

Consent Document

BACKGROUND

You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The purpose of this study is to develop activities for training people who provide care to persons with dementia. These activities involve viewing examples, practicing, and discussing ways to prepare for dementia caregiving. We think that activities, like this, will help caregivers better plan for providing care to persons with dementia. This study is being conducted by Jacqueline Eaton, Assistant Professor in *The College of Nursing at the University of Utah*.

STUDY PROCEDURE

This study will happen over 14 weeks. Participants will be put into one of two groups, randomly decided by a computer. The first group will participate in three caregiver meetings over 6 weeks. This will be followed by data collection check-ins over 8 weeks. The second group will begin with 8 weeks of data collection check-ins, followed by three caregiver meetings over 6 weeks. Each meeting will be scheduled every two weeks and last 60 minutes. Before you begin, we will explain the study and ask your permission to participate. You will be asked to complete a survey regarding caregiver wellbeing and intervention activities. This survey will be repeated six times over 14 weeks. Surveys will be gathered each time we meet. On the weeks we do not meet, you will have the choice of completing the survey via phone or internet.

Meetings will involve individual, small, and large group activities. Each meeting will be with other dementia caregivers. We will work through three steps at each session. In step one, the group will view a short video focusing on a caregiving situation specific to difficult behavior. During step two, the group will practice managing difficult behavior. During step three, the group will discuss observations and choices made during the previous two steps.

Caregiver meetings will be digitally recorded using video to identify participant reactions to activities. At the end of each meeting, you will be given a brief survey to complete online, which will ask you to provide feedback on the activities for that day. This survey will take 3 minutes to complete. Following meeting one and two, you will be given take home activities which will ask you to reflect on the experience. These will involve journaling about topics related to the previous meeting.

Two weeks after your last meeting, caregivers will be invited to meet together to discuss thoughts about the caregiver training activities. This will help us identify how to improve the experience. The audio from this meeting will be digitally recorded to document your thoughts and ideas.



RISKS

The risks of this study are minimal. You may feel upset thinking about or talking about personal information related to caregiving. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience, you can tell the researcher, and she will tell you about resources available to help. Confidentiality and privacy may also be at risk, in that you will be meeting in groups with other caregivers. Specific things that we will do to reduce these risks are described below.

BENEFITS

We cannot promise any direct benefit for taking part in this study. However, possible benefits include meeting new people. You may also value the chance to let people know about your opinions and experiences.

CONFIDENTIALITY

We will take steps to protect personal information. All participants will be instructed to not share personal information about other participants. Audio and video recordings will be kept in a locked file cabinet, where only the principal investigator can access them. We will write out the words from the audio recordings and change any information that identifies participants. For example, names and locations will be changed. Identifying information will not be retained on any information made public, including publications from study results. Electronic materials will be stored in password-protected files on secure devices. All identifying information will be destroyed five years after project completion. It is anticipated that this will be no later than December 31, 2028.

A description of this clinical trial will be available on <http://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 and find this study using the registration number NCT04920006.

If you disclose information that gives study staff a reason to believe that a child, disabled, or older adult has been subjected to abuse or neglect, study staff will report that information to Child Protective Services, Adult Protective Services, or the nearest law enforcement agency to the extent required by law. There are some cases in which a researcher is obligated to report issues, such as serious threats to public health or safety.

PERSON TO CONTACT

If you have questions, complaints, or concerns about this study, you can contact Jacqueline Eaton at 801-362-5303. If you think you may have been injured from being in this study, please call Jacqueline Eaton during the hours of 8:00 AM and 10:00 PM.



Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu. For the Department of Human Services IRB, please contact Jacob Murakami by phone at (801) 538-4641 or by e-mail at jmurakami@utah.gov.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell us that you do not want to be in this study. You can start the study and then choose to stop the study later. We will still answer any questions that you have and you will not receive a penalty or lose any benefits. Your decision will not affect your relationship with the researcher or the study team in any way.

If you do not want to take part in the study, there are other caregiver support groups available through the Utah Caregiver Support Program and the Alzheimer's Association. You may choose to explore these options, and we will provide you with contact information at your request.

COSTS AND COMPENSATION TO PARTICIPANTS

You will not be charged for any part of this study. You will receive \$25.00 for each caregiver meeting that you attend, \$10 for the completion of three surveys gathered outside of meetings, and \$50 to attend the final focus group meeting. It is possible to receive \$155.00 total in compensation. Payment will be distributed at the end of the study either through direct deposit or check. You will only be paid for each visit or survey that you complete. If you discontinue early from the study, you will receive a partial amount based on how many meetings and surveys you complete.

Since you will be paid for participating in this study, it is necessary for us to collect your Social Security Number. You will provide this information for a Federal W-9 Form that is filed with our Accounts Payable department. Accounts Payable will have limited access to the study information (e.g. the name of the study) for payment purposes. The amount you receive for taking part in this study will be turned into the Internal Revenue Service (IRS) as taxable income. You can choose not to provide us with your Social Security Number for this form and still participate in this study; however we will not be able to pay you as outlined in this consent form.

DATA SHARING

As part of this study, we would like to place the data gathered from you in a database so that other researchers can use it in the future. This data will not include information that identifies you. This means that researchers will not be able to connect you to the data. The type of data that will be included

involves: de-identified transcripts from focus groups, survey questions about perceived stress, caregiver burden, positive aspects of caregiving, resilience, imagined interactions, caregiver appraisal, and experience caregiving. Audio and video files will not be included or shared.

Future research about caregiving for persons living with dementia may be done to learn more about the experience. Your data will be kept by Dr. Jacqueline Eaton who manages this data set at the University of Utah.

The data shared will be completely de-identified. This means that once saved for future research the data will not be able to be removed. In addition, future results will not be returned to you as the data will not be linked to you as a participant.

You do not have to participate in data sharing to be in the main part of this study. No matter what you decide to do, your decision will not affect your status in this study. You can tell us your choice by initialing one of the options below:

___ YES, my data may be saved for future research.
(initial)

___ NO, my data must be destroyed at the end of this research project.
(initial)

FUTURE RESEARCH

May we contact you to invite you to participate in future research studies?

___ YES, I am interested in learning more about future research opportunities.
(initial)

___ NO, please do not contact me about future research opportunities.
(initial)



CONSENT

By signing this consent form, I confirm that I have read the information in this consent form and have had the opportunity to ask questions. I will be given a signed copy of this consent form. I voluntarily agree to take part in this study.

Printed Name of Participant

Signature of Participant

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

