Developing a Distance Education System to Train Savvy Caregiver Program Interventionists: Extending Access and Capacity in Community-Based Delivery of Evidence-Based Interventions

NCT04060355

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Emory University
Oral Consent Script and Information Sheet
For a Research Study

Study Title: Savvy Training System
Principal Investigator: [redacted], PhD, Nell Hodgson School of Nursing, Emory University
Funding Source: NIH National Institute on Aging

Introduction and Study Overview

Thank you for your interest in our dementia caregiver research study. We would like to tell you everything you need to think about before you decide whether or not to join the study. Please also read the information sheet we have provided to you. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study and it will not affect your care or the patient's care in any way.

1) The purpose of this study is to test the psychoeducational program "the Savvy Caregiver." Savvy is an in-person group education program for persons who, like you, are providing care for someone living with an illness like Alzheimer's disease.
2) The study is funded by the National Institutes of Health National Institute on Aging.
3) The study is being conducted by Emory University in Atlanta, Georgia
4) This study will take 6-9 months to complete.
5) If you join, you will be randomly assigned to either take part in the Savvy Caregiver immediately or to wait 4 months for the next offering of the program. The Savvy Caregiver program involves six weekly group sessions led by a trainer whom we have trained and attended by 6-12 other caregivers like yourself. We will ask you to participate in 3 or 4 interviews over the course of the 6-month study, depending on whether you join the Savvy program immediately or after a wait period. These interviews will assess your experience as a caregiver. You may be invited to participate in one de-briefing interview about your overall experience. All interviews will be limited to 30 minutes, and we will record the interviews, either with video and audio or just with audio, if you prefer.
6) You will be provided a $25 gift card for participating in each interview.
7) There are minimal risks involved in taking part in the study. One potential risk is a loss of privacy through a breach of confidentiality. However your privacy is very important to us and we will be very careful with your information. The lessons and questionnaires are focused on your caregiving, and that may be an emotional topic. Any information we collect about you will be kept confidential. There is a chance you might benefit from the study by becoming better equipped to handle your role as caregiver. The lessons you will get are designed to help you understand the disease your loved one has and build new skills to help you manage daily life.
8) The following persons or groups may use and /or disclose your research information for this study:
    - The Principal Investigator and the research staff.
    - The NIH, who funds this Research, and people or companies they use to carry out the study
    - Emory offices who are part of the Human Research Participant Protection Program, and those who are involved in research-related administration and billing and the Emory IRB.
    - Any government agencies who regulate the research including the Office of Human Subjects Research Protections (OHRP)
9) We will disclose your research information when required to do so by law in the case of reporting child abuse or elder abuse.
10) If you choose not to participate, it will not impact your care or the patient's care in any way. You will still have access to the in-person Savvy Caregiver program and other local resources.

11) A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

12) The investigators have obtained a Certificate of Confidentiality for this study. If Emory received a subpoena for study records that identify you, we would say no, and the Certificate gives us this authority. The Certificate does not prevent you or someone other than you from disclosing your information. The Certificate also does not prevent Emory from releasing information about you:

a. Information to state public health offices about certain infectious diseases
b. Information to law officials if child abuse has taken place
c. Information Emory gives to prevent immediate harm to you or others
d. Information Emory gives to the study sponsor as part of the research

Contact Information

If you have questions about this study, your part in it, your rights as a research participant, or if you have questions, concerns or complaints about the research you may contact the following:

[redacted], Project Director [redacted]
Emory Institutional Review Board: [redacted] or toll-free at [redacted] or by email at [redacted]

Consent

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Participant agrees to participate: Yes No

If Yes:

_____

Name of Participant

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time

_____

Name of Person Conducting Informed Consent Discussion