Department of Geriatrics

Cognitive-behavioral therapy versus yoga for the treatment of worry in anxious older adults:
A randomized preference trial
Informed Consent Form to Participate in Research

Gretchen A. Brenes, Ph.D and Suzanne C. Danhauer, Ph.D., Co-Principal Investigators

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have worries and anxiety. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family. This study has been approved by Institutional Review Board (IRB), which is a group of people who review the research to protect your rights.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to better understand treatments for worry in adults 60 years of age and older. The study will provide two different types of treatments for worry: cognitive-behavioral therapy (CBT; a type of talk therapy) or gentle yoga. We do **NOT** provide medication in this study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We will enroll 500 people in this study.

WHAT IS INVOLVED IN THE STUDY?

This study is a **randomized preference trial.** People will be randomly assigned (like a flip of a coin) by computer to one of two groups. The **first group** is one where the computer again decides (like the flip of the coin) if you get to be in the CBT group or the gentle yoga group. The **second group** is one where you get to choose CBT or gentle yoga.

Cognitive-behavioral therapy (CBT) will consist of:

- You will be given a workbook. Each chapter in the workbook provides information about a different coping strategy for managing worry.
- You will have a daily assignment in the workbook to complete (10-15 minutes) on your own before your call with your personal study coach.
- You will participate in 10 (50-minute) weekly sessions.
- The calls will be confidential with a personal study coach.
- The weekly sessions will be by telephone with a personal study coach.
- You and your personal study coach will review the assigned chapter and your completed homework during your weekly telephone sessions.

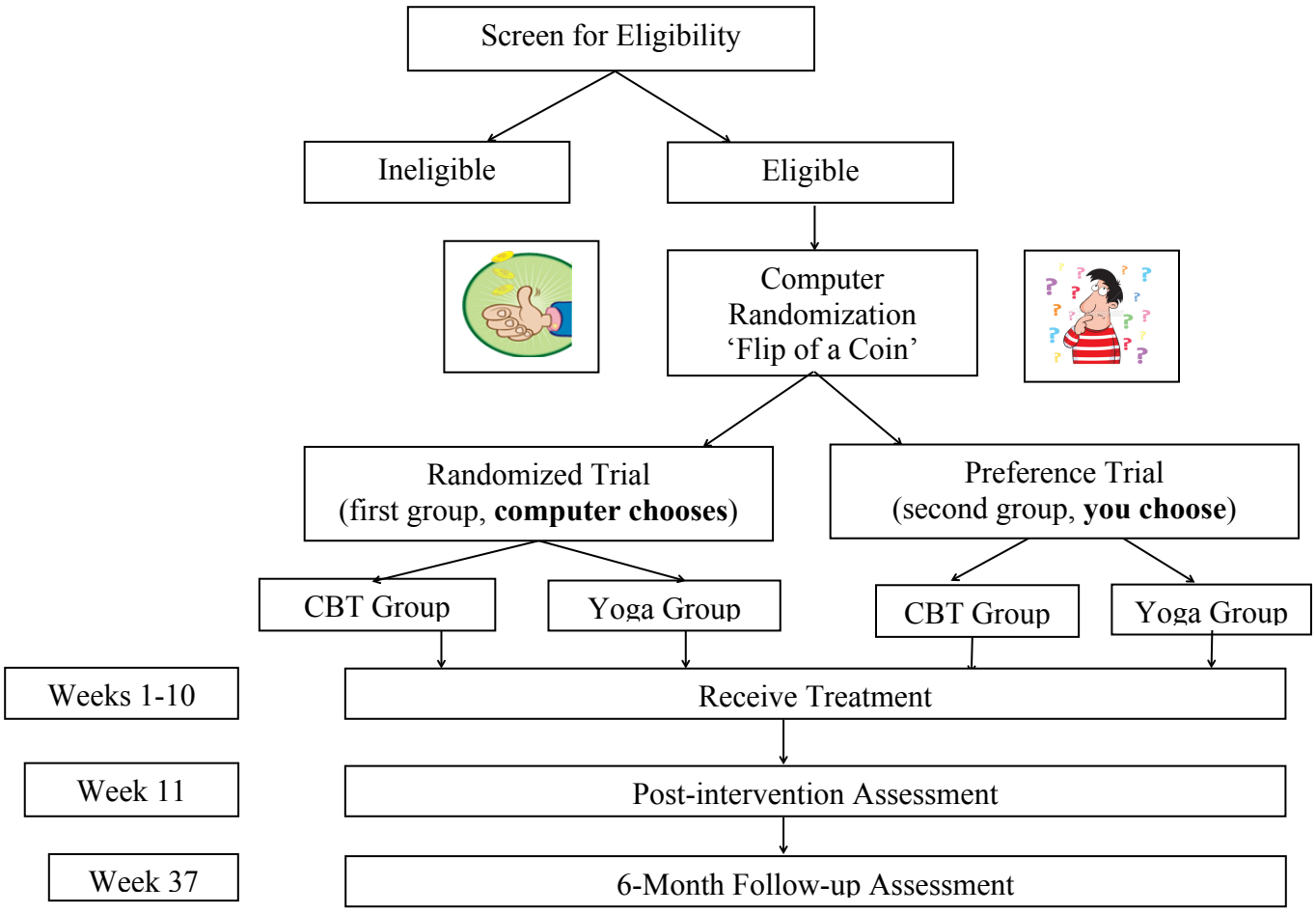
Gentle yoga will consist of:

- You will participate in 20 (75 minute) group classes; classes are twice a week for 10 weeks with a trained yoga instructor at a location in the community.
- You do **not** have to be in good shape to do this form of yoga. The gentle yoga has been modified so it is safe for people who are older and may have medical and physical problems. The yoga can be done in a chair, if necessary or on the floor if you are able.
- The yoga classes will combine physical postures, breathing, and deep relaxation.
- Yoga is not a religion or religiously-based program. Participation in yoga classes should not undermine your faith.
- There will be no more than 10 participants in a class at a given time.

Further, we will be collecting information from you throughout the study. We will ask you to fill out a packet of questionnaires at three different times during the study:

- First to determine if you are eligible
- Immediately after completing either cognitive-behavioral therapy or gentle yoga
- 6 months after completing treatment sessions

These questionnaires will take 30-60 minutes to complete.
Additionally, midway through your time with talk therapy or yoga classes, you will be asked to fill out a few questionnaires.



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As part of this research study, if you participate in the cognitive-behavioral therapy sessions (CBT) your one-on-one calls with the study coach will be audiotaped. An expert psychologist on our study team will review randomly selected sessions in order to make sure the study coaches are handling all calls in the same way. You may request the recording of the calls be stopped at any time during the course of the research study. If you participate in the gentle yoga classes your instructor will be videotaped. Expert, Dr. Stephanie Sohl at Wake Forest Health Sciences, will review randomly selected sessions in order to make sure the instructors are teaching classes in the same way. Please choose one of the following regarding the use and disclosure of the tapes used in this research study:

_____ I would like the tapes of me to be destroyed once their use in this study is finished.

____ The tapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an Institutional Review Board (IRB). I understand that I will not be able to inspect, review or approve their future use.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for 10-12 consecutive weeks with a 6 month follow up. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves minimal risk.

Every effort will be made to address each participant's concerns or problems in the most supportive, empathic, and therapeutic manner. Some individuals may find discussing their problems with others to be uncomfortable, embarrassing, and/or stressful.

Taking part in this research study may involve providing information that you consider confidential or private. Participants will be assigned a study ID number and only the ID number will be associated with the data. Research records are secure, and only the study team will have access to research records. They are required to keep your information private. When we present results from this study, we will not provide the identities of our participants.

There is minimal risk associated with yoga. Individuals who overexert themselves or who practice yoga too aggressively may experience pain, cartilage tears, and/or muscle or ligament sprains. In most cases, there is typically no pain experienced from practicing yoga. If any discomfort occurs, tell the yoga instructor. They will help you to change the poses so that you will be more comfortable. It is also possible that you may experience slight emotional discomfort or anxiety during quiet periods of relaxation during the yoga practice.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

We hope the information learned from this study will benefit other people in the future by increasing knowledge about if and how CBT and yoga affects individuals with worries and anxieties. The benefits of participating in this study may be a decrease in your worry and anxiety. There is not yet definite proof of benefit.

WHAT OTHER CHOICES ARE THERE?

Participation in this study is voluntary. You may talk to your doctor about all the choices that you have, such as prescription medications, professional counseling, or other alternative therapies to treat your anxiety.

LIMITS OF CONFIDENTIALITY

At any point during the study, confidentiality will be broken if a participant is 1) imminently suicidal, 2) found to be homicidal, or 3) suspected of committing child or elder abuse as defined by the statutes of North Carolina. Further, we may contact your emergency contacts if you seem to be experiencing any significant confusion or may be medically ill.

WHAT ABOUT MY HEALTH INFORMATION?

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 revealed in order to meet the requirements of the federal Food and Drug Administration (FDA). The Certificate does not prevent you or a member of your family from voluntarily releasing information about 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.

Even with the Certificate of Confidentiality, the investigators continue to have ethical and legal obligations to report child abuse or neglect and to prevent you from carrying out any threats to do serious harm to yourself or others. If keeping information private would immediately put you or someone else in danger, the investigators would release information to protect you or another person.

If you sign this document, you give permission to Tranquil Moments II team (**Gretchen A. Brenes, Ph.D. and Suzanne C. Danhauer, Ph.D.,** Co-Principal Investigators) to use or disclose (release) your health information (commonly referred to as HIPAA) that identifies you for the research study described herein.

The health information that we may use or disclose (release) for this research includes but is not limited to **your name, date of birth, address, telephone number, medical record number, physician, date of physician visit, your health history, and information collected from you from study visits, phone calls, questionnaires, and audio- and video-recordings.** If you are to be randomized into the yoga intervention, the yoga instructor will ask you to fill out a separate form to offer health information to ensure your safety while participating; this information collected will be specifically for instructors to review. The other data collected throughout the study will not be shared with the yoga instructors.

We will make every effort to keep your health information private. We will store records of your health information in a cabinet in a locked office or on a password protected computer. The health information listed about you may be used released to the Institutional Review Board of Wake Forest School of Medicine, the Data Safety and Monitoring Board of Wake Forest School of Medicine, and the Patient-Centered Outcome Research Institute (PCORI), the organization that funds this research.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for 3 years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are finished.

You may change your mind and take back this Authorization at any time. Even if you take back this Authorization, the Tranquil Moments II Team may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to:

Gretchen A. Brenes, Ph.D.
[redacted]

This Authorization does not have an expiration date.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

We ask that you complete a packet of forms three times throughout the study. You will be paid a $15 gift card for fully completing each of these three packets of forms, for a possible total of $45 in gift cards. If you do not complete them, you will not be paid. All information you provide will be kept strictly confidential.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Patient-Centered Outcomes Research Institute (PCORI). The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research-related injuries or to report a study related illness, adverse event, or injury, you should call **Gretchen A. Brenes, Ph.D. at** [redacted] or **Suzanne C. Danhauer, Ph.D.** at [redacted]. For an after-hours emergency (5pm-8:30am M-F or anytime Sat or Sun), call [redacted] and ask for the psychiatrist on call.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WFU School of Medicine
Institutional Review Board
IRB Number: IRB00041530
Meeting Date Approved 2/9/2018
Version Valid Until: 1/7/2019

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions or if you would like to withdraw your consent, you can contact:
Gretchen A. Brenes, Ph.D., at [redacted] or email at [redacted]
Suzanne C. Danhauer, Ph.D. at [redacted] or email at [redacted]
For an after-hours emergency (5pm-8:30am M-F or anytime Sat or Sun), call [redacted] and ask for the psychiatrist on call.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

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