	2.5 To assess caregiver distress 30 and 60 days after discharge from a skilled nursing facility.
Endpoints:	Primary Endpoint: 1.1 The Care Transitions Measure-15 (CTM-15),[26] assessed at seven days post discharge. 1.2 The Preparedness for Caregiving Scale (PCS),[29] assessed at seven days post discharge. Secondary Endpoints: 2.1 The McGill Quality of Life Questionnaire-Revised (MQoL-R), [85] assessed at 30- and 60-days post discharge. 2.2 The Life Space Assessmen[86], assessed at 30- and 60-days post discharge. 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] 2.4 The Zarit Caregiver Burden Scale[88], assessed at 30- and 60-days post discharge. 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. 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. 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

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

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

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.

<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.

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).

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.

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)

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.

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.

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

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

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

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.

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.

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 θ=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

- 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.

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