

論文の内容の要旨

論文題目: Effects of an internet-based cognitive behavioral therapy (iCBT) intervention for improving depression among workers: A randomized controlled trial

(労働者に対するインターネット認知行動療法 (iCBT) による抑うつ症状改善効果: 無作為化比較試験)

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Aims

The purpose of this study was to develop a new six-week internet-based cognitive behavioral therapy (iCBT) program for workers and to examine the effects of the iCBT program for improving symptoms of depressive symptoms at three- and six-month follow-ups using a randomized controlled trial (RCT) design among workers employed in private information technology (IT) companies in Japan.

Methods

Trial design: The study was a RCT. Allocation ratio was 1:1 on intervention group and control group, which was registered at the UMIN Clinical Trials Registry (ID = UMIN000006210).

Participants: All workers in an IT company A (N=290) and all workers who belonged to three selected departments (N=about 1,500) of the head quarter of an IT company B (the total employee size, c.a. 11,000) were recruited by an invitation e-mail. The inclusion criteria were below; 1) not diagnosed as major depressive disorder in the past month (using the web-version of the WHO-Composite International Diagnostic Interview version 3.0 (WHO-CIDI 3.0); 2) not diagnosed as lifetime bipolar disorder (WHO-CIDI 3.0); 3) not having sick leave days of 15 days or more in total due to own health problems during the past three month. 4) not going to a medical treatment for mental health problems during the past month.

Intervention: A six-week six-lesson iCBT program was newly developed, with using a comic story of a psychologist and a client worker to facilitate the understanding of the participants. The program included several CBT skills: self-monitoring, cognitive restructuring, assertiveness, problem-solving, and relaxation. About 30 minutes are needed to learn one lesson including homework. Participants submitted their homework received a feedback from trainer staff (clinical psychologists). For the intervention group, participants studied six weekly lessons with homework of the iCBT program. They were allowed to complete the six lessons during 10 weeks after the baseline survey. Participants were reminded by e-mail to complete a lesson and/or to submit a homework if they did not. For the control group, participants in the control group received an e-mail message. Each e-mail message was consisted about 500 words in Japanese including stress management tips once a month.

Outcome measures: Depressive symptoms (BDI-II) were assessed as primary outcome. Psychological distress (K6), Dysfunctional attitude (DAS), work engagement (UWES), work performance (HPQ), Sick leave days during past 3 month, knowledge and self-efficacy were assessed as secondary outcomes. Demographic data such as age, gender, marital status, occupation, education, chronic disease and

overtime hours during past a month were also collected.

Randomization: Participants who fulfilled the inclusion criteria were randomly allocated to an intervention or control groups (N=381 for each group). Stratified permuted-block randomization was conducted. Participants were stratified four stratum by two factors as K6 score (5 or greater or less than 5) at baseline survey and company (A or B) to which they belong.

Statistical analyses: Mixed-model for repeated measures conditional growth model analyses were conducted using a group (intervention and control) * time (baseline, 3 month, and 6 month follow-up) interaction as an indicator of intervention effect. Intention-to-treat analysis (ITT) was conducted. Effect sizes were calculated using Cohen's d among those who completed the questionnaire at baseline and at a follow-up. Subgroup analyses were conducted separately among respondents who had high (5 or higher score of K6) and low (4 or less score) at baseline.

Results

Participant flow: Participants were recruited from 2 companies (N=1790) and 850 (47.5%) participated in a baseline survey and 762 participants were randomly allocated to an intervention or control group (N=381 for each). At 3 month follow-up, 270 (70.9%) completed follow-up survey in the intervention group and 336 (88.2%) in the control group. At 6 month follow-up, 272 (71.4%) completed follow-up survey in intervention group and 320 (84.0%) in the control group.

Recruitment: Recruitment and the baseline survey were conducted during the period from September to October in 2011. The intervention group and control group were surveyed at approximately 3 month later (from December 2011 to January 2012) and approximately 6 month later (from March to April in 2012) from baseline survey.

Baseline characteristics: There were no significant differences in demographic characteristics between the intervention and control groups. In both groups, most of participants were males, professionals, university graduates, and had no chronic disease.

Effects of the iCBT program on outcome variables: On the primary outcome, the iCBT program showed a significant effect on BDI-II ($t = -1.99, p < 0.05$). The effect sizes were small. For BDI-II, the effect size was -0.14 at 3-month follow-up and -0.15 at 6-month follow-up. On the secondary outcomes, the iCBT program showed a significant effect on DAS ($t = -2.43, p = 0.02$), UWES ($t = 2.03, p = 0.04$), and all variables on knowledge and efficacy ($p < 0.05$) except for efficacy of problem-solving. Effect sizes for DAS, UWES, and improvement of self-efficacy were small, while effect sizes for variables on knowledge were medium.

Subgroup analyses: For the intervention group who scored 5 or more on K6 at baseline, the iCBT program showed a significant effect on BDI-II ($t = -2.12, p = 0.04$). The effect size for BDI-II was small: -0.16 at 3-month follow-up and -0.21 at 6-month follow-up. The iCBT program showed a significant effect on DAS ($t = -2.36, p = 0.02$), all variables on knowledge, efficacy of stress management, assertive communication and relaxation training ($p < 0.05$). While the effect sizes of DAS and self-efficacy were small, those for variables on knowledge were medium. For participants who scored less than 5 on K6 at baseline, the iCBT program showed no significant effects on any of the primary outcomes. The iCBT

program showed a significant effect on all variables on knowledge and efficacy of cognitive restructuring ($p < 0.05$). Most (89%) of the intervention group completed the lesson 1 and 65% submitted their homework after the lesson 1. About two third of the intervention group completed all six lessons, while only a quarter of them submitted all six homework. Average number of lessons which a respondent learned was 4.5. Average number of homework submitted by a respondent was 2.7.

Discussion

To our knowledge, the present study first demonstrated that an internet-based computerized CBT was effective in improving depressive symptoms in a non-clinical working population. About the factor related in increasing the BDI-II and K6 scores in the control group compared with intervention group, after the baseline survey, one of the two companies under study merged with another company. The observed increase in psychological distress and depressive symptoms in the control group was partly attributable to increased workload associated with the organizational change. The current iCBT program seems to improve depressive symptoms or at least to prevent depression to some extent under severe working conditions. The intervention effect was more prominent for BDI-II than for K6. The current iCBT program mainly consisted of the cognitive restructuring technique, which is supposed to be more effective in improving depressive symptoms than anxiety. The effect size of the current iCBT program was small to moderate in its effect size. However, in comparison to the effect of previous study at 3 month after the intervention, the current iCBT program showed a greater effect size for improving depressive symptoms than the popular CCBT program. The current iCBT program might be effective in improving depressive symptoms among workers to a similar or greater extent compared to the ordinary CCBT program. The iCBT program could deliver a CBT as effective as the evidence-based CBT program to much more workers with less cost using the internet. The present study suggests that the iCBT is a very promising approach in promoting mental health among workers.

For the secondary outcomes, the iCBT program showed a significant intervention effect on DAS and UWES. The present findings on DAS are consistent with a previous one, which reported a similar effect size. To date, there was no previous research on the effect of a CBT program on improving work engagement among workers. The current iCBT program may have enhanced work engagement though improving those psychological resources. In the intervention group, knowledge and efficacy of most components of CBT were increased significantly more than in the control group. The effect sizes were moderate for knowledge and small for self-efficacy. This iCBT program may be useful in increasing knowledge and self-efficacy about CBT-based stress management. In present study, there was only small difference in effect sizes among the CBT components.

For the group with high psychological distress at baseline, the iCBT program showed a significant intervention effect on BDI-II. The effect size for BDI-II was still small, but slightly higher than ones observed in of the whole sample. In the group with low psychological distress at baseline, the iCBT program showed no significant effects on BDI-II. The iCBT program may be more effective for workers who have high psychological distress or non-clinical depressive symptoms and anxiety. Furthermore, in the subgroup with high psychological distress, the iCBT program showed a significant effect on DAS, all

variables on knowledge, efficacy of stress management, assertive communication, and relaxation training. This is probably due to higher DAS score and lower scores of knowledge and self-efficacy at baseline among the group with high psychological distress, which gave this group a more chance to improve these scores. Also, workers with high psychological distress may be more motivated to achieve knowledge and self-efficacy for the CBT components. The content of the iCBT program might fit better the need of participants with high psychological distress.

According to the process evaluation of this iCBT program, the proportions of those who completed lessons and submitted homework gradually decreased for the later lessons. About two third of the intervention group completed all six lessons, while only a quarter of them submitted all six homework. The low rates of completing the lessons and submitting homework may have resulted in smaller effect size in this study. A possible benefit of using a comic story in the present iCBT program was not systematically assessed in the study. However, relatively greater effect sizes for knowledge and self-efficacy may reflect participants being easier to participate in the program and understand the content.

Limitations

First, participants were recruited from two IT company in Japan. Most of participants were males, working as professionals, and university graduates. They had their own PC at office or home. The participants were also supposed to have much experience using a PC and studying from online programs. Higher education level also may help to learn from the iCBT program. The generalization of the present findings to the general working population is limited. Second, the rate of completing lessons and homework was low. Only 93 participants submitted all homework, and average number of homework submitted was 2.7 per respondent. This may weaken the findings. Third, the dropout rates in the present study were 29.1% and 28.6% at three- and six-month follow ups, respectively. The drop-outs may cause a selection bias. A further RCT should be conducted to examine if the iCBT program is effective in reducing incidence of depressive disorders as well as improving physiological indicators of stress, such as blood pressure and saliva cortisol, in a larger sample of workers with diverse characteristics particularly in terms of occupation and education.

Conclusions

The newly developed six-week iCBT program delivered through internet proved to be effective in improving depressive symptoms in a general working population. The effect has also been found for dysfunctional attitude, work engagement, and knowledge and self-efficacy of CBT components. This iCBT program may be useful to provide a quality-assured online psycho-education to improve depressive symptoms among workers.