STUDY INFORMED CONSENT

Adapting Connect-Home Transitional Care to Fit the Unique Needs of Persons With Alzheimer's Disease and Other Dementias and Their Caregivers: A Pilot Study

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ADRD Verbal Consent Aim 2 Caregivers_20210624

CONCISE SUMMARY

The purpose of this study is to utilize adaptations gained by its' parent study, Connect-Home Clinical Trial toward the unique transitional care needs of persons with Alzheimer's disease and related dementia (AD/ADRD) and their caregivers. The proposed study will also examine the feasibility, acceptability and outcomes of the adapted intervention within this study population.

The setting for the study will be four skilled nursing facilities (SNF) that currently use the Connect-Home intervention. Persons with Alzheimer's disease and related dementias (AD/ADRD) who receive care in skilled nursing facilities (SNF) as well as their caregivers and SNF and home care staff will assist in participation.

This study will be conducted in two aims. Aim 1 will be set in 4 SNFs where the research team will engage stakeholders in formative research to help identify unmet needs of persons with AD/ADRD and caregivers through focus group and individual interviews.

Aim 2 will pilot-test the adapted intervention in 2 of the 4 SNFs. A single-arm post-test-only trial design will be conducted with a sample of 20 persons and their caregivers using the adapted protocol and collected data through telephone questionnaires.

This study will generate new knowledge for improving health care of AD/ADRD population and their caregivers. We are not able to confirm that participants will directly benefit from participating in the study. Risks related to participating in this study are minimal, including emotional distress related to learning more about medical and functional challenges and plans for care at home and a possible loss of confidentiality.

Duration of participation in this study is conducted through 4 visits: 1 30-minute recruitment visit and 3 30-minute telephone surveys to be conducted at 7, 21 and 30 days after discharge.

IRB Study #20-2406

Hello, my name is_____. I am a (student/faculty member/staff member) from the University of North Carolina at Chapel Hill conducting a survey (research) about Adapting Connect-Home clinical trial. Your participation in this study is completely voluntary. This means that you do not have to participate in this study unless you want to.

Would you be willing to answer some questions to help me determine if you are eligible for this study? (If yes, proceed; if no thank them for their time and end the call).

Good. I will read off a list of questions. If you answer to any of them is no, wait until I am all done and tell me that when I am finished. I do not want you to answer each question, individually.

1.) Are you the caregiver of [insert patient's name]?
2.) Are you over the age of 18?

Would your response to any of these questions be no? (If person says yes, thank them for their time and state that they are not eligible for the study. If they answer no, proceed)

The purpose of this research study is to look at using Connect-Home Plus for the unique transitional care needs of persons with challenges related to thinking and memory, and their caregivers.

You are being asked to be in the study because your loved one, [insert patient's name] has listed you as their caregiver to contact for study participation in this study.

We estimate that approximately 20 patients and their caregivers from two participating skilled nursing facilities will enroll in this study.

If you agree to participate in this study, the study team will call you and [insert patient name] at 7, 21 and 30 days after [insert patient's name] discharge from the nursing home. In addition, you will receive post-discharge calls from a dementia caregiver specialist as needed. We will ask questions to help us learn the effectiveness of care in the nursing home. This will include answering questions about your role as the caregiver for [insert patient name].

Only state next paragraph if the caregiver is a legally authorized representative:

Since you are [insert patient's name] "legally authorized representative" we will not call (him or her) to ask questions, and we will call you instead to complete their surveys. A legally authorized representative is an individual authorized under applicable law to consent on behalf of a potential subject to the subject's participation in the procedures involved in the research.

If caregiver is not a legally authorized representative, continue reading here:

If [insert patient's name] is at any time unable to answer their survey questions, we may ask you to answer their questions on their behalf.

Each call will last approximately 15-20 minutes. You can also refuse to answer any question on the surveys.

There is a small chance that some of the questions may make you feel uncomfortable. You don't have to answer those questions if you don't want to. In fact you don't have to answer any question that you choose not to answer. And that is fine. We will just skip that question and go on to the next one.

All the information I receive from you by phone and/or via zoom, including your name and any other identifying information {if applicable}, will be strictly confidential and will be kept under lock and key. I will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. If it is okay with

you, I might want to use direct quotes from you, but these would only be quoted as coming from "a person" or a person of a certain label or title, like "one woman said." When I finish with all the phone surveys from everyone who has agreed to participate, I will group all the answers together in any report or presentation. There will be no way to identify individual participants. None of your de-identified data will be used for future studies without additional consent.

The only risk to you might be if your identity were ever revealed. But I will not even record your name with your responses, so this cannot occur. There are no other expected risks to you for helping me with this study. There are also no expected benefits for you, either.

This study is being funded by the NIH. Portions of Dr. Toles' and his research team's salaries are being paid by this funding.

This study will be listed at clinicatrials.gov.

Do you have any questions?

You can also call Dr. Mark Toles at 919-966-5684 with questions about the research study. All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Do you agree to be in this study? **Or** Do I have your permission to begin asking you questions?