Study Protocol

Study Title:
Developing a Low-Intensity, Primary Care Intervention for Anxiety Disorders

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Overall Protocol Summary:

Primary care patients with anxiety disorders (ADs) have worse functioning, poorer outcome of their medical illnesses, and are among the greatest users of primary care resources. There is a strong need for scalable treatments. Low-intensity, computerized treatments may be particularly implementable, as they may require less professional assistance and have a broader reach than face-to-face or even telehealth treatments. Low-intensity treatments are suited for delivery linked to primary care, as this setting has a great unmet need, is often the first access point for treatment, and allows for monitoring by a physician.

Cognitive Bias Modification is a promising intervention for ADs that may be ideally suited for primary care settings. CBM directly targets cognitive processes (i.e., attention and interpretation biases) underlying ADs. The current study will develop a personalized CBM program called Face Anxiety (formerly referred to as AIM), comprising 8, 30-minute computer sessions. In these sessions, participants practice disengaging their attention from threatening stimuli and interpreting ambiguous social scenarios in a benign manner.

The primary goals of our 3-year, 2-phase project are to develop Face Anxiety for primary care linkage and assess its feasibility, acceptability, and efficacy. We integrate implementation methods in our early development work. In order to conduct ongoing evaluation, a team of "end users," including PCPs, nurses, patients and practice leaders at the Family Care Center (FCC) of Memorial Hospital of Rhode Island, our study site, and at other sites in Rhode Island and Massachusetts, have agreed to participate on an Advisory Panel (AP).

Phase 1 has 2 parts.

Part A: develop Face Anxiety including a: 1) personalization computer program that will create an idiographic stimulus set for each participant to be used in the treatment; 2) self-administered, personalized, CBM treatment; and 3) protocol for primary care linked delivery.

Part B: an open trial of Face Anxiety comprising 3 iterations of 6 patients each. After each iteration, our study team and the AP will review data on feasibility and acceptability of Face Anxiety and delivery methods, and make revisions as needed

Phase 2 goals are to refine and pilot the intervention, with input from relevant groups. With continued AP feedback, we will pilot an RCT of Face Anxiety vs. control to further refine the program and delivery methods, and further assess their feasibility /acceptability along with that of our RCT research protocol.

Phase 1 A was approved by the IRB 4/1/14 (14-10).
Phase 1 B was approved by the IRB 9/2/14
Phase 2 was approved by the IRB 9/25/15

As stated above, Phase 1B is an open trial of Face Anxiety comprising a total of 18 patients. (3 iterations of 6 patients each). In Phase 1B, interested participants, who give informed consent, will participate in a 5-minute screening interview. Potentially eligible participants will then complete the full open trial consent form and complete a pre-treatment/eligibility assessment. All eligible participants will then complete 8, bi-weekly computer intervention sessions (Please see Appendix for a detailed description of the Face Anxiety program). The first session will occur in the primary clinic, with assistance by study staff, to assure participant's familiarity with using the on-line program. After completion of the first session in the primary care clinic, participants will be permitted to choose to complete the remaining sessions at home, or in the clinic. Participants will have flexibility in scheduling at home sessions, as long as they complete no more than two sessions per week. Participants

completing sessions in the clinic will be asked to book a time, to assure that a computer is available to them. The study will provide laptop computers for use in the clinic. Participants will be asked to make up any missed sessions, so that all participants would ideally complete 8 sessions. All sessions must be completed within 6 weeks. All participants will complete pre- and post-program assessments of anxiety, depression, quality of life, treatment satisfaction, and cognitive biases. All participants will also complete weekly measures of anxiety and depression. [See attached list of assessments] After completion of the post-program assessment, participants will complete a qualitative interview to obtain feedback about acceptability, perceived helpfulness, and suggestions for improvement.

Phase 2 is a randomized controlled trial comparing Face Anxiety to a symptom tracking control condition comprising a total of 42 patients. The eligibility criteria, screening and consent process, assessments, and safety monitoring are identical to those approved for Phase 1B.
As in Phase 1B, in Phase 2, interested participants, who give informed consent, will participate in a 5-minute screening interview. Potentially eligible participants will then complete the full randomized trial consent form and complete a pre-treatment/eligibility assessment. All eligible participants will then be randomized to complete either the 8, bi-weekly computer intervention sessions (Please see Appendix for a detailed description of the Face Anxiety program) or a symptom tracking control.

Face Anxiety – Mental Habits Program.
This arm of the RCT will function exactly as did the already IRB approved and currently running Open Trial. (see description of Phase 1B above)

Face Anxiety - Symptom Tracking Program.
This arm of the RCT is new since the open trial and will serve as the control group in the RCT. In Face Anxiety – Symptom Tracking, participants will complete weekly symptom assessments in the same manner as proposed for all participants in the IRB approved Open Trial proposal – via self-report. Specifically, each week the Face Anxiety Specialist will contact participants with information on how to complete the symptom questionnaires. This will typically occur by emailing participants a computer link to their surveys, which can be accessed on a website using SSL encryption (see details below). Participants will be informed of the risks associated with unencrypted email in the consent form. In the event a participant does not have internet access at home, they will be offered the opportunity to complete the symptom measures on a computer in the clinic, or, if necessary, over the phone with the Face Anxiety Specialist. These assessments will be conducted, in part, as a means of continuing to monitor patient safety and potential clinical deterioration. Further though, they would be conducted to provide patients and their PCPs with feedback regarding any patients' deterioration so that the PCP may then choose to use to adjust the patient's care. Similar to the Mental Habits condition, participants in this condition will be given a credible treatment rationale regarding the benefits of regular self-monitoring and feedback. This symptom tracking control group would permit us to answer a crucial question for the future success of implementing FaceAnxiety: Does our low-intensity intervention add any benefit beyond what patients might more commonly be offered in primary care settings (medication, and possibly very brief onsite behavioral health services).

A study staff member will serve as the "FaceAnxiety Specialist" (FAS) who will check in with participants once a week during the 4 weeks that they are completing the Face Anxiety sessions to answer any questions, monitor participants' progress, and communicate participants' progress to their physician via the Electronic Medical Record (EMR) and/or personal contact. Specifically, the FAS will review patients' responses to the GAD-7 and PHQ-9 (see Measures and Protection Against Risk sections), as well as their completion (or lack thereof) of the computer tasks. If patients are having difficulty completing the program, the FAS will help them troubleshoot technical problems.

Additionally, if a patient has a diagnosis of PTSD, the FAS will administer the PCL-C on a weekly

basis to monitor PTSD symptoms (see Measures and Protection Against Risk sections). In the Face Anxiety – Mental Habits arm, the FAS will also discuss and address any difficulty the participant may be having with motivation to complete the program. If participants choose to complete the sessions at home, the FAS will offer to contact them by phone. If participants choose to complete the sessions in clinic, the FAS will be available to meet with them while they are in clinic. All meetings with the FAS will be audio-recorded.

All participants will complete pre-program, mid-program, post-program, and 3-month-follow-up assessments of anxiety, depression, quality of life, treatment satisfaction, and cognitive biases. These assessment visits include a self-report packet of questionnaires, 4 computer tasks, and a qualitative interview (post-program only). An FAS will conduct the assessment visits, with the exception of the clinical interviews (SCID, HARS/CAS), which will be conducted by one of our blinded clinical assessors. Participants will also complete weekly measures of anxiety and depression. [See attached list of assessments] After completion of the post-program assessment, participants will complete a qualitative interview to obtain feedback about acceptability, perceived helpfulness, and suggestions for improvement.

Statistical Analysis Plan

Descriptive statistics will be calculated to examine our a priori benchmarks for feasibility, acceptability, safety, and preliminary efficacy.