論文題目　**Effects of a smartphone-based stress management program on depression and anxiety among hospital nurses in Vietnam**
(ベトナム病院看護師におけるスマートフォンベースのストレスマネジメントプログラムの抑うつおよび不安に対する効果)

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Introduction

Nurses in low- and middle-income countries (LMIC) experienced high psychological stress, which affects their well-being and work performance. It is crucial to develop effective and appropriate mental health interventions that are reliable and affordable for nurses in LMICs with limited resources. Empirical evidence suggests that smartphone-based stress management interventions potentially facilitate the improvement of nurses' emotional and social well-being via an accessible and cost-effective delivery of support. However, only few randomized control trials (RCT) on technology based mental health intervention for nurses were conducted even in high-income countries with limited generalizability to nurses in LMICs. This is the first RCT with the aims of 1) examining the effects of two smartphone-based stress management programs to improve depression and anxiety among hospital nurses in Vietnam, and 2) comparing nurses' adherence between these two programs.

Methods

This study applied the RCT design in a large tertiary hospital at the central/national level in Hanoi city, Vietnam's capital, from 2018 to 2019. Participants were invited to join this study if they met two inclusion and five exclusion criteria. The two inclusion criteria included: 1) A full-time registered nurse, and 2) Have access to the internet via a mobile device such as a smartphone. The five exclusion criteria consisted of: 1) Plan to leave the hospital (change or quit the job) in the next seven months, 2) An assistant nurse or helper, not registered nurse, 3) Non-regular or part-time employed, 4) Sick leave for 15 days or more for a physical or mental condition in the previous three months, and 5) Currently received treatment for a mental problem from a mental health professional. However, the exclusion criteria no. 4 and 5 were removed before the recruitment to increase the participation rate. The sample size was calculated with an expected small effect size (0.25), an alpha error rate of 0.05, and a beta error rate of ·0.15.

The estimated sample size was 289 participants in each study group or 867 as a whole sample Study participants were equally randomized into two intervention groups and a control group following block permuted randomization method. The study included three data collection waves, namely a baseline survey in late September 2018, three-month and seven-month follow-ups (mid-January and early May 2019, respectively). The ten-week intervention following the baseline survey started from October to mid-December 2018. The study protocol was registered at the University Hospital Medical Information Network Clinical Trials Registry (UMIN000033139).

In this study, two smartphone-based stress CBT management programs with six modules each were developed for two intervention groups. The first program consisted of six modules in which participants could select one module per week in any order they preferred (program A). With the second program, nurses had to read one module per week in the sequence that was appointed by the researcher (program B). For both programs, all the modules were delivered in the form of an animated conversation between two narrative characters: a mental health counselor and a distressed nurse. The development of the Vietnamese version of programs A and B included four steps: 1) selection of modules and design of main characters, 2) language translation and finalization, 3) visualization, and 4) development of smartphone application, pilot, and finalization. Both programs had three similar modules, namely Behavioral activation, Cognitive restructuring, and Problem-solving. Three other modules of program A included Assertiveness, Self-compassion, and Job crafting. Meanwhile, program B was equipped with The transactional model of stress and coping, Self-case formulation based on the cognitive-behavioral model, and Relaxation. In addition, several features were developed for both programs to provide guidance (introduction module), increase the customizability (self-check stress scale) and privacy (log-in function).

Participants in two intervention groups were required to complete the assigned program A or B within ten weeks after the baseline survey. App training sessions were organized before the intervention to deliver technical support. It took an average of ten to fifteen minutes to complete one module. The intervention groups were encouraged to use the program as often as they wanted during these ten weeks. Chat groups via social media apps (such as Facebook Messenger, Zalo, Viber), phone's short message services (SMS) text and hotline were applied for regular reminder and communication during the intervention period. Participants in the control group did not receive any intervention program during the intervention and follow-up periods. However, nurses in both the intervention groups and the control group could use available services in the hospital,

such as occupational health and safety services. Participants in the control group had an opportunity to use the intervention programs after the seven-month follow-up (June to August 2019).

Nurses' anxiety and depression were measured using the self-reported 21-item Depression Anxiety and Stress Scale in the baseline and three- and seven-month follow-ups. Participants' demographic information were collected in the baseline survey. Process app use, users' satisfaction and usefulness, contamination of information, adverse effects of app use were self-administered at both follow-ups. Qualitative in-depth interviews and group discussion with hospital management representatives and nurses were conducted to gather data regarding advantages, disadvantages, feasibility, and scalability of the investigated programs.

The mixed procedure was applied to compare the primary outcome between two intervention groups and a control group with the intention-to-treat principle. Cohen's d was applied to measure the intervention effect. Pooled and subgroup analyses among participants who scored ≥10 in the DASS21-Depression subscale at the baseline survey, were conducted separately. For comparisons of participants' baseline characteristics and process evaluation, the Chi-square tests and t-tests were performed. All statistical analyses were conducted using the SPSS Statistics V.22.0 (IBM). The level of statistical significance for all analyses in this study was below 0.05. Thematic analysis was applied for the qualitative discussion/interview transcripts, using Microsoft Excel 2007 to map qualitative contents. The study procedures were approved by the Research Ethics Review Board of Graduate School of Medicine/Faculty of Medicine, the University of Tokyo (no 11991), and the Ethical Review Board for Biomedical Research of Hanoi University of Public Health (no 346/2018/YTCC-HD3).

Results

Nine hundred forty-nine eligible nurses participated in the baseline survey. Average retention rates were 93.0% and 92.0% at three- and seven-month follow-ups, respectively. Both programs (a fixed-order, internet cognitive behavioral therapy (iCBT) program B and a multimodule stress management techniques program A with a free-choice sequence) showed nonsignificant effectiveness on improvement of anxiety and depression among nurses at the end of the study. There were only significant but the small effect (p=0.048, Cohen's d = -0.18, 95% CI: -0.34 to - 0.02) of program B on depression score compared to that of the control group at the three-month follow-up. However, this

effect became nonsignificant at the seven-month follow-up (p= 0.92). Program A with free-choice modules did not significantly affect depression scores compared with the control group. Both programs obtained no significant effect on anxiety scores at both follow-up surveys.

Regarding process evaluation, 83.3% of nurses completed program A, and 86.1% of participants completed program B. The completion rates of two intervention groups were similar (χ^2 = 0.95, p = 0.38). The percentage of nurses knowing about the program from other nurses in the control group was significantly higher than that of two intervention groups in both follow-up surveys (p<0.001). Both programs received positive evaluation on users' satisfaction and usefulness. Qualitative results reported smartphone-based approach and programs' features as advantages. The programs had high feasibility and scalability.

This study had several limitations. First, the results are generalizable to nurses with similar characteristics. Second, all outcomes were measured by self-reported tools, which may produce bias. Third, institutional-based individual-level randomization and group reminders might result in nurses' awareness of other nurses' participation and study groups, causing contamination of information. Fourth, adverse events that likely affect nurses' mental health were not included in the analysis of the intervention effect. However, this study is the first RCT to examine the effect of the smartphone-based stress management program among clinical nurses in Vietnam, a LMIC.

Conclusion

The self-guided smartphone-based standardized CBT stress management program B is effective in improving depressive symptoms after three months for the participating nurses. The program A showed a nonsignificant effect on depression. Neither programs were efficacious to improve anxiety among study participants. Good adherence was observed for both programs A and B. The study demonstrated the effectiveness and feasibility of the technology-based stress management to improve depression for hospital nurses in Vietnam, a LMIC. This fully automated iCBT stress management program requires only minimum cost for server maintenance and operation. In addition, since the program is entirely self-guided, it is highly applicable in a setting with limited expertise in psychotherapy. Our evidence-based iCBT stress management program may be an optimal option for improving mental health among nurses in Vietnam and other LMICs.

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