Study Protocol
Attention, Teleconferencing and Social Anxiety

Date: 12/02/2020

Identifiers: NCT04729803
Unique Protocol ID: STUDY00000106

STUDY ELEMENT IDENTIFICATION

6 Study Elements

Click on the check box (or double click and type an "X" if using Google Docs) each procedure included in your study.

A full description of all study procedures should be provided in the Procedures (Details) section below and/or the applicable supplement form.

☐ Bio-specimens	☐ Biometrics	☐ Registry or Repository
☐ Focus Group	☐ Genetic Analysis	☐ Genomic Data Sharing
☐ International Research	☒ Interview/Survey	☐ MRI
☐ Protected Health Information	☐ Observation	☐ Record Review
☐ Sensors (Externally Placed)	☐ Sensors (Inserted)	☒ Video/Audio Recording
☐ X-Ray		

7 Study Intervention

Click on the check box (or double click and type an "X" if using Google Docs) if you will implement any of the following interventions.

A full description of all study interventions should be provided in the Procedures (Details) section below and/or the applicable supplement form.

☒ Behavioral	☐ Device	☐ Drug/Biologic

8 Clinical Trial

Click on the following check box (or double click and type an "X" if using Google Docs) if the research meets the below definition of a clinical trial.

☒ **This study meets the definition of a clinical trial according to clinical trials.gov in that it involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

9 Additional Oversight

Click on the check box (or double click and type an "X" if using Google Docs) each activity that requires oversight from additional UT committees.

☐ **Biohazards, Recombinant DNA, or Gene Transfer**

☐ **Energy introduced to the subject (electrical, magnetic, light)**

☐ **Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos**

☐ **Radiation exposure without direct clinical benefit**

10 Alternatives to Participation in This Study

To input text, click in the light grey area below.

Individuals who do not wish to participate in the study will be able to leave the study at any time. Participants in the research pool have an alternative to completing research for credits (written assignment). Participants who begin Part 2 will be provided with referral resources.

STUDY PROCEDURE DESCRIPTION

11 Procedure Description

Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable:

- Provide a description of all research procedures being performed and when they are performed, in sequential order.
- All research measures/tests that will be used and state if questions or measures are standardized or published (upload copies of all surveys, scripts and data collection forms)
- Secondary data or specimens that will be obtained, how they will be collected, and how they will be used
- Where each activity will take place, the duration of each, and who will perform each activity
- Include time commitment of participants

To input text, click in the light grey area below.

***All activities will be conducted online via Qualtrics and Gorilla.**

R***ecruitment and Eligibility*.** Participants (*N*=2,000*)* will be recruited via a range of online recruitment methods including the research pool, social media, and email. We will recruit both male and female participants regardless of race or ethnicity. Potential participants will complete the study in two stages, all online.

Stage 1 Procedures: Participants will complete a series of questionnaires. Participants will be randomized to one of two groups if they are eligible for the second stage of the study.

Positive Interaction. Participants in this condition will be prompted with a question by audience members who were positive in their interactions with the other audience members.

Negative Interaction. Participants in this condition will be prompted with a question by audience members who were negative in their interactions with the other audience members.

At the end of this stage of the study participants will be able to choose whether they would like to continue to the intervention.

Stage 2 (Intervention) Procedures. Participants may be asked to wait 1-week prior to beginning the intervention. Participants will complete four intervention (i.e. exposure) sessions within two weeks. Participants will sign up for all four sessions at the start of the intervention.

For the first session:

1) Participants will receive a brief standardized psychoeducation module, presented via a video recording. This video will explain the intervention, its rationale, and the procedure.

For each subsequent session:

2) Participants will then complete up to 10 analogue teleconferencing calls, each lasting a maximum of two minutes. During each call participants will be prompted by one of the audience members.
3) Between speeches participants will have a 1-minute break.
4) Participants will complete the subjective units of distress scale (SUDS) before and after each speech trial.

Attention Guidance Condition. The experimental attention guidance condition consists of three unique components: (1) the intervention rationale will include information about the importance of visually attending to the faces of the audience; (2) participants will be given target audience members to focus their gaze on during the their impromptu response. They will be told that they should look at and focus on the target audience member for the whole response.

Standard Exposure Condition. Participants in the standard exposure condition will complete Steps 1-4 above but not receive any of the attention guidance components used in the experimental condition.

Exposure + Attention Control. Participants in the attention control condition will complete steps 1-4 consist of a unique component where participants will be given a central region of the screen (non-audience member) to focus on.

Table 1. Measures and Assessment Schedule

Assessment	Part 1 ~30 min	Part 2: Intervention ~30-45 minutes/session	1-week follow-up ~ 15 min	2-Week Follow-up ~15 min
DEMO	X			
SCID-5-SR	X			
TRT	X			
BAT	X	X	X	X
LSAS	X	X	X	X
PRCA-24	X	X	X	X
SATI	X			X
SUDS	X	X	X	X
EYE-TRACK	X	X	X	X
OPEN	X	X	X	X

Note. DEMO = demographics questionnaire (age, sex, etc.); SCID5-SR = Structured Clinical Interview for DSM-5; TRT = current treatment assessment; BAT = Behavioral Approach Task to assess peak fear, which will consist of giving a three-minute speech to an audience that is different from the audience during the intervention; LSAS = Leibowitz Social Anxiety Scale; PRCA-24 = Personal Report of Communication Apprehension; SATI = Speech Anxiety Thoughts Inventory; SUDS = subjective units of distress scale (e.g. peak fear); EYE-TRACK = Eye tracking data. OPEN = open-ended text boxes where participants can provide their impressions of the study

SUBJECT POPULATION

12 Protected Subject Populations

Click on the check box (or double click and type an "X" if using Google Docs) each population, if they are specifically studied for this research.

☐ Active military personnel	☐ Children	☐ Decisionally impaired adults
☐ Emancipated minors	☐ Fetuses	☐ Individuals with limited English proficiency
☐ Neonates	☐ Pregnant Woman	☐ Prisoners

☒ UT Students ☐ UT or Seton Staff/Employees

13* Research Participant Information

Describe the research population.

**For multiple research populations (e.g., teachers, students, and parents), copy this section as necessary to describe your population.*

a Participant Group Name

To input text, click in the light grey area below.

b Minimum Age

To input text, click in the light grey area below.

18

c Maximum Age

To input text, click in the light grey area below.

75

d Inclusion Criteria

To input text, click in the light grey area below.

Part 1: (1) Age 18-75, (2) fluent in English because the data collection materials have not yet been standardized in other languages, (3) having access to a computer with a webcam and ability to record audio

Part 2: Completed Part 1 + (1) Personal Report of Communication Apprehension > 55; (2) Leibowitz Social Anxiety Scale > 30 *and* Meets DSM-5 Criteria for Social Anxiety Disorder *or* Leibowitz Social Anxiety Scale > 60

e Exclusion Criteria

To input text, click in the light grey area below.

Part 1:
Significant visual impairment precluding the use of the eye tracking equipment

Part 2: Part 1 + Current, or history of bipolar disorder; current, or history of psychosis

f Additional Population Information

To input text, click in the light grey area below.

14 Total Sample Size

To input text, click in the light grey area below.

2,000

15 Sample size rationale

To input text, click in the light grey area below.

To ensure sufficient enrollment and completion of part 2 of the study

SCREENING AND RECRUITMENT

16 Identification and Screening

Click on the check box (or double click and type an "X" if using Google Docs) if true.

☐ **This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:**

1. Oral or written communication with the prospective subject or LAR
2. By accessing records containing identifiable private information or stored identifiable biospecimens.

17 Identification and/or Screening Procedures

Describe the identification and/or screening procedures below.
To input text, click in the light grey area below.

18 Recruitment Overview

Click on the check box (or double click and type an "X" if using Google Docs) all recruitment methods utilized for this research.

☒	E-mail	☐	Flyer
☐	In-Person	☐	Letter
☒	Social Media	☒	Research Pool
☐	Telephone/Text	☐	Snowball Sampling

☒ **Web-post** ☐ **Word of Mouth**

19 **Describe the recruitment process, including where recruitment will take place.**

Describe the recruitment procedures below.
To input text, click in the light grey area below.

Recruitment will take place primarily within UT Austin's research pool, but may also involve recruitment of other participants using different online strategies.

If participants are recruited via the research pool they will be able to sign up for the study via SONA (the undergraduate research pool portal).

If participants are recruited through social media they will be able to click a link in post (no information will be collected about the participant through social media)

If participants are recruited through email they will receive an email containing a link to the survey (no personal data will be collected through their email)

If participants are recruited through web-post they will be able to click a link in post (no information will be collected about the participant through web-posting)

OBTAINING INFORMED CONSENT

20 **Consent Overview**

Click on the check box (or double click and type an "X" if using Google Docs) all applicable items.

☒ **Obtaining Written Informed Consent**

☐ **Requesting a Waiver of Documentation of Informed Consent**

☐ **Requesting a Waiver of Informed Consent**

☐ **Requesting an Alteration of the Required Elements of Informed Consent**

☐ **Obtaining Child Assent**

☐ **Obtain Consent Using a Short Form with a Witness**

21 Consent and Assent Processes

Provide a detailed description of the consent process including who will obtain consent, where, and when consent will occur in such a manner that participants have sufficient time for adequate consideration.

To input text, click in the light grey area below.

Participants completing part 1 will first review the part 1 study procedures and indicate their consent by clicking a check box before starting any study procedures. Participants who opt-in to complete part 2 will first be provided the link to a secure Qualtrics questionnaire containing the ICD, which they will be able to digitally sign. For both ICDs study personnel contact information will be provided if there are additional questions. Copies of the ICDs are attached

22 Consent and Translation

Click on the check box (or double click and type an "X" if using Google Docs) to indicate that consent will be translated.

☐ **The study population will likely include participants whose limited English speaking status requires translation of the consent form.**

Translation Process

Click on the check box (or double click and type an "X" if using Google Docs) that best describes the translation process, either 21 or 22.

23 ☐ **The consent documents will be translated by a certified translator.**

24 ☐ **A non-certified translator will translate the consent documents.**

If selected, complete the next two questions below.

i **Describe the translator's qualifications**

To input text, click in the light grey area below.

ii ☐ **Another individual will confirm that the translation is accurate and appropriate.**

Waiver of Documentation of Informed Consent

To approve a waiver of documentation of informed consent, one of the following options below must be justified by the researcher.

Only complete the sections below if requesting a waiver of documentation of informed consent. *If not requesting a waiver of documentation of consent, skip to 27.*

Please choose one waiver option and provide additional information as prompted. The Office of Research Support and Compliance recommends using Waiver Option 2 in most cases.

25 **Waiver Option 1**

Provide confirmation for the following criteria and follow the additional instructions.

Additional Instructions:
1. Include this choice in the informed consent form.
2. Articulate the destruction process for signed consent forms in the privacy and confidentiality section.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The only record linking the subject and the research would be the consent document.**

b ☐ **The principal risk would be potential harm resulting from a breach of confidentiality.**

c ☐ **Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.**

26 **Waiver Option 2**

Provide confirmation for the following criteria and follow the additional instructions.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The study is minimal risk.**

b ☐ **Written consent would not be required outside the research context.**

27 **Waiver Option 3**

Provide confirmation for the following criteria and provide additional information as requested.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm**

b **Describe the cultural group or community.**

To input text, click in the light grey area below

c ☐ **The research presents no more than minimal risk of harm to subjects.**

d ☐ **There is an appropriate alternative mechanism for documenting that informed consent was obtained.**

e **Describe mechanism for documenting that informed consent was obtained**

To input text, click in the light grey area below

Waiver or Alteration of Informed Consent

To approve a waiver or alteration of informed consent all of the following criteria below must be justified by the researcher.

Only complete the sections below if requesting a waiver of informed consent. *If not requesting a waiver or alteration of consent, skip to 31.*

28 **The research involves no more than minimal risk to the subjects.**

To input text, click in the light grey area below

29 **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

To input text, click in the light grey area below

30 **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining informed consent is required and not just impracticable to obtain consent).**

To input text, click in the light grey area below

31 **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

To input text, click in the light grey area below.

Deception and Debriefing

Only complete the sections below if requesting an alteration of informed consent that involves deceiving research participants. *If this study does not involve deception, skip to 35.*

See IRB Policies and Procedures Section 15 for a description of deception.

Click on the check box (or double click and type an "X" if using Google Docs).

32 ☐ **It is appropriate to provide additional pertinent information to the subject after research activities are complete (e.g., the researcher needed to deceive to subject to the nature of the study).**

33 ☐ **Research participants will have the opportunity to withdrawal their data during the debriefing.**

34 **Describe the nature of deception and why it is necessary to conduct the research.**

To input text, click in the light grey area below.

35 **Describe debriefing procedures.**

To input text, click in the light grey area below.

Participants will be given additional information about the purpose of the study and information about treatment for social anxiety. Participants that are not eligible for or opt-out of the intervention will be debriefed immediately after completing part 1 of the study. If participants complete the intervention component they will be debriefed following the final assessment (week 2 follow-up)

BENEFITS

36 **Benefits to Society**

Describe the scientific and societal benefit(s) below.

To input text, click in the light grey area below.

Findings will contribute to the understanding of the impact of teleconferencing specifically on social anxiety. This may be useful in designing effective intervention efforts to reduce social anxiety around teleconferencing.

Benefits to Participants

Click on the applicable check box (or double click and type an "X" if using Google Docs).

37 ☒ **There is no anticipated direct benefit to participants.**

38 ☐ **There are anticipated benefits to participants.**

39 **If applicable, describe the potential direct benefits to participants.**

To input text, click in the light grey area below.

RISKS

40 **Describe the risks associated with each activity in this research**

To input text, click in the light grey area below.

The research includes some risk of emotional discomfort.

41 **Describe how each risk is mitigated/minimized.**

To input text, click in the light grey area below.

The emotional discomfort will be related to perceived social interactions and is transient. Participants will be able to stop the study at any point (simply by closing their browser window). At any point during the study participants will be able to reach out to the researchers to discuss any emotional discomfort should it be persistent. At the end of the study participants will be debriefed and learn that the interaction was not live, which should mitigate any further discomfort. Furthermore, participants will be provided with referral resources at the end of the study.

Data Safety Monitoring

For additional information regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.

Click on the check box (or double click and type an "X" if using Google Docs).

42 ☒ **This study is minimal risk and does not require a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB).**

43 ☐ **This study does not have a Data Safety Monitoring Board, but researchers have an internal plan/policy to monitor for safety.**

Complete Data Safety Monitoring Details (44-51).

44 ☐ **This study has a Data Safety Monitoring Board (DSMB).**

Complete Data Safety Monitoring Details (44-51) or upload this study's Data Safety Monitoring Board's charter.

Data Safety Monitoring (Details)

45 **How is safety information collected?**

To input text, click in the light grey area below.

46 **When will safety data collection start (for each participant or for the whole study, as applicable)?**

To input text, click in the light grey area below.

47 **How frequently will safety data be collected?**

To input text, click in the light grey area below.

48 **Who will review the data for safety?**

To input text, click in the light grey area below.

49 **How frequently will data be monitored for safety concerns?**

To input text, click in the light grey area below.

50 **What data will be reviewed?**

To input text, click in the light grey area below.

51 **State the frequency or periodicity of the review of cumulative data?**

To input text, click in the light grey area below.

52 **State any conditions that would trigger an immediate suspension of the research.**

To input text, click in the light grey area below.

Early Withdrawal

Only complete this section if there are planned conditions under which a participant will be withdrawn from the study. *If not applicable, skip to 56.*

Include this information in your consent form.

53 **List the criteria for withdrawing individual participants from the study (e.g., safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).**

To input text, click in the light grey area below.

54 **Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.**

To input text, click in the light grey area below.

55 **Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.**

To input text, click in the light grey area below.

REQUIRED DISCLOSURES

Required Consent Disclosures

Identify each element below that may require additional information to be disclosed in the consent form.

Click on the check box (or double click and type an "X" if using Google Docs).

56 ☐ **It is reasonable that researchers could discover or suspect child or elder abuse.**

57 ☐ **It is reasonable that researchers could learn of an incident that could require reporting under Title IX.**

58 ☐ **It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition.**

59 **Articulate methods for addressing and reporting incidental findings, if applicable.**

To input text, click in the light grey area below.

PRIVACY AND CONFIDENTIALITY

60 **Privacy**

Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants.

Describe methods to ensure participants' privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.

To input text, click in the light grey area below.

All data associated with the project will be kept strictly confidential. Except for the questionnaires that are completed during participant screening, all data will be de-identified with a generated ID number. Audio data will be accessed only by researchers directly involved in the project. To further protect subjects' privacy, all data will be paperless with all data being encrypted and stored securely on Qualtrics, Gorilla, and UT Box. Only members of the research team will have access to the project's data. Publications resulting from the research will not include any personally identifiable information

Confidentiality and Data Security Plan

Click on the check box (or double click and type an "X" if using Google Docs) that best describes the confidentiality and data security plan and provide additional details regarding how you will protect the confidentiality of data or address confidentiality concerns.

We will use Qualtrics/Gorilla - generated user IDs to protect confidentiality. All potential identifying information will be stored separately and securely on UT Box. All non-identifiable data will be stored in HIPAA secure, encrypted digital files in Qualtrics, Gorilla, and UT Box. Non-identifiable data will be saved indefinitely, whereas files containing identifiable data will be deleted on the date of project completion. Identifiable and non-identifiable information will be stored separately to further protect confidentiality.

61 ☒ **Identifiers will be coded to protect confidentiality.**

61a If true, state how data is coded and where identifiers are stored.

To input text, click in the light grey area below.

Data will be coded using a random number generator in Qualtrics and stored internally within Qualtrics as well as in a single spreadsheet stored separately from the data on UT Box.

62 ☒ **Identifiable data will be destroyed.**

62a If true, describe destruction plan and timeline

To input text, click in the light grey area below.

The document linking identifiers and data will be destroyed at the end of the study. The audio data will only be destroyed following the completion of analyses.

63 ☐ **Identifiable data will not be destroyed.**

63a If true, provide rationale for retaining identifiable data indefinitely.

To input text, click in the light grey area below.

64 **Data Access**

Click on the check box (or double click and type an "X" if using Google Docs) for each group of individuals that will have access to study data.

If you plan on creating a repository, complete the repository form as well.

☒	Study Team Members	☐	External Collaborators	☐	Data coordinating center
☒	Sponsor	☒	Future Sharing with other researchers		

☐ **Others**

Describe below. To input text, click in the light grey area below.

65 **Describe data sharing plan for each group checked above and state whether researchers plan on sharing identifiable, coded, or de-identified data**

To input text, click in the light grey area below.

Study team members and Sponsor will have direct access to UT Box and Qualtrics. Shared data will only include de-identified data.

Certificate of Confidentiality

Click on the check box (or double click and type an "X" if using Google Docs) to identify each element below that may require additional information to be disclosed in the consent form.

If a Certificate of Confidentiality is not applicable for this study, skip to 68.

66 ☐ **The study requires a Certificate of Confidentiality.**

67 ☐ **NIH has issued a Certificate of Confidentiality for this study.**

68 ☐ **A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.**

COMPENSATION AND COSTS

Compensation

Click on the check box (or double click and type an "X" if using Google Docs).

69 ☒ **Subjects receive compensation.**

70 ☐ **Subject will not receive compensation.**

Skip to question 74 if subjects will not receive compensation.

71 **Total Amount of Compensation**

To input text, click in the light grey area below.

Participants will receive course credit proportional with the time spent engaged in study activities (up to 5 credits) if participating through the undergraduate subject pool.

Participants will be entered into a drawing for each part of the study they complete, participants can receive up to $85 if they are drawn for all three parts.

72 **Type of Compensation**

Click on the check box (or double click and type an "X" if using Google Docs) for each form of compensation that will be provided.

☒	Cash	☐	Check	☐	Gift Card
☒	Course Credit	☐	ClinCard	☐	Tango Card
☐	Other				

Describe, To input text, click in the light grey area below.

73 **Proration Schedule**

To input text, click in the light grey area below.

Participants that are participating for course credit will receive .25 credits for every 15 minutes of participation in the study.

Participants not participating for credit will be entered into a different drawing for each part of the study they complete. The drawing for part 1 of the study will be for $10. The drawing for part 2 of the study will be $50. There will be 5 drawings for each part. Participants can receive up to $60 that will be provided digitally through Venmo or Paypal.

74 ☒ **Amount of compensation and its form is reasonable for this population for the activities requested of them.**

75 **Costs**

Click on the check box (or double click and type an "X" if using Google Docs) each applicable item regarding costs.

☒ **Participants will have no costs associated with this study**

☐ **Standard of care procedures contributing to study data**

☐ **Research procedures not associated with standard of care**

☐ **Administration of drugs / devices**

☐ **Study drugs or devices**

☐ **Transportation and parking**

76 **Describe all costs below.**

To input text, click in the light grey area below.