UNIVERSITY of SOUTH FLORIDA
USF RESEARCH & INNOVATION

Informed Consent to Participate in Research Involving Minimal Risk

Information to Consider Before Taking Part in this Research Study

Title: Doxy.me VR vs. Telemental Health-Based Exposure Therapy

Study # 006215

Overview: You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by Brian Bunnell, PhD who is an Assistant Professor at University of South Florida. This person is called the Principal Investigator. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at the University of South Florida and is supported by the National Institute of Mental Health (NIMH). The purpose of this study is to see if our new telehealth Virtual Reality clinic is as helpful as standard telehealth when providing therapy for people with a strong fear of snakes, dogs, or spiders. This study will take place over three months and include spending 30 minutes during this first visit completing a few questionnaires and a short interview; participating in twelve, weekly 1-hour therapy sessions remotely; spending about 30 minutes a few days per week practicing skills learned during therapy; and spending 20 minutes completing questionnaires half-way through and at the end of treatment.

Subjects: You are being asked to take part because you are an adult (≥18 years old) who speaks English, resides in Florida, has a strong fear of snakes, dogs, or spiders, and has access to the internet and a computer or smartphone with video conferencing capabilities.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Alternatives to participating in the study include pursuing a similar treatment in your area.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. Possible benefits may include reductions in anxiety associated with dogs, snakes, or spiders. You will be compensated $50 for your participation following the first visit, $50 following the sixth therapy visit and $50 for your participation in the final visit. There is no partial compensation. This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life or would face if you were to pursue therapy in your community.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

Study Procedures:

If you take part in this study:

1. We'll continue this first visit and ask you to complete some questionnaires and a short interview. These assessments will help us understand your fear of dogs, snakes, or spiders, and your overall mental health. Your answers will decide if you're eligible for the rest of the study. The questionnaires and the short interview will ask you about your mental health history and current symptoms.

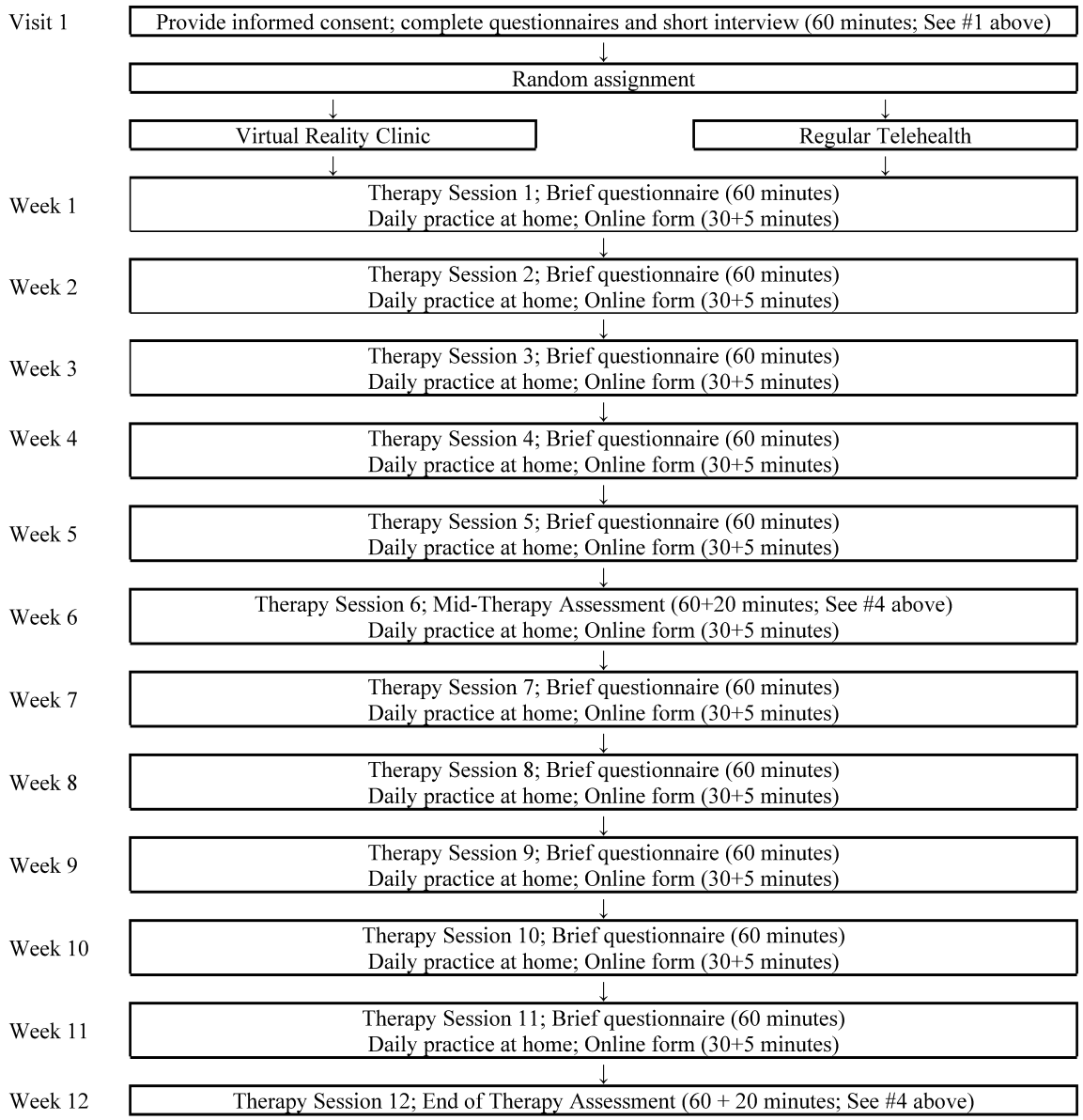
2. We're testing whether our new telehealth Virtual Reality Clinic works as well as regular telehealth for helping people who are very afraid of snakes, dogs, or spiders. Some participants will use the Virtual Reality Clinic during their therapy, and others will use regular telehealth with video calls. We'll randomly choose which group you'll be in, like flipping a coin – there's an equal chance of being in either group.
    a) **Virtual Reality Group** – In every therapy session, we'll begin with regular telehealth and then switch to the Virtual Reality Clinic. Here, you'll practice exposure therapy using a virtual version of the animal you fear, with the goal of helping you become more comfortable around them in real life. *We will send you a Meta Quest 2 Virtual Reality headset with the Virtual Reality Clinic app pre-loaded on the device. This headset is owned by the University of South Florida and must be returned when you end your participation in the study–postage paid by us.*
    b) **Telehealth Group** – Therapy sessions will take place through regular telehealth, using photos and videos of the animal you fear, with the goal of helping you become more comfortable around them in real life.

3. If you're eligible to continue, we'll schedule your first of 12 weekly 60-minute therapy sessions (study visits 2-13):
    - All therapy sessions will take place remotely, similar to how we're meeting now.
    - During these sessions, you will learn new techniques to gradually become more comfortable around the animal you fear. This approach is called exposure therapy and it's well-tested. You will rank a list of situations involving the animal you fear with the help of the study therapist during the first session. You will face the situation you are least afraid of during the second session and gradually work through the list.
    - At the end of each session, we'll ask you to answer a few questions about how you felt during the session. If you are in the VR group, you will answer six multiple choice questions about symptoms of cybersickness. If you are in the VR or TMH group, you will answer one question about how present you felt in the session. These questions will be completed at the very end of session and are not part of your homework.
    - You'll also need to practice the techniques you learn in the sessions for around 30 minutes a day during the week as homework. You will practice facing the same situation you faced in session. We'll send you an online form by text or email to track your practice.
    - We'll audio record therapy sessions so that Dr. Bunnell can review them and make sure that the study therapist is following the therapy protocol. These recordings will be stored in a secure, password protected location that only trained study staff will have access to, and they'll be deleted 5 years after the study is over.

- ❑ I give my permission for the study therapist, the Clinical Psychology Postdoctoral Fellow, to audio record my therapy sessions
- ❑ I **do not** give permission for my therapist to audio record my therapy sessions

4. After six therapy sessions, we'll ask you to spend 20 minutes completing some questionnaires about your fears and experience during therapy (i.e., whether you are satisfied with therapy and your current symptoms). After 12 therapy sessions, or about 3 months from now, we'll ask you to complete those same questionnaires and the ones you do during this first visit so that we can see your progress. Both 20-minute assessments will be completed during your therapy session and not between sessions as part of your homework.

Here's a timeline of the study:



Total Number of Subjects

About 30 individuals will take part in this study at USF: 15 in Virtual Reality and 15 in Telehealth.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study. Alternatives to participating in the study include pursuing therapy available in your area. You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

There are circumstances that might require study staff to withdraw you from the study without your consent. This might occur if you: (1) participate in mental health therapy from a therapist outside of the study; (2) have any changes to medications that treat mental health disorders; (3) report intent and plans to harm yourself or someone else; (4) report seeing/hearing/feeling things that others do not see/hear/feel; (5) or report the occurrence of epilepsy or seizures; or (6) move from the state of Florida during the study. If you withdraw from this study, we will try to provide you will a referral to a therapist in your area.

Benefits

The potential benefits of participating in this research study include reduced fear of dogs, snakes, or spiders.

Risks or Discomfort

This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life or would face if you were to pursue therapy in your community.

The following risks may occur:

1. Possible breach of your privacy and/or confidentiality
2. Possible breach of the security of online data
3. Possible discomfort due to completing psychological questionnaires and assessments
4. Possible discomfort due to having therapy sessions audio recorded
5. Discomfort during exposure therapy exercises. This discomfort is temporary but necessary for treatment gains to occur.
6. Possible discomfort or cybersickness as a result of using Virtual Reality, which usually goes away in 5-10 minutes.
7. Possible disclosure of suicidality or homicidality requires mandatory reporting if you are at imminent risk of endangering yourself or others. In the event that this occurs, we will follow the standard procedures set forth by the USF Department of Psychiatry and Behavioral Neurosciences.

Compensation

You will be compensated with a $50 gift card for completing the first study visit, $50 gift card for the sixth therapy visit, and a $50 gift card for completing the final study visit. You are paid for completing each assessment. There is no partial compensation for the last assessment if you withdraw during treatment or do not complete the entire assessment. If you are a USF employee and would like

to receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not tell them what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid. If you do not want to complete the tax payer ID form you can still participate in the study, however if the form is not completed you will not be compensated.

Costs

It will not cost you anything to take part in the study. However, you may exceed your monthly data or text message limits during this study resulting in additional costs that you will be responsible for covering.

Conflict of Interest Statement

The person leading this medical research study and a study coordinator on this study might benefit financially from this study. Specifically, this research study is being conducted in collaboration with Doxy.me Inc. Dr. Brian Bunnell and Ms. Janelle Barrera have a financial interest in Doxy.me Inc. and receive extra money from Doxy.me Inc. for work that is not a part of this study. These activities may include consulting, advisory boards, giving speeches, or writing reports.

The Institutional Review Board that reviewed this study and a committee at the University of South Florida have reviewed the possibility of financial benefit. They believe that the possible financial benefit to Dr. Bunnell and Ms. Janelle Barrera is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Privacy and Confidentiality

We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. These individuals include:

- The research team, including the Principal Investigator, study therapist (Postdoctoral Fellow/Clinical Psychologist), and study coordinator (Research Manager)
- Certain government and university people need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- Any agency of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP).
- The USF Institutional Review Board (IRB) and its related staff have oversight responsibilities for this study, and staff in USF Research Integrity and Compliance.
- The National Institute of Mental Health (NIMH)

Your identifiers might be removed from your private records or your samples. Your information or samples could be used and/or distributed to another investigator for future research studies without additional consent from you or your Legally Authorized Representative. We will do our best to protect your data and samples during storage if they are shared. However, there remains a possibility that someone could identify you.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

If completing an online survey, it is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet. If you complete and submit an anonymous survey and later request your data is withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a subject in the research project under certain circumstances. The investigative team will voluntarily comply with Florida Statutes and federal regulations, which may mandate or permit certain disclosures of protected information by the investigative team to appropriate individuals.

Per NIH's required data sharing policy, data from this research will be shared with other researchers via an open-source database. This website will not include information that can identify you, but no guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this database involves risks similar to a person's everyday use of the Internet. If you complete this study and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database."

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

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available.

We may learn things about you from the study activities that could be important to your health or to your treatment. If this happens, this information will be provided to you. This includes your assessment results, which will be provided verbally to you. The results will not be placed in your medical record.

You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call the study postdoctoral fellow/study therapist, Dr. Kaitlyn Schuler at 813-396-9169 or Dr. Brian Bunnell at 813-974-8607. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

Consent to Take Part in Research

I freely give my consent to take part in this study. I understand that by signing this form I agree to take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study Date

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Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent and Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

_____ _____

Signature of Person Obtaining Informed Consent Date

_____

Printed Name of Person Obtaining Informed Consent