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

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

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## Summary of Changes from Previous Version:

| Affected Section(s) | Summary of Revisions Made | Rationale |
|---|---|---|
| Section 2, 5, 6, 8 10 | Recruitment procedures updated to allot for virtual recruitment | COVID-19 safety precautions |

**Table of Contents**

Statement of Compliance ....3
1 Protocol Summary ....4
1.1 Synopsis ....4
1.2 Schedule of Activities (SoA) ....7
2 Introduction ....10
2.1 Study Rationale ....10
2.2 Background ....10
2.3 Risk/Benefit Assessment ....11
2.3.1 Known Potential Risks ....11
2.3.2 Known Potential Benefits ....13
2.3.3 Assessment of Potential Risks and Benefits ....14
3 STUDY OBJECTIVES ....15
4 Study Design ....19
4.1 Overall Design ....19
4.2 Scientific Rationale for Study Design ....20
4.3 End of Study Definition ....20
5 Study Population ....21
5.1 Inclusion Criteria ....21
5.2 Exclusion Criteria ....21
5.3 Screen Failures ....22
5.4 Strategies for Recruitment and Retention ....22
6 Study Intervention ....24
6.1 Study Intervention(s) Administration ....24

6.1.1 Study Intervention Description ..... 24
6.2 Measures to Minimize Bias: Randomization and Blinding ..... 27
6.3 Study Intervention Compliance ..... 27
7 Study Intervention Discontinuation and Participant Discontinuation/Withdrawal ..... 29
7.1 Discontinuation of Study Intervention ..... 29
7.2 Participant Discontinuation/Withdrawal from the Study ..... 29
7.3 Lost to Follow-Up ..... 30
8 STUDY ASSESSMENTS AND PROCEDURES ..... 31
8.1 Efficacy Assessments ..... 31
8.2 Adverse Events and Serious Adverse Events ..... 35
8.2.1 Definition of Adverse Events (AE) ..... 35
8.2.2 Definition of Serious Adverse Events (SAE) ..... 35
8.2.3 Classification of an Adverse Event ..... 35
8.2.4 Time Period and Frequency for Event Assessment and Follow-Up ..... 36
8.2.5 Adverse Event Reporting ..... 36
8.2.6 Serious Adverse Event Reporting ..... 36
8.3 Unanticipated Problems ..... 37
8.3.1 Definition of Unanticipated Problems (UP) ..... 37
8.3.2 Unanticipated Problem Reporting ..... 37
9 Statistical Considerations ..... 38
9.1 Statistical Hypotheses ..... 38
9.2 Sample Size Determination ..... 38
9.3 Populations for Analyses ..... 39
9.4 Statistical Analyses ..... 39
9.4.1 General Approach ..... 39
9.4.2 Analysis of the Primary Efficacy Endpoint(s) ..... 40
9.4.3 Analysis of the Secondary Endpoint(s) ..... 40
9.4.4 Baseline Descriptive Statistics ..... 41
10 Supporting Documentation and Operational Considerations ..... 43
10.1 Regulatory, Ethical, and Study Oversight Considerations ..... 43
10.1.1 Informed Consent Process ..... 43
10.1.2 Study Discontinuation and Closure ..... 43
10.1.3 Confidentiality and Privacy ..... 44
10.1.4 Future Use of Stored Specimens and Data ..... 44
10.1.5 Safety Oversight ..... 44
10.1.6 Clinical Monitoring ..... 45
10.1.7 Quality Assurance and Quality Control ..... 45
10.1.8 Data Handling and Record Keeping ..... 45
10.1.9 Protocol Deviations ..... 45
10.1.10 Publication and Data Sharing Policy ..... 46
10.1.11 Conflict of Interest Policy ..... 46
10.2 Abbreviations ..... 47
10.3 Protocol Amendment History ..... 48
11 References ..... 49

## STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Conference on Harmonization Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of the study and consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

# 1 PROTOCOL SUMMARY

## 1.1 SYNOPSIS

| | |
|---|---|
| **Title:** | Connect-Home: Testing the Efficacy of Transitional Care of Patients and Caregivers during Transitions from Skilled Nursing Facilities to Home |
| **Study Description:** | The proposed study will test the efficacy of Connect-Home, a transitional care intervention, targeting seriously ill Skilled Nursing Facility (SNF) patients who discharge to home and their primary caregivers. The study will be set in six North Carolina SNFs and in the patient's home (during intervention periods only). Using a stepped-wedge cluster-randomized trial design, six SNFs will be randomly allocated to standard discharge planning (control period) vs. the Connect-Home intervention (intervention period) over six sequential time-periods.<br><br>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, 30, and 60 days after patients return home. |
| **Objectives:** | Primary Objective:<br>1.1: To assess patient preparedness for discharge seven days after discharge from a skilled nursing facility.<br><br>1.2: To assess caretaker preparedness for the caregiving role seven days after discharge from a skilled nursing facility.<br><br>Secondary Objectives:<br>2.1 To assess patient quality of life 30 and 60 days after discharge from a skilled nursing facility.<br><br>2.2. To assess patient function 30 and 60 days after discharge from a skilled nursing facility.<br><br>2.3 To assess patient days of acute care use 30 and 60 days after discharge from a skilled nursing facility.<br><br>2.4 To assess caregiver burden 30 and 60 days after discharge from a skilled nursing facility. |

| | |
|---|---|
| | 2.5 To assess caregiver distress 30 and 60 days after discharge from a skilled nursing facility. |
| **Endpoints:** | Primary Endpoint:<br>1.1 The Care Transitions Measure-15 (CTM-15),[26] assessed at seven days post discharge.<br>1.2 The Preparedness for Caregiving Scale (PCS),[29] assessed at seven days post discharge.<br><br>Secondary Endpoints:<br>2.1 The McGill Quality of Life Questionnaire-Revised (MQoL-R), [85] assessed at 30- and 60-days post discharge.<br><br>2.2 The Life Space Assessmen[86], assessed at 30- and 60-days post discharge.<br><br>2.3 The self-reported combined number of days the patient spends in the ED or hospital in 30- and 60-days post discharge.[87]<br><br>2.4 The Zarit Caregiver Burden Scale[88], assessed at 30- and 60-days post discharge.<br><br>2.5 The Distress Thermometer, [89] assessed 30- and 60-days post discharge. |
| **Study Population:** | This study will enroll 360 seriously ill patients in SNFs and 360 caregivers.<br><br>Patients must be English speaking, have a minimum data set of 3.0, Section GG Mobility Assessment Score of 3 or less, indicating the patient requires at least 25-50% assistance for functional mobility, be diagnosed with at least 1 serious medical illness, and have a caregiver who can be enrolled in the study.<br><br>Caregivers must be English speaking and self-report that they assist the patient at home. For patients with cognitive impairment, 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 is additionally required. |
| **Phase:** | N/A |

| | |
|---|---|
| **Description of Sites/Facilities Enrolling Participants:** | Six SNFs owned by one organization will participate in this study (none participated in the Connect-Home pilot study). Inclusion criteria for SNFs: location within 120 miles of UNC and at least 15 post-acute admissions per month. Six SNFs and six home health nurses and two alternate SNFs and two alternate home health nurses for each SNF have agreed to participate. If a study site or a home health nurse becomes unavailable to participate, the alternate SNFs and nurses will participate in Connect-Home training. |
| **Description of Study Intervention:** | Connect-Home is a two-step transitional care intervention: 1) SNF staff create an individualized Transition Plan or Care and prepare the patient and caregiver to manage the patient's illness at home; and 2) within 24 hours of SNF discharge, a Connect-Home Activation RN visits the patient's home and helps the patient and caregiver 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 and activity; and 6) coordination of follow-up medical care. |
| **Study Duration:** | This study will be ongoing for four years. |
| **Participant 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. |

## 1.2 SCHEDULE OF ACTIVITIES (SOA)

**Schedule of Activities for Patients (Control):**

| Assessments and Procedures | Screening | Pre-Discharge | Discharge | 24 Hours Post-Discharge | 7 Days Post-Discharge (+ 10/- 3 days) | 30 Days Post-Discharge (+/- 7 days) | 60 Days Post-Discharge (+/- 7 days) |
|---|---|---|---|---|---|---|---|
| Informed Consent | X | | | | | | |
| Confirm Eligibility | X | | | | | | |
| Study of Osteopathic Fractures Index | | X | | | | | |
| ENRICHD Social Support Inventory | | X | | | | | |
| SNF Chart Abstraction | | | | | X | | |
| CTM-15 | | | | | X | | |
| MQoL-R | | | | | | X | X |
| Life Space Assessment | | | | | | X | X |
| Falls Assessment | | | | | | X | X |
| Hospice Enrollment Assessment | | | | | | X | X |
| Home Health Care Chart Abstraction | | | | | | | X |
| Hospital Use Assessment | | | | | | X | X |
| Emergency Department Use Assessment | | | | | | X | X |

**Schedule of Activities for Patients (Intervention):**

| Assessments and Procedures | Screening | Pre-Discharge | Discharge | 24 Hours Post-Discharge | 7 Days Post-Discharge (+ 10/- 3 days) | 30 Days Post-Discharge (+/- 7 days) | 60 Days Post-Discharge (+/- 7 days) |
|---|---|---|---|---|---|---|---|
| Informed Consent | X | | | | | | |
| Confirm Eligibility | X | | | | | | |
| Study of Osteopathic Fractures Index | | X | | | | | |
| ENRICHD Social Support Inventory | | X | | | | | |
| SNF Chart Abstraction | | | | | X | | |
| Connect-Home Intervention in SNF (Step 1) | | X | | | | | |
| Connect-Home Intervention in Home (Step 2) | | | | X | | | |
| CTM-15 | | | | | X | | |
| MQoL-R | | | | | | X | X |
| Life Space Assessment | | | | | | X | X |
| Falls Assessment | | | | | | X | X |
| Hospice Enrollment Assessment | | | | | | X | X |
| Home Health Care Chart Abstraction | | | | | | | X |
| Hospital Use Assessment | | | | | | X | X |
| Emergency Department Use Assessment | | | | | | X | X |

**Schedule of Activities for Caregivers (Control):**

| Assessments and Procedures | Screening | Pre-Discharge | Discharge | 24 Hours Post-Discharge (+3 days) | 7 Days Post-Discharge (+/- 2 days) | 30 Days Post-Discharge (+/- 7 days) | 60 Days Post-Discharge (+/- 7 days) |
|---|---|---|---|---|---|---|---|
| Informed Consent | X | | | | | | |
| Confirm Eligibility | X | | | | | | |
| Baseline Questionnaire | | X | | | | | |
| Preparedness for Caregiving Scale | | | | | X | | |
| Zarit Caregiver Burden Scale | | | | | | X | X |
| Distress Thermometer | | | | | | X | X |
| Death Assessment | | | | | | X | X |

**Schedule of Activities for Caregivers (Intervention):**

| Assessments and Procedures | Screening | Pre-Discharge | Discharge | 24 Hours Post-Discharge (+3 days) | 7 Days Post-Discharge (+/- 2 days) | 30 Days Post-Discharge (+/- 7 days) | 60 Days Post-Discharge (+/- 7 days) |
|---|---|---|---|---|---|---|---|
| Informed Consent | X | | | | | | |
| Confirm Eligibility | X | | | | | | |
| Baseline Questionnaire | | X | | | | | |
| Connect-Home Intervention in SNF (Step 1) | | X | | | | | |
| Connect-Home Intervention in Home (Step 2) | | | | X | | | |
| Preparedness for Caregiving Scale | | | | | X | | |
| Zarit Caregiver Burden Scale | | | | | | X | X |
| Distress Thermometer | | | | | | X | X |
| Death Assessment | | | | | | X | X |

# 2 INTRODUCTION

## 2.1 STUDY RATIONALE

Skilled nursing facility (SNF) patients are medically complex with incurable chronic conditions, dependence on caregivers for activities of daily living, and have a recent acute illness, such as septicemia and hip and femur procedures.[1-3] Despite the high prevalence of acute care use and mortality after SNF patients return home (>50% in 90 days),[3] SNF patients and their caregivers do not receive transitional care that prepares them to manage the patient's serious illnesses at home. No efficacy studies of transitional care have targeted this population, or measured whether interventions resulted in improved patient and caregiver outcomes.[4] This study will test the efficacy of Connect-Home, a successfully piloted transitional care intervention, targeting both seriously ill SNF patients who discharge to home and their caregivers.

Connect-Home will generate a new model of transitional care not dependent on research staff for delivery, thereby accelerating translation of the intervention from research to clinical practice.

## 2.2 BACKGROUND

Annually, 1.7-1.8 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, medical and nursing care. [1-3] SNF patients are seriously ill: 56-62% are ≥80 years old; 100% have recent acute illness (e.g., hip fracture, heart failure, genitourinary and pulmonary infections with & without sepsis); 28-34% are treated in intensive care during the index hospital stay; and 29-43% have ≥1 hospitalization in the year prior to the index hospital and SNF stay.[2,4-7] In addition, these individuals have underlying incurable chronic conditions: 29-35% are cognitively impaired; 46% have Charlson Comorbidity scores ≥2, 28% have scores ≥3; and nearly all experience multi-morbidity, for example, 82% of those with heart failure have 5 co-occurring chronic conditions.[2,8-10] SNF patients also are functionally impaired and frail with an average of three or more geriatric syndromes (e.g., depressive symptoms, poor sleep, unplanned weight loss) and depend on caregivers for 3-6 activities of daily living.[6,8,11,12] Complicating these challenges, 25% of SNF patients live alone and 20-25% are co-insured with Medicaid. After returning home, former SNF patients are at high risk for falls and functional impairment; in a recent study, 61% showed little or no functional improvement one year after SNF discharge.[13-15]

SNF patients are also at an exceptionally high risk for return to acute care, continued functional decline, and death. In a preliminary analysis of 55,000 SNF patient transitions to home, >50% of patients returned to the hospital within 90 days of discharge or died: 25.9% used ED services, 20.1% were re-hospitalized, and 8.1% died within 90 days of returning home.[3] Moreover, lacking advance directives and goals of care, 33% of discharged SNF patients who died within the next month, died in hospital rather

than at home.[16] Thus, SNF patients are a seriously ill and functionally impaired population, supported by stressed caregivers.

These seriously ill patients, as they draw closer to the end-of-life, also experience multiple transitions between healthcare providers and settings.[17-19] Much evidence demonstrates that hospital-based transitional care improves patients' preparedness for discharge and decreases the rate of re-hospitalization within 30 days of discharge.[20-22] However, in a systematic review of SNF-based transitional care, no randomized clinical trials were identified and only a limited set of observational studies of transitional care were found.[4] In the set of observational studies, there were substantial limitations, including intervention designs lacking caregiver support, advance care planning, and home follow-up after SNF discharge and serious methodological flaws (non-experimental designs with small samples and no reliable measurement of intermediate and 30 or 60 day patient- and care-giver outcomes).[4] Lacking transitional care, SNF patients (and their caregivers) are not prepared to manage the patient's serious illness at home, and are at high risk for new acute medical events, diminished quality of life and other poor health outcomes.[23-26]

Systematic reviews of studies, describing the efficacy of transitional care interventions to prepare hospital patients for transitions to home, established that transitional care, compared to usual discharge planning, reduced the rate of re-hospitalization 30 days after patient discharge. Findings from the pilot-test of Connect-Home and systematic review of related observational studies provided foundational evidence to support the premise that transitional care of SNF patients and their caregivers will prepare seriously ill patients for discharge, promote quality of life and function at home, and reduce hospital readmissions.[27] Targeting patients with caregivers is a logical extension, because they provide the direct care needed for seriously ill patients to bridge the vulnerable period following SNF discharge.[28-32]

## 2.3 RISK/BENEFIT ASSESSMENT

### 2.3.1 KNOWN POTENTIAL RISKS

Physical Risks:

Patients and caregivers in control periods will receive discharge planning in the SNF, and those in intervention periods will receive transitional care in the SNF and in the patient's home. Discharge planning and 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.

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. During the control and intervention periods, staff in the SNF and in the home health agency will engage patients and caregivers in conversations to plan strategies for managing the patient's serious 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. Staff will also review the patient's advance directives. These study-related activities may also involve a chance for emotional distress.

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.

In intervention and control periods, 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.

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.

### 2.3.2 KNOWN POTENTIAL BENEFITS

The major potential benefit of this study is new knowledge about ways to improve outcomes for seriously ill SNF patients and/or their caregivers. The intervention 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. Participants in the control periods in the SNFs will receive usual discharge planning.

As a result of the research, we will know whether and to what degree the intervention, compared to usual care, increased the capacity of SNF patients to achieve health care goals at home after SNF discharge and caregivers to avoid burden and distress related to the caregiving role. If the intervention is successful, this study will provide an evidence-based practice rationale for intervention with seriously ill SNF patients or their caregivers. It will also provide new knowledge related to care of adults with serious illness in the context of the COVID-19 pandemic.

### 2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The predicted risks for this study are minimal, and feasible precautions will be taken to protect all subjects in this study. The benefits that will be obtained, both as direct benefits to the participants in the intervention phase and potential benefits to the community at large, do not exceed the risks outlined in section 2.3.1.

## 3 STUDY OBJECTIVES

| OBJECTIVES | ENDPOINTS | JUSTIFICATION FOR ENDPOINTS |
|---|---|---|
| Primary | | |
| 1.1 To assess patient preparedness for discharge seven days after discharge from a skilled nursing facility. | 1.1 The Care Transitions Measure-15 (CTM-15), assessed at seven days post discharge.[33,34] | 1.1 The CTM-15 has a high reliability (alpha range = 0.93-0.95) and measures self-reported knowledge and skills for continuing care at home. Higher scores are associated with less acute care use after discharge. |
| 1.2 To assess caretaker preparedness for caregiving seven days after discharge from a skilled nursing facility. | 1.2 The Preparedness for Caregiving Scale (PCS), assessed at seven days post discharge.[35] | 1.2 The PCS has moderate to high reliability (alpha= 0.86-0.92). Range = 0-32; higher scores are associated with less anxiety[103] |
| Secondary | | |
| 2.1 To assess patient quality of life 30 and 60 days after discharge from a skilled nursing facility. | 2.1 The McGill Quality of Life Questionnaire (MQoL-R), assessed at 30- and 60-days post discharge.[36,37] | 2.1 The MQoL-R has moderate reliability (alpha= .80); the scale is recommended for studies of palliative care [72] and measures quality of life across disease trajectories. [85] |
| 2.2. To assess patient function 30 and 60 days after discharge from a skilled nursing facility. | 2.2 The Life Space Assessment, assessed at 30- and 60-days post discharge.[38,39] | 2.2 The Life Space Assessment has high reliability (alpha=0.96). Range is 1-120, and lower scores are associated with falls and hospitalization. |
| 2.3 To assess patient days of acute care use 30 and 60 days | 2.3 The self-reported combined number of days the patient spends in | 2.3 This composite variable indicating total acute care is a reliable measure of the |

| OBJECTIVES | ENDPOINTS | JUSTIFICATION FOR ENDPOINTS |
|---|---|---|
| after discharge from a skilled nursing facility. | the ED or hospital in 30- and 60-days post discharge.[40] | patients' time at home after SNF care is interrupted by subsequent acute care needs. |
| 2.4 To assess caregiver burden 30 and 60 days after discharge from a skilled nursing facility. | 2.4 The Zarit Caregiver Burden Scale, assessed at 30- and 60-days post discharge.[41,42] | 2.4 The Zarit Caregiver Burden Scale has high reliability (alpha-0.89), measures caregiver perceptions that "caregiving has an adverse effect on their emotional, social, financial, physical and spiritual functioning." Scores range 0-48; higher scores associated with depression and social isolation. |
| 2.5 To assess caregiver distress 30 and 60 days after discharge from a skilled nursing facility. | 2.5 The Distress Thermometer, assessed 30- and 60-days post discharge.[28] | 2.5 The Distress Thermometers includes 1 item on an 11-point scale, measuring negative affect related to caregiving for a severely ill person. Score ranges 0-10, with scores >4 associated with poor coping and depression. |
| Tertiary/Exploratory | | |
| E.1 To assess the number of patients falls with injury 30 and 60 days after discharge from a skilled nursing facility. | E.1 Patient assessment of number of falls with injury, assessed 30- and 60-days post discharge. Falls are defined as an "unintentional change in position resulting in a resident coming to rest on the ground or lower level."[43] | E.1 Prior exploratory studies suggest that falls are a frequent event in the immediate post-discharge period. The count of falls in this study will be among the first to describe the impact of a transitional care |

| OBJECTIVES | ENDPOINTS | JUSTIFICATION FOR ENDPOINTS |
|---|---|---|
| | | intervention on the falls rate in the post discharge period. |
| E.2 To assess patient enrollment in hospice 30 and 60 days after discharge from a skilled nursing facility. | E.2 Patient assessment of enrollment in hospice, assessed 30- and 60-days post discharge. | E.2 No prior transitional care study reports the rate of hospice enrollment after SNF-home transfers. Data collected with this item will suggest hospice use in a severely ill sample of SNF patients. |
| E.3 To assess the patient's number of days in home health care 30 and 60 days after discharge from a skilled nursing facility. | E.3 Nurse and rehabilitation therapist assessment of number of days in home health care, assessed 30- and 60-days post discharge. | E.3 Data collected wit this measure will indicate the intensity of home care services in the post discharge period. These data will support a secondary analysis to determine the degree that outcomes of the Connect-Home intervention are mediated by the intensity of home health care use. |
| E.4 To assess the patient's number of hospital readmissions (acute or observational stays), 30 and 60 days after discharge from a skilled nursing facility. | E.4 Patient assessment of count of hospital readmissions, assessed 30- and 60-days post discharge. | E.4 All cause re-hospitalizations is the most widely used measure of transitional care interventions. These data will be collected to estimate the representativeness of the study sample and the generalizability of the study findings. |
| E.5 To assess the patient's number of emergency department visits without a | E.5 Patient assessment of the count of emergency department visits without a | E.5 ED use is a most widely used measure of transitional care interventions. These |

| OBJECTIVES | ENDPOINTS | JUSTIFICATION FOR ENDPOINTS |
|---|---|---|
| hospital stay 30 and 60 days after discharge from a skilled nursing facility. | hospital stay, assessed 30- and 60-days post discharge. | data will be collected to estimate the representativeness of the study sample and the generalizability of the study findings. |
| E.6 To assess caregiver-reported death of the patient 30 and 60 days after discharge from a skilled nursing facility. | E.6 Caregiver reported death of the patient, assessed 30- and 60-days post discharge. | E.6 Change in the rate of patient death is not an expected study outcome; however, these data will be used to describe the sample. |

# 4 STUDY DESIGN

## 4.1 OVERALL DESIGN

Connect-Home is a stepped-wedge cluster randomized trial (SW-CRT) to test the Connect-Home intervention against standard discharge planning (control), using both patients discharged to home (N=360) and their caregivers (N=360) in 6 SNFs.[44] In this design, SNFs will be randomly allocated to one of six sequences of time-periods defined by the month at which a SNF begins the control condition and, after a two-month staff training period, the time-period (or "step") that begins the Connect-Home protocol condition (Figure 2). [45] Thus, all SNFs will contribute data for both the Connect-Home intervention and standard care in a uni-directional crossover design at the cluster (SNF) level; a patient and their caregiver receives either standard discharge planning or Connect-Home consistent with the treatment condition of the SNF at the time of the patient's enrollment.

Randomization will be conducted for all sites simultaneously by a study statistician blinded to SNF identity. The randomized allocation sequence of the SNF will determine the beginning and end dates for three phases of patient and caregiver enrollment: (1) standard care, (2) the pre-implementation phase when staff are trained and neither patients nor caregivers are enrolled, and (3) the implementation phase when newly enrolled patients and their caregivers receive Connect-Home.

Patients and caregivers will be enrolled on a rolling basis at the rate of 4-5 dyads per month anytime during the control or intervention period. There will be three phases of patient and caregiver enrollment: (1) standard of care (indicated by blue boxes in Figure 2), (2) the pre-implementation phase when staff are trained and neither patients nor caregivers are enrolled (indicated by orange boxes in Figure 2), and (3) the implementation phase when newly enrolled patients and their caregivers receive the Connect-Home intervention (indicated by green boxes in Figure 2).

**Figure 2**. Stepped Wedge Design with treatment condition by month for 6 SNFs enrolling 4 patients and their caregivers per month (N= 360 patients and 360 caregivers)

| SNF | Period = 1 month | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
| 1 | 4 | 4 | 4 | 4 | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | | | | |
| 2 | | 4 | 4 | 4 | 4 | 4 | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | | | |
| 3 | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | | |
| 4 | | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | |
| 5 | | | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | |
| 6 | | | | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | | 4 | 4 | 4 | 4 | 4 |

The primary objectives will be assessed 7 days after discharge. The secondary and exploratory outcomes will be assessed 30 and 60 days after discharge.

## 4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

The study will utilize a SW-CRT, as it retains statistical power to evaluate efficacy of the intervention on the primary outcome in a relatively small number of SNFs. Observing SNF's under standard practice followed by the Connect-Home intervention is also consistent with the actual practice of implementing organizational change in SNFs and provides opportunities for evaluating implementation procedures. Cluster randomization at the nursing home level reduces risk of contamination between control and Connect-Home participants (Figure 2).

## 4.3 END OF STUDY DEFINITION

The end of study will be when the study team completes the final enrolled participant's 60-day assessments, and all data (including the final home health care chart reviews) have been collected from all study subjects. If a subject is withdrawn from the study due to an early termination caused by hospitalization, SNF re-admission and/or death; end of study for these patients will occur on day of early termination.

# 5 STUDY POPULATION

## 5.1 INCLUSION CRITERIA

Patients must satisfy all the following inclusion criteria prior to being enrolled:

1. English-speaking;
2. Have a Minimum Data Set 3.0, Section GG Mobility Assessment Score of 3 or less, indicating the patient requires at least 25-50% assistance for functional mobility;
3. Diagnosed with at least 1 serious medical illness (neurodegenerative dementia, cancer, chronic kidney disease, cirrhosis, congestive heart failure, chronic obstructive or interstitial lung disease, acute infection with sepsis, acute major motor stroke, acute coronary syndrome, acute hip fracture, diabetes with end organ complications, or intensive care for > 3 days while hospitalized);
4. Have a caregiver who can be enrolled in the study.

For patients with cognitive impairment, (defined as documented diagnosis of dementia and/or a Brief Interview for Mental Status score of ≤ 12 in Section C of the Minimum Data Set) additional criteria include:

1. Documentation in the medical record of a caregiver who is the patient's legally authorized representative;
2. Consent of the caregiver to participate in the study as the patient's representative.

Caregivers must satisfy all of the following inclusion criteria prior to being enrolled:

1. Must self-report assisting the patient at home;
2. English-speaking.

## 5.2 EXCLUSION CRITERIA

Patients will not be entered into Connect-Home if the criterion below is satisfied:

1. Planned hospital readmission for procedures or treatments within 90 days post enrollment.

Caregivers in the study have no noted exclusion criteria.

## 5.3 SCREEN FAILURES

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.

## 5.4 STRATEGIES FOR RECRUITMENT AND RETENTION

**Recruitment:**

The study team will obtain a limited waiver of HIPAA authorization to allow pre-screening for patient eligibility. The team will consult at least weekly with the Minimum Data Set Nurse, social worker, or other personnel involved in coordinating clinical care for newly admitted patients in each SNF by phone, email, or in-person to identify patients that are expected to be discharged from the SNF to home, and subsequently screen the medical records of all patients expected to discharge from the SNF to home.

After identifying potentially eligible patients, 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 patients with cognitive impairment, the team will recruit the patient's legally authorized representative to respond to survey questions as the patient's proxy.

Recruitment will be conducted in the SNFs through in-person interactions (or, when risk mitigation related to COVID-19 prevents in-person contact, we will recruit virtually, using an iPad and connection via ZOOM). If necessary, recruitment can also be conducted by telephone for caregivers. All participants will provide written informed consent (or, when risk mitigation related to COVID-19 prevents in-person contact, we will obtain consent verbally using an iPad and connection via ZOOM) for study participation. When written consent is not feasible, we will obtain witnessed verbal consent with the assistance of nursing home personnel via the iPad and Zoom connection). Legally authorized representatives will give consent for patients with cognitive impairment. Consent and HIPAA Authorization could also be obtained verbally in the situation that a participant is unable to physically sign these documents.

**Retention:**

During recruitment, study personnel will give the patient and caregiver a study flyer providing the study team's contact information, a schedule of planned follow-up calls, and information regarding compensation for completing data collection. When study personnel is unable to provide these study flyers directly to the patient, the study team will provide flyers to NH staff to announce the study and the possibility that a study team member will speak with potential study participants in-person or

virtually (using an iPad) about participating in the study. The study team will also mail reminder letters to patients and caregivers one week before 30 and 60-day data collection calls

The study team will also continuously monitor retention throughout the study. If retention falls below the anticipated rate, study personnel will further emphasize data collection in recruitment and will send additional written reminders to participants.

# 6 STUDY INTERVENTION

## 6.1 STUDY INTERVENTION(S) ADMINISTRATION

### 6.1.1 STUDY INTERVENTION DESCRIPTION

The Connect-Home intervention will introduce new organizational structure to support staff delivery of transitional care processes for seriously ill patients being discharged from the SNF to home.[27] New elements of organization structure in the Connect-Home intervention include:

- The "Transition Plan of Care Template" EHR tool, to be installed in the SNF EHR system prior to randomization. It contains domains that SNF staff and home visit RNs use to record and deliver the two-step Connect-Home intervention.[27]
- The "Connect-Home Toolkit", a bound workbook that contains a description of the EHR template and other EHR tools, the two-step Connect-Home intervention protocol, checklists and cue sheets, and the intervention schedule.[27]
- Site leadership training, where the Investigator trains 1-5 SNF project leaders on the Connect-Home protocol and study procedures.
- Executive sponsor and QI nurse monthly calls during intervention phase
- Monthly accountability calls with QI nurses and individual facilities to maintain accountability to protocol
- Staff Training, where the Investigator will train social workers, nurses, rehabilitation therapists, and the Connect-Home Activation RN on patient and caregiver key care needs, protocols for using the two-step intervention to address patient's key care needs, using the "Transition Plan of Care Template" EHR tool, advance care planning, and integrating SNF-based and home-based care.[27] The training will also include American Geriatrics Society recommendations for self-care at home in the context of the COVID-19 pandemic (when applicable).
- Focused training for the Connect-Home Activation RN, where the Investigator will train the Connect-Home activation RN on strategies for implementing transition plans of care, home safety screening, responding to medical needs, and handing off care to home health nurses.

After these elements of organizational structure are in place, the SNF staff will use the Connect-Home intervention care processes to deliver the 2-step transitional care intervention.[27] Further details are provided in Table 1.

- 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. Staff also will use American Geriatrics Society recommendations for self-care at home in the context of the COVID-19 pandemic (when applicable).

- In Step 2, the Connect-Home Activation RN (employed in the collaborating home health agency) 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. Nurses also will use American geriatrics Society recommendations for self-care at home in the context of the COVID-19 pandemic (when applicable).

**Table 1**. Connect-Home: Transitional Care Processes (Time estimates based on 20 day SNF stay)

| **Process** | Patient/Caregiver Services and Supports | **Day** |
|---|---|---|
| **Step 1.** Transitional care in the SNF[27] | **Set goals for home-based care** (**45 minutes**)<br>Consulting with the patient/caregiver, SNF staff use the EHR template to describe goals in the patient's Transition Plan of Care, targeting 6 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). Staff will use American Geriatrics Society recommendations for self-care at home in the context of the COVID-19 pandemic (when applicable).<br>• **Nurses** create goals for planned treatments at home, and responses to emerging symptoms or other health changes at home<br>• **Rehabilitation therapists** create goals for mobility, transfers and self-care at home.<br>• **Social worker** creates goals for caregiver support, follow-up care & discharge disposition. | 2 - 17 |
| | **Meet to plan the patient's transition to home-based care (30 minutes)**<br>In dialogue with the patient/caregiver, the treating nurse, social worker and therapists will develop a plan for home-based care, targeting 6 key care needs (home safety and level of assistance, advance care planning, symptom management, medication reconciliation, function and activity, and coordinator of care).<br>• **Nurses** focus on medications, elements of advance care planning and symptom management.<br>• **All staff** help the patient and caregiver describe their needs for continuing medical, supportive and rehabilitative care at home.<br>• **Social worker** reviews participation in Connect-Home, including the Transition Plan of Care and the Connect-Home Activation RN Visit. | 5 - 10 |

| | | |
|---|---|---|
| | **Prepare the patient and caregiver for home-based care (2.5 hours)**<br>1. Teach skills and plans for home-based care, targeting 6 key care needs (home safety and level of assistance, advance care planning, symptom management, medication reconciliation, function and activity, and coordinator of care). Staff will use American Geriatrics Society recommendations for self-care at home in the context of the COVID-19 pandemic (when applicable).<br>• **Nurses** teach symptom management (e.g., pain), clarify advance care planning preferences, and reconcile medication orders<br>• **Rehabilitation Therapists** teach skills for function, safety and continuing rehabilitation at home.<br>• **Social worker** schedules and explains appointments, home-based care & cost<br>2. Initiate hand-off to home-based care (over the last 1-2 days before discharge)<br>• **SNF staff** send medical records and copies of any advance care planning documents to the patient's physician and the Connect-Home Activation RN<br>• **Nurses**: 1) reconcile medications, 2) provide supplies and medications, and 3) re-teach the written Transition Plan of Care and medication list.<br>• **Social Worker** coordinates the hand-off of care to the Connect-Home Activation Nurse. | 6 - 20 |
| **Step 2.** Transitional care in the patient's home | **Implement the Transition Plan of Care at home (2 hours)**<br>**Connect-Home Activation Nurse** visits the patient and caregiver at home to:<br>• Reconcile medications on the discharge medication list and in the home,<br>• Reviews TPOC and adds materials for patient care as needed<br>• Help family implement new care routines, addressing 6 key care needs (home safety and level of assistance, advance care planning, symptom management, medication reconciliation, function and activity, and coordinator of care).<br>• Conduct a brief home safety & falls prevention screen, and<br>• Coordinate care and communicate the plan of care to follow-up clinicians and home health care nurses, and others as applicable. Nurses will use American Geriatrics Society recommendations for self-care at home in the context of the COVID-19 pandemic (when applicable). | 21 |

## 6.2 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

**Randomization**

Randomization will be conducted for all 6 sites simultaneously by a study statistician blinded to SNF identity. The randomized allocation sequence of the SNF will determine the beginning and end dates for three phases of patient and caregiver enrollment: (1) standard of care, (2) the pre-implementation phase when staff are trained and neither patients nor caregivers are enrolled, and (3) the implementation phase when newly enrolled patients and their caregivers receive the Connect-Home intervention.

**Blinding**

Professional data collectors from the Carolina Survey Research Lab (CSRL) will collect data from patients and caregivers at 7, 30, and 60 days post-discharge. These data collectors will be blinded to both the study hypothesis and to treatment group assignment.

## 6.3 STUDY INTERVENTION COMPLIANCE

The NIH Behavior Change Consortium's "Treatment Fidelity Protocols" will be used to ensure fidelity to the intervention.[46] Fidelity will be assessed in five domains as described below.

Design: The researchers will use standardized tools (e.g., Connect-Home Toolkit, the EHR template and staff training protocols) to deliver the intervention.

Training: To prevent contamination between SNFs during the intervention phase, the researcher will train staff in individual SNFs and Connect-Home Activation RNs in individual home health care offices. A detailed training protocol will be used, specifying the researcher roles, content, participants, and time required for training activities.

Delivery: A researcher will observe staff training activities on a random schedule to assess fidelity of the trainer to the staff training protocols. The research team will develop plans to address deviations from the training protocol. A Training Contact Database will be used, in which researchers will record staff participation in training activities. Staff members will be assigned identification numbers for tracking participation.

Receipt of Treatment: Researchers will administer post-tests to all participating staff after the staff training session; additional one-to-one re-training will be provided as needed for those who score

<100%. Researchers will also use return demonstration of home visit procedures with Connect-Home Activation RNs, followed by re-training as needed until nurses demonstrate a high level of ability.

Enactment of Skills: The study team will audit medical records for intervention patients to assess fidelity to the study protocol. Protocol elements to be assessed will include the following: a) completing the Transition Plan of Care; b) convening care plan meetings; c) reviewing advance directives in the SNF; d) scheduling follow-up medical appointments; e) transmitting records to follow-up clinicians; g) completing home visits within 24 hours after dis-charge; h) reconciling medications in the patient's home; i) completing the home safety evaluation; and j) communicating patient status to the on-coming home health nurse. As part of enactment monitoring, the Connect-Home Activation RN will keep a log describing medication discrepancies and the patients referred for a rehabilitation therapy after discharge home. Further, the researcher will host at least one 30-minute monthly meeting, during the intervention phase in each SNF, to relay feedback and discuss findings from fidelity monitoring with SNF staff and the Connect-Home Activation RN. Finally, a researcher will observe 10% of staff as they deliver Connect-Home and, using a standard checklist, the researcher will provide feedback about enactment of the Connect-Home protocols. If in-person observations are not possible (owing to risk mitigation related to COVID-19), we will monitor enactment fidelity via Zoom-based observations of care plan meetings and/ or day of discharge teaching sessions. SNFs failing to achieve 70% of operationalized fidelity steps will undergo re-training.

# 7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

## 7.1 DISCONTINUATION OF STUDY INTERVENTION

The study will adhere to 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
4. Other situations occur that might warrant stopping the trial

## 7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Subjects have the right to discontinue their participation in the Connect-Home study for any reason without penalty. The Investigator also may discontinue subjects from the study if he feels as if it is in the best interest of the subject, or if the subject is noncompliant.

Due to the inclusion criteria requiring patient and caregiver participation, if either the patient or the caregiver withdraws or is discontinued from the study, the other subject will automatically be withdrawn.

The study team will cease data collection for an individual as soon as the subject withdraws from the study. The study team will retain data collected while the subject was participating in the Connect-Home trial.

If a patient enrolled in the study does not transfer from the SNF to home (i.e., they die in the SNF or are transferred from the SNF to the hospital or to long-term care), their data will not be analyzed, and the patient and the caregiver will be withdrawn.

If a patient is discharged from the SNF to home, and then dies prior to all data being collected, the data that was collected prior to the subject's death will be retained and included in analysis. If a patient has a reported death after discharge, only the data collected prior to the date of death will be used for data collection.

If a patient is discharged from the SNF to home, and then has a hospitalization and/or re-admission to a SNF; the patient will be withdrawn from the study by research team as they are now non-compliant for data collection. The data that was collected prior to the event will be retained and included in analysis.

## 7.3 LOST TO FOLLOW-UP

After patient discharge from the SNF, study subjects will be considered lost to follow-up if 3 data collection phone calls have been made to the subject with no response.

# 8 STUDY ASSESSMENTS AND PROCEDURES

## 8.1 EFFICACY ASSESSMENTS

The procedures and assessments described in this section will be performed at the time point(s) described in the schedule of activities schedule in section 1.3.

All variables will be measured with chart reviews and/or interview-questionnaires with patients and caregivers. Data collection will be identical for intervention and control periods.

**Care Transitions Measure-15 (CTM-15)**[33]

Self-reported preparedness for discharge will be assessed using the CTM-15. It includes 15 questions on a 4-point scale, with a summary score ranging from 0-100. Higher scores are associated with less acute care use after discharge.

This measure will be assessed at 7 days post-discharge, through telephone interview with the patient (or with the patient's legally authorized representative, responding to survey questions as the patient's proxy in cases of patients with cognitive impairment).

**Preparedness for Caregiving Scale (PCS)**[35]

Self-reported preparedness for caregiving will be assessed using the PCS. It includes 8 questions on a 5-point Likert scale (0-4), with a range of 0-32. Higher scores are associated with less anxiety.

This measure will be assessed at 7 days post-discharge, through telephone interview with the caregiver.

**McGill Quality of Life Questionnaire - Revised (MQoL-R)**[37]

Quality of life across disease trajectories is measured using the MQoL-R. It includes 16 items on a 0-10 point Likert scale.

This measure will be assessed at 30 and 60 days post discharge, through telephone interview with the patient (or with the patient's legally authorized representative, responding to survey questions as the patient's proxy in cases of patients with cognitive impairment).

**Life Space Assessment**[38]

Patient function is measured using the Life Space Assessment. It includes 5 Likert scales that correspond to a hierarchy of levels of mobility (each scored 0-4). Weights are the product of the "Life-space Level" (range 1-5) and the "independence" score (range 1-2). Score ranges from 1-120, and lower scores are associated with falls and hospitalization.

This measure will be assessed at 30 and 60 days post discharge, through telephone interview with the patient (or with the patient's legally authorized representative, responding to survey questions as the patient's proxy in cases of patients with cognitive impairment).

**Zarit Caregiver Burden Scale**[41,42]

Caregiver burden is measured using the Zarit Caregiver Burden Scale. It includes 12 items on a 5-point scale. Scores range 0-48, and higher scores are associated with depression and social isolation.

This measure will be assessed at 30 and 60 days post-discharge, through telephone interview with the caregiver.

**Distress Thermometer**[28]

Caregiver distress is measured using the Distress Thermometer. It includes 1 item on an 11 point scale. Scores range 0-10, with scores >4 associated with poor coping and depression.

This measure will be assessed at 30 and 60 days post-discharge, through telephone interview with the caregiver.

**Number of Patient Falls with Injury and Without Injury**

This assessment is self-reported by the patient; falls are defined as an "unintentional change in position resulting in a resident coming to rest on the ground or lower level."

This measure will be assessed at 30 and 60 days post discharge, through telephone interview with the patient (or with the patient's legally authorized representative, responding to survey questions as the patient's proxy in cases of patients with cognitive impairment).

**MD Visit**

This assessment is self-reported by the patient; it is asked in a yes/no question format.

This measure will be assessed at 30 and 60 days post discharge, through telephone interview with the patient (or with the patient’s legally authorized representative, responding to survey questions as the patient’s proxy in cases of patients with cognitive impairment).

**Hospice Enrollment**

This assessment is self-reported by the patient; it is asked in a yes/no question format.

This measure will be assessed at 30 and 60 days post discharge, through telephone interview with the patient (or with the patient's legally authorized representative, responding to survey questions as the patient's proxy in cases of patients with cognitive impairment).

**Home Health Care Use**

This assessment is reported by the nurses and rehabilitation therapists of the patient, as a count of the number of days in home health care.

This measure will be assessed at 30 and 60 days post discharge, through telephone interview with the nurses or rehabilitation therapists.

**Hospital Readmissions**

This assessment is self-reported by the patient; it is a count of hospital readmissions, either acute or observational stays after SNF discharge.

This measure will be assessed at 30 and 60 days post discharge, through telephone interview with the patient (or with the patient's legally authorized representative, responding to survey questions as the patient's proxy in cases of patients with cognitive impairment).

**Emergency Department Use**

This assessment is self-reported by the patient; it is a count of emergency department visits without a hospital stay after SNF discharge.

This measure will be assessed at 30 and 60 days post discharge, through telephone interview with the patient (or with the patient's legally authorized representative, responding to survey questions as the patient's proxy in cases of patients with cognitive impairment).

**Death Report by Caregiver**

This assessment is self-reported by the caregiver regarding patient death after SNF discharge.

This measure will be assessed at 30 and 60 days post discharge, through telephone interview with the caregiver.

Co-variate assessments will be collected in-person and from the medical record. For some caregivers, co-variate data can be collected by phone. Co-variate data are as follows:

- Patient Data collected in person:
    - Study of Osteopathic Fractures Index [109], measuring frailty of the patient
    - ENRICHD Social Support Inventory [110], measuring social support of the patient
- Patient data collected with SNF chart abstraction:
    - Demographics
    - Health insurance status
    - Medical Information
    - Depression (Minimum Data Set section D) [94]
    - Function (Minimum Data Set section GG) [94]
    - Cognitive status (Minimum Data Set section C) [94, 111]
    - SNF care (i.e., SNF length of stay, urgent or acute treatment while in the SNF)
    - Discharge destination
    - Charlson Comorbidity Index scores [112] (calculated using the problem list in the medical record)
    - Yes or No that the SNF admission date was before the mandated pause in research activities (related to the COVID-19 pandemic)
    - History of COVID-19 diagnosis and treatment in the index hospitalization and/or in the SNF
- Caregiver data collected in-person or by phone:
    - Demographics
    - Relationship to patient
    - Employment
    - Count of days per week providing patient care
    - History of COVID-19 diagnosis and treatment

## 8.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

### 8.2.1 DEFINITION OF ADVERSE EVENTS (AE)

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms.

### 8.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event is serious when the outcome for the subject is:

- Death;
- Life- threatening (place the subject at immediate risk of death from the event as it occurred);
- Inpatient hospitalization or prolongation of existing hospitalization;
- Persistent or significant disability/incapacity;
- congenital anomaly/birth defect; or

when the event does not fit the other outcomes but, based upon appropriate medical judgement, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes.

### 8.2.3 CLASSIFICATION OF AN ADVERSE EVENT

There will be no classification of adverse events for this minimal-risk study.

#### 8.2.3.1 SEVERITY OF EVENT

The severity of all AEs will be characterized as "mild, moderate, or severe" according to the following definitions:

| | |
|---|---|
| Mild | An event that does not have an impact on the patient |
| Moderate | An event that causes the patient some minor inconvenience |
| Severe | An event that causes substantial disruption to the patient's well-being. |
| Potentially Life-Threatening | An event that places the subject at immediate risk of death |
| Death | An event resulting in death |

#### 8.2.3.2 RELATIONSHIP TO STUDY INTERVENTION

All AE's will be categorized according to the likelihood that they are related to the study intervention, using the following terms:

- Unrelated to study intervention
- Possibly related to study intervention
- Probably related to study intervention

or

- Definitely related to study intervention

### 8.2.3 EXPECTEDNESS

Due to the severity of illness present in the study population, unrelated, adverse events are expected to happen during this study that result in worsening of existing medical conditions, hospitalizations, life-threatening events and/or death. All adverse events will be documented and reported to the DSM and reported on a yearly basis.

### 8.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

Given that no adverse events are expected related to this minimal risk intervention, adverse events will be documented and assessed as they occur and will be followed until resolution.

### 8.2.5 ADVERSE EVENT REPORTING

Adverse events must be promptly documented and recorded. All adverse events observed or reported must be recorded, regardless of causality and/or clinical significance.

### 8.2.6 SERIOUS ADVERSE EVENT REPORTING

Unexpected and/or intervention-related serious adverse events will be reported by the principal investigator within 24 hours to the independent monitor. A report will also be sent to the University of North Carolina IRB and the NIH in accordance with requirements.

Anticipated or unrelated serious adverse events will be reported by the principal investigator within one week to the independent monitor. A report will also be sent to the University of North Carolina IRB and the NIH in accordance with requirements on an annual basis.

## 8.3 UNANTICIPATED PROBLEMS

### 8.3.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

An Unanticipated Problem (UP) is any incident, experience, or outcome that:

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB -approved research protocol and informed consent document; an(b) the characteristic of the participant population being studied;
- Is related or possibly related to a participant's participation in the research; and
- Is serious or suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) that was previously known or recognized.

### 8.3.2 UNANTICIPATED PROBLEM REPORTING

All unanticipated problems must be reported to the IRB within 7 calendar days of the event.

# 9 STATISTICAL CONSIDERATIONS

## 9.1 STATISTICAL HYPOTHESES

Specific aims of this research study include:

1. Evaluate the efficacy of Connect-Home to improve SNF patient and caregiver preparedness for care at home.
    a. Hypothesis 1a: Compared to patients enrolled in control periods, Connect-Home patients will experience greater preparedness for discharge (primary outcome, measured with the CTM-15), assessed 7 days after discharge home
    b. Hypothesis 1b: Compared to caregivers of patients enrolled in control periods, Connect-Home caregivers will experience greater preparedness for caregiving (primary outcome, measured with the Preparedness for Caregiving Scale), assessed 7 days after discharge home.
2. Evaluate the efficacy of Connect-Home to improve SNF patient and caregiver outcomes after discharge home.
    a. Hypothesis 2a: Compared to patients enrolled in control periods, Connect-Home patients will experience better quality of life and function (secondary outcomes), and fewer falls requiring medical assistance (exploratory), measured 30 and 60 days after discharge home
    b. Hypothesis 2b: Compared to caregivers from control periods, Connect-Home caregivers will experience less burden and caregiver distress (secondary outcomes), measured 30 and 60 days after discharge home
3. Evaluate the efficacy of Connect-Home to prevent acute care use up to 60 days after SNF discharge.
    a. Hypothesis 3a: Compared to patients enrolled in control periods, Connect-Home patients will have fewer days of acute care use (composite of emergency department and hospital use) (secondary outcome) and more hospice enrollment (exploratory), measured 30 and 60 days after discharge home

## 9.2 SAMPLE SIZE DETERMINATION

Computer simulations were used to calculate statistical power for comparing control (standard discharge procedures) and intervention (Connect-Home) conditions for primary outcomes and selected secondary outcomes. For each scenario, 1000 simulated datasets were generated with outcomes clustered within SNFs for the stepped-wedge design in Figure 2 and the respective linear mixed models (Log CTM-15, Preparedness for Caregiving Scale, MQoL-R, Life Space Assessment, Zarit Caregiver Burden scale) and MZIP random intercept model (Days of acute care use). Based on preliminary data for Aim 1, we assumed that the group difference in log CTM-15 scores was $\theta$=0.15. We also assumed that responses from patients within the same SNF in the same period would have an intra-cluster correlation of 0.10 ($ICC_W$). We assumed that responses from patients or caregivers in the same site but from different periods would have an intra-cluster correlation of 0.05 ($ICC_B$); together with the total variance of the outcome ($SD^2$), these values determine and in the linear mixed models of Aims 1 and 2. Under these assumptions and accounting for 23% dropouts, 277 patients at 7 days post-discharge will provide 89% power to detect an increase of 0.15 in the mean log CTM-15 score (equivalent to a 16% increase in

the mean CTM-15 score) among intervention patients relative to control patients, using a two-sided test at the 5% significance level. Power for Caregiver Preparedness is similarly determined. Power for secondary outcomes at 30 days post-discharge assumes a 30% dropout rate. For the control group in Aim 3, we assumed a prevalence of 22% of patients having at least one day of acute care use and, among those patients, a truncated-at-zero mean of 4.0 days. These assumptions imply that the overall mean number of acute care use days is 0.881 and the excess zero probability is 0.776. For the intervention group, we assumed an overall mean acute care use days of 1.8 and excess zero probability 0.685. Thus, assuming 30% dropout and (optimistically) zero intraclass correlation within SNFs, the MZIP model for independent outcomes has 82% power (not shown); however, the MZIP model with empirical standard errors adjusting for possible clustering within SNFs has 71% power. If there is positive intraclass correlation, power will be lower. However, for days of acute-care use within 60 days of discharge, power is higher than for 30 days due to higher prevalence and mean number of days of acute care use.

## 9.3 POPULATIONS FOR ANALYSES

An intent to treat analysis will be used in which all patients/caregivers are included in the analysis according to their treatment allocation at enrollment, regardless of whether they receive the full intervention.

## 9.4 STATISTICAL ANALYSES

### 9.4.1 GENERAL APPROACH

Descriptive statistics will be used for all variables. If patients or caregivers with missing covariates are few (< 5%), unconditional mean imputations will be used to impute missing values for continuous covariates and unconditional mode imputation for categorical covariates. If 5%-15% of patients or caregivers have missing covariates, conditional mean imputation will be used. If missing covariate data exceed 15%, multiple imputation will be used. Missing outcomes will not be imputed. For continuous variables that are highly skewed, the statistical team will log-transform the data for analysis. All statistical tests will be two-tailed with 0.05 significance levels. Also, descriptive statistics will be used to describe intervention fidelity (receipt, delivery and enactment). Finally, in the absence of strong temporal effects, balance in covariates is expected between control and intervention patients; supplemental analyses will involve assessing the impact of the covariates (i.e., insurance provider, SNF length of stay, race, gender, and others determined with bivariate analyses) on outcomes in the statistical models for aims 1-3.

Finally, to determine the extent the intervention effect can be attributed to home health care use, a general multilevel approach will be used to causal mediation analysis to evaluate home health care use as a mediator for intervention effect on outcomes as a secondary analysis. This approach uses two

random effects models within the counterfactual framework: 1) for the mediator (number of days of home health care use) as a function of treatment condition and covariates and 2) for the outcome as a function of treatment condition, mediator, and covariates. Outputs include indirect and direct effects of the intervention.

### 9.4.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

In the models for patient preparedness for discharge (CTM-15 score), data will be included that was provided by the patient or by caregiver (for patients that are not able to answer survey questions). We will use hierarchical linear models (HLM) to compare observations between intervention and usual care periods for CTM-15 score at seven days post-discharge. Linear mixed models or HLM allow for different numbers of patients per site, while accounting for correlated responses between patients within the same SNF. Let $Y_{ijk}$ denote the CTM-15 score for patient k in SNF i and period (enrollment month) j; (i = 1, 6; j = 1, …, 22). The basic HLM is, where is an intercept term, is a random effect for SNF, accounts for a potential linear temporal trend,  is a random effect for period j nested within SNF i, is an indicator for the treatment condition (i.e., 1 if Connect-Home; 0 is standard discharge procedures), θ is the treatment effect, and  is an error term. Furthermore, we assume a variance components structure such that all random effects are independent with, and where subscripts “c”, “p” and “e” denote cluster (i.e., SNF), period and error variance components, respectively. The correlation structure induced by these random effects allows the within-SNF correlation of outcomes from two patients enrolled in the same month ($ICC_W$) to be different from the within-SNF correlation of outcomes from patients enrolled in different months ($ICC_B$). Specifically, by denoting the total variance, the intraclass correlations are $ICC_W$ =, and $ICC_B$ =.  For CTM-15, the basic HLM model will be amended by including additional explanatory variables as fixed effects: CTM-15 score source (patient or caregiver), patient age, gender and race. Due to skewness of the CTM-15 score distribution found in our preliminary data, we expect this outcome will be log-transformed prior to analysis. The group difference in log CTM-15 scores (intervention vs. control) across the study periods will be estimated along with a 95% confidence interval. A sensitivity analysis will be conducted to assess whether the effect of Connect-Home depends on the number of months that an SNF has been operating under the Connect-Home protocol. This is achieved by extending the HLM so that separate effects of Connect-Home are estimated when the Connect-Home protocol has been implemented for ≤ 3 months versus > 3 months in order to examine whether the impact of Connect-Home is sustained three months following its initial implementation in the staff training period. A similar linear mixed model will be applied for the Preparedness for Caregiving outcome, except that respondent source is not included.

### 9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

In Aim 2, linear mixed models will be used that are extensions of those in the Aim 1 analysis for the analysis of quality of life (MQoL-R), patient function (Life Space Assessment), patient falls (exploratory outcome), caregiver burden (Zarit scale) and distress (Distress Thermometer). The statistical team will augment the basic HLM in the Aim 1 analysis with a random effect for patients and additional fixed effects for visit and treatment by visit interactions to model the day 30 and 60 outcomes simultaneously

as repeated measures. A statistically significant visit by treatment condition interaction would indicate that the impact of Connect-Home varies according to elapsed days since discharge. Because the main interest is in day 30 and 60 outcomes, differential treatment effects will be examined at these two time points and, if differences exist, estimate the effect of the Connect-Home intervention and its 95% confidence at each time point. In hypothesis 2b, separate Poisson mixed models will be used with log link for each post-discharge time point in the assessment of the intervention effect on falls with a similar structure for fixed and random effects as described in the Aim 1 analysis. Therefore, instead of modeling the repeated outcomes as the number of falls between day 0-30 and between days 31-60, respectively, the statistical team will separately model the cumulative number of falls by day 30 and 60, respectively, to assess whether the Connect-Home intervention reduces the cumulative fall rates post-discharge at these two time points. We will estimate the incident rate ratio and its 95% confidence interval.

The main outcome for Aim 2.3, the number of cumulative days of acute care use, (i.e., days due to re-hospitalizations and emergency department visits), will be modeled using separate marginalized zero-inflated Poisson (MZIP) models with log link. The statistical team will test and estimate the overall effect of Connect-Home relative to standard discharge procedures through exponentiation of the treatment regression coefficient for the overall mean as an incidence rate ratio (IRR) and its 95% confidence interval, basing these on empirical standard errors to allow for possible intraclass correlation within SNFs. MZIP was chosen over the standard ZIP model because although a large number of zero counts (event outcomes) are anticipated, the overall exposure effect of Connect-Home is of interest, and not its effect on an unobserved subpopulation (i.e., latent class). Separate time point-specific generalized linear mixed models (GLMM) with logit link will be used for the binary outcome of whether a resident visited the ED within 30 or 60 days of discharge, respectively, from the SNF. This model type is an extension of ordinary logistic regression that includes random intercepts and period effects for SNFs to account for the within SNF correlation induced by the stepped-wedge design. A similar GLMM will be applied to compare the proportion of hospice referrals between standard discharge procedures and Connect-Home. When events are sparse, SNFs will be treated as fixed effects to mitigate model non-convergence problems.

### 9.4.4 BASELINE DESCRIPTIVE STATISTICS

Co-variate data will be collected about patients in person and from the medical record. Data about caregivers will be collected in person or by phone.
Patient data collected in person:

- Frailty (Study of Osteopathic Fractures Index)[47]
- Social support (ENRICHD Social Support Inventory)[48]

Patient data collected with SNF chart abstraction:

- Demographics
- Health insurance status (Medicare Advantage/Medicare fee-for-service/Medicaid/private)

- Living arrangements before index hospitalization
- Medical history (primary diagnosis in the hospital discharge summary, hospital care (critical care, surgery and length of stay)
- Depression (Minimum Data Set section D)[49]
- Function (Minimum Data Set section GG)[49]
- Cognitive status (Minimum Data Set section C)[49]
- SNF care (i.e., SNF length of stay, urgent or acute treatment while in the SNF)[49]
- Discharge destination

Using the problem list in the medical record, the Charlson Comorbidity Index scores will be calculated for each patient.[50]

Patient data collected with Home Health Care chart abstraction:

- Number of days of home health care use in 30 and 60 days after SNF discharge[40]

Caregiver data collected in person or by phone:

- Demographics
- Relationship to patient
- Living arrangements
- Employment
- Count of days per week providing patient care.

# 10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

## 10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

### 10.1.1 INFORMED CONSENT PROCESS

The informed consent process will be held with consideration to the patients' privacy. The consent discussion will be led by study personnel delegated to conduct the consent process. The study subjects will have the opportunity to read through the consent form, while study personnel will explain the consent form to the subject. The study subject will have the opportunity to ask any questions they may have regarding the consent before signing. A copy of the consent will be given to the patient for their records, and the consent process will be documented in each study subject's file.

Consent could also be obtained verbally in the situation that a participant is unable to physically sign these documents or if risk mitigation procedures, related to the COVID-19 pandemic in the nursing homes, require that virtual contact (with an iPAD via Zoom) is needed. When this occurs, the study team will document in study records that the full consent form was read to the subject and/or LAR as well as any notes of the consent conversation.

For the caregivers in this study, informed consent will be obtained through an IRB approved verbal consent script. The study team will take the same considerations for consent in these instances as they do for patient written consent and will document the caregivers' responses.

In cases where the subject has a cognitive impairment, the subject's legally authorized representative will be involved in the consent process in place of the patient. The same procedure as detailed above will be followed by study personnel.

#### 10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

The study team will provide a copy of the signed consent form to all participants who consent to the study. For cases where virtual consent is necessary, copies of blank consent forms will be provided to staff in the nursing homes so that they can be provided to the participants.

#### 10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

The study team will document the informed consent process on a paper form.

### 10.1.2 STUDY DISCONTINUATION AND CLOSURE

The study team will retain all study files for the duration of time that is required by the UNC IRB and/or the NIH. When the required time for retaining the identifiable data expires, all files with identifiers will be destroyed.

### 10.1.3 CONFIDENTIALITY AND PRIVACY

The study team will use multiple procedures to protect confidentiality, including:

- Using study codes on data documents;
- Keeping a separate document that links the study code to subjects' identifying information locked in a separate location, to be stored on password-protected, encrypted computers;
- De-identification of data to remove the possibility that data could be connected to individuals that consented to participate in the study;
- Encrypting identifiable data;
- 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.

### 10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

No identifiable data will be shared beyond the study team nor used in future studies.

### 10.1.5 SAFETY OVERSIGHT

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.

Study progress and safety will be reviewed monthly (and more frequently if needed). Progress reports, including patient recruitment, retention/attrition, and AEs will be updated regularly and distributed to the committees on a frequent schedule laid out in the Data Safety and Monitoring Plan. An annual report will be compiled and will include a list and summary of AEs. In addition, the annual report will address (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. The annual report will be signed by the independent monitor and will be forwarded to the IRB and NIH. The IRB will review progress of this study on an annual basis.

### 10.1.6 CLINICAL MONITORING

The Independent Monitor for this study is Dr. Linda Beeber, Professor of Nursing at the University of North Carolina; she is an expert in clinical trials research with a long history of NIH funded research. Dr. Beeber is not associated with this research project, and she is qualified to review the patient safety data generated by this study because of her unique expertise in the area of clinical trials research.

### 10.1.7 QUALITY ASSURANCE AND QUALITY CONTROL

The study team will review all data collection forms on an ongoing basis for data completeness and accuracy as well as protocol compliance. A statement reflecting the results of the review will be sent to the NIH in the annual report (non-competing continuation).

### 10.1.8 DATA HANDLING AND RECORD KEEPING

#### 10.1.8.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

All data collected by the study team will be kept in strict confidence, and all data will only be identified using an identification code unique to the subject.

The database used to manage the data will be secured with password protection, and it will only be available to members of the study team. This database only includes 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. 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

#### 10.1.8.2 STUDY RECORDS RETENTION

Study records will be retained per NIH guidelines.

### 10.1.9 PROTOCOL DEVIATIONS

All protocol deviations will be promptly reported to the principal investigator and logged on a protocol deviation log. All deviations that are classified as unanticipated problems will be reported to the IRB within 7 days of the event.

### 10.1.10 PUBLICATION AND DATA SHARING POLICY

No identifying data will be shared for this study. All results will be shared as de-identified and aggregated data.

Publications arising from the study will not contain personal information.

### 10.1.11 CONFLICT OF INTEREST POLICY

The University of North Carolina at Chapel Hill's Policy on Conflicts of Interest and Commitment includes a rebuttable presumption that an investigator may not conduct human subjects' research that is related to a financial interest of the investigator (or immediate family) except in compelling circumstances. Compelling circumstances are those facts that convince the reviewer that a covered individual who has a financial interest should be permitted to conduct human subjects' research, taking into account the following factors:

- The nature of the research,
- The nature and magnitude of the financial interest
- How closely the financial interest is related to the research
- The extent to which the interest may be affected by the research
- The degree of risk to the human subjects involved that is inherent in the research protocol
- The extent to which the investigator is uniquely qualified to perform a research study with important public benefit
- The extent to which the interest is amenable to effective oversight and management.

The applicable UNC-Chapel Hill COI Chair and/or Committee takes into these criteria into account when reviewing any disclosed conflict of interest in the context of the human study.

- The COI Chair or Committee considers the following factors into their review: How the research is supported or financed,
- The nature and extent of the conflict,
- The role and responsibilities of the conflicted individual in the design, conduct, and reporting of the research, and
- The ability of the conflicted individual to influence the outcome of the research.

The IRB has final authority to determine whether the research, the COI, and the related management plan, if any, allow the research to be approved.

## 10.2 ABBREVIATIONS

| | |
|---|---|
| AE | Adverse Event |
| ANCOVA | Analysis of Covariance |
| CFR | Code of Federal Regulations |
| CLIA | Clinical Laboratory Improvement Amendments |
| CMP | Clinical Monitoring Plan |
| COC | Certificate of Confidentiality |
| CONSORT | Consolidated Standards of Reporting Trials |
| CRF | Case Report Form |
| CTM-15 | Care Transitions Measure-15 |
| DCC | Data Coordinating Center |
| DHHS | Department of Health and Human Services |
| DSMB | Data Safety Monitoring Board |
| DRE | Disease-Related Event |
| EC | Ethics Committee |
| EHR | Electronic Health Record |
| eCRF | Electronic Case Report Forms |
| FDA | Food and Drug Administration |
| FDAAA | Food and Drug Administration Amendments Act of 2007 |
| FFR | Federal Financial Report |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practices |
| GMP | Good Manufacturing Practices |
| GWAS | Genome-Wide Association Studies |
| HIPAA | Health Insurance Portability and Accountability Act |
| IB | Investigator's Brochure |
| ICH | International Conference on Harmonisation |
| ICMJE | International Committee of Medical Journal Editors |
| IDE | Investigational Device Exemption |
| IND | Investigational New Drug Application |
| IRB | Institutional Review Board |
| ISM | Independent Safety Monitor |
| ISO | International Organization for Standardization |
| ITT | Intention-To-Treat |
| LSMEANS | Least-squares Means |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MOP | Manual of Procedures |
| MQoL-R | McGill Quality of Life Questionnaire-Revised |
| MSDS | Material Safety Data Sheet |

| | |
|---|---|
| NCT | National Clinical Trial |
| NIH | National Institutes of Health |
| NIH IC | NIH Institute or Center |
| OHRP | Office for Human Research Protections |
| PCS | Preparedness for Caregiving Scale |
| PI | Principal Investigator |
| QA | Quality Assurance |
| QC | Quality Control |
| RN | Registered Nurse |
| SAE | Serious Adverse Event |
| SAP | Statistical Analysis Plan |
| SMC | Safety Monitoring Committee |
| SNF | Skilled Nursing Facility |
| SOA | Schedule of Activities |
| SOC | System Organ Class |
| SOP | Standard Operating Procedure |
| SW-CRT | Stepped-Wedge Cluster-Randomized Trial |
| UP | Unanticipated Problem |
| US | United States |

## 10.3 PROTOCOL AMENDMENT HISTORY

| **Version** | **Date** | **Description of Change** | **Brief Rationale** |
|---|---|---|---|
| 2.0 | 2020Jul02 | Addition of virtual recruitment methods due to COVID-19 risk mitigation procedures | Because in-person interactions will not be possible during COVID-19 risk mitigation periods, virtual recruitment and study retention methods needed to be initiated within this study protocol. |
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