

## 論文内容の要旨

論文題目

Development and evaluation of a computer-based stress management program for workers:  
A cluster randomized controlled trial

和訳

労働者を対象としたコンピュータによるストレスマネジメントプログラムの作成および評価：  
クラスター無作為化比較試験

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### Introduction

Stress at work has been increasingly recognized as a major risk factor for chronic disease, injury, and poor quality of life among employees in a contemporary society. In Japan, 58% of workers feel high anxiety and stress at work. A “lack of experts” is among the most prevalent reasons for not delivering mental health services at the workplace, followed by “occupational staff doesn’t know how to address mental health services”. Given the lack of experts, it is important to find channels other than occupational mental health experts to provide employees with training to manage job stress and improve mental health. Computer-based self-help programs may be an effective and inexpensive alternative to traditional face-to-face SMT programs. The purpose of this study was to develop a computer-based stress management training (SMT) program and evaluate its effectiveness on employees’ coping style, psychological well-being (i.e., psychological distress, work engagement, job satisfaction, and work performance), social support and knowledge about stress management.

### Methods

#### *Participants*

This study was conducted between May and December in 2009 as a mental health promotion program in a manufacturing company. Twelve work units from the research and development divisions and support staff (N = 266) were invited to participate in the study. All participants were full-time employees. Participants were informed about the program by an informational poster as well as by their supervisor during meetings. Participants were randomly assigned by work unit to either an immediate access (intervention group) or a 20-weeks delayed access (wait-list control group) group to a computer-based SMT program. No inclusion or exclusion criteria were adopted because the intervention was planned for all employees in the research and development divisions, with the exception of 1 employee who worked as the coordinator between the company and the author of this study, and 1 other who moved to another workplace prior to the baseline survey.

## *Design*

The study was a cluster randomized controlled trial. In May 2009, a baseline survey (T0) was conducted, and then participants were randomly assigned to a computer-based intervention group (8 work units, n = 142) or to a wait-list control group (4 work units, n = 121) by work unit. Additionally, participants were required to answer online questionnaires at 9 weeks (T1) and 19 weeks (T2) after the baseline survey. The intervention group started the 7-week program immediately after the baseline survey, while the wait-list control group started after the T2 follow-up survey.

## *Intervention program*

The computer-based SMT program is self-paced and consists of the following 3 parts: (a) behavior, (b) communication, and (c) cognition. Additionally, each part is divided into 2 topics based on cognitive behavioral skills: (a) problem-solving and time management skills for the behavioral section, (b) assertion and delegation skills for the communication section, and (c) cognitive restructuring and causal attribution skills for the cognitive section. The process and results of training were stored in their private web page. The SMT program was developed through an university/industry collaboration.

One of the office staff served as the coordinator between the participants and author. Participants in both groups were given individual IDs and passwords before starting the program. Participants underwent the program during their working hours. To increase participants' motivation and decrease dropout rates, 3 types of e-mail were sent as reminders or prompts: an "encouragement mail" to those who had not finished all 6 topics, a "congratulations mail" to those who finished all topics for the first time, and an "application enhancement mail" to those who finished all topics and were ready for skill application.

## *Measurements*

All data were measured by self-report questionnaires and all measurements were conducted on the web. Questionnaires, as well as the learning program, were only accessible with an ID and password.

**Knowledge about stress management:** Knowledge about how to cope with stress was assessed using 6 questions on the following topics: 1) problem-solving skills, 2) time management skills, 3) assertion skills, 4) delegation skills, 5) cognitive restructuring skills, and 6) causal attribution skills. Respondents were asked to choose the most suitable option among 4 presented.

**Coping style:** Coping style was assessed using the corresponding subscale of the Brief Scales for Coping Profile (BSCP). The BSCP consists of 6 subscales (i.e., active solution, seeking help for solution, changing mood, emotional expression involving others, avoidance and suppression, and changing point of view). The current study used an "active solution" scale for problem-solving, and a "seeking help for solution" scale for seeking social support.

**Psychological well-being:** Psychological distress was assessed using the Brief Job Stress Questionnaire (BJSQ) regarding irritability-anger, fatigue, anxiety, depression, and lack of vigor. Work performance was assessed using the World Health Organization (WHO) Health and Work Performance Questionnaire (HPQ). Respondents were asked to rate their overall work performance during the past 4 weeks. Job satisfaction was assessed using a single item of the BJSQ; that is, to which extent the participant was satisfied with his/her job. Work engagement was assessed using the short form of the Japanese version of the Utrecht Work Engagement Scale (UWES-J) regarding employee's attitude towards one's work (i.e. vigor, dedication, and absorption).

**Social support:** Supervisor support and coworker support were assessed using the BJSQ.

**Covariates:** Quantitative demand was assessed using the BJSQ.

**Demographic data:** Sex, age, and job position were also collected in the questionnaire.

### *Randomization*

Randomization was performed with a table of random numbers. At first, work units were numbered and blinded a coordinator, and then random assignment was conducted by the author.

### *Sample size calculation*

The statistical power analysis was conducted using the G\*Power 3 program. We assumed an intraclass correlation of  $\rho = 0.2$ , 15 patients for each unit. To prove an intervention effect with an effect size of Cohen's  $d = 0.4$  and with an error probability  $\alpha = 0.05$  and 80% power,  $n = 128$  people in each study arm were required for analysis.

### *Statistical analyses*

Baseline characteristics of the intervention and wait-list control groups were compared and tested with *t*-tests for continuous data and with chi-square tests for ordinal or categorical data. To assess the interventional effects on primary and secondary outcomes, the group  $\times$  time interaction was tested using mixed-model analyses of variance for repeated measures with the restricted maximum likelihood (REML) estimation method. We included time and group as fixed effects and subject nested within unit as random effects. Quantitative demand was adjusted in the model. When the group  $\times$  time interaction was interpreted as significant, time main effect was computed for each group, and then paired *t*-tests for T0 to T1 and T0 to T2 were computed to test for simple main effects. We conducted additional two analyses. First, we assessed intervention effects excluding the "dashed study group" members, which included participants (a) who had not finished all 6 topics, (b) who had finished the program in 1 day, or (c) who had joined the program 2 days before the study deadline. Second, we conducted a sub-group analysis according to the level of psychological distress at T0; participants were dichotomized using the median score to examine whether psychological distress moderated the intervention effect.

### *Ethics*

The study procedures were approved by the Research Ethics Review Board of the University of Tokyo, Graduate School of Medicine (ID = 2196-(1)).

## **Results**

### *Participants flow*

A total of 266 participants were invited to the study and 263 participants were qualified for inclusion in the analysis. At T0, 142 employees from the intervention group and 121 employees from the wait-list control group completed the questionnaire (response rates, 99.3% and 100%, respectively). Following the intervention period, 9 weeks after T0, 135 employees from the intervention group and 119 employees from the wait-list control group filled out the post-test questionnaire at T1 (response rates, 95.1% and 98.3%, respectively). At T2, another 10 weeks later, 131 employees from the intervention group and 117 employees from the wait-list control group filled out the follow-up questionnaire (response rates, 92.3% and 96.7%, respectively). Of the 142 employees in the intervention group, 127 participants (89%) completed all 6 topics, and 16 employees (11%) could not finish it. Regarding to the order of topics that participant learned, 113 (80%) participants in the intervention group learned problem solving skills first.

### *Baseline characteristics*

The mean age for the intervention group was 39.7 (10.4) years (range 24–62); 95.1% were male and 26.1% were managerial. On the other hand, the mean age for the wait-list control group was 38.0 (10.7) years (range 21–62); 90.1% were male and 19.8% were managerial. There were no significant differences in demographic characteristics between the intervention and wait-list control groups. Although the intervention group had significantly higher scores on work engagement than the wait-list control group,

no significant differences were found between the groups in any of the other outcome variables.

#### *Dropout analysis*

The non-completers, who answered the T0 questionnaire but (1) did not complete all the topics and (2) did not answer the T1 and/or T2 questionnaires, had significantly higher scores of psychological distress and lower scores of seeking social support and changing a point of view than non-completers.

#### *Effects of intervention*

At T1, significant favorable effects were observed on coping style (problem-solving and seeking social support) and psychological well-being (work performance and job satisfaction). At T2, the positive effects on coping style (problem-solving and seeking social support) and psychological well-being (job satisfaction) were maintained. Furthermore, significant favorable effects were observed on knowledge about stress management. However, no favorable effects were found on psychological distress and work engagement at T1 and T2.

#### *Effects of intervention*

In whole data analysis, we detected no group  $\times$  time interaction in primary and secondary outcomes except for “knowledge about stress management.” However, when selecting participants who used more than 3 days to complete the program, group  $\times$  time interaction was observed on “problem solving,” “avoidance and suppression,” and “knowledge about stress management.” Furthermore, in additional analysis among those with initially low psychological distress, group  $\times$  time interaction was observed on “knowledge about stress management.” In contrast, among those with initially high psychological distress, group  $\times$  time interaction was observed on “seeking social support”. However, we detected no group  $\times$  time interaction on any of the other variables.

### **Discussion**

The purpose of this study was to develop a computer-based SMT program and evaluate its effectiveness on employees’ psychological well-being (i.e., psychological distress, work engagement, job satisfaction, and work performance). In this study, we used a cluster randomization design by work unit. One advantage of this design is the prevention of information leaks about the program contents. If individual allocation had been used for this study, participants in the control group might have been affected by interactions with their colleagues in the intervention group. Furthermore, this computer-based SMT program addressed a wider variety of topics on stress management skills in contrast to previous interventions, which have typically focused on a single topic. It was also expected that interventions would be more effective if participants could choose topics according to their needs and interests. Additionally, the program includes a function to facilitate the participants’ interaction with the program, whereby participants can make notes on their own personal webpage. The element of interactivity helps participants engage in applying the learned skills in their real life and accelerate skill acquisition.

Contrary to our expectations, we found a favorable effect only on “knowledge about stress management” at T1 but no favorable effects on any other primary and secondary outcomes at T1 and T2. In our study, 40% of participants (i.e., dashed study group) finished the program in 1 or 2 days, and almost all of them accessed the program 2 days before the deadline for the first time. This suggests that they did not have enough time to apply the learned knowledge and skills into everyday life. Previous research reported that more frequent use of stress-reduction skills was significantly correlated with greater improvement in stress indices. Hence, more time would have been needed for them to show the improvement of outcomes variables. This explanation can be justified by the fact that we found favorable effects not only on knowledge but also on coping skills (i.e., problem solving, and seeking social support)

at T1 and T2 when excluding data from dashed study group in the analyses. More frequent use of problem solving and seeking support skills in their everyday life may have led to the improvement of the scores.

Although stressed employees had the tendency to drop out throughout the trial, they could improve their seeking support skills once they completed the whole program. Our completers with high psychological distress likely had higher needs to improve seeking support skills, which maintained their learning motivation for a longer time.

Despite the methodological rigor of the present study, there are 7 limitations that should be addressed for future research on this topic. The first limitation is the nature of the participants. All participants were employees working in a manufacturing company consisting mainly of men. Therefore, this population is not necessarily representative of the general working population. The second limitation is that a mostly-female population tested the program in the pilot trial. Therefore, the program contents may mainly reflect women's view, which may have resulted in the participants' motivation and intervention effects. The third limitation is that our computer-based SMT program consisted of 6 topics, but we did not examine the order effect. Future study is needed to clarify the effective order of program learning. The fourth limitation is that although the completion rate was high, the learning period was relatively short, suggesting low fidelity of our participants. Hence, it seems important to improve fidelity in future studies. The fifth limitation is that the study relied on self-reported information. Self-reported data could increase the problem of common method variance. Objective indicators on physical health and work performance should also be considered. The sixth limitation is that we could not assess education level. Although we could not access the personnel information, our participants seemed comparatively highly educated because they engaged in the development of new machinery that required higher knowledge. The advanced education level may have promoted the efficacy of intervention. The seventh limitation is that we could not find any specific indications of how long it took for the intervention effect to appear or disappear, further studies are needed.

To conclude, this study found that our newly developed computer-based SMT program contributed to the improvement of participants' coping style and knowledge about stress management if participants had enough time (at least 3 days) to complete all sessions.