The Alzheimer's Companion Engagement (ACE) Project

NCT Number: NCT04856462

February 19, 2025

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: The Alzheimer's Companion Engagement (ACE) Project
Principal Investigator: Sheria Robinson-Lane, PhD, MHA, MSN, RN, School of Nursing
Study Sponsor: National Institutes of Health, National Institute on Aging

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

1.1 Key Information

Things you should know:

- The purpose of the study is to test a new form of support for Black family caregivers of persons with dementia.
- If you choose to participate, you will be asked to participate in an 8-week program during which time you will
    - Complete two surveys and a program evaluation
    - Participate in 1 hour weekly virtual support group meetings for caregivers for 6 weeks
    - Review a 1-2 page document each week that reviews information about dementia care management or personal health
    - Take your blood pressure each week and submit the results to researchers
- Risks or discomforts from this research include possibly feeling sad or uncomfortable by some the questions asked in the survey or topics covered in the support group meetings and there is the potential for some discomfort from the use of the blood pressure cuff. There is also a small risk of breach of confidentiality due to the electronic nature of data collection and storage and the group nature of support groups.
- The direct benefits of your participation may include improved health, reduced or better maintenance of healthy blood pressure, reduced pain, improved mental health, and increased ability care for a person with dementia.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose of this study is to test a newly developed support group format developed specifically for Black caregivers of older adults with dementia. We would like your feedback on the program and would like to understand if your participation in the program improves your health and your sense of your ability to provide care for your relative with dementia.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

Individuals who would like to participate in this study must meet the following criteria:

- Be Black or African American
- At least 18 years old
- Able to speak and understand spoken English
- Related to, or has a close personal relationship to a person over the age of 55 that has dementia
- Regular access to a smartphone, tablet or computer with internet access that will allow participation in the weekly virtual support groups.
- You must provide regular care assistance to your relative with dementia. This **may** include (but are not limited to) supervision or monitoring for safety, managing medications, ensuring that bills are paid, providing meals, assisting with dressing, grooming or other daily personal care activities.
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3.2 How many people are expected to take part in this study?

We plan to enroll 36 people in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

1. After your study eligibility has been determined from the screening survey, you will receive a personalized invitation to complete a survey that will ask information about you, how you feel about providing care, how you manage problems, your health, the type of support that you have available, what help your relative requires, and the care tasks that you help them with.
2. You will take your blood pressure each week using an electronic wrist cuff. You will be provided instructions on how to use the cuff properly. We will send you a link each week to upload your weekly blood pressure reading.
3. You will review a 1-2 page document each week that discusses a topic related to dementia care or personal health management
4. You will participate in a weekly support group with as many as 4 other participants. This group will meet virtually for 6 weeks and will be facilitated by the study primary investigator—a registered nurse with expertise in dementia care and family caregiving. Participants will be removed from the study if they do not complete the 1st study survey or do not attend support group meetings.
5. You will take another survey at the end of the program and complete a program evaluation.

4.2 How much of my time will be needed to take part in this study?

This study will take place over 8 weeks and will require approximately 1 hour and 30 minutes of your time each to complete, read study materials, participate in the support group meetings, and upload your blood pressure data. Each survey (one taken week 1 and one taken week 8) will take approximately 1 hour to complete. It will take approximately 10 minutes to take your blood pressure and upload the results to the link you will be provided. The weekly support group meetings will take place over 6 weeks and will last approximately 1 hour.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Some of the questions we ask in our surveys about your mental health or current levels of support may make you feel uncomfortable or sad. You may also be uncomfortable with some of the topics that may come up during support group meetings. You do not have to answer any questions that you do not feel comfortable answering. Although the wrist blood pressure cuff you will receive was selected due to its wide availability in stores, comfort, and ease of use, it is also possible that you may experience some temporary discomfort with its use. Please notify the study team if this is the case. There is also a small and unlikely risk of breach of confidentiality due to the electronic nature of data collection and storage. In addition, a large part of this study involves participating in small groups for support. Though we ask all participants to maintain the confidentiality of other group members, you should be thoughtful about what you choose to disclose and may opt to use an alias during support group meetings.

See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 How could I benefit if I take part in this study? How could others benefit?

The direct benefits of your participation may include improved health, reduced or better maintenance of healthy blood pressure, reduced pain, improved mental health, and increased ability care for a person with dementia. Your participation in this study and feedback will also help to improve the program for future participants.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive $200 in Mastercard gift cards (or check if preferred) for your participation in the study. It will be distributed as follows:

- $50 following the completion of the initial program survey
- $50 following the completion of 3 support group meetings and blood pressure readings from the 1st three weeks

- $50 following the completing of 6 support group meetings and blood pressure readings from the last 3 weeks.
- $50 following the completion of the final program survey and evaluation

If you withdraw from the study prior to it's completion you will be compensated for your participation up to your withdrawal time as noted above.
If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

Your name and any other identifying information will be secured and stored separately from your research data in an electronic encrypted file. The information that you provide in surveys will only be linked to a numerical identifier. Only the Principal Investigator and members of the research team will have access to your research files including personally identifiable information. We will only use first names in our support group meetings and participants have the option of using an alias if they choose. Notes we may take during support group meetings will not contain any of your identifying information.

Your research information will be stored electronically on the cloud; the term "cloud" refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we will share study data that has your personal

information removed to the Deep Blue public data repository at the conclusion of this study. We may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.

- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, and of some communicable diseases.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://grants.nih.gov/policy/humansubjects/coc.htm

If you tell us or we learn something that makes us believe that you or others have been or may be abused, neglected, or exploited, we may, and in some cases must, report that information to the appropriate agencies.

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

8.3 What will happen to the information collected in this study?

We will keep the de-identified information that we collect about you during this study for future research and record-keeping. Your name and other information that can directly identify you will be stored securely and separately from your research data. Any linkages between your personal information and study data will be destroyed at the conclusion of the study (when data analysis is complete). We will keep the data you provide us for 7 years. The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

8.4 Will my information be used for future research or shared with others?

This study receives funding from the National Institutes of Health (NIH). NIH requires us to develop a plan regarding how we may share some information about you with other researchers so that they can use it in their studies. Their research may be similar to this study or may be completely different. Once we have shared information about you with other researchers, we will not be able to get it back.

Although we will do our best to protect your information, both during storage and when sharing it with others, it's possible that unauthorized people might gain access to your information.

We will remove all details from your information that identify you individually and assign it a random code before sharing it with other researchers.

Your information will be openly available to the general public. Researchers who wish to access and use your information in their studies will not be required to obtain permission.

Permitting us to store and share your information is a condition of participating in this study. If you do not want us to share your information with other researchers, you should not take part in this study.

8.4.1 Special Requirements

This behavioral trial will be registered and will report results on www.clinicaltrials.gov. This site 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.

We will also put the information we collect from you into the Deep Blue data repository managed by the University of Michigan. The repository contains information about many people. Your information will be de-identified –or- labeled with a code, instead of your name or other information that could be used to directly identify you.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Sheria Robinson-Lane, Phd, RN
Email: grices@umich.edu
Phone: 734-764-9280

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)

2800 Plymouth Road
Building 520, Room 2144
Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

I understand that my PARTICIPATION IS VOLUNTARY. I have the right to decline to be in this study, or to withdraw at any time without penalty. I will be mailed a printed copy of this document with other study materials if I agree to participate.

○ Yes, I wish to participate in the Alzheimer's Companions Engagement (ACE) Project

○ No, I do not wish to participate in the Alzheimer's Companions Engagement (ACE) Project