Safety aid elimination as a brief, preventative intervention for social anxiety: A randomized controlled trial in university students

Honami Arai1,2,3 · Shin-ichi Ishikawa4 · Sho Okawa2 · Kohei Kishida4 · Kristina J. Korte5 · Norman B. Schmidt6

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Abstract

Although there are a variety of treatment options for social anxiety, effective prevention strategies for those with subclinical social anxiety are limited. This study evaluated a single session group formatted prevention program focused on the reduction of safety behaviors in both a proof-of-concept study and a randomized controlled trial (RCT). Participants (N = 59) were non-treatment seeking Japanese university students with high levels of social anxiety. Participants were randomized to either an active treatment focused on identification and elimination of safety behavior or a control group involving the discussion of healthy coping strategies. Both conditions met for 120 min in small groups (4 to 6 participants per group). The preliminary proof-of-concept study as well as the RCT demonstrated high levels of acceptability. Findings from the RCT indicated significant improvement in social anxiety symptoms among those in the active treatment condition at post-treatment, which was maintained at follow-up. In addition, participants in the treatment condition showed significant improvement in levels of depression. The effect size difference in symptoms between conditions was in the large range. The present study provides preliminary support for the efficacy of a newly developed treatment program targeting safety behaviors in students with subclinical social anxiety. The current results also illustrate the promise of a brief, indicated prevention strategy focused on safety behavior among those with subclinical social anxiety.

Keyword Prevention; group intervention; anxiety; social anxiety; safety behavior

Social anxiety disorder (SAD) is characterized by excessive fear and avoidance of social and/or performance situations (APA, 2013). The prevalence rate of SAD is approximately 12%, making it one of the most common psychiatric conditions in the world (Kessler et al., 2012). Social anxiety is a frequently reported problem among college students and is associated with other challenges including elevated rates of depression and substance use (Beidel & Turner, 1998; Pachankis & Goldfreid, 2006). Furthermore, social anxiety, even at the subsyndromal level, can lead to substantial impairment in social, occupational, and familial domains (Merikangas et al., 2002; Davidson et al., 1994; Ruscio, 2010).

Over the last several decades, empirically supported treatments have been developed for anxiety psychopathology including SAD (Chambless & Ollendick, 2001). Cognitive-behavioral therapy (CBT) is one form of treatment that has been shown to be efficacious for anxiety disorders (Mayo-Wilson et al., 2014). Despite the effectiveness of CBT, relatively few individuals obtain access to its treatment due to many barriers, including logistical and financial constraints (Schleider et al., 2019). Furthermore, treatment response is often incomplete and the prevalence of anxiety disorders including SAD remains high (Kessler et al., 2012; Springer et al., 2018), suggesting a need for increased efforts aimed at their prevention.

Brief interventions for youth mental health problems have shown promise in reducing and preventing anxiety (Cardamone-Breen et al., 2018). Given that most adolescents with
significant anxiety problems go without services (Kataoka et al., 2002), brief interventions may serve as helpful alternatives or adjuncts to traditional, multi-session psychotherapy. Brief intervention is more cost-effective (Hazlett-Stevens & Craske, 2008). It may also be more likely to be offered in settings in which resources are scarce or demand is high. Furthermore, stigma related to mental health hinders accessibility and compliance (Kardas et al., 2013); hence, brief treatment offered on campus might be especially useful for students. Korte and Schmidt (2020) developed a single-session, intervention specifically focused on mitigating subclinical social anxiety in college students. This intervention was based on the elimination of safety behavior, that is, strategies used to manage or cope with anxiety. The intervention, “Safety Aid Elimination Intervention” (SAFE), is a one-session, 120 min program targeting safety behaviors. This brief preventative intervention was based on treatment studies that utilize a similar approach of focusing on the identification and elimination of safety behavior among those with clinically significant anxiety (Riccardi et al., 2017; Schmidt et al., 2012).

The utilization of safety behavior is believed to play a key role in accelerating the development and maintenance of anxiety (Salkovskis, 1991). In the context of perceived threat, some individuals may rely on so-called safety behavior to help them manage their anxiety. These strategies often help reduce anxiety in the short term, but they can contribute to increased anxiety by essentially validating erroneous threats and strengthening a biased threat beliefs (Engelhard et al., 2015; Helbig-Lang and Peterman, 2010). Safety signals causes safety behaviors to be increased and maintained (Angelakis & Austin, 2015). Moreover, as the developmental trajectory progresses, an individual may increasingly utilize safety behavior, which further strengthens these fears. Prior work indicates that False Safety Behavior Elimination Therapy (F-SET) is effective when delivered in a group as well as an individual format to patients with anxiety psychopathology (Riccardi et al., 2017; Schmidt et al., 2012).

This prior work led to an adaptation of the protocol to evaluate whether it might also be effective as a preventative intervention for those experiencing subclinical anxiety (Korte & Schmidt, 2020). The rationale for this adaptation is consistent with theory suggesting that the use of safety behavior may play a role in the development of anxiety disorders in those experiencing subclinical levels of anxiety (Deacon & Maack, 2008). Korte and Schmidt (2020) tested the efficacy of SAFE in a randomized controlled trial (RCT) with university students who had elevated anxiety symptoms. Fifty-three participants were randomized to either one session of SAFE or a health-focused control group. Results revealed significant between group differences in the reduction of social anxiety, worry, and levels of impairment in the active intervention group relative to the control group. Furthermore, change in safety aid utilization was a significant mediator of outcomes. Despite the promising findings in this initial trial, SAFE was delivered in an individual format, thereby limiting the potential cost-effectiveness of a group delivered preventative intervention.

The current study is the first study to extend SAFE in the individual format to group format. There is an increasing demand for mental health services and professionals in Japan, especially in educational institutions, and a group intervention offers a more efficient and cost-effective way to provide quality mental health care to a larger number of students (Chiumiento et al., 2017; Rith-Najarian et al., 2019). Moreover, one strength of group formats for intervening with social anxiety is that a group setting necessarily promotes social exposure and interaction (Taube-Schiff et al., 2007). We were interested in determining whether a group-based, single session of SAFE could be effective in reducing students' social anxiety as well as related forms of psychopathology (e.g., depression).

Social anxiety symptoms are relative to a particular culture, and potential cultural differences in the expression of social anxiety are suggested between Eastern countries (e.g., Japan, China, etc.) and Western countries (e.g., US, UK, etc.). For example, a lack of self-expression is considered as sign of social anxiety in Western cultures whereas minimal self-expression is considered to be acceptable in Eastern cultures, where harmony within group is a priority concern (Krieg, Xu, Cicero, Miyamoto, & Krieg, 2019). Although there are cultural differences in expression of social anxiety, a similar CBT program is effective for SAD in both Eastern and Western countries (e.g. Yoshinaga et al., 2016). In addition, similar measures are used as outcome to compare the efficacy of CBT program throughout countries (Yoshinaga et al., 2016). Of note, no prevention program targeting social anxiety has been examined to Japanese population, and the degree to which a prevention program for Japanese population is similarly effective as Western population is unknown.

Based on prior work, we conducted a proof-of-concept (pilot) open trial followed by a randomized controlled trial of SAFE. The proof-of-concept study was designed to evaluate the acceptability of the adapted SAFE protocol in a small cohort of college students with elevated social concerns. It was hypothesized that the protocol would be acceptable (based on low dropouts) and efficacious based on reduction in targeted outcomes (e.g., social anxiety symptoms). This study was followed with a 2 (SAFE vs. heathy coping control group) × 3 (pre, post treatment, and one-month follow-up) randomized study design in college students with elevated social anxiety. The primary aim of this study was to examine whether a group formatted version of SAFE is similarly efficacious relative to the version formatted for individuals. Since CBT for Japanese SAD patients is similarly effective as CBT conducted in Western countries, we hypothesized...
that SAFE would lead to a greater reduction in the primary symptom outcome (social anxiety symptoms) as well as secondary outcomes (depression and social impairment) at a one-week and one-month follow-up compared to control group. Consistent with Korte and Schmidt (2020), we also hypothesized that the changes in safety behavior would mediate the association between the experimental conditions and social anxiety symptoms at follow-up.

**Methods**

**Proof-of-Concept Study**

Before the RCT, we first conducted a pilot study with six students to determine acceptability and provide initial efficacy data. Acceptability was assessed based on drop-out rates as well as using a brief questionnaire rated on a 5-point Likert Scale (Shiraishi & Koshikawa, 2010), assessing participants’ subjective perceptions of the program (e.g., understandability, user-friendliness). In addition, a short battery of self-report measures was completed before and after the program as well as at a one-month follow-up period to assess symptom change. The primary outcome measure was the Japanese version of the Social Interaction Anxiety Scale (SIAS) since it has demonstrated stronger correlations than the Social Phobia Scales (SPS) with other social anxiety scales (Brown et al., 1997; Heimberg et al., 1992). Secondary outcomes were scores on the Japanese version of SPS (Kanai et al., 2004), the Japanese version of Beck Depression Inventory (BDI-II; Kojima et al., 2003), the Japanese version of Sheehan Disability Scale (SDS; Yoshida et al., 2004), and the Japanese version of Subtle Avoidance Frequency Examination (SB; Arai et al., 2015). Study participants were recruited from university classes with the inclusion criteria of (1) students 18 years older, (2) reporting no suicidal ideation nor receiving current pharmacological or psychological treatments. Participants received ¥6000 in compensation, equivalent to $50.00. A total of six people took part in the group program; the participants had a mean age of 25.17 (SD = 5.04) and half of them were women. Consistent with high levels of acceptability, there were no dropouts during the intervention or follow-up. In addition, SAFE was rated positively on the acceptability questionnaire (How well did you understand the program materials?: M = 4.67, Was it worth your time participating in the program?: M = 3.83, Do you think the content of the program is easy to include in your daily life?: M = 3.50, How much did the program burden to you?: M = 3.50, Do you want to continue what you learned in the program?: M = 3.83). Preliminary efficacy data were also consistent with expectation (see Table 1) in indicating reductions in the primary and secondary outcomes.

**Randomized Controlled Trial**

**Participants**

We recruited participants through the psychology department’s undergraduate research pool. Inclusion criteria were (1) students 18 years older, (2) total scores in the Social Interaction Anxiety Scale (SIAS; Kanai et al., 2004) of 40 or higher. While there is no established clinical thresholds for the Japanese version of the SIAS, this cutoff was chosen based on soliciting feedback from Japanese experts (psychiatrists and psychologists) in social We also administered the Mini-International Neuropsychiatric Interview (M.I.N.I.) to ensure that participants did not meet criteria for SAD. Exclusion criteria were (1) reporting suicidal ideation, (2) receiving current pharmacological or psychological treatments. Individuals who signed up for the research study received ¥6000 ($50.00) in compensation.

|        | Pre  | Week 1 | Month 1 | Pre-Week 1 | Pre-Month 1 |
|--------|------|--------|---------|------------|-------------|
| Mean   | SD   | Mean   | SD      | Mean       | SD          |
| SIAS   | 41.00| 11.89  | 36.33   | 11.09      | 28.67       | -4.67       | -7.66       |
| SPS    | 15.17| 11.44  | 16.17   | 10.23      | 9.83        | 5.60        | 1.00        | -5.34       |
| BDI-II | 5.50 | 2.59   | 3.17    | 2.86       | 1.83        | 1.80        | -2.33       | -3.67       |
| SDS    | 9.83 | 5.80   | 5.17    | 2.22       | 4.17        | 2.04        | -4.66       | -5.66       |
| SB     | 76.17| 16.53  | 70.67   | 13.84      | 62.50       | 18.60       | -5.50       | -13.67      |

SIAS = Social Anxiety Interaction Scale, SPS = Social Phobia Scale, BDI-II = Beck Depression Inventory, SDS = Sheehan Disability Scale, SB = Subtle Avoidance Frequency Examination
Study Design

This randomized controlled trial used a parallel-group design. An independent researcher generated random allocation sequences using a computer and stratified randomization by sex. Allocation ratio was 1:1 to SAFE or active control. All procedures performed in studies involving human participants were in accordance with the ethical standards and approved by the institutional review board of the first author (#17,063). The trial was pre-registered in the UMIN clinical trials (UMIN000030875). The recruitment of the trial was started on April 6, 2018 and the follow-up was completed on July 7, 2018 based on completion of prerequisite sample size. Based on a power analysis using the mean reduction of SIAS from pre to one-month follow-up reported by Korte & Schmidt (2020), using G*Power (Faul, Erdfelder, Buchner, & Lang, 2009), the required sample size was calculated as $N = 28$ for a single arm when power $1-\beta$ was 0.90 and type 1 error was 5%. Therefore, we were determined to recruit 30 participants per cell to be adequately powered to evaluate the primary study outcome variable.

Assessment Measures

Primary outcome

The primary outcome was social anxiety symptoms, measured using the total scores of the Japanese version of SIAS which contains 20 items. The SIAS assesses general fears of social interaction. The SIAS has been found to be a reliable measure of social anxiety, exhibiting good convergent and discriminate validity (Brown et al., 1997; Heimberg et al., 1992). The SIAS demonstrated good reliability at baseline ($\alpha = 0.78$), and Month 1 ($\alpha = 0.79$). Internal consistency of the SIAS was 0.86 in the current sample. The partial metric invariance of SIAS in Japanese and European Americans is confirmed in a previous study (Krieg et al., 2019).

Secondary outcomes

The secondary outcomes were scores on the SPS (Kanai et al., 2004), the Japanese version of BDI-II (Kojima et al., 2003), the Japanese version of SDS (Yoshida et al., 2004), and the Japanese version of SB (Arai et al., 2015). The Internal consistency of the SPS, the BDI-II, the SDS, and the SB in the current sample were 0.82, 0.83, 0.79, 0.86 respectively. The configural invariance of SPS in Japanese and European Americans is confirmed in a previous study (Krieg et al., 2019); however, the measurement invariance for BDI-II, SDS, and SB have not been examined.

Acceptability of the intervention

Acceptability was based on relative dropout rates as well as homework compliance rates. The homework compliance rate was calculated by dividing the number of participants who completed the homework sheet by the total number of participants in the group. Dropout rates of CBT in controlled trials for anxiety disorders are typically 5.6–19.0% (Otto et al., 2004). Therefore, we set an acceptable dropout rate threshold of lower than 12%. For safety, we set a threshold of zero severe adverse events for SAFE.

Diagnostic measure

The M.I.N.I. (Sheehan et al., 1998) was used to examine whether the participants fulfilled the diagnostic criteria of SAD. The M.I.N.I. comprises modules for 17 psychiatric diagnoses. We used the module for Social Anxiety Disorder. It consists of four items (G1 to G4) to identify SAD and is a two-case "yes" or "no" questionnaire. Those who answered all four items were considered to be currently suffering from social anxiety disorder.

Procedure

Screening Appointment  Upon arrival, participants first read and signed an informed consent form. Then they were asked to complete a self-report battery of questionnaires. They then completed the M.I.N.I. and additional self-report questionnaires to determine their eligibility. Participants that did not meet the inclusion criteria were debriefed, thanked for their time and dismissed from the study. Those who met inclusion criteria were asked their contact address and the study coordinator contacted them later to adjust the schedule to join the intervention. Eligible participants were randomly assigned to one of the two intervention conditions, either the Safety Aid Fading and Eliminating Intervention (SAFE) condition or the Health Education and Adaptive Living (HEAL) condition. Participants were blinded to the allocation they were assigned.

Intervention Appointment  Participants were provided with materials from the intervention, homework sheets, and extra reading materials. To control for level of participation across experimental conditions, the number of group discussions and the number of writing worksheets were matched in both groups. Both interventions were delivered by the first author, who is a clinical psychologist with training in CBT for anxiety disorders. The first author was trained on the SAFE protocol by the authors of the original SAFE protocol (Korte & Schmidt, 2020). Following completion of the intervention, participants were scheduled for their one-week check-in appointment.

One-Week Check-In Appointment  The researcher sent an e-mail to the participants one day before their one-week...
check-in appointment, to remind them of the appointment time and to bring completed homework forms. Upon arrival, participants were asked to complete the one-week self-report questionnaire battery. The homework forms were collected at the check-in, and participants also had the opportunity to privately discuss with the therapist any questions they had about their homework for the coming week. If a participant needed guidance on their homework, the therapist provided assistance. Time spent with a therapist was kept to a minimum with the typical amount of interaction being under 5 min. The therapist encouraged the participants to continue their homework exercises after one-week post toward one-month follow-up.

One-Month Follow-Up One-month follow-up questionnaires were collected online. The flowchart of the procedure is shown in Fig. 1.

Description of experimental conditions. SAFE active group (Table 2)

SAFE is modeled on the F-SET manual (Schmidt et al., 2012). In F-SET, safety behaviors are conceptualized as behavioral and cognitive coping strategies that an individual engages in to manage anxiety. Although these behaviors may help to relieve anxiety in the short-term, they often exacerbate anxiety in the long-term. F-SET, therefore, outlines an educational and behavioral protocol commonly employed in the treatment of anxiety disorders. The SAFE intervention was designed as a two-hour session to ensure that it would be relatively brief, while also providing enough time to cover the key topics in the F-SET manual. The intervention session is comprised of two parts. The first part focuses on providing psychoeducation on anxiety. A conceptual model of anxiety, which includes all anxiety disorders, is explained. Fear is explained as a memory structure (i.e., a fear structure) that is based on personal history. Participants are also informed of the emotional processing model of anxiety, and they learn to identify their false alarms resulting from various stimuli. The session then transitions to the second part that focuses on safety behavior. Consistent with the F-SET protocol, the participants learn to identify and fade their false safety behavior. For example, a participant reporting avoidance of asking their teachers questions

Fig. 1 Flow chart of the study procedure

| Intervention Group | Homework |
|--------------------|----------|
| Pre SAFE program 120 min | Safety Aid Fading Form |
|                     | Antiphobic Exercises Form |
| Post FU 4 weeks     |                      |

| Control Group |
|---------------|
| Pre HEALTH program 120 min |
| Post FU 4 weeks |
| 1 week |

Table 2 Contents of the SAFE program

| Part 1 | min | Part 2 | min |
|--------|-----|--------|-----|
| 1–1 Cognitive-Behavioral Model of Anxiety 5 2–1 Fading Safety Aids 10 | 10 2–2 Phobic & Antiphobic Attitude |
| 1–2 Emotional Processing Model of Fear 10 | 15 Antiphobic Exercises |
| 1–3 Fear Structures 10 | 15 Homework Forms for post session |
| 1–4 Nature of Safety Aids 15 | 25 | Safety Aid Fading Form |
| Types of Safety Aids Maladaptive nature of safety aids | 25 | Antiphobic Exercises Form |
| 1–5 Identifying Safety Aids Safety Aid Identification Form | Total Duration 120 min |
because of a fear of negative evaluation, might focus on this behavior by first asking a question after class. An individualized plan would then be created that included first asking questions outside of class or on the phone or email and then progressing to asking in class.

Another key component of F-SET is the utilization of antiphobic exercises. Antiphobic exercises are behaviors in direct opposition to the participant’s phobic tendencies (doing the opposite of what they fear). Whereas having a phobic attitude involves avoiding stimuli that may trigger a false fear structure, having an antiphobic attitude involves adopting attitudes and behaviors that are designed to purposefully bring about the feared situation. For example, a person who is afraid of saying something wrong would be instructed to misspeak or give incorrect answers intentionally. To develop an antiphobic attitude, the therapist assisted participants in incorporating antiphobic behaviors as part of their weekly homework.

Manual translation process of the programs

We developed a Japanese version of the SAFE manual that was semantically equivalent to the original by following a translation/back-translation procedure. First, the first author translated the original version into Japanese. Second, Japanese psychologists modified some of the words and phrases in the draft of the Japanese version. Third, two professional translators and a professional proofreader, who did not participate in the Japanese translation, back-translated the modified Japanese version into English. Fourth, the authors of the original manual compared the original and back-translated versions and confirmed that the two versions were essentially equivalent. To carry out SAFE in a group format, the contents of the program manual were converted to PowerPoint slides. We develop the HEAL control program using the same process.

HEAL control group (Table 3)

To control for time and attention with the experimenter across experimental groups, control participants (HEAL) attended a health-focused group lecture. The HEAL manual was developed based on the control program utilized in the previous study (Korte & Schmidt, 2020). Psychoeducation was provided by the same therapist conducting the SAFE group. The control condition took place over one session and lasted for approximately two hours. The intervention session was separated into two parts. The first part focused on the importance and benefits of good nutrition. Participants were asked to recall what they had eaten for breakfast, lunch, and dinner, and they scored the meals according to a nutrition table. The therapist then provided guidelines for achieving healthy diet habits. The second part covered sleep habits, and the therapist discussed how students could monitor and improve sleep habits themselves. After the session, participants were given nutrition and sleep-monitoring forms and instructed to fill in the forms daily for the next week.

Data Analysis

All analyses were done on the intent-to-treat (ITT) sample. The SAFE and HEAL groups were compared at baseline on demographic and clinical outcomes using between-subjects analyses of variance (ANOVs) and chi square analysis.

The first hypothesis was that the SAFE intervention would lead to greater reductions in social anxiety symptoms, depression and social impairment at a one-week and one-month follow-up compared to HEAL intervention. To examine the first hypothesis, we conducted a linear mixed model with a maximum likelihood estimator and calculated an effect size. We first compared a random intercept model and random intercept and slope model, and the best fit was the random intercept and slope model. Therefore, we conducted the linear mixed analysis using a model with a random intercept and slope. We set the group (SAFE, HEAL), time (pre, post, follow-up), and interaction (group by time) as fixed effects. Participants were entered as random effects. The effect size of Hedge’s g and 95% confidence intervals (CI) were calculated for pre to post and pre to follow-up changes on clinical outcomes. The effect size was interpreted to be small (0.20–0.49), medium (0.50–0.79), or large (0.80 and above) (Cohen, 1988). Missing data were handled by the last-observation-carried-forward method. The linear mixed model, the effect size of Hedge’s, and 95% CI were
calculated using STATA 16. The mediation analyses were conducted using Mplus 8.4.

We conducted the structural equation modelling using maximum likelihood estimation to examine the role of safety behavior as mediating differences between social anxiety for the SAFE and HEAL groups. We estimated bias-corrected bootstrapped confidence intervals (CIs) using 5,000 bootstrap samples for indirect effects. The effect was interpreted as significant if the 95% CIs did not include zero.

Results

Baseline characteristics

A total of 127 individuals were recruited to participate in this study. Of the 127 participants, 68 did not enroll in the study. As such, fifty-nine participants were randomized to either the SAFE active group \((n = 26)\) or the HEAL control group \((n = 33)\). A majority of the participants were women with a mean age of 19.82 \((SD = 0.81)\). 10% of the participants met at least one of the four items of the M.I.N.I, but none of the participants meet all criteria for SAD. No participant reported other current or past mental health disorders. There were no significant differences between two conditions in terms of age, \(F(1, 57) = 2.74, p = 0.1\) or gender, \(\chi^2(1) = 0.03, p = 0.87\). In addition, all the baseline clinical characteristics were compared between groups and there were no significant differences in percent meeting for diagnostic status or symptoms: SIAS: \(F(1, 57) = 0.73\), SPS: \(F(1, 57) = 0.01\), BDI: \(F(1, 57) = 0.21\), SAFE: \(F(1, 57) = 0.19\).

The CONSORT diagram of enrollment is shown in Fig. 2.

Fig. 2 CONSORT diagram of the study

Homework compliance, dropout rates and adverse events

Homework completion was generally good with 85% of SAFE group participants completing home practice assignments at week 1. In HEAL, 100% of participants completed home practice assignments at week 1. There were no dropouts in both conditions as well as no adverse events.

Primary and secondary outcomes

The descriptive statistics for primary and secondary outcome measures are shown in Table 4. The interaction (group by time) for each outcome is shown in Table 3. In the primary analyses to examine the SIAS change score, a significant interaction between group and time was found (Fig. 3). The estimates showed the decrease in SIAS score from pre to one-week post in the SAFE group was significantly larger than in the HEAL group. Similarly, the decrease in SIAS score from pre to one-month follow-up in the SAFE group was significantly greater than in the HEAL group suggesting durability of the intervention effects. For the secondary outcome measures, findings for
Each outcome measure are reported in Table 5. There were no significant interactions between group and time in any of the secondary outcome measures. The decrease in BDI-II score from pre to follow-up for SAFE group was greater than in the HEAL group, but it did not reach statistical significance ($p = 0.07$). The pre to follow-up change in SB scores between the SAFE and HEAL groups was also trending but not significant ($p = 0.06$).

**Effect sizes**

Table 6 shows effect sizes (Hedge’s $g$) between pre to one-week post and pre to one month follow-up for each group. For pre to one-week post, the effect size for SIAS and BDI-II were moderate to large in SAFE group while the effect size for all the outcomes were small in HEAL group. For pre to one-month follow-up, the effect sizes for the SIAS, SPS, BDI, and SB in the SAFE group were moderate to large. For the HEAL group, only SPS had a large effect size and effect size of all the other outcomes were small.

**Mediation Analyses**

We also hypothesized that change in safety behavior would mediate the association between intervention conditions...
(SAFE vs. HEAL) and reduction in social anxiety symptoms, as measured by the SIAS. To establish temporal precedence of the mediator, we examined whether safety behavior from pre- to post-treatment mediated the relationship between condition and social anxiety symptom at follow-up assessment by constructing a simplex model with lagged pathways (see supplemental material for the detail) in accordance with Goldsmith, MacKinnon, Chalder, White, Sharpe, & Pickles (2018). In this model, the lagged paths were drawn from SB at pre-assessment to SIAS at post-assessment and SB at post-assessment to SIAS at follow-up assessment. The indirect effect of treatment condition to SIAS at follow-up assessment via SB was calculated by multiplying the path from treatment condition to SB at post-assessment and the path from SB at post-assessment to SIAS at follow-up assessment. Estimate for the indirect effect was 0.071 (95%CI: -0.54  ~ 1.81). Results revealed that the 95% confidence interval of the indirect effect overlapped with zero for SIAS, indicating no mediational effect.

Discussion

This RCT study was designed to examine the feasibility and efficacy of a brief group prevention program for subclinical social anxiety. Despite the brevity of the intervention, significant reductions in social anxiety symptoms were evident one-week following the group session and these reductions appear to be durable up to one month following the intervention. These favorable outcomes in terms of the primary outcome were comparable to the previous study (Korte & Schmidt, 2020) showing significant reductions in SIAS. As we hypothesized, similar effect was observed in a Japanese population. However, Korte and Schmidt did not find one-week group differences, as these were only apparent at one month. One explanation for these differences is that the group format may foster more rapid change in social anxiety than would the individual format. Our group model also incorporated required discussions in a social setting, as well as the implicit social exposure involved in the two-hour group meeting. Previous work has suggested that group interventions for social anxiety helped reduce a sense of isolation and fostered solidarity (Taube- Schiff et al., 2007). The group may help normalize experiences and provide a ready-made social format in which to take risks and break maladaptive habits (Fogarty et al., 2019).

Findings were less consistent with regard to the secondary outcomes. More specifically, there were no statistically significant group differences despite evidence for substantial effect sizes in the SAFE group. For example, within group effect sizes for pre to one-month follow-up was large in SPS, BDI-II, and SB in SAFE group. This level of improvement for the SAFE intervention is comparable to effects seen in more elaborate CBT protocols for social anxiety in Western countries (Goldin et al., 2016) and in Japan (Yoshinaga et al., 2013, 2016). Failure to find condition differences on these measures is partly due to a lack of power as well as partly due to the control condition showing substantial reductions in some measures, particularly the SPS and the BDI-II. Such effects for the control condition may simply be due to expectancy or social desirability (Boot et al., 2013). It is also possible, however, that the active control produced real effects either from the social exposure that was inherent to attending a group or to the content of the HEAL protocol, which includes a variety of healthy lifestyle techniques such as increasing exercise or sleep hygiene, which have been shown to positively affect mood and anxiety (Conn et al., 2011; Craft & Landers, 1998; Petruzzello et al., 1991).

The mediation hypothesis was not supported. Unfortunately, the indirect effect from treatment condition to SIAS at follow-up assessment via SB at post-assessment was not significant and temporal mediation was not supported. Of note, this pattern of effects is consistent with the relative level of change in safety behaviors noted in this group, which generally suggested that these behaviors did not change very rapidly. There was very little change at one-week and more substantial movement at one month. This rate of change is consistent with previous work on safety behaviors. For example, Korte et al. (2018) suggested that it is common for individuals to become more aware of their safety behavior during the process of learning about and eliminating them. These authors suggest that it is not unusual for patients to discover new safety behavior at the beginning stages of treatment. In hindsight, it would have been better to assess safety behaviors after two to three weeks to provide more opportunity for safety aid reduction to take place and still allow for a test of temporal mediation. Thus, safety behavior score at one month follow-up was significantly lower than one-week treatment.

High levels of homework compliance have been cited as a factor influencing the effectiveness of cognitive behavioral therapy (Kazantzis et al., 2016). In the present study, more than 85% of the research participants assigned to the intervention group performed antiphobic exercises in daily situations. However, homework sheets were collected anonymously in this study, it was not possible to confirm the effect of the number of exposures on improvement in social anxiety. In future research, it is necessary to evaluate homework adherence in a more rigorous fashion. The no dropout rate in this trial was consistent with other SAD prevention efforts (9%) (Bijorson et al., 2011) as well as traditional CBT (5.6%-19.0%) (Otto et al., 2004). This result is also consistent with a previous study (Korte & Schmidt, 2020), in which dropout rate was 4%. These results speak to the viability of SAFE in university settings.
Findings from the present study supported a very brief but effective intervention for social anxiety that can be delivered in a group format. A group format version of SAFE has advantage of its cost-effectiveness which contains only one session and can be delivered to a larger number of students relative to interventions that require one on one attention with a therapist. Dissemination of efficacious treatments is a critical challenge as relatively few individuals experiencing psychopathology receive state-of-the-art empirically based treatments (World Health Organization & World Bank, 2011). Indeed, a large number of college students suffering from social anxiety and the majority of adolescents are unable to access to any services (Kataoka, Zhang, & Wells, 2002). While we recognize that such a brief intervention is unlikely to completely address social anxiety issues, from a cost benefit analysis, these findings suggest that many people could receive substantial benefits from even a brief treatment. Therefore, brief, group delivered interventions should be considered in the context of a more comprehensive stepped care model for mental health on college campuses.

As with any study, there are several limitations to consider. First, participants in these studies were highly educated university students. This was by no means a diverse sample, and it is unclear whether the SAFE program would work effectively for youth with less education. Future studies should recruit subclinical participants in other settings, such as community settings, is an important next step. Second, this study only relied on self-report data as primary and secondary outcomes; it would have been preferable to have behavioral outcomes such as a public speaking task (Allen et al., 2016) to get a broader picture of the treatment effects. Third, this study did not include a long-term follow-up. Thus, it is unclear whether symptom reduction would be maintained for a longer duration. Relevant to the brief intervention design, occasional long-term prevention sessions, so-called booster sessions, might be incorporated to enhance efficacy further or reduce the likelihood of relapse of anxiety symptoms (Christensen et al., 2010; Neil & Christensen, 2009). Fourth, in this study, the same implementer conducted the program for both the intervention and control groups. This may have allowed for implementer bias to influence the effectiveness of the programs. In future studies, it is necessary to reduce the bias by separating the implementers for the intervention and control groups and by preparing multiple implementers. Fifth, the measurement invariance for BDI-II, SDS, and SB for Japanese and Western countries have not been confirmed in any previous studies. To gain valid evidence for whether our outcomes are measuring similar concept as the outcomes from Western samples, examination of the measurement invariance is needed.

Because a mental health professional led the SAFE group, it is unclear whether the efficacy of SAFE would differ if lay professionals or educators led the group. Because SAFE is designed as a selected preventative intervention (Feldner et al., 2004) that could be widely implemented, using lay professionals is one method of making such interventions more scalable. Such approaches seem promising as educators have provided school-based CBT in with promising results (Stallard et al., 2014; Teubert & Pinquart, 2011). One advantage of SAFE relative to other CBT approaches is that it is relatively simple and straightforward. In the future work, it would be interesting to evaluate whether non-clinicians can effectively deliver SAFE with minimal training.

In summary, the findings of the current study support the use of a single session group intervention designed to treat subclinical social anxiety. Despite the brevity of the intervention, SAFE shows promise in improving social anxiety symptoms. However, further research is warranted to determine the robustness of the current findings, and explore ways to disseminate this promising intervention.

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**Authors’ contributions** HA designed the study, delivered all psychological treatment sessions, and wrote the manuscript. SI and KK contributed to the management of the research. SI, KK, and NS critically revised the manuscript for intellectual content. SO analyzed the data, and discussed the study results and contributed to the final manuscript. NS contributed to the overall supervision of the study and the development of the conclusions. All authors read and approved the final manuscript.

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**Data availability** Not applicable.

**Code availability** Not applicable.

**Declarations**

**Ethics approval** All procedures performed in studies involving human participants were in accordance with the ethical standards and approved by the institutional review board of the first author (#17063). The trial was pre-registered in the UMIN clinical trials (UMIN000030875).

**Consent to participate** Informed consent was obtained from all individual participants included in the study.

[1] Allen, E. A., Acton, G. C., & Siqueland, R. (2016). A brief, group delivered prevention program for adolescent social anxiety symptoms. Current Psychology, 35(4), 656-666.

[2] Christensen, H., Griffiths, K., & poly, A. (2010). Psychotherapy for social anxiety disorder: A single session approach. Social anxiety and social phobia: From research to practice, 1-9.

[3] Feldner, M. T., Fava, M., & Rush, A. J. (2004). Antidepressant treatment of obsessive-compulsive disorder. Journal of Clinical Psychiatry, 65(1), 28-35.

[4] Neil, S., & Christensen, H. (2009). A brief, group delivered prevention program for adolescent social anxiety symptoms. Current Psychology, 35(4), 656-666.
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References

Allen, A. P., Kennedy, P. J., Dockray, S., Cryan, J. F., Dinan, T. G., & Clarke, G. (2016). The Trier Social Stress Test: Principles and practice. Neurobiology of Stress, 6, 113–126. https://doi.org/10.1016/j.jnsstr.2016.11.001

Angelakis, I., & Austin, J. L. (2015). Maintenance of safety behaviors via response-produced stimuli. Behavior Modification, 39, 932–954. https://doi.org/10.1177/0145445515610314

American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.). American Psychiatric Press.

Arai, H., Aoki, S., Kanai, Y., & Sakano, Y. (2015). Psychometric properties of the Japanese version of the subfile avoidance frequency examination (SAFE-J): Factor structure reliability, and validity in Japanese college students. Japanese J Arch Psych Diagnos Clin Evaluation, 8, 114–125.

Beidel, D. C., & Turner, S. M. (1998). Shy children, phobic adults: Nature and treatment of social phobia. Am Psych Ass. https://doi.org/10.1037/10285-000

Bjornsson, A. S., Bidwell, L. C., Brosse, A. L., Carey, G., Hauser, M., Mackiewicz Sghete, K. L., Schulz-Heik, R. J., Weatherley, D., Erwin, B. A., & Craighhead, W. E. (2011). Cognitive behavioral group therapy versus group psychotherapy for social anxiety disorder among college students: A randomized controlled trial. Depression and Anxiety, 28(11), 1034–1042. https://doi.org/10.1002/dia.20878

Boot, W. R., Simons, D. J., Stothart, C., & Stutts, C. (2013). The Pervasive Problem With Placebos in Psychology: Why Active Control Groups Are Not Sufficient to Rule Out Placebo Effects. Perspectives on Psych Sci: A J Assoc Psych Sci, 8(4), 445–454. https://doi.org/10.1177/1745691613491271

Brown, E. J., Turovsky, J., Heimberg, R. G., Juster, H. R., Brown, T. A., & Barlow, D. H. (1997). Validation of the Social Interaction Anxiety Scale and the Social Phobia Scale across the anxiety disorders. Psych Assess, 9(1), 21–27. https://doi.org/10.1037/10435909.1.21

Cardamone-Breen, M. C., Jorm, A. F., Lawrence, K. A., Rapee, R. M., Mackinnon, A. J., & Yap, M. (2018). A Single-Session, Web-Based Parenting Intervention to Prevent Adolescent Depression and Anxiety Disorders: Randomized Controlled Trial. J Med Int Res, 20(4), e148. https://doi.org/10.2196/jmir.9499

Cohen, J. (1988). Statistical Power Analysis for the Behavioral Sciences (2nd ed.). Routledge. https://doi.org/10.4324/9780203771587

Conn, V. S., Hafdahl, A. R., & Mehr, D. R. (2011). Interventions to increase physical activity among healthy adults: Meta-analysis of outcomes. Am J Public Health, 101(4), 751–758. https://doi.org/10.2105/AJPH.2010.194381

Craft, L. L., & Landers, D. M. (1998). The effect of exercise on clinical depression and depression resulting from mental illness: A meta-analysis. J Sport & Exercise Psych, 20(4), 339–357. https://doi.org/10.1123/jsep.20.4.339

Chambless, D. L., & Ollendick, T. H. (2001). Empirically supported psychological, interventions: Controversies and evidence. Ann Rev Psych, 52, 685–716. https://doi.org/10.1146/annurev.psych.52.1.685

Chiumento, A., Hamdani, S. U., Khan, M. N., Dawson, K., Bryant, R. A., Sijbrandij, M., Nazir, H., Akhtar, P., Masood, A., Wang, D., van Ommeren, M., & Rahman, A. (2017). Evaluating effectiveness and cost-effectiveness of a group psychological intervention using cognitive behavioural strategies for women with common mental disorders in conflict-aﬀected rural Pakistan: Study protocol for a randomised controlled trial. Trials, 18(1), 190. https://doi.org/10.1186/s13063-017-1905-8

Christensen, H., Pallister, E., Smale, S., Hickie, I. B., & Callear, A. L. (2010). Community-based prevention programs for anxiety and depression in youth: A systematic review. J Primary Prevent, 31, 139–170. https://doi.org/10.1007/s10935-010-0214-8

Davidson, J. R., Hughes, D. C., George, L. K., & Blazer, D. G. (1994). The boundary of social phobia Exploring the threshold. Arch Gen Psych, 51(12), 975–983.

Deacon, B., & Maack, D. J. (2008). The effects of safety behaviors on the fear of contamination: An experimental investigation. Behavior Res Therapy, 46(4), 537–547. https://doi.org/10.1016/j.brat.2008.01.010

Engelhard, I. M., van Uijen, S. L., van Seters, N., & Velu, N. (2015). The effects of safety behaviors directed towards a safety cue on perceptions of threat. Behavior Therapy, 46, 604–610. https://doi.org/10.1016/j.beth.2014.12.006

Faul, F., Erdfelder, E., Buchner, A., & Lang, A. G. (2009). Statistical power analyses using G*Power 3: tests for correlation and regression analyses. Behavior Res Methods, 41(4), 1149–1160. https://doi.org/10.3758/BRM.41.4.1149

Feldner, M. T., Zvolensky, M. J., & Schmidt, N. B. (2004). Prevention of anxiety psychopathology: A critical review of the empirical literature. Clin Psych: Sci Practice, 11, 405–424. https://doi.org/10.1093/cips/hip098

Fogarty, C., Hevey, D., & McCarthy, O. (2019). Effectiveness of cognitive behavioural group therapy for social anxiety disorder: Long-term benefits and aftercare. Behavioural and Cognitive Psychotherapy, 47(5), 501–513.

Goldin, P. R., Morrison, A., Jazaieri, H., Brozovich, F., Heimberg, R., & Gross, J. J. (2016). Group CBT versus MBSR for social anxiety disorder: A randomized controlled trial. J Consult Clin Psych, 84(5), 427–437. https://doi.org/10.1037/ccp0000092

Goldsmith, MacKinnon, Chalder, White, Sharpe, & Pickles (2018). Tutorial: The practical application of longitudinal structural equation mediation models in clinical trials. Psychological Methods, 23(2), 191-207. https://doi.org/10.1037/met0000154

Hazlett-Stevens, H., & Craske, M.G. (2008). Brief cognitive-behavioral therapy: Definition and scientific foundations.

Heimberg, R. G., Mueller, G. P., Holt, C. S., Hope, D. A., & Liebowitz, M. R. (1992). Assessment of anxiety in social interaction and being observed by others: The social interaction anxiety scale and the social phobia scale. Behavior Therapy, 23(1), 53–73. https://doi.org/10.1016/S0005-7949(05)80308-9

Helbig-Lang, S., & Petermann, F. (2010). Tolerate or eliminate? A systematic review on the effects of safety behavior across anxiety disorders. Clin Psych: Sci Pract, 17, 218–233.
Kardas, P., Lewek, P., & Matyjaszczyk, M. (2013). Determinants of patient adherence: A review of systematic reviews. *Front Pharmacol, 4*, 91. https://doi.org/10.3389/fphar.2013.00091

Kataoka, S. H., Zhang, L., & Wells, K. B. (2002). Unmet need for insurance status. *Am J Psych, 159*(9), 1548–1555. https://doi.org/10.1176/appi.ajp.159.9.1548

Kanai, Y., Sasagawa, S., Junwen, C., Suzuki, S., Shimada, H., & Sakano, Y. (2004). Development and Validation of the Japanese Version of Social Phobia Scale and Social Interaction Anxiety Scale. *Japanese Psych Med, 44*(11), 841–850.

Kazantzis, N., Whittington, C., Zelencich, L., Kyrios, M., Norton, P. J., & Hofmann, S. G. (2016). Quantity and quality of homework compliance: A meta-analysis of relations with outcome in cognitive behavior therapy. *Behavior Therapy, 47*, 755–772.

Kessler, R. C., Petukhova, M., Sampson, N. A., Zaslavsky, A. M., & Wittchen, H.-U. (2012). Twelve-month and lifetime prevalence and lifetime morbid risk of anxiety and mood disorders in the United States. *Int J Methods Psych Res, 21*(3), 169–184. https://doi.org/10.1020/pdf.mpr.1359

Kojima, M., Furukawa, T. A., Takahashi, H., Kawai, M., Nagaya, T., & Tokudome, S. (2003). Cross-cultural validation of the Beck Depression Inventory-II in Japan. *Psych Res, 110*, 291–299.

Korte, K. J., Norr, A. M., & Schmidt, N. B. (2018). Targeting Safety Behaviors in the Treatment of Anxiety Disorders: A Case Study of False Safety Behavior Elimination Treatment. *Am J Psych, 71*(1), 9–20. https://doi.org/10.1176/appi.ajp.20180001

Korte, J. K., & Schmidt, N. B. (2020). Transdiagnostic preventative intervention for subclinical anxiety: Development and initial validation. *J Psych Res, 126*, 34–42. https://doi.org/10.1016/j.jpsychires.2020.04.001

Krieg, A., Xu, Y., Cicero, D. C., Miyamoto, S., Krieg, H. (2019). Undergraduate Psychology: A Cognitive Account. *Behavioural Psychology, 368–376*. https://doi.org/10.1016/S2215-0366(14)70329-3

Krieg, A. M., Ruscio, A. M. (2010). The latent structure of social anxiety disorder: Consequences of shifting to a dimensional diagnosis. *J Abnormal Psych, 119*(4), 662–671. https://doi.org/10.1037/a0019341

Ruscio, A. M. (2010). The latent structure of social anxiety disorder: Consequences of shifting to a dimensional diagnosis. *J Abnormal Psych, 119*(4), 662–671. https://doi.org/10.1037/a0019341

Salkovskis, P. M. (1991). The importance of behaviour in the maintenance of anxiety and panic: A cognitive account. *Behavioural Psychotherapy, 19*, 6–19. https://doi.org/10.1071/413473700011472

Schleider, J. L., Abel, M. R., & Weisz, J. R. (2019). Do Immediate Gains Predict Long-Term Symptom Change? Findings from a Randomized Trial of a Single-Session Intervention for Youth Anxiety and Depression. *Child Psych Human Develop, 50*(5), 868–881. https://doi.org/10.1007/s10578-019-00889-2

Schmidt, N. B., Bucker, J. D., Woolaway-Bickel, K., Preston, J. L., & Norr, A. (2012). Randomized Controlled Trial of False Safety Behavior Elimination Therapy: A Unified Cognitive Behavioral Treatment for Anxiety Psychopathology. *Behavior Therapy, 43*, 518–532. https://doi.org/10.1016/j.beth.2012.02.004

Sheehan, D. V., Lecrubier, Y., Sheehan, K. H., Amorim, P., Janavs, J., Weiller, E., Hergueta, T., Baker, R., & Dunbar, G. C. (1998). The Mini-International Neuropsychiatric Interview (M.I.N.I.): The development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psych, 59*, 22–33.

Shiraishi, S., & Koshikawa, F. (2010). The effects and issues of mental health interventions for undergraduates. *Bullet Integrated Res Center Educ Practice, Utsunomiya Univ, 33*, 153–160.

Springer, K. S., Levy, H. C., & Tolin, D. F. (2018). Remission in CBT for adult anxiety disorders: A meta-analysis. *Clin Psychol Rev, 61*, 1–8. https://doi.org/10.1016/j.cpr.2018.03.002

Stallard, P., Skryabinia, E., Taylor, G., Phillips, R., Daniels, H., Anderson, R., & Simpson, N. (2014). Classroom-based cognitive behaviour therapy (FRIENDS): A cluster randomised controlled trial to Prevent Anxiety in Children through Education in Schools (PACES). *Lancet Psych, 1*(3), 185–192. https://doi.org/10.1016/S2215-0366(14)70244-5

Taube-Schiff, M., Suvak, M. K., Antony, M. M., Bliing, P. J., & McCabe, R. E. (2007). Group cohesion in cognitive-behavioral group therapy for social phobia. *Behavior Res Therapy, 45*(4), 687–698. https://doi.org/10.1016/j.brat.2006.06.004

Teubert, D., & Pinquart, M. (2011). A meta-analytic review on the prevention of symptoms of anxiety in children and adolescents. *J Anxiety Disorders, 25*(8), 1046–1059.

Yoshida, T., Ohtsubo, T., Tsichida, H., Wada, Y., Kaniijama, K., & Fukui, K. (2004). Development of Sheehan Disability Scale (SDISS) and its reliability and validity. *Japanese J Ringsyo- Seishin-Yakuri, 7*, 1645–1653.

Yoshinaga, N., Ohshima, F., Matsuaki, S., Tenaka, M., Kobayashi, T., Iibu, H., ... Shimizu, E. (2013). A preliminary study of individual cognitive behavior therapy for social anxiety disorder in Japanese clinical settings: A single-arm, uncontrolled trial. *BMC Research Notes, 6*(1), 74. https://doi.org/10.1186/1756-0500-6-74

Yoshinaga, N., Matsuaki, S., Niitsu, T., Sato, Y., Tanaka, M., Iibu, H., Takahashi, R., Ohshiro, K., Ohshima, F., Asano, K., Kobori, O., Yoshimura, K., Hiranow, Y., Sawaguchi, K., Koshizaka, M., Hanaoka, H., Nakagawa, A., Nakazato, M., Iyo, M., & Shimizu, E. (2016). Cognitive Behavioral Therapy for Patients with Social Anxiety Disorder Who Remain Symptomatic following Antidepressant Treatment: A Randomized, Assessor-Blinded. *Controlled Trial, Psych Psychotherapy, 58*(4), 208–217. https://doi.org/10.1007/s11285-015-04422-1

World Health Organization & World Bank. (2011). World report on disability 2011. World Health Organization. https://apps.who.int/iris/handle/10665/44575

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