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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STUDY PROTOCOL

Complete Title: 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

Short Title: Adapting Connect-Home: a pilot study

Drug or Device Name(s): n/a

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Study Principal Investigator: Mark Toles, PhD, RN
University of North Carolina at Chapel Hill
Carrington Hall, Campus Box #7460
Chapel Hill, NC 27599-7460
Phone 919-966-5684
email: mtoles@email.unc.edu

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Lead Investigator:

Mark Toles, PhD, RN

University of North Carolina at Chapel Hill

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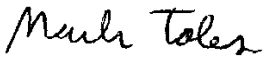
I confirm that I have read this protocol and understand it.

Principal Investigator Name: Mark Toles

Principal Investigator Signature: 

Date: June 12, 2023

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1. Abbreviations and Definitions of Terms

Abbreviation	Definition
SNF	Skilled nursing facility
ADRD	Alzheimer's disease and related dementias
CTM-15	Care Transitions Measure - 15
PCS	Preparedness for Caregiving scale
BIM	Brief Inventory of Mental Status
EHR	Electronic Health Record
HIPAA	Health Insurance Portability and Accountability Act
RC	Research Coordinator
DEMQOL	Dementia Quality of Life Scale
ED	Emergency department
AE	Adverse event
SAE	Serious adverse event
RN	Registered nurse
SMC	Safety Monitoring Committee
LAR	Legally authorized representative

2. PROTOCOL SYNOPSIS

Study Title	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
Funder	National Institute of Nursing Research
Clinical Phase	Phase I
Study Rationale	The proposed study will examine the feasibility and acceptability of Connect-Home Plus, a transitional care intervention, targeting Skilled Nursing Facility (SNF) patients with Alzheimer's disease and related dementias (ADRD) who discharge to home and their primary caregivers. The study will be set in two North Carolina SNFs and in the patient's home (during intervention periods only). Using a single-arm, post-test-only trial design, SNF patient and caregiver pairs will be enrolled in a study to prepare for discharge to home-based care and implement plans for home-based care after SNF discharge. The study will describe the feasibility and acceptability of Connect-Home Plus and to estimate the impact of Connect-Home Plus on their outcomes in 7 and 30 days. Patients will be identified by consultation with SNF clinical staff and medical record review. After informed consent, baseline enrollment surveys will be collected for patients and caregivers. Additionally, a medical record review for data related to continued health outcomes will be conducted for patients. Telephone questionnaires will be used to survey patients and caregivers at 7, 21, and 60 days after patients return home.
Study Objective(s)	**Primary** • Feasibility of the intervention. The feasibility items include: (1) completing the Transition Plan of Care; (2) convening the care plan meeting with caregiver attending; (3) reviewing advance directives in the SNF; (4) scheduling follow-up medical appointments; (5) transmitting records to follow-up clinicians; (6) home care nurse completion of the first home visit within 24 hours after discharge; (7) completion of first caregiver support call within 72 hours of discharge; (8) completion of the second and third caregiver support call within one month of discharge. • Patient satisfaction with services, including services were easy or difficult to use, supports were or were not helpful, and services helped to manage issues related to ADRD at home. • Mean caregiver intervention satisfaction scores, including services were easy or difficult to use, supports were or were not helpful, and services helped to manage issues related to ADRD at home. **Secondary**

	• Patient preparedness for discharge will be measured by the Care Transitions Measure-15 (CTM-15), which measures self-reported knowledge and skills for continuing care at home. • Caregiver preparedness for caregiving will be measured by the Preparedness for Caregiving Scale (PCS), which measures self-reported readiness for caregiving. • Patient function will be measured using the Life Space Assessment, where scores are the product of the "Life-space level" (range 1-5) and the "independence" score (range 1-2). • The quality of life of the patient will be assessed with the Dementia Quality of Life Measure. • When the patient is unable to rate their quality of life, the quality of life will be rated by their caregiver, using the Dementia Quality of Life-Proxy measure. • Patient-reported Days of Emergency Department or Hospital Use 30 Days After Skilled Nursing Facility Discharge. • Caregiver burden will be measured using the Zarit Caregiver Burden Scale, measuring caregiver perceptions that "caregiving has an adverse effect on their emotional, social, financial, physical and spiritual functioning." • Caregiver distress will be measured using the Distress Thermometer.
Test Article(s) *(If Applicable)*	Connect-Home Plus is a two-step transitional care intervention: 1) SNF staff create an individualized Transition Plan or Care and prepare the patient with ADRD and caregiver to manage the patient's illness at home; and 2) within 3 days of discharge a home care nurse visits the patient and caregiver at home and within 30 days of SNF discharge, a dementia caregiving specialist calls the caregiver at home and helps them implement the written Transition Plan of Care. Both intervention steps focus on 6 key care needs to optimize patient and caregiver outcomes: 1) home safety and level of assistance; 2) advance care planning; 3) symptom management; 4) medication reconciliation; 5) function.
Study Design	The study will use a single-arm, post-test-only trial design to examine the feasibility and acceptability of the intervention and estimate of patient and caregiver outcomes in 7 and 30 days after SNF discharge.
Subject Population key criteria for Inclusion and Exclusion:	Patient Inclusion Criteria: • be able to speak English • have a goal of discharge to home • have a diagnosis of ADRD, or a Brief Inventory of Mental Status (BIMS) score <13, or (for persons unable to complete the BIMS assessment), have a Cognitive performance score of ≥3 (calculated using data in the Minimum Data Set 3.0 and an algorithm for estimating cognitive impairment using Minimum Data Set 3.0 data other than BIMS) • have a caregiver willing to participate. • for patients with documentation in the medical record of a caregiver who is the patient's legally authorized representative,

	consent of the caregiver to participate in the study as the patient's representative. Patient Exclusion Criteria: • be unable to speak English Caregiver Inclusion Criteria • self-report assisting the patient at home • be able to speak English. Caregiver Exclusion Criteria • be unable to speak English
Number Of Subjects	20 persons with ADRD and their 20 caregivers in 2 SNFs
Study Duration	Participants will be recruited during the SNF stay, when baseline data will be collected, and they will participate in the study for up to 60 days post-discharge. The entire study is expected to last 6 months.
Study Phases Screening Study Treatment Follow-Up	The study team will use a limited waiver of HIPAA authorization to pre-screening for patient and caregiver eligibility during the SNF admission. The study team will recruit SNF patients and their caregivers in-person (or, when risk mitigation related to COVID-19 prevents in-person contact, we will recruit virtually, using an iPad and connection via ZOOM) within 10 days of their admission and will review the patient's medical record to confirm eligibility. The study team will obtain written consent (or, when risk mitigation related to COVID-19 prevents in-person contact, they will obtain verbal consent) of SNF patients and their caregivers. The study team will collect baseline data during the SNF admission. SNF patients and caregivers will receive the Connect-Home Plus intervention in the SNF and the SNF caregivers will receive the intervention after the SNF discharge in a home visit with the home care nurse and in telephone calls with the dementia caregiving specialist in 30 days after SNF discharge. The study team will collect outcome data from the patient and caregiver (or from the caregiver only if the patient is not able to participate in data collection) in 7, 21, and 30 days after SNF discharge. The chart review of medical records will occur in 30 days after SNF discharge.
Efficacy Evaluations	The study will not generate efficacy data. The primary outcome evaluation will use descriptive statistics to describe feasibility and acceptability of Connect-Home Plus.
Pharmacokinetic Evaluations	n/a
Safety Evaluations	Study progress and safety will be reviewed monthly (and more frequently if needed). Progress reports will include patient and caregiver recruitment, retention/attrition, and adverse events. In addition, safety evaluation will include (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely.

Statistical And Analytic Plan	Descriptive statistics will be used to describe the feasibility of the intervention. Descriptive statistics will be used to describe the acceptability of Connect-Home Plus to patients and caregivers. De-identified, exemplar patient or caregiver statements will be identified to illustrate trends in the satisfaction survey responses. Descriptive statistics will be used to describe secondary outcomes, including patient and caregiver reported preparedness for care after discharge; patient quality of life and patient functional mobility; caregiver burden and distress; and patient use of hospital and ED services after discharge.
DATA AND SAFETY MONITORING PLAN	This study will require a Data Safety Monitoring Committee and Plan. An Executive Committee and Adverse Event Monitoring Committee will be created to assure that the study meets expectations and any risk to participants are reduced to a minimum. These committees will meet on a regular basis as laid out in the Data Safety and Monitoring Plan

3. BACKGROUND AND RATIONALE

Introduction

The study setting is two SNFs that participated in earlier Connect-Home pilot studies (2014-2018) and have sustained Connect-Home implementation to date.(1) The pilot-test of Connect-Home Plus will be in the SNFs and the homes of the caregivers of patients with ADRD, where a community-based, dementia caregiving specialist will call the caregiver after SNF discharge.

The rationale for the study is to determine the feasibility and acceptability of the Connect-Home Plus intervention that is designed to promote successful transitions of care of SNF patients with ADRD and their caregivers during transitions from SNF to home.

Name and Description of Investigational Product or Intervention

Connect-Home Plus will introduce new organizational structure to support staff delivery of transitional care processes. Consistent with Donabedian, we anticipate that these changes in structure and care processes will be associated with improved patient and caregiver outcomes.(2) New elements of organizational structure include an EHR template, the Connect-Home Toolkit, and Staff Training protocols; we developed, refined and tested these, finding them to be feasible, acceptable, and associated with improved patient and caregiver experiences of care. After new structural elements are in place, SNF staff will use Connect-Home Plus care processes to deliver the 2-step transitional care intervention. In **Step 1**, SNF nurses, rehabilitation therapists, and social workers will develop a Transition Plan of Care and prepare the patient and caregiver to manage the patient's serious illness and functional needs at home. In **Step 2**, a home care RN will visit the patient and caregiver at home within 24 hours of discharge and the Dementia Caregiver Specialist will call the caregiver at home within 72 hours of the patient's discharge to home and up to two more times, within one month of the discharge to home.

Non-Clinical and Clinical Study Findings

The study is expected to have minimal risks, which are described below. Potential benefits are identified after the risks below.

Risks

Physical Risks: Patients and caregivers will receive transitional care in the SNF and in the patient's home. Transitional care activities involve verbal assessments, conversation, education, and planning. There is a possibility that participants could be fatigued from participation in the data collection activities. For example, while participating in a care-planning meeting, a patient might feel fatigued or need to take a break. Protection: If any participant has a physical injury, the study team will help them seek immediate medical attention. If a SNF patient or caregiver expresses fatigue during data collection, the data collection session will be terminated immediately, and a follow-up appointment scheduled.

Psychological Risks: Emotional distress related to learning more about medical and functional challenges and plans for care at home is a potential psychological risk. Staff in the SNF and in the home after discharge will engage patients and caregivers in conversations to plan strategies for managing illness at home. Also, during enrollment and data collection activities, staff will assess the patients' quality of life, functional mobility, falls at home, days at home without acute care use and caregivers' burden and distress related to the caregiving role. These study-related activities may also involve a chance for emotional distress. Protection: The study team will refer distressed patients and caregivers to their attending or primary care physicians for support with emotional distress.

Social Risks: During enrollment and data collection activities, study staff will collect data from participants about their health, function and quality of life; if others observed patients or caregivers participating in these activities, there is a chance that it could embarrass or distress patients or caregivers. Protection: The study team will recruit and collect baseline data for participants in a private room. When necessary, this data may also be obtained virtually when research personnel are not able to encounter face to face interactions with study participants. When these occasions arise, all virtual interactions will be conducted at a time when the patient is alone and not able to be overheard. Study team will conduct these in private settings as well ensuring that no questions and/or responses will be overheard. During telephone calls to collect outcome data, the identity of patients will be confirmed. All research staff will be trained by the PI and other study team members to collect data with the utmost respect and sensitivity to support participants and help them feel comfortable during data collection activities. The research team members will remind participants that participation in the study is voluntary, and that they have the right to withdraw from the study at any time if they are not comfortable. The team will assure patients and caregivers that withdrawal from the study will not have an impact on their medical care.

Risk of Loss of Confidentiality: During enrollment and data collection activities, staff will obtain health information about patients and caregivers. Thus, a potential risk to SNF patients and caregivers is loss of confidentiality. Protection: All research study personnel will be trained in IRB and HIPAA guidelines to maintain the security and confidentiality of the data. During the consenting process, the study team will explain the confidentiality protections and will inform the participants of their right to skip items, pause during participation, and withdraw from the study at any time. When face to face interaction is not feasible, study discussions will occur in a virtual manner. In order to avoid a loss of confidentiality, these interactions will be conducted in a private area where the discussions will not be overheard. Risks for loss of confidentiality will be minimal secondary to use of procedures to protect confidentiality, including (a) using study codes on data documents and keeping a separate document that links the study code to subjects' identifying information locked in a separate location and restrict access to this document to certain members of the study team; (b) de-identification of data to remove the possibility that data could be connected to individuals that consented to participate in the study; (c) encrypting identifiable data; and (d) securely storing data documents within locked locations. All identifying information will be destroyed at the earliest possible time following completion of the study. In addition, data will be reported in aggregate form, without identifying information by site or individual. Publications arising from the study will not contain personal information. All SNF patients or caregiver participants will continue to receive routine medical care from their health care providers throughout the study.

Potential Benefits

The major potential benefit of this study is new knowledge about ways to improve outcomes for SNF patients with ADRD and/or their caregivers. The patients will receive valuable information, training and plans about their diagnosis, indicators of emerging medical problems, medications, treatments, advance care directives, follow-up appointments and studies, home care services, questions to ask their community physicians, strategies to avoid

falls at home, self-care at home in the context of the COVID-19 pandemic (when applicable), and discrepancies in their home medications that should be addressed with community or SNF physicians. Their family caregivers will also receive this information and training as well as training to support the patient and strategies to relieve stress and hardship related to the caregiver role. As a result of the research, we will discover the feasibility and acceptability of the Connect-Home Plus intervention. If the intervention is feasible and acceptable, this study will provide an evidence-based practice rationale for a clinical trial to determine the efficacy of the Connect-Home Plus intervention. It will also provide new knowledge related to care of adults with ADRD in the context of the COVID-19 pandemic.

Relevant Literature and Data

SNF patients with ADRD are an under-studied population with very high risk for complications during care transitions and poor outcomes after discharge home.(3) Annually, 1.6 million older adults undergo episodes of care consisting of hospitalization followed by a "short stay" in a nursing home, where they use the Medicare SNF benefit for rehabilitation and nursing care.1 SNF patients typically are frail, dependent, and seriously ill: a) 100% have recent acute illness (e.g., hip fracture, heart failure, genitourinary and pulmonary infections with & without sepsis);(4, 5) b) 28-34% were treated in intensive care during the index hospital stay;(4, 6) and c) 29-43% had ≥1 hospitalizations in the year prior to the index hospitalization and SNF stay.(6, 7) About 36% of persons admitted to SNFs are diagnosed with dementia,3 although rates are probably higher given the number of undiagnosed cases of dementia.(8) A growing literature indicates that transitions in care are especially challenging in the population with ADRD, who frequently experience unmet needs, including: (1) informed and collaborating family caregivers to manage illness at home, (2) support to prevent delays in discovery of changes in health (e.g., respiratory infections), (3) follow-up referrals for medical care of dementia (e.g., diagnosis and treatment planning), and (4) transition planning to assure adequate nutrition, hydration, pain control, medication management and follow-up medical care.(9-11) Lacking these and other essential supports during transitions in care, persons with ADRD are especially vulnerable to poor health outcomes. In one study, 89.2% of persons with ADRD experienced ≥1 hospitalization per year(12) and 23% of persons with ADRD experienced rehospitalization within 30 days of returning home.(13) Furthermore, caregivers for persons with cognitive impairment (i.e., spouses, children, friends) often lack time, resources, and training to keep up with the mounting challenges of care at home.(14-16) Preparing patients and caregivers for the transition to home is urgently needed; yet, healthcare systems often provide suboptimal transitional care planning, and their staff lack expertise in dementia care.(17, 18) Thus, the proposed study is significant because it will extend SNF transitional care research to persons with ADRD and their caregivers.

This study will build on findings in an ongoing clinical trial of the Connect-Home intervention, which tests a transitional care intervention with high potential for adapting to the unique needs of persons with ADRD and caregivers.(19) The objective of the Connect-Home trial (ongoing) is to conduct a stepped-wedge cluster-randomized trial to test Connect-Home transitional care against standard discharge planning (control) using individuals discharged to home (N=360) and their caregivers (N=360) in 6 SNFs.28 The Specific Aims are to evaluate the efficacy of Connect-Home to improve: (1) SNF patient and caregiver preparedness for discharge (primary outcome, assessed 7 days after discharge), (2) patient quality of life, function, and acute care use, and (3) caregiver burden and distress (secondary outcomes assessed 30 and 60 days after discharge home). The setting is six SNFs and, for participants in the intervention arm, patient homes, where community-based RNs visit them within 24 hours of discharge. The Connect-Home Intervention involves new organizational structure, including: (1) the "Transition Plan of Care Template," installed in the SNF EHR system, which staff use to record transitional care goals and deliver the intervention; (2) the "Connect-Home Toolkit," a manual with standard procedures and tools; and (3) staff training to deliver transitional care processes that address key care needs of SNF patients and their caregiver. Connect-Home structures support transitional care processes in the SNF and the person's home.19 In collaboration with the SNF patient and their caregiver, SNF nurses, social workers and

rehabilitation therapists (1) set goals for home-based care, (2) make plans for transition from SNF to home, and (3) make preparations for home-based care (e.g., teach symptom management). Following discharge, community-based RNs implement the transition plan (e.g., set-up new routines for self-care at home).(19) In the proposed study, Connect-Home structure and processes provide a robust foundation for adapting transitional care for persons with ADRD and their caregivers.

The study, described in this protocol, builds on a completed, systematic adaptation of Connect-Home to align with the Alzheimer's Association "Practice Recommendations for Person-Centered Care" and address unmet care needs of persons with ADRD.(20) Numerous frameworks describe adaptation as a systematic progression using steps required to modify an intervention to fit the needs of new populations or contexts and ensure acceptability to key stakeholders.(21) A central goal of adaptation is to modify the form of the intervention (i.e., structure), while maintaining fidelity to its underlying program theory.(21) Consistent with this goal, we modified Connect-Home structures (plan of care template, toolkit, training) while retaining the underlying program theory. We modified structures with the goal of building staff capacity to tailor the existing set of six Connect-Home transitional care processes to the distinct needs of persons with ADRD and their caregivers. In doing so we retained fidelity to the program theory, which hypothesizes that the six key processes are the causal mechanisms through which Connect-Home improves patient and caregiver outcomes.(1, 22) Thus, for example, the adaptation of Connect-Home added elements to the EHR template for the Transition Plan of Care (structure) to prompt for staff to tailor coordination of medical care (key process) to include needed referrals for dementia follow-up care.(16, 23) Another adaptation was to modify the Connect-Home training protocol (structure) and add staff training content on tailoring care plans for symptom management (key process), with guidance for needed home-based care of neuropsychiatric symptoms such as withdrawal, agitation, and resistance to care. Our approach to adaptation followed the five steps described by Chen et al. (2013).(24) This included: learning from staff in SNFs with four years of experience using the un-adapted version of Connect-Home, convening a steering committee, determining the fit of Connect-Home with the transitional care needs of persons with ADRD and their caregivers, summarizing findings and create a list of unmet needs, and making choices about how to adapt Connect-Home to address unmet needs.

The objective of this study is to test the feasibility and acceptability of the adapted intervention (Connect-Home Plus) in a total sample of 20 patients and 20 caregivers in two SNFs. The rationale for this study is that testing Connect-Home Plus will generate a new model of transitional care for a future trial. The specific aim is to determine the feasibility and acceptability of the adapted version of Connect-Home (primary outcomes) and estimated mean outcomes of persons with ADRD and their caregivers (secondary outcomes, i.e., preparedness for discharge, quality of life, hospital readmission, and caregiver burden).

4. STUDY OBJECTIVES

the objective of this study is to test the feasibility and acceptability of the adapted intervention (Connect-Home Plus) in a total sample of 20 patients and 20 caregivers in two SNFs.

Primary Objective: Determine the feasibility and acceptability of the adapted version of Connect-Home.

Secondary Objective: Determine estimated mean outcomes of persons with ADRD and their caregivers, e.g., preparedness for discharge, quality of life, hospital readmission, and caregiver burden).

5. INVESTIGATIONAL PLAN

a. Study Design

The study will use a single-arm, post-test-only trial design to examine the feasibility and acceptability of the intervention and estimate of patient and caregiver outcomes in 7 and 30 days after SNF discharge.

Study phases: The study team will use a limited waiver of HIPAA authorization to pre-screening for patient and caregiver eligibility during the SNF admission. The study team will recruit SNF patients and their caregivers in-

person (or, when risk mitigation related to COVID-19 prevents in-person contact, we will recruit virtually, using an iPad and connection via ZOOM) within 10 days of their admission and will review the patient's medical record to confirm eligibility. The study team will obtain written consent (or, when risk mitigation related to COVID-19 prevents in-person contact, they will obtain verbal consent) of SNF patients and their caregivers. The study team will collect baseline data during the SNF admission. SNF patients and caregivers will receive the Connect-Home Plus intervention in the SNF admission and the SNF caregivers will receive the intervention by telephone in 30 days after SNF discharge. The study team will collect outcome data from the patient and caregiver (or from the caregiver only if the patient is not able to participate in data collection) in 7, 21, and 30 days after SNF discharge. The chart review of medical records will occur in 30 days after SNF discharge.

b. Study Duration

Participants will be recruited during the SNF stay, when baseline data will be collected, and they will participate in the study for up to 60 days post-discharge. The entire study is expected to last 12 months.

c. Enrollment and Number of Subjects

20 persons with ADRD and their 20 caregivers in 2 SNFs

d. Study Population

Patient Inclusion Criteria:

- be able to speak English
- have a goal of discharge to home
- have a diagnosis of ADRD, or a Brief Inventory of Mental Status (BIMS) score <13, or (for persons unable to complete the BIMS assessment), have a Cognitive performance score of ≥3 (calculated using data in the Minimum Data Set 3.0 and an algorithm for estimating cognitive impairment using Minimum Data Set 3.0 data other than BIMS).(25)
- have a caregiver willing to participate.
- for patients with documentation in the medical record of a caregiver who is the patient's legally authorized representative, consent of the caregiver to participate in the study as the patient's representative.

Patient Exclusion Criteria:

- be unable to speak English

Caregiver Inclusion Criteria:

- self-report assisting the patient at home
- be able to speak English.

Caregiver Exclusion Criteria:

- be unable to speak English

6. STUDY PROCEDURES

The study team will use a limited waiver of HIPAA authorization to pre-screening for patient and caregiver eligibility during the SNF admission. The study team will recruit SNF patients and their caregivers in-person (or, when risk mitigation related to COVID-19 prevents in-person contact, we will recruit virtually, using an iPad and connection via ZOOM) within 10 days of their admission and will review the patient's medical record to confirm eligibility. The study team will obtain written consent (or, when risk mitigation related to COVID-19 prevents in-person contact, they will obtain verbal consent) of SNF patients and their caregivers. The study team will collect baseline data during the SNF admission. SNF patients and caregivers will receive the Connect-Home Plus intervention in the SNF and the SNF caregivers will receive the intervention after the SNF discharge in a home visit

with the home care nurse and in telephone calls with the dementia caregiving specialist in 30 days after SNF discharge. The study team will collect outcome data from the patient and caregiver (or from the caregiver only if the patient is not able to participate in data collection) in 7, 21, and 30 days after SNF discharge. The chart review of medical records will occur in 30 days after SNF discharge.

a. Screening/Baseline Visit procedures

For persons with ADRD, inclusion criteria are: (1) be able to speak English; (2) have a goal of discharge to home; (3) have a diagnosis of ADRD, or a BIMS score <13, or (for persons unable to complete the BIMS assessment) a CPS of ≥3 (calculated using data in the Minimum Data Set 3.0 and an algorithm for estimating cognitive impairment using Minimum Data Set MDS data other than BIMS (26, 27)); and (4) have a caregiver willing to participate. We will recruit a representative for persons with ADRD who have a legally authorized representative (LAR); in addition, we will recruit a family caregiver to represent persons admitted to the SNF who are not able to complete the BIMS or who have a BIMS score ≤7. Exclusion criterion for patients: planned hospital readmission for procedures/treatments in next 30 days (thus distorting assessment of patient and caregiver outcomes). Inclusion criteria for caregivers: 1) self-reports assisting the patient at home; and 2) the ability to speak English. We will identify caregivers using documentation in the medical record that the caregiver provides care at home and/or is legally authorized representative of the person with ADRD. We will use procedures from the Connect-Home parent study to recruit staff, persons with ADRD, and caregivers. To recruit persons with ADRD and caregivers, a Research Coordinator (RC) will use a HIPAA waiver allowing prescreening for eligibility and will: 1) consult the nursing director in each SNF to identify persons admitted to the SNF; and 2) screen the medical record of persons with ADRD who are expected to be discharged home. Using IRB approved forms and consent procedures, the RC will recruit persons with ADRD and caregivers in-person or by phone during the SNF stay until the recruitment goal is reached. The RC will recruit staff using procedures from the parent study. All participants will give written informed consent for study participation.

The RC will administer baseline enrollment surveys to collect measures of co-variates while the person with ADRD is in the SNF, or from the caregiver or legally authorized representative of the person.

b. Intervention/Treatment procedures (by visits)

Connect-Home Plus is a two-step transitional care intervention: 1) SNF staff create an individualized Transition Plan or Care and prepare the patient with ADRD and caregiver to manage the patient's illness at home; and 2) within 3 days of discharge a home care nurse visits the patient and caregiver at home and within 30 days of SNF discharge, a dementia caregiving specialist calls the caregiver three times at home and helps them implement the written Transition Plan of Care. Both intervention steps focus on 6 key care needs to optimize patient and caregiver outcomes: 1) home safety and level of assistance; 2) advance care planning; 3) symptom management; 4) medication reconciliation; 5) function. See Section 5 for additional detail.

c. Follow- up procedures (by visits)

Schedule of Activities for Patients:

See next page

Assessments and Procedures	Screen	Pre Discharge	Discharge	1-3 days post discharge	7 Days Post-Discharge (+ 10/- 3 days)	21 Days Post-Discharge (+/- 7 days)	30 Days Post-Discharge (+/- 7 days)
Informed Consent	X						
Confirm Eligibility	X						
Baseline interview		X					
Chart Abstraction					X		
Connect-Home in SNF		X					
Home Care Nurse visits				X			
CTM-15					X		
Satisfaction interview						X	
DEMQoL							X
Life Space Assessment							X
Chart Abstraction							X
Hospital and ED use assessment							X

Schedule of Activities for Caregivers:

Assessments and Procedures	Screen	Pre Discharge	Discharge	1-3 days post discharge	7 Days Post-Discharge (+ 10/- 3 days)	21 Days Post-Discharge (+/- 7 days)	30 Days Post-Discharge (+/- 7 days)
Informed Consent	X						
Confirm Eligibility	X						
Baseline interview		X					
Connect-Home in SNF		X					
Home Care Nurse visits				X			
Readiness for Caregiving assessment					X		
Dementia Caregiving Specialist calls				X	X	X	
Satisfaction interview						X	
DEMQoL-proxy assessment							X
Caregiver burden and distress assessment							X

d. Subject Completion/ Withdrawal procedures

All identifying information will be destroyed at the earliest possible time following completion of the study. In addition, data will be reported in aggregate form, without identifying information by site or individual. Publications arising from the study will not contain personal information.

e. Screen failure procedures

Subjects who discontinue following consent (i.e., post in-person questionnaires at recruitment) but prior to receiving the Connect-Home intervention or control will be considered screen failures. No additional data will be collected from the time of screen failure, but data collected prior to screen failure and reason for screen failure will be kept.

7. STUDY EVALUATIONS AND MEASUREMENTS

Data Collection Procedures

The research coordinator (RC) will administer baseline enrollment surveys to collect measures of co-variates while the person with ADRD is in the SNF, or from the caregiver or legally authorized representative of the person. Second, the RC will collect outcome data by phone from persons with ADRD and caregivers in 7, 21, and 30 days after SNF discharge. Finally, also using procedures from the parent study, after a patient's discharge from the SNF, the RC will use a standardized tool to abstract data from the medical record in the SNF and the RC will audit the log maintained by the dementia caregiving specialist (study staff) who will make the caregivers calls after the patient discharges from the SNF.

Variables that will be abstracted from medical charts

Patient data collected from SNF medical records include: age, sex, race, ethnicity, health insurance status (Medicare/Medicaid Advantage/Medicare fee-for-service/private), living arrangements before index hospitalization, educational attainment, medical history (primary diagnosis in the hospital discharge summary, hospital care (critical care, surgery and length of stay), depression (Minimum Data Set section D), function (Minimum Data Set section GG), cognitive status (Minimum Data Set section C or the CPS score, SNF care (i.e., SNF length of stay, urgent or acute treatment while in the SNF), discharge destination. Using the problem list in the medical record, we also will calculate the Charlson Comorbidity Index scores for each patient.[57]

Variables that will be abstracted from the intervention log maintained by the dementia caregiving specialist (study staff)

As part of Connect-Home Plus, a dementia caregiver specialist will maintain a written log of details from supportive calls with the caregiver after the patient transfer from SNF to home, including one post-discharge support call within 72 hours after discharge and two additional calls within one month of discharge. Data collected from the Call-back log will include: number of days after discharge on which the call occurred, duration of the call, transition challenges identified on the call, caregiver education provided on the call, and follow-up actions and next steps identified on the call.

Baseline evaluation

Patient data collected in person or from the caregiver representing the person with ADRD who cannot participate in data collection: frailty (Study of Osteopathic Fractures Index),(28) and social support (ENRICHD Social Support Inventory).(29) Caregiver data collected in person or by phone: age, sex, relationship to patient, living arrangements, education, employment, and number of days per week providing patient care.

Outcome Measures

- Primary Outcome Measures:

- Number of participants for whom the intervention components were feasible. Feasibility will be measured using an instrument to audit skilled nursing facility medical records of the patient and the intervention log of services for the patient.(1) It includes eight dichotomous (yes-no) items that indicate feasibility of the Connect-Home Plus intervention. The feasibility items include: (1) completing the Transition Plan of Care; (2) convening the care plan meeting with caregiver attending; (3) reviewing advance directives in the SNF; (4) scheduling follow-up medical appointments; (5) transmitting records to follow-up clinicians; (6) home care nurse completion of the first home visit within 24 hours after discharge; (7) completion of first caregiver support call within 72 hours of discharge; (8) completion of the second and third caregiver support call within one month of discharge. A "Yes" answer indicates that the intervention component was feasible to provide for the patient and caregiver dyad.

- Mean patient intervention satisfaction scores. This interview guide will be used to assess the acceptability of Connect-Home Plus with persons with ADRD. The interview will include questions about (1) factors that made the Connect-Home Plus transitional care services easy or difficult to use, (2) specific supports that were and were not helpful, (3) the effect of Connect-Home Plus on how to manage issues related to ADRD at home, and (4) unmet needs for care of issues related to ADRD at home.(1) Responses to the interview guide questions will be used to generate 3 4-point Likert scale acceptability scores, including (how helpful was Connect-Home Plus, (2) how difficult were these services to use, and (3) how well did these services prepare you for care at home. The scores will include 0 meaning not applicable, and scores 1-3 indicating acceptability, with lower scores indicating higher acceptability.

- Mean caregiver intervention satisfaction scores. This interview guide will be used to assess the acceptability of Connect-Home Plus with caregivers of persons with ADRD.(1) This interview guide will include questions about (1) factors that made the Connect-Home Plus transitional care services easy or difficult to use, (2) specific supports that were and were not helpful, (3) the effect of Connect-Home Plus on how to manage issues related to ADRD at home, and (4) unmet needs for care of issues related to ADRD at home. Responses to the interview guide questions will be used to generate 3 4-point Likert scale acceptability scores, including (how helpful was Connect-Home Plus, (2) how difficult were these services to use, and (3) how well did these services prepare you for care at home. The scores will include 0 meaning not applicable, and scores 1-3 indicating acceptability, with lower scores indicating higher acceptability

- Secondary Outcome Measures

  - Care Transitions Measure-15. The patient's preparedness for discharge will be measured by the Care Transitions Measure-15 (CTM-15), which includes 5items on a 4-point scale.(30) The CTM-15 measures self-reported knowledge and skills for continuing care at home. Summary score range 0-100, with higher scores associated with less acute care use after discharge.

  - Preparedness for Caregiving Scale. The caregiver's preparedness for caregiving will be measured by the Preparedness for Caregiving Scale (PCS), which includes 8 items on a five-point Likert scale (0-4).(31) The PCS measures self-reported readiness for caregiving. Range = 0-32, with higher scores associated with less anxiety.

  - Life Space Assessment. Patient's function will be measured using the Life Space Assessment, which includes 5 Likert scales corresponding to a hierarchy of levels of mobility (each scored from 0-4) where weights are the product of the "Life-space level" (range 1-5) and the "independence" score (range 1-2).(32) The range is 1-120. Lower scores are associated with falls and hospitalization.

- Dementia Quality of Life Measure (patient). The quality of life of the patient will be assessed with the Dementia Quality of Life Measure.(33) It has 28 items that cover four quality of life dimensions: daily activities, memory, negative emotion and positive emotion. The score range is 28-112 with higher scores indicating better quality of life.

- Dementia Quality of Life-Proxy measure (DEMQOL-Proxy). When the patient is unable to rate their quality of life, the quality of life will be rated by their caregiver, using the Dementia Quality of Life-Proxy measure.(33) The score range is 31-124 with higher scores indicating better quality of life.

- Self-Reported Days of ED or Hospital Use 30 Days After Skilled Nursing Facility Discharge. Patient's days of acute care use will be measured using the self-reported number of combined number of days the patients pends in the Emergency Department (ED) or hospital in 30 days after SNF discharge.(19)

- Zarit Caregiver Burden Scale. Caregiver burden will be measured using the Zarit Caregiver Burden Scale, which includes 12 items on a five-point scale, measuring caregiver perceptions that "caregiving has an adverse effect on their emotional, social, financial, physical and spiritual functioning."(34) Scores range 0-48; higher scores are associated with depression and social isolation.

- Distress Thermometer. Caregiver distress will be measured using the Distress Thermometer, which includes 1 item on an 11-point scale, measuring negative affect (e.g., sadness and fear) related to caregiving for a severely ill person. Score ranges 0-10, with scores >4 associated with poor coping and depression.(35)

a. Safety Evaluations

- Study progress and safety will be reviewed monthly (and more frequently if needed). Progress reports will include patient and caregiver recruitment, retention/attrition, and adverse events. In addition, safety evaluation will include (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely.
- An adverse event (AE) is any untoward medical occurrence in a subject temporally associated with participation in the clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment or any combination of these. A Serious Adverse Event (SAE) is any adverse event that results in one or more of the following outcomes:
    - Death
    - A life-threatening event
    - Inpatient hospitalization
    - A persistent or significant disability/incapacity
    - Important medical event based upon appropriate medical judgment

Potential sources of information for identification of AEs include (but may not be limited to) nursing home staff reports of events while the patient is in the nursing home, and patient or caregiver reports of events while the patient is in the nursing home or at home. For example, the proposed study team will be in contact with the patient and caregiver over 30 days after the patient discharges from the nursing home to home. We will be calling the patient and caregiver at 7, 21 and 30 days. Any event that is discovered will be immediately relayed to the PI, or if he is away, another member of the research team so that we can execute safety plans and reporting plans described here.

AEs will be labeled according to severity, which is based on their impact on the patient. An AE will be termed ‘mild’ if it does not have an impact on the patient, ‘moderate’ if it causes the patient some minor inconvenience

and 'severe' if it causes a substantial disruption to the patient's well-being. AEs will be categorized according to the likelihood that they are related to the study intervention. Specifically, they will be labeled either definitely, probably, possibly or unrelated to the study intervention. If any IRB actions occur, the PI will email a report within 24 hours for the Independent Monitor, the second Independent monitor, and the Program Officer in the NINR in accordance with requirements.

8. STATISTICAL CONSIDERATIONS

The study will provide descriptive data about the feasibility and acceptability of the Connect-Home Plus Intervention, and to provide a description of patient and caregiver outcomes in the small sample of participants in the feasibility and acceptability study. Therefore, a small sample 20 patients and their caregivers will be used to achieve these goals.

Primary Endpoint

The sample of 20 patients and their 20 caregivers is sufficient to determine feasibility (i.e., the extent that staff will be able to deliver components of the Connect-Home Plus as intended) and the acceptability of Connect-Home Plus (i.e., the perceptions of the patients and caregivers that the intervention is easy to use, helpful, and provides skills for care of the patient at home.

Secondary Endpoint

The sample of 20 patients and their 20 caregivers is sufficient to describe preparedness for care after discharge (patient and caregiver); patient quality of life, functional mobility and acute care use; and caregiver burden and distress.

Statistical Methods

- Baseline data. Descriptive statistics will be used to analyze data collected in baseline surveys and chart reviews and describe patient clinical and non-clinical characteristics. Descriptive statistics will also be used to analyze baseline data collected from caregivers and describe nonclinical characteristics of caregivers.
- Efficacy Analysis. The study will not include an analysis of efficacy; rather, descriptive statistics will be used to describe the feasibility and acceptability of the intervention and to describe patient and caregiver outcomes in 30 days after SNF discharge. The primary outcome evaluation will use descriptive statistics to describe feasibility of providing the 8 intervention components identified in the feasibility chart review guide. The primary outcome evaluation will also use descriptive statistics to describe the acceptability of Connect-Home Plus. In addition, the secondary outcome evaluation will use descriptive statistics to describe preparedness for care after discharge (patient and caregiver); patient quality of life, functional mobility and acute care use; and caregiver burden and distress.
- Safety Analysis.
  Descriptive statistics will be used to describe patient and caregiver recruitment, retention/attrition, and adverse events.

Sample Size and Power

- 20 persons with ADRD and 20 caregivers in 2 SNFs over 12 months to determine the feasibility and acceptability of the adapted intervention.

Interim Analysis

- None

9. STUDY INTERVENTION

Connect-Home Plus will introduce new organizational structure to support staff delivery of transitional care processes.(19) Consistent with Donabedian, we anticipate that these changes in structure and care processes will be associated with improved patient and caregiver outcomes. New elements of organizational structure include an EHR template, the Connect-Home Toolkit, and Staff Training protocols; we developed, refined and tested these, finding them to be feasible, acceptable, and associated with improved patient and caregiver experiences of care.(1) See Table 4.

Table 4. Connect-Home Plus Structures

EHR tool	In the 2 study SNFs, an earlier version of the Connect-Home "**Transition Plan of Care Template"** was installed in the SNF EHR system. Before the pilot begins, the Transition Plan of Care template will be modified for Connect-Home Plus. The adapted template contains free text fields in 6 key care domains that SNF staff and home care RN, and dementia caregiver specialist (who makes post-discharge follow-up calls) use to record transition goals and deliver the two-step intervention.
Toolkit	The **"Connect-Home Plus Toolkit,"** a staff training workbook, based on the version of the workbook that was previously used in the parent study. It contains the Connect-Home Plus EHR template, 2-step intervention protocol, checklists and cue sheets, and intervention schedule.
Staff Training	**Site Leadership Training** (1 hour). PI trains 1-2 SNF project leaders. Content: the Connect-Home Plus protocol and study procedures.
	Staff Training (2 hours) In each SNF, the SNF staff were previously trained with the Connect-Home protocol. Thus, staff training with the Connect-Home Plus protocol will be two hours (as opposed to 4 hours in the parent study), with a special focus on services to care for persons with ADRD and their caregivers. The PI will train social workers, nurses, rehabilitation therapists. Training content: **1)** Patient and caregiver key care needs (home safety and level of assistance, advance care planning, symptom management, medication reconciliation, function and activity, and coordination of follow-up medical care). **2)** Protocols for using the two-step intervention to address patients' key care needs and unique needs of persons living with dementia and their caregivers. **3)** Using the EHR template to individualize patients' Transition Plan of Care. **4)** Advance care planning (identify surrogate, Health Care Power of Attorney, existing advance directives). **5)** Integrating SNF-based and home-based care (e.g., clinical hand-offs from SNF to home care RNs, the dementia caregiver specialist, and follow-up medical providers). Teaching Strategy: Presentation, the Connect-Home Plus Toolkit and teach-back.
	Focused Training for Home Care RNs (1.5 hours). The PI will provide additional training for home care RNs in up to 3 home care agencies that will participate in the pilot study (**Table 2**, below). Training content: The importance of home care follow-up within 24 hours of discharge, strategies for implementing the Transition Plans of Care, key care needs of persons living with ADRD and their caregivers and responding to medical needs. Teaching strategy: Presentation, the Connect-Home Plus Toolkit and teach-back.
	Focused Training for Dementia Caregiver Specialist (2 hours). The PI will train an occupational therapist to serve in the role of dementia caregiver specialist. Training content: **1)** the Connect-Home schedule of care, **2)** the Transition Plan of Care, **3)** key care needs of persons living with ADRD and their caregivers, **4)** the post-discharge call back script, **5)** procedures for communication with the SNF staff, and **6)** procedures for maintaining a record of call backs using the Call-
	New Staff Training (1-2 hours, as needed): The PI trains replacement staff to use the Connect-Home Plus protocol.

After new structural elements are in place, SNF staff will use Connect-Home Plus care processes to deliver the 2-step transitional care intervention. In **Step 1**, SNF nurses, rehabilitation therapists, and social workers will develop

a Transition Plan of Care and prepare the patient and caregiver to manage the patient's unique care needs related to ADRD and other functional and health care needs at home. In **Step 2**, a home care RN will visit the patient and caregiver at home within 24 hours of discharge; the nurse will work with them to activate the Transition Plan of Care at home. In addition, the Dementia Caregiver Specialist will call the caregiver at home to reinforce the discharge plan that was developed in the nursing home. The Dementia Caregiver Specialist will call within 72 hours of the patient's discharge to home and up to two more times, within one month of the discharge to home. See Table 5.

Table 5. Connect-Home Plus transitional care processes

Process	Patient/Caregiver Services and Supports	Day
Step 1. Transitional care in the SNF	**Set goals for home-based care** (**45 minutes**) Consulting with the patient/caregiver, SNF staff use the EHR template to describe goals in the patient's Transition Plan of Care, targeting key care needs and tailoring goals to the unique needs of persons with ADRD and their caregivers. The staff will identify concordance of observed signs and symptoms of impairment in the patient's thinking and memory (or other behavioral impairments) and the evidence of impairment from standardized assessments of cognitive impairment in the Minimum Data Set (e.g., BIMS score), other standardized measures of cognitive impairment staff use in routine care, and/or a diagnosis of dementia of any type in the medical record. • **Nurses** create goals for treatments and responses to symptoms or other health changes • **Rehabilitation therapists** create goals for mobility, transfers and self-care. • **Social worker** creates goals for caregiver support, follow-up care & discharge	2 - 17
	Meet to plan the patient's transition to home-based care (30 minutes) In dialogue with the patient/caregiver, the treating nurse, social worker and therapists will develop a plan for home-based care, targeting key care needs. The SNF staff members will discuss evidence of impairment in the patient's thinking and memory and/or the diagnosis of dementia, the caregiver's understanding of impairment in thinking or memory, and unique care needs and plans for coordinating the patient's transition to home. The staff will assist the patient and caregiver with planning for safety at home. • **Nurses** focus on medications, advance care planning and symptom management. • **All staff** help the patient and caregiver describe their needs for continuing care at home. • **Social worker** reviews Transition Plan of Care, home care plans, and the dementia caregiver specialist call-backs.	5 - 10
	Prepare the patient and caregiver for home-based care (2.5 hours) 1. Teach skills and plans for home-based care, targeting key care needs. • **Nurses** teach symptom management (e.g., pain), clarify advance care planning preferences, and reconcile medication orders • **Rehabilitation Therapists** teach skills for function and safety at home. • **Social worker** schedules and explains appointments, home-based care & cost 2. Initiate hand-off to home-based care (over the last 1-2 days before discharge) • **SNF staff** send medical records and copies of any advance care planning documents to the patient's physician and the home care RN. Provide caregiver with the Connect-Home Plus Discharge Planner) and notify the dementia caregiver specialist of the day of discharge. **Nurses**: 1) reconcile medications, 2) provide supplies and medications, and 3) re-teach the written Transition Plan of Care and medication list.	6 - 20

Step 2. Transitional care in the patient's home	Implement the Transition Plan of Care at home (3 hours) Home care RN visits the patient and caregiver at home within 24 hours of discharge to: • reconcile medications on the discharge medication list and in the home, • help family implement new care routines, addressing key care needs, • conduct a brief home safety & falls prevention screen Dementia Caregiver Specialist calls the caregiver within 72 hours of discharge and two more times withing one month of discharge (20 minutes / call) • Answer caregiver questions about implementing new routines of care at home • Provide education about care of a person living with ADRD and the unique care needsof a care transition for a person with ADRD. Relay information	21 (home care visit) & before day 51 (3 call backs)

10 SAFETY MANAGEMENT

To assure that the study meets expectations and any risk to participants is reduced to a minimum, the proposed study will use the Executive Committee and Safety Monitoring Committee (SMC) that was created in the parent study (Connect-Home Clinical Trial [R01NR017636]).

Executive Committee. The Executive Committee of the parent study will oversee the conduct of the study. The PI will chair the committee, which will meet quarterly, or more often as warranted, to review the activities of the study including management, personnel, recruitment, performance, and any emerging problems.

Safety Monitoring Committee (SMC). The SMC has seven members. The members of the Executive Committee and two members of the committee who will be independent of the protocol. Despite usual precautions, we are aware that adverse events may occur and this committee will monitor the occurrence of adverse events and the overall risk of the study to SNF patients, caregivers and staff. We will develop a system to test whether abnormalities are equally distributed between the intervention and control groups. Data will be presented to the committee if a significant increase in abnormalities is noted. The SMC will use the following stopping rules: (1) the intervention is associated with adverse effects that significantly impact the risk-benefit ratio, (2) study recruitment or retention becomes futile, (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping the trial. They will use these standards before they recommend modification or premature termination of the study on the basis of safety. Additionally, standards for discontinuing subjects from the study due to related adverse events will be established. The SMC will provide the PI with recommendations regarding problems that would require premature termination of the study for safety reasons. Minutes of each meeting will be kept, and all actions and decisions documented to establish an audit trail. The committee will also provide the PI with advice on whether there is any reason to change the design of the study.

Any serious adverse events or deaths that occur during the study will be reported by telephone immediately to the Human Participants Research Review Committee Chairperson. An incident report will be sent by electronic mail by the Executive Committee members and the project manager. The PI will follow-up immediately with patient or caregiver to investigate, and prepare a report for all members of the Human Participants Committee, and comply with all regulations regarding the reporting of serious adverse events. The event will be evaluated for relatedness to the study intervention. The PI or a Co-Investigator in his absence will be responsible for complying with all regulations concerning the reporting of a serious adverse event and will prepare a full report for NIH if the event is related to study intervention. The PI will meet with the Co-Investigators and project manager and make a subject or study termination decision as the situation warrants. Process notes will be kept concerning any termination decisions.

Data and Safety Management

Study Identification Information

- NIH Study Number – TBD
- Study Title – Adapting Connect-Home Transitional Care to Fit the Unique Needs of Persons with Cognitive Impairment and their Caregivers: A Pilot Study

- Name of Principal Investigator – Mark Toles, PhD, RN

Study Overview

Brief Description of the Purpose of the Study – The objectives of the proposed formative study are to adapt the Connect-Home transitional care intervention to fit the needs of persons with ADRD and their caregivers and to test the feasibility and acceptability of the adapted intervention in a total sample of 20 patients and 20 caregivers in two SNFs.

Adherence Statement – The Data Safety Monitoring Plan (DSMP) outlined below for the proposed study will adhere to the protocol approved by The University of North Carolina at Chapel Hill Office of Human Research and Ethics Institutional Review Board.

Confidentiality

Protection of Subject Privacy – Protections of subject privacy in the proposed study are described in the following. In study activities related to Aim 1 and Aim 2, after enrollment we will collect baseline data from persons with ADRD in person while they are in the SNF (using surveys and a chart review) and baseline data from the caregiver in person or by telephone (using surveys). In study activities related to Aim 1, we will collect data from persons with ADRD and their caregivers within 14 days after discharge from the SNF to home. In study activities related to Aim 2, we will collect data from persons with ADRD and caregivers by telephone at Time 1 (seven days after SNF discharge), Time 2 (21 days after SNF discharge), and Time 3 (30 days after SNF discharge). In study activities related to Aim 1, we will also collect data from staff members in the SNF and home care agency. Data collected from staff will not include protected health information and will focus on the nature of transitional care and discharge planning provided for persons with ADRD and their caregivers. Appropriate questionnaires and measurements will be collected at all time points. All of the materials collected are for research purposes only, and data will be kept in strict confidence. No information will be given to anyone without permission from the subject. The consent form includes the informed consent statement required by The University of North Carolina at Chapel Hill. This statement guarantees confidentiality and identifies the subject as the owner of the information from the analysis. Confidentiality is assured by use of identification codes. All data will be identified with an identification code unique to the subject.

Database Protection –The database is secured with password protection. The data base includes ONLY coded information, and data are entered into the database under those identification numbers. Electronic communication with outside collaborators involves only unidentifiable information. The study database will comply with current data security standards, and will provide real-time data entry validation, and will provide audit trails documenting any changes or corrections of the study data. Data entry or review will require logging into a secure portal with a username and password. The database is hosted by the School of Nursing at the University of North Carolina-Chapel Hill, and is HIPAA-compliant. The two servers in the University of North Carolina School of Nursing are connected using a Compaq Storage Area Network (SAN), which has 728 gigabytes of shared storage, also deployed in a RAID 5 array, with an additional 72.8 gigabyte drive available as a spare that can be swapped into operation with no interruption of service. The servers are fully redundant; all services can run on either node or be load-balanced between them. The SONBACKUP, which operates exclusively to perform backup for our servers and personal computers. Backup is performed regularly on an HP Storage Works Super DLT 320 tape backup unit.

Explicit identifying information will be recorded on separate forms and will NOT be sent to the database; these forms will be maintained in a secure location.

Confidentiality During Adverse Event (AE) Reporting – AE reports and annual summaries will not include subject- identifiable material. Each will include the identification code only.

11. RECRUITMENT STRATEGY

The study team will use a limited waiver of HIPAA authorization to pre-screening for patient and caregiver eligibility during the SNF admission. The study team will recruit SNF patients and their caregivers in-person (or, when risk mitigation related to COVID-19 prevents in-person contact, we will recruit virtually, using an iPad and connection via ZOOM) within 10 days of their admission and will review the patient's medical record to confirm eligibility. For persons with ADRD, inclusion criteria are: (1) be able to speak English; (2) have a goal of discharge to home; (3) have a diagnosis of ADRD, or a BIMS score <13, or (for persons unable to complete the BIMS assessment) a CPS of ≥3 (calculated using data in the Minimum Data Set 3.0 and an algorithm for estimating cognitive impairment using Minimum Data Set MDS data other than BIMS (26, 27)); and (4) have a caregiver willing to participate. We will recruit a representative for persons with ADRD who have a legally authorized representative (LAR); in addition, we will recruit a family caregiver to represent persons admitted to the SNF who are not able to complete the BIMS or who have a BIMS score ≤7. Exclusion criterion for patients: planned hospital readmission for procedures/treatments in next 30 days (thus distorting assessment of patient and caregiver outcomes). Inclusion criteria for caregivers: 1) self-reports assisting the patient at home; and 2) the ability to speak English. We will identify caregivers using documentation in the medical record that the caregiver provides care at home and/or is legally authorized representative of the person with ADRD. We will use procedures from the Connect-Home parent study to recruit staff, persons with ADRD, and caregivers. To recruit persons with ADRD and caregivers, a Research Coordinator (RC) will use a HIPAA waiver allowing prescreening for eligibility and will: 1) consult the nursing director in each SNF to identify persons admitted to the SNF; and 2) screen the medical record of persons with ADRD who are expected to be discharged home. Using IRB approved forms and consent procedures, the RC will recruit persons with ADRD and caregivers in-person or by phone during the SNF stay until the recruitment goal is reached. The RC will recruit staff using procedures from the parent study. All participants will give written informed consent for study participation.

12. CONSENT PROCESS

As in the parent study, written informed consent will be obtained from each participant at entry into the study. Informed consent is obtained by the following process:

- The recruitment coordinator or project manager will read the study consent form to the participant;
- The recruitment coordinator or project manager will review the form, to confirm the participant's understanding of the study, and to answer any questions that the participant might have; and
- Once the participant demonstrates understanding of the study and agrees to participate in the study, the consent will be signed.

In the proposed study, we will enroll persons with ADRD. Inclusion criteria are: (1) be able to speak English; (2) have a goal of discharge to home; (3) have a diagnosis of dementia, or a BIMS score <13, or (for persons unable to complete the BIMS assessment) a CPS of ≥3 (calculated using data in the Minimum Data Set 3.0 and an algorithm for estimating cognitive impairment using Minimum Data Set MDS data other than BIMS); and (4) have a caregiver willing to participate; and (4) for persons admitted to the SNF, who have a legally authorized representative, who cannot complete the BIMS, or who have a BIMS score ≤7, we will recruit a family caregiver as the representative of the patient. We will enroll caregivers of persons with ADRD. Inclusion criteria for caregivers are the ability to speak English and being in the role of caregiver for the person with ADRD at home.

13. PLANS FOR PUBLICATION

Findings from the study will be published in a peer-reviewed journal with a clinical readership in nursing and care of persons with ADRD and their caregivers. Findings will be shared in scientific meetings and in presentations with clinical and administrative staff in participating nursing homes and home health care organizations.

14. REFERENCES

1. Toles M, Colon-Emeric C, Naylor MD, Asafu-Adjei J, Hanson LC. Connect-Home: Transitional Care of Skilled Nursing Facility Patients and their Caregivers. J Am Geriatr Soc. 2017;65(10):2322-8.
2. Donabedian A. Evaluating the quality of medical care 1966. The Milbank Quarterly. 2005;83(4):691-729.
3. Medicare Payment Advisory Commission. Report to the Congress 2019 [Available from: http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec_rev.pdf?sfvrsn=0.
4. Carnahan JL, Slaven JE, Callahan CM, Tu W, Torke AM. Transitions From Skilled Nursing Facility to Home: The Relationship of Early Outpatient Care to Hospital Readmission. J Am Med Dir Assoc. 2017;18(10):853-9.
5. Toles M, Anderson RA, Massing M, Naylor MD, Jackson E, Peacock-Hinton S, et al. Restarting the cycle: incidence and predictors of first acute care use after nursing home discharge. J Am Geriatr Soc. 2014;62(1):79-85.
6. Makam AN, Nguyen OK, Xuan L, Miller ME, Goodwin JS, Halm EA. Factors Associated With Variation in Long-term Acute Care Hospital vs Skilled Nursing Facility Use Among Hospitalized Older Adults. JAMA internal medicine. 2018.
7. Middleton A, Downer B, Haas A, Lin YL, Graham JE, Ottenbacher KJ. Functional Status Is Associated With 30-Day Potentially Preventable Readmissions Following Skilled Nursing Facility Discharge Among Medicare Beneficiaries. J Am Med Dir Assoc. 2018;19(4):348-54.e4.
8. Lin PJ, Zhong Y, Fillit HM, Chen E, Neumann PJ. Medicare Expenditures of Individuals with Alzheimer's Disease and Related Dementias or Mild Cognitive Impairment Before and After Diagnosis. J Am Geriatr Soc. 2016;64(8):1549-57.
9. Lin PJ, Fillit HM, Cohen JT, Neumann PJ. Potentially avoidable hospitalizations among Medicare beneficiaries with Alzheimer's disease and related disorders. Alzheimer's & dementia : the journal of the Alzheimer's Association. 2013;9(1):30-8.
10. Prusynski RA, Gustavson AM, Shrivastav SR, Mroz TM. Rehabilitation Intensity and Patient Outcomes in Skilled Nursing Facilities in the United States: A Systematic Review. Phys Ther. 2021;101(3).
11. Sloane PD, Schifeling CH, Beeber AS, Ward KT, Reed D, Gwyther LP, et al. New or Worsening Symptoms and Signs in Community-Dwelling Persons with Dementia: Incidence and Relation to Use of Acute Medical Services. J Am Geriatr Soc. 2017;65(4):808-14.
12. Callahan CM, Tu W, Unroe KT, LaMantia MA, Stump TE, Clark DO. Transitions in Care in a Nationally Representative Sample of Older Americans with Dementia. J Am Geriatr Soc. 2015;63(8):1495-502.
13. Callahan CM, Arling G, Tu W, Rosenman MB, Counsell SR, Stump TE, et al. Transitions in care for older adults with and without dementia. J Am Geriatr Soc. 2012;60(5):813-20.
14. Kodate N, Timonen V. Bringing the Family in through the Back Door: the Stealthy Expansion of Family Care in Asian and European Long-Term Care Policy. J Cross Cult Gerontol. 2017;32(3):291-301.

15. national Academies of Sciences Engineering and Medicine. Families Caring for an Aging America. Washington (DC): The National Academies Press; 2016.

16. Whitlatch CJ, Orsulic-Jeras S. Meeting the Informational, Educational, and Psychosocial Support Needs of Persons Living With Dementia and Their Family Caregivers. Gerontologist. 2018;58(suppl_1):S58-s73.

17. Hirschman KB, Hodgson NA. Evidence-Based Interventions for Transitions in Care for Individuals Living With Dementia. Gerontologist. 2018;58(suppl_1):S129-s40.

18. Prusaczyk B, Olsen MA, Carpenter CR, Proctor E. Differences in Transitional Care Provided to Patients With and Without Dementia. J Gerontol Nurs. 2019;45(8):15-22.

19. Toles M, Colón-Emeric C, Hanson LC, Naylor M, Weinberger M, Covington J, et al. Transitional care from skilled nursing facilities to home: study protocol for a stepped wedge cluster randomized trial. Trials. 2021;22(1):120.

20. Fazio S, Pace D, Maslow K, Zimmerman S, Kallmyer B. Alzheimer's Association Dementia Care Practice Recommendations. Gerontologist. 2018;58(suppl_1):S1-s9.

21. Escoffery C, Lebow-Skelley E, Udelson H, Boing EA, Wood R, Fernandez ME, et al. A scoping study of frameworks for adapting public health evidence-based interventions. Transl Behav Med. 2019;9(1):1-10.

22. Toles M, Colon-Emeric C, Naylor MD, Barroso J, Anderson RA. Transitional care in skilled nursing facilities: a multiple case study. BMC Health Serv Res. 2016;16:186.

23. Maslow K, Fortinsky RH. Nonphysician Care Providers Can Help to Increase Detection of Cognitive Impairment and Encourage Diagnostic Evaluation for Dementia in Community and Residential Care Settings. Gerontologist. 2018;58(suppl_1):S20-s31.

24. Chen EK, Reid MC, Parker SJ, Pillemer K. Tailoring evidence-based interventions for new populations: a method for program adaptation through community engagement. Eval Health Prof. 2013;36(1):73-92.

25. Center for Medicaid and Medicare Services. Minimum Data Set 3.0 RAI Manual 2013 [Available from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.

26. Morris JN, Fries BE, Mehr DR, Hawes C, Phillips C, Mor V, et al. MDS Cognitive Performance Scale. J Gerontol. 1994;49(4):M174-82.

27. Thomas KS, Dosa D, Wysocki A, Mor V. The Minimum Data Set 3.0 Cognitive Function Scale. Med Care. 2017;55(9):e68-e72.

28. Cawthon PM, Marshall LM, Michael Y, Dam TT, Ensrud KE, Barrett-Connor E, et al. Frailty in older men: prevalence, progression, and relationship with mortality. J Am Geriatr Soc. 2007;55(8):1216-23.

29. Mitchell PH, Powell L, Blumenthal J, Norten J, Ironson G, Pitula CR, et al. A short social support measure for patients recovering from myocardial infarction: the ENRICHD Social Support Inventory. J Cardiopulm Rehabil. 2003;23(6):398-403.

30. Coleman EA, Mahoney E, Parry C. Assessing the quality of preparation for posthospital care from the patient's perspective: The care transitions measure. Med Care. 2005;43(3):246-55.

31. Archbold PG, Stewart BJ, Greenlick MR, Harvath T. Mutuality and preparedness as predictors of caregiver role strain. Res Nurs Health. 1990;13(6):375-84.

32. Baker PS, Bodner EV, Allman RM. Measuring life-space mobility in community-dwelling older adults. J Am Geriatr Soc. 2003;51(11):1610-4.

33. Smith SC, Lamping DL, Banerjee S, Harwood RH, Foley B, Smith P, et al. Development of a new measure of health-related quality of life for people with dementia: DEMQOL. Psychol Med. 2007;37(5):737-46.

34. Zarit SH, Todd PA, Zarit JM. Subjective burden of husbands and wives as caregivers: a longitudinal study. Gerontologist. 1986;26(3):260-6.

35. Roth AJ, Kornblith AB, Batel-Copel L, Peabody E, Scher HI, Holland JC. Rapid screening for psychologic distress in men with prostate carcinoma: a pilot study. Cancer. 1998;82(10):1904-8.