論文の内容の要旨

論文題目　Effects of a multi-component workplace intervention program with environmental changes on physical activity among Japanese white-collar employees: a cluster randomized controlled trial

（複数の要因からなる環境調整を伴う職場介入プログラムが日本人ホワイトカラー労働者の身体活動に及ぼす影響：クラスター無作為化比較試験）

氏名　渡　辺　和　広

Background

Promoting workers' physical activity is indispensable for occupational health promotion and for a sustainable workforce. Regular engagement in this behavior is effective for reducing risks of all-cause mortality and for improving mental health. In addition, it has repeatedly been suggested that physical activity improves work-related outcomes such as absenteeism, job stress, employee turnover, and work ability. However, levels of physical activity in the population are usually low. Therefore, a need for intervention strategies to promote physical activity among workers has been widely recognized.

To address this research question, many studies have already been conducted on workplace intervention strategies to promote physical activity and have been summarized in systematic reviews. These previous reviews concluded that multi-component interventions, including both an individual-level approach and environmental modifications at the workplace, more effectively increased physical activity among employees than single-component interventions. However, the quality of evidence regarding the effectiveness of these interventions is still not very high with only a few randomized controlled trials (RCTs) on this issue. In addition, since environmental modifications are conducted at the worksite or company level, cluster-level randomization is needed to accurately detect the effects, but there have been even fewer cluster RCTs (cRCTs) investigating the effectiveness of workplace interventions and no study has been conducted in Japan. Moreover, these cRCTs targeted predominantly large companies or organizations that had many resources to support employees' healthy behaviors. Conducting the same intervention program with the same components is not realistic for all worksites, especially small and medium-sized enterprises (SMEs, with fewer than 50 and 50-299 employees). The SMEs may suffer from

low monetary and human resources for implementing environmental changes. A more feasible and more flexible program incorporating environmental changes is needed.

In this study, I aimed to develop a new 3-month multicomponent workplace intervention program including environmental changes and investigated its effects among Japanese white-collar employees, using a cRCT design. The primary outcome was the level of moderate to vigorous physical activity. The secondary outcomes were self-regulation for physical activity, psychological distress, and subjective health status. I hypothesized that the level of physical activity, self-regulation for physical activity, psychological distress, and subjective health among employees would be significantly improved at intervention worksites compared with the control worksites.

Methods

An original intervention program was developed consisting of 13 elements including environmental changes. The program was developed based on 1) a literature review, 2) a validated scale, and 3) good practices to promote physical activity at Japanese worksites while also considering its feasibility and applicability for SMEs. The intervention study was a two-arm, parallel-group cRCT. The protocol of the intervention was registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR, ID=UMIN000024069) and 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).

Of 208 worksites approached in the Kanto area through some of the health insurance associations and chambers of commerce, eight Japanese worksites (190 employees) agreed to participate and were randomly assigned to an intervention or a control group. There were no eligibility criteria for worksites; eligible employees were white-collar workers (managerial, professional, technical, clerical, and other job types which require desk work or sitting work) employed by participating worksites and aged 18 years or older. There were no exclusion criteria for participants enrolled in this study. An average sampling cluster size was set at 20 employees.

The worksites were randomly assigned to an intervention or a control group after completion of a baseline survey. The randomization was conducted stratified by worksite size (≤49, 50-299, and ≥300 employees), permuted blocked (blocked size = 2), and non-blinded. The intervention group worksites (n = 3) were offered the intervention program for 3 months and the control group worksites (n = 5) were offered

the same feedback three times provided to the intervention group worksites and basic occupational health services as the usual treatment. Depending on the resources and situations of the intervention worksites, the program provided an opportunity for choosing the most relevant elements from the 13 elements offered.

The post surveys were conducted immediately after the completion of the intervention (3-month follow-up) and at a 6-month follow-up in both the intervention and control groups. The level of physical activity was measured using a self-reported questionnaire (Global Physical Activity Questionnaire, GPAQ). Self-regulation for physical activity, psychological distress, and subjective health status were also measured using a self-reported questionnaire. Multi-level latent growth modeling (LGM) for categorical outcomes was conducted as the main analysis to examine the effects of the intervention program on physical activity levels. Intention-to-treat (ITT) analysis using full information maximum likelihood estimation was conducted, including all employees who completed the baseline survey.

Results

All three worksites in the intervention group from small, medium, and large worksites implemented the same number (six) of the 13 elements of the program. An increase in the proportion of employees with a high physical activity level was observed at the intervention worksites (from 13.0% at baseline to 20.7% at the 3-month follow-up), while the proportion less increased at the control worksites (8.2% at baseline and 10.6% at the 3-month follow-up). In addition, the proportion of those with a high physical activity level increased even after the 6-month follow-up (21.5%) at the intervention worksites. LGM for the primary outcomes yielded a coefficient that was positive and significant for the intervention dummy variable with respect to the linear slope of the level of overall physical activity (γ=0.45 [SE=0.19], p=0.018). The estimated proportional odds ratio for the levels of physical activity at 6 months (Exp [γ*2]) was 2.47 (95% CI, 1.17-5.22). Coefficients for levels of domain-specific activities (occupational, transport-related, and leisure-time physical activity) were not significant.

For the secondary outcomes, the effect of the intervention program on subjective health status was positive but insignificant (γ=0.07 [SE=0.10], p=0.485, Cohen's *d*=0.11 [95% CI, -0.18 to 0.39]). Coefficients for the total score of self-regulation (γ=0.81 [SE=0.62], p=0.194, Cohen's *d*=0.18 [95% CI, -0.11 to 0.46]) and the total score of psychological distress (γ=-0.22 [SE=0.57], p=0.698, Cohen's *d*=-0.05 [95% CI, -0.33 to 0.24]) were also not significant. For subgroup analyses, the intervention effect on the level of overall physical activity was significant among medium and large worksites but not among small

worksites (γ=0.35 [SE=0.44], p=0.424). Psychological distress was significantly improved among the intervention worksites in suburban and local areas (γ=-3.61 [SE=1.21], p=0.004) but not in urban areas.

Conclusion

In conclusion, this is the first study to indicate the significant and positive effects of multi-component workplace intervention with environmental changes on the level of physical activity including small and medium-sized worksites in Japan. The newly developed program is unique because it was developed with a comprehensive set of elements to promote physical activity in the workplace based on a literature review. In addition, because the program was feasible and flexible, it should be easy to implement at worksites even if they do not have enough resources. Because most worksites in Japan are SMEs, these findings might be useful for this population. However, the intervention effect was smaller and non-significant for small-sized worksites. These workplaces might receive less benefit from the intervention program. Additional elements and/or new technologies such as mobile applications and Internet of Things might be needed to make the program more effective at small-sized worksites. Worksite location may also be an important modifying factor with respect to workplace interventions. The differences by worksite location might be attributed to differences in the domains of increased physical activities; for example, transport-related activities might be more likely to increase at worksites in urban areas, whereas leisure-time activities might be more likely to increase at worksites in suburban/local areas. The differences in domain-specific physical activities resulting from the intervention program could be related to improving health-related outcomes; leisure-time physical activity may be more favorable than other activities for improving mental health. Since it is not clear that the newly developed intervention program was effective for improving the secondary outcomes, further studies are needed to clarify the differences among activities in specific domains with respect to mental health. This study had several limitations: the small sample size and self-reported measurement for physical activity. Since the quality of this study was not very high due to the limitations, further studies are needed.