IRB Use Only
Approval Date: January 31, 2021
Expiration Date: January 31, 2022

Title of Study: Reducing Anxiety and Improving Functioning in Older Veterans	
Title of Consent (if different from Study Title): Anxiety Treatment Study in Veterans aged 60+	
Principal Investigator: **Christine Gould, Ph.D.**	VAMC: VA Palo Alto HCS

Reducing Anxiety and Improving Functioning in Older Veterans

Anxiety Treatment Study in Veterans aged 60+

Are you participating in any other research studies? _____ yes _____no

PURPOSE OF RESEARCH

You are invited to participate in a research study examining whether psychological intervention delivered by video reduces anxiety in Veterans aged 60 years and older. Participants who are eligible for the study will be randomly assigned (like flipping a coin) to receive the BREATHE (relaxation) or Healthy Living for Reduced Anxiety (education). You were selected as a possible subject in this study because you expressed interest in a study that aims to treat anxiety.

This research study is looking for 75 people whose stress or anxiety affects quality of life. The VA Palo Alto expects to enroll 75 research study subjects. During the course of the grant, 175 research study subjects will be enrolled.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care you are entitled to through the VA. You have the right to refuse to answer particular questions.

DURATION OF STUDY INVOLVEMENT

This research study will last 12 weeks. You will be asked to complete a 3 hour in person assessment at the beginning of the study. If you are eligible, you will receive an intervention consisting of watching a 30-minute video each week for weeks 1 through 4. During weeks 5 to 12, participants will be asked to continue to use what they learned in the videos on their own. A second 2.5 to 3 hour assessment will occur at 12 weeks. This assessment can be done in person or by phone.

PROCEDURES

If you choose to participate, Dr. Gould and her research study collaborators will describe the procedures to be followed, including their purposes, how long they will take and their frequency. Dr. Sherry Beaudreau, Dr. Mary Goldstein, and Dr. Ruth O'Hara are co-investigators on this study. They will be advising Dr. Gould on the study. As a clinical psychologist, Dr. Beaudreau would oversee the study intervention in Dr. Gould's absence. A study coordinator(s) will assist with the study procedures.

The purpose of this study is to examine whether video-based psychological interventions reduce anxiety. The intervention is delivered by watching four videos on a DVD. If you would like, you will be lent a portable DVD player for the duration of the study this will need to be returned upon completion of the study. The videos are also available on a password-protected website.

First Assessment

You will first be asked to complete an in-person interview and some tests for 2.5 to 3 hours to see if you are eligible for the study. The clinical interview involves questions about anxiety, stress, and mood symptoms and whether they interfere with your life. The purpose of the interview is to see if participants meet criteria for an anxiety disorder, which would make them eligible for the study. Any participants with Obsessive Compulsive Disorder, serious mental illness (Bipolar Disorder), or psychotic disorders will be excluded from the study because effective treatments better suited for those problems exist. The clinical interview will be audiotaped to ensure accuracy. The recording will be deleted from the recording device once the scoring for accuracy in diagnosing is completed. The digital files will be kept on a secure VA server according to VA record retention policies. Only the investigator and the research team will have access to the audio recordings while they are still saved on the device. Under no circumstances will anyone else listen to the audio without your written permission. You will be asked to initial this consent to give us permission to voice record you as part of the research. You may still participate in the research if you do not give permission to record. You will be asked to complete questionnaires about anxiety and mood, and complete a task about the activities you do. We also will review your VA medical record to obtain information about the number, type, and severity of chronic medical problems that you may have.

Assignment to Groups

After this initial assessment, you will be randomly assigned (like flipping a coin) to one of two possible groups. You have a fifty percent chance of being assigned to receive the BREATHE relaxation videos or the Healthy Living for Reduced Anxiety education videos. Neither you nor the researchers can choose the group to which you will be assigned.

BREATHE Intervention - Only

The relaxation intervention is called BREATHE or Breathing, Relaxation, and Education about Anxiety in the Home Environment. The four week BREATHE treatment is delivered via video. Participants will watch a 30-minute DVD each week for the first four weeks of the study. The videos are also available via a password-protected website. Participants will learn about anxiety, learn diaphragmatic breathing, and learn two versions of progressive muscle relaxation (PMR). PMR involves tensing and then relaxing the muscles. If a participant has pain in certain areas, they can still participate and will be instructed to imagine the tensing portion of the PMR. Participants in the BREATHE group will be asked to practice PMR twice a day for four weeks. They will also be asked to try to use breathing or PMR in different situations that may be stressful.

Participants will receive a weekly check-in call during weeks one through four to check-in about problems with the videos or with the intervention. These telephone conversations may be recorded to check on how the study staff deliver the information in the calls. During weeks 5 through 12, participants will be asked to continue to practice PMR every day. Study staff will complete a questionnaire with the participant by phone at week 4 and week 8.

Healthy Living for Reduced Anxiety Education - Only

The Healthy Living group will watch an educational 30-minute video each week for four weeks. The videos are available via DVD or on a password-protected website. The videos will discuss what anxiety is, how to cope with anxiety, and how to reduce anxiety through healthy living. Participants will learn about tips for a better night's sleep, physical activity, and healthy eating.

Participants will receive a weekly check-in call during weeks one through four to check-in about problems with the videos or with the intervention. These telephone conversations may be recorded to check on how the study staff deliver the information in the calls. Study staff will complete a questionnaire with the participant by phone at week 4 and week 8.

End of Study

At the end of the study (12 week visit), you will be asked to complete a 2.5 to 3 hour assessment. This assessment can be done in person or by phone. This assessment will include a clinical interview, questionnaires, and a task about what activities you do. You also will have an opportunity to share your experience with the interventions. Completion of the study is estimated at 12 weeks. Participants in either group may receive the other videos at this time.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the investigators and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the investigators or research study staff to reschedule as soon as you know you will miss the appointment.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigators or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled and your decision will not affect your ability to receive medical care for your condition.

If you want to stop being in the study you should tell the investigators or study staff. You can do this by phone by calling Dr. Christine Gould at (650) 493-5000, press 1 for Palo Alto and dial extension 68899. You can reach the study coordinator at extension 67023.

If you withdraw from the study, you must return the portable DVD player.

The investigators may also withdraw you from the study without your consent for one or more of the following reasons: Failure to follow the instructions of the investigators and/or study staff; the investigators decide that continuing your participation could be harmful to you; you need treatment not allowed in the

study; the study is cancelled; for other administrative reasons; and for unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

This study involves the following risks, discomforts, and possible inconveniences. These deserve careful thought. You should talk with the Protocol Director if you have any questions. Your participation in this study may involve risks that are currently unforeseeable due to the investigational nature of this study. However, if any new risks become known in the future you will be informed of them. The following explains the precautions we are taking and the risks involved in these procedures:

- The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. As explained in the confidentiality statement of the consent, we do not intend to disclose this information.
- If information is revealed about child abuse or neglect, elder or dependent abuse or neglect, or potentially dangerous future behavior to others or yourself, the law requires that this information be reported to the proper authorities.
- Because this is an experimental treatment it is possible that this treatment may involve risks to you, which are currently unforeseeable.
- Some of the psychosocial tests can be associated with the experience of negative emotion, although this experience is usually fleeting. It is possible that you might become tired or frustrated by some of our testing. You may find answering the questionnaires annoying, boring, or repetitive. If this happens, please tell us and we will take a break.
- If you are in the BREATHE group, you will be asked to tense your muscles as part of the relaxation procedures. Please follow instructions as they are given in the video and do not tighten your muscles as hard as you can as overtightening may cause muscle soreness.

You will need to travel to our office for your initial appointment; for some people, this is an inconvenience.

POTENTIAL BENEFITS

Potential benefits of your participation in this study include improved mood and

decreased anxiety. Your participation may help us to learn more about the best way to treat anxiety in adults aged 60 years and older without medication.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY DIRECT BENEFITS FROM THIS STUDY.

ALTERNATIVES

You do not have to participate in this research study in order to receive treatment for any medical condition. Your study doctor will discuss any alternatives with you before you agree to participate in this study. Alternative treatments include referral to another VA clinic or provider for treatment. One alternative to participating in this study is to not participate.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

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.

CONFIDENTIALITY

We will keep your name and all the information about you used in this study as confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of

Research Oversight and the VA Office of the Inspector General may have access to your information.

FINANCIAL CONSIDERATIONS

Payment: Participants will be paid $60 for the initial assessment and $60 for the assessment at post-treatment regardless of whether the interview is done in person on over the telephone (12 weeks). You will receive $10 for completing each telephone assessment at week 4 and week 8. Any participants excluded from the study during the initial assessment will be paid $60. You may need to provide your social security number to receive payment.

You will not have to pay anything to be in this study.

Sponsor: The VA Office of Rehabilitation Research and Development is providing financial support for this study.

The Geriatric Research Education and Clinical Center (GRECC) and the Sierra Pacific Mental Illness Research, Education, and Clinic Center (MIRECC) are providing space for this study. The study staff conducting assessments are supervised by Dr. Gould.

COMPENSATION for Research Related Injury

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence. For further information, you may call the Human Protections Administrator at (650) 493-5000, press 1 for Palo Alto and dial extension 67593 or the V.A. Regional Counsel at (415) 750-2288.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the principal investigator Dr.

Christine Gould at (650) 493-5000, press 1 for Palo Alto and dial extension 68899. You should also contact her at any time if you feel you have been hurt by being a part of this study.

*Injury Notification: If you feel you have been hurt by being a part of this study, please contact the principal investigator, Dr. Christine Gould at (650) 493-5000, press 1 for Palo Alto and dial extension 68899.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact Dr. Christine Gould at (650) 493-5000, press 1 for Palo Alto and dial extension 68899.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;

- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you (by phone or mail) about future research studies that may be of interest to you? ____Yes ____No

I give consent to be audiotaped during this study:
Please initial: ___Yes ___No

May we contact a family member or friend during the study if we are unable to reach you within 14 days? ___Yes ___No
A separate VA release of information form will be obtained.

Signing your name means you agree to be in this study and that you were given a copy of this consent form.

_____ _____
Signature of Participant Date

_____
Print Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

This page separates the
Informed Consent Document *(above)*
from the
HIPAA Authorization document
(below)

To preserve formatting, please
DO NOT DELETE this page

Authorization To Use and Share Your Health Information For Research Purposes

HIPAA (Health Insurance Portability & Accountability Act) is a federal privacy law that protects the confidentiality of health information collected about you. The following explains how health information collected about you will be used by the investigators and who they may share your health information with as part of this research.

What is the purpose of the research study, and how will my health information be utilized in the study?

This is a research program examining a DVD-based intervention for anxiety. Information we collect about you will be added to information about other people and analyzed to help researchers and clinicians better understand which treatment of anxiety has beneficial effects on medical conditions. Results from this study will be presented as conference proceedings, in a peer-reviewed journal, to the grant sponsor, and in future applications to obtain additional funding in this area. Results may include individual descriptions of the presenting concerns, pre/post treatment testing, and treatment process and outcome. These descriptions will not include patient identifiable information.

What Personal Health Information Will Be Used or Shared?

The following health information, linked to you will be used for this research: information about anxiety and chronic medical conditions (number, type, and severity) in the VA medical record (if applicable); your reported medical history; study staff progress notes; and Survey/Questionnaire responses.

Who May Use or Share Your Health Information?

By signing this document, you allow the following individuals and entities to obtain, use and share your health information for this research study:

- The Principal Investigator Dr. Christine Gould and members of the VA research team.
- Departments within the VA Health Care System responsible for the oversight, administration, or conduct of research.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and other Stanford University Officials responsible for the oversight, administration, or conduct of research.

Who May Receive and Use Your Health Information

The investigators may share your health information with the following individuals/entities as part of this research study.

- Your personal physician may receive some data collected for this study, if you request (in writing) that we send information to him/her
- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Health information shared pursuant to this authorization may no longer be protected by Federal laws or regulations and may be further shared by the above individuals/entities who receive the health information.

Do I have to sign this form?

No. Signing this form is voluntary. The VA may not condition treatment, payment, enrollment or eligibility for benefits based on signing this form. If you decide not to sign the form, you will not be able to take part in this study.

If I sign now, can I decide later not to continue in the study?

Yes. You are free to take back your permission and stop being in the study. The investigators will not collect any more information about you after you take back your permission, but they can continue to use your information that was collected before you took back your permission.

Your request to take back your permission must be done in writing. Either give or send your written request to the investigator: Dr. Christine Gould, VA Palo Alto Health Care System, 3801 Miranda Avenue, Mail Code 182B, Palo Alto, CA 94304.

Does My Permission for the use my Personal Health Information Expire?

Yes. Your information cannot be used forever. Your permission related to the use and sharing of your health information expires when this research study is completed or on December 31, 2075.

HIPAA regulations require you to give separate written permission (signature) for the use of your protected health information.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant