the intervention programme described above for 3-months. At the starting stage of the intervention, policies will be implemented and informational messages will be provided to employees (No. 1-No.4). The individual competition programme (No. 6) and the optional elements for facilitations (No. 8-No. 13) will also be started. The exercise programme (No. 5) and the psychological education (No. 7) will also be conducted in each worksite. In addition to the intervention programme, three-times feedback (baseline, 3-month, and 6-month follow-up surveys) of the assessment of the amount of physical activity, and basic occupational health service in each worksite will be offered as the TAU.

Control worksites

Worksites in the control group will be offered the three-times feedback and basic occupational health service as the TAU. Worksites and employees enrolled in the control group will be put on a waiting list to receive the same intervention programme with the intervention worksites after completing the 6-month follow-up survey.

Outcomes

All outcomes, including the primary and secondary outcomes (self-regulation for physical activity, psychological distress, and subjective health), will be measured at the baseline survey, and at the 3-month and 6-month follow-up surveys (Table 2).

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Physical activity

Physical activity will be measured using the Japanese version of Global Physical

Activity Questionnaire (GPAQ v2)[49]. This scale is widely used and has demonstrated reliability and convergent validity among 9 countries, including Japan[50]. The GPAQ can assess three domain specific physical activities in moderate-to-vigorous intensity per week in fewer items than previous questionnaires (the International Physical Activity Questionnaire, IPAQ)[51,52]: occupational; transportation; and leisure-time, and sitting time in a day. Although the GPAQ were developed as a tool for population surveillance across the world at first, it has also been used for assessment of the outcomes of intervention studies[53,54]. In this study, we adopted the GPAQ because of its easiness and low cost to answer, while its criterion validity with pedometers and accelerometers was poor-fair[50]. There will be certain limitation for overestimation of physical activity when compared with pedometers and accelerometers[50,55]. Metabolic equivalents (METs) will be used as a unit of physical activity intensity. We will calculate the total amount of physical activity per week (METs-hours/week), according to the GPAQ analysis guide[56]. We will assume that physical activity is promoted for employees with higher levels of physical activity.

Self-regulation for physical activity

Self-regulation for physical activity will be measured using the Japanese version of the 12-item Physical Activity Self-Regulation scale (PASR-12)[57,58]. The internal consistency, convergent validity, and structural validity of the Japanese version of the PASR-12 have been confirmed in a previous study[58]. The PASR-12 asks the workers how frequently they utilized cognitive and behavioural methods for physical activity in the past 4-weeks (e.g., "I mentally kept track of my physical activity"). The PASR-12 consists of 12 items and six factors: self-monitoring; goal setting; eliciting social support; reinforcements; time management; relapse prevention. All items are rated on a

five point Likert scale (1=Never to 5=Very Often). We will calculate individual 6-factor scores and total PASR-12 scores.

Psychological distress

Questions from the Brief Job Stress Questionnaire (BJSQ)[59] will be used to measure psychological distress at work in terms of vigor (three items, e.g., "I have been very active"), irritation (three items, e.g., "I have felt angry"), fatigue (three items, e.g., "I have felt extremely tired"), anxiety (three items, e.g., "I have felt tense"), and depression (six items, e.g., "I have felt depressed"). This scale has been widely used to assess responses to stress in Japan and has demonstrated reliability and validity[60,61]. All items are rated on a 4-point Likert scale (1=Hardly to 4=Almost). In this study, we will calculate each factor and total scores. As vigor measures a positive aspect of psychological distress, vigor scores will be reverse-coded in calculating the total scores; higher scores indicate higher psychological distress.

Subjective health

Overall subjective health status will be measured using one question "Overall, how good is your health?" rated on 7-point Likert scale (1=Not very good to 7=Very good). Higher scores indicate better subjective health status.

Sample size calculation

The required sample size was calculated according to the guidelines in the Consolidated Standards of Reporting Trials (CONSORT) for cluster RCTs[62], taking into account intra-class correlations (ICC) of the outcomes nested by the worksites (Table 3). Sample sizes in cRCTs should be multiplied by design effect $(1+[m-1]\rho)$, where m is the average cluster size and ρ is ICC[63]. In our previous study[38], ICC for physical activity among Japanese employees was 0.009. In another study[64] 1.1% in the variance of

leisure-time physical activity was found in working groups among employees. Therefore, the estimated ICC for the primary outcome in this study was set to 0.01 and cluster size was set to 20[65]. An effect size of the intervention programme for individual physical activity was estimated based on a previous meta-analysis[17] and a cRCT[34]. The former meta-analysis concluded standardized mean difference (*d*) of workplace interventions on physical activity was 0.21. Cohen's *d* of the cRCT was calculated using the reported descriptive statistics and the standardized Cohen's *d* for vigorous and moderate physical activity was 0.24. The required sample size ranges between 436 to 569 employees in each arm; thus, from 22 to 29 worksites they should be recruited, in the case of alpha error probability of 0.05 and a power (1-*β*) of 0.90, using G*Power version 3.1.9.2 (Table 3)[66,67].

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Randomization

Enrolled worksites which meet the inclusion criteria will be randomized to intervention or control groups. The randomization will be stratified into three strata based on worksite size (≤ 49, 50-299, and ≥ 300 employees) because the intervention effect might be different based on this factor; it has been proven that it is easier for large worksites to facilitate health and welfare systems[38]. Permuted-blocked randomization (blocked size = 2) will be adopted for equal randomization. Because each employee who participate in the study will not notified of the result of the randomization, assessment of the amount of physical activity (self-reported) will be blinded. On the other hand, the coordinators in the participating worksites will be notified of the result

of the randomization. Data analysis conducted by the corresponding author (KW) will also be open to blinded. A stratified permuted-block random table will be created by an independent biostatistician. This table will be managed by another research assistant and will be blinded to the researchers (KW and NK).

Statistical analysis

Multi-level latent growth modelling (LGM)[34,68] using robust maximum likelihood estimation will be conducted as the main analysis to examine the effects of the intervention programme on the promotion of physical activity among white-collar employees (Figure 2). In this study, we will determine three-levels of information: repeated measures for employees at level 1, physical activity within employees at level 2, and workplace environment within worksites at level 3. However, because estimation for the total amount of physical activity at baseline and changes of physical activity can be accounted for in latent variables in LGM, the number of hierarchical levels will be one less than the number of hierarchical levels in other multi-level modelling approach[68]. We will investigate the significance of the coefficient from a dummy variable for the intervention (control = 0, intervention = 1) compared to the linear slope of physical activity as the effect of the intervention programme. We will reference some model fit indices, such as chi square ($\chi 2$), comparative fit index (CFI), Tucker-Levis index (TLI), and root mean square error of approximation (RMSEA). We will consider that the model demonstrates good fit if CFI and TLI exceed 0.95 and RMSEA is less than 0.06[69]. Intention to treat (ITT) analysis using full information maximum likelihood (FIML) estimation will be conducted, including all employees who complete the baseline survey. When results of LGM are misspecification or improper solutions, we will consider conducting three-level mixed model analysis using the restricted maximum likelihood

estimation (REML). Mplus version 7.4[70] for LGM and the PASW statistics version 18 (IBM SPSS software) for mixed model analysis will be used. Analyses for secondary outcomes (self-regulation for physical activity, psychological distress, and subjective health) will also be conducted using the same methods.

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Potential subgroup analyses will be conducted, stratified by worksite size, age, gender, job categories (e.g., manufacture, services, construction, transportation), and initial levels of physical activity or self-regulation for physical activity.

Some mediation analyses will also be conducted using multi-level structural equation modelling. We will model (1) the intervention dummy variable for physical activity, mediated by self-regulation for physical activity and (2) the intervention dummy variable for psychological distress and subjective health, mediated by physical activity.

Data monitoring

A Data Monitoring Committee (DMC) will be set up, consisting of the corresponding author (KW) and the coordinator in each worksite because human resources are limited. The DMC will be held every 3-months following the randomization in each worksite. The purpose of the meetings will be to review the participation rates and reasons for study dropout. The DMC will be independent from any sponsor and competing interest.

Ethics and dissemination

Ethical considerations

This study protocol was ethically approved by the research ethics committee of the Graduate School of Medicine and Faculty of Medicine at The University of Tokyo, Japan (No. 11230). We will obtain informed consent from all representatives of the worksites and all employees (Appendix 1, 2). The consent form will inform the worksites and employees that we guarantee protection of personal information, and that the data will be anonymous and only used for academic purposes. The surveyed data will be saved on a password-protected digital device (USB memory stick). The device will be stored in a research room at the Department of Mental Health in the Graduate School of Medicine at The University of Tokyo. The data will be stored as anonymous. Only the authors will have access to the final dataset. There is no competing interest. This work is supported by the Grant-in-Aid for the Japan Society for the Promotion of Science Fellows (15J04085).

Dissemination of research findings

Results and findings will be submitted and published in a scientific peer-reviewed journal according to the guidelines in the Consolidated Standards of Reporting Trials (CONSORT) for cluster RCTs[62]. Participants will be informed of conference presentations and publications.

Strengths and limitations

To the best of our knowledge, this study will be the first cRCT of a multi-component workplace intervention programme with environmental changes among Japanese white-collar employees. The study will include the majority of the worksites in Japan, including small-sized worksites. In addition, operational definitions and components of the intervention programme are developed based on a validated

scale. The findings will be generalisable because future intervention programmes will be developed according to the same scale. The study will also be the first to investigate the effects of a multi-component workplace intervention both on physical activity and psychological distress.

This study is subject to several limitations. All measurements are self-reported; therefore, there will likely be measurement errors and information bias. Especially, the assessment of the amount of physical activity can be over-estimated. This bias can also be applicable for conducting the specific element among the intervention programme (No. 6, individual competition). Additionally, since there is a shortage in our human and monetary resources we will not be able to recruit worksites from large areas within Japan. Sampling method will not be at random for both the worksite- and the employee-level, possibly causing a selection bias. Furthermore, we will not be able to offer all of our interventions for free, potentially limiting the impact of our proposed interventions. Other possible limitations will be small sample sizes and high attrition rates.

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Author's contributions

Kazuhiro Watanabe and Norito Kawakami have made substantial contributions to the conception and design, writing of and revision of the protocol for important intellectual content, and approving the final version of the protocol to be published. All authors will be involved in all of the study process (i.e., recruitment, assessment, intervention, and analysis).

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Competing interests

The authors have no conflicts of interest to declare.

Article summary

Strengths and limitations of this study

－This study will be the first cluster RCT of the multi-component workplace intervention programme with environmental changes among white-collar employees, including the majority of the worksites in Japan, which are small-sized worksites.

－The findings will be generalisable because of the validated scale used for the standard operational definitions.

－The study will also be the first to investigate the effects of a multi-component workplace intervention both on physical activity and psychological distress.

－The shortage of our human and monetary resources could be a limitation causing selection bias, and impacting small sample size and high attrition rates.

－Another limitation is that all measurements (e.g., physical activity, psychological distress) are self-reported, causing potential measurement errors and informational bias.

Figure Legend

Figure 1. Participant flow chat

Figure 2. Latent growth modelling (LGM) for the study

Table 1. Elements of the intervention programme with environmental changes

No	Elements	Japanese EAT variables[38]	Operational definitions	Functions
1	Policy making and declaration	Written policies	Whether the worksite has a written policy statement supporting employee physical fitness and the policy is posted or otherwise communicated to employees	Employer policy support Building awareness and social norms
2	Posters detailing the programme contents and recommendations for physical activity	Signs/Bulletin boards/Advertisements	How many posters are displayed at the worksite	Informational messages Building awareness and social norms
3	Notifications provided on intra-website/electronic bulletin board systems	Signs/Bulletin boards/Advertisements	Whether the worksite inform the programme contents via an intra-website and/or an electronic bulletin board system	Informational messages Building awareness and social norms
4	Prompts for stair-use at stairs and elevators	Stairs/Elevator	Whether any prompt for stair-use is displayed at stairs or elevators	Informational messages Building awareness and social norms
5	Exercise	Health promotion programmes: physical activity	Whether any exercise programme is provided before office hours, at lunch time, or after office hours	Enhancing accessibility for physical activity
6	Individual competition of physical activity within the worksite	Health promotion programmes: physical activity	Whether any competition programme is provided by employers	Employer incentives Support for self-regulation Enhancing accessibility for physical activity
7	Psychological education to increase self-regulation for physical activity	Health promotion programmes: physical activity	Whether any education programme is provided that help employees enhance self-regulative strategies for physical activity	Behavioural-cognitive approach Increasing self-regulation for physical activity
8	Subsidization of a membership to offsite exercise facilities	Physical activity/Fitness facilities	Whether membership at offsite exercise facilities is subsidized by employers	Enhancing accessibility for physical activity

9	Providing onsite fitness facilities	Physical activity/Fitness facilities	Whether any aerobic and strength equipment are provided at the workplace, and whether four stations per 500 employees are provided at the worksite	Enhancing accessibility for physical activity
10	Providing bike rack spaces	Parking/Bike	Whether any bike rack space is provided at the worksite	Enhancing accessibility for physical activity
11	Providing changing facilities	Shower/Changing facilities	Whether any changing facility is provided at the worksite	Enhancing accessibility for physical activity
12	Providing shower facilities	Shower/Changing facilities	Whether any shower facility is provided at the worksite	Enhancing accessibility for physical activity
13	Contract for sponsorship with sports teams	Physical activity/Fitness facilities	Whether employers contract any sponsorship with any sports team	Employer support Building awareness and social norms

Abbreviations: EAT, Environmental Assessment Tool.

Table 2. Outcome measures

Measurement	Aim	Baseline	3-month follow-up	6-month follow-up
Primary outcome				
GPAQ v2	The amount of physical activity	×	×	×
Secondary outcomes				
PASR-12	Self-regulative strategies for physical activity	×	×	×
BJSQ	Severity of psychological distress	×	×	×
Subjective health	Overall subjective health status	×	×	×

Abbreviations: GPAQ, Global Physical Activity Questionnaire; BJSQ, Brief Job Stress Questionnaire; PASR, Physical Activity Self-Regulation.

Table 3. Sample size calculation for the cluster randomized controlled trial

Article	Mean change between groups	SD	Effect size (*d*)	Required sample size (each arm)[a]	Design effect	Required sample size for cluster RCT (each arm)	Required number of Worksites (each arm)
Conn *et al*. (2009)[17]	-	-	0.21	478	1.19	568.82	28.4
Dishman *et al.* (2010)[34]							
Vigorous physical activity	6.0	25.0	0.24	366	1.19	435.54	21.8
Moderate physical activity	3.3	13.9	0.24	366	1.19	435.54	21.8

a: $\alpha = 0.05$, $(1-\beta) = 0.90$, allocation ratio = 1:1.
Abbreviations: SD, standard deviation; RCT, randomized controlled trial.

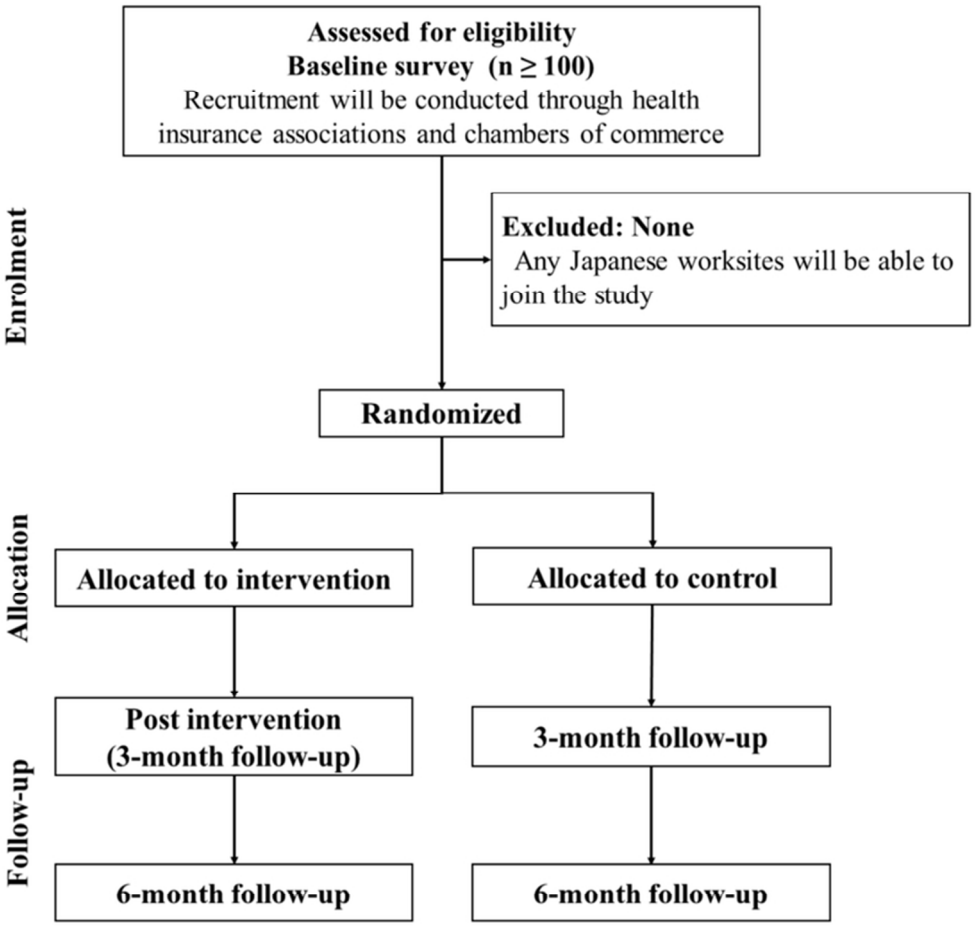

Figure 1. Participant flow chat

69x69mm (300 x 300 DPI)

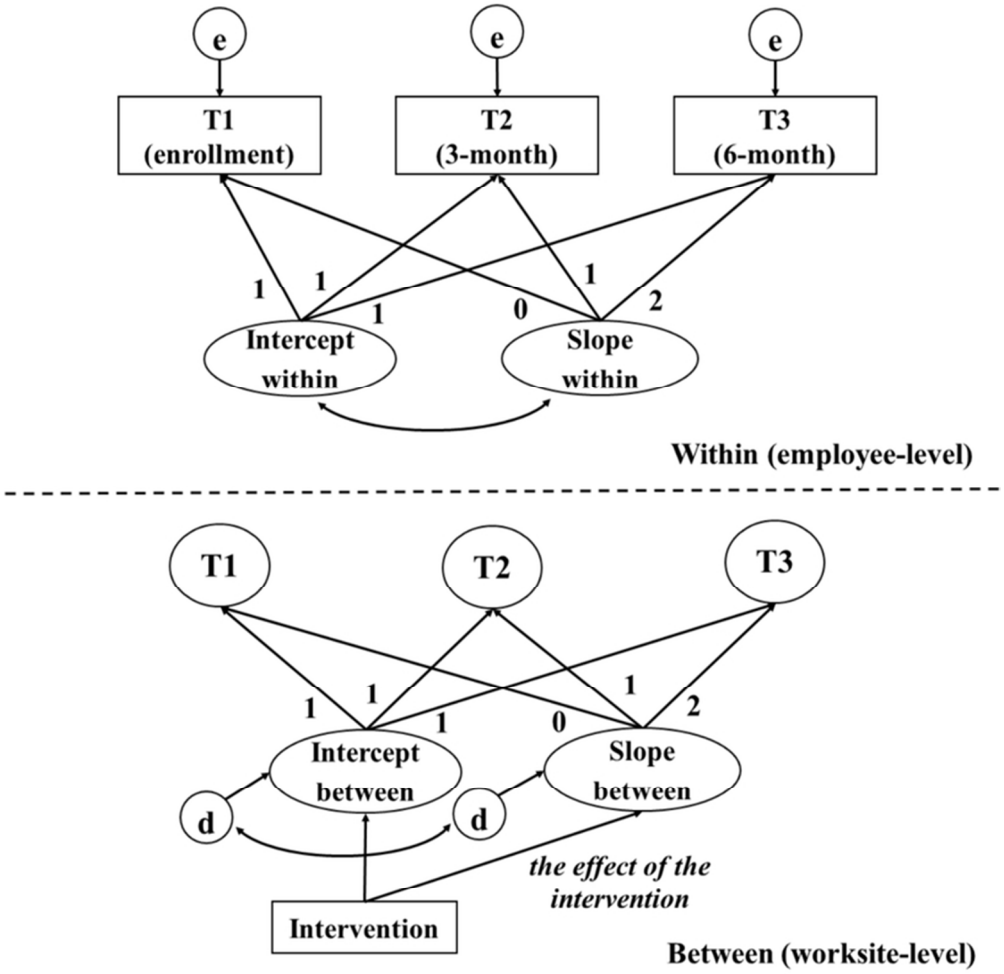

Figure 2. Latent growth modelling (LGM) for the study

69x69mm (300 x 300 DPI)

承　諾　書

東京大学医学系研究科長・医学部長　殿

研究課題「ホワイトカラー労働者の身体活動促進のための職場介入研究」

私は、上記研究への参加にあたり、説明文書の記載事項について、
連絡担当者　渡辺和広から説明を受け、これを十分理解しましたので、
事業所として上記研究に協力することを承諾いたします。

以下の項目について、説明を受け理解しました。

- □　この研究の概要について
- □　研究協力の任意性と撤回の自由について
- □　個人情報の保護について
- □　研究結果の公表について
- □　研究参加者にもたらされる利益及び不利益について
- □　研究終了後の資料（試料）等の取扱方針について
- □　事業所側の費用負担について
- □　その他について

平成　　年　　月　　日

事業所名 _____

代表者氏名（自署）_____

承　諾　撤　回　書

東京大学医学系研究科長・医学部長　殿

研究課題「ホワイトカラー労働者の身体活動促進のための職場介入研究」

私は、上記研究への事業所としての参加にあたり、説明文書の記載事項について説明を受け承諾しましたが、承諾の是非について再度検討した結果、承諾を撤回いたします。

平成　　年　　月　　日

事業所名 _____

代表者氏名（自署）_____

同　意　書

東京大学医学系研究科長・医学部長　殿

研究課題「ホワイトカラー労働者の身体活動促進のための職場介入研究」

私は、上記研究への参加にあたり、説明文書の記載事項について、連絡担当者　渡辺和広から説明を受け、これを十分理解しましたので本研究の研究参加者となることに同意いたします。

以下の項目について、説明を受け理解しました。

- □　この研究の概要について
- □　研究協力の任意性と撤回の自由について
- □　個人情報の保護について
- □　研究結果の公表について
- □　研究参加者にもたらされる利益及び不利益について
- □　研究終了後の資料（試料）等の取扱方針について
- □　あなたの費用負担について
- □　その他について

平成　　年　　月　　日

氏名（自署）＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

同　意　撤　回　書

東京大学医学系研究科長・医学部長　殿

研究課題「ホワイトカラー労働者の身体活動促進のための職場介入研究」

私は、上記研究への参加にあたり、説明文書の記載事項について説明を受け同意しましたが、同意の是非について再度検討した結果、同意を撤回いたします。

平成　　年　　月　　日

氏名（自署）＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Reported on page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p.3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	p.3
Funding	4	Sources and types of financial, material, and other support	p.20, 30
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p.1, 30
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	pp.4-6
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	pp.6-7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	p.7
Methods: Participants, interventions, and outcomes			

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	pp.7-9
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	p.7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	pp.9-14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p.19
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	pp.14-16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	pp.8-9, Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	p.16-17
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	pp.7-9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	pp.17

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	pp.17
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	pp.17
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	pp.17
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	pp.7-9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	pp.18-19
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	pp.18-19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	pp.17-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	pp.19
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	pp.17-19
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	pp.19

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p.19-20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p.19-20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	p.19-20
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	pp.20, 30
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	p.19-20
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	p.19-20
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A

Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.