Connect-Home: Testing the Efficacy of Transitional Care of Patients and Caregivers during Transitions from Skilled Nursing Facilities to Home

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants-Patients Consent Form Version Date: 30Jan2019
IRB Study # 18-1513
Title of Study: Connect-Home: Testing the Efficacy of Transitional Care of Patients and Caregivers during Transitions from Skilled Nursing Facilities to Home
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What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this study is to test a new transitional care intervention (the care you receive between being discharged from a nursing home to being settled in your own home) intervention called Connect-Home. The intervention's purpose is to help older adults return home safely and more effectively continue care at their home.

The Connect-Home intervention aims to target the care needs of older skilled nursing facility patients who want to improve their quality of life and the ability to function at home. It targets six key care needs, including home safety and level of assistance for the patient, advanced care planning, symptom management, assistance with medication lists, the patient's function and activity, and coordination of care.

Are there any reasons you should not be in this study?
You should not be in this study if:

- You do not speak English
- If you are younger than 18 years old
- You have any other conditions judged at the discretion of the study doctor to prohibit you from being in the study

How many people will take part in this study?
A total of 720 people in 6 nursing homes will take part in this study. This includes 360 patients and 360 of those patient's caregivers.

How long will your part in this study last?
Your part in the study will last from the time you sign this consent until 60 days after you discharge from the nursing home.

Additionally, a final review of your medical record by our research team will occur within 90 days of the time you sign this consent.

What will happen if you take part in the study?
The study consists of four visits. The first will be conducted in-person, and the other three will be conducted by telephone.

Based on the time that you were admitted to the nursing home, you will receive usual transitional care or you will receive the intervention of the Connect-Home transitional care.

Visit 1 (In-Person, Before Nursing Home Discharge):

- We will obtain informed consent from you
- You will answer some questions about your health and health care needs
- We will review your medical chart at the nursing home

If you received the Connect-Home intervention, you will have a home health nurse visit after you are discharged home.

Visit 2 (Telephone, 7 Days After Nursing Home Discharge):

- You will complete a survey over the phone

Visit 3 (Telephone, 30 Days After Nursing Home Discharge):

- You will complete a survey over the phone

Visit 4 (Telephone, 60 Days After Nursing Home Discharge):

- You will complete a survey over the phone
- We will review your medical chart

During this study, your caregiver will also participate. We will call your caregiver three times to have them complete surveys. If at any time you are unable to answer your survey questions, we will ask your caregiver to answer your questions on your behalf.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?

Psychological Risks

During your time in the nursing home and at home, you will talk to staff from both the nursing home and the home health agency about how to manage your illness at home. This may cause some emotional distress, or make you feel uncomfortable.

Also, during surveys for the study, the study team will ask you questions about your quality of life, general health, and other topics. These questions may also cause emotional distress or make you feel uncomfortable. You can refuse to answer any question at any time.

Physical Risks

During your time in the nursing home and at home, you will talk to staff from both the nursing home and the home health agency about how to manage your illness at home. In addition, you will talk to the study staff to complete surveys. This may cause fatigue. If you would like to stop a survey because you feel fatigued, you can at any time.

Risk of Loss of Confidentiality

We will never attach your name of any identifiers to the research data. Still, there is a rare risk of loss of confidentiality. When we collect data about you for the research study, there is a risk that data could be misplaced or that other people could learn about your personal medical care in the nursing home. However, the research team will make every effort to prevent loss of confidentiality. The research team will keep all data and records in either a locked file cabinet (for paper records) or a password-protected, encrypted computer (for electronic records). None of your personal information will be linked with the surveys we collect from you, or any other data for the study.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
The research team will make every effort to protect your privacy and confidentiality. Those efforts include:

- Using a study ID to categorize your data, and not any personal identifiers that could link the data back to you.
- Storing study records on paper in a locked cabinet in a locked office in the University of North Carolina at Chapel Hill, School of Nursing
- Storing electronic records on password protected, encrypted computers

Participants in this study will not be identified in any report or publication about this study.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because the entire study has been stopped.

Will you receive anything for being in this study?
You will receive $20 for completing visits 2, 3, and 4, up to $60.00.Any payment provided for participation in this study may be subject to applicable tax withholding obligations. If you voluntarily withdraw or are withdrawn from the study, you will only be paid for visits completed up to your withdrawal date.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on 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.

What if you have questions about your rights as a research participant?
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, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Legally Authorized Representative Date

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent