

## 論文の内容の要旨

論文題目 The effectiveness of an online peer gatekeeper training program for students on suicide prevention: a randomized controlled trial

(オンライン学生ピアゲートキーパー育成プログラムの効果検証：無作為化比較対照試験)

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**Introduction:** Suicide is one of the most severe public health problems in the world. It is the leading cause of death among individuals between 15 and 39 years old in Japan and is also the leading cause of death for college and university students. Therefore, suicide prevention measures for young people, especially students, are urgently needed.

A previous study showed that about 80% of college students who died by suicide had no prior contact with campus mental health professionals. Another study showed low service utilization rates among students with mental health problems, and 85% of college students with moderate to severe depression did not get treatment. Therefore, awareness by other persons, such as gatekeepers who can detect and refer at-risk individuals, are essential for students experiencing difficulties. Past studies have shown that college students are most likely to talk to friends about suicidal ideation or ask for treatment when recommended by a friend, so students are especially advantageous as gatekeepers.

A gatekeeper is someone aware of the signs of suicide that can take appropriate action (i.e., aware of people in need, speak to them, listen closely to them, direct those in need to resources for support, and watch over them). Gatekeeper training is a program to foster development of gatekeepers and aims to help non-professionals identify and respond to those at risk of suicidal behavior and is the most general intervention in suicide prevention. Gatekeeper training builds the self-efficacy of those acting as a gatekeeper, such as speaking to people at risk of suicide. A recent meta-analysis in the United States reported the effectiveness of gatekeeper training in universities for suicide prevention knowledge, skills, and self-efficacy. Thus, increasing a student's self-efficacy as a gatekeeper may lead to more gatekeeper actions and, as a result, suicide prevention.

Students, however, may encounter obstacles in attending gatekeeper training programs. The most significant hurdle for students may be a lack of time and resources to participate in face-to-face training sessions. In addition, gatekeeper training programs conducted at a school or in a class unit often involve familiar acquaintances, and as gatekeeper training also includes private content, such as sharing experiences and opinions in group work, some may not want to participate due to privacy concerns. As such, on-demand online gatekeeper training programs may be helpful in overcoming such hurdles for students.

To date, to the best of our knowledge, there is no online gatekeeper training program for students in Japan. Moreover, no randomized controlled trials have been conducted to verify the effectiveness of online gatekeeper training programs for students.

Gatekeeper behavior application has been conceptualized with the theory of planned behavior (TPB). Based on TPB, one hypothesis is that self-efficacy as a gatekeeper affects "Attitudes towards the Behavior" and "Perceived Behavioral Control", leading to actual behavior as a gatekeeper. Few programs have reported on the effectiveness of gatekeeper training programs for decreasing the number of suicides. Most studies reported on suicide knowledge, attitudes, and skill of trainees instead of the number of suicides. Therefore, in this study, we decided to use a surrogate outcome. Assuming that encouraging action for suicide countermeasures as a gatekeeper lowers the suicide rate, a gatekeeper training (GKT) program was created aimed at increasing self-efficacy, which affects behavior as a gatekeeper based on the attitude of TPB.

Accordingly, the aims of this research were to: (1) create an online peer GKT program for students; and (2) verify its effectiveness through randomized controlled trials.

Moreover, enhancing mental health literacy through the GKT program may also support the mental health of the gatekeeper themselves through an understanding of mental disorders and their treatment, and promotion of help-seeking behavior. Hence, the GKT program was also investigated for effects on the mental health of the gatekeeper themselves, their understanding of mental disorders, and help-seeking behavior as secondary endpoints.

**Method:** This study was a two-arm parallel-group non-blinded randomized controlled trial with a GKT intervention group and a waitlist control group (WL). Staff at various institutions or individuals were sent requests through snowball sampling which disseminated information about the GKT research and an invitation to students via email or social media and other platforms. The target RCT population was students in Japan who are 18 to 29 years old and in vocational school, junior college, college, graduate school, or a college of technology. Participants who fulfilled the eligibility criteria were randomly assigned to either an online program intervention group or a wait-list control group.

A new GKT program was created. The intervention program contained a platform for participants to take the program, videos of the GKT program (sections 1-6) via YouTube, a comment section (online discussion board), and a text download page. The participants in the intervention group learned six sections within ten days. Because it was played on YouTube, the modules were designed so that the participant controlled every aspect of the module, such as skipping or replaying a movie, adjusting playback speed, and switching the voiceover or subtitles on or off. Of course, during the intervention period, participants could watch the video at any time and place.

The sample size calculation was based on the difference between means of change in the primary outcome (self-efficacy as the gatekeeper) from baseline (pre-) to post-intervention ( $t_1$  survey) in both arms (complete case analyses). Based on previous studies on gatekeeper training, mean effect sizes of around  $d = 0.5$  were expected in per-protocol analyses for improving self-efficacy. The expected study dropout was about 60% (dropouts occur at random within each group), and this meant that 320 participants (160 per group) must be included in the study.

Primary outcomes were measured for self-efficacy as a gatekeeper using the Gatekeeper Self-Efficacy Scale (GKSES) at baseline ( $t_0$ ), post intervention ( $t_1$ : about ten days after  $t_0$ ), and two months after  $t_1$  ( $t_2$ ). Secondary outcomes were measured using: Literacy of Suicide Scale (LOSS), Sense of Coherence (SOC), Mental Illness and Disorder Understanding Scale (MIDUS), help-seeking styles “Freestanding” for help-seeking, Kessler Psychological Distress Scale (K6), Japanese version of the Rosenberg self-esteem scale for self-esteem, Tachikawa resilience scale for resilience, behavior as gatekeepers, internet use, and fear of COVID-19. The primary endpoint (difference of GKSES total score between pre and post-survey) between the intervention and control groups were compared based on a t-test. The primary analysis followed the modified intention to treat (ITT) principle. Secondary endpoints were also compared similarly.

A subgroup analysis was done between high and low internet abuse groups and high and low fear of COVID-19. The Implementation Outcome Scales for Digital Mental Health (iOSDMH) was used for process evaluation.

**Result:** A total of 321 eligible students participated in this study. For the primary outcome, as compared with the control group, the intervention group revealed a significant intervention effect in GKSES from baseline to both the  $t_1$  and  $t_2$  follow-ups ( $t_1$ - $t_0$ : Cohen’s  $d = 1.61$  [95%CI 1.34 – 1.88],  $t_2$ - $t_0$ : Cohen’s  $d = 0.93$  [95%CI 0.67 – 1.18]). As compared with the control group, the intervention group had a significant favorable difference in GKSES from baseline to  $t_1$  and  $t_2$  ( $t_1$ - $t_0$ :  $t = 13.07$ ,  $p < 0.01$ ,  $t_2$ - $t_0$ :  $t = 7.58$ ,  $p < 0.01$ , respectively).

For the secondary outcomes, as compared with the control group, the intervention group had a significant preferable difference from baseline to  $t_1$  and  $t_2$  in LOSS ( $t_1$ - $t_0$ :  $t = 10.69$ ,  $p < 0.01$ ,  $t_2$ - $t_0$ :  $t = 6.53$ ,  $p < 0.01$ ), SOC ( $t_1$ - $t_0$ :  $t = 1.99$ ,  $p = 0.048$ ,  $t_2$ - $t_0$ :  $t = 2.89$ ,  $p < 0.01$ ), MIDUS "Treatability of illness" ( $t_1$ - $t_0$ :  $t = 2.20$ ,  $p = 0.028$ ,  $t_2$ - $t_0$ :  $t = 2.34$ ,  $p = 0.020$ ), "Efficacy of medication" ( $t_1$ - $t_0$ :  $t = 2.57$ ,  $p = 0.011$ ,  $t_2$ - $t_0$ :  $t = 2.65$ ,  $p < 0.01$ ) and total score ( $t_1$ - $t_0$ :  $t = 2.63$ ,  $p < 0.01$ ,  $t_2$ - $t_0$ :  $t = 2.74$ ,  $p < 0.01$ ). As compared with the control group, the intervention group had no significant difference in MIDUS "Social recognition of illness," help-seeking, K6, self-esteem, and resilience. In the action implementation status as a gatekeeper within two months after the  $t_1$  survey, there was no significant difference in all items.

Participants in the intervention group who responded to the  $t_1$  survey answered that they viewed the videos for all sections. Regarding overall satisfaction, 124 (94.6%) answered satisfied or somewhat satisfied with the ‘online student peer GKT program’ among the respondents at the  $t_1$  follow-up in the intervention group. Regarding harms, 19.1% reported mental symptoms during use, and 26.0% reported it to be too time-consuming.

The subgroup analysis results between high and low internet abuse groups and high and low fear of COVID-19 groups were similar to the overall results. There was a significant difference in resilience from baseline to  $t_2$  follow-up only in the high fear of COVID-19 group.

**Discussion:** Our results showed significant improvements in self-efficacy as a gatekeeper with large effect sizes due to the online student peer GKT program. In the total sample and all subgroup analyses, the online

student peer gatekeeper intervention program showed a significant intervention effect on self-efficacy as a gatekeeper. The results of this study supported the hypothesis that an online GKT program for students improves self-efficacy as a gatekeeper. This result may be because our program is student-specific, and the contents are highly tailored to students, such as SNS. In addition, the results of this program suggest that the online implementation may have been more effective than face-to-face implementation.

The GKT intervention program showed a significant effect on increasing suicide literacy in the total sample targeting program completers. This is consistent with a systematic review that examined gatekeeper training program intervention effects on knowledge of suicide. In our GKT program, we included a quiz to test knowledge about suicide. This quiz might influence the acquisition of knowledge about suicide.

The results of this study did not detect an increase in gatekeeper behavior in the  $t_2$  survey. Acting as a gatekeeper can take a long time to be observed. Therefore, it is necessary to consider a long-term and large-scale survey regarding action as a gatekeeper as seen in previous surveys (long-term surveys at each school level nationwide are required). In this study, more than half of the participants lived in an area where pre-emergency measures were announced at the time of the  $t_2$  survey, and the largest number of students had five days or more of online lessons per week. However, due to circumstances around COVID-19, it is possible that they had fewer opportunities to meet friends (acquaintances) than in regular times. Based on this result, it is necessary to re-examine the action as a gatekeeper over a study period that is not affected by an infectious disease outbreak.

Regarding process evaluation, the completion rate of the program was very high, and overall satisfaction was also high. Regarding harm, 19.1% of participants answered that using this program caused mental symptoms. As this psychological burden was an expected possibility, a notice was provided at the beginning of each section of a video and the home page provided a list of resources. However, as 19% of students indicated mental symptoms during the program, and since this program deals with the delicate theme of suicide, it is necessary to take further measures for people who experience psychological burdens during the program. Future program revisions will take this issue into further consideration.

**Conclusion:** In conclusion, this RCT of a fully automated online student peer GKT program found positive effectiveness in self-efficacy as a gatekeeper among students in Japan. Additionally, significant findings were found in other domains (literacy of suicide, sense of coherence, mental illness and disorder understanding). Future research can pursue measures to further improve effectiveness by modifying the program and the process. Additionally, further methods will be pursued to increase promotion of this program to more students in the future.

The study protocol was registered at the University Hospital Medical Information Network Clinical Trials Registry (UMIN000045325).