Confirmatory Efficacy Trial of a Traditional vs. Gamified Attention Bias Modification for Depression

University of Texas at Austin, Dr. Christopher G. Beevers

Initial NIH Grant Approval Date: July 2023 Initial IRB Approval Date: 4/5/2024

Consent to Participate in Online Research

Identification of Investigator and Purpose of Study

You are invited to participate in a research study, entitled "Confirmatory Efficacy Trial of Attention Bias Modification for Depression." This consent form will help you choose whether to participate in the study. Feel free to ask if anything is not clear in this consent form.

The study is being conducted by Dr. Christopher Beevers through the Mood Disorders Laboratory at the University of Texas at Austin.

Preferred method of contact: utattentionbiasstudy@gmail.com
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Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- The purpose of the study is to examine whether cognitive training exercises help with symptoms of depression.
- To participate, you must be at least 18 years of age and experiencing symptoms of depression.
- If you choose to participate, you will be asked to: a) complete a 2-hour, in-person onboarding appointment at the University of Texas at Austin; b) complete four one-hour laboratory appointments that are one week apart at the University of Texas at Austin; c) use the mental health program 4 times a week, each session lasting approximately 14 minutes each; and d) complete symptom assessments (15 minutes each) three times during a 6-month follow-up period.
- Risks or discomforts from this research include emotional discomfort, as some of the survey questions are of a personal nature and some of the stimuli are negative and therefore may make some participants uncomfortable. Breach of confidentiality is possible with downloading an app as identifiable data is collected. There is a risk of uncomfortableness with the use of infrared light during eye tracking.
- Participating in the study may result in some improvement in depression symptoms.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

Study Overview:

This research study is a randomized controlled trial testing the efficacy of a mental health app as a treatment for symptoms of depression. The app uses game-based training exercises designed to target key emotional and attentional patterns associated with depression. If you choose to

participate, you will be randomly assigned to one of three versions of the app: two versions of the app include the active ingredients thought to reduce depression and one version does not include these active ingredients. You will not know which version you are assigned to (nor does the research assistant). This study involves an investigational mental health app, which means that the study app is still being investigated in research studies and is not approved by the U.S. Food and Drug Administration (FDA).

Your participation in the study will contribute to a better understanding of the cognitive mechanisms involved in depression, and how they might be impacted by a digital therapeutic app. You are free to contact the investigator at the above email address to discuss the study. You must be at least 18 years old to participate.

If you agree to participate, below is the overall time commitment of the study:

- At the beginning of the study, you will be asked to schedule a 2-hour, in-person onboarding appointment at the University of Texas at Austin with a research assistant. You will complete laboratory tasks (described below), including eye tracking that uses infrared light, an interview about current and past psychiatric symptoms, and then they will walk you through downloading and registering the app and troubleshoot any technology issues.
- Four times a week, you will be asked to complete, at a location of your choosing, 1 session of game play on the app that will involve viewing stimuli and responding to them which will take approximately 14 minutes each. The study will last for 4 weeks (4 times per week x 4 weeks = 16 sessions of game play total).
- Once weekly, you will be asked to return to the University of Texas at Austin for one hour to complete laboratory tasks in which stimuli (e.g. words, or images of faces, scenes, or objects) will be presented and you will respond according to the instructions.
- After this four-week period, to assess how long the potential benefits of completing the app last, you will complete symptom assessments (15 minutes each) three times during a 6-month follow-up period at a location of your choosing.

Time commitment: ~ 56 minutes of game play + 60 minutes of assessment per week for 4 weeks, followed by 3 monthly assessments (15 minutes each) across a 6-month follow-up period. You will be compensated for all the assessments (see **Compensation** below). The total time commitment is approximately 8 hours across six months.

Benefits/Risks/Confidentiality of Data

You may or may not benefit from this study. It is possible that you may experience some improvement in depression symptoms from participating. At the conclusion of the study, we will provide additional digital intervention options to anyone who is interested.

Possible risks associated with this study include emotional discomfort, as some of the survey questions are of a personal nature and some of the stimuli are negative and therefore may make some participants uncomfortable. You may skip any questions that make you uncomfortable. You could experience uncomfortableness with the use of infrared light during eye tracking, and if so, you can stop at any time. You may contact the researchers with the contact information listed on this sheet to request mental health resources if you wish. There will be no cost to you for participating in this study.

Please note that while we check our email during normal business hours (9 am – 5 pm CST), we do not monitor our email constantly. If you are experiencing feelings of discomfort and wish to

discuss them or seek help, we encourage you to either call a local counseling center, call the National Suicide Prevention Lifeline by dialing 9-8-8, or go to your nearest emergency room.

In the case that contact is made with us and your discomfort is related to a personal concern that arose through participation and you are contacting us because you are in distress, we will be happy to briefly discuss your experience at utattentionbiasstudy@gmail.com. If your distress endures, we can refer you to several supportive resources, depending on the specific nature of your concern.

Your name and email address will be kept during the data collection phase by our study personnel for study support and tracking purposes only. It is possible, but very unlikely, that a breach of confidentiality could occur. We will minimize this risk by storing data securely, identifying data only with a numeric code, and only allowing research personnel to access the research. A limited number of research team members will have access to the final data during data collection. Identifying information will be stripped from the final dataset.

For our records and to be able to pay you for the assessments, we do need to verify your identity. During the initial in-person assessment, we will ask you to present a photo ID so we can verify your name and date of birth. We only need to confirm your identity with our records, and will not record or photograph your ID.

One of the conditions uses an app (Therapeutic Mobile Game) that collects your contact information (email address) and technical data. Your email is used by the app to provide you with a verification code to register, to send you notifications, and for technical support for the clinical study.

The technical data is not itself personal data and is associated and affiliated with the contact information you provide (i.e. your email address). Technical data includes, for example, information about your app usage (e.g., when a Study App was first launched), app version and installation ID, device identifier, and technical data about your device, such as operating system and model. The non-personal technical information may be used for purposes including, but not limited to:

- To conduct and support the Study
- To develop therapeutic and health-related products, including improving the usability of the application

Arcade Therapeutics (our collaborator on this project) may share your information with companies who provide services for or on behalf of the Study App such as data storage or interpretation of de-identified analytical data. These companies are obligated to protect your information. Detailed information about the apps privacy policies can be found here: https://arcadetherapeutics.com/legal/. Additionally, there may be tools used as part of this study that will collect specific digital data about participants' use of the app (i.e., when and how long the app was used, speed of reactions during gameplay in the app), such as those from Arcade Therapeutics, Inc., the creator of the app. This data is crucial for monitoring participant app use during the 30-Day treatment phase and will allow research assistants to identify participants who may need reminders to complete the four 14-minute sessions per week to maintain study enrollment. This data will only be accessed by study-approved research personnel.

To make the most of these valuable data resulting from your participation, we will make deidentified data available to the research community. In these cases, the data will contain no identifying information that could associate it with you or with your participation in this study.

There are certain situations in which we may break confidentiality. If during the study we learn about child neglect, child or elder abuse, or that someone is a clear, serious, and direct harm to self or others, we may report the information to appropriate authorities, including the police, the Texas Department of Family and Protective Services (or relevant state agency if outside of Texas), and/or an emergency medical facility.

Texas Education Code, Chapter 51, Subchapters E-2 and E-3, requires reporting incidents of sexual assault, sexual harassment, dating violence, or stalking committed by or against a person who was a student enrolled at or an employee of UT Austin at the time of the incident. However, the researchers working on this study have been designated as confidential employees. This means that if we learn about any incidents of sexual assault, sexual harassment, dating violence, or stalking, we are only required to report the type of incident reported and the date we learn about the incident. We will not report any information that could identify you.

Information about you may be given to the following organizations:

- The study sponsor (National Institutes of Health) and/or representative of the sponsor;
- Representatives of UT Austin and the UT Austin Institutional Review Board;
- Officials of the Department of Health and Human Services.

The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study. Researchers will not contact you for additional permission to use this data.

We will keep your research data to use for secondary data analyses. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project. Your name and information that could identify you will be deleted from the research data 3 years after completion of the research, per UT Austin data retention requirements. The de-identified data will be retained indefinitely.

A description of this study will be available on http://www.ClinicalTrials.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.

Compensation

There is no compensation for using the app. Compensation is offered in the form of gift cards only for completing the assessments and will depend on how participants engage with the study. You will receive $25 for each of the five weekly assessments you complete ($125). After these assessments, there will be three symptom and functioning follow-up assessments. These will be completed remotely. You will receive $15 per assessment (which we expect will take approximately 15 minutes each) with completion bonuses increasing for each additional follow-up assessment (i.e., $10, $15, $30) for a total of $100 if all the follow-up assessments are completed. Total compensation will be $225 for all assessment visits. Discontinuing this study will have no bearing on your relationship with the University of Texas.

___ I confirm that I understand the maximum I can earn is $225.

Participation or Withdrawal

Your participation in this study is voluntary. You may decline to answer any question and you have the right to withdraw from participation at any time. Withdrawal will not affect your relationship with The University of Texas in any way. If you do not want to participate either simply stop participating or contact a study coordinator at utattentionbiasstudy@gmail.com. Participants who decline to participate will be offered additional options for digital interventions. Similarly, participants who complete the study will be offered the same digital intervention resources at the end of the study.

To ensure that we can test the efficacy of this intervention, we require that participants receive a minimum amount of training sessions in this study. If you miss 4 or more of the total 16 trainings, you will be withdrawn from the study. At this point, you will not be able to complete additional trainings or additional assessments for compensation.

___ Type your initials here to indicate you understand that if you miss 4 or more of the 16 trainings, you will be withdrawn from the study and will not be able to continue further, including completing additional assessments.

If you do not want to receive any more study reminders, you may email us at utattentionbiasstudy@gmail.com.

Contacts

If you have any questions about the study or need to update your email address, contact the researcher at (512) 471-7557 or send an email to utattentionbiasstudy@gmail.com. This study has been reviewed by The University of Texas at Austin Institutional Review Board and the study number is **STUDY00004323.**

Questions about your rights as a research participant.
If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 232-1543 or email at irb@austin.utexas.edu.

If you agree to participate, click “Yes” below.

Please type/sign your full name in the box below if you consent to participate in this study.

Thank you.

Name: _____

Signature: _____

Date: _____

Please print a copy of this document for your records.