Web-based Interpretation Training for Anxiety

Study Protocol & Statistical Analysis Plan

NCT02382003

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Human Research Protection Program
Institutional Review Board for Social & Behavioral Sciences
iProtocol

Current User: **Petz, Kaitlyn (kdp8y)**

Protocol Number: 2703

IRB of Record: UVA

Title: Testing Target Engagement and Effectiveness of Web-based Interpretation Training for Anxiety

Descriptive Title: anxiety; cognitive bias modification; interpretation bias; digital interventions

Previous IRB-SBS Protocol Number: 2013-0331-00

Date Approved: **2020-09-23**

This protocol record was electronically approved on 2020-09-23

This protocol record is currently Approved.

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CITI Training:
2023-01-19 - Conflicts of Interest - Stage 1
2019-01-07 - Conflicts of Interest - Stage 1
2015-01-27 - Conflicts of Interest - Stage 1
2023-02-25 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2014-02-05 - IRB-HSR RESEARCHER BASIC COURSE
2023-02-19 - IRB-HSR RESEARCHER REFRESHER COURSE
2020-02-23 - IRB-HSR RESEARCHER REFRESHER COURSE
2017-03-02 - IRB-HSR RESEARCHER REFRESHER COURSE
2022-05-19 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2016-06-16 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2021-12-04 - Undue Foreign Influence: Risks and Mitigations

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2016-09-09 - Biomedical Responsible Conduct of Research
2020-07-21 - IRB-HSR RESEARCHER BASIC COURSE
2016-09-11 - IRB-HSR RESEARCHER BASIC COURSE
2017-07-13 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2017-07-13 - IRB-SBS RESEARCHER REFRESHER COURSE
2016-09-09 - Social and Behavioral Responsible Conduct of Research

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2017-08-12 - Conflicts of Interest - Stage 1
2023-07-10 - IRB-HSR RESEARCHER BASIC COURSE
2020-04-11 - IRB-HSR RESEARCHER BASIC COURSE
2023-07-10 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2017-07-13 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
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CITI Training:

2020-02-26 - Conflicts of Interest - Stage 1
2020-04-20 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2021-07-20 - IRB-HSR RESEARCHER BASIC COURSE
2018-06-19 - IRB-HSR RESEARCHER BASIC COURSE
2021-07-20 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
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2022-09-05 - IRB-SBS RESEARCHER REFRESHER COURSE
2019-09-12 - IRB-SBS RESEARCHER REFRESHER COURSE
2021-10-26 - Undue Foreign Influence: Risks and Mitigations

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CITI Training:

2010-08-10 - Biomedical Responsible Conduct of Research
2020-10-05 - Conflicts of Interest - Stage 1
2016-09-05 - Conflicts of Interest - Stage 1
2023-01-03 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2021-04-20 - IRB-HSR RESEARCHER BASIC COURSE
2015-08-26 - IRB-HSR RESEARCHER BASIC COURSE
2024-03-28 - IRB-HSR RESEARCHER REFRESHER COURSE
2021-04-20 - IRB-HSR RESEARCHER REFRESHER COURSE
2018-04-18 - IRB-HSR RESEARCHER REFRESHER COURSE
2013-04-12 - IRB-HSR RESEARCHER REFRESHER COURSE
2024-03-28 - IRB-SBS RESEARCHER REFRESHER COURSE
2022-02-14 - Undue Foreign Influence: Risks and Mitigations

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2019-03-06 - Conflicts of Interest - Stage 1
2020-07-07 - IRB-HSR RESEARCHER BASIC COURSE
2020-11-12 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
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2023-09-22 - Conflicts of Interest - Stage 1
2019-03-06 - Conflicts of Interest - Stage 1
2017-02-17 - IRB-HSR RESEARCHER BASIC COURSE
2020-02-19 - IRB-HSR RESEARCHER REFRESHER COURSE
2023-03-06 - IRB-SBS RESEARCHER REFRESHER COURSE
2020-02-19 - IRB-SBS RESEARCHER REFRESHER COURSE
2017-02-17 - Social and Behavioral Responsible Conduct of Research
2022-02-24 - Undue Foreign Influence: Risks and Mitigations

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2017-06-05 - Biomedical Responsible Conduct of Research
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2016-09-04 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2019-09-06 - IRB-SBS RESEARCHER REFRESHER COURSE
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2022-11-23 - Conflicts of Interest - Stage 1
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2021-04-04 - GCP for Social and Behavioral Research Best Practices for Clinical Research - Basic Course
2018-02-03 - GCP for Social and Behavioral Research Best Practices for Clinical Research - Basic Course
2022-11-23 - IRB-HSR RESEARCHER BASIC COURSE
2023-08-10 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2020-08-16 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2017-08-17 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2018-02-03 - Social and Behavioral Responsible Conduct of Research

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CITI Training:
2019-08-30 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2016-09-21 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS

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2020-02-26 - Conflicts of Interest - Stage 1
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2021-02-01 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS

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2020-02-25 - Conflicts of Interest - Stage 1
2021-08-23 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2018-12-13 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2019-01-26 - Social and Behavioral Responsible Conduct of Research

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CITI Training:
2019-02-08 - Biomedical Responsible Conduct of Research
2017-09-07 - Conflicts of Interest - Stage 1
2023-02-23 - GCP FDA Refresher
2021-03-07 - GCP for Clinical Investigations of Devices
2023-03-01 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2017-09-29 - IRB-HSR RESEARCHER BASIC COURSE
2024-03-06 - IRB-HSR RESEARCHER REFRESHER COURSE
2021-01-12 - IRB-HSR RESEARCHER REFRESHER COURSE
2021-01-12 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2017-08-18 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2020-02-04 - Responsible Conduct of Research for Engineers - Basic Course
2019-02-08 - Social and Behavioral Responsible Conduct of Research

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2021-01-06 - IRB-HSR RESEARCHER BASIC COURSE
2018-11-04 - IRB-HSR RESEARCHER BASIC COURSE
2018-11-02 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS

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2020-01-13 - Conflicts of Interest - Stage 1
2015-12-07 - Conflicts of Interest - Stage 1
2022-02-01 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2019-02-17 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2015-12-08 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2021-11-30 - Undue Foreign Influence: Risks and Mitigations

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CITI Training:
2021-08-30 - Conflicts of Interest - Stage 1
2017-07-11 - Conflicts of Interest - Stage 1
2020-01-20 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2017-02-17 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2021-10-06 - Undue Foreign Influence: Risks and Mitigations

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non-UVA Research Team (Sub-Investigators)

non-UVA Engaged Institutions (in the United States)

Use this section for non-UVA Institutions which are located in the United States.

Use the International Research section, farther down this page, for non-UVA Institutions located outside of the United States.

Is more than one institution located in the United States (another university, commercial institution, etc.) engaged in this research proposal? *(required)*

Study Overview

Anticipated end date for collecting data: 2019-01-31

Anticipated end date for analyzing data: 2021-12-31

Is this research funded? Yes

Funding Source(s): Federal government

Supply all Agency Grant Numbers & Titles currently associated with this protocol:

NIMH R34MH106770

Do any of the Funding Sources create a Conflict Of Interest for the Principal Investigator, Faculty Sponsor or Research Tea (Sub-Investigators) listed on this protocol? No

What is the purpose in conducting this research? How does this study contribute to the advancement of knowledge and why is it worth doing?

Approximately half of the U.S. population experiences serious mental health problems during their lifetime, including 29% with anxiety pathology severe enough to qualify for an anxiety disorder diagnosis. Critically, more than two thirds of individuals struggling with a mental illness do not receive treatment. With this level of mental illness burden, it is clear that treating people one-on-one in an office setting will never meet the existing needs. There are many barriers to treatment, including costs, difficulties accessing evidence-based treatments in many regions, and associated stigma. Thus, there is a pressing need to consider alternative, larger scale approaches to delivering mental health services. Cognitive Bias Modification (CBM) interventions hold considerable promise as a way to meet these needs, especially for anxiety difficulties. These computer-based programs are designed to alter biased ways of thinking, such as a tendency toward negative interpretations, which cause and maintain anxiety. Because these programs do not require therapist contact and can be administered on any computer with an Internet connection, CBM holds promise as a cost-effective method that can be disseminated widely. However, while CBM for interpretation bias (CBM-I) has established efficacy when administered in-person in the laboratory, it now needs to be tested with broader populations using a web-based infrastructure to examine: a) whether the program will be effective in a web environment, b) whether the program continues to engage the targeted mechanism (i.e., interpretation bias), c) the feasibility of this delivery method, and d) the modifications needed to adapt the program for the web (in particular, to prime anxiety-linked negative thinking in an online environment, we test the effect of adding a guided anxious imagery exercise to prime feared outcomes prior to each training session).

What will participants do in this study? Please provide an overall summary of the study plan. Where and when it will be conducted? What do you hope to learn from these activities? If the study has more than one phase, clearly map out the different phases. You will be required to describe the study components in more detail in later sections but use this paragraph to help your IRB reviewer to understar the general outline of the study. Other sections in the protocol form can be seen below.

Approximately half of the U.S. population experiences serious mental health problems during their lifetime, including 29% with anxiety pathology severe enough to qualify for an anxiety disorder diagnosis. Critically, more than two thirds of individuals struggling with a mental illness do not receive treatment. With this level of mental illness burden, it is clear that treating people one-on-one in an office setting will never meet the existing needs. There are many barriers to treatment, including costs, difficulties accessing evidence-based treatments in many regions, and associated stigma. Thus, there is a pressing need to consider alternative, larger scale approaches to delivering mental health services. Cognitive Bias Modification (CBM) interventions hold considerable promise as a way to meet these needs, especially for anxiety difficulties. These computer-based programs are designed to alter biased ways of thinking, such as a tendency toward negative interpretations, which cause and maintain anxiety. Because these programs do not

require therapist contact and can be administered on any computer with an Internet connection, CBM holds promise as a cost-effective method that can be disseminated widely. However, while CBM for interpretation bias (CBM-I) has established efficacy when administered in-person in the laboratory, it now needs to be tested with broader populations using a web-based infrastructure to examine: a) whether the program will be effective in a web environment, b) whether the program continues to engage the targeted mechanism (i.e., interpretation bias), c) the feasibility of this delivery method, and d) the modifications needed to adapt the program for the web (in particular, to prime anxiety-linked negative thinking in an online environment, we test the effect of adding a guided anxious imagery exercise to prime feared outcomes prior to each training session).

- Together, the current proposal will develop an infrastructure to pilot test the effectiveness of web-based CBM-I for anxiety symptoms. CBM-I training will target moderate to severe anxiety symptoms, a widespread problem area with considerable occupational and social impairment. Participants will be visitors to Project Implicit Mental Health (PIMH; soon to be renamed Project Implicit Health), an existing website directed by the Principal Investigator that allows visitors to assess their cognitive biases tied to mental health concerns. Consistent with the RFA's priorities, this approach encourages efficiencies by capitalizing on the existing PIMH site and its heavy traffic. Further, the site's large number of visitors and use of automated assessments will make it efficient to assess baseline demographic characteristics and interpretation bias as moderators of CBM-I effects that can be tested in future trials.

- **Aim 1:** Develop and evaluate usability and acceptability of web-based CBM-I for anxiety symptoms. Aim 1 will build the web-based interpretation bias training program using the PIMH infrastructure. We will pilot the program on a small test group of moderate to highly anxious participants (N=15) who will complete questionnaires and semi-structured interviews to provide feedback on the programs' usability and acceptability. Further, an advisory board (N=8) of anxiety researchers, clinicians, and experts in CBM and web-based research will provide feedback on the program and study protocol. Using a "deployment-focused" approach, this feedback from experts and end-users will be used to iteratively modify the program for the trial planned for Aims 2 and 3. Thus, even at this initial pilot stage, we will measure the targeted outcome (anxiety symptoms) and mechanism (interpretation bias) to determine whether modifications to enhance target engagement are needed. Note, within RDoC, this outcome falls under the Potential Threat/Anxiety construct within the Negative Valence System, and the targeted mechanism (interpretation bias) falls under the Response Selection, Inhibition construct within the Cognitive (effortful) control system. Both the outcome and mechanism will be objectively measured using multiple units of analysis (e.g., behavior and self-report). Further, mechanisms underlying the guided anxious imagery prime's effects will be measured by assessing subjective distress, imagery vividness, and activation of feared outcomes following the manipulation. This prime was selected in part because of its potential to be disseminated widely in future trials, given it does not require human contact.

- **Aim 2:** Test target engagement, feasibility and effectiveness of web-based CBM-I.

- **Aim 3:** Evaluate the impact of an anxious prime on web-based CBM-I for anxiety symptoms.

- Aims 2 and 3 will test the feasibility of an 8-session web-based interpretation training program called "MindTrails" among individuals with moderate to severe anxiety symptoms (based on screening at the PIMH site). Participants will be randomly assigned to either active CBM-I (100% positive scenario training) or a 50% positive/50% negative condition, or a no scenario control condition. Half the participants in each of these 3 conditions will receive an anxious imagery prime prior to each training session, and half will receive a neutral imagery prime, resulting in a 3 training condition x 2 prime design. Feasibility will be determined by analyses of recruitment, attrition, acceptance of randomization, adherence to and appropriateness of the measurement model, caseness, extent of missing data, and safety. Additionally, target engagement (change in interpretation bias) and preliminary tests of effectiveness at reducing anxiety symptoms will be evaluated.

- Furthermore, a group of up to 10 participants will be randomly selected to receive the additional benefit of coaching. These participants will be contacted through email and directed to a separate consent form regarding the coaching protocol. The coaching protocol itself will involve a series of brief phone calls and/or Google Voice messaging sessions with the purpose of increasing adherence to the MindTrails program. The coaching contacts will involve discussing goals for login and site use, reinforcing use, and addressing questions about the site's functionality and applicability. This is not therapy by phone and participant disclosure of symptoms will not be required. We will use undergraduate and graduate student-level coaches and will follow an adapted version of the standard training protocol for TeleCoach (with consultation from David Mohr, developer of the intervention). The coaching protocol has already been approved in UVA IRB SBS protocol 2017-0234-00. Including this additional service is expected to help refine the coaching protocol as well as increase adherence to the program.

- **Materials:**

- *Cognitive Bias Modification for Interpretations (CBM-I).* A modification of the paradigm used by Mathews and Mackintosh (2000) involving the ascription of threat meanings to ambiguous scenarios will be used to train interpretation biases. Note that similar procedures have been used in already approved protocols (e.g., Protocol # 2007028100 "Finishing Stories," Protocol # 2009028500 "Heights Fear Reduction," and Protocol # 2011039200 "Finishing Brief Stories").

- Participants will be asked to read about and then imagine themselves in approximately a series of different situations involving ambiguous anxiety-relevant scenarios. At the end of each scenario, participants will be asked to complete a word fragment (which has only one solution) that resolves the meaning of the preceding text in a positive or negative direction, depending on the condition. For example, participants reading a positive interpretation scenario would read, "Your partner asks you to go to an anniversary dinner

that their company is holding. You have not met any of his/her work colleagues before. Getting ready to go, you think that the new people you will meet will find you fr_endly." Participants would then complete the fragment with the word "friendly." For the equivaler negative interpretation scenario, participants would read the same scenario, but the word fragment would be "b_ring," which participants would complete with the word "boring." All participants would then read the same comprehension question, to insure tha they had made the correct interpretation. For the above example, participants would be asked "Were you disliked by your new acquaintances?"

- To maintain participants' interest across sessions (and attain desirable difficulty to enhance learning; see Hertel & Mathews, 2011) we may change the number of missing letters in word fragments (e.g., word fragments may be missing only 1 letter in the first 4 sessions, and 2 letters in the second 4 sessions).

- Depending on condition, participants may either complete all positive versions of the scenarios ("active CBM-I"), half positive/half negative versions of the scenarios ("50/50"), or not complete any training scenarios ("imagery only, no scenarios").

- *Recognition Ratings (modified from Mathews & Mackintosh, 2000).* To measure interpretation bias, participants will read ~9 ambiguous scenarios with titles. After, participants will see the titles of each scenario, followed by 2 disambiguated interpretations of the scenario: 1 positive and 1 negative. Participants will be asked to rate each disambiguated interpretation based on how similar in meaning it is to the original scenario. Depending on available time, participants may also see 2 additional disambiguated interpretations of each scenario that are unrelated to anxiety (labeled "foils") to evaluate specificity of training effects.

- *Brief Body Sensations Interpretation Questionnaire (BBSIQ; Clark et al., 1997).* The BBSIQ is a 14-item version of the Body Sensations Interpretation Questionnaire, which is modified from McNally and Foa's (1987) Interpretation Questionnaire. In the present study, very minor wording modifications were made to make the measure more prototypic of American rather than British English. Participants are presented with ambiguous events and then asked to rank order three alternative explanations for why the event might have occurred. One option is always negative, whereas the other responses are either neutral and/or positive. Half of the items refer to events consistent with the theoretical prediction of a catastrophic misinterpretation of bodily sensations (referred to as 'Panic' items), and the remaining items (referred to as 'External Threat' items) reflect other potentially threatening events (relatec mainly to fears of negative social evaluation). An example of a panic item is, "You notice that your heart is beating quickly and pounding." The three alternative explanations are, "because you have been physically active," "because there is something wrong with your heart," or "because you are feeling excited." Participants rate the extent to which they believe each of the explanations on a 0-8 Likert scale.

- *Imagery Primes.* Participants will be randomly assigned to complete either an anxious imagery prime (where they do a guided imagery exercise imagining an upcoming anxiety-provoking situation to prime feared outcomes) or a neutral control imagery exercise (where they do a guided imagery exercise imagining upcoming mundane tasks, like brushing one's teeth or getting dressed, that is matched for time and simulation of a future event). See Appendix for scripts. The choice to test an anxiety prime as a key modification of lab-based CBM for the web follows results from a recent CBM study of attention training for social anxiety administered on the web, which found that the group instructed to activate social anxiety fears prior to each CBM training session achieved greater anxiety symptom reduction than both a control CBM group and a group doing CBM without the anxiety prime, and even did as well as a full web-based CBT condition. Further, the gains remained at a 4-month follow-up assessment. These results strongly support the argument that one reason some prior CBM (for attention) studies have not shown strong results on the web is due to lack of emotion or bias activation on the web. The choice to use imagery for the prime is based on the ease with which this ca be administered online in an automated way so that it can ultimately be scaled up for broad dissemination. Also, imagery can readily activate feared outcomes (e.g., catastrophic thinking), which is expected to strengthen training as people practice new ways of thinking while the biases are activated.

- *Measuring Impact of Imagery Primes.* Following the anxious or neutral imagery prime, participants will be asked to estimate the probability that the situation they imagined will turn out well or badly, and their ability to manage that situation. We will also assess subjective distress (using the Subjective Units of Distress Scale) and vividness of the image.

- **Procedure for Aim 1:** Once the materials and training programs (termed the "MindTrails" Project) are fully assembled and ready for testing, we will solicit feedback from two groups: 1) a small test group of highly anxious participants (who will be compensated $40 for their study visit, which will last approximately 2 hours); 2) an expert advisory board (who we do not plan to provide with financial compensation, given they will be participating as a professional courtesy). Both groups will try out the tasks and complete the measures to provide feedback on the programs' usability and acceptability via a survey and semi-structured interview (see above measures). We will assess numerous aspects of user experience, including clarity of the materials, ease of navigating the site, appropriateness of the intervention materials (re. language used, targets selected for stimuli), affective response to the materials, and extent materials are engaging and acceptable, perceived measurement burden of the assessment battery, etc. The semi-structured interview for each participant will follow completion of the user experience questionnaire, so that the interviewer can probe the responses and ask follow-up questions about potential ways to address the identified weaknesses of the program (e.g., participants' ideas about ways to make the tasks more engaging, the instructions clearer, etc.). These interviews will be conducted by the PI or trained project staff and graduate student collaborators on the project. This feedback will be used to modify all aspects of the programs in preparation for Aims 2 and 3.

- Note, we will also pilot the MindTrails site materials (e.g., CBM scenarios) on mobile phones using analogous procedures.

- **Procedure for Aims 2 and 3:** This study will be completed over the Internet, through an extension of Project Implicit Mental Health (www.implicitmentalhealth.com). Participants will be individuals recruited directly from the Project Implicit Mental Health website, as well as those who are invited to the site through a variety of online and offline advertisements and outreach efforts. The target population will be adults age 18 and over who score in the moderate to extremely severe anxiety range (i.e., 10 or higher) on the Depression, Anxiety, Stress Scales – Short Form: Anxiety Subscale (DASS21-AS).

- If individuals score above the established cutoff during their Project Implicit Mental Health study, they will be alerted to their eligibility for this study via a message added to their standard debriefing form following completion of the anxiety and depression study measures. (See attached Debriefing forms to see additions to the standard Project Implicit Mental Health form). Individuals may also see if they're eligible for the study by clicking an icon at the front page of the Project Implicit Mental Health site.

- Following consent, participants who are eligible will be randomly assigned to one of 6 groups (active CBM-I + anxiety imagery prime, 50/50 + anxiety imagery prime, no scenario control + anxiety imagery prime, active CBM-I + neutral imagery prime, 50/50 + neutral imagery prime, no scenario control + neutral imagery prime condition), matched for gender ratio. Participants will be asked t complete eight sessions of their assigned intervention, over the course of four weeks (~two sessions per week). Each session will last approximately 20 minutes.

- Prior to the first session, participants will receive a rationale about the intervention, followed by a series of questionnaires and online tasks assessing psychological symptoms, mental health history and demographics, interpretation bias, quality of life, etc. Following the third, sixth, and eighth sessions, participants will also be asked to complete the assessment battery. Finally, two month after the intervention, participants will be asked to complete a follow-up assessment, before being debriefed and provided with feedback about their change in symptom scores. Please see Measures Schedule in the Appendix for list of specific measures at each time point.

- Following completion of the first training session, up to 10 participants will be randomly selected to receive coaching. These participants will be emailed upon their selection and directed to a separate consent form. After completion of the consent process, participants will participate in weekly sessions with their coaches. These sessions will be used to discuss usability and engagement issues with the MindTrails program and will be held either over the phone or through Google Voice messaging. Coaching will stop after the (eighth) MindTrails session. We will offer $40 to participants for taking part in coaching.

- If participants are randomly assigned to a control condition, they will be offered the opportunity to complete one of the actual interventions following completion of the study.

Is this study topic relevant to cancer risk factors, prevention, cancer treatment, or survivorship (e.g., pain, financial toxici etc.), or will the study purposefully include participants currently or previously diagnosed with cancer, or their caregivers *(required)*

(optional) **Study Overview file upload**: Below you have the option to upload additional files to help the Board better understand your study. You are not required to provide any additional explanation beyond completing the text boxes provided in this Study Overview section; however, for example, if you are using a new technology or a complicated process that would be more easily demonstrated with image or video, you can upload the file here.

Participant Groups

Participant Group Name: Anxious participants

Age Range (years): 18 and older

Vulnerable populations: includes students

Maximum number of participants, in this group, expected to enroll over the life of the study: 1800

Minimum number of participants, in this group, expected to enroll over the life of the study: *(required)*

Total number of participants, in this group, ever enrolled: 1710

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We are performing data analysis only, in this group (i.e. we are not actively collecting data from participants in this group)

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

Gender: Mixed
Race: All/any
Estimated number of participants: 1000 (plus ~100 MTurk pilot participants)

The target populations for Aims 2 and 3 will be adults aged 18 and older who experience distress and/or impairment following from symptoms of anxiety. They will be selected based on established cut points on symptom screening measures. Specifically, the DASS21-AS will be used to determine eligibility. Individuals who score 10 or higher (suggesting moderate to extremely severe anxiety) on this measure at will be invited to participate in the study. Participants will be recruited via online recruitment methods (Craigslist, Project Implicit Mental Health, Facebook, etc.)

Depending on participant interest and management of technical issues, we may allow participants who are not eligible (based on thei DASS21-AS score) to still complete the intervention (without the assessments and without payment) if they would like. (These would not be study participants.)

Additionally, approximately 100 participants will be recruited via Amazon's mTurk to pilot study materials (e.g., rate how positive or negative stimuli are). These participants will not be screened for anxiety, although they will see the same consent and debriefing information as other participants. These participants will be paid $2.00 for their time. See protocol #2013020200 for more information about Amazon's mTurk. We will approve payment to all participants who complete the study, following mTurk protocol. W will also pay participants who contact us via email saying that they withdrew from the piloting study and would like to receive payment.

Will participants in this group be *compensated* for taking part in your study? Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? No

Describe your payment process, including information about the amount participants will be paid and how payment will b issued and delivered to participants.

The Amazon mTurk participants will be paid $2.00 for their time. We will approve payment to all participants who complete the study, following mTurk protocol. We will also pay participants who contact us via email saying that they withdrew from the piloting study an would like to receive payment.

Participant Group Name: Pilot participants

Age Range (years): 18 and older

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 23

Minimum number of participants, in this group, expected to enroll over the life of the study: *(required)*

Total number of participants, in this group, ever enrolled: 22

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We are performing data analysis only, in this group (i.e. we are not actively collecting data from participants in thi group)

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

In Aim 1, which focuses on development of the web-based interpretation bias and attention bias training programs, we will pilot the program tasks and materials on a small test group of moderate to highly anxious participants (N=15). Aim 1 pilot anxious participant will be recruited via online recruitment methods (e.g., Craigslist) to obtain a sample that will be as comparable as possible to the sample planned for Aims 2 and 3.

These individuals will be selected based on established cut points on the symptom screening measure, the Depression, Anxiety, Stres Scales – Short Form: Anxiety Subscale (DASS21-AS; (Lovibond & Lovibond, 1995)). Individuals who score 10 or higher (suggesting moderate to extremely severe anxiety) will be invited to participate. Further, an advisory board (N=8) of anxiety researchers,

clinicians, experts in Internet interventions, and experts in CBM will provide feedback on the programs. These individuals will be recruited through personal invitations by the PI and study team.

Will participants in this group be *compensated* for taking part in your study? Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? Yes

Participants are paid using UVA funds issued as: A

A: Oracle issued check for any amount and can have ID linked to check.

Describe your payment process, including information about the amount participants will be paid and how payment will b issued and delivered to participants.

The anxious pilot participants will be compensated $40 for their study visit and compensation will be issued by check. We do not plan to provide the expert advisory board participants financial compensation, given they will be participating as a professional courtesy.

Participant Summary

Participant Group Name: Anxious participants

Maximum number of participants, in this group, expected to enroll over the life of the study: 1800

Participant Group Name: Pilot participants

Maximum number of participants, in this group, expected to enroll over the life of the study: 23

What special experience or knowledge does the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators) have that will allow them to work productively and respectfully with the participants in this protocol and/o participant data?

Bethany Teachman, the PI, is a licensed clinical psychologist who has extensive experience in the treatment and reasearch of anxiety disorders. She was trained at Yale University and then at Massachusetts General Hospital in anxiety treatment, and currently supervises multiple graduate students in the research, assessment and treatment of anxiety problems. Additionally, she is Director of the online Project Implicit Mental Health, a website devoted to measuring implicit associations and other cognitive processes related to mental health.

What is the relationship between the participants of this study, and the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators)? Does the Principal Investigator, Faculty Sponsor, or the Research Team (Sub-Investigators) know any of the participants personally or hold any position of authority over the participants (including bu not limited to: grading authority, professional authority, etc.)? Do any of the researchers listed on the protocol stand to ga financially from any aspect of this research?

No relationship is expected between the PI and the anxious participants. The PI will be contacting her colleagues to serve as the expert users for the Aim 1 pilot study.

Recruitment & Consent

How will participants be approached or contacted for recruitment into the study?

Participants will be recruited through Project Implicit Mental Health (implicitmentalhealth.com), a website that allows users to learn about their implicit associations relating to mental health topics and is the sister-site to Project Implicit (PI; a website that allows users to learn about their automatic associations relating to social topics). Project Implicit Mental Health users find the site through PI, assignments for work or school, or other PI recruiting efforts (see approved SBS Protocol # PIMH general protocol #2007025900)

A Facebook page (https://www.facebook.com/mindtrailsproject/) is established to promote Mindtrails' exposure on social media. It is

dedicated as a platform only for disseminating news for updates and press. Comments and post from other users are disabled by setting. We will also put Ads on website like Craigslist to enhance recruitment. Participants may also arrive at the MindTrails study sit directly via online searches or links.

Volunteers who take the DASS-anxiety, either to determine if they are eligible for this study, or as part of the anxiety study at Project Implicit Mental Health will be told whether they qualify for the experimental anxiety intervention. For those who are eligible, a link to more information about the intervention will appear (see sample text in Appendix at the "Invitation to Participate" and "About MindTrails" pages).

Individuals interested in the intervention that do not qualify for the study will see text (similar to the following) notifying them that they are ineligible:

"Thank you for completing our assessment.

Unfortunately, you do not currently qualify for the study, but we appreciate your interest. We want to be sure we are offering the program to people we think are most likely to find it helpful.

If you wish to participate in other research, we encourage you to visit the Project Implicit site, implicit.harvard.edu, where there are other studies that you can try today, or complete another study at Project Implicit Mental Health, implicitmentalhealth.com.

To access treatment for your anxiety, please see the following list of Mental Health Resources.

Thank you for your interest!

Note. You are welcome to complete the eligibility questionnaire at a later time to determine if your eligibility changes (e.g., based on symptom changes or new study criteria)."

Do participants have any limitations on their ability to *consent* **?** No

Describe the limitations on their ability to consent:

What are the consent processes for this study?

Participants will be provided an opportunity to read the consent form (different versions for the anxious pilot Ps, expert user group, and mTurk pilot Ps are attached for Aim 1, and see Appendix for Aim 2 consent). There will be a separate consent form for the participants selected to receive coaching. We will be clear that participants have the right to withdraw from the study at any time. Coaching participants will receive $40 for participating in coaching.

Will participants be deceived and/or have information withheld from them about the study? Yes

Explain what is being withheld or describe the deception. Justify why the deception and/or the withholding of information from the participants is necessary.

Participants will not be told the full purpose of the study until debriefing. There will be no deception.

Will participants be debriefed? Yes

Describe your debriefing procedures:

Participants will not be told what condition they were in until debriefing. Following completion of the study, participants are linked to the debriefing text. When a participant chooses to exit the study, a link is provided to the debriefing text. When a participant chooses to discontinue participation in the study, after 21 days their account is automatically closed and an email is sent with a link to the debrifing text.

Recruitment & Consent Tools

Consent or Notification (no signature required)
View File: 2703 - Previously Approved Consent for Pilot Coaching.docx

date uploaded: 2019-06-07, by: Behan, Henry *(hb7zz)*
This file is approved.
date approved: 2019-06-10

Consent or Notification (no signature required)
View File: 2703 - Previously Approved Consent v2.docx
date uploaded: 2019-06-10, by: Behan, Henry *(hb7zz)*
This file is approved.
date approved: 2019-06-10

Debrief
View File: 2703 - Previously Approved Debriefing.docx
date uploaded: 2019-06-07, by: Behan, Henry *(hb7zz)*
This file is approved.
date approved: 2019-06-10

Associate Recruitment & Consent Tools with Participant Groups

Participant Group Name: **Anxious participants**
✔ Recruitment & Consent Tool: **2703 - Previously Approved Consent for Pilot Coaching.docx**
✔ Recruitment & Consent Tool: **2703 - Previously Approved Debriefing.docx**

Participant Group Name: **Pilot participants**
✔ Recruitment & Consent Tool: **2703 - Previously Approved Debriefing.docx**

Data Sources

Data Source Name: Data Source

Are the data already collected? Yes

Describe this Data Source.

> Data will consist of Ps' responses collected on the study site.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

> Any information participants provide on this site will be stored on a secured database. Information collected will be associated with a unique ID and not with the participant’s email address. When data is used for analysis, no personally identifying information will be associated with the data.

Associate Data Sources with Data Sources

No requirements.

Associate Data Sources with Participant Groups

No requirements.

Data Sources Upload

Instrument
View File: 2703 - Previously Approved Measures.docx
date uploaded: 2019-06-06, by: Behan, Henry *(hb7zz)*
This file is approved.
date approved: 2019-06-10

Permission to Access Data Source and Participant Group

Are there any rules or restrictions to access Data Sources and/or Participant Groups? No

Permissions and/or Agreements

Data Reports & Storage

How will data/materials be stored? What measures will be taken to secure these data during collection and analysis? If th data includes recordings, what will be done with the recordings (including if/when the recordings will be destroyed)? Describe the long-term plan for maintaining the data when the active research phase is completed. Please note that you n need additional "material release" consent forms if you are using recordings for purposes beyond the study.

This study site has implemented stringent protections to safeguard participants' confidentiality. All communication between project servers and participants' computers is routed through Secure Sockets Layer (SSL) encryption technology, the gold standard for protecting data transfer from unauthorized access. This is the same secure hypertext transfer protocol (HTTPS), that banks and other commercial websites use to transfer credit card information in an encrypted format.

Participant's email address will not be shared with third parties.

Any information participants provide on this site will be stored on a secured database. Information collected will be associated with a unique ID and not with the participant's email address. When data is used for analysis, no personally identifying information will be associated with the data.

Please remember that we cannot guarantee the confidentiality of information sent by e-mail.

Technical Details

Web Hosting:
We will be using servers hosted by the University of Virginia to run a medium size Linux virtual machine running Tomcat for hosting our Java based web application.

Data Storage:
We will be using a MySQL database hosted on the same server that is running the web service. On a regular schedule (every 5 minutes) all non-essential data participants provide - specifically including any medical history information, will be pulled onto a separate server where it can't be directly associated with any identifying information about the participant. Please see the full Data Security document for additional information.

Form Security:
Once data files are downloaded, they will be stored securely on an investigator's computer. Results will be reported in aggregate.

At the software level, our security model is built on the popular Spring Security Framework. We currently use a form based authentication (a web login form) that provides the following basic projections and features:

- Every URL in the site requires authentication.
- CSRF attach prevention (http://en.wikipedia.org/wiki/Cross-site_request_forgery)
- Session Fixation Protection (http://en.wikipedia.org/wiki/Session_fixation)
- Security header integration
- HTTP Strict Transport Security for secure requests
- X-Content-Type-Options integration
- Cache Control
- X-XSS-Protection integration
- X-Frame-Options integration to help prevent Clickjacking

How will data/materials be reported for this study? Will the results be reported in aggregate or will individual data be discussed?

Results will be reported in aggregate.

If a participant decides to withdraw from the study, how will you handle their data?

We do not delete any of the information we have previously collected on a participant when they withdraw from the study.

Do you plan to publish your raw data after the study is completed *(i.e. open-access or open source publishing)*? Yes

Will other parties (i.e. other corporations, institutions, researchers) have access to or retain a copy of the data? Yes

International Research

Risks & Benefits

You have indicated that this study will include the **2 items** displayed in the list below. These **2 items** are areas that often require more scrutiny from the Board. When framing your responses regarding the risks in this study, address the study as a whole, and also conside the **2 items** specifically as well.

Items:
1. includes students
2. deception

Is loss of confidentiality and/or privacy a risk to participants? No

Describe any remaining potential risks to participants. For example, are any of your participants or participant groups "ris sensitive"? Include information about the probability of harm (i.e. how likely it is that harm will occur). What will be done reduce risk to participants? If something unexpected involving risk happens, how will you handle it?

There is a possibility that the active CBM interventions will not work and the participants assigned to these conditions will not improve. Moreover, it is expected that participants assigned to the control conditions will not improve (though we do not expect symptom worsening beyond normal variations, and all participants will be offered an active CBM condition following the end of their 2-month follow-up assessment).

Notwithstanding, there is a possibility of worsening symptoms, which we will monitor. Across studies and conditions, participants may experience some anxiety or discomfort from the discussion of their personal information, completion of the symptom questionnaire, and the anxiety imagery. However, completion of these measures is a critical component of the research, and is not expected to caus enduring distress. Some participants may initially feel some discomfort discussing sensitive topics over the Internet, or over the phone for those participants receiving coaching, which is one reason we are not requesting last names. Finally, the lack of contact with a therapist was deemed important to appropriately test the feasibility of these interventions through an online platform, but we recognize that this limits our ability to individually tailor treatments, or respond to unique concerns that arise. This is one reason that we note how to contact the researchers (and the technical support staff) at numerous places at the website, and aslo make clear in multiple places at the site that MindTrails does not provide specific diagnostic or medical advice on our website, and we are limited in how we can respond to your responses.

Participants will be clearly instructed that they have the right to withdraw from the study at any time without penalty. Further, we wil have trained staff to manage emails submitted to the research team that are of a clinical nature (separate staff are in place to handle concerns related to technical difficulties). In particular, Dr. Bethany Teachman, the Principal Investigator and a licensed clinical psychologist, will be available to respond to any clinical issues. Coaches will also notify Dr. Teachman regarding any clinical issues tha participants may express during coaching sessions. We also provide extensive information at the MindTrails website about how and where to access treatment and mental health resources, and have these links included in the debriefing form to ensure participants are aware of the resources. Importantly though, we will also make clear at the site that we are not offering personal therapy or diagnostic advice, and will provide referrals for hotlines and other emergency contacts at the site should those be needed. Coaches will also make it clear to their participants that they are not therapists and cannot offer therapy or diagnosis and will direct participants to other resources if needed. If substantial worsening of a participant's anxiety symptoms occurs (regardless of training condition) during sessions 2 thru 8, as evidenced by more than a 50% increase in symptoms relative to that person's baseline score, he or she will be notified of the change and we will offer to help the participant find alternate treatment options. The 50% increase criterion was selected because a change of 50% matches the definition of a "reversal" of a treatment gain in the sudden gains literature (e.g., Tang & DeRubeis, 1999).

The intervention email address inbox will be checked daily for clinically-relevant messages from participants, and all clinical emails wi be addressed within 24 hours. Though unexpected, given that no questions explicitly ask about suicidality, in the event that a participant indicates suicidal intent via email to researchers, we will: a) email the person information about how to access emergency services, national suicide hotlines, and suicide prevention websites, and b) offer the participant the opportunity to speak with Dr. Teachman (or another on-call licensed clinician if Dr. Teachman cannot be reached). Specifically, we will ask the participant to provide his or her phone number so that the licensed clinical psychologist can call the individual to more directly help connect the person with services, including both emergency hotlines and local therapy options. This protocol will also be followed if a participant indicates

suicidal intent during a coaching session. Note, this approach is similar to what we do in our lab, which has worked well for more than a dozen years. Given this possibility, we will clearly note the limits of confidentiality related to mandating reporting requirements in the informed consent document (i.e., if we learn of possible child abuse or neglect, or danger to self or others).

Further, all participants in the control conditions will be offered one of the active CBM interventions after they have completed the control training sessions and their 2-month follow-up assessment.

To help participants make informed choices about whether to pursue subsequent care, at the completion of the follow-up assessment participants will receive automated, individualized feedback about their performance, which will be written in an understandable and sensitive way. This will include a summary of their symptom scores, and how these have changed over time. They will also receive information (e.g., web site links) about how to identify and access alternate treatments, such as local providers, though we will be clear we are not endorsing any particular provider. Finally, as part of the debriefing process, participants will be given psychoeducation about cognitive biases and these biases' hypothesized role in symptom onset and recovery.

The proposed intervention is best classified as a low-risk, single-site, phase II trial. Moreover, we are not recruiting particularly vulnerable participants in that they are expected to be competent to make treatment decisions. However, as an added level of safety for participants, in consultation with National Institute of Mental Health Program Staff and the Office of Clinical Research, we elected to add an Independent Safety Monitor (ISM), and structured this person's role commensurate with the minimal risks of the intervention.

The identified ISM, Dr. Dianne Chambless, is the Merriam Term Professor of Psychology and Director of Clinical Training in the Department of Psychology at the University of Pennsylvania. She is a licensed psychologist with decades of experience studying anxiety disorders, cognitive-behavior therapy, prediction of treatment outcome, and identification of empirically supported psychological interventions

Dr. Chambless and the Principal Investigator have never collaborated on a research project, so she can provide an independent evaluation of this work. The Principal Investigator and ISM know each other primarily through work on professional organizations (e.g., Society for a Science of Clinical Psychology) and at conferences.

The ISM will review materials prior to study launch and then receive progress reports every 6 months via teleconference following launch. In particular, prior to the first meeting, the ISM will be provided with the study protocol and all study materials. In the initial meeting(s) prior to launch, the ISM will meet with the Principal Investigator to review the protocol and discuss any issues regarding the intervention (including data and safety monitoring, and human subjects provisions) and will make recommendations following the discussion. Prior to the subsequent meetings, the ISM will be provided with a written summary of study progress (e.g., participant recruitment), a current, de-identified data set, and a summary of any adverse events and key outcome indices (i.e., change in interpretation bias and symptom severity) aggregated by masked training condition (e.g., group A, group B). Moreover, the ISM will receive group-level tables highlighting key feasibility indicators (e.g., completion and attrition rates, again separated by masked training condition). During the subsequent meetings, the ISM will consider issues of protocol adherence, data integrity, and participant safety. The Principal Investigator will make herself available to the ISM, presenting an update on study progress and responding to her questions, and will inform the ISM if any substantial modifications have been made to the study protocol. The ISM will thus serve as an additional protection for human subjects (above and beyond that of the UVa IRB).

Further monitoring: Weekly, the study investigators and affiliated researchers will discuss the progress of the intervention. The group will discuss adverse events, attrition/completion rates, preliminary feasibility results, and protocol adherence, in addition to any other information relevant to the intervention. During each meeting, issues of participant safety and user experience will be on the agenda to ensure that they remain primary concerns throughout the project.

Are there direct benefits to the participants in this study? No

Describe the overall benefit of this study.

There are no direct benefits for participating in the study. However, the primary goal of the proposed research is to determine the feasibility of the proposed intervention and to gain knowledge about ways to maximize its effects (e.g., by exploring whether baseline bias or symptom severity moderates effects, etc.). Secondarily, participants in the active CBM conditions may also experience a reduction in cognitive biases and anxiety symptoms that persists after training, based on the promising lab-based findings for CBM in anxious samples. Thus, we believe that any risks of discomfort associated with the interventions would be offset by what will be learned regarding the potential for future widespread dissemination of a cost-effective intervention. Additionally, participants in all conditions will receive links to referral information in the Debriefing forms, which could help those in need of further care to access treatment. During debriefing, participants will also be given psychoeducation regarding the interplay between biased cognitive processing and symptomatology. Therefore, in light of the potential benefits, the risk of participation appears justified.

Continuation

Are you applying for a continuation of your protocol's approval? Yes

Was this project undertaken? Yes

Are there any additional risks to participants or new information about risk to participants in the study not described in th previously approved protocol? No

Describe what you did during the past year:

Data collection for this study ended in January 2019. Data analysis is ongoing.

In addition, go to the Participant Groups section and provide updated information regarding participant enrollment.

Modification

Does this protocol version include any changes that were made to the previously approved protocol (protocol form, conse documents, etc)? *Minor edits are considered changes!* No

Unexpected Adverse Events

Did a negative event associated with the research occur and does it meet one of the following conditions:

is not described as a possibility in the previously approved protocol OR;

did not occur within the parameter described (i.e. an increase in frequency or severity)?

No