Efficacy of an Attention Guidance VR Intervention for Social Anxiety Disorder

Study Protocol

Date: 06/18/2020

Identifiers: NCT03683823 Unique Protocol ID: 2018-04-0011

IRB USE ONLY
Study Number: 2018-04-0011
Approval Date: 06/18/2020
Expires: 06/17/2021
Name of Funding Agency (if applicable): NIMH

Consent for Participation in Research

Title: Efficacy of an attention guidance VR intervention for social anxiety disorder

Introduction

The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research study. The researcher will be able answer any of your questions. Read the information below and ask the researcher about any questions you might have, before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent.

Purpose of the Study

You have been asked to participate in a research study about a treatment for social anxiety disorder (SAD). The purpose of this study is to test the relative effectiveness of different approaches for helping people with SAD.

A description of this study will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

What will you to be asked to do?

- If you choose to participate in the study you will be asked to complete an assessment that consists of questionnaires, a brief clinical interview with a trained graduate student researcher, and a brief speech. This assessment will take approximately 45 minutes in total.
- If you are eligible following the assessment, you will be randomly assigned to one of two intervention groups: (1) Attention Guidance; (2) Standard exposure. The intervention will be conducted by a trained graduate student researcher.

- You will be asked to complete two intervention sessions and a follow-up in the lab. There is an additional follow-up that you will be asked to complete online.
- Your heart rate will be monitored throughout the study

Both interventions involve:

1) A brief standardized psychoeducation module, presented via a 15-minute video recording. This video will explain the intervention, its rationale, and the procedure.
2) You will have 5 minutes to plan and outline a speech based on a provided topic; everyone will receive the same topic and will not be allowed to use an outline during the public speaking exposure trials.
3) You will then give six speeches that are each 3 minutes long on the same topic. All the speeches will be given in the immersive 360º-video environment. Between speeches you will have a 1-minute break and will complete the subjective units of distress scale (SUDS) before and after each speech trial.
4) You will complete steps 2-3 on the second session, with a different speech topic.
5) You will complete the two intervention sessions within a single week.

- Standard exposure involves: only those components described above (1-5).
- Attention guidance involves three additional components: (1) the intervention rationale will include information about the importance of visually attending to the faces of the audience; (2) in addition to being provided a speech topic, you will be given target audience members to focus on during the speech. You will be told that they should look at and focus on the target audience member for the whole speech; (3) between speeches, the researcher will tell participants the percentage of time they were focused on the target face.
- 1 week after you complete the intervention we will ask you to return to the lab to complete a follow-up assessment. This assessment will be similar to the assessment completed before treatment and will last approximately 20 minutes.
- One month after you complete intervention we will ask you to complete an assessment online that will be emailed to you. This assessment will take approximately 10 minutes.

The study is completed in three in-person visits.

Completing the entire study will take approximately 3 ½ hours and will include up to 200 study participants.

At the end of the study, you will be provided with referrals for additional treatment, which may cost money. However, participation in additional treatment is not part of this study.

This is a research study and, therefore, not intended to provide a medical or therapeutic diagnosis or treatment. The intervention provided in the course of this study is not necessarily equivalent to the standard method of prevention, diagnosis, or treatment of a health condition.

Your participation will be video recorded.

What are the risks involved in this study?

There are no foreseeable risks to participating in this study. However, there is a possibility that participating in the study may cause mild to moderate fear, anxiety, or discomfort during assessment and treatment procedures in which you will be asked to complete speeches.

You may experience some motion sickness (i.e. nausea) during virtual reality. This form of motion sickness rarely occurs with the current technological setup being used, is generally brief in duration, and mild in symptoms. A researcher will always be present and should you experience any motion sickness alert a researcher.

If you wish to discuss the information above or any other risks you may experience, you may ask questions now, or call or email the researcher (Michael Telch) listed on the last page of this form. You are not obligated to participate in this study and can leave the study at any time.

What are the possible benefits of this study?

The possible benefits of participation are learning more about social anxiety disorder, and potentially experiencing a reduction in symptoms related to social anxiety disorder. Furthermore, study findings may assist in the development of more potent treatments for social anxiety disorder.

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with The University of Texas at Austin in anyway.

Will there be any compensation?

Participation in the study will involve being entered in a drawing for a $50 prize. The drawing will take place for every 30 participants that enter the study. Your name will be entered once into the drawing for each part of the study you complete (up to 3 times). After 30 people have participated in the study we will randomly draw two names. Your name cannot be drawn twice.

If you are participating in this study through the Psychology 301 subject pool, you will receive credit on SONA based on the time spent participating in the study, up to five hours (the maximum number). Alternatively, to get credit for your class, you may also participate in experiments other than this one, or you could complete a research paper.

What if you are injured because of the study?

If injuries occur as a result of study activity, eligible University students may be treated at the usual level of care with the usual cost for services at the Student Health Center, but the University has no program or plan to provide payment in the event of a medical problem. Continuing medical care and/or hospitalization for research-related injuries will not be provided free of charge nor will financial compensation be available.

How will your privacy and confidentiality be protected if you participate in this research study?

Your privacy and the confidentiality of your data will be protected by the use of de-identified participant numbers. Specifically, all data we collect will be labeled with assigned identification numbers, and will not be attached to any identifying information of the participant. A link between the identification numbers and the participant name will be stored

separately from the data in a secure location (on a secure, password-protected server on a password protected document) and only members of the research team will have access to this information. After data collection is complete, this linking document will be destroyed, and no identifying information of any of the participants will be retained. De-identified data resulting from your participation may be used for future research or be made available to other researchers for research purposes not detailed within this consent form.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. If you endorse suicidal intent during the baseline interview, the assessor is required by law to ensure your safety, which may require them to break confidentiality. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study.

If you choose to participate in this study, you will be video recorded. Any video recordings will be stored securely and only the research team will have access to the recordings. Recordings will be kept for up to five years and then erased.

Whom to contact with questions about the study?

Prior, during or after your participation you can contact the researcher Michael Telch at (512)-967-1074 or send an email to telch@austin.utexas.edu for any questions or if you feel that you have been harmed.

This study has been reviewed and approved by The University Institutional Review Board and the study number is 2018-04-0011.

Whom to contact with questions concerning your rights as a research participant?

For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 471-8871 or email at orsc@uts.cc.utexas.edu.

Participation

If you agree to participate, please use the mouse to sign in the signature box below and click 'submit'. If you would like a copy of the form a researcher will provide you with a hardcopy, or if you would prefer you can have it emailed to you.

Signature

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ I agree to be audio and video recorded.

_____ I do not want to be audio and video recorded.

Follow-up Study

We will also be conducting a follow-up study that will take place at some point in the future (after you have completed the current study). It will involve in-person assessment here in the lab and will include financial compensation. Please indicate below whether you agree to potentially be contacted in the future.

_____ I agree to be contacted in the future.

_____ I do not want to be contacted in the future.