



Research paper

Effects of video viewing smartphone application intervention involving positive word stimulation in people with subthreshold depression: A pilot randomized controlled trial

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ABSTRACT

Background: A smartphone application (i.e., SPSRS) was developed to help people with subthreshold depression (StD) improve depressive symptoms by presenting positive word stimuli in videos. However, to date, no randomized controlled trials (RCTs) were conducted to investigate SPSRS application interventions for depressive symptoms in people with StD. Therefore, a pilot RCT was conducted to assess the preliminary efficacy of the SPSRS application intervention for people with StD.

Methods: In a pilot RCT, 32 participants (female = 34.4%, mean age = 20.06, SD = 1.24) with StD were randomized to SPSRS application intervention for approximately 10 min/a day for 5 weeks (experimental group; n = 16) or no intervention (wait list control group; n = 16). The primary outcome is the change from baseline in the Center for Epidemiologic Studies Depression Scale (CES-D) score after the 5-week intervention. The secondary outcomes are the change from baseline in the Kessler Screening Scale for Psychological Distress (K-6) score and the Generalized Anxiety Disorder 7-item scale (GAD-7) after the 5-week intervention.

Results: No participants dropped out of the study. The experimental group displayed medium, small, and small improvements in CES-D, K-6, and GAD-7 scores (adjusted Hedge's $g = -0.64, -0.29, \text{ and } -0.40$), respectively, compared with control.

Limitations: The observed effects must be considered preliminary due to the small sample size.

Conclusions: The results suggest the potential of intervention using the SPSRS application to reduce depressive symptoms in people with StD. Future studies should replicate these findings in a full-scale RCT.

1. Introduction

Subthreshold depression (StD), which is also called subsyndromal or minor depression, fails to meet the criteria for major depressive disorder (MDD) (Rodríguez, Nuevo, Chatterji, & Ayuso-Mateos, 2012). However, it is characterized by the presence of clinically significant depressive symptoms (Rodríguez et al., 2012). Previous studies reported the prevalence of StD at 4.0–53.2% (Meeks, Vahia, Lavretsky, Kulkarni, & Jeste, 2011; Takahashi, Takada, Inoue, et al., 2019; Vaccaro et al., 2017; Xiang, Leggett, Himle, & Kales, 2018), which leads to poor health (Ayuso-Mateos, Nuevo, Verdes, Naidoo, & Chatterji, 2010), poor quality

of life (Cuijpers, Smit, & van Straten, 2007; Goldney, Fisher, Dal Grande, & Taylor, 2004; Rodríguez et al., 2012), increased mortality (Ho, Jin, Nyunt, Feng, & Ng, 2016), and increased economic costs (Cuijpers, Smit, Oostenbrink, et al., 2007). Notably, StD is a precursor to MDD and an important risk factor for the onset of MDD (Cuijpers, Smit, & van Straten, 2007; Lee et al., 2019; Naber & Bullinger, 2018; Wesselhoeft, Sørensen, Heiervang, & Bilenberg, 2013). Therefore, StD is a group that has an extremely high risk of onset of MDD. In other words, if StD is a precursor to MDD (Cuijpers, Smit, & van Straten, 2007), which is a major public health problem, then StD is a clear target for preventive intervention and requires appropriate intervention for its early

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recognition and treatment. Psychological treatments, such as cognitive behavioral therapy and mindfulness, are effective interventions for StD and may prevent the onset of MDD (Cuijpers et al., 2014; Walsh, Eisenlohr-Moul, & Baer, 2016). A meta-analysis finds that psychotherapy reduces the risk of depressive symptoms and future MDD in adults with StD (Cuijpers et al., 2014; Cuijpers, Smit, & van Straten, 2007). However, although evidence suggests that such programs are effective, several obstacles to their widespread implementation have been observed. Psychotherapy requires a qualified and specialized staff and increases costs, thus limiting the scale of treatment (Zhou, Li, Pei, Gao, & Kong, 2016). Another barrier is the limited access to psychotherapy especially for rural people and outpatients with restricted mobility (Titzler, Saruhanjan, Berking, Riper, & Ebert, 2018). Moreover, patients may hesitate to receive treatment because of stigma and embarrassment (Cuijpers, van Straten, & Andersson, 2008; Pedersen & Paves, 2014). Given the limitations of psychotherapy, developing accessible interventions for improving depressive symptoms in people with StD is required. Interventions using smartphone applications may address the abovementioned issues. The previous years have seen an explosive increase in interest and development in smartphone applications, thus paving the way for new treatments for mental health (Firth et al., 2017; Miralles et al., 2020). An advantage of smartphone applications is that many cheap or free applications that improve access to treatments are available and may be easier and less burdensome to patients (Grist, Porter, & Stallard, 2017; Miralles et al., 2020). These factors enable patients to receive interventions tailored to their personal lifestyle in their communities and even homes. This convenience could ultimately provide significant benefits to the society in general and the insurance system in particular. Several smartphone applications have been developed for MDD or StD (Firth et al., 2017; Miralles et al., 2020). However, to date, smartphone applications using video viewing for MDD or StD have not been developed (Firth et al., 2017; Miralles et al., 2020). Video viewing is a rapidly growing trend around the world (Madathil, Rivera-Rodriguez, Greenstein, & Gramopadhye, 2015). Given that many people now rely on smartphones for their video viewing methods, video-based interventions can reach a large number of individuals who are eligible for treatment via smartphones. If the intervention using video viewing proves effective, then it may become a new intervention strategy in the treatment of StD and shed new light on this condition. Therefore, the study developed a smartphone application (i.e., SPSRS) that uses video viewing for the treatment of StD (Takahashi, Takada, & Hirao, 2019). The central therapeutic goal of the SPSRS application is to improve depressive symptoms in people with StD by presenting positive word stimulation through videos (Takahashi, Takada, & Hirao, 2019). In this manner, progression to MDD is prevented and users are enabled to manage their health.

The first study on interventions using SPSRS applications that targeted people with StD investigated the feasibility of such interventions (Takahashi, Takada, & Hirao, 2019). As a result, no adverse events were noted during the intervention through SPSRS applications. Moreover, the present study found that the SPSRS application is safe and easy-to-use. In addition, a previous study suggested that intervention through the SPSRS application could improve depressive symptoms in people with StD (Takahashi, Takada, & Hirao, 2019). However, the study conducted was a single-arm trial without a control group. Therefore, a rigorous randomized controlled trial (RCT) is required to assess the efficacy of SPSRS application interventions for people with StD. However, formal sample size calculations were difficult due to the lack of published RCT data on the potential impact of SPSRS application interventions on depressive symptoms in people with StD. Validating the preliminary efficacy through pilot trials can provide information for subsequent full-scale RCT sample size calculations, which is especially advisable in the absence of previous study data (Thabane et al., 2010). Therefore, as a preliminary step toward a full-scale RCT implementation, the present conducted a pilot RCT aimed at verifying the preliminary efficacy of the SPSRS application for people with StD. We

hypothesized that people with StD who received the SPSRS application intervention experienced a greater amelioration of depressive symptoms before and after treatment than those who had StD but did not receive the SPSRS application intervention.

2. Methods

2.1. Trial design

The study was designed as a single-center, assessor-blind, two-arm, randomized, parallel-group, pilot controlled trial. The Ethics Review Board of Kibi International University approved the study protocol (approval numbers: 19–33) and registered with ClinicalTrials.gov (NCT04136041). The details of study design are published in a protocol paper (Kato et al., 2020). The study was conducted according to the CONSORT 2010 extension to randomized pilot and feasibility trials (Eldridge et al., 2016).

2.2. Randomization

All eligible participants were randomly assigned to the experimental or wait list control group at a 1: 1 ratio after baseline evaluation. An Excel spreadsheet by a third party independent of the study was used to generate a randomized list based on the permuted block method (block size 4). The created randomized list was sent to the Central Registration Center, which is set up at Kurashiki Heisei Hospital in Japan and where random allocation was made. In this manner, the allocation process was concealed.

2.3. Settings and recruitment

Details on the recruitment of participants are published in the protocol paper (Kato et al., 2020). The participants were recruited through Kibi International University in Okayama Prefecture, Japan. Okayama Prefecture has a population of approximately 1,890,000, of which approximately 45,000 (2.4%) are university students. Kibi International University has approximately 1,800 students. Kibi International University not only has a healthcare center but also works closely with the local community and surrounding organizations. This permits access to professional counseling and other services when participants show signs of poor mental or physical health. Research leaflets, emails, and social networking services were used to invite potential participants. All materials included a dedicated email address for contacting the research team. The researchers briefed the participants regarding the details of the study using informational materials. The participants were then sent the URL of an online questionnaire to assess eligibility. Informed consent was provided through the questionnaire, which was administered prior to the baseline assessment. Consent was confirmed by pressing the consent button. After assessing eligibility using the online questionnaire and completing the baseline assessment, the participants were randomly assigned to an experimental or a wait list control group.

2.4. Participants

Participants in this study were recruited from Kibi International University using the convenience sampling method.

The eligibility criteria for participants were as follows.

Inclusion Criteria:

- 1) 18 years and older
- 2) Center for Epidemiologic Studies Depression Scale (CES-D) score \geq 16 (Shima, Shikano, Kitamura, & Asai, 1985)
- 3) Owns a smartphone with an iOS® operating system
- 4) Written informed consent prior to participation

Exclusion Criteria:

- 1) Lifetime history of psychiatric disorders
- 2) Currently receiving treatment for a mental health problem from a mental health professional
- 3) Vision or hearing deficits that negatively impact everyday life
- 4) Experience of a major depressive episode 2 weeks prior to the study as determined using the Mini-International Neuropsychiatric Interview (MINI) (Otsubo et al., 2005)

We strongly encouraged participants to seek additional assistance if major depressive episodes were observed using MINI and provided information on relevant health services (such as the university healthcare center and professional counseling).

2.5. Sample size

One of the objectives of the study is to calculate the sample size suitable for a full-scale trial implementation. Thus far, no RCT has used the SPSRS application for people with StD. Therefore, sample size calculations for future full-scale trials can be derived from the results of the CES-D score, which is the primary outcome of this pilot trial. Although no formal sample size calculations are required for pilot RCTs (Thabane et al., 2010), a total of 15–20 participants per group are required to ensure the scientific validity of the results (Hertzog, 2008). Therefore, the study aimed to attract a total of 32 participants at 16 members per group.

2.6. Assessment measures

An assessor blinded to the objectives of the study collected the primary and secondary outcomes online. As part of the baseline assessment, this study collected demographic data such as age and sex, as well as lifestyle characteristics such as sleep time, smoking habits, exercise habits, and drinking habits. Sleep time was defined as the average sleep time per week (Hall et al., 2008). Drinking habits were defined as drinking at least one bottle (approximately 500 mL) of beer per day, ≥ 3 days a week (Takimoto, Yokoyama, Yoshiike, & Fukuoka, 2005). Smoking habits were defined as “daily smoker” or “have occasional smoking days (Akhtar, Haw, Currie, Zachary, & Currie, 2009).” Exercise habits were defined as exercise periods “once 30 min or more” performed at least twice a week and continued for at least 1 year (N. Nishi, Yoshizawa, & Okuda, 2017).

2.6.1. Primary outcome measure

2.6.1.1. Center for Epidemiologic Studies Depression Scale (CES-D). The primary outcome denotes the change from baseline in the CES-D score after the intervention. CES-D is a 20-item self-reported questionnaire, where each item is scored from 0 to 3 points (Radloff, 1977; Shima et al., 1985). The total scores on the CES-D ranged from 0 to 60, with high scores indicating high levels of depressive symptoms (Radloff, 1977; Shima et al., 1985). The reliability and validity of CES-D have been reported elsewhere (Ohno et al., 2017; Radloff, 1977; Sakurai, Nishi, Kondo, Yanagida, & Kawakami, 2011; Shima, Kitagawa, Kitamura, Fujinawa, & Watanabe, 1994; Shima et al., 1985; Thombs, Hudson, Schieir, Taillefer, & Baron, 2008). The CES-D score had a high internal consistency (Cronbach $\alpha = 0.81$ – 0.88) (Ohno et al., 2017; Sakurai et al., 2011; Thombs et al., 2008).

2.6.2. Secondary outcome measures

2.6.2.1. Kessler Screening Scale for Psychological Distress (K-6). K-6 is a 6-item self-reported questionnaire used to measure psychological distress (Furukawa et al., 2008; Kessler et al., 2002). Each item is scored from 0 to 4 points. The total score ranges from 0 to 24 points, and the higher the score, the stronger the psychological distress. The reliability

and validity of K-6 have been verified elsewhere (Furukawa et al., 2008; Hajebe et al., 2018; Kessler et al., 2002; A. Nishi, Noguchi, Hashimoto, & Tamiya, 2012; Sakurai et al., 2011). The K-6 score had a high internal consistency (Cronbach $\alpha = 0.85$ – 0.90) (Nishi et al., 2012; Sakurai et al., 2011).

2.6.2.2. Generalized Anxiety Disorder-7 (GAD-7). GAD-7 is a 7-item self-reported questionnaire used to measure generalized anxiety disorder, with each item scoring 0–3 points (Muramatsu, 2010; Spitzer, Kroenke, Williams, & Lowe, 2006). The total score ranges from 0 to 21 points, which indicate that the higher the score, the stronger the anxiety symptoms. The reliability and validity of GAD-7 have been verified elsewhere (Kroenke, Spitzer, Williams, Monahan, & Lowe, 2007; Lowe et al., 2008; Muramatsu, 2010; Sawaya, Atoui, Hamadeh, Zeinoun, & Nahas, 2016; Sousa et al., 2015; Spitzer, Kroenke, Williams, & Lowe, 2006). The GAD-7 score had a high degree of internal consistency (Cronbach $\alpha = 0.90$ – 0.92) (Micoulaud-Franchi et al., 2016; Spitzer, Kroenke, Williams, & Löwe, 2006).

2.7. Blinding

Independent evaluators who were unaware of group assignments, research objectives, and the trial design performed the primary and secondary outcome assessments. For evaluation, online questionnaire was adopted to reduce the burden of visits by participants. The participants and therapists could not be blinded to the study protocol due to the nature of the intervention. However, the study reduced bias that may occur between the interveners and participants by providing concealment of the research hypotheses, standardized intervention guidance, and standardized text message feedback.

2.8. Interventions

The experimental group received intervention with the SPSRS application. The wait list control group was non-interventional and did not receive the SPSRS application intervention during the intervention period (up to 5 weeks from the start of the intervention).

2.8.1. Experimental group

The Subliminal Priming with Supraliminal Reward Stimulation (SPSRS) is an iPhone (iOS 9.1 or greater) application designed on the basis of verbal stimulation from research-based evidence and positive language as reported by previous qualitative studies on people with StD (Aarts, Custers, & Marien, 2008; Aoyama et al., 2017; Takahashi, Takada, Inoue, et al., 2019; Takarada & Nozaki, 2014). The SPSRS application is designed to improve depressive symptoms in people with StD by presenting positive word stimuli through videos. Furthermore, the SPSRS application is programmed to display videos that feature general confidence-boosting words, such as “able,” “let us try,” “good luck,” “can,” and “do not worry” (Takahashi, Takada, Inoue, et al., 2019). Each word is randomly displayed in the four corners of the screen for 17 ms (Aoyama et al., 2017). Afterward, positive words, such as “great,” “fantastic,” “nice,” “satisfactory,” and “enjoyable,” are displayed in the center of the screen (150 ms each) (Takarada & Nozaki, 2014). Positive words to increase confidence are automatically displayed on top of the video when the participant selects the video they like. The SPSRS application is free. Its main feature is the use of the YouTube Application Programming Interface, which enables the viewing of videos uploaded to YouTube. Given the wide variety of videos uploaded to YouTube from various sources (Madathil et al., 2015), the SPSRS application, which automatically presents positive word stimulation through YouTube videos, allows users to select videos. Therefore, working toward reducing depressive symptoms according to user preferences becomes possible. The SPSRS application consists of approximately 10 min of video viewing per day (at least 70 min per

week) for 5 weeks (at least 350 minutes). The participants freely selected the videos to be viewed. However, because the SPSRS application is filtered, participants are unable to watch inappropriate videos (sad videos, violent videos, etc.) published on YouTube. The research team developed and provided a manual that demonstrates the installation and use of the SPSRS application as an educational resource. Three occupational therapy students on the research team disseminated the manual among the participants prior to the start of the intervention. Currently, SPSRS applications do not include push notifications.

Instead, once a day, a text message was sent to encourage the use of the SPSRS application to maintain better adherence to video viewing with the SPSRS application. The history function in the SPSRS application was used to monitor the usage status of each participant's SPSRS application. SPSRS application usage history is stored locally in the device. The recorded history comprises the viewing date and time, and personal data such as participant-identifiable information (name, address, etc.) and the name of the video viewed are not recorded. Each participant was instructed to send a usage record of the SPSRS application to the research team once a week. Furthermore, the data exchanged via the Internet is encrypted by a Secure Sockets Layer to ensure security. The collected data are stored on a USB memory stick with a password and can only be accessed by the research team. The appropriate text message from the message pool was sent to the participants dependent on the viewing time of each participant. In other words, if the participants achieved the required amount of video viewing time per week (i.e., 70 min or more), they were sent a text message encouraging them to continue watching the video. However, if the required video viewing time was not reached, a sent a text message is sent stating that the required video viewing time for the week was not achieved. In addition, a text message was sent urging the supplementation of the shortage of viewing time in the following week. Occupational therapy students on the research team sent the templated text messages to participants through social network services.

2.8.2. Wait list control group

The wait list control group was non-interventional and did not receive the SPSRS application intervention during the intervention period up to 5 weeks from the start of the intervention. However, the researchers explained prior to the intervention that receiving the intervention through the SPSRS application after the 5-week outcome measurement.

2.9. Statistical analysis

The linear mixed model (LMM) with a restricted maximum likelihood estimation method was used to estimate the mean values of the pre-specified primary and secondary outcomes and compare the change from baseline to 5 weeks post-treatment across the two groups (Gueorguieva & Krystal, 2004). LMM is suitable for intention to treat-based analysis because it can address defects that occur in clinical trials and can use data from all assigned participants (Gueorguieva & Krystal, 2004). Group assignment, assessment time points, and interaction between group assignment and assessment time points were considered fixed-effects factors, whereas the participants were considered random-effect factors. The model used a fixed-effect type-III test. In the LMM, the main group effect denotes average score differences between groups at the pre-treatment assessment. The time effect denotes the average score change from pre-treatment to post-treatment across both groups. The group \times time effect denotes the difference scores between groups from pre-treatment to post-treatment (Gueorguieva & Krystal, 2004). Two-sided significance tests were performed in the analyses. P value < 0.05 was considered significant for the primary and secondary outcomes. SPSS v.26.0 (IBM Japan, Tokyo, Japan) was used for analyses. Effect size (ES) used Hedge's g (Hedges, 1981; Hedges & Olkin, 1985). The study calculated pre- and post-ES between the two groups. In addition, the adjusted ES was calculated by subtracting the pre-ES from

the post-ES (Durlak, 2009). Values of 0.2, 0.5, and 0.8 between groups were considered small, medium, and large differences, respectively (Cohen, 1988).

3. Results

3.1. Enrollment and baseline characteristics

Fig. 1 depicts the flow of the trial. Between October 2019 and January 2020, a total of 180 participants were evaluated for eligibility. Out of them, 32 (18 to 24 years old) met the study eligibility criteria and were randomly assigned to the experimental ($n = 16$) or wait list control ($n = 16$) group after baseline evaluation. The participants completed the assigned intervention and were evaluated after 5 weeks. As a result, none of the participants discontinued the study due to adverse events after the start of the intervention. Table 1 shows the demographic characteristics of the participants at baseline. The mean age (SD) was 20.00 (0.82) for the experimental group and 20.13 (1.59) for the wait list control group. Females comprised 31.25% of the experimental group and 37.5% of the wait list control group.

3.2. Effect of SPSRS application intervention on the outcomes

Table 2 shows the estimated effect of the SPSRS application on the cited outcomes based on LMM analysis of the experimental and wait list control groups. Furthermore, Table 3 displays the mean and SD of the baseline and 5-week outcome measures, as well as the ES (Hedge's g) values between the two groups. The effect of time on the primary outcome (CES-D score) was significant ($P < 0.001$), whereas the group ($P = 0.92$) and group \times time interactions ($P = 0.16$) were non-significant. The adjusted ES between the two groups was -0.64 . The effect of time on the secondary outcome (K-6 score) was significant ($P = 0.01$), whereas the group ($P = 0.82$) and group \times time interactions ($P = 0.37$) were non-significant. The adjusted ES between the two groups was -0.29 . The time ($P = 0.12$), group ($P = 0.28$), and group \times time interactions ($P = 0.25$) for the GAD-7 scores were non-significant. The adjusted effect size between the two groups was -0.40 .

3.3. Adherence

The mean and SD of video viewing time during the 5-week intervention was 356.59 ± 351.55 min. Adherence rate was calculated by dividing the number of participants who achieved the required viewing time for the duration of the intervention by the number of participants in the experimental group. Of the 16 participants, five complied with the SPSRS application intervention. Thus, an adherence rate of 31% was achieved.

3.4. Post-hoc power analyses

Data from the trial were used to calculate the sample size required to achieve two-sided $\alpha = 0.05$, 80% power. The difference in mean change of the CES-D scores between the experimental and wait list control groups was 2.87 points. The average SD value of the two groups was 5.43 points. Therefore, a sample size of 58 individuals per group (a total of 116) was estimated.

4. Discussion

The pilot RCT aims to verify the preliminary effectiveness of the SPSRS application intervention in improving the depressive symptoms of people with StD. The findings suggest that the SPSRS application intervention was effective. At the end of the 5-week intervention, the CES-D score of the experimental group improved by 5.56 points, whereas the CES-D score in the wait list control group improved by only 2.69 points. The difference in the mean change of the CES-D scores

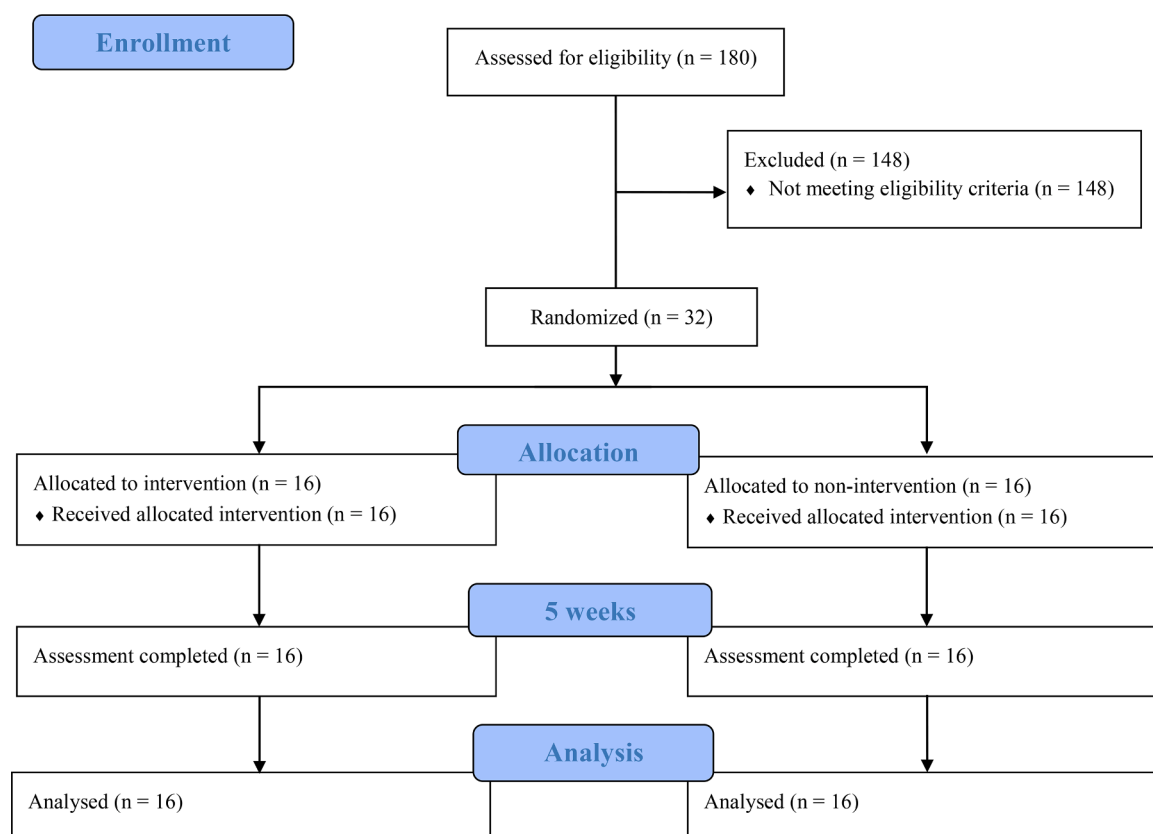


Fig. 1. Flowchart of trial.

Table 1
Baseline characteristics of the two groups.

Characteristics	Experimental group (n = 16)	Wait list control group (n = 16)
Age (years)	20.00 (0.82)	20.13 (1.59)
Sex		
Male	11 (68.75%)	10 (62.5%)
Female	5 (31.25%)	6 (37.5%)
Drinker		
Yes	1 (6.25%)	1 (6.25%)
No	15 (93.75%)	15 (93.75%)
Sleep time (h)	6.25 (0.86)	6.00 (0.82)
Smoker		
Yes	3 (18.75%)	1 (6.25%)
No	13 (81.25%)	15 (93.75%)
Exercise habits		
Presence	9 (56.25%)	5 (31.25%)
Absence	7 (43.75%)	11 (68.75%)

Data are means (standard deviation) or numbers (%).

between the experimental and wait list control groups was non-significant, whereas medium ES (−0.64) was observed. This result exceeds the ES value (0.28–0.35) reported in various meta-analyses on psychotherapy (e.g., cognitive behavioral therapy and interpersonal counseling) for people with StD (Cuijpers et al., 2014; Zhou et al., 2016). Furthermore, the finding suggests that the SPSRS application intervention may be more effective than other interventions. Given that the SPSRS application is easy to use and free, it may be an alternative strategy for improving depressive symptoms among people with StD.

Several studies demonstrated the effectiveness of smartphone applications against depressive disorders (Miralles et al., 2020). However, despite the suggestion that StD-specific interventions are required to alleviate the depressive symptoms of StD (Takagaki et al., 2014), no RCTs have investigated the effectiveness of smartphone applications

Table 2
Results of LMM analysis for the experimental and wait list control groups.

Outcomes	F	df	P
CES-D			
Group Effect	0.01	1, 30	0.92
Time Effect	16.99	1, 30	<0.001
Group × Time	2.06	1, 30	0.16
K-6			
Group Effect	0.05	1, 30	0.82
Time Effect	6.93	1, 30	0.01
Group × Time	0.84	1, 30	0.37
GAD-7			
Group Effect	1.21	1, 30	0.28
Time Effect	2.64	1, 30	0.12
Group × Time	1.38	1, 30	0.25

LMM: Linear Mixed Models

CES-D: Center for Epidemiologic Studies Depression Scale

K-6: Kessler Screening Scale for Psychological Distress

GAD-7: Generalized Anxiety Disorder-7

exclusively for people with StD (Miralles et al., 2020). The SPSRS application is the first smartphone app that has proven to be effective in RCTs by targeting only those suffering from StD. As such, the SPSRS application may be a promising approach for improving depressive symptoms in people with StD compared with the existing applications for depressive disorders.

The difference in mean changes in K-6 and GAD-7 scores between the experimental group and the wait list control group was not significant. However, a small ES was observed between the two groups with a K-6 score (−0.29) and GAD-7 score (−0.40). This result is comparable with the ES values for anxiety symptoms and psychological distress reported in RCTs of CBT conducted with people with StD (Imamura et al., 2014; Mullin et al., 2015; Proudfoot et al., 2013). Therefore, SPSRS applications may be able to alleviate anxiety symptoms and psychological

Table 3

Results of effect size analysis between groups.

Variable	Experimental (n = 16) Mean ± SD	Wait list control (n = 16) Mean ± SD	pre-ES Hedge's g	post-ES Hedge's g	adjusted ES Hedge's g
CES-D					
Pre	20.00 ± 4.18	18.44 ± 3.52			
Post	14.44 ± 5.23	15.75 ± 4.85			
K-6					
Pre	3.81 ± 3.51	3.13 ± 3.52	0.19	−0.10	−0.29
Post	2.00 ± 2.25	2.25 ± 2.70			
GAD-7					
Pre	3.56 ± 2.34	3.94 ± 3.55	−0.12	−0.52	−0.40
Post	2.00 ± 3.39	3.69 ± 2.92			

ES: Effect Size

CES-D: Center for Epidemiologic Studies Depression Scale

K-6: Kessler Screening Scale for Psychological Distress

GAD-7: Generalized Anxiety Disorder-7

distress in people with StD to the same extent as CBT. In addition, the data support the need for intervention of various mental states (i.e., anxiety and psychological distress) present in StD prior to the onset of MDD. The likelihood that the SPSRS application is associated with the reduction of anxiety and psychological distress in people with StD may provide hope for the prevention potential of the SPSRS application intervention. Specifically, the categorical predictors of MDD onset in StD are anxiety symptoms in addition to depressive symptoms, as indicated by findings from previous study (Bot, Pouwer, Ormel, Slaets, & de Jonge, 2010). These findings highlight the clinical importance of anxiety symptoms and psychological distress in StD, and emphasize the potential of early intervention in modifying the course of the disease and preventing the development of MDD. Addressing anxiety symptoms and psychological distress may be another promising method for improving StD or preventing MDD. However, the results should be interpreted with caution due to the inherent inaccuracy of small data samples.

In the future, large-scale clinical efficacy trials based on the calculated sample size (58 people per group or 116 people in total) are required to determine the effect of the SPSRS application intervention on depression, anxiety, and psychological distress in people with StD. Therefore, further consideration of the measures for recruiting a large number of calculated participants will be an important step for the success of a full-scale RCT. By selecting collaborative research designs with other institutions, using opt-out technology, and providing incentives, the recruitment rate could be improved (Briel, Speich, von Elm, & Gloy, 2019; Brueton et al., 2013; Junghans, Feder, Hemingway, Timmis, & Jones, 2005). In addition, making the SPSRS application available on other smartphones (such as Android) in addition to the iPhone (iOS 9.1 or greater) may improve the recruitment rate.

The majority of the participants assigned to the experimental group did not achieve the 5-week video viewing time set, and adherence rate was low. Low treatment adherence can affect the effectiveness of SPSRS applications. Therefore, future research should improve the low adherence rate of the SPSRS application intervention. Based on the experience of a previous feasibility study that demonstrated a low adherence rate (50%) for the SPSRS application (Takahashi, Takada, & Hirao, 2019), this subsequent study sent a text message once a day to the experimental group with the objective of increasing the adherence rate of the SPSRS application. However, the adherence rate was 31%. Thus, the effort to increase the adherence rate of the SPSRS application was ineffective. This result contradicts the findings of studies that reported the benefits of text messages on treatment adherence (Finitis, Pellowski, & Johnson, 2014; Lester et al., 2010; Pop-Eleches et al., 2011; Wald, Bestwick, Raiman, Brendell, & Wald, 2014). This discrepancy may be explained by the frequency of text messages sent between studies. For example, one study found that interventions that messaged participants more than once a day, due to reasons, such as habituation and response fatigue,

resulted in lower adherence rates than interventions that messaged participants several times a week (Finitis et al., 2014). Therefore, future research should consider the optimal frequency of text messages, which is an important aspect that should be evaluated before conducting a full-scale study. In addition, considering the use of reminders (push notifications and phone calls to use the app) other than text messages may further optimize adherence. In previous systematic reviews, almost all apps used some kind of reminder feature to drive adherence rates (Ahmed et al., 2018). Of these, push notifications were used most often (Ahmed et al., 2018). Push notifications notify you even if the app is not running on your smartphone (Van Dantzig, Geleijnse, & Van Halteren, 2013). As such, push notifications may encourage user treatment adherence more efficiently than text messages. It has also been suggested that once or twice weekly telephone reminders may also improve adherence rates and reduce participant dropout (Kim & Oh, 2003). Therefore, encouraging the use of SPSRS applications over the phone may also increase adherence rates. In addition, several techniques for behavioral change applied to increase adherence rates in mobile health applications include individual goal setting, self-monitoring of behaviors, and rewards for adherence, which are used in combination (Morrissey, Corbett, Walsh, & Molloy, 2016). Therefore, future research should consider using these techniques for behavioral change and consider additional support to encourage high rates of adherence to the SPSRS application.

5. Limitations

Several limitations should be considered based on the study results. First, the study was small-scale, and the sample size was small. The observed intervention effects should be considered preliminary because data from small samples contain inherent inaccuracies. Future trials should replicate the effectiveness of the SPSRS application intervention for people with StD based on the calculated sample size. Second, the participants were 18 to 24 years old and age-skewed. The generalizability of the current findings is limited across age groups because the current sample is not representative of a diverse population. Third, therapist-participant bias may exist due to the nature of the intervention because therapists and participants could not be blinded. However, the study's hypotheses were masked to reduce potential bias due to the lack of blinding. Furthermore, efforts were made to maintain data quality by providing standardized intervention guidance and uniform text feedback. Fourth, follow-up evaluation is lacking. Therefore, whether the effects of the treatment will persist after the 5-week intervention remains unclear. However, the improvement in depressive symptoms observed in people with StD warrants further testing, including a follow-up evaluation, to investigate the sustained effects of the intervention. Finally, participants had to own an iPhone to use the SPSRS application.

As a result, potential participants with other smartphones (such as the Android) were not invited to the pilot study. This limits the number of participants and could bias the demographic profile of participants. Future research will require the SPSRS application to be compatible with other smartphones (such as Android).

6. Conclusions

The results of the pilot RCT suggested that the SPSRS application has a medium ES against improvement in depressive symptoms in people with StD. Therefore, conducting further trials using the SPSRS application for people with StD is worthwhile. However, strategies for improving the methods of recruiting more participants and increasing the adherence rate of the SPSRS application need to be considered before conducting a full-scale trial in the future. By addressing these issues, recruiting according to the calculated sample size of the study, and conducting full-scale trials with follow-up evaluations, determining whether the SPSRS application improves depressive symptoms and prevents the future development of MDD in people with StD is possible.

CRediT authorship contribution statement

Kaito Kageyama: Conceptualization, Data curation, Investigation, Writing - review & editing. **Yudai Kato:** Conceptualization, Data curation, Investigation, Writing - review & editing. **Takanori Mesaki:** Conceptualization, Data curation, Investigation, Writing - review & editing. **Hiroyuki Uchida:** Conceptualization, Formal analysis, Methodology, Writing - original draft, Writing - review & editing. **Kana Takahashi:** Investigation, Writing - review & editing. **Risako Marume:** Investigation, Writing - review & editing. **Yoshiyuki Sejima:** Investigation, Writing - review & editing. **Kazuki Hirao:** Conceptualization, Formal analysis, Funding acquisition, Methodology, Project administration, Supervision, Writing - original draft, Writing - review & editing.

Declaration of Competing Interest

None of the authors have any conflicts of interest to declare.

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