Evaluation of a Self-Monitoring Intervention to Reduce Safety Behavior in Social Anxiety

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PROTOCOL TITLE:

Text Message Safety Behavior Fading Intervention for Social Anxiety

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	6/10/2021	Change of Participant compensation	Yes
2	8/24/2021	Change in duration of Participant participation in study	Yes

Table of Contents

1.0 Study Summary

Study Title	Safety Behavior Fading Intervention for Social Anxiety
Study Design	Randomized Control Trial
Primary Objective	To investigate the efficacy of a text message based safety behavior fading paradigm.
Secondary Objective(s)	Explore the effect of safety behavior fading on: 1) Levels of emotional disclosure. 2) Reductions in levels of perceived loneliness.
Research Intervention(s)/ Investigational Agent(s)	1) A control condition where participants are asked to participate in healthy behaviors 2) A safety behavior fading condition in which participants receive reminders to change their behavior.
Study Population	Adults aged 18-65
Sample Size	500
Study Duration for individual participants	Approximately 4 hours across a 4 week period.
Study Specific Abbreviations/ Definitions	

2.0 Objectives*

2.1 The current study aims to explore the efficacy of a text message based Safety Behavior Fading Intervention compared to a control intervention.

2.2 We hypothesize that individuals practicing safety behavior fading will exhibit (1) decreased social anxiety symptoms and report (2) increased levels of emotional disclosure, and (3) greater reductions of perceived loneliness compared to the control group.

3.0 Background*

3.1 Safety behaviors are defined as behavioral strategies deemed necessary for preventing or minimizing a feared outcome. Theoretical models suggest that excessive use of safety behaviors may serve a casual and/or maintaining role among a range of psychopathology, including social anxiety disorder (Well et al., 1995), a disorder characterized by an intense fear of being judged or negatively evaluated by others, or rejected in a social or performance situation.. While social anxiety disorder causes both distressing and impairing symptoms, studies have begun to show a link between increased social anxiety and decreased self-disclosure, and resulting decreased feelings of emotional intimacy.

4.0 Study Endpoints*

4.1 N/A

5.0 Study Intervention/Investigational Agent

5.1 Description: Social anxiety safety behavior fading intervention procedures will follow methodology previously used in the Cougle Lab. The safety behavior fading intervention is designed to target a decrease or elimination of five social anxiety safety behaviors that an individual has self-identified that they engage in most frequently and/or to the greatest extent.

Individuals randomly assigned to the safety behavior fading condition will receive instructions to decrease or eliminate their five social anxiety safety behaviors. In addition, they will receive daily reminders via text message to decrease these behaviors, along with a safety behavior monitoring checklist in which the participant indicates the extent to which they decreased and/or eliminated each safety behavior over the previous day. The daily reminder will include the following language: "Hi! This is a friendly reminder to avoid using your checklist behaviors. Please tap the link below to access today's checklist: [link to checklist]."

Individuals randomly assigned to the control condition will receive text messages to encourage fading of "unhealthy behaviors". They will follow the same procedure as the safety behavior fading group.

6.0 Procedures Involved*

6.1 Participants will be recruited through online postings.

Once they sign up, all participants will be asked to provide informed consent before participating in the current study. After consenting, the participant will complete the first battery of self-report measures. If the participant scores a 30 or lower on the SPIN, they will not be eligible to participate

If they score a 30 or above on the SPIN and meet all eligibility criteria, participants will be randomly assigned to one of two experimental conditions: Safety Behavior (SB) Fading Condition or control condition. During this pre-assessment virtual appointment, participants will complete a questionnaire battery assessing related symptoms and concerns, as well as safety behaviors. Participants in the SB fade condition will select five behaviors from their completed Safety Avoidance Frequency Examination (SAFE) that they engage in the most. They will be informed that the researchers are interested

in the extent to which people can engage in these behaviors less than they normally do on a daily basis, for twoweeks. Participants in the "healthy behaviors" group will be told they will be sent a checklist of healthy behaviors.

Participants will also receive instructions regarding how to complete their daily safety behavior monitoring checklist. They will receive 14 checklists via text over the course of the nexttwo weeks (assessment period). Daily checklists will take roughly 5-minutes each.

At the end of four weeks all participants will be sent a second set of questionnaires via email to complete.

6.2 ***Screening:*** *Social Phobia Inventory (SPIN; Connor et al., 2000)*

Pre-assessment virtual appointment components:

Component 1: Self-Report Assessments – Participants will complete a battery of self-report measures that assess relevant constructs. The questionnaires included are:

1. Basic demographic information

2. SCID-II Personality Questionnaire: Avoidant Personality Disorder (AVPD) Items (American Psychiatric Association, 1986)

3. Center for Epidemiologic Studies Depression Scale (CESD; Radloff, 1977)

4. Self-Disclosure Index (SDI; Miller et al., 1983)

5. Emotional Self-Disclosure Scale (ESDS; Snell et al., 1988)

6. UCLA Loneliness Scale (ULS; Hays & Dimatteo, 1987)

7. Subtle Avoidance Frequency Examination (SAFE; Cuming et al., 2009)

8.Social Phobia Inventory (SPIN; Connor et al., 2000)

Component 2: Treatment rationale. Participants wil receive the following treatment rationale:

Safety Behavior: Safety behaviors are behaviors we use to make us feel less anxious and prevent bad things from happening. For example, when in a social situation, some people might hide their faces so others won't see them blush, or they may seek reassurance from others about things they said or how they look. Safety behaviors can be problematic because when we use them, we are never able to see that the outcome we fear doesn't come true. We say to ourselves, "the reason nothing bad happened is because I got reassurance from others, I spoke softly, I didn't draw attention to myself…" or used other safety behaviors. Safety behaviors can become a crutch and make you feel less confident in social situations. Research has found that dropping safety behaviors can help reduce anxiety.

Unhealthy Behaviors: Social anxiety like many other problems can keep us from taking care of ourselves. Engaging in unhealthy behaviors can make us feel even worse, and more anxious. For example, if people don't sleep or eat enough, they might tend to be tired and feel like they are less able to handle their anxiety. This can create a cycle where we engage in unhealthy behaviors because of our anxiety and then that can make our anxiety worse and then engage in more unhealthy behaviors as a result. Also, spending too much time on social media or not moving around enough might lower your confidence and make it harder for you in social situations. Research has found that decreasing certain unhealthy behaviors can make you more confident and help improve mood and anxiety.

They will then complete the Credibility/Expectancy Questionnaire (CEQ; Devilly & Borkovec, 2000).

twp-week assessment period:

Component 3: Safety Behavior Checklist (completed daily)

Post-treatment:

Component 4: Self-Report Assessments – Participants will complete a battery of self-report measures that assess relevant constructs. This battery will include all items from Component 1.

Component 7: Debriefing – All participants will be informed of the actual, full study purpose.

One month follow-up:

Component 8: Self-Report Assessments – Participants will complete a battery of self-report measures that assess relevant constructs. This battery will include all items from Component 1

6.3 The potential risks associated with participation in this study appear to be minimal (see below). Nevertheless, precautions will be taken to minimize participants' risk in the proposed study. All individuals will be informed of the nature of the investigation and the types of assessments and procedures. Participants will asked to sign an informed consent statement prior to participating in the project. Several safeguards for maintaining participant confidentiality will also be in place (see below). In addition, referrals to appropriate clinical services (e.g. FSU Psychology Clinic) will be provided for any participants seeking treatment.

7.0 Data and Specimen Banking*

7.1 Data will be stored in de-identified databases in password protected files on encrypted computers.

7.2 Results from questionnaires and surveys will be stored.

7.3 Data will not be released.

8.0 Sharing of Results with Subjects*

8.1 Individual results will not be shared with participants. Participants will be able to read resulting journal articles as they are published.

9.0 Study Timelines*

9.1 The total duration of an individual subject's participation in the study is 6 weeks. This will include an initial questionnaire battery , four week manipulation assessment period, and the post-treatment questionnaire's and one month follow up. We predict that it will take roughly 12-18 months to enroll all study subjects.

10.0 Subject Population*

10.1 Adults aged 18-65 recruited from across the United States

10.2 Inclusion Criteria: The primary inclusion criteria for this study will be elevated social anxiety symptoms as defined by a score of 30 or higher on the SPIN. The only software/hardware requirements are that participants have access to a smartphone or computer that is connected to the internet.

Exclusion Criteria: 1) Score of 29 or lower on the SPIN, 2) Currently receiving treatment (therapy, counseling, etc.) for anxiety or depression, 3) If applicable, unstable psychiatric medication usage any time over the past 4 weeks.

10.3 We will not include: Adults unable to consent, Individuals who are not yet adults (infants, children, teenagers), Pregnant women, or Prisoners.

11.0 Vulnerable Populations*

11.1 N/A

12.0 Local Number of Subjects

12.1 500

13.0 Recruitment Methods

13.1 Participants will be recruited from across the United States through posting on internet websites such as Craigslist, Facebook, Reddit etc. Participants will be asked to sign consent before completing the SPIN and other screening questions.

13.2 Participants will be recruited from across the United States.

13.3 Participants who score at or above a 30 on the SPIN be invited to participate in the current study and provided with their questionnaire battery.

13.4 Potentially eligible participants will be contacted via email, with the initial questionnaire battery.

13.5 Participants will be entered into a raffle for 10 $20 Amazon gift cards when they complete the post treatment assessment and will receive an additional entry into the raffle if they complete the one month follow up assessments. Raffles will occur at the end of 12 months of study enrollment. We anticipate participants will have 1 in 10 chance or greater of receiving a gift card. Participants email addresses will be retained until that time to deliver the gift cards. No other identifying information will be retained for this purpose.

14.0 Withdrawal of Subjects*

14.1 Participants will be withdrawn if there are circumstances that severely compromise the integrity of their data such as experimenter error, or if they do not meet eligibility criteria.

14.2 Participants are allowed to withdraw from participation in the study at any point, and data collection will stop at that point. Participants will be consults as to whether or not they want their data removed from the final dataset.

15.0 Risks to Subjects*

15.1 Risks to human subjects in the present study are believed to be minimal. Nevertheless, precautions will be taken to minimize participants' risk in the proposed study. All individuals will be informed of the general nature of the investigation and the types of assessments and procedures. Participants will be given an opportunity to have any questions answered to their satisfaction and then will be asked to sign an informed consent statement prior to participating in the project. The specific potential risks involved in the proposed investigation are enumerated below.

There are two main areas of risk:

1) <u>Self-report Measures:</u> Some participants may be hesitant to record their social anxiety and/or depressive symptoms on assessment forms. It is possible that questionnaires relating to social anxiety, depression, and perceived loneliness could lead to emotional discomfort for some participants.

2) <u>Confidentality:</u> We will be collecting information about the participant that could cause social and psychological risk if released inappropriately.

The above areas of risk will be minimized by the following procedures:

1) Participants will be made aware that they are free to omit questions they feel uncomfortable answering and are free to terminate their participation at any time during the study without penalty. While some participants may be hesitant to answer the assessment forms, others may derive benefit from the self-assessment as it could increase their awareness of the relationship between their symptoms and environmental, cognitive, and interpersonal factors. Participants will be encouraged to contact study staff at any point during the study if they have questions or concerns. Referrals to appropriate clinical services (e.g., FSU Psychology Clinic, the Anxiety and Behavioral Health Clinic) will be provided for any participants seeking treatment. All research staff will be trained to deal with sensitive clinical issues and will be available during the assessment process should participants need assistance.

2) Breach of confidentiality is highly unlikely. Researchers will emphasize that information obtained during the study is confidential and will be used solely by research staff for research purposes. No data form will ever have a participant's name on it. All records will be kept in locked files and secure servers and it will only be available to the necessary research personnel who know about human participant protection guidelines. A cross index of identity information will be kept in a separate location. In addition, all data will contain only a codified Identification Code, all assessment procedures will be closely supervised, and staff will be trained and reminded of the need to keep all information confidential. No names will be used in presenting the data in lectures, seminars, and papers. No individual responses will be reported in any publications. Information will be released only with the written consent of the participant. Having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues will minimize potential risk of loss of confidentiality. All information will be treated as confidential material and will be available only to research and clinical staff. The Key-file associating Identification Codes with identifying information will be destroyed once data collection is complete. We have used this approach with hundreds of participants in the past and have never had any problems with a breach of confidentiality.

16.0 Potential Benefits to Subjects*

16.1 A direct benefit to participants is that they will be entered in a raffle for 10 $20 gift cards. We anticipate participants will have 1 in 10 chance or greater of receiving a gift card.

Based on previous research, we anticipate, the safety behavior fading group may benefit from the study, as it is possible that reducing safety behaviors may result in reductions in symptoms and an increase in emotional disclosure.

17.0 Data Management* and Confidentiality

17.1 2 X 2 mixed model ANOVAs will be conducted to evaluate the effect of the manipulation on study variables of interest.

17.2 Subjects' names and email addresses will be recorded upon their consenting to participate and used to send participants reminders about appointments. Further, participants in the SB Fade group will receive daily emails/texts during the two assessment weeks to remind them to complete their Behavior Checklist each day. However, no names or direct identifiers will be linked with the data collected over the course of the study. Each participant will be assigned a unique, codified Identification Code that is unrelated to the participants' identifying information. All questionnaires will be labeled using their codified Identification Code. The Key-file associating Identification Codes with participant names, email addresses, and phone numbers will be kept by the principal investigator separate from all other study data and consent forms in a secured file. Email addresses are needed in order to send links to and reminders for the online appointments. Phone numbers are needed in order to send daily text message reminders to participants in the SB Fade condition. If an individual is unable or unwilling to supply their phone number, daily reminders will be sent to their email address. All study data will be stored in de-identified databases in password protected files on encrypted computers.

No individual will ever be publicly identified. We will only report results that have been averaged over participants. No records or assessment information will be released to any other person. All identifying information will be deleted after data collection is complete.

Participants will be informed that there are certain situations in which we may break confidentiality. If during the study we learn about child neglect, child or elder abuse, or that someone is a clear, serious, and direct harm to self or others, we may report the information to appropriate authorities, including the police or an emergency medical facility. Such a possibility is therefore explicitly stated in the consent document. All data and paperwork will be protected to the extent provided by law.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

NA

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 To facilitate privacy, participants will be informed that they can decline to answer any questions they do not wish to.

Participants will not have access to responses to any questionnaire from any other participants, nor will future participants have access to the current participant's responses.

19.2 Participants are explained the limits of confidentiality and are told they do not have to answer any questions they do not want to.

19.3 The aforementioned Key-file will contain identifying information (e.g., subject name, contact information) and study Identification Code numbers. This list will be kept separate from all other study data and will be password protected. Only study personnel will be given the password to this Key-file by the PI. All other data will contain Identification Code numbers only—no identifying information will be listed on any other data.

20.0 Compensation for Research-Related Injury

20.1 We do not anticipate any risk of research related injury to our participants.

20.2 NA

21.0 Economic Burden to Subjects

21.1 We do not anticipate that participation in our study will cause any economic burden to our participants.

22.0 Consent Process

22.1 The participant will be given the opportunity to read through the consent form and give signed informed consent if they agree to participate. No data will be collected before consent is obtained.

23.0 Process to Document Consent in Writing

23.1 We will follow "SOP: Written Documentation of Consent (HRP-091)."

24.0 Setting

24.1 Participation will involve completion of questionnaires and computer tasks on their personal computer.

25.0 Resources Available

25.1 Costs of research are estimated to be minimal and will be covered by funds from the Cougle Lab.

- *The research group has had success in the past recruiting student populations for online and in person studies including intervention studies.*
- *The researchers will have access to the research group lab space located on the Florida State University Campus, which will provide the necessary staff, equipment, and materials.*
- *All research personnel will complete the required Human Subjects Training and will be asked to demonstrate competence with the procedures per the standards of the study prior to their involvement. They will receive supervision and training from the graduate student overseeing the project regarding the study protocol, procedures, and their duties. All study personnel will also be trained to deal with sensitive clinical issues and will be available during the assessment process should participants need assistance.*