Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: March 2026

Subject Name:

MRN or DOB:

Protocol Title: Randomized Controlled Trial of the BraveBot Intervention as an Adjunctive Treatment for Young People with Anxiety and Related Disorders Receiving Outpatient, Exposure-Based Cognitive Behavioral Therapy

Principal Investigator: Madelaine Abel, PhD

Site Principal Investigator: N/A

Description of Subject Population: Young people ages 12-22 years old who are receiving exposure-based cognitive behavioral therapy (CBT) for anxiety and related problems at Mass General Brigham outpatient therapy programs

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part. Throughout the consent form, "you" always refers to the person who takes part in the study.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are between 14 and 22 years old and are receiving (or are about to receive) exposure-based cognitive behavioral therapy (CBT) for anxiety or a related disorder (such as obsessive–compulsive disorder [OCD]) at a Mass General Brigham (MGB) outpatient therapy program.

We are doing this research to find out whether "BraveBot," an AI-based audio coach used during at-home exposure tasks, can help people do their exposure homework.

If you agree, you will continue in your usual CBT treatment and, between sessions, you will receive text message reminders about your at-home exposure tasks. Some individual exposure exercises will be randomly assigned (like flipping a coin) by computer to be done with BraveBot's real-time audio coaching, and others will be done on your own without BraveBot. After each exposure that you complete, you will answer a few short questions about how it went. You will also complete three sets of online questionnaires about your symptoms.

You may be in the study for up to 12 weeks of BraveBot access (or until you receive 45 days/approximately 6 weeks of exposure reminders, whichever comes first), followed by a final survey 3 weeks later. How much time you spend in this study may vary depending on what you and your clinician decide about your work together.

The main risks of being in the study are:

- Feeling anxious or uncomfortable while doing at-home exposure tasks (which is also a normal part of exposure-based CBT)
- Possible frustration or confusion if BraveBot's suggestions feel different from what your therapist has said
- Possible distress if the automated safety system pauses a BraveBot session and shows crisis information

You may or may not benefit from taking part in this research study. Using BraveBot might help you understand your exposure assignments better, put in more effort, stay with exposures when they are hard, and feel that exposures help you cope with your anxiety over time. If you take part in this study, your participation may help people in the future.

If you decide not to be in the study, another thing that might help your condition is continuing to receive CBT as usual without BraveBot.

You will be paid up to $122 in electronic gift cards for taking part in this research study. Later in this form, you will find more information about the payment amount for each part of the study and about what happens if you do not complete all study visits.
You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Madelaine Abel, PhD is the person in charge of this research study. You can call her at 617-643-9435 on weekdays 9am-5pm. You can also speak with the study coordinator, Mr. Joshua S. Steinberg, MA by calling 617-945-3115 on weekdays or by emailing him at jssteinberg@mgb.org.

If you have questions about the scheduling of appointments or study visits, call Joshua Steinberg, MA at 617-945-3115.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:
- A complaint, problem, or concern
- Ask questions, offer input, or obtain information
- Your rights as a research participant

Detailed Information

A description of this clinical trial 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.

Why is this research study being done?

We are doing this research to learn whether BraveBot, a computer-based, audio coach powered by artificial intelligence (AI), can effectively help young people do their at-home exposure therapy tasks when they are in CBT for anxiety or related disorders.

Exposure-based CBT asks you to gradually face situations, thoughts, or sensations that make you anxious ("exposures") so that your anxiety can go down over time. A large part of exposure-based CBT is doing exposure exercises between sessions. Many people find it hard to start or stick with these exercises on their own.

BraveBot is designed to:

- Remind you what your at-home exposure task(s) is and why you are doing it
- Guide you step-by-step through the exposure
- Encourage you to stay with exposures when they feel hard
- Help you notice and reduce "safety behaviors" (things you do to quickly lower your anxiety that can get in the way of learning)
- Help you reflect afterward on what you learned

BraveBot does **not** replace your therapist. It does not diagnose you, change your treatment plan, or make decisions about your care. It only helps with exposure tasks that your therapist has already assigned.

This is a behavioral research study. There are no study drugs, no medical devices, no radiation, and no genetic testing involved.

Who will take part in this research?

We are asking you to take part in this research study because you:

- Are between 14 and 22 years old
- Have symptoms or a diagnosis of an anxiety or related disorder (for example, panic disorder, social anxiety disorder, or obsessive-compulsive disorder) for which exposure-based CBT is recommended
- Are receiving, or expected soon to receive, exposure-based CBT at a participating Mass General Brigham outpatient program, including the Mass General Hospital (MGH) Child

CBT Program, the MGH Adult CBT Program, or the McLean Anxiety Mastery Program (MAMP)

About 40 people ages 12–22 will take part in this research study.

This study is supported by research funds from the American Psychological Foundation and is being conducted in collaboration with researchers from Mass General Brigham, Harvard University, and TheraLoop AI, Inc., the company that provides the BraveBot software.

What will happen in this research study?

If you join the study, the following things will happen. Many of these steps are part of your usual care, and some are specific to the research study.

1. Baseline questionnaires
After you consent, you will complete online questionnaires through a platform called REDCap. These take about 20–30 minutes and will ask about any anxiety, OCD, or other symptoms you are experiencing and how you cope with your anxiety. You will also watch a short pre-recorded video that walks you through how BraveBot works.

2. Orientation to BraveBot
At the first therapy session where exposure tasks are assigned after you join the study, your therapist will spend about 10–15 minutes showing you how BraveBot works.

3. Exposure assignments entered into the BraveBot system
Using a secure clinician portal, your therapist will enter your exposure assignments, such as:

- A short description of each exposure (for example, “touch the toilet seat without washing your hands”)
- The fear or concern it is meant to target (for example, contamination)
- How often you are asked to do it (for example, daily or several times per week)
- Whether the goal is to stay in a feared situation longer or to do a task more quickly with fewer safety behaviors

For each exposure, your therapist will also indicate whether it is BraveBot-eligible. BraveBot-eligible exposures are ones your therapist thinks are okay for you to do independently, can be done while you speak out loud, and do not require other people to take part.

Exposures that are not BraveBot-eligible can still be assigned, but BraveBot will not be used for them.

4. Text message reminders and links
Once you have been assigned a BraveBot exposure, you (or a caregiver, if preferred) will receive text message reminders up to 3 times per day. Each message will contain a link that, when clicked, displays that day's exposure assignments and provides secure links for completing them.

5. Randomization of each exposure instance
Each time you click on a link for a BraveBot exposure, the system will randomly assign that specific exposure attempt (that single "instance") to one of two conditions

- BraveBot-assisted exposure, or
- Self-guided exposure (no BraveBot coaching).

This assignment is done by computer, with a 50/50 chance for each option.

Once the assignment is shown on the screen, you can choose:

- "Start now" – to begin the assigned exposure right away,
- "Do later today" – to postpone that same exposure instance until later that day, or
- "Skip for today" – to skip that exposure instance for that day.

6. What happens during a BraveBot-assisted exposure?
If the computer assigns BraveBot and you click "Start now," your browser will open a webpage where you can "talk" (or type) with BraveBot; BraveBot does not use video input. BraveBot will guide you through a structured conversation that may include:

- Reviewing what the exposure is and why you are doing it
- Asking how anxious you feel
- Encouraging you to keep going when your anxiety rises
- Asking if you are using any "safety behaviors" (things that make anxiety go down quickly but may interfere with learning)
- Asking if you feel like you are "white-knuckling" (pushing through without really paying attention)
- Asking some questions at the end about what happened and what you learned

If the automated safety system detects language that might suggest self-harm, harm to others, or other serious risk, BraveBot will immediately pause the conversation, remind you that it is not a person and not a crisis service, and display instructions to contact a trusted adult, call or text 988, or go to the nearest emergency room. The session will then end. At the same time, your therapist and the study coordinator will get a secure alert asking them to review the session and follow up according to clinic procedures.

Your speech is processed in real time so that BraveBot can respond, but the raw audio is not saved. BraveBot generates written transcripts of the conversations; these transcripts and

summaries are stored securely and may be viewed by your therapist and the research team. The underlying AI model does not use your conversations to train itself.

7. What happens during a self-guided exposure?
If the computer assigns self-guided exposure and you click "Start now," the webpage will show the exposure instructions and remind you to do the exposure on your own. You are asked to keep the page open while you complete the exposure. When you are finished, you will click the "I finished" button.

8. Brief post-exposure survey
Right after each exposure that you complete, you will be asked to answer a few questions (0–100 rating scales) about how much effort you put into the exposure, how capable you felt of handling anxiety, how well you understood what you were supposed to do and why, how well you were able to stick with the exposure when it was hard, and how helpful the exposure felt in "fighting back" against anxiety. Your therapist will not see your 0–100 ratings; those numbers are stored separately for research. Your therapist may see that you completed a survey and may see BraveBot transcripts and summaries.

If the exposure was BraveBot-assisted, you will also be asked whether BraveBot said anything that did not match what your therapist has told you, whether you had any technical problems, and whether you ever felt unsafe or unsupported.

Each survey usually takes about 1–2 minutes.

9. End-of-BraveBot assessment
After you have either reached 45 assignment-reminder days (days on which you received a reminder to complete an exposure) or reached 12 calendar weeks since starting BraveBot but have not yet had 45 reminder days, your BraveBot access will stop. You will then receive a link (by text) to complete an online assessment that includes:

- The same symptom and functioning questionnaires you filled out at baseline
- Short questions testing what you remember about key exposure therapy ideas
- A brief usability survey about how easy or hard BraveBot was to use
- Questions comparing BraveBot-assisted exposures with self-guided exposures (for example, which felt more helpful)

This takes about 20–30 minutes.

10. Follow-up assessment
Three weeks after the end-of-BraveBot assessment, you will receive another link to complete some of the same questionnaires provided previously. This also takes about 20–30 minutes.

If you are under 18 years old, we will also ask your parent/guardian some questions about their thoughts on BraveBot once you are done using BraveBot.

11. After the study
When the study ends, your therapy can continue as you and your clinician think is best. However, BraveBot will no longer be available to you.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified data in other research. It won't be possible to link the information back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

You should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study information from many people. It could take many years before anyone knows whether the results have any meaning. Your therapist may, as part of your usual care, look at some of your questionnaire scores (such as anxiety questionnaires) or BraveBot transcripts and use that information to help guide your treatment. This is part of routine clinical practice and is separate from returning research "results."

What are the risks and possible discomforts from being in this research study?

1. Emotional discomfort from exposures
Exposure exercises are designed to make you feel anxious or uncomfortable in the short term so that anxiety can improve over time. This is a normal and expected part of exposure-based CBT, whether or not you are in the study.

2. Distress or confusion related to BraveBot
You might sometimes feel confused or annoyed if BraveBot gives suggestions that seem different from what your therapist has said, or if the conversation does not feel natural to you.

3. Risk-related conversations

If you talk with BraveBot about self-harm, wanting to die, harming others, or other serious safety concerns, the system is designed to immediately stop the BraveBot conversation, remind you that BraveBot is not a human or crisis service, and show you instructions to contact a trusted adult, call or text 988, or go to the nearest emergency room. The system will also send an alert to your therapist and the study coordinator, who will review the transcript and follow up according to usual clinic procedures.

In addition, one of the questionnaires you will be asked to complete (the Revised Child Anxiety and Depression Scale) includes an item that asks whether you think about death. If you endorse this item, a pop-up message will remind you to tell a trusted adult, call 988, or go to the nearest emergency room if you feel unsafe. The study coordinator will also notify your therapist so they can follow up as needed.

4. Technical problems
You may experience:

- Difficulty receiving or opening text message links,
- Audio glitches, dropped connections, or delays while using BraveBot, or
- Temporary loss of access to BraveBot if there are system outages.

If there are technical issues, you can still complete your exposure assignment on your own, and your regular therapy will continue as usual.

5. Privacy and confidentiality risks
Because this study uses electronic systems, there is a risk that your information could be seen by someone who is not authorized, for example if someone else sees the text messages on your phone. Someone who can see the phone receiving messages may see that it is getting reminders about exposure assignments. Twilio, the service that sends the SMS reminders, and the phone carrier may have access to basic message information (phone numbers, dates, and times). Messages will be brief and will not contain detailed clinical information.

We describe below how we will try to protect your privacy and who may see your information. There may be other risks that are currently unknown.

What other treatments or procedures are available for your condition?

Anxiety and related disorders can be treated with CBT without BraveBot or without being part of this study.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.
We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

Yes. You can earn up to $122 for participating in this study. You will earn $4 for each post-exposure survey you complete, for up to 20 surveys (maximum $80). You may complete more than 20 surveys, but only the first 20 will be paid. You can earn $14 for each of the three longer questionnaire batteries (at baseline, end of BraveBot period, and the 3-week follow-up) for a total of $42.

You do not have to complete all surveys to be paid. If you leave the study early, you will be paid for the surveys you have already completed.

Payments will be combined and emailed to you at the end of your study participation as an electronic gift card.

We may use your data to provide evidence supporting the use of a product to be sold. The Sponsor, hospital, or researchers may benefit if this happens. There are no plans to pay you if evidence from this study leads to commercialization in this way.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. There are no extra charges to you for using BraveBot itself or for completing the study surveys, although standard message and data rates may apply when receiving SMS reminders about exposure tasks.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.
If you are injured as a direct result of taking part in this research study, we will assist you in obtaining the medical care needed to treat the injury. This means arranging for (but not paying for) transportation to an acute care center for treatment of the injury.

If you are participating in this study in connection with your treatment at McLean Hospital, please note that McLean Hospital is a psychiatric care facility and does not provide general health care services.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research

- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.
If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____

Print Name

_____ _____ _____

Subject Signature Date Time (optional)

Subject Phone Number: _____

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____
Print Name

_____ _____ _____
Signature of Parent(s)/Guardian for Child Date Time (optional)

Parent/Guardian Phone Number: _____

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Child:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

_____
Print Name

_____ _____ _____
Signature of Child, Ages 14-17 Date Time (optional)

Child Phone Number: _____

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Print Name

Signature of Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version Date (04/16/2026)