Official Title: A Pilot Study Yoga for Caregivers and Persons With Dementia
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Wake Forest®
School of Medicine

Department of Internal Medicine,
Section of Gerontology and Geriatric Medicine

A PILOT STUDY OF YOGA FOR PERSONS LIVING WITH DEMENTIA AND THEIR CARE PARTNER

Informed Consent Form to Participate in Research
Gretchen A. Brenes, Ph.D, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine the feasibility and acceptability of yoga classes for persons living with dementia (PLWD) and their care partners. You are invited to be in this study because you either have dementia or you are a care partner of a PLWD. Your participation in this research will involve up to 20 visits and last up to 10 weeks.

Participation in this study will involve completing questionnaires and attending gentle yoga classes twice a week for up to 10 weeks. All research studies involve some risks. A risk to this study that you should be aware of is that you may feel sore after class. You may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include doing nothing. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Gretchen A. Brenes, Ph.D., Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted] or [redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted]

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 dementia or you are a care partner of someone with dementia. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask the 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.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if persons living with dementia and their care partners are willing and able to complete up to 10 weeks of group yoga classes. We are also interested in the effects of yoga on your emotional well-being.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Ten people at one research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will participate in up to 20 group yoga classes; classes are twice a week for up to 10 weeks with a trained yoga instructor at a location in the community. Classes will last up to 75 minutes. 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 before starting the yoga program and immediately after completing the final yoga class. The questionnaires should take less than 30 minutes to complete.

As part of this research study, all yoga classes will be videotaped to ensure that the instructors are teaching the classes in the same manner. . Although the camera will be aimed at the instructor, there is a chance that a participant may be captured on the video. If you do not consent to the videotaping, you cannot participate in the study. You should also understand that you will not be able to inspect, review, or approve the videotapes before they are used in this study. All videos will be destroyed after use in the study.

Please choose one of the following regarding the use and disclosure of the videotape used in this research study:

_____ I agree to the use of video during the yoga classes and understand that I may be captured as a study participant although the camera will be aimed primarily at the yoga instructor. I understand that the videos will be destroyed after the study is complete.

____ I do not agree with the use of video during the yoga classes and understand that, as a result I am no longer eligible to participate in this study since the study protocol requires all classes be videoed.

How Long Will I Be in the Study?

You will be in the study for up to10 weeks.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first.

What Are the Risks of the Study?

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.

In addition, there is a slight risk of a breach of confidentiality. 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. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be a reduction in stress and anxiety.

What Other Choices Are There?

You do not have to be in this study to receive yoga. Instead of being in this study, you may seek yoga elsewhere, such as local fitness or community centers.

What Are the Costs?

All study costs will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Video recordings will be stored electronically. If you do not consent to the videotaping, you cannot participate in the study. Video recordings will be deleted no more than 3 years after the last date of data collection.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences.

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 University 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 University 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 University 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] during business hours or [redacted] after hours and ask for the geriatrician on call.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** Number of yoga classes attended, measures of emotional well-being, and feedback

regarding your experiences in participating in the yoga classes.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least three 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.

You can tell Dr. Gretchen A. Brenes that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

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

[redacted]

However, if you take away permission to use your Protected Health Information prior to completing the study you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a North Carolina Baptist Hospital (NCBH) medical record will be created for you to ensure that this important information is available to doctors in case of an emergency. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

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, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

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

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Gretchen A. Brenes, Ph.D. at [redacted]3 during business hours or [redacted] after hours and ask for the geriatrician 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 you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the

Research Subject Advocate 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

Caregiver Name (Printed):_____

Caregiver Signature: _____Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

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