Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study

Title of research study: Providing support to caregivers of frail older adults with cognitive impairment to reduce caregiving burden

Version Date: October 10, 2018

Investigator: Machiko R. Tomita

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are a family caregiver of a community-dwelling older adult who is a member of the Program of All-inclusive Care for the Elderly (PACE).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Machiko Tomita, Ph.D., 623 Kimball Tower, University at Buffalo, Buffalo, NY 14214, Phone: (716) 829-6740, e-mail: machikot@buffalo.edu. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?

The purpose of this study is to reduce caregiver burden and related negative aspects of caregiving and increase satisfaction and confidence through occupational therapy related support to address challenges that you face in caring for your care recipient.

How long will the research last?

We will work with you to solve your caregiving problems/challenges for 1- 2 months and 2 months later, we will do a follow-up interview at 4 months. Then we will contact you again 6 months after the intervention study. Therefore, altogether 10 months.

How many people will be studied?

We expect to include about 60 - 75 caregivers.

What happens if I say yes, I want to be in this research?

- We will interview you taking about 30 minutes. During the interview, you will be asked about demographic information (age, length of care, living status, etc.) and the positive and negative impacts of caregiving including satisfaction, confidence, burden, depression, and fatigue. We also ask your perception of your care recipient's functional status and cognitive level. This interview will be conducted by an occupational therapy graduate student in the Department of Rehabilitation Science at University at Buffalo, who are trained for this research study.
- During the interview, if you show a depressive symptom, scoring 15 or above in the Center for Epidemiology Studies-Depression scale, we will inform you and the PACE about it and the PACE may contact you.
- During the interview, if you are not sure about the cause of cognitive impairment for the care recipient, we will ask the PACE about it with your permission.
- Then we will discuss challenges that you are facing in caring for your recipient and possible solutions. This may take another 30-45 minutes.
- If your difficulty involves your movement in helping the care recipient, we may videotape for recommendations, with your consent.
- Within a week, you will be contacted again to discuss the solutions that experts came up with, but final solutions should be developed by you and the OTGS. If one of the solutions is safe movements to care for your recipient, it will be shown to you and you will need to practice it until you are comfortable.
- If you are injured while caring for your care recipient, we are not responsible and we will not compensate for the injury.
- About a month later, we will contact you and ask how you are doing regarding the challenges.
- You can contact us when you have doubts or questions regarding these challenges and solutions. The OTGS will provide you her cell phone number.
- Two months and four months later from the initial interview, we will visit you again and ask the same questions as the first interview.
- Six months after the intervention, we will invite you for a phone interview asking the same questions, and your care recipient's falls and emergency visits during the past 10 months.
- At the end of each interview, we will pay you $20 in cash and ask you to sign a receipt.
- Your name, challenges, and solutions will be shared with the PACE but not the results of the interview, except for the depression situation stated above.

- Individual data we obtained from you will not be revealed except for the video of your movement. When we do, we will ask your permission in writing. Only aggregated data will be presented in a seminar, conference, and publication.

What happens if I do not want to be in this research?

Your participation in this research study is voluntary. You may choose not to enroll in this study. Your decision will no way affect your or your care recipient's relationship with the PACE.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. If you leave the research, your information and interview data will be used up to the point of your withdrawal from the study.

Is there any way being in this study could be bad for me?

During the interview, answering questions about depression may make you feel emotional or vulnerable. If you feel uncomfortable, you can choose to take a break or decide to finish the interview on another date. If the score of depression assessment is 15 or higher, we will inform you and the PACE about it because it indicates a depressive symptom. The PACE may contact you according to their policy.

As our purpose of the study is to ease your difficulty, we don't think this study would harm you.

Will being in this study help me in any way?

The purpose of this study is to help you to ease the difficulty that you are experiencing in caring for your care recipient. Therefore, this support should solve the problems, and as a result, we expect that your caregiver burden and depression levels will decrease and satisfaction and confidence in caring will increase.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. A summary of study findings will be shared with the PACE; however, the PACE will not have access to identifiable information.

Can I be removed from the research without my OK?

No, you will not be removed from the research without your agreement.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date

Permission to Take Part in a Human Research Study

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent