# Brief Enhanced Anxiety Sensitivity Treatment: A Pilot Study

NCT05416203

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**BEAST One-Arm Pilot Consent Script**

You are being invited to take part in this research because you are a Veteran who may experience some form of anxiety. This VA research study hopes to learn more about strategies and treatments to improve this anxiety. Our team has developed a one-session telehealth-delivered and mobile app-enhanced intervention to help Veterans develop skills to improve this anxiety in hopes that these improvements will enhance Veterans capacity to handle life stressors.

**What is involved in the study?**

Approximately 15 Veterans are expected to participate in this trial through the VA Finger Lakes Healthcare System to receive the intervention being studied through this clinical trial. The assessments and intervention session will be completed by telehealth. Each assessment session will last approximately 30-60 minutes. You will be asked to complete surveys via a mobile app daily at several points in the study. You will complete an initial baseline session. During this session, we will also guide you through downloading a mobile app that you will be using for the remainder of the study. You will complete several daily surveys on the app for one week. You will next complete the intervention with a study therapist. After this intervention session, you will again use the mobile app to complete several surveys as well as practice the skills learned through the session for two weeks. Next, you will complete a post-intervention session and then two follow-up sessions, one and three months after the post-intervention session. For one week after each of these assessments, you will complete surveys on a mobile app.

If you decide to participate, you will be asked to complete some questionnaires about your anxiety and its impact on your life. I will then guide you through installation of a mobile app that you will be using as part of the intervention. Appointments will occur by telehealth when interested and/or available and the first one will occur (1) prior to starting the intervention (potentially today if you are available). After completing your initial assessment, we will schedule your intervention session. We will also collect information on your current medical and mental health problems, and treatment use from your electronic medical record, if available. The intervention session utilizes several common therapy techniques, including challenging negative thoughts and completing exercises where you elicit physical sensations similar to those experienced when anxious. The intervention session is audio-recorded; however the recording will not contain any personally identifiable or health information. The audio recordings of the interviews are used to create research notes, which are collected from all participants and grouped together for analysis.

**Confidentiality**.

All the information collected will be treated as confidential. Electronic information will be kept on secure password-protected VA computers on servers behind the VA firewall. Any paper records will be kept in locked filing cabinets, within locked offices at the Center of Excellence for Suicide Prevention, which is a secure facility at the Canandaigua VA Medical Center. None of your identifying information will be connected to your responses.

Importantly, none of this information will have any bearing on the healthcare that you receive. You proceed with your normal healthcare regardless of whether you choose to participate. At any time during this study, you can choose to withdraw from the study without prejudice or penalty. You can also choose not to answer any question at any time without any bearing on the healthcare that you receive from the VA. Again, these research activities do not replace your care as usual. Therefore, if you are already engaged in treatment for mental health, you will be encouraged to continue that treatment as appropriate and addressing ongoing concerns can be done with your regular treatment provider. If not engaged in care, but you are interested in initiating treatment during or after the study, please let research staff know and we can provide a list of treatment resources for both within and outside the VA. If, however, you have any concerns about the ongoing study or your one-time contact with our interventionist, you should feel free to bring that up with study staff or the primary investigator, [redacted].

**What are the risks of participation?**

Participation in this project is completely voluntary and you may withdraw at any time. Participation may involve risks that are unforeseeable. Risks or discomforts that you might experience include discomfort when engaging in some anxiety exposure exercises (such as hyperventilation). When engaging in the exposure exercises, you are meant to experience physical sensations that mimic feeling anxious, such as a rapid heartbeat, shortness of breath, and dizziness. These sensations will likely be uncomfortable, but they are not dangerous. You will first practice these exercises to elicit these sensations with your therapist, and the exercises after will be scheduled and expected, allowing you to ensure you are in a comfortable and appropriate environment for completing these exercises. Additionally, the research team will be available for any questions or to assist in dealing with these uncomfortable sensations. There is the possibility, though unlikely, that responding to questions on the survey may produce distress. Examples of distress include anxiety symptoms (e.g., shortness of breath, fear) or feeling down. If you experience distress during the interview, please discuss this with your interviewer. You may decide to stop the interview. We have no intention of sharing any of this information with your medical providers. However, if we are concerned about your safety, we will discuss it with you first and as a last resort reach out to emergency services if necessary. If you report any new medical concerns, we encourage you to let your medical provider know of these concerns; we will not contact them ourselves. Based on decisions made by the Principal Investigator, you may be withdrawn from the study if unanticipated consequences---like extreme distress---occur that are not part of the planned intervention.

**Are there benefits to participating in the study?**

If you decide to take part in the study, there may or may not be direct medical benefits to you in terms of your mental health or medical conditions. However, you will be receiving an intervention that is designed to improve your sensitivity to anxiety. We hope the information learned from the study will benefit other Veterans in the future as well. By conducting research studies such as this one, we can identify if these interventions can improve the mental health of Veterans experiencing anxiety.

You will receive compensation for your time for participating in the study. This compensation will be in the form of direct deposits, debit cards, or checks mailed to you by the VA following each completed session. The amount is as follows: Initial assessment: $40; post-intervention assessment: $40; 1-Month Post-Treatment Follow-Up Assessment $30, 3-Month Follow-Up $30. Veterans can also receive $30 weekly for completed the tasks through the mobile app, which will be five weeks in total. Each week a Veteran completes > 80% of their EMA surveys delivered to their mobile phone they receive a $10 bonus.

The total compensation for completing all components of the study is $340. Participants who do not complete the entire study for any reason will receive compensation for the components that were completed per the above pro-rated amounts and per the schedule of payments.

There is no cost to you for your participation.

**All participants will have a Certificate of Confidentiality. What does this mean?**

A Certificate of Confidentiality has been received from the Department of Health and Human Services. The Certificate prevents Investigators and other project staff from being forced, even by court order subpoena, to reveal that you are in the project or to release any research data by which you may be identified. The Certificate does not prevent the Investigators and other project staff from releasing such information, but it would only be released according to both the strict confidentiality procedures of the VA and the rules of ethical research practice under the following circumstances: if you report planning to harm yourself, others, or for child abuse. If any of these are disclosed, we would be mandated to report this information to the appropriate parties in order to protect the safety of yourself and/or others.

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

There is a possibility that data collected from this study could be used in forthcoming studies. If this occurs, identifiers will be removed from all identifiable private information before being used for future research studies by the current researchers, or other researchers taking part in similar research, without obtaining additional informed consent from you, the participant.

If you have questions about this study or to report a research-related injury, you can contact: [redacted]. If you have general questions about giving your consent or your rights as a participant in this study or you would like to speak with an individual who is unaffiliated to this specific research study to discuss problems, concerns, and questions; obtain information or offer input you may call the Chairman of the Syracuse IRB or the Human Research Protection Program Administrator, at [redacted] or the Syracuse VA Patient Advocate at [redacted]. You can also contact your local Patient Advocate: [redacted] in Rochester, [redacted] in Canandaigua, or [redacted] in Syracuse.

**Do you have any questions? Would you like to participate in the study today?**

***If the individual agrees to participate in the study, proceed with the Comprehension of Verbal Informed Consent below***

**Comprehension of Verbal Informed Consent**

Participant Name: _____

Date: _____

"Now that we have reviewed the details about the study, I'm going to ask you a few questions to make sure you fully understand the research study. This is standard procedure for research studies completed over the phone."

1. **What is the purpose of this research study?**
2. **How long will the phone interviews take?**
3. **Will the information you share during this study be kept confidential?**
4. **Can you decide to stop answering the questions at any time?**

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I would like to now confirm, are you willing to participate in this study?

□ Yes: Document oral consent below and continue.

□ No: Thank them for their time.

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**Name of Subject** [print]

**Person Obtaining Consent**

I have read this form to the subject. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. The subject has provided oral consent to participate in this study.

_____

**Name** [signature] **Title** [print] **Date**