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

NCT05168020

11/24/2021

Title of the Study: Text Message Behavior Fading Intervention for Social Anxiety

Principal Investigator: Nora E. Mueller, MS

Faculty Advisor: Jesse Cougle, PhD

You are being invited to take part in a research study. Please find below information about this research for you to think about before you decide to take part. Ask us if you have any questions about this information or the research before you decide to take part.

What is this study about?
Researchers at Florida State University are studying human behavior, and are interested in investigating a treatment for people with social anxiety. You are one of 500 persons to take part in this study. If you are eligible, your involvement in the study is expected to last 4 hours over the course of the next 6 weeks.

What will happen during this research?
If you agree to be in this research, we would ask you to complete a total of 3 questionnaire's over the course of 6 weeks(a screening questionnaire, a baseline assessment, a second assessment at the 2 week mark, and a follow-up assessment at the 6 week mark. After you complete this form you will be asked a series of questions, if you qualify for continuing in the study you will complete questionnaires about your mood, behaviors, thoughts, feelings, personality dispositions, and psychiatric symptoms. You will then be randomized into one of two conditions, this will be done by a computer program so you have an equal chance of landing in each condition. You will then be asked to monitor and decrease specific behaviors, which will vary depending on the condition. During the six weeks of the study between visits, you will be asked to monitor or change your routine behaviors for 14 full days; if so, you will be provided with information about the specifics of these behaviors along with examples. You will be provided with daily checklists via text to complete each of the study days (total of 14 checklists). During your second, and follow-up virtual study appointments, everyone will again complete questionnaires about mood, thoughts, etc. If you indicate you are interested, you may be asked to complete additional, optional follow-up appointments for up to the next 12 months which will also involve questionnaires.

We will tell you about any new information that may affect your willingness to continue to take part in this research.

What will you do to protect my privacy?
The results of the study may be published or presented, but no information that may identify you will ever be provided or released in publications or presentations. We will take steps to protect your privacy and confidentiality within the limits of the law. When you enroll in the study, you will be assigned an Identification Code (ID Code) with which all of your questionnaires, audio recording, and study data will be labeled. All of the answers you provide will be identified by your ID Code number, not your name. The link between your name and ID Code will be destroyed following the completion of the study. Surveys completed on the study website will be secure, password-protected and only accessible to study personnel. No records or assessment information will be released to any other persons.

Despite taking steps to protect your privacy or the confidentiality of your identifiable information, we cannot guarantee that your privacy or confidentiality will be protected. For example, if you tell us

something that makes us believe that you or others have been or may be physically harmed, we may need to report that information to the appropriate agencies.

Individuals and organizations responsible for conducting or monitoring this research may be permitted access to and inspect the research records. This includes the Florida State University Institutional Review Board (FSU IRB), which reviewed this study.

If identifiers are removed from your identifiable private information that are collected during this research, that de-identified information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

What are the risks of harms or discomforts associated with this research?
The risks of harms or discomforts associated with the research include feeling uncomfortable describing thoughts and behaviors or engaging in daily behaviors that may different from your normal routine. However, such situations should not be any more distressing than situations commonly experienced in day-to-day life. You may stop participation at any time.

In addition to the risks of these harms or discomforts, this research may have risks of harms or discomforts that are unknown at this time. If in the future we become aware of any additional harms or discomforts that may affect you, we will tell you.

How might I benefit from this research?
Personal benefits you may get from this study include increased awareness of your thoughts, feelings, and behaviors. Participation in this study may also provide an educational benefit, as you will be given the opportunity to develop a better understanding of research methodology and will be providing research with valuable insight.

What is the compensation for the research?
You may earn up to $20 for participating in this study. You will be entered into a raffle for one of ten $20 gift card for completing the post treatment visit and will receive an additional raffle entry if you complete the one month follow up assessment. Raffles will happen once very 12 months. We will keep your email information until the next raffle so we can contact you if you win. We anticipate you will have at least a one in ten chance of winning a gift card.

What will happen if I choose not to participate?
It is your choice to participate or not to participate in this research. Participation is voluntary. Alternatives to participation are completing a research paper instead.

Is my participation voluntary, and can I withdraw?
Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. Your decision whether to participate will not affect your relationship with FSU. There are no penalties if you do not participate.

You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without consequences.

If you withdraw from the study, contact the investigator and the investigator will discuss with you whether you would like to remove your already collected data from the study database.

Can I be removed from the research without my OK?
We may remove you from the research study without your approval. Reasons we would do this include experimenter error, the study is suspended or cancelled, you do not adequately follow study instructions, and ineligibility as determined by the experimenter.

Who do I talk to if I have questions?
If you have questions, concerns, or have experienced a research-related injury, contact the research team at:

Nora Mueller, MS – Doctoral Student
(571) 278-5415
mueller@psy.fsu.edu

Jesse Cougle, PhD - Advisor
(850) 645-8729
cougle@psy.fsu.edu

The Florida State University Institutional Review Board ("IRB") is overseeing this research. The FSU IRB is a group of people who perform official independent review of research studies before studies begin to ensure that the rights and welfare of participants are protected. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Florida State University IRB
2010 Levy Drive, Suite 276
Tallahassee, Florida 32306
850-644-7900
humansubjects@fsu.edu

STATEMENT OF CONSENT
I have read and considered the information presented in this form. I confirm that I understand the purpose of the research and the study procedures. I understand that I may ask questions at any time and can withdraw my participation without prejudice. I have read this consent form. My clicking 'Yes, I consent to participate' below indicates my willingness to participate in this study.

◯ Yes, I consent to participate ◯ No, I do not consent to participate

I agree to be contacted for future research related to this study for up to the next 12 months

◯ Yes ◯ No