OSU CHS IRB
Approval Effective:
April 22, 2021

OKLAHOMA STATE UNIVERSITY
Center of Health Sciences
PARTICIPANT INFORMATION and CONSENT FORM

Title of Project: Interactive Voice-Based Administration of the GAD-7 Pilot Study

Sponsor: OSU-CHS Department of Psychiatry and Behavioral Sciences

Investigator(s): Jason Beaman D.O.
Chair, Department of Psychiatry and Behavioral Sciences
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RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What you should know about participating in this research study:

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why are we doing this research?

You are being asked to participate in a study that analyses a new delivery system of the Generalized Anxiety Disorder – 7 (GAD-7). The GAD-7 is a clinically accepted tool for diagnosing generalized anxiety disorder. The purpose of the study is to examine if the new delivery system of the GAD-7 is effective at capturing participant anxiety levels. The new version uses Amazon Alexa to record voice responses to the assessment. The device in this study uses an Amazon Fire Stick on a smart television with a mirror interface. We will be comparing the responses on this device to those given on the clinically established paper format. If proven effective at capturing anxiety levels of patients, future studies may investigate if the new format can be used to improve at home clincal care.

Participating in this study will NOT affect your reputation or clinical care in any way and this will not be shared with your physician.

How long will my part in this research take?

We expect that your part in this research will last one month. The sessions will each take about 10 minutes and will be completed after your first two appointments at the clinic.

What happens to me if I agree to take part in this research?

Participation in this study will not affect you as an individual nor will it affect your clinical care. In this study, you will complete two assessments. Assessments will be done at baseline and at a follow up appointment 1 month later, which is current practice at the clinic. You will be randomly assigned to one of two arms. The first arm will take the assessment with pen and paper at baseline, which is currently the standard of care; the other arm will use the Amazon Alexa equipped device to take the assessment. The device, which is similar to a smart television with a mirror interface, records verbal responses to the GAD-7 assessment through Amazon Alexa. At the follow up session one month later, you will complete the second assessment in the alternate format that you did not use in the baseline session. You will also complete a user experience questionnaire and a supplemental survey collecting your demographic information such as your age, gender, and ethnicity at each session.

What are my responsibilities if I take part in this research?

Answering survey questions as honestly as possible at the initial and follow up appointments.

How many people will be studied?

The study will involve approximately 40 participants.

Could being in this study hurt me?

While there are minimal physical risks or discomforts involved in this study, the largest potential risk would be the possibility of the release of personal information.

While the research team has taken steps to protect the data that will be collected in the study and any publications would not involve personal information, the GAD-7 assessment on Major Depressive Disorder could have potentially harmful social consequences if released.

What happens to the information we collect?

The private information and your medical record will be shared with individuals and organizations that review the research, including: Government agencies, such as the Food and Drug Administration, the Institutional Review Board (IRB) that reviewed this research.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

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.

We plan to publish the results of this research. However, your participation in the study will be kept anonymous.

Deidentified data collected in this research might be used for future research or distributed to another investigator for future research without your consent.

Will being in this research help me?

You will receive no direct benefits from participating in this research study. We cannot promise any benefits to you or others from your taking part in this research. However, on possible benefit to others, in the future, may be the possibility of using the alternative format from home, instead of requiring in office visits.

What happens to me if I decide not to take part in this research?

You may decide not to take part in the research and it will not be held against you. A refusal to participate in this research study will not involve a penalty or loss of benefits to which you are otherwise entitled. Refusal will not affect your clinical care.

If you decide not to participate in the study but continue your clinical care at this facility, then the assessments you will take will be completed by pen and paper as is current clinical practice.

What happens if I agree to be in the study, but change my mind later?

You can agree to take part in the research now and stop at any time. Discontinuing participation will not result in penalty or loss of benefits to which you are otherwise entitled. You may skip questions that you do not want to answer and stop the survey at any time. Changing your mind will not affect your clinical care.

If you decide to leave the research, contact the researcher at: Jason Beaman, 918.561.8269 or Jason.beaman@okstate.edu.

Who can answer my questions about this research?

Although this consent form provides detailed information about this study, a research team member is available to answer any questions you may have about this study and/or participation in it. If you have questions, concerns, or complaints, talk to the researcher at: Dr. Jason Beaman, 918.561.8269, Jason.beaman@okstate.edu.

This research has been reviewed and approved by the Oklahoma State University Center for Health Sciences Institutional Review Board (IRB). You may contact the chairperson of this committee at 918-561-8487 for any of the following:

- Your questions, concerns, or complaints are not being answered by the researcher or research team.
- You cannot reach the researcher or a member of the research team.
- You want to talk to someone other than the researcher or the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research or your experience in this research study.

Will I be paid for taking part in this research?

You will not be paid for taking part in this research.

Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date