Research Proposal

Efficacy of an Attention Guidance VR Intervention for Social Anxiety Disorder

Study Protocol

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Research Proposal

1. Title

   Efficacy of an attention guidance VR intervention for social anxiety disorder

2. Principal Investigator
   Mikael Rubin, mr52447, Psychology
   Michael Telch, telch, Psychology
   Mary Hayhoe, mmh739, Psychology

3. Purpose

   Social anxiety disorder (SAD) is a prevalent mental health concern with 12% lifetime prevalence[1,2]. SAD rarely remits without treatment[3] and is associated with significant reduction in quality of life[4,5], functional impairment[6], and significant financial burden [7]. Even following treatment, improvements in symptoms are modest, with meta-analyses of empirically supported treatments indicating only moderate effect sizes[8,9] and remission rates that are only approximately 30-40%[10].

   Attentional processes (i.e. how attention is allocated towards salient information) have been implicated in the maintenance of anxiety disorders, including SAD[11]. Among individuals with SAD, there is evidence of heightened avoidance of faces (i.e. threat of negative social evaluation)[12,13-16]. This pattern of avoidance may operate as a maintaining risk factor for SAD[17], and thus a potentially important treatment target.

   The primary aims of this study are two-fold. First, we propose to conduct a pilot randomized clinical trial to assess the efficacy of an attentional redirection treatment augmentation strategy for enhancing the outcome of exposure therapy for SAD. Second, we propose to conduct mediational analyses to examine whether the experimental intervention exerts its effects by reducing face avoidance.

4. Procedures

   See Table 1 (below) for a summary of the visit measures, and Figure 2 (below) for a diagram of the study design. Completion of the entire study is estimated to take approximately 3 ½ hours.

A. <u>Online Prescreen</u>

Participants will complete brief online questionnaires to assess for social anxiety (LSAS and PRPSA). Participants will be invited based on their scores on the LSAS and PRPSA (see Eligibility criteria below).

We will recruit up to 200 participants in order to enroll 80 participants who meet criteria for the study.

VISIT 1

Baseline Assessment (approximately 45 minutes)

Informed Consent: Participants will view a brief video about the purpose, risks, and benefits of the study. They will also be informed that participation is voluntary, and that they can withdraw from the study at any point in time. The researcher will then answer any questions the participant might have about the study and the consent form. Participants will indicate

their willingness to participate by signing a consent form on Qualtrics (see the 'obtaining informed consent' section below for more details). Participants will be able to print a copy of the ICD or will be given a copy by a researcher.

Self-report Questionnaires: Participants will then be seated in front of a computer screen and asked to complete a series of questionnaires (see below for a breakdown of the specific measures).

Interview: One of the researchers (a graduate student in clinical psychology) will use selected modules from the SCID-5 (Structured Clinical Interview for DSM-5) to assess the presence of any of the following DSM-5 mental disorders: alcohol or substance use disorders; bipolar disorder; psychosis; and social anxiety disorder. Suicidal risk will be assessed with the Columbia Suicide Severity Rating Scale (C-SSRS).

Behavioral Approach Task: Participants will be fitted with oculus rift headset and then complete a 3-minute speech on an assigned topic, which will be given while watching the video of an audience filmed with 360º-video that is displayed on the oculus rift. This procedure has been previously used in our prior study (IRB # 2016-08-0025).

Figure 1. A researcher wearing the oculus rift VR headset and standing at the podium

Randomization: Following the baseline assessment, if participants are eligible they will be randomized to one of the two intervention conditions (described below).

Intervention – Session 1 (approximately 1 hour)

Intervention Procedures:

Common Intervention Procedures. All participants will complete two intervention (i.e. exposure) sessions within one week. All exposures will be conducted using the VR equipment with videos of an audience, similar to the BAT described above. The intervention will use a standardized protocol. A similar approach has been used by a several studies investigating experimental behavioral intervention strategies for SAD[18-20]. See below for protocol details:

1) On the first session, participants will receive a brief standardized psychoeducation module, presented via a 15-minute video recording. This video will also explain the intervention, its rationale, and the procedure.
2) Participants will have 5 minutes to plan and outline a speech based on a provided topic; all participants will receive the same topic and will not be allowed to use the outline during the public speaking exposure trials.
3) Participants 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 to a video of audience members. Between speeches participants will have a 1-minute break and will complete the subjective units of distress scale (SUDS) before and after each speech trial.
4) Participants will complete steps 2-3 on the second session, with a different speech topic.
5) Participants will complete the two intervention sessions within a single week.

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) in addition to being provided a speech topic, participants will be given target audience members to focus their gaze on during the speech. They 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.

Standard Exposure Condition. Participants in the standard exposure (i.e. control) condition will complete Steps 1-5 above, but will not receive any of the attention guidance components used in the experimental condition.

VISIT 2

Intervention – Session 2 (approximately 45 minutes)

See intervention procedures described above. All procedures are the same as in session 1 with the exclusion of the psychoeducation component.

Post-treatment Assessment (approximately 20 minutes)

Immediately following the second intervention session participants will complete a series of self-report questionnaires and a behavioral approach task.

VISIT 3

1-week Follow-up Assessment (approximately 20 minutes)

One week after the post-treatment assessment participant will return to the lab and complete self-report questionnaires and a behavioral approach task, as in the post-treatment assessment.

ONLINE FOLLOW-UP

1-month Follow-up Assessment (approximately 10 minutes)

One month after the 1-week assessment, participants will receive a link to a brief survey containing self-report questionnaires.

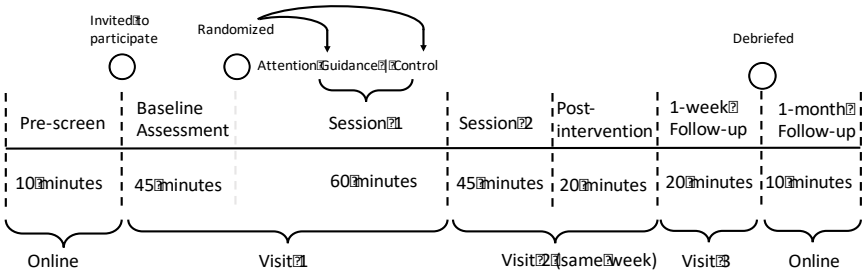

Figure 2. Presents a diagram illustrating the study overview

Additional Follow-up

In-person Follow-up Assessment (approximately 1 hour)

During the consent process participants will have the option to opt-in to be contacted about an additional follow-up session which will consist of an assessment similar to the baseline assessment conducted during Visit 1 of this study. The primary difference is that the assessment include a speech given to a live audience while using a wearable eye tracking device. Participants will complete a separate ICD for this follow-up appointment and will receive financial compensation.

a. Location

Laboratory for the Study of Anxiety Disorders (rooms: 3.112A, 3.112B, 3.112C, 3.112D, 3.112E, 3.112F, 3.122A, 3.122B, 3.122C, 3.122D, 3.122E, 3.122F), and in the Vision, Cognition, and Action Virtual Reality lab (SEA 4.330).)

b. Resources

Dr. Telch's departmental account.

c. Study Timeline

Estimated time for study recruitment is two years, plus one year for data analysis.

Table 1. Assessment Schedule

Assessment	Online Prescreen	Baseline Assessment (Visit 1)	Intervention Session 1 (Visit 1)	Intervention Session 2 (Visit 2)	Post-intervention assessment (Visit 2)	1-Week Follow-up (Visit 3)	1-month Follow-up (Online)
DEMO	X	X					
SCID-5		X					
TRT	X	X					X
C-SSRS		X					
BAT		X			X	X	
LSAS	X	X			X	X	X
PRPSA	X	X			X	X	X
SATI		X				X	X
SUDS		X	X	X	X	X	
EYE-TRACK		X	X	X	X	X	
Heart-Rate		X	X	X	X		

Note. DEMO = demographics questionnaire (age, sex, etc.); SCID-5 = Structured Clinical Interview for DSM-5 Disorders; TRT = current treatment assessment; C-SSRS Columbia Suicide Severity Rating Scale; 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; PRPSA = Personal Report of Public Speaking Anxiety; SATI = Speech Anxiety Thoughts Inventory; SUDS = subjective units of distress scale (e.g. peak fear); EYE-TRACK = Eye tracking data. Heart-Rate = Heart rate data.

5. Measures (see table 1 above for time points at which measures will be given)

Screening and other questionnaires or assessments

Personal Report of Public Speaking Anxiety (PRPSA[21]): The PRPSA is a 34 item scale that assesses public speaking anxiety. It has been well validated as an instrument and has empirically derived cutoffs indicated low, moderate, and high public speaking anxiety.

Speech Anxiety Thought Inventory (SATI[22]): The SATI is a 23-item scale that assesses cognitions associated with public speaking. It has been well validated as an instrument.

Columbia Suicide Severity Rating Scale (C-SSRS[23]): The C-SSRS is an interviewer administered scale assessing suicidal ideation and behavior. It has demonstrated good convergent and divergent validity, and high sensitivity and specificity.

Structured Clinical Interview for DSM-5 (SCID-5[24]): The SCID-5 is a structured clinical interview used to assess DSM-5 diagnoses.

Demographics: Participants will complete a brief demographic questionnaire including age, gender, ethnicity, etc.

Treatment History: Participants will complete a brief questionnaire asking about current and past psychotherapy and pharmacotherapy.

Liebowitz Social Anxiety Scale (LSAS[25]): The Liebowitz Social Anxiety Scale is a 24 item scale that separately measures fear and avoidance behaviors concerning social

interactions and performance situations. It is a commonly used measure of social anxiety, and demonstrates strong psychometric properties.

Subjective Units of Distress (SUDS): Visual Analogue Scales will be used to assess levels of fear, anxiety, self-efficacy, performance, stress, anger, shame, and disgust, before and after each speech.

VR Experiences Questionnaire: A questionnaire assessing the participant's experiences during the VR task.

Autism Spectrum Quotient (AQ-10): A brief 10-item questionnaire assessing a basic likelihood threshold for Autism Spectrum Disorder

Physiological measures

Eye-tracking: Eye tracking data during the orientation and speech (described above) will be collected with the SMI eye tracking hmd upgrade for the oculus rift dk2 system.

Skin Conductance Response: Skin conductance will be collected with the Stens NeXus-4 Wireless Bluetooth Biofeedback system.

Pupil dilation data: Pupil dilation will be assessed using the part of the screen capture data including the eyes of the participants (see below).

Heart Rate: Heart Rate will be measured using the Polar heart rate tracking system.

Other measures

Screen capture data: Screen capture data (of the fixation dot in the virtual environment) will be collected with the GeForce application. This will allow us to check that the eye movements made during the speech are being analyzed correctly by the algorithm that uses the data recorded during eye-tracking. Screen capture data also includes video of the eyes of the participants, which is used to check tracking data when the eyes are closed (e.g. during blinks).

Participants

a. Target Population

Participants will include men and women who are community volunteers and undergraduate students at the University of Texas at Austin ($N = 80$). The expected ethnicity of the sample based on previous studies in this laboratory is Caucasian (74%), Mexican-American (13%), African-American (7%), Asian-American (5%), and Indian-American (1%). During the consent process, all participants will be clearly informed that they can withdraw from the study at any point in time without consequences (e.g., Psychology 301 participants will still receive full credit for their visit). Participants will

complete the study in 3 sessions. We will recruit up to 200 participants to ensure that we have at least 80 participants complete the study.

b. Inclusion/Exclusion

Some of the measures (PRPSA, SCID-5) used in this study have not been validated in a language other than English; therefore, participants not fluent in English will be excluded.

Inclusion Criteria:
(1) Age 18-65 (Online pre-screen & Baseline assessment – self-reported)
(2) Fluent in English (Online pre-screen & Baseline assessment – self-reported)
(3) Personal Report of Public Speaking Anxiety > 98 (Online pre-screen & Baseline assessment – self-reported)
(4) Leibowitz Social Anxiety Scale > 30 (Online pre-screen & Baseline assessment – self-reported)
(5) Peak fear ≥ 50 or average fear ≥ 50 on the behavioral approach task during the baseline assessment (Baseline Assessment – BAT)
(6) Meets DSM-5 Criteria for Social Anxiety Disorder (Baseline assessment – SCID-5).
Exclusion Criteria:
(1) Currently receiving CBT for Social Anxiety Disorder (Online pre-screen self-reported)
(2) Significant visual impairment precluding the use of virtual reality equipment (Online pre-screen self-reported)
(3) Unstable dose of psychotropic medications within 3 weeks prior to baseline assessment (Online pre-screen self-reported)
(4) Current alcohol or substance use disorders (Baseline assessment – SCID-5)
(5) Current, or history of bipolar disorder; current, or history of psychosis (Baseline Assessment – SCID-5)
(6) Serious suicidal risk (Baseline assessment – C-SSRS).
(7) Crosses threshold for likelihood of Autism Spectrum Disorder on the Autism Spectrum Quotient (AQ)

c. Benefits

Although not guaranteed, participants may benefit directly by taking part in the study interventions. Specific potential benefits include: (a) reduction in social anxiety symptoms; and (b) increased knowledge about the nature and causes of social anxiety disorder. There are also indirect benefits to society resulting from the increase in scientific knowledge accrued from the study findings.

d. Risks

1. Participants in either of the active treatment conditions may experience moderate discomfort or increases in distress at the start of the exposure. However, previous research suggests that any symptom exacerbation due to exposure therapy is transient, and does not affect treatment outcome or dropout. Additionally, during the informed

consent process, we will make it clear to participants that they are free to leave the study at any point in time, and, if applicable, they will still receive full course credit proportional to their participation.

2. Participants may report suicidality either during the initial assessment or at any point during the intervention. Those displaying evidence for suicidality during the Visit 1 screening, will be excluded from participation. Enrolled partiicpants displaying evidence suggesting significant suicidal risk will be withdrawn from the study. The IRB-approved suicidality SOP has been uploaded (see the 'suicidality SOP' document). A graduate student in clinical psychology will administer the suicidality assessment. Should significant suicidal ideation/intent be reported they will follow the procedure outlined in the SOP.

3. Earlier applications of VR created a form of vestibular distress sometimes referred to as *Cyber Sickness*. Symptoms may include blurred vision, sweating, eyestrain, salivation, headaches, vertigo, dizziness, nausea, and vomiting. Symptoms are temporary and resolve within a few minutes to a few hours. However, the new VR systems including that used in the current study have markedly reduced risk of motion sickness while using the gear. Each exposure trial to the virtual reality environment is for a short duration (maximum of 5 minutes) making cyber sickness significantly less likely than if the exposure were prolonged. Researchers will be trained to situate the participant comfortably until the symptoms pass in the case of a participant experiencing cyber sickness. Should symptoms persist beyond a few hours the researcher will contact and refer participants to University Health Services. In case of acute distress where the symptoms worsen, the researcher will call 911. Participants will be free to terminate the experiment at any time should they experience any discomfort. In our prior study using the same VR equipment no participants reported significant vestibular distress (IRB # 2016-08-0025).

e. Recruitment

Participants will be recruited through the Psychology 301 subject pool at the University of Texas at Austin and through advertisements in the Austin area.

If participants are in the Psychology 301 subject pool they may complete several questions related to social anxiety as part of SONA. If so they will subsequently be contacted via email (see attached recruitment email) to provide them with an informed consent document regarding the online pre-screen via Qualtrics. They will then be asked to complete some questionnaires. At the end of the questionnaire they will be provided with a link that will take them to a separate questionnaire where they will be asked to provide their name, phone number, and email address so that they can be contacted to schedule an appointment. Participants in the psychology 301 subject pool will also be able to find the Qualtrics link via the SONA posting.

Participants outside the Psychology 301 subject pool will be recruited through flyers and web-based methods (e.g. craigslist, Facebook, our lab website etc.). All

potential participants will be instructed to complete the prescreen or contact us via email. Individuals that are from the Austin community and express interest in participating will be emailed (see attached recruitment email) an online questionnaire via Qualtrics as described above.

Following the online prescreen participants that may be eligible will be invited to the lab for the baseline assessment.

Following the baseline assessment, those who meet the inclusion and do not meet the exclusion criteria for our study will be invited to participate in the remainder of the study.

f. Obtaining Informed Consent

Before completing the online screening, consent will be obtained via an online form. Because the screening will be conducted over the internet, a waiver of signed consent is being requested.

Upon arrival at the lab**,** participants will be greeted by a project staff member and asked to view a video presentation describing the purpose and procedures of the study. Following the video, participants will read the informed consent document on the computer screen (ICD; please see attached) and sign it using a mouse, or their finger (if using an ipad). These ICDs will be stored in Qualtrics online and will not be linked to any of the data collected, they will be stored as an individual, standalone survey. The participants for this study must be capable of understanding the nature of this study as well as the potential risks and benefits. These will be fully explained by the introductory video. The video will also review the ICD, making sure to highlight that the different data that will be collected, and that participation is completely voluntary (the participant is free to withdraw from the study at any point in time with no penalty). Prior to signing the ICD, the experimenter will ask the participant if they have any questions that were not answered by the video or in the form. A copy of the ICD will be provided for the participant. Participants will be able to print a copy of the ICD or request a copy from a researcher.

6. Privacy and Confidentiality

Participants' data will be stored and reported in a de-identified fashion. The rooms in which the face-to-face assessment, computer-based self-report assessments, and intervention will be conducted are private. To facilitate confidentiality of the data, we will utilize computer data entry for all self-report assessments. When participants' complete measures onsite a researcher will always be available.

Confidentiality of the Data or Samples

a. Data Collection

- All participant self-report and treatment related data will be collected using Qualtrics.
- Eye tracking data will be collected with the SMI eye tracking hmd upgrade for the oculus rift dk2 system.
- Skin conductance data will be collected with the Stens NeXus-4 Wireless Bluetooth Biofeedback system.
- The video/audio recording during the speeches will be collected with a digital camera.
- Screen capture data of participant fixations in the virtual reality environment.

b. Data storage and security

The self-report data, ICDs, and the non-SONA prescreen, will be stored on Qualtrics and UTBOX. Qualtrics is a web-based platform designed to create surveys and store data on a secure, password-protected server. Qualtrics meets privacy standards outlined by HIPPA and has received SAS 70 Certification (an internationally-recognized auditing standard which certifies that organizations are using appropriate controls in operations).

Video/audio recordings collected during the speeches will be promptly copied to UTBOX and the recording will be deleted from the device. The device will be kept in a locked cabinet in the LSAD (SEA room 3.112c).

Screen capture data will be stored on UTBOX and an external encrypted hard drive.

All participant data will only be referred to using a subject ID (participant identification number). A tracking form that links the subject ID and participants' name and email will be stored in a separate document on a secured, password protected server.

ICDs will be retained on Qualtrics for at least three years.

c. Data identification

De-identified data will be kept indefinitely. Data in identifiable form (video recordings) and the document linking subject ID with identifiable information will be kept until analyses are complete and then destroyed (by using the 'secure empty trash' function).

d. Data confidentiality

The data collected in non-identifiable form (subject ID) will not contain the participants name or any identifying information. Data in identifiable form (video recordings) will only be available to designated researchers. The only place that information linking the subject ID and identifying information will be kept on is a password protected excel

document located in a secure server that links the subject identifying information with their study ID. Signed consent forms will be stored securely and separately from participant data. Only de-identified data will be shared with other researchers.

After all data has been collected the document linking the data and participants will be destroyed.

e. Data destruction

The linking file will be destroyed as soon as all data has been collected using the "secure empty trash" function which permanently erases data from a computer or electronic storage device.

The video/audio recordings will be destroyed using the 'secure empty trash' function, rendering them unrecoverable.

ICDs and prescreen data (for both eligible and ineligible participants) will be destroyed by deleting the files on Qualtrics which is non-recoverable and from UTBOX by using the "secure empty trash" function which permanently erases data from a computer or electronic storage device.

7. Compensation

Participants from the Psychology 301 subject pool will receive up to four hours of course credit, pro-rated based on their participation, for the Psychology 301 course for participation in this study. 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. The participants name will be entered once into the drawing for each part of the study they complete (up to 3 times). After 30 people have participated in the study two names will be randomly drawn, but a participant can only receive one prize – if their name is drawn twice a name will be drawn again until a different person's name is drawn.

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