Developing a Novel Digital Therapeutic for the Treatment of Generalized Anxiety Disorder

NCT03683472

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BROWN UNIVERSITY

MAIN CONSENT FOR RESEARCH PARTICIPATION

Unwinding Anxiety Study

Version 6, 5/2/19

KEY INFORMATION SUMMARY:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: To test how well the Unwinding Anxiety (UA) phone app reduces anxiety by collecting questionnaires from participants with a moderate-to-high score on a self-report measure of anxiety.
- PROCEDURES: You will come in for an in-person visit to download the UA app on your phone and complete a questionnaire. You will be instructed to complete the UA program over the course of 30 days using your phone. Finally, you will fill out two surveys by email.
- TIME INVOLVED: The screening call takes roughly ~15 minutes. The baseline session takes roughly ~60 minutes. The daily app use will take roughly ~10-15 minutes a day, and you will be asked to complete the daily app lesson once per day for thirty days. You will also receive check-in calls at day 7, 14, and 45 and be asked to complete two email surveys taking roughly ~15 minutes each.
- COMPENSATION: You will receive up to $80 for your time if you provide feedback at all 3 sessions: $10 at the in-person baseline visit, and $35 for the two email surveys.
- RISKS: 1) Loss of privacy protection: It is possible the data we collect could be lost or revealed. We will do everything we can to protect your privacy. 2) Possible side effects of using Unwinding Anxiety program: While we have not had reported side effects from this program, there have been some reports of side effects from other mindfulness meditation training interventions which will be described in more detail below.
- BENEFITS: You will receive free training for managing anxiety, and free lifetime access to the Unwinding Anxiety application.
- ALTERNATIVES TO PARTICIPATION: Standard treatments for anxiety disorders include medication and talk therapy. Please contact your doctor for more information about anxiety treatments.

1. Researcher(s):

Principal Investigator: Judson Brewer, MD-PhD

2. What is this study about?

The purpose of this study is to test how well an app (Unwinding Anxiety) reduces anxiety. You are being asked to be in this study because you are above the age of 18, have a smartphone, and have a self-report anxiety score (the GAD-7) within the target range, and are eligible for the main study.

3. What will I be asked to do?

The study began with a screening phone call to see if you are eligible. You will come in for a baseline visit at Brown University, where you will have the opportunity to sign this consent form and enroll in the main study. This study has two different groups of research participants. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. The groups are explained in more detail below:

If you are randomized into Group A – You will be asked to complete a survey at baseline, 30 days, and 60 days. Upon your completion of the 60-day survey, you will be invited to download Unwinding Anxiety on your phone and receive a free lifetime subscription to the app.

If you are randomized into the Group B – You will be asked to complete a survey at baseline. Upon your completion of the baseline survey, you will be asked to download Unwinding Anxiety on your phone and receive a free lifetime subscription to the app. You will complete the introductory module (~10-15 minutes) and complete an initial survey (~15 minutes). You will then be instructed to complete the 30-day Core Training program of Unwinding Anxiety (~10-15 minutes per day). You will be sent an email survey on day 30 and day 60 (~15 minutes). You will be asked to fill out the survey even if you have not yet finished the 30-day Core Training program. After completing the Core Training, you may complete as many post-training modules as you wish.

You will be contacted for check-in calls regarding your experience with the app. These calls will occur at day 7, 14, and 45. App usage will be monitored and you may receive an additional phone call to troubleshoot any problems.

You can always decline to answer or skip any question asked of you however this will remove you from the study. You may choose to not continue in the study at any time for any reason. The final survey has a section asking about childhood trauma, and we will give you a head's up before it appears. You may choose to skip that section for any reason and still receive compensation.

We expect the study to last a total of approximately 2 months.

4. Will I be paid?

You can receive a maximum of $80 compensation in the form of an Amazon electronic gift card. You will receive a $10 credit for the baseline visit, and $35 credit for each of the two email surveys. You will also receive free training for managing anxiety, and lifetime access to the Unwinding Anxiety application (including access to the support of an online community and future post-program modules).

5. What are the risks?

There is a small risk that your personal information could be lost or exposed. This is very unlikely to happen and we will do everything in our power to make sure that your information is protected. Details below (part 7).

While we have not had report of side effects from this program "Unwinding Anxiety," there have been some reports of side effects from other mindfulness meditation training interventions. These rare side effects include trouble thinking clearly or making decisions, increased anxiety symptoms, repeated thoughts of a stressful experience from the past, irritability, trouble enjoying things that were previously enjoyable, feeling distant or cut off from people, difficulty sleeping, headaches and/or body pain, hearing sensitivity, feeling disconnected from everything, feeling negative emotions more strongly, feelings of distress. We will ask you about side effects from the program after completion.

6. What are the benefits?

You may learn more about your anxiety and your anxiety may decrease.

7. How will my information be protected?

All study data will be recorded in a secure research database application. Every participant will be given a Participant ID number and all data will be matched to the Participant ID instead of name or contact information. An identifier "Key" matching the ID to the name and contact information will be saved separately from study data. Only the researchers named in this document will have access to the data and the Key. The research team will track the number of modules you complete through a password-protected server. All data will be password-protected, and we will store

it for at least 3 years unless directed otherwise by Brown. Signed and dated consent from will be kept under lock and key for at least 3 years after the end of the study.
The Key linking participant ID to name/contact information is needed to contact research participants. This Key will be kept on a secure, password-protected server and will be completely separated from the study dataset.

Brown University staff and the National Institute of Health sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your study records may be examined. The reviewers will protect your confidentiality.

8. What are my rights to confidentiality?

This research is covered by a license called a "Certificate of Confidentiality" from the National Institutes of Health (NIH). This Certificate prevents anyone from using the data in this study against you in court. The first exception is when a law requires researchers to report information to the police for safety. (For example, this Certificate will not hide your information from the police if you discuss hurting a child or hurting yourself.) The second exception is when this study is being reviewed. The NIH funded this study, and this Certificate cannot prevent them from reviewing this study to make sure it is done correctly. The NIH will do everything in their power to protect your confidentiality.

If you want to disclose data from this study (for example, if it can be *useful* to you in a court case), you can request that the researchers release your data.

9. Are there any alternatives to this study?

Standard therapy for anxiety includes medication (such as selective serotonin-reuptake inhibitors) and behavioral treatments (such as cognitive behavioral therapy). You can contact your doctor for more information.

10. What if I want to stop?

You do not have to be in this study if you do not want to. Even if you initially agree to be in this study, you can change your mind and stop at any time for any reason.

If you refuse to participate in or leave the study, your current or future relationship with Brown University will not be affected.

11. What are the financial interests in this study?

Dr. Brewer is the lead researcher in this study and is one of the founders of Mindsciences, the company that created Unwinding Anxiety. If the program is successful, he may benefit financially.

Dr. Brewer will not be enrolling or consenting participants. Any publication of this study will require a statistician independent of the study and the Mindsciences company. Dr. Brewer will disclose his relationship to the company in any publications or presentations about this study.

You are being given this information so that you can decide if this interest affects whether you want to participate in this study. If you have any questions, please contact a member of the research team or the Human Research Protection Program (see below).

12. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can contact:

Alexandra Roy
- (401) 297-0268
- alexandra_roy@brown.edu

Dr. Judson Brewer, MD-PhD, the Principal Investigator:
- (401) 863-2826
- judson_brewer@brown.edu

13. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

14. Where can I learn more about this clinical trial?

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

15. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be given a copy of this form.

Participant's Signature	/	Date	/	PRINTED NAME
Researcher's Signature	/	Date	/	PRINTED NAME