

1. **Protocol title** – Outcomes of Nursing Management Practice in Nursing Homes

(Short title: CONNECT-Community)

2. **Purpose of the study** – objectives & hypotheses to be tested

The **specific aims** of this longitudinal, two arm, randomized intervention study are:

Aim 1: In nursing homes, compare the impact of the CONNECT intervention **plus** a falls reduction QI intervention (CONNECT+FALLS) to the falls reduction QI intervention alone (FALLS) on fall risk factor reduction indicators (orthostatic blood pressure, sensory impairment, footwear appropriateness, gait, physical therapy, toileting, environmental modifications, vitamin D, and psychotropic medication reduction).

Aim 2: In nursing homes, compare the impact of CONNECT+FALLS to FALLS alone on fall rates and injurious falls and determine whether these are mediated by the change in fall risk factor reduction indicators.

Aim 3 (exploratory): Compare the impact of CONNECT+FALLS to FALLS alone on complexity science measures (communication, NA participation in decision making, local interaction strategies, safety climate, and staff perceptions of quality) and determine whether these mediate the impact on fall risk factor reduction indicators, fall rates, and injurious falls.

Purpose of Minority Supplement Research:

The purpose of the minority supplement is to support investigator Michael Cary, RN, PhD to address these crucial knowledge gaps by a) conducting a pilot of functional measures to examine the trajectories of function over a 30-day period in a cohort of short-stay patients receiving post-acute care in nursing homes and prospectively record occurrence of falls, recurrent falls, and injurious falls and b) describing system-level management practices that selected facilities use to ensure safety and reduce falls and fall risk among short stay patients. Addressing both patient level and system level factors will allow for development of more robust interventions.

3. **Background & significance** –

Although several clinical trials have identified interventions that reduce adverse outcomes such as falls in nursing home (NURSING HOME) residents, attempts to translate those interventions into practice using widely accepted quality improvement (QI) techniques^{1,2} have not led to expected improvements.^{3,4} Problems encountered in previous studies of translating knowledge into routine practice in nursing homes point directly to the need for effective nursing management practices (NMPs).^{1,3,5} Many studies now show that relationship-oriented NMPs such as open communication, participation in decision-making, teamwork, and leadership result in better resident outcomes.⁵⁻¹⁰ Our recent multiple case-study described how NMPs actually work in day-to-day work, and identified new NMPs associated with better nursing home care. We found that staff at all levels engaged in these NMPs, suggesting that nursing homes have substantial untapped capacity to provide better resident care.¹¹⁻¹⁵ However, not all nursing home staff engaged in these “capacity building” NMPs, nor were they practiced routinely. This suggests the need for an intervention that fosters systematic use of capacity-building NMPs. In particular, systematic use of these NMPs may provide the foundation for more effective QI programs in nursing homes.

QI programs are the standard for translating evidence-based care into practice for common and costly conditions such as falls, pressure ulcers, pain, and depression. Such geriatric syndromes, of which falls is a prototype, are inherently multi-factorial, requiring modification of multiple risk factors to improve outcomes.^{16,17} Trials using study staff to implement multiple risk factor reduction have shown improvements in resident outcomes.¹⁸⁻²⁰ Unfortunately, studies encouraging existing nursing home staff to implement multiple risk factor reduction through standard QI techniques have not shown significant effects.^{1,21-24} One proposed reason for this failure is that QI programs seek to change individual clinician behavior or modify nursing home routines, but fail to account for the interactive dynamics of care. Supporting this theory, fall risk factor reduction tasks that require coordination between multiple team members are the least likely to be implemented.²¹ We propose that CONNECT, an intervention to foster systematic use of capacity-building NMPs, will enhance the effectiveness of a Falls QI program in nursing homes by strengthening the one-on-one staff interactions that are necessary for clinical problem-solving about geriatric syndromes.

We have developed the CONNECT intervention based on complexity science and empirical research²⁵ to target these local interactions among staff in a new approach to facilitating organizational learning. CONNECT is a multi-component intervention that includes: 1) helping staff identify important relationships and then encouraging interaction at the point of care; 2) teaching new strategies to improve the effectiveness of day-to-day staff interactions; and 3) mentoring to reinforce and sustain newly acquired interaction behaviors. Complexity science and empirical research suggest that interaction patterns determine information flow, ease of

knowledge transfer, and capacity to monitor behaviors and outcomes in health care settings.^{10, 26-28} Thus, the CONNECT intervention has the potential to improve resident outcomes when combined with QI programs for clinical problems such as falls.

Rationale for the Supplement Research: In the parent study, we aim to change practice and encourage staff to use evidence-based interventions to reduce falls and fall risk. However, the evidence is from studies conducted mainly on long-stay resident populations. We know little about short-stay (defined by CMS as having a length of stay <= 100 days) post-acute patients at risk for falling or whether we need additional prevention processes for them; this is an area of significance given the growing short stay population in nursing homes. Because of their shorter lengths of stay, we will have little data about them from our abstraction processes in the parent study. Our evidence-based fall reduction processes in the QI program focus on direct care but we know little about what and how system-level management practices (e.g., falls teams, quality improvement programs, and post-fall huddles) might also facilitate safety among short stay patients, concerning falls and fall prevention. Thus, the purpose of the minority supplement is to support investigator Michael Cary, RN, PhD to address these crucial knowledge gaps

4. Design & procedures –I

This 5-year study will use a prospective, cluster-randomized, outcome assessment blinded design, with nursing homes (n=16) randomized to either CONNECT+FALLS or FALLS alone. Due to one site’s withdrawal during the final year, an effort will be made to maintain random assignment to the intervention, and two potential sites will be added for recruitment. Two willing sites will be randomized to receive either “CONNECT+FALLS,” or “non-participating” status. The “non-participating” site will be offered an abbreviated delivery of the CONNECT Program to the site as a benefit to going through the randomization process, and no data will be collected from the site. This approach allows recruitment of an active CONNECT+FALLS study site without introducing bias and design limitations associated with breaking random assignment to the tested intervention. We estimate that 560 residents and 576 staff members will participate. These 16 nursing homes will be in addition to the 4 facilities already enrolled. Measurements of staff interaction and residents’ fall-related outcomes will be taken at baseline, post intervention, 3 and 6 months. Facility fall rates and the proportion of recurrent fallers are the primary study outcomes. Exploratory measures include fall-related process measures and staff interaction measures (safety climate, and staff perceptions of quality communication; participation, local interaction strategies, and safety culture). To better understand how to facilitate the sustainability of the CONNECT protocols within participating nursing homes and to disseminate CONNECT to a wider nursing home audience, we will conduct focus groups (see attached focus group protocol) with one group of administrators/department heads/or managers and one group of front line staff. Analysis will use a 3-level mixed model to account for the complex nesting of patients and staff within homes, and control for covariates associated with fall risk, including baseline facility fall rates.

The study interventions include CONNECT and FALLS. CONNECT will be implemented over 12 weeks followed by FALLS. CONNECT protocols (detailed in Table 5.4.1.2) are designed to help participants learn new strategies to facilitate and sustain thoughtful local interactions that increase exchange of new information, increase the number and quality of connections among people, and increase cognitive diversity for better problem-solving. The FALLS intervention (detailed in Table 5.4.2.2) simulates real-world QI processes that are currently employed by community nursing homes and thus represents the standard of care practices. Thus this study compares CONNECT and FALLS to standard practice alone (ie. FALLS alone). (See appendix 2 and 3 for full detail on intervention protocols).

Table 5.4.1.2. CONNECT Protocol Activities, Rationale, Who is Involved and Time Required

CONNECT Protocols	Rationale/Outcome	Who	Time
Relationship Map Protocols			
(1) Group-to-group maps <u>Session 1.</u> Researcher assists staff to describe actual interactions between work groups (e.g., NAs, LPNs, SW, Dietary, etc.). Between session 1 and 2, staff then reflect on how to improve these interactions. <u>Session 2.</u> Researcher assists staff to depict new interaction patterns that will become the goal for improved group-to-group interaction patterns.	Assists staff to make interaction patterns explicit (develop a group-to-group relationship map) and agree on goals for change.	Mid-level managers, e.g., directors of nursing, social work, dietary	1, 1-hr class; 1, 70 min class occurring 1 week apart (2 hrs, 10 mins total)
(2) Individual-to-individual maps <u>Session 1.</u> Researcher reviews the “ideal” group-to-group maps and assists individual staff to develop “relationship maps” that define their ideal individual-to-individual local interaction patterns with other	Assists staff to develop individual-to-individual relationship maps and agree on interaction	Floor staff (RNs, LPNs, NAs) and selected mid-	1, 30 min session (30 min total)

specific staff members. Participants will learn to self-monitor their local interactions using the relationship maps (available on a laminated card) and paper/pencil recording sheets.	patterns. Self-monitoring reinforces and sustains newly acquired behaviors and provides a measure of adherence and behavior change.	level managers and administrators.	
Learning Protocols			
(1) Interdisciplinary In-Class Learning Protocols			
<u>Session 1.</u> Introduces local interaction strategies using storytelling. Participants practice associated behaviors using role-playing in the context of falls prevention.	Interdisciplinary learning facilitates skill acquisition, creation of new horizontal and vertical connections among staff, and enhances learning through cognitive diversity.	RNs, LPNs, NAs, social work, activities, rehab, MD, NP; dietary, administration	2, 30 min sessions occurring 2 weeks apart (1.0 hrs total)
<u>Session 2.</u> Brief review followed by focus on the more advanced strategies of cognitive diversity using storytelling and role-playing, with discussion of participants' experiences in applying the concepts.			
(2) Co-Facilitator Protocols			
<u>Co-Facilitator Training.</u> Uses storytelling and role playing to increase self-efficacy in practicing and communicating about local interaction behaviors. Co-facilitators will learn strategies for co-facilitating interdisciplinary in-class learning sessions and practice strategies such as mentoring and problem-solving at the point of care to improve local interactions.	Prepares in-house clinical and supervisory staff to build trust and maintain consistency of CONNECT with the local culture. Facilitates information exchange between nursing home staff and research staff. Co-Facilitator develops self-efficacy in using existing time (chance encounters) to model local interaction and mentor staff in same behaviors.	Supervisory or clinical professionals in nursing, social work, activities, or other department. Selected because they have supervisory role and access to large numbers of staff.	1, 1 hr learning session; Up to 1 hr of shadowing during regular work activities; 5, 10 min discussions (up to 2 hrs, 50 min total)
<u>Chance Encounter Mentoring Training.</u> Researcher shadows the co-facilitator during the work day to identify mentoring opportunities and model "chance encounter mentoring" behaviors; observes and advises the co-facilitator as he or she practices the behaviors; and to jointly problem solves. (1 session of about 1 hour)			
<u>Phone Support by research facilitators.</u> The researcher will contact co-facilitators weekly for support and advising; co-facilitators will also have a phone number to call to seek help from research staff as needed.			
Unit Based Mentoring Protocols			
(1) Structured Mentoring			
During the 2 weeks following each in-class session, the researcher will engage each participant in a 10-minute dialogue to discuss and reflect upon the participant's recent experiences applying CONNECT concepts. The researcher will use semi-structured questions to elicit concerns about using local interaction strategies.	Facilitates authentic learning which occurs only when learners can directly and independently apply concepts. ²⁹	All study participants	2, 10 min sessions (20 min total)
(2) Chance Encounter Mentoring			
Co-facilitators engage in point-of-care discussions with staff to practice CONNECT behaviors and jointly problem solve, using the "chance encounter" protocol. Co-facilitators will record the number and descriptions of chance encounter mentoring sessions, using predefined drop-down menus on a PDA. At least 5 such encounters should occur daily although more are expected because opportunities arise naturally and frequently during usual work activities. Co-facilitators will call the 1-800 number and summarize issues that she/he noted during mentoring.	Identifies staff concerns and barriers, facilitates ongoing learning about local interaction; and strengthens sustainability of CONNECT behaviors. Co-facilitators learn to use existing time differently.	Co-facilitators engage with study participants in their department or work unit	2, 10 min sessions/participant (20 min total) 1.25 hrs/day for co-facilitator (37 hrs total)

Table 5.4.2.2. FALLS Protocol Activities, Rationale, Who is Involved and Time Required

FALLS Protocols	Rationale/Outcome	Who	Time
FALLS Coordinator Role			
Training Session Researcher reviews: 1) role of FALLS Coordinator; 2) clinical practice guidelines for fall prevention in nursing homes; 3) annotated slide presentation on practical aspects of fall prevention; 4) toolkit materials; 5) study expectations	Staff member becomes champion of fall prevention, monitors changes. Simulates nursing home QI practice	FALLS Coordinator, Assistant FALLS Coordinator, DON	1, 4 hour session
Weekly FALLS Coordinator teleconference	Reinforces key	FALLS	11, 30

Researcher contacts FALLS coordinator weekly during 3 month intervention for open problem-solving/discussion, and briefly highlights a topic chosen by the coordinator. Topics include: 1) using adult learning principles; 2) strategies to engage medical providers; 3) fall-talk with patients and families; 4) measurement challenges; 5) restraints and falls; 6) drugs and falls; 7) hip protectors; 8) Vitamin D and falls; 9) exercise and falls; 10) environment and falls	concepts of multifactorial risk reduction, supports FALLS Coordinator and maintains enthusiasm.	Coordinator, and any other team members s/he wishes	min sessions weekly (5.5 hrs total)
Staff Education			
Case-Based Modules (online and paper form will be available)			
<u>Nurse module.</u> Covers impact, risk factor assessment and intervention focusing on orthostatics, gait, toileting, medications, environmental hazards.	Uses case-based learning to impart knowledge and change attitudes about multi-factorial fall risk factor reduction.	RNs, LPNs, NAs, MDs, NPs, PAs, Consultant Pharmacists and others (PT, SW, Activities etc)	30-60 min
<u>NA module.</u> Covers risk factor assessment and intervention focusing on gait, footwear, toileting, hip protectors, and environmental hazards.			
<u>Prescriber/pharmacist module.</u> Covers epidemiology/impact, risk factor assessment, risk factor reduction focusing on psychotropic medication reduction and Vitamin D.			
Post-Fall Problem-solving			
Academic Detailing Nursing home staff will be invited to participate in "consultations" with the Researcher and FALLS Coordinator regarding their most challenging residents with falls. Sessions occur at each nursing station during the day and evening shifts.	Reinforces key concepts, promotes behavior change and interdisciplinary discussions. ²⁹	Nurses, NAs, other interested staff	2, 20 min sessions (40 min total)
Audit and Feedback			
Feedback Report Report using visual (bar graph) and written depictions of the nursing homes current practice on fall-related process and outcome measures, and how it compares with the median and the 90 th percentile of peer nursing homes. Researcher presents and explains the feedback report to FALLS Coordinator during teleconference.	Identifies areas for improvement, promotes behavior change. ²⁹	FALLS Coordinator determines dissemination	30 min
Toolbox			
(1) Morse Fall Scale: Validated scale that quantifies fall risk in nursing home residents	Provides modifiable tools to assist with communication, implementation, and documentation of multifactorial risk reduction.	FALLS Coordinator determines dissemination	Voluntarily
(2) Nurse Fall Risk Reduction Worksheet: Prompts nurse to identify and modify reversible fall risk factors. Can be used for chart documentation.			
(3) Prescriber/Pharmacist Medication Reduction Worksheet: Prompts consideration of dose reduction or discontinuation of high fall-risk medications, including lower risk substitution options.			
(4) Environmental Checklist: Facilitates identification of hazards in resident room, bathroom, and common areas.			
(5) Wheelchair maintenance log and stickers: Facilitates regular assessment and repair of wheelchair brakes.			
(6) Fall Risk Fax Communication Form: Allows nurse/pharmacist to communicate about concerns about medications with prescribers.			
(7) Patient and Family Brochure: Describes interventions that the nursing home is using to reduce falls.			
(8) Physician/Prescriber Brochure: Describes the fall reduction program and encourages review of medication reduction worksheets and faxes.			
(9) Fall prevention posters: Colorful reminders to staff, residents, and families about the importance of ongoing mindfulness about fall risk.			

Supplement Research Procedures, Measures and Analysis (Preliminary)

NOTE: Dr. Cary, the supplement investigator will use the first three months of his two year timeline to develop a detailed research plan and select appropriate measures. Thus an amendment to the protocol will be submitted with the details for sample selection, recruitment, consent, data collection, analysis and data safety will be submitted at that time. THE FOLLOW IS PRELIMINARY ONLY.

A sample of nursing homes will be selected from facilities that participated in the parent study (N=4). We will select one facility from each of four quartiles (low to high) based on fall rates when they completed their parent study participation. Facilities will be invited to participate; if any decline, a replacement facility will be chosen. This sampling plan will facilitate variation in findings.

Aim 1: Conduct a pilot study of functional measures to examine the trajectories of function over a 30-day period in a cohort of short-stay patients who are at risk for falls receiving post-acute care rehabilitation in nursing homes. The preliminary plan for this pilot project is that in the four selected nursing homes, Dr. Cary

will select short stay post-acute care rehabilitation patients (N=20) at risk for falls (5 in each facility) to describe trajectories of functional status during the first 30 days of short-stay rehabilitation. The sample of 20 residents will allow us to describe the range of common trajectory patterns in the population, and will provide means and standard errors for calculating the sample size of a larger subsequent study with which to perform trajectory analysis. Potential subjects must meet these criteria to be selected for the pilot: (1) have healthcare needs that require skilled nursing care; (2) have experienced a loss in function as a result of an injury and/or worsening illness; and (3) be identified as at risk for falls as indicated in the Minimum Data Set (MDS) 3.0 Fall History on Admission assessment. Patients will be excluded if: (1) they have greater than moderate cognitive impairment; (2) the patient was not discharged directly from an acute care hospital prior to SNF admission; (3) does not speak English; (4) is expected to stay greater than 30 days; and (5) was not living in the community (i.e., home, board and care, and assisted living residence) prior to acute care admission.

Dr. Cary will prepare a detailed data collection and analysis plan that the MPIs will approve before he proceeds. This is a pilot study, in part, because we need to determine how frequently measurements need to occur to detect meaningful change in physical and cognitive function. The MDS data are collected at 5-Day, 14-Day, 30-Day (60-Day and 90-Day) assessment periods, which we believe is not frequent enough to determine meaningful change and evaluate the effects of treatment. Dr. Cary will begin in 1 facility, and will approach all consecutive rehabilitation admissions until 5 eligible subjects have been enrolled. He will follow the 5 subjects every 4 days until discharge or 30 days, and then begin enrollment in the next facility. In selecting functional measures for the pilot study, Dr. Cary will identify measures of motor and cognitive functioning collected within standardized patient assessment tools mandated by the Centers for Medicare and Medicaid Services and may use more than one measure to evaluate sensitivity to changes in trajectories. Two measures that will likely be used are the MDS 3.0 items (guided by mentor Eleanor McConnell, RN, PhD) that measure motor and cognitive function and the recently developed Continuity Assessment Record and Evaluation (CARE) Tool (guided by collaborator Anne Deutsch RN, PhD) which was designed to measure function across post-acute settings including both SNFs and IRFs. It is important to select functional measures that can be standardized based on performing specific physical activities (performance-based) but to also include broader functional measures (patient-reported) that capture health and psychosocial factors relevant to a person's daily life (Bean, et al. 2011). For this reason, Dr. Cary will also review patient-reported measures of functioning used in the National Institutes of Health (NIH) Patient Reported Outcomes Measurement Information System (PROMIS). Evaluating performance-based and patient-reported measures of function will introduce Dr. Cary to measurement theory. Dr. Cary will derive evaluation criteria (i.e., brevity, reliability, validity, clinical utility, and responsiveness to change) based on a literature. In collaboration with the MPIs, Dr. Cary will determine the appropriate measures for this study. This study will provide a first description of trajectories of both motor and cognitive function in this population. We will examine the data by creating trajectory lines of the functional measures to determine if a more frequent data collection is needed to see transition points at which a functional change is triggered and evaluate if selected measures vary in sensitivity. Concurrently, Dr. Cary will review the medical record for contextual and explanatory detail on the patients' status and prospectively record any falls that may have occurred, whether they involved injury, and if so, describe the nature of the injury. Other clinical characteristics will include data such as admitting diagnosis; comorbidities; pain, and depression. All patients will provide written informed consent prior to data collection. We will use visual and statistical analyses with the guidance of the Methods Core in the P30 Center. Dr. Cary will submit abstracts for presentation about these results to relevant conferences and the MPIs will guide him in writing a manuscript.

Aim 2: Describe system-level management practices that selected facilities use to ensure safety and reduce falls and fall risk among short-stay, post-acute care patients. The MPI's will guide Dr. Cary in developing interview questions and procedures using protocols developed in Anderson's previous qualitative study. Dr. Cary will interview the nursing home administrator, director of nursing, nursing staff working with short-stay patients, and the lead rehabilitation staff member (N=16) in the four selected facilities. All staff members providing formal interviews or observations will provide written informed consent. A professional transcriptionist will transcribe interviews and Dr. Cary will verify accuracy. *Before he begins data collection*

and analysis, Dr. Cary will write a detailed methods and analysis plan, using knowledge gained from the activities in his training plan; both MPIs will approve the plan before he proceeds. The R01 MPIs, who are both highly experienced in qualitative methods, will guide Dr. Cary throughout his work on aim 2; they will ensure that he reliably uses content analysis to make valid inferences from the data and proposes hypotheses about system level management practices for fall risk reduction and prevention. Dr. Cary will submit abstracts for presentation about these results to relevant conferences and the MPIs will guide him in writing a manuscript.

5. MEASURES

The measures and the time points at which these will be collected are summarized in Table 3.c.2.5 (Complexity Science Measures) and Table 3.c.2.6. (Fall-related measures). Details of the scales and instructions are contained in Appendixes 3 (of the full NIH Grant) (Complexity Science Measures) and 4 (Fall-related measures). In addition, data will be collected about each NH.

NURSING HOME DATA. Characteristics including bed size, nursing staff hours, chain and religious affiliation will be collected from publicly available sources (www.nhcompare.gov). Nursing staff turnover during the intervention period will be obtained from administrators. We will collect both voluntary and involuntary terminations for the total of all nursing staff in each enrolled nursing home. Administrators will be emailed our form, based on the same method used by Advancing Excellence in Nursing Homes (<http://www.nhqualitycampaign.org/>) program because many administrators may already be familiar with this method. These data will be used as covariates in the multivariable outcomes analyses.

An additional measure to capture staff level information on falls quality indicators will also be collected at staff survey 3 and 4 time periods. This new scale will be accompanied by a randomized vignette based on resident attributes (3.c.2.5a) that may impact the selection of fall prevention strategies. Staff will be asked to complete 2 vignettes at both our survey 2 and survey 3 time periods allowing for a baseline measure before the FALLS Protocols start and a follow-up after they conclude. We will ask that only enrolled, or newly enrolled, staff in the following departments fill out the vignettes: RNs, LPNs, CNAs (restorative and med techs included) and therapy staff (physical therapy, occupational therapy, and speech). The falls quality indicators assessed using the vignettes can be found in table Table 3.c.2.6 (rows a-h).

COMPLEXITY SCIENCE MEASURES

Complexity Science Measures are summarized in table 3.c.2.5, and will be collected at time points as indicated. Scaled items are contained in Appendix 3 (see full NIH grant). We will ask staff to report their experience over the last month; this time frame was chosen to capture the usual monthly cycle of meetings and events that may influence interactions. Although not all staff will have participated in CONNECT, we expect a system effect (confirmed in the R56 study) and, thus, all staff members should perceive changes.

Table 3.c.2.5 Complexity Science Measures, Data Sources, Psychometrics, and Time Points

Concept Measured; Source	Psychometrics; Calculation	Base line	3 mo	6 mo	9 mo
Demographics; self-report	Age, sex, job title, years in position, education, and ethnicity (collected at baseline or at enrollment into the study. Categorical measurement)	X			
Communication patterns; all staff participants	Mean scores on Roberts & O'Reilly openness, accuracy scales ⁹⁹ and Shortell's timeliness scale. ¹⁰⁰ The scales show adequate reliability and validity in various settings. ⁹⁹⁻¹⁰¹ In our preliminary studies scales showed reliability alphas of .81, .72 and .68, respectively; construct validity confirmed by factor analysis and hypothesis testing. ^{16, 24, 102}	X	X	X	X
Concept Measured; Source	Psychometrics; Calculation	Base line	3 mo	6 mo	9 mo
NA participation in decision making about resident care; all staff participants	Mean score on Anderson et al.'s ¹⁰² Participation in Decision-making Instrument (PDMI). The PDMI is established with demonstrated reliability in NHs ^{16, 17, 102-104} and construct validity established through factor analysis ¹⁰² and hypothesis testing. ^{16, 103, 105} NH samples achieved alpha coefficients of >.90.	X	X	X	X
Local Interaction Measure; all staff participants	Mean Scores on Anderson et al.'s Local Interaction Scale, designed to measure staff's perception of co-worker's use of the 20 local interaction strategies (listed in Figure 3.a.1, defined in protocols, Appendix A). The items were developed using the language of case study participants (2RO1NR03178). The measure was pilot tested in the R56 with 136 NH staff (RNs, LPNs, NAs, others) and demonstrated alpha coefficients >.90. Eta ² of .20 (p <.001) indicated that the measure is reliable at the NH level. Evidence of construct validity is indicated by a time by group effect (p=.10) in the R56 RM-ANOVA analysis. The reading level is 6 th grade.	X	X	X	X
Safety organizing scale; all staff participants	Mean score on Vogus & Sutcliff's scale designed to measure 5 "interrelated behavioral processes: preoccupation with failure, reluctance to simplify interpretations, sensitivity to operations, commitment to resilience, and deference to expertise." ^{106, p. 47} In a large sample of hospital RNs,	X	X	X	X

	the 9-item, 7-point scale showed reliability (alpha = .88), convergent and discriminant validity, and criterion validity, and was reliability aggregated to reflect a unit-level construct. ¹⁰⁶ We revised the wording to reflect NHs. Alphas were >.90 in both the baseline and follow up survey in our preliminary studies.				
Perceived quality scale; all staff participants	Mean scores of Colón-Emeric's scale The Perceived Quality Scale, ¹⁰⁷ designed to measure staff's perception of the quality of care provided in their NH. We developed items using case-study data (2RO1NR03178) from four cases and then pilot tested with staff in the next four case studies, following which we clarified items and achieved high reliabilities. Using R56 sample data, we scored two subscales, quality of caregiving (n=7 items) and quality of care planning (n=15 items) each with alpha > .80. The reading level is 6 th grade.	X	X	X	X

3.c.2.5a Vignette Dimensions (576 possible vignette variations)		
Dimension Measured	Levels of Dimension	What level looks like in vignette
1. Age	<ul style="list-style-type: none"> 75 0/2 (reference category) 90 0/1 	[information is from picture only]
2. Sex	<ul style="list-style-type: none"> Male / Female 	[information is from picture only]
3. Race	<ul style="list-style-type: none"> White 0/1 (reference category) African-American 0/1 	[information is from picture only]
4. Falls history	<ul style="list-style-type: none"> No hx / Hx of frequent falls 	This resident [has/or has not] fallen in the last 3 months.
5. Multiple fall risk factors	<ul style="list-style-type: none"> Yes/no 	This resident [has/or has not had] past strokes, Parkinson's disease, and vision impairment.
6. Assistive device use	<ul style="list-style-type: none"> Walker 0/1 Wheelchair 0/1 None 0/1 (reference category) 	This resident uses a [walker/wheelchair] to get around the facility, but needs assistance. This resident does not use any assistive devices.
7. Type of nursing home stay (rehab, hospice, long term care)	<ul style="list-style-type: none"> Rehab 0/1 (reference category) Hospice 0/1 Long-term care 0/1 	This resident is here for [insert type of care].
8. History of Dementia	<ul style="list-style-type: none"> Yes/no 	This resident is usually confused and cannot remember to call for help OR usually has normal memory and thinking.

FALL MEASURES (TABLE 3.C.2.6)

FALL Risk Factor Reduction Indicators. Measures chosen for this study 1) are a component of previous efficacy trials and fall clinical practice guidelines; 2) were found to be reliably measured by chart abstraction in previous studies;^{7 9} and 3) are included in the educational components of the FALLS intervention. These indicators were previously found to be reliably measured, sensitive to change, and not impacted by a ceiling effect.⁷ We will calculate the proportion of fallers with medical record evidence of the fall risk reduction indicator, and determine indicator counts for each resident. The timing of the risk factor reduction will be recorded as: within 48 hours of a fall, within 1 month of a fall, during the 6 month abstraction period. Definitions for the indicators are listed in Table 3.c.2.6.

FALL RATE. Consistent with the MDS, we define a fall as an unintentional change in position resulting in a resident coming to rest on the ground or lower level⁴ regardless of cause.² Recurrent falls are defined as 2 or more falls within the 6 month study period.⁴ These measures have been successfully employed in previous studies.²⁻⁴ Due to underreporting of falls,¹⁰⁸ data will be collected from multiple sources including the medical record, ^{2, 108} MDS reports, fall logs, and incident reports. We will calculate fall rates and recurrent falls as defined in the table below. From our previous falls study and national data, we assume a baseline fall rate of 1.5 falls/bed/yr, and an average bed occupancy rate of 90 bed days/home/month. We therefore project that there will be a total of 2160 falls in the study NHs over the study period. The proportion of repeat fallers and

the proportion of injurious falls (defined as the proportion of falls resulting in injury including skin tear, hematoma, fracture, laceration, need for imaging or urgent medical assessment) will be measured as secondary fall endpoints.

Table 3.c.2.6 Fall Measures, Data Sources, Calculation, and Time Points.

Concept Measured; Source	Calculation/Definition	Inclusive of 6 mo prior to base line	Inclusive of 6 mo after FALLS complete
Demographics; Medical record	Sex, Age, and race. Nominal	X	X
Fall Rate; Medical Record, MDS, Incident reports, Weekly census	Numerator: number of falls occurring in a 6 month period Denominator: number of occupied facility bed days	X	X
Probability of recurrent falls; as above, weekly census	Proportion of residents with 2 or more falls occurring in a 6 month period	X	X
Fall Risk Reduction Indicators; Medical record, RAI, Incident reports	Count of documented fall risk reduction indicators defined below	X	X
a) Orthostatic Blood Pressure	Documentation of blood pressure in at least 2 body positions, OR intervention to decrease orthostatic hypotension including discontinuation of a medication associated with orthostasis, prescription of volume expanding medication, or use of compression stockings	X	X
b) Sensory Impairment	Documentation of the presence or absence of visual impairment, OR Intervention to change corrective devices or add assistive technology to optimize sensory input (e.g. magnification devices, lighting level)	X	X
c) Footwear	Documentation that footwear has been evaluated, modified, or recommended to patient/family	X	X
d) Gait and Assistive Devices	Physical therapy assessment or training, change in assistive device, or participation in restorative ambulation program	X	X
e) Toileting	Documentation of scheduled toileting or a previous attempt in residents with at least intermittent urinary or bowel continence	X	X
f) Environment	Documentation of a search for environmental factors contributing to fall risk (e.g., low toilet seat, room clutter, burned out light bulb) OR a change in environment likely to reduce falls or injury risk, including replacing or repairing grab bars, changing floor surfaces, changing lighting, re-arranging furniture, using a low bed or floor mat, and alarms	X	X
g) Psychotropic Medication Reduction ^{77, 78}	Dose reduction or discontinuation of any of the following classes of psychoactive medications within 1 month of a fall; benzodiazepines, tricyclic antidepressants, antipsychotics, propoxyphene, and selected anticholinergic agents (diphenhydramine, sedating antihistamines, immediate-release oxybutynin, skeletal muscle relaxants)	X	X
h) Calcium and Vitamin D	Prescription of at least 1000 mg of calcium daily or 800 IU of vitamin D daily, OR an equivalent in weekly or monthly dose regimens. Multivitamins containing vitamin D and combination calcium/vitamin D preparations will be added to the total daily dose calculation.	X	X

COVARIATES. Non-modifiable fall risk factors will be used in the analysis to adjust for differences in level of risk between residents. The resident's most recent history and physical, problem list, discharge summaries, and RAI will be reviewed for the following: age; sex; race; history of stroke; peripheral neuropathy; Parkinson's disease; visual impairment; cognitive impairment; assistive device use; and ambulatory status.

6. Selection of Subjects

SETTING AND SAMPLING RATIONALE. The sample will be drawn from the 134 nursing homes in North Carolina located within 100 miles of Duke University who participate in Medicare and Medicaid and are not part of a hospital. We will do our first round of recruiting from the group of nursing homes that are less than 80 miles one-way from Duke (n=89 eligible nursing homes). If 16 matched pair nursing homes cannot be recruited within this range we will then extend out to 80-100 miles (n=45 eligible nursing homes) one-way from Duke.

Table 5.2.1 displays descriptive Online Survey Certification and Reporting data³⁰ for the nursing homes in the sampling pool compared to nursing homes in NC and the rest of the Nation. The nursing homes in the sampling pool have higher RN minutes per resident day and are larger. All other variables are within 2% of the nation suggesting that the sampling frame is nationally representative.

TABLE 5.2.1. COMPARISON OF MEANS: NURSING HOMES IN NORTH CAROLINA, STATE AND NATION

Variable Names	Pool (N=69)	NC (N=421)	National (N> 17,000)
Number of residents	101.00	99.50	95.60
RN minutes/resident day	36.00	30.00	30.00
LPN minutes/resident day	46.35	54.00	48.00
NA hrs/resident day	2.39	2.26	2.26
% of long stay residents who are physically restrained	5%	7%	5%
% of long stay residents whose ability to move about in and around their room got worse	11%	14%	12%
% of long stay residents who have lost too much weight	10%	10%	8%

NURSING HOME RECRUITMENT AND RANDOMIZATION. NH recruitment will be done by the NC Quality Improvement Organization, the Carolinas Center for Medical Excellence (CCME), which has more than 10 years of experience recruiting NHs. We will send out a letter of invitation to all eligible NHs; if more than 16 volunteer we will randomly select the sample from this pool using a random number generator, otherwise NHs will be contacted over the phone in random order until 16 agree to participate. This strategy was used successfully to recruit 38 NHs in the PI's previous QI study.³¹

Because chain-affiliation is a determinant of care quality,^{32, 33} we will block randomize to ensure equal balance for potentially confounding variables such as corporate policies. Recruitment will be completed in 1 waves from our eligible list of NHs that are less than 80 miles one way from Duke. Chain-owned NHs will have an equal number randomized to each study arm, and independent NHs will have an equal number randomized to each study arm. NHs will be assigned a study number, and a second investigator blinded to NH name and characteristics will randomize them using a random number generator. If 16 nursing homes cannot successfully be recruited that are less than 80 miles one way from Duke, we will then recruit from the list of eligible nursing homes that are up to 100 miles one way from Duke. Nursing homes that were previously recruited from our R56 pilot and expressed an interest will be given a priority in participating in this new study.

Additional exclusion criteria have been added; nursing homes meeting the following criteria will be excluded. 1) Nursing homes that are listed as being located “within a hospital” by Medicare.gov on the Nursing Home Compare website; 2) Nursing homes that are listed as state owned; 3) nursing homes with less than 75 beds due to the requirement of abstracting 50 resident charts at baseline and follow-up; 4) Nursing homes that are part of a Continuing Care Retirement Community (CCRC) will only be included in the study if a matched pair can be made for both study arms (CONNECT+FALLS and FALLS only), 5) Nursing homes that are structured in a neighborhood/household facility design. If 16 nursing homes, with a standard layout that match cannot be adequately recruited, only then will nursing homes with a neighborhood/household layout be considered for participation. They will only be invited if a matched pair can be found for both study arms (CONNECT+FALLS and FALLS only).

RESIDENT SAMPLE. Eligibility criteria include: 1) ≥ 65 years of age; 2) sustained a fall as defined by Minimum Data Set (MDS) criteria in the study period; and 3) remained in the facility for at least 30 days after the fall event. This sampling strategy will allow us to measure fall risk factor reduction activities completed by the NH staff for their highest risk residents (i.e., known fallers). Previous studies suggest a fall rate of 1.5 falls/bed-year, of which 40% are recurrent fallers.^{37, 87} Of the approximately 1600 residents in the study NHs, we estimate a resident pool of n=1440 unique fallers which exceeds our needed resident sample size of 800. Lists of residents who have fallen during the study period will be generated from the facility MDS and incident reports. A random sample of 50 unique residents from each facility will be selected for chart abstraction using a random number generator. Because this is a minimal risk study in which residents are not followed prospectively, we have obtained a waiver of informed consent.

STAFF SAMPLE. Staff members who work with residents in a clinical capacity (e.g., RNs, LPNs, NAs, Social workers, Dietary, Activities staff, Physical and Occupational Therapists) on skilled and assisted living units will be eligible to participate. The only exclusion criterion is inability to speak and understand English. In prior intervention research, 62-85% of NAs participated in survey completion and behavioral training

interventions.^{37,24-38} Thus, we conservatively estimate that, of approximately 960 staff members, 60% will participate in training and complete study surveys for an estimated enrollment of 576 staff members.

7. Subject recruitment and compensation

a. Human Subjects Involvement and Characteristics

- **Proposed involvement of human subjects**

Human subjects in this study are 1) nursing home residents, and 2) nursing home staff. Nursing home resident data are collected through medical record review to assess the impact of the staff intervention on the quality of their falls-related care. Nursing home staff participation includes participation in the CONNECT and/or FALLS educational sessions, and completion of a demographic form and surveys for the CONNECT outcomes measures.

- **Characteristics of the subject population, including their anticipated number, age range, and health status.**

NURSING HOME RESIDENTS. Nursing home residents (n=800) will be older adults (ranging from 65 to over 100 years) with multiple chronic health problems; approximately 75% will have some degree of cognitive impairment due to dementia.

NURSING HOME PERSONNEL. Nursing home senior administrators and mid-level managers (e.g., department heads and supervisors from nursing, social work, housekeeping, dietary, environmental services, activities, maintenance, business office) and front line staff (e.g., RNs, Licensed Practical Nurses, nurse assistants), will be included in the study. Overall, our anticipated staff enrollment is n=576. These participants are of working age (18-65) and will be without major health conditions that would influence participation in the study.

- **Criteria for inclusion or exclusion of any subpopulation.**

NURSING HOME RESIDENTS. Inclusion criteria include: 1) age \geq 65 years; 2) sustained a fall as defined by Minimum Data Set (MDS) criteria in the study period; and 3) remained in the facility for at least 30 days after the fall event. NURSING HOME STAFF. All staff members at the study sites who are willing to participate in protocol testing activities are eligible to participate. The only exclusion criterion is inability to speak and understand English and participants must be at least 18 years of age.

INCLUSION OF WOMEN

Residents: The sample will be representative of the residents at participating nursing homes, with estimated proportion men being 27%.²¹¹

Nursing Home Staff: Because women are over represented among nursing home staff, participation of women will not be an issue. Men, however, may be under-represented. We base our estimates for gender participation using data from our ongoing case study research (preliminary study 4.1) which has recruited over 400 personnel (all job categories) in four nursing homes within a 60 mile radius of Duke University, representing the local nursing home community. We expect the sample to be 80% women and 20% men. We will monitor enrollment of men and seek participation of men who work in the nursing home where possible and appropriate to the study's aims.

INCLUSION OF MINORITIES

Residents: The sample will be representative of the residents at participating nursing homes, with estimated proportion of under-represented minorities of 16%.²¹¹

Nursing Home Staff: The sample will be representative of the racial diversity observed in our ongoing case study research which has recruited over 700 personnel (all job categories). We expect the sample to be 45% African American and 52% Caucasian. The remaining 3% are expected to be Asian American or other. We expect that less than 2% will be Hispanic. Participants will be asked to self-identify their race/ethnicity at the time of recruitment. We have successfully recruited African American, Latino, and Asian American participants in our ongoing case study research (preliminary study 4.1) and exceed representation of minorities in similar "health support occupations" as reported for the nursing home workforce in North Carolina in the 2000 census (57% white, 39% African American, and the remaining 3% being American Indian, Asian or other).¹⁶⁰ No minority group will be excluded from this study. Should minority enrollment be less than expected, we will use techniques such as recruitment of local minority group opinion leaders to encourage participation, multiple invitations, and small incentives.

8. Consent process –

RESIDENT RECRUITMENT AND CONSENT. A waiver of HIPAA authorization and informed consent has been obtained from our Institutional Review Board for this minimal risk, retrospective chart review. NURSING HOME

STAFF RECRUITMENT AND CONSENT. Nursing Home recruitment will be completed by CCME, the NC Quality Improvement Organization that has a strong regional reputation for QI programs in nursing homes. When recruited, the administrators and directors of nursing will be asked to agree to include CONNECT in-class learning sessions and/or FALLS as part of the required training in the nursing home; thus, these activities will not require consent of staff to participate and no data will be recorded in study database on individuals who have not signed informed consent. Once facility administrators and directors of nursing have agreed to participate, Duke study personnel will recruit nursing home staff to participate in the CONNECT and/or FALLS programs and data collection. Using recruitment methods we have found reliable in our case study research (see progress report), we will attend staff meetings and routine gatherings, on all three shifts, and describe the study, asking for participation in the study (completing surveys, self-monitoring of interactions, structured mentoring, and or focus group), for which we will obtain informed consent. These Staff members that have not attended meetings may be approached individually by researchers and invited to participate. All staff members will be given at least one day before deciding to consent.

The following process takes place with nursing home staff to provide information to them about the study and give them the opportunity to participate: a) the study is explained to staff and the consent form reviewed in a small group setting but without managers present. While general questions about the study may be answered in a group setting, subjects are informed they have the option of individually moving to a private location to have their questions answered immediately after the meeting or subjects may contact the study team after the meeting to have their questions answered over the telephone, b) Staff are given a consent form to take home and review. They are told that the research assistant will be available to meet with them individually and answer any questions privately over the next week, c) Staff can return the form to the Research Interventionist in person, or via the locked drop box (which happens rarely), and d) If the consent form is returned via the locked drop box, the research assistant then signs the form upon pick-up, makes copies and provides the research subject their fully signed copy in person. This provides an additional point of contact to answer any questions. This “delayed signature” is described in the protocol.

Because consent forms may be signed at home by participants, the dates on the informed consent for date of consent and the date the consent form is collected may differ. Data will be collected only from staff members who have agreed to participate in these other aspects of the study. Consents will be stored in locked file cabinets in the research office, separate from any study data. All staff will be 18 years of age or over. In North Carolina at age 18 an individual may consent to research participation without parental consent. We will not collect birthdates from nursing home staff because they can be highly suspicious of outsiders and we do not need their birthdates. We will collect their age and ask via the consent form for them to certify by signing the consent that they are at least age 18 or older. Because birthdates are not being collected we cannot record birthdates on our consent forms. Instead we will record participant names and study ID numbers in the top right corner of each participant’s consent. Flyers will also be used to remind staff of any scheduled CONNECT intervention sessions. For the first two CONNECT and Learn sessions the flyers state that nursing home staff not participating in the research study can also participate. These flyers will be placed in communications binders and other places (e.g. bulletin boards, break rooms) deemed appropriate by our nursing home contact. To increase consented staff retention in our second and third waves of data collection we will provide two days of scheduled 15 minute sessions, during/around lunch time to provide lunch (pizza) to consented study participants and possibly any new staff who would like to participate and consent to be in the study. We have designed a flyer for these purposes. Because our protocol prevents us from giving a list of enrolled participants to any management staff at our nursing home, participating nursing homes will flyer all staff pay checks 2 weeks before the scheduled 15 minute sessions. We have discussed this method with our participating nursing homes and they believe it will work best to inform staff about the sessions. Flyers may also be hung up in various locations around the nursing homes (break rooms, bulletin boards, etc.). We may also enroll new participants as a result of this flyer. We will continue to follow all of our protocol procedures for consenting/enrolling any new staff. If a future nursing home prefers not to use this method we will not require these schedule sessions to occur and will distribute and collect staff surveys as we have previously specified.

Two informational study flyers, each designed to go to nursing homes receiving CONNECT and FALLS or FALLS only, are designed to inform nursing home staff about their facility’s participation before our first information meetings about the study with staff. These flyers were recommended by a participating nursing home. These flyers build from our already approved 1-page CONNECT Project Summary but are tailored to be intervention specific and focus more on an overview of what staff participation means. These flyers would be

used as an informational notice to all nursing home staff before we arrive to the facilities to conduct our informational sessions; they could also be given to any staff at a later date including new staff that are interested in enrolling. Flyers like this have been used in the past for our follow-up surveys and have been used by the nursing homes to attach to pay checks to notify staff of our scheduled presence. These flyers may also be hung up in various locations around the nursing homes (break rooms, bulletin boards, etc.). We will ask each nursing home moving forward their preference to attach the flyer to paychecks and/or to hang the flyers in various approved locations in their facility.

Who will conduct the consent process with prospective participants? Give the person's role in this study (PI, Study Coordinator, etc.).

Nursing homes: The Carolinas Center for Medical Excellence, (CCME) the North and South Carolina State Quality Improvement Organization, has been a partner in developing the proposed protocol, and will assume responsibility for facility recruitment. Mark Massing, MD, PhD, the director of research at CCME, has been a valued partner in previous projects with the Duke research team, and will serve as a subcontractor for the proposed study. He will delegate these activities to CCME project personnel as appropriate. Cathleen Colon-Emeric (PI) oversees this aspect of the study.

Staff: Recruitment of the nursing homes will be completed by CCME, the NC Quality Improvement Organization that has a strong regional reputation for QI programs in nursing homes. When recruited, the Duke Principal Investigator and Project Director will consent the administrators and directors of nursing will be asked to sign consents. Once facility administrators and directors of nursing have agreed to participate, Duke study personnel will recruit nursing home staff to participate in the CONNECT and/or FALLS programs and data collection. Trained Duke Research staff will recruit staff participants. The Researchers will be supervised in this activity by the Project Director. Ruth Anderson (PI) oversees this aspect of the study.

How much time will the prospective participant (or legally authorized representative) have between being approached about participating in the study and needing to decide whether or not to participate? If you are not giving the person overnight to consider whether or not to participate, please justify.

Staff: Staff members will have at least overnight to consider participation in the study before deciding.

Where will the consent process occur?

Staff: Using recruitment methods we have found reliable in our recent research, we will attend staff meetings and routine gatherings, on all three shifts, and describe the study, asking for participation in the study (completing surveys, self-monitoring of interactions, structured mentoring, and focus group), for which we will obtain informed consent the next day. Staff members that have not attended meetings may be approached individually by researchers and invited to participate and will be given at least one day before being asked to sign a consent. Data will be collected only from staff members who have agreed to participate in the study.

What steps will be taken in that location to protect the privacy of the prospective participant?

Using strategies that worked in our recent nursing home study, we will take the participant to a location of his/her choosing such as the resident rooms, meeting areas located throughout the nursing homes, staff break room, the courtyard or porch.

How much time will be allocated for conducting the initial consent discussion, including presenting the information in the consent document and answering questions, with each prospective participant?

Staff: We will ask for a 15 minute block of time to explain the study and answer questions during group meetings at which we present the study. Staff members who are approached directly will be given the time they need to read the consent and ask questions. In our past experience this has taken about 10 minutes.

What arrangements will be in place for answering participant questions before and after the consent is signed?

Protocols call for the research staff to ask what for questions at the time that the study is explained and before the consent is signed. In addition, the research staff will be available in the facility to nursing home staff members for follow-up questions in the case that the staff member(s) take the consent form home and opt to sign it there. The consent form and study materials (handouts) contain information for contacting the study staff to ask questions.

Describe the steps taken to minimize the possibility of coercion or undue influence.

Statements in the consent form indicate that participation is voluntary and that if the resident or staff member chooses not to participate, that it will not impact employment or their relationships with Duke (if relevant). We also stress that the participant may withdrawal from the study at any time.

What provisions will be in place to obtain consent from participants who do not read, are blind or who do not read/understand English?

If a person does not read/understand English, he/she does not meet the inclusion criteria for the study.

9. Subject's capacity to give legally effective consent

Staff: Nursing home staff will be considered to be capable of consent by virtue of employment status. Periodic reassessment will not occur.

10. Study Interventions –See above.

11. Risk/benefit assessment

No more than minimal risks are anticipated from this study and these stem principally from potential harm resulting from a breach of confidentiality.

RESIDENTS. We take several measures to avoid an adverse impact on resident care due to staff time away for study activities: (a) we will work with the nursing home administration to have in-class sessions and FALLS modules as part of the mandated staff training provided by the home (confirmed as feasible in the pilot study, Appendix 1C); (b) we designed the interventions to be incorporated into usual care activities and confirmed feasibility through pilot studies so that workflow is not interrupted; and (c) we will ask staff to complete surveys after usual working hours and provide incentives. Further, because the training activities contained in the FALLS protocol are the current industry standard to reduce falls rates, we expect the impact of this training to be beneficial or at least neutral to resident welfare. Resident data confidentiality will be protected using the same strategies outlined below for staff.

NURSING HOME STAFF Nursing home personnel may be concerned about loss of confidentiality related to their responses on survey questionnaires and focus group, which could potentially reach their supervisor and affect employment status and burden from participation in study activities. There is also a risk that a staff participant would be injured during the intervention although it is unlikely that the injury would be related to the intervention.

RISKS TO NURSING HOME STAFF will be minimized by procedures that protect confidentiality of individual respondents and their responses in survey questionnaires. Focus group participants will include only direct care staff and thus no supervisors will hear the discussion. Participants will be instructed not to discuss the focus group with people who did not participate. Data will be protected by using codes. While data collectors are in the nursing home, any previously completed surveys for data collection forms will be kept in a secure place, such as the trunk of a car, until they can be delivered to the research office for data entry where they will be kept in a locked file cabinet. No names will be used on completed data collection forms. Codes will be used to identify the nursing home and all individual subjects. All keys that link codes to the nursing homes or individual respondents will be kept in a secure file to which only the PI, project director, and database manager will have access. Participants will be assured that all data will be used only for the purposes of the study. Reports of the data will appear only in aggregate form. We anticipate that these procedures will be effective because using similar procedures we had no breach of confidentiality in two prior R01s involving in total over 5000 participants (see progress report). We will take several steps to minimize potential participant burden; (a) we revised the intervention to reduce the total number of contact hours required; (b) we will work with the nursing home administration to have in-class sessions and FALLS modules for the study as part of the required hours of mandated staff training provided by the home (confirmed as feasible in the pilot study, Appendix 1C) which then does not significantly increase the total number of training hours per year; (c) we designed the interventions to be incorporated into usual care activities and confirmed feasibility through pilot studies so that workflow is not interrupted; and (d) we will ask staff to complete surveys after usual working hours and provide incentives. All nursing home staff are high school graduates and will be at least 18 years old, an age considered to be adult for consenting to participate in research.

Describe the possible benefits to the subject. What is the importance of the knowledge expected to result from the research? Nursing home residents who reside in the study homes have the potential to benefit from improved staff knowledge and process of care around fall prevention. For nursing home staff, we will draw on

strategies we have used successfully in our previous research to provide incentives, including offering continuing education credits for attendance at learning sessions, and a certificate of participation to each nursing home. The nursing home staff may receive some psychological benefit from discussing staff to staff interaction and learning skills to assist them in providing emotional support to each other and improving information exchange and problem solving. The investigators will offer an exit-interview consultation to the nursing home administrator and staff, during which we will present the results of the CONNECT and FALL measures and feedback about other study results. We have used the exit-interview consultation successfully as a method for gaining participation in our case studies, and participants have described the exit as beneficial.³⁹ At the time of the exit-interviews, each nursing home will be presented with an exterior, vinyl banner and a framed certificate of participation, as an optional display of their partnership efforts with the CONNECT study toward fall prevention research.

The risks to subjects are limited to mild psychological discomfort or violations of confidentiality, both of which have been successfully avoided in prior studies. The importance of the knowledge to be gained is significant. This is the first test of this intervention designed to improve staff interactions required to ensure more consistent and effective staff to staff information exchange about resident care. The potential benefits to improving the quality of care, not just for falls but for a variety of geriatric syndromes, are tremendous. Moreover, improved participation in decision making, self-efficacy and other staff-related outcome measures may positively impact the work environment in this setting plagued by high turnover and burnout. The above mentioned benefits, in combination with knowledge gained about the influence of nursing management practices on outcomes in nursing homes, far outweigh the risks.

Staff Participant incentives: We propose that one staff incentive will be CE credits for RNs and LPNs and a certificate for aides and individuals from other disciplines for attendance at CONNECT in-class learning sessions, FALLS module completion, and FALLS problem-solving sessions. In addition, we will enter staff members into drawings for prizes that will occur weekly over the four weeks at baseline, and all follow-up data collection points. We will also offer incentives (\$25 and under weekly, during the first 6 weeks of the 12 week CONNECT intervention. Participating staff members will be entered into the drawing for each activity in which they participate (e.g., complete survey, attend in-class session, and engage in structured mentoring session). During the second 6 weeks of the CONNECT intervention, participants will be entered into a drawing every other week (matching the intervention mapping feedback activity) and one staff per CONNECT site, at each drawing (n=24 staff total) will be eligible to win a mini iPod worth \$49.99. Everyone who is entered will receive a token prize, such as a study logo keychain, that is given out at the beginning and end of the 12 week intervention.

12. Costs to the subject, and compensation

There is no direct cost to the subject to participate in this study. No compensation is provided.

13. Data Analysis & Statistical Considerations

PRELIMINARY QUANTITATIVE ANALYSES. Descriptive Statistics including graphical displays will be obtained for all dependent variables, and baseline and over-time statistics will be obtained for all variables. In initial analyses we will test each dependent variable for violations of distributional assumptions (normality, skew, etc.) and employ standard fixes (logarithmic or other transformation) or nonlinear models where necessary.

STATISTICAL MODELS. To analyze the effects of the intervention on our dependent variables at 3 and 6 months, we will use a class of statistical models referred to as mixed models,⁴⁰⁻⁴² hierarchical linear models,⁴³ and multilevel models.⁴² With this approach, each subject's repeated measures on a dependent variable are first parameterized as an individual growth trajectory plus an error term. In a second stage, the estimated trajectories are modeled as a function of differences between individuals on independent variables of interest. Mixed models extend the standard repeated measures ANOVA to allow for a variety of error structures, measurements taken at unequal intervals, and time changing independent variables. They also make better use of available information when missing data are present.⁴¹ Our design will necessitate a three-level model, as residents and staff are nested within nursing homes. These models can be estimated with SAS PROC MIXED (SAS/STAT, 2004) for normally-distributed outcomes,⁴⁰ and with the SAS PROC GLIMMIX⁴⁴ for non-normally distributed outcomes. We will also estimate the correlations between the process and the fall-related outcomes at each time point.

ANALYSES FOR SPECIFIC AIMS. For each aim, models will be estimated for each dependent variable. We expect that the effect of treatment will not vary with time, and the models below are specified accordingly. In initial analyses, we will test for a treatment by time interaction, and add a product term to the model if an interactive effect is present. Potential Confounders. To control on between-person differences prior to the intervention, we will include a baseline measure of each dependent variable as a control in each analysis. We will also control on facility and individual-level potential confounders when they are related to an independent variable of interest. The confounders to be used in this study include: age, sex, race, history of stroke, peripheral neuropathy, Parkinson's disease, visual impairment, cognitive impairment, assistive device use, fall in the previous 6 months, ambulatory status, facility bed-size and staffing levels. Facility ownership status (corporate vs. independent) is a blocking variable for randomization and thus will be equally distributed in the study arms.

STATISTICAL POWER. Power analyses were performed using algorithms developed to estimate power for longitudinal models allowing for an independence working correlation matrix, and based on the formulae of Jung and Ahn.^{45,46} We estimated power to detect a treatment effect for normally distributed, poisson-distributed, and dichotomous outcomes. For each aim, power was calculated assuming a 15% rate of attrition (over 9 months), a type I error rate of .05 and a two-tailed test. For aim 1, the resident sample will provide 80% power to detect a 20% difference due to intervention in the fall rate, and an 11% difference in the probability of a recurrent fall. For aim 2, we will have 80% power to detect 10% differences in the risk factor assessment and intervention scores. For the continuous outcomes in aim 3, we will have 80% power to detect standardized differences of .21, a magnitude considered "small" in the statistical literature.⁴⁷ As we have a single primary outcome (fall rate), and several additional outcomes which are exploratory, we do not adjust our significance tests for multiple tests.

Focus group analysis. Focus group data will be transcribed verbatim and transcripts will be linked to the nursing home by a random number to blind the research team to the nursing home identify. It will not be possible to blind the team to intervention group because the staff's comments will reveal the intervention experience. To ensure rigor in the research method, each transcript will be read by all researcher team members and coded by at least 2 team members to identify common themes regarding staff's perceptions about the impact of the interventions in fostering organizational learning. The full team will review the coded data to discuss and resolve any substantive differences in the themes identified. Next we will construct a conceptual-thematic description of the use of social constructivist learning in each nursing home; this type of analysis allows the observed phenomenon to be reframed based on existing theory. Cross-case comparison will be used to identify differences between nursing homes, and develop insights about the impact of the interventions on organizational learning. As a further check on researcher bias the full team will evaluate the themes and conclusions to address: 1) Are findings consistent with the data?; 2) Are inferences logical? (Are analytic strategies applied correctly? Are alternative explanations considered?); 3) Are the thematic structures and condensed meanings appropriate?; 4) Were there shifts in methods and, if so, are they justified?; 5) What is the degree of researcher bias (e.g., premature closure, unexplored data, lack of search for negative examples)? Any questions raised about the reliability or validity of the themes or conclusions will be reviewed by the team and if appropriate, codes and theme comparisons will be revisited and revised.

14. Data & Safety monitoring –

We plan several quality controls to both maintain the scientific integrity as well as ensure the safety of participants. We will submit a detailed data and safety monitoring plan to the IRB and to the NIH for approval prior to implementation.

Oversight for this study will be provided by the PIs with delegation of responsibilities to designated study personnel. They will ensure all entry criteria are met prior to the initiation of the protocol and all study procedures and reporting of adverse events are performed according to the IRB-approved protocol. Any actions taken and associated follow-up activities will be recorded in the study database and will be discussed at the project team meetings that will include research staff from both Duke and CCME allowing for communication of safety issues to all investigators. All intervention-related adverse events occurring at in the nursing home sites will be reported by the PIs to members of the research team (both at Duke and CCME) and the IRB within 3-7 days. The PIs will assess the level of risk from adverse events as mild (no interference in usual activities); moderate (some interference in usual activities); or severe (usual activities were significantly interrupted). The PIs will rate the assessment of attribution to the study as not related, unlikely, possible, probable, or definite.

Potential Adverse Events. Categories of adverse events in this randomized trial of a behavioral intervention are expected to be limited to: 1) breach of confidentiality of subject responses on questionnaires; 2) accidents or injuries to staff occurring during study activities; and 3) unexpected worsening in falls rates or quality indicators in the study facilities.

Breach of Confidentiality of Staff Responses: Staff will be provided with the PIs' contact information during the informed consent process and encouraged to contact the investigators or other study staff if they feel that their participation has adversely impacted their work environment or employment. Any reports of staff concerns will be reported to the PIs immediately. They will contact the subject for additional information if possible. The PIs and subject will mutually determine who else should be involved in resolving the concern, potentially including (but not limited to) the Safety Officer. Once additional information from the subject has been obtained, or if the subject complaint was anonymous or the subject cannot be reached, the PI will convene a conference with the relevant study staff, and the Safety Officer who will review the available information, and determine the next course of action. These may include gathering additional information, temporarily suspending study activities, revising the data collection or storage process. The complaint and its resolution will be reported to the subject (if appropriate), Institutional Review Board and the NIH program officer within 3-7 business days.

Accidents or Injuries Occurring During Study Activities: Study activities involve classroom training, web-modules, and unit-based mentoring during usual work activities. Because the intervention is incorporated into usual employment activities, any accidents or injuries are expected to be unrelated to the study intervention itself. Nevertheless, study staff will assist the staff member in obtaining appropriate medical attention, and immediately report the incident to Dr. Colón-Emeric (PI) or Dr. Anderson (PI), who will record it in an adverse event log and report it to the Safety Officer. If the injury meets the FDA definition of a severe adverse event and can be attributed to the study, it will be reported immediately to the Institutional Review Board and the NIH program officer will be notified within 1 business day.

Unexpected worsening of Falls Rates or Process Measures in Study Facilities: Although the FALLS intervention is the current standard of care for improving falls quality of care in nursing homes, it is possible that process measures or fall rates may worsen after the intervention. Because data collection does not occur until after the intervention is completed in all facilities, there is no plan for an interim analysis of the outcomes data. The site Medical Director and Director of Nursing will be provided with audit and feedback information about their facility's falls rates before and after the intervention, to use in their internal quality assurance programs. The Safety Officer will review all falls data before it is reported to research sites.

Safety Officer: We will appoint a Safety Officer with both clinical and interventions research expertise to serve as the study Safety Officer. The Safety Officer will be independent from the present study design or implementation. The Safety Officer will review the protocol, intervention components, and all data collection processes prior to study implementation. The Safety Officer will review the all reports of adverse events quarterly and when necessary, make recommendations to the PIs concerning continuation, termination or modification of any study protocol/ procedure based on observed beneficial or adverse effects.

We will submit annual reports to the Duke IRB that will contain:

1. The number of adverse events and an explanation of how each event was handled
2. The number of complaints and how each complaint was handled
3. The number of subject withdrawals and an explanation of why the subject withdrew or was withdrawn
4. The number of protocol violations and how each was handled.

15. Data storage & confidentiality

Explain how you will ensure that the subject's privacy will be protected:

Risks to residents will be minimized by study procedures that safeguard privacy as discussed in 14 below. Resident demographic and medical information are entered directly onto password-protected laptop computers, with only a subject study number as an identifier. These data will be transferred to the School of Nursing's secure server daily and deleted from the lap-top. The key linking residents' PHI to their data will be kept in a separate file on a secure server, and destroyed at the conclusion of the study. Reports of the data will appear only in aggregate form.

Risks to nursing home staff will be minimized by procedures that protect confidentiality of individual respondents and their responses in survey questionnaires. Data will be protected by using codes. Codes will be used to identify the nursing home and all individual subjects. All keys that link codes to the nursing homes or individual respondents will be kept in a secure file to which only the PI, project director, and database manager will have access. Participants will be assured that all data will be used only for the purposes of the study. Reports of the data will appear only in aggregate form.

Describe how research data will be stored and secured to ensure confidentiality:

Data will be protected by using codes. Codes will be used to identify the nursing home and all individual subjects. While data collectors are in the nursing home, any previously completed surveys for data collection forms will be kept in a secure place, such as the trunk of a car, until they can be delivered to the research office for data entry where they will be kept in a locked file cabinet. No names will be used on completed data collection forms. All keys that link codes to the nursing homes or individual respondents will be kept in a secure file to which only the PI, project director, and database manager will have access. Participants will be assured that all data will be used only for the purposes of the study. Reports of the data will appear only in aggregate form. We anticipate that these procedures will be effective because using similar procedures we had no breach of confidentiality in two prior R01s involving in total over 5000 participants.

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2. SPECIFIC AIMS

Efficacy trials¹ have shown that care to reduce fall risk factors delivered by specially-hired external study-staff lowers fall rates, recurrent falls, and injurious falls in nursing home (NH) residents.²⁻⁵ However, prior attempts to move fall risk factor reduction into everyday practice by in-house staff have not been successful.⁶⁻¹⁰ Quality Improvement (QI) interventions^{11, 12} are the current gold standard for introducing evidence-based care into nursing homes. These QI interventions provide the content for reducing falls but do not ensure that the processes needed to successfully implement fall reduction strategies are in place.¹³ A particular barrier for QI programs is that they do not fully address staff interdependencies inherent in care for falls or other geriatric syndromes. These syndromes by definition result from multiple risk factors and require multifactorial, interdisciplinary interventions to improve outcomes.¹⁴ For example, falls efficacy trials have intervened on gait, incontinence, sensory impairment, cognitive impairment, psychoactive medications, orthostasis, toileting, and environmental factors.¹⁴ Reducing multiple risk factors may be difficult because it requires many staff members to have strong connections that permit effective information flow and problem-solving from varied perspectives. Thus, an intervention is needed to address implementation processes. Such an intervention would help nursing home staff establish relationship networks and communication channels to support the learning and behavior changes required to implement new practices introduced by QI programs.

Complexity science provides useful insights for addressing barriers to effective staff interdependence. It suggests that nursing management practices (NMPs) that facilitate self-organization are most likely to enhance a NH's ability to achieve effective interdependence and high quality outcomes.¹⁵⁻¹⁸ Through self-organization, staff interact and mutually adjust their behaviors using what they learn from each other to cope with changing care and environmental demands.¹⁶ Relationship-oriented nursing management practices (NMPs)^{11, 16, 19} such as open communication, participation in decision-making and teamwork result in better resident outcomes, possibly through better staff connections and information flow.^{16, 20-25} Our recent case-studies identified additional NMPs associated with enhanced staff connections, and these NMPs are particularly suited to foster the effective interdependence needed to care for people with geriatric syndromes such as falls. Staff at all levels used these NMPs, but only erratically. Therefore, an intervention that fosters systematic use of these relationship-oriented NMPs would facilitate more effective interdependence by creating networks and communication channels for learning together, exchanging care information, and problem solving. Based on complexity science^{26, 27} and our prior research,^{7, 15, 18, 28-35} we have developed the CONNECT intervention which we propose will create the foundation (processes) for staff to effectively implement QI interventions (content) to reduce falls, through more effective self-organization.

CONNECT is a multi-component intervention that helps staff to: 1) learn new strategies to improve day-to-day interactions; 2) establish relationship networks for creative problem solving; and 3) sustain newly acquired interaction behaviors through mentorship. Complexity science and empirical research suggest that interaction patterns determine information flow, knowledge transfer, and capacity to monitor behaviors in health care settings.^{15, 17, 24, 36} In a preliminary test of CONNECT, we found support for the hypothesis that the intervention would improve staff interactions and reduce falls (see progress report). We propose that CONNECT, when combined with a content focused falls QI program (FALLS), will result in better resident outcomes when compared to FALLS alone. We chose falls for this test of CONNECT because: 1) falls rates are high in NHs,^{37, 38} 2) accepted practice guidelines and fall prevention programs exist³⁹⁻⁴², and 3) there is ample evidence from efficacy trials that multi-factorial risk reduction interventions reduce fall rates.^{3-5, 13, 43}

The **specific aims** of this longitudinal, two arm, randomized intervention study are to:

Aim 1: In nursing homes, compare the impact of the CONNECT intervention plus a fall reduction QI intervention (CONNECT+FALLS) to a fall reduction QI intervention alone (FALLS) on fall risk factor reduction indicators (orthostatic blood pressure, sensory impairment, footwear appropriateness, gait, physical therapy, toileting, environmental modifications, vitamin D, and psychotropic medication reduction).

Aim 2: In nursing homes, compare the impact of CONNECT+FALLS to FALLS alone on fall rates and injurious falls, and determine whether these are mediated by the change in fall risk factor reduction indicators.

Aim 3: Compare the impact of CONNECT+FALLS to FALLS alone on complexity science measures (communication, NA participation in decision making, local interaction strategies, safety climate, and staff perceptions of quality) and determine whether these mediate the impact on fall risk factor reduction indicators, fall rates, and injurious falls.

CONNECT is an approach to enhance the NH staff's ability to integrate multi-factorial fall risk factor reduction into practice because it helps them establish processes for effective interdependence and learning. Our preliminary work shows that CONNECT is feasible and effective in improving staff interactions and quality of care. Since CONNECT changes processes at a system level, it may be used to implement evidence-based practices for other complex clinical problems such as pain, pressure ulcers, dementia behaviors, or functional decline.

3. RESEARCH STRATEGY

3.a. SIGNIFICANCE

Improving resident outcomes in NHs remains a national priority. While effective practices are known from efficacy trials, there is a lack of knowledge about how NH staff can implement these practices.^{2-5, 13} CMS contracts with quality improvement organizations (QIOs) to implement QI programs, including QI Collaboratives, educational programs, and toolkits to reduce geriatric syndromes such as falls, pressure ulcers, incontinence, pain, delirium, and depression.⁴⁴⁻⁴⁶ Unfortunately, such efforts have not resulted in the expected improvements.^{6, 7, 9, 47} Complexity science suggests that a major barrier to the effectiveness of QI programs is their content focus; they do not impact the processes needed to actually implement practice change. This study is significant because it will test a novel intervention (CONNECT) that is designed to develop processes for effective interdependence by creating relationship networks and channels of communication for learning together, exchanging information, and problem solving. We expect that CONNECT will create the foundation needed for NH staff to implement content learned in QI programs such as FALLS. Thus, CONNECT has the potential to have a broad and far-reaching impact on QI efforts nationally, and influence care for multiple geriatric syndromes.

Of further significance, this study uses existing staff and resources to improve resident care. Several randomized trials have shown the efficacy of fall risk factor reduction in reducing fall rates, recurrent falls, and injurious falls in NHs.²⁻⁵ However, these studies used external study staff to provide fall risk factor reduction; having dedicated study staff does not address the underlying interdependencies among NH staff who actually deliver care day to day. For example, our previous work demonstrated that fall risk reduction tasks that could be completed by a single staff member were far more likely to improve than tasks that required collaboration among multiple staff members.⁷ CONNECT, which targets local interactions among staff, strengthens these interdependencies, and also addresses other common barriers to interdisciplinary problem-solving such as omitting Licensed Practical Nurses (LPNs) and Nurse Aids (NAs) from decision-making,^{30, 31, 48} poor communication between provider groups,⁴⁹ and over-reliance on hierarchical management.^{24, 30, 50-52} CONNECT, if successful, thus has the potential to be generalizable to real-world NH settings without the need for additional staffing.

Figure 3.a.1. Complex Adaptive System Parameters and Related Nursing Management Practices

System Parameters with Local Interaction Strategies
1. Information exchange: rate of new information flow through the system
Related Local Interaction Strategies
<ul style="list-style-type: none">• Listen• Give information• Receive information• Explain• Verify meaning
2. Connection: nature of interconnections between staff members
Related Local Interaction Strategies
<ul style="list-style-type: none">• Be approachable• Pitch in• Seek assistance• Reciprocate• Show appreciation• Give respect• Say thank you• Give praise• Coach/Mentor
3. Cognitive diversity: level of diversity within and between cognitive schema of staff
Related Local Interaction Strategies
<ul style="list-style-type: none">• Pay attention & act• Ask questions• Give feedback• Receive feedback• Suggest alternatives• Sensemaking

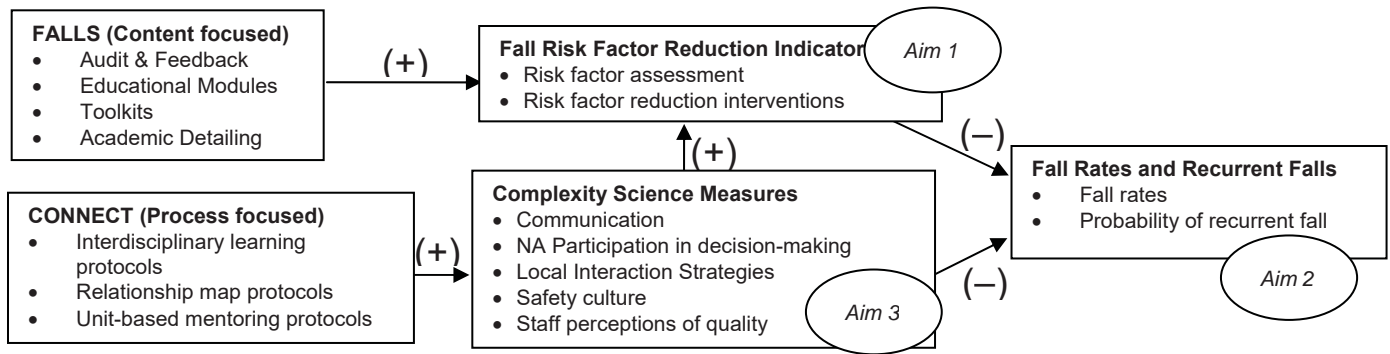
Further, this study is significant because it puts the tools of change into the hands of direct care staff. CONNECT will establish networks for new information about fall risk factor reduction to spread throughout the NH. These networks are critical because NAs provide 80% to 90% of the hands-on care to residents⁵³ and they often are the first to observe early signs of fall risk.⁵⁴ Yet NAs frequently lack the interactions with the multi-disciplinary team needed to intervene effectively.^{31, 55-57} CONNECT will create opportunities for more rapid information exchange and problem-solving among multiple disciplines, and will increase the likelihood that the NA will carry out appropriate fall prevention care. In our prior work,^{15-18, 24, 28-31, 33, 34, 58} we found that both managers and staff can use these NMPs to influence self organization and produce better quality of care. In CONNECT, staff will learn to consider three system parameters²⁷ derived from the theory of complex adaptive systems²⁷ to guide their use of NMPs. These relationship-oriented NMPs are collectively called local interaction strategies (Figure 3.a. 1). The system parameters are information exchange, connection between staff members, and cognitive diversity. When staff use the NMPs, they create and recreate meaning of events, change beliefs, foster creativity, and promote reflection on their performance.^{26, 27} For example, when staff members interact they *exchange information*, which generates new understanding and knowledge.⁵⁹⁻⁶¹ With this knowledge, staff learn, change their behaviors,⁶² and become capable of something new. When staff interact, they develop networks.⁶³ These new networks of *connections* allow local changes in behavior to result in system-wide change.⁶⁴ Finally, *cognitive diversity*, the use of multiple perspectives to make sense of information,^{28, 65} arises from interaction among people. The more diverse the individuals (e.g., varying roles, education, social or cultural backgrounds, age cohorts,⁶⁶ and external collaborations⁶⁷) the richer the interpretation of data, the more appropriate the decision making, and the more effective the action planning.^{68, 69} We propose that systematic use of these NMPs to

create relationship networks and channels of communication for learning together, exchanging information,

and problem solving, is a prerequisite to the ability to effectively implement a fall reduction program. Based on complexity science theory, if we achieve expected changes in staff interactions, we will observe changes in measures of communication, participation in decision-making, safety culture, and perceptions of quality (Figure 3.a.2.). These measures in turn are expected to be related to more effective fall risk factor reduction strategies, and thereby to lower fall rates, recurrent falls, and injurious falls.

CONNECT is expected to work in combination with QI programs because CONNECT creates the NH processes for group learning and implementation of evidence based content introduced by the QI program. FALLS will include content on evidence based practices found to reduce falls in efficacy trials.^{2, 4} Modifiable fall risk factors suggested by clinical practice guidelines and AHRQ's fall management program are: 1) orthostatic

Figure 3.a.2. Proposed Relationship between the FALLS and CONNECT Interventions and Outcomes



hypotension;^{70, 71} 2) sensory impairment;^{72, 73} 3) footwear; 4) gait and assistive devices;^{4, 74} 5) toileting needs;⁷⁵ 6) environmental problems;⁷⁶ 64, 65 7) fall-related medications.^{77, 78 79} and 8) Vitamin D.⁸⁰⁻⁸² CONNECT is an important companion for QI interventions such as FALLS because it creates relationship networks and communication channels for learning, information exchange, and problem solving.

In summary, the proposed study uses in-house staff and resources to improve resident care, and thus it is generalizable to real-world NHs. CONNECT will allow learning about fall risk factor reduction to spread throughout the NH because it creates opportunities for more rapid information exchange and problem-solving. This increases the likelihood of practice change by all levels of staff that carry out fall prevention interventions. CONNECT puts the tools of change into the hands of both managers and staff; using local interaction strategies, staff and managers learn together to create the desired behaviors for better outcomes. Because CONNECT embeds networks for information exchange and learning, it can enhance the effectiveness of evidence-based QI interventions for a broad array of geriatric syndromes. Thus, this study has the potential for a far-reaching impact on QI efforts nationally, and will have implications for policy makers, NH administrators, and providers.

3.B. INNOVATION

Our use of complexity theory of self-organization in developing an intervention to enhance nursing home care effectiveness is highly innovative. Although other researchers have recognized that NHs are complex adaptive systems in which self-organization is of central importance, to our knowledge there have been no interventions tested which target this process. This point is significant because local interaction among staff is the engine of self-organization. If self-organization is fueled by a strong network of relationships, rapid information exchange, and use of diverse perspectives, then staff will generate more effective behaviors than in NHs where self organization is fueled by poor relationships, little information exchange and lack of cognitive diversity. Further, targeting the CONNECT intervention at the systems level is an innovative approach to improving nursing home care, because improvements in effective self-organization have the potential to result in better care for a wide range of common medical and psychosocial problems in NH residents. Our study design will allow us to determine which system parameter changes are associated with improved fall care processes and outcomes, and therefore will add substantial information to both complexity theory and implementation science in nursing homes.

Finally, our approaches to delivering CONNECT address common issues in NH training methods, increasing the likelihood of sustained behavior change. For example, CONNECT was developed using the language and stories of NH staff obtained from our prior research (2 RO1 NR03178-04). CONNECT includes NMPs that are used, albeit to a limited extent, by all levels of nursing home staff, thus making the new behaviors of the intervention familiar and readily accessible.

3.C. APPROACH

3.C.1. PROGRESS REPORT Outcomes of Nurse Management Practice in Nursing Homes (LAST REVIEWED 6/02/2009; NEW FUNDING 56NR003178, PIs Anderson/Colón-Emeric, 09/01/09-08-31/10; NCE through

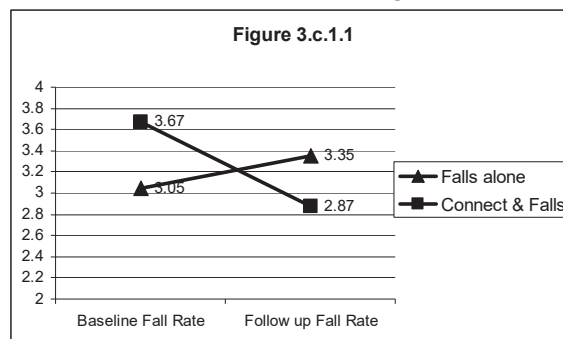
We report the progress of the R56 in combination with a parallel study (VA HSR&D EDU 08-417, PI Colón-Emeric, CONNECT for Better Falls Prevention in VA Community Living Centers) that uses identical study protocols and measures, collecting data in Veterans Affairs NHs. The aims differ in that they are focused on testing the educational approaches. Because this parallel study has a different timeline, it has been completed in only one VA site, which was randomized to CONNECT+FALLS. Data from this VA site are included below.

Aims: The R56 is a randomized, controlled study testing whether NHs receiving CONNECT plus FALLS will have greater improvements in: 1) fall risk factor reduction measures; 2) fall rates; and 3) staff complexity science measures compared to NHs receiving FALLS alone.

Sample: The sample includes 2 matched pairs (n=4) of NHs randomized to CONNECT+FALLS or FALLS alone. Four R56 NHs and 1 VA NH have completed the intervention. Thus the data reported here include 5 sites (3 CONNECT+ FALLS and 2 FALLS alone). NHs were randomized in matched pairs based on chain ownership (community) or academic affiliation (VA). Measurement was performed as indicated in tables 3.c.2.5 and 6. The Carolinas Center for Medical Excellence (CCME) recruited the four community facilities using the methods proposed in section 3.c.2. Within one week we enrolled four sites with an additional NH on a waiting list. In the 4 R56 NHs, 326 staff members were invited and 80-84% completed surveys.

Interventions: Interventions (described in Tables 3.c.2.1 and 3.c.2.2) were readily accepted by staff and administrators, with no participants withdrawing, other than those that left employment. No concerns were raised about interfering with resident care or work regulations. Interventionists delivered the protocol elements with over 96% adherence for each protocol in both CONNECT and FALLS. Of consented nursing staff, 81% participated in one or more CONNECT intervention component.

Findings: Data collection is ongoing, but preliminary data addressing Aims 2 and 3 provide strong support for the effectiveness of the intervention. For Aim 2, we have compared the impact of CONNECT+FALLS to FALLS alone on facility fall rates. Three months of fall rate follow-up data have accrued in FALLS only NHs following the completion of the FALLS intervention, and were compared to 3 months of fall rate data in CONNECT+FALLS NHs (the last 2 months during the FALLS intervention plus 1 month following the completion of the intervention). Although the measurement periods in relation to



the intervention were not identical, this would tend to bias against finding a fall rate reduction in CONNECT+FALLS facilities because they had not yet completed the full FALLS intervention. Despite this bias, fall rate trends suggest that CONNECT+FALLS has led to a greater reduction in fall rates than FALLS alone (Figure 3.c.1.1). Because we will not have follow up fall risk reduction indicators for several months, we cannot fully test Aim1; however, baseline fall risk reduction indicators (Table 3.c.1.1)

Table 3.c.1.1. Baseline Fall Risk Reduction Indicators and Fall Rates in 5 Completed Nursing homes

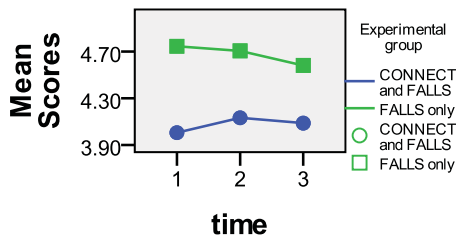
ID	Percent of Fallers with Documented Activity in 6 month period									Fall Rates	
	Ortho Vital	Vision Eval	PT Eval	Toileting Program	Any Env Change	Psych Med Change	Calcium + Vit D	Hip Protecto r	Baseline Falls/bed/ year	Follow-up Falls/bed/ year	
1	3	66	71	57	100	10	37	4	3.1	2.0	
2	23	100	46	6	71	56	49	0	4.5	3.6	
3	3	97	30	40	86	55	43	0	3.0	4.7	
4	3	100	22	25	31	0	49	3	2.0	1.5	
5	2	64	61	36	89	32	11	8	4.5	3.5	

Ortho Vital=Orthostatic Vital Signs; Eval=Evaluation; PT=Physical Therapy; Env=Environmental; Psych Med=Psychotropic Medication; Vit D=Vitamin D

showed variability with no evidence of a ceiling effect. Interrater agreement for all falls risk reduction indicators (measured by chart abstraction) exceeded 90%.

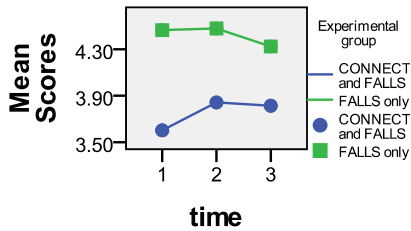
To partially explore aim 3, we compared the impact of CONNECT+FALLS to FALLS alone on complexity science measures. To avoid multiple comparisons, we used factor analysis to test whether it was reasonable to combine the complexity measure scores (communication openness, accuracy, timeliness, participation in decision making, relational coordination, psychosocial safety, safety culture, perceived quality of care). The factor analysis produced one strong factor, indicating that we could combine the scores. At measurement time points 2 and 3, we added a new measure of local interaction strategies (see methods section 3.c.2 for psychometrics). We evaluated the data using repeated measures analysis of variance (RM-ANOVA), rather than the proposed analysis because we do not yet have complete data and we have only 5 sites. Because RM-ANOVA is longitudinal, this is a more conservative test; thus, if we find an effect with RM-ANOVA with low power, we will likely have significant findings in the larger study. Comparing data at 3 time points, there was a trend toward a group by time effect for the combined set of complexity science measures (p=.16)

Figure 3.c.1.2. Complexity Science Measures (all combined)



(Figure 3.c.1.2). We explored the data further by creating a combined score for scales that individually demonstrated differences between groups over time (communication openness, accuracy, timeliness, CNA participation, safety climate, perceptions of care giving quality, and local interaction strategies), and found a strong group by time effect ($p=.01$) (Figure 3.c.1.3). In the CONNECT +FALLS group we saw improvement in the subset of complexity science measures that was sustained through the 6 month measure (Figure 3.c.1.3). The FALLS only group showed no improvement at 3 months, and decreased at 6 months. These statistically significant differences are evidence that CONNECT is having an important system-wide effect, even though not all staff who completed surveys directly participated in CONNECT. It also confirms that our sample size is adequate to measure a meaningful change.

Figure 3.c.1.3 Subset of Complexity Science Measures



Focus Groups. To further evaluate the intervention, we conducted two focus groups with participants in each of the four R56 sites. Focus group goals were to gather participants' descriptions of what and how they learned about fall prevention in the intervention. Focus groups were recorded, transcribed verbatim, and then verified for accuracy. Data were analyzed by 4 research team members who first read through all of the transcripts. One team member created a matrix with all of the quotations associated with each focus group question and then reduced the number of quotations to reflect the predominant ideas expressed by

participants. The other 3 researchers then verified that the reduced table (Table 3.c.1.2) reflected the important participant comments.

Focus group findings. Both groups expressed that the FALLS QI content was familiar, reminded them about what to watch for to prevent falls, and helped them pay better attention and engage in teamwork. However, the data reveal some important differences between the groups. The CONNECT groups mentioned that CONNECT & Learn and mapping sessions helped them identify and correct communication weaknesses. The CONNECT groups described deeper, more complex relationships among staff following the intervention, and believed that these relationships helped them more effectively manage falls. The CONNECT groups described additional aspects in which they perceived that they had improved. They described talking more openly and in more depth about a resident who had falls. They reported improved understanding about the roles of various disciplines and what each contributes to fall prevention. They noted improved job attitudes such as more cooperation with other staff and "less stress and drama" on the units. NAs reported a greater willingness to stick to interventions such as toileting programs. Finally, they reported paying attention and responding quickly to fall hazards, and being willing to go directly to anyone (housekeeper, administrator) who needs information or who may be able to help prevent falls. One CONNECT participant stated that "with the two, the CONNECT and the FALLS portion of it; they seemed to connect themselves, so [there was no] gap... It all flowed together, so it helped us to understand and learn better." Participants also mentioned that the intervention would be helpful for learning about other topics, such as behavior problems. Participants at one site suggested that administrators should make CONNECT & Learn sessions mandatory.

Table 3.c.1.2. Focus Group Comments by Intervention Participants

Question	FALLS Only Sites (n=21)	CONNECT & FALLS Sites (n=16)
What did you learn other about preventing falls?	<ul style="list-style-type: none"> Getting information out to staff. A lot of the interventions we already had in place, but following up to make sure we were using them correctly. Working as a team to prevent falls. Shift to shift [report] to come up with an idea and make sure that it is followed by the whole crew. 	<ul style="list-style-type: none"> We need to think ahead, anticipate so that we can prevent falls. I find that a lot of staff talk a lot more in depth about needs of patients and they tend to understand where each other is coming from since this [intervention]. We've seen an improvement in attitude as far as if you ask them to do something or if they ask you to do something; they're more thoughtful of each other. I think one of the important things I learned is that it's important to see how each discipline connects directly with care because you get another piece of the puzzle. [We] learned as a group. We would all get together, everybody with different ideas.
Were you encouraged to discuss how to prevent falls with staff and each other?	<ul style="list-style-type: none"> When we have pretty much tried all the interventions and we need to come together as a team to discuss something else to do. It puts you more on alert and it helped us communicate better with each other about residents. There were a lot of staff that only know their residents but now it's like they are all our residents. 	<ul style="list-style-type: none"> One of the biggest points is that we really talk more about [falls] in depth, is there a specific time? Is there a specific place? What can we do to change it? You got us to look at the whole picture; as a group, not as an individual. Just try to make the whole facility aware. Even the housekeeper. The main difference is the communication that I've seen improve since this, I mean, it has been a huge help. It's taken a lot of stress off the hall and drama because it's hard to prevent falls when you're dealing with attitudes and if everyone respects each other's position, it's been helpful. It's like we're more willing to stick to toilet programs and things now that we've been able to communicate and it's not like I'm bossing you around.
Were	<ul style="list-style-type: none"> You took a variety of staff; you took 	<ul style="list-style-type: none"> I think there's been a more openness to realizing the skill of each department.

diverse opinions valued?	<p>CNAs, home makers, dietary aides...not just nurses.</p> <ul style="list-style-type: none"> • Me being a CNA I felt like now... I could go to my nurse and say hey I really think Jane Doe needs to be up here closer to the nurse's station. 	<ul style="list-style-type: none"> • Well, I don't mind grabbing anybody from an administrator on down to anybody if I have a problem and there's no shame. I grab them and tell them what I need. • Before, I think it was [my own] responsibility to do this, but now, it's all teamwork; ... That has really taken an effect, every department. • We did the mapping and things and realized that there was a lack of communication between us and administration or us and NAs on different departments.
What new expectations for talking and working with peers did you learn?	<ul style="list-style-type: none"> • It was good to hear but we're pretty good at preventing falls. • I learned that it was about care of residents. You have to step up.... It doesn't really matter who's in charge. 	<ul style="list-style-type: none"> • We've become more open with each other and understand each other more; the interventions we do with the residents [are] more effective because now we communicate and understand each person's abilities better. • You can go to anybody if you have a concern for a resident. You can go to housekeeping and say, well, keep an eye on so and so or if you see anything, let me know and vice versa. And we report back, well, this is what's going on. And they respond too.
In what ways did your understanding of managing falls change during the project?	<ul style="list-style-type: none"> • I [already] knew [the interventions], but I didn't automatically go and look. • Now that everybody is aware of the falls committee, it's not just one group of people, it's everybody. • I think the communication between the CNAs from shift to shift [is better]. • The biggest positive thing I gained is that it is not about who to blame. 	<ul style="list-style-type: none"> • If I see a floor mat and it's not on the floor, I want to know why. I'll pay attention. • Truly; I think one of the things that we weren't open to, as much [is that] it doesn't take just one discipline [to] help the resident. • So, it's taught me to look for different things and kind of recognize different things from what I hear and I give a report to my NAs, so they know what's going on. • People have become accountable for the residents. It doesn't matter if you work in the kitchen or if you work outside on the grounds or whatever. We have an eye, you're trained to just pay attention to little things and pass it along.

Based on preliminary results we made several changes to the proposed study that were tested and found feasible in the R56. We adapted CONNECT & Learn sessions to be delivered at nursing stations during evening/night shift, so as not to remove staff from the care environment when staffing is lighter. We developed a "mini" CONNECT & Learn session that can be delivered in 15 minutes to people who cannot participate in the formal class for logistical reasons. We combined the two individual mapping sessions into one 30 minute session using paper and pencil for self-reporting. We revised the in-house facilitator protocol to separate the mentoring role, which can be assumed by a wide range of staff, from the role of delivering CONNECT & Learn to new staff during orientation. These protocol revisions increase transportability and flexibility. We eliminated the 1-800-CALL CONNECT protocol because we only received two calls in the study. Participants brought issues directly to the Research Interventionists because they were frequently present in the NH. Based on preliminary results for complexity science measures, we eliminated three measures (LPN participation in decision making, relational coordination, and psychological safety), and we will add two new measures, perceptions of caregiving quality and the local interaction measure, both of which were sensitive to change. This creates a net reduction of 62 survey items, reducing respondent burden. We added a 9-month data collection time-point for the complexity science measures to assess sustainability better. We will vary the order of the measures in the survey at each time-point to reduce potential boredom for staff. Finally, we are using multiple, cross-sectional samples of resident fallers to measure fall risk reduction indicators, rather than following a cohort of residents longitudinally, thus eliminating the need for resident consent.

In summary, we demonstrated that both CONNECT and FALLS are feasible and acceptable to NH staff. The results provide evidence that the proposed, larger study will demonstrate significant results and contribute important knowledge to the fields of nursing, geriatrics, and complexity science.

3.c.2. RESEARCH DESIGN AND METHODS

OVERVIEW. Sixteen NHs will be randomized to either CONNECT followed by FALLS, or to FALLS alone. The CONNECT intervention focuses on helping staff incorporate connections, information flow, and problem solving into day-to-day work. It is delivered before FALLS because it is theorized to create processes for group learning and implementation of evidence based content introduced by the QI program. The FALLS intervention will simulate real-world quality improvement (QI) interventions, the current gold standard. Data from the complexity science measures will be collected at baseline, 3 months, 6 months, and 9 months to evaluate the immediate and sustained impact of CONNECT on staff interactions. Falls risk reduction indicators and fall rates will be collected for the 6 months prior to baseline and the 6 months after the intervention period.

SAMPLE AND SETTING

NH Recruitment and Randomization. A sample of NHs will be drawn from 69 NHs in North Carolina (NC) that participate in Medicare and Medicaid and are within 100 miles of Duke. Nursing Home compare data⁸³ show that NHs in the sampling pool are not substantially different from national averages. The NC Quality Improvement Organization, the Carolinas Center for Medical Excellence (CCME), will recruit for our study. They successfully recruited 38 NHs in the PI's previous QI study⁸⁴ and 4 NHs in the R56 study. Because of the delay between proposal and funding and the need for matched pairs, we have not yet recruited NHs. However, based on our prior NH recruitment experience, including the R56 pilot of the proposed study, we do not anticipate recruitment delays. Because chain-affiliation relates to care quality,^{85, 86} we will block randomize to ensure equal balance for potential confounders such as corporate policies. Eligible NHs will be contacted in random order by CCME until 16 agree to participate. Because participation is voluntary, there is unavoidable

potential for participation bias. To assess for this, we will compare participating and refusing nursing homes using available data such as size, ownership, and nursing staffing. To avoid long delays between recruitment and participation, we will recruit in 2 waves. An investigator blinded to NH name and characteristics will randomize recruited NHs into study groups using a random number generator.

RESIDENT SAMPLE. Eligibility criteria include: 1) ≥ 65 years of age; 2) sustained a fall as defined by Minimum Data Set (MDS) criteria in the study period; and 3) remained in the facility for at least 30 days after the fall event. This sampling strategy will allow us to measure fall risk factor reduction activities completed by the NH staff for their highest risk residents (i.e., known fallers). Previous studies suggest a fall rate of 1.5 falls/bed-year, of which 40% are recurrent fallers.^{37, 87} Of the approximately 1600 residents in the study NHs, we estimate a resident pool of n=1440 unique fallers which exceeds our needed resident sample size of 800. Lists of residents who have fallen during the study period will be generated from the facility MDS and incident reports. A random sample of 50 unique residents from each facility will be selected for chart abstraction using a random number generator. Because this is a minimal risk study in which residents are not followed prospectively, we have obtained a waiver of informed consent.

STAFF SAMPLE. Staff members who work with residents in a clinical capacity (e.g., RNs, LPNs, NAs, social workers, dietary, activities, physical and occupational therapists) on skilled and assisted living units will be eligible to participate. The only exclusion criterion is inability to understand English. Using current staff lists provided by the Administrator, we will invite staff to participate. In our pilot studies, 80-84% of staff participated in survey completion and the CONNECT and FALLS intervention.^{88,158-89} Thus, we conservatively estimate that of about 960 staff members, 60% will participate in training and complete surveys for an estimated enrollment of 576 staff members. New employees will be invited to participate in CONNECT up to the fourth week of the intervention. Those joining later will be invited to enroll only to complete the cross-sectional staff interaction measures. Based on data from the 2000 U.S. Census, we project that staff racial composition will be 57% white, 39% African American, and 3% other races.⁹⁰ Our pilot studies included 34% underrepresented minority participants.

RISKS AND CHALLENGES

A major challenge for NH research is the potential for staff turnover. Using a successful strategy from our prior studies, we will secure a written commitment from the NH administrator, director of nursing, and if relevant, a corporate representative, that the study will continue even if one or more top administrators leave. We also have designed this study to be robust to staff turnover by incorporating the CONNECT in-class learning sessions into the NH’s orientation for new staff. Exploratory analyses will determine whether staff turnover affects the fall-related processes or fall rate measures. Another challenge for NH research is designing approaches that are appropriate and acceptable for all levels of staff, regardless of education and socio-economic background. We use storytelling, which is an efficient yet high-impact method of conveying information, infused with relevant NH cultural norms, values, and beliefs⁹¹. Because storytelling and role play are based on descriptive verse, they may attenuate learning barriers associated with low literacy and English as a second language.⁹²

THE INTERVENTIONS

CONNECT will be implemented over 12 weeks, followed by FALLS for an additional 12 weeks. CONNECT components, rationale, participants, and times required are detailed in Table 3.c.2.1. The complete CONNECT protocols are contained in Appendix 1. The FALLS intervention is a modification of interventions previously tested by the PI^{7, 84} and is based on the Falls Management Program developed by the Agency for Healthcare Research and Quality (Appendix 2A)^{74, 93, 94}. The intervention components, rationale, participants, and time required for FALLS are in Table 3.c.2.2., and the complete protocols are in Appendix 2B-F.

Table 3.c.2.1. CONNECT Protocol Activities, Rationale, Who is Involved and Time Required

CONNECT Protocols	Rationale/Outcome	Who	Time
Learning Protocols			
(1) CONNECT & Learn Protocols <u>CONNECT Basics (Session 1).</u> Introduces local interaction strategies using storytelling and practice using role-play in context of falls prevention. <u>CONNECT Advanced (Session 2).</u> Brief review followed by focus on the more advanced strategies of cognitive diversity, using storytelling, role-playing, and discussion of participants’ experiences in applying concepts.	Interdisciplinary learning facilitates skill acquisition, creation of new horizontal and vertical connections among staff, and learning through cognitive diversity.	RNs, LPNs, NAs, social work, activities, rehab, MD, NP; dietary, administration	2, 30 min sessions occurring 2 weeks apart (1.0 hrs total)
(2) In-House Facilitator Training Protocols <u>In-House Facilitator Class Training.</u> In-house facilitators learn to facilitate interdisciplinary in-class learning and/or practice mentoring and problem-solving at the point of care to improve local interactions. <u>Chance Encounter Mentoring Training.</u> Researcher shadows the In-house facilitator trainee during the work day to identify mentoring opportunities and model “chance encounter mentoring;” observe and advise trainee as s(he)	Prepares in-house care and supervisory staff to build trust and maintain consistency of CONNECT with the local culture. Facilitates information exchange between NH staff and research staff. In-house facilitators	Care staff or managers in clinical departments (e.g., nursing, social work, activities).	1, 1 hr learning session; Up to 1 hr of shadowing during regular work

practices the behaviors; and jointly problem solve (1 session of 1 hour). <u>Support by research facilitators.</u> The researcher contacts the in-house facilitators weekly for support and advising; in-house facilitators also have a phone number to call to seek help from research staff as needed.	develop self-efficacy in using chance encounters to model local interactions and to mentor staff.	Individuals self-selected with encouragement of study staff.	activities; 5, 10 min discussions (up to 2 hrs, 50 min total)
Relationship Map Protocols			
(1) Group-to-group maps <u>Session 1.</u> Researcher assists staff to describe actual interactions between work groups (e.g., NAs, LPNs, SW, Dietary, etc.). <u>Session 2.</u> Researcher assists staff to depict new interaction patterns and develop guidelines for improved group-to-group interaction patterns.	Assists staff to make interaction patterns explicit (develop a group-to-group relationship map), and agree on guidelines for improved interactions.	Mid-level managers and selected LPNs, NAs.	1, 1-hr class; 1, 70 min class; 1 week apart (2 hrs, 10 min total)
(2) Individual-to-individual maps Researcher assists staff to draw an individual "relationship map" that defines his/her ideal interactions with selected co-workers; reviews strategies for improving interactions. Participants learn to self-monitor and record interactions using relationship maps (available on a laminated card) and paper/pencil recording sheets.	Assists staff to evaluate relationships. Self-monitoring reinforces and sustains newly acquired behaviors and provides a measure of adherence and behavior change.	All CONNECT participants	1, 30 min session (30 min total)
Unit Based Mentoring Protocols			
(1) Structured Mentoring (by Research Facilitator) During the 2 weeks following each in-class session, the researcher engages each participant in a 10-minute session to discuss and reflect on his/her experiences applying CONNECT concepts. The researcher uses a semi-structured guide to elicit concerns about using the strategies.	Facilitates authentic learning, which occurs only when learners can directly and independently apply concepts. ⁹⁵	All CONNECT participants	2, 10 min sessions (20 min total)
(2) Chance Encounter Mentoring (by In-house Facilitator) In-house facilitators engage in point-of-care discussions with staff to practice CONNECT behaviors and jointly problem solve, using the "chance encounter" protocol. They record the number and descriptions of chance encounter mentoring sessions. At least 5 such encounters should occur daily during naturally occurring usual work activities.	Identifies staff concerns and barriers, facilitates ongoing learning about interaction, and strengthens sustainability of new behaviors. Facilitators learn to use existing time differently.	In-house Facilitators engage with floor staff in their department or work unit	1.25 hrs/day for in-house facilitator (37 hrs total)

Table 3.c.2.2 FALLS Protocol Activities, Rationale, Who is Involved and Time Required

FALLS Protocols	Rationale/Outcome	Who	Time
FALLS Coordinator and Team Role			
Training Session Researcher reviews: 1) role of FALLS Coordinator and Team members; 2) Falls Management Program rationale and main components; 3) annotated slide presentation on practical aspects of fall prevention; 4) toolkit materials; 5) study expectations.	Falls Team members champion fall prevention, identify area to improve, monitor changes.	FALLS Coordinator, Falls Team, DON	1, 4 hour session
Weekly FALLS Team teleconference Researcher contacts FALLS team weekly during 3 month intervention for problem-solving/discussion, and highlights a topic from the Fall Management Program in more depth. Topics include 1) staff fall prevention education; 2) medications and falls 3) patient and family fall education; 4) orthostatic hypotension; 5) vision assessment and intervention; 6) gait and balance assessment and intervention 7) environmental assessment and intervention; 8) challenging behavior management; 9) establishing a culture of safety; 10) audit and feedback; and 11) Wrap-up and re-setting goals	Reinforces key concepts of multi-factorial risk reduction, supports FALLS Coordinator and maintains enthusiasm.	FALLS Coordinator, and any other team members s/he wishes	11, 30 min sessions weekly (5.5 hrs total)
Staff Education			
Case-Based Modules (online and paper form) <u>Nurse module.</u> Covers impact, fall risk factor assessment and intervention focusing on orthostatics, gait, toileting, medications, environmental hazards. <u>NA module.</u> Covers fall risk factor identification and intervention focusing on gait, footwear, toileting, hip protectors, and environmental hazards. <u>Prescriber/pharmacist module.</u> Covers epidemiology/impact, risk factor assessment, risk factor reduction focusing on psychotropic medication reduction and Vitamin D.	Uses case-based learning to impart knowledge and change attitudes about multi-factorial fall risk reduction.	RNs, LPNs, NAs, MDs, NPs, PAs, Consultant Pharmacists and others (PT, SW, Activities etc)	30-60 min
Post-Fall Problem-solving			
Academic Detailing NH frontline staff is invited to participate in consultations with the researcher and FALLS Coordinator regarding their most challenging residents with falls, modeling risk factor assessment and multi-factorial interventions. Sessions occur at each nursing station during the day and evening shifts.	Reinforces key concepts and promotes behavior change and interdisciplinary discussions. ⁹⁵	Nurses, NAs, other interested staff	2, 20 min sessions (40 min total)
Audit and Feedback			
Feedback Report Report uses visual (bar graph) and written depictions of the NH's current practice on fall-related process and outcome measures, and how this compares with peer NHs. Researcher presents and explains the feedback report to FALLS Team.	Identifies areas for improvement, promotes behavior change. ⁹⁵	FALLS team, others as desired by Falls Coordinator	30 min
Toolbox			

Morse Fall Scale: Validated scale that quantifies fall risk in NH residents; **Nurse Fall Risk Reduction Worksheet:** Prompts nurse to identify and modify reversible fall risk factors. Can be used for chart documentation; **Prescriber/Pharmacist Medication Reduction Worksheet:** Prompts consideration of dose reduction or discontinuation of high fall-risk medications, including lower risk substitution options; **Environmental Checklist:** Facilitates identification of hazards in resident room, bathroom, and common areas; **Wheelchair maintenance log and stickers:** Facilitates regular assessment and repair of wheelchair brakes; **Fall Risk Fax Communication Form:** Allows nurse/pharmacist to communicate concerns about medications with prescribers; **Patient and Family Brochure:** Describes interventions that the NH is using to reduce falls; **Physician/Prescriber Brochure:** Describes the fall reduction program and encourages review of medication reduction worksheets and faxes.

Provides modifiable tools to assist with communication, implementation, and documentation of multifactorial risk reduction.

FALLS Coordinator determines dissemination

Voluntary

INTERVENTION TIMELINES. Timelines are shown in Table 3.c.2.3 (CONNECT) and in Table 3.c.2.4 (FALLS).

Table 3.c.2.3 CONNECT+FALLS Interventions Timeline

Activities (in months)	Base-line		CONNECT			Follow up Measures	FALLS			Follow-up Measures			Exit
	1	2	3	4	5	6	7	8	9	10	13	16	17
Staff recruitment	→	→											
Resident Chart abstraction	→	→										→	
CONNECT Intervention													
CONNECT & Learn sessions			→										
Group-to-Group Maps			→										
Individual Relationship Maps			→										
Structured mentoring			→	→	→								
Co-facilitator training			→										
In-house facilitator training			→										
In-house facilitator support			→	→	→								
Chance encounter mentoring			→	→	→								
FALLS Intervention													
Fall Coordinator Training								→					
Fall Coordinator Phone support								→	→				
Learning modules distributed								→					
Audit and feedback								→					
Academic detailing sessions								→					
Measurements													
Staff interaction measures		X				X				X		X	
Fall-related measures		X										X	
Exit interview													→

TREATMENT FIDELITY PROTOCOLS use the NIH Behavior Change Consortium's⁹⁶ model of treatment fidelity. **DESIGN.** To ensure design fidelity,¹⁶ we standardized the CONNECT and FALLS protocols to a specified dose in terms of number, frequency, and length of contact. **TRAINING.** CONNECT and FALLS will be delivered by different research interventionists who are trained separately to minimize contamination. The protocol specifies training content, structured practice, and role-play exercises to ensure that interventionists' skills meet established standards. **DELIVERY.** To ensure that CONNECT and FALLS are delivered as intended, a research team member will observe the interventionists on a random schedule, completing standardized checklists. The interventionists and PIs will discuss the results and problem-solve barriers to adherence with repeat of concepts and role-play as needed (Fidelity Protocols are found in Appendix 1D). We will track participants for completion of study components. For CONNECT, we will use 1) contact summary sheets for each visit to a research site; 2) databases for interventionists to record contacts with participants; and 3) sign in sheets to

Table 3.c.2.4 Timeline for FALLS alone

Activities (in months)	Base-line		FALLS Intervention			Follow-up Measures			Exit
	1	2	3	4	5	6	8	9	12
Staff recruitment	→	→							
Resident chart abstraction	→	→							→
FALLS									
Fall Team Training			→						
Fall Team Phone support			→	→	→				
Learning modules distributed			→	→	→				
Audit and feedback			→						
Academic detailing sessions			→	→	→				
Measurements									
Staff interaction measures	X					X		X	
Fall-related measures	X								X
Exit interview									→

document participation in sessions. For FALLS, we will use 1) contact sheets to record each contact between interventionists and the Fall Team; 2) sign-in sheets to document participation in post-fall problem-solving sessions; and 3) track completion of educational modules via requests for continuing education credit or certificate of completion. **RECEIPT OF TREATMENT.** For CONNECT, participants' self-monitoring of local interactions will provide a measure of adherence and behavior change. The class sessions will include discussion and practice during which skills can be systematically assessed. For FALLS, participants will complete post-tests in the educational modules. **ENACTMENT OF SKILLS.** Researchers will systematically assess enactment when they shadow the in-house facilitators to observe how they practice mentoring behaviors. They will assess and record enactment by participants during structured mentoring. Finally, the researchers will assess enactment by observing at least two orientation sessions in which the in-house facilitator delivers the in-class session to new employees. Fall risk reduction indicators will be

used to measure enactment of the FALLS intervention.

Recruitment and Data Collection Procedures.

STAFF RECRUITMENT AND CONSENT. When we recruit NHs, administrators and directors of nursing will agree to include CONNECT & Learn sessions and/or FALLS as regular in-service training. In meetings (e.g., nurses meetings, CNA meetings), researchers will explain the study and invite staff to participate in the other

aspects of the study (completing surveys, structured mentoring). Staff not attending meetings will be approached individually. A research team member will answer questions and obtain written informed consent.

STAFF INCENTIVES. As in our prior case studies, we will offer an exit-interview consultation⁹⁷ during which we will share study results with participants. Continuing Education credits or a certificate of completion will be given to staff for completing CONNECT & Learn sessions and/or FALLS educational modules. Everyone completing both learning sessions and staff surveys will receive practical items (water bottles, tote bags) with the study logo.

DATA COLLECTION FROM STAFF. (Appendix 3) Data will be collected from enrolled staff at time points shown in Table 3.c.2.5. Obtaining reliable data from NAs requires special attention because some may have low literacy or English as a second language; our team has experience collecting data from diverse subjects. To ensure complete and reliable data, we have chosen questionnaires that have been used previously in NHs and are at a sixth grade reading level. Instructions for completing the questionnaires have been written to reflect Oskamp's⁹⁸ approaches to reducing response set bias due to social desirability. To ensure confidentiality, participants can place completed surveys directly in a secure drop box in the NH. Because surveys will be completed 4 times, we will order the scales differently each time to reduce the likelihood the respondents will rely on memory of previous responses.

DATA COLLECTION FROM RESIDENTS. A list of eligible residents who have fallen in the study periods will be obtained from the MDS nurse or the Falls Coordinator. We will select a sample of residents via a random number generator for chart abstraction. We have obtained a waiver of HIPAA authorization and informed consent for resident chart abstraction for the falls-related process measures.

FALLS DATA SOURCES AND ABSTRACTION TIMING. Data sources include the Minimum Data Set (MDS), resident medical record, medication administration records (MAR), fall or incident logs, and administrative facility bed-occupancy rates. All data sources will be examined over the 6 months preceding study initiation and 6 months following the FALLS intervention (Table 3.c.2.6). Medical records are retained in the NH by law for at least 2 years after resident discharge. The timing of abstraction is indicated in Table 3.c.2.6.

ABTRACTOR QUALIFICATIONS, TRAINING, AND BLINDING. Data abstractors will hold clinical degrees and will be trained using practice charts and a manual including definitions, data locations, and detailed instructions. (Appendix 4) Instruction will be repeated until inter-rater reliability exceeds 90% for all fall risk reduction indicators. Data collectors are employed by CCME, and will be blinded to the NH's intervention status and the study hypotheses. Blinding will be assessed by asking data collectors which study group they believe the NH was assigned to.

DATA RELIABILITY. To ensure data quality, a random 5% of resident charts at each time period will be abstracted by a second data collector, with inter-rater reliability calculated using kappa. Refresher training will be completed if kappa falls below 0.7 for any measure.

MEASURES

The measures and the time points at which these will be collected are summarized in Table 3.c.2.5 (Complexity Science Measures) and Table 3.c.2.6. (Fall-related measures). Details of the scales and instructions are contained in Appendixes 3 (Complexity Science Measures) and 4 (Fall-related measures). In addition, data will be collected about each NH.

NURSING HOME DATA. Characteristics including bed size, nursing staff hours, chain and religious affiliation will be collected from publicly available sources (www.nhcompare.gov). Nursing staff turnover during the intervention period will be obtained from administrators. These data will be used as covariates in the multivariable outcomes analyses.

COMPLEXITY SCIENCE MEASURES

Complexity Science Measures are summarized in table 3.c.2.5, and will be collected at time points as indicated. Scaled items are contained in Appendix 3. We will ask staff to report their experience over the last month; this time frame was chosen to capture the usual monthly cycle of meetings and events that may influence interactions. Although not all staff will have participated in CONNECT, we expect a system effect (confirmed in the R56 study) and, thus, all staff members should perceive changes.

Table 3.c.2.5 Complexity Science Measures, Data Sources, Psychometrics, and Time Points (Appendix 3)

Concept Measured; Source	Psychometrics; Calculation	Base line	3 mo	6 mo	9 mo
Demographics; self-report	Age, sex, job title, years in position, education, and ethnicity (collected at baseline or at enrollment into the study. Categorical measurement)	X			
Communication patterns; all staff participants	Mean scores on Roberts & O'Reilly openness, accuracy scales ⁹⁹ and Shortell's timeliness scale. ¹⁰⁰ The scales show adequate reliability and validity in various settings. ⁹⁹⁻¹⁰¹ In our preliminary studies scales showed reliability alphas of .81, .72 and .68, respectively; construct validity confirmed by factor analysis and hypothesis testing. ^{16,24,102}	X	X	X	X

Concept Measured; Source	Psychometrics; Calculation	Base line	3 mo	6 mo	9 mo
NA participation in decision making about resident care; all staff participants	Mean score on Anderson et al.'s ¹⁰² Participation in Decision-making Instrument (PDMI). The PDMI is established with demonstrated reliability in NHs ^{16, 17, 102-104} and construct validity established through factor analysis ¹⁰² and hypothesis testing. ^{16, 103, 105} NH samples achieved alpha coefficients of >.90.	X	X	X	X
Local Interaction Measure; all staff participants	Mean Scores on Anderson et al.'s Local Interaction Scale, designed to measure staff's perception of co-worker's use of the 20 local interaction strategies (listed in Figure 3.a.1, defined in protocols, Appendix A). The items were developed using the language of case study participants (2RO1NR03178). The measure was pilot tested in the R56 with 136 NH staff (RNs, LPNs, NAs, others) and demonstrated alpha coefficients >.90. Eta ² of .20 (p <.001) indicated that the measure is reliable at the NH level. Evidence of construct validity is indicated by a time by group effect (p=.10) in the R56 RM-ANOVA analysis. The reading level is 6 th grade.	X	X	X	X
Safety organizing scale; all staff participants	Mean score on Vogus & Sutcliff's scale designed to measure 5 "interrelated behavioral processes: preoccupation with failure, reluctance to simplify interpretations, sensitivity to operations, commitment to resilience, and deference to expertise." ^{106, p.47} In a large sample of hospital RNs, the 9-item, 7-point scale showed reliability (alpha = .88), convergent and discriminant validity, and criterion validity, and was reliability aggregated to reflect a unit-level construct. ¹⁰⁶ We revised the wording to reflect NHs. Alphas were >.90 in both the baseline and follow up survey in our preliminary studies.	X	X	X	X
Perceived quality scale; all staff participants	Mean scores of Colón-Emeric's scale The Perceived Quality Scale, ¹⁰⁷ designed to measure staff's perception of the quality of care provided in their NH. We developed items using case-study data (2RO1NR03178) from four cases and then pilot tested with staff in the next four case studies, following which we clarified items and achieved high reliabilities. Using R56 sample data, we scored two subscales, quality of caregiving (n=7 items) and quality of care planning (n=15 items) each with alpha >.80. The reading level is 6 th grade.	X	X	X	X

FALL MEASURES (TABLE 3.C.2.6)

FALL Risk Factor Reduction Indicators. Measures chosen for this study 1) are a component of previous efficacy trials and fall clinical practice guidelines; 2) were found to be reliably measured by chart abstraction in previous studies;^{7, 9} and 3) are included in the educational components of the FALLS intervention. These indicators were previously found to be reliably measured, sensitive to change, and not impacted by a ceiling effect.⁷ We will calculate the proportion of fallers with medical record evidence of the fall risk reduction indicator, and determine indicator counts for each resident. The timing of the risk factor reduction will be recorded as: within 48 hours of a fall, within 1 month of a fall, during the 6 month abstraction period. Definitions for the indicators are listed in Table 3.c.2.6.

FALL RATE. Consistent with the MDS, we define a fall as an unintentional change in position resulting in a resident coming to rest on the ground or lower level⁴ regardless of cause.² Recurrent falls are defined as 2 or more falls within the 6 month study period.⁴ These measures have been successfully employed in previous studies.²⁻⁴ Due to underreporting of falls,¹⁰⁸ data will be collected from multiple sources including the medical record,^{2, 108} MDS reports, fall logs, and incident reports. We will calculate fall rates and recurrent falls as defined in the table below. From our previous falls study and national data, we assume a baseline fall rate of 1.5 falls/bed/yr, and an average bed occupancy rate of 90 bed days/home/month. We therefore project that there will be a total of 2160 falls in the study NHs over the study period. The proportion of repeat fallers and the proportion of injurious falls (defined as the proportion of falls resulting in injury including skin tear, hematoma, fracture, laceration, need for imaging or urgent medical assessment) will be measured as secondary fall endpoints.

Table 3.c.2.6 Fall Measures, Data Sources, Calculation, and Time Points.

Concept Measured; Source	Calculation/Definition	Inclusive of 6 mo prior to base line	Inclusive of 6 mo after FALLS complete
Demographics; Medical record	Sex, Age, and race. Nominal	X	X
Fall Rate; Medical Record, MDS, Incident reports, Weekly census	Numerator: number of falls occurring in a 6 month period Denominator: number of occupied facility bed days	X	X
Probability of recurrent falls; as above, weekly census	Proportion of residents with 2 or more falls occurring in a 6 month period	X	X
Fall Risk Reduction Indicators; Medical record, RAI, Incident reports	Count of documented fall risk reduction indicators defined below	X	X
a) Orthostatic Blood Pressure	Documentation of blood pressure in at least 2 body positions, OR intervention to decrease orthostatic hypotension including discontinuation of a medication associated with orthostasis, prescription of volume expanding medication, or use of compression stockings	X	X
b) Sensory Impairment	Documentation of the presence or absence of visual impairment, OR Intervention to change corrective devices or add assistive technology to optimize sensory input (e.g. magnification devices, lighting level)	X	X
c) Footwear	Documentation that footwear has been evaluated, modified, or recommended to patient/family	X	X

Concept Measured; Source	Calculation/Definition	Inclusive of 6 mo prior to base line	Inclusive of 6 mo after FALLS complete
d) Gait and Assistive Devices	Physical therapy assessment or training, change in assistive device, or participation in restorative ambulation program	X	X
e) Toileting	Documentation of scheduled toileting or a previous attempt in residents with at least intermittent urinary or bowel continence	X	X
f) Environment	Documentation of a search for environmental factors contributing to fall risk (e.g., low toilet seat, room clutter, burned out light bulb) OR a change in environment likely to reduce falls or injury risk, including replacing or repairing grab bars, changing floor surfaces, changing lighting, re-arranging furniture, using a low bed or floor mat, and alarms	X	X
g) Psychotropic Medication Reduction ^{77, 78}	Dose reduction or discontinuation of any of the following classes of psychoactive medications within 1 month of a fall; benzodiazepines, tricyclic antidepressants, antipsychotics, propoxyphene, and selected anticholinergic agents (diphenhydramine, sedating antihistamines, immediate-release oxybutynin, skeletal muscle relaxants)	X	X
h) Calcium and Vitamin D	Prescription of at least 1000 mg of calcium daily or 800 IU of vitamin D daily, OR an equivalent in weekly or monthly dose regimens. Multivitamins containing vitamin D and combination calcium/vitamin D preparations will be added to the total daily dose calculation.	X	X

COVARIATES. Non-modifiable fall risk factors will be used in the analysis to adjust for differences in level of risk between residents. The resident's most recent history and physical, problem list, discharge summaries, and RAI will be reviewed for the following: age; sex; race; history of stroke; peripheral neuropathy; Parkinson's disease; visual impairment; cognitive impairment; assistive device use; and ambulatory status.

3.C.3. STUDY TIMELINE. Study activities will be completed over the project period as outlined in Table 3.c.3. To minimize administrative turnover between recruitment and onset of study activities, recruitment will occur in 2 waves. The total duration of participation for each NH inclusive of recruitment, intervention, and follow-up data collection is 14 months.

	FY01	FY02	FY03	FY04	FY05					
Activities (in months)	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
Personnel recruitment and training	→									
Preparation of study materials	→									
1st wave recruitment of nursing homes (NH)	→									
Connect+Falls in NH #1		C+F	→							
Connect+Falls in NH #2		C+F	→							
Falls alone in NH #3 (Connect offered after)		F	→	C	→					
Falls alone in NH #4 (Connect offered after)		F	→	C	→					
Connect+Falls in NH #5			C+F	→						
Connect+Falls in NH #6			C+F	→						
Falls alone in NH #7 (Connect offered after)			F	→	C	→				
Falls alone in NH #8 (Connect offered after)			F	→	C	→				
Connect+Falls in NH #9				C+F	→					
Falls alone in NH #10 (Connect offered after)				F	→	C	→			
2nd wave recruitment of nursing homes			→							
Connect+Falls in NH #11				C+F	→					
Falls alone in NH #12 (Connect offered after)				F	→	C	→			
Falls alone in NH #13 (Connect offered after)				F	→	C	→			
Connect+Falls in NH #14					C+F	→				
Connect+Falls in NH #15					C+F	→				
Falls alone in NH #16 (Connect offered after)					F	→	C	→		
Analysis										→
Dissemination										→
Annual/Final Reports		X		X		X		X		X

3.C.4. ANALYSES FOR SPECIFIC AIMS. For each aim, models will be estimated for each dependent variable. Baseline differences on each outcome variable will be controlled along with the following potential confounders at the facility and the individual levels: age, sex, race, history of stroke, peripheral neuropathy, Parkinson's disease, visual impairment, cognitive impairment, assistive device use, fall in the previous 6 months, ambulatory status, facility bed-size and staffing levels. Facility ownership status is a blocking variable. In sensitivity analyses, we will examine whether the effect of the intervention varies with level of staff turnover.

The effects of our intervention will be assessed at the facility level (mean counts, probabilities, levels by intervention group). We will estimate 3-level hierarchical models, to decompose within and between-site

variability, and time-related variability in significance testing.¹⁰⁹ SAS PROC GLIMMIX will be used for counts and dichotomous outcomes. SAS PROC MIXED will be used for continuous outcomes.¹¹⁰ MPLUS¹¹¹, which allows for multiple mediators and nonlinear dependent variables, will be used to estimate indirect effects. Unless otherwise specified, each model will include the baseline value on the dependent variable of interest, a dummy variable indicating intervention, and all covariates which are significantly related to an outcome.

AIM 1 (Primary). Compare the impact of CONNECT+FALLS to FALLS alone on fall risk reduction indicators, and determine whether these mediate the impact on fall rates.

HYPOTHESIS 1. Residents in NHs randomized to NHs that receive CONNECT+FALLS will show greater improvements in fall risk reduction indicator counts from the 6 month period preceding the intervention (baseline) to the 6 month period after the intervention (follow-up), than residents in NHs randomized to NHs that received FALLS alone.

We will use SAS PROC GLIMMIX to estimate a poisson regression model. In initial analyses, we will test for over dispersion, and employ a negative-binomial model if over dispersion is present.

AIM 2 (EXPLORATORY). Compare the impact of the CONNECT intervention plus a fall reduction QI intervention (CONNECT+FALLS) to the fall reduction QI intervention alone (FALLS), on fall rates.

HYPOTHESIS 2A. Residents in NHs randomized to receive CONNECT+ FALLS will have lower fall rates than similar residents in NHs receiving FALLS alone.

HYPOTHESIS 2B. Residents in NHs randomized to receive CONNECT+ FALLS will have a lower probability of recurrent falls during the 6 months post intervention, than similar residents in NHs receiving FALLS alone.

HYPOTHESIS 2C. Intervention-related improvements in fall rates will be mediated by improvements in fall risk reduction indicators.

We will use PROC GLIMMIX to estimate a poisson model with fall rates as the dependent variable and using the same set of predictors. For the probability of a recurrent fall (H2b), we will use PROC GLIMMIX to estimate a discrete-time proportional odds model with a dummy dependent variable.¹¹² To test H2c, we will use MPLUS software.¹¹³

AIM 3 (EXPLORATORY). Compare the impact of CONNECT+FALLS to FALLS alone on complexity science measures as reported by NH staff, and determine whether these mediate the impact on fall risk reduction indicators and fall rates.

HYPOTHESIS 3A. Staff in NHs randomized to receive CONNECT+FALLS will report greater improvements on (a) communication openness, accuracy and timeliness; (b) NA participation in decision-making; (c) local interaction strategies; (d) safety climate, and (e) staff perceptions of quality than staff in NHs receiving FALLS alone, at 3, 6 and 9 months after the intervention.

For these continuous outcomes, we will use SAS PROC MIXED. Due to staff turnover, some staff members will be trained by a facility staff member rather than our original team of trainers. We will code a dummy variable for trainer (original vs. other) and include it as a covariate in the aim 3 analyses. We also will explore whether the effect of the intervention varies with type of trainer.

HYPOTHESIS 3B. Improvements in fall risk reduction indicators and fall rates will be mediated by changes in complexity science measures. To test H3b, we again will use MPLUS software.

STATISTICAL POWER. We used algorithms developed to estimate power for longitudinal models based on the formulae of Jung and Ahn,^{114,115} a type I error rate of .05 (two-tailed), and a 15% rate of attrition for the staff samples. For Aim [1], we will have 80% power to detect a 15% difference in risk factor assessment and intervention scores, which is considered to be the minimally clinically significant improvement in falls care practice. For Aim [2], the resident sample will provide 80% power to detect a 23% difference in the fall rate due to intervention, and a 23% difference in the probability of a recurrent fall. Because this is a real world effectiveness study, this change in fall rate is slightly smaller than that seen in a randomized controlled trial of multifactorial risk factor reduction, but still clinically meaningful. For the continuous outcomes in Aim 3, we will have 80% power to detect standardized differences of .21, a magnitude considered small in the statistical literature.¹¹⁶ As we have a single primary outcome and several additional outcomes which are exploratory, we will not adjust our significance tests for multiple tests.

MISSING DATA. Item-specific missing data on potential covariates will be handled with the maximum-likelihood and multiple imputation techniques.¹¹⁷ Missing values can be imputed with SAS PROC MI using the Markov chain Monte Carlo algorithm, which can be used with complex missing data patterns as well as for continuous, ordinal, and dichotomous measures.¹¹⁸ We expect 15% attrition on our dependent variables across waves. Recent work by Chang et al¹¹⁹ shows how shared parameter models^{120, 121} can be used to address potential bias due to a failure to meet the missing at random assumption. These models will be operationalized where necessary.

3.C. 5. FUTURE PLANS.

CONNECT is an approach to enhance the NH staff's ability to integrate multi-factorial fall risk factor reduction into practice because it helps them establish processes for effective interdependence and learning. Our preliminary work shows that CONNECT is feasible and effective in improving staff interactions and quality of care. Since CONNECT changes processes at a system level, it may be used to implement evidence-based practices for other complex clinical problems such as pain, pressure ulcers, dementia behaviors, or functional decline. Results of this clinical trial will lead to future work that will establish correlates of the sustainability of the intervention in NHs and examine transferability to other clinical problems and other health care settings. The results of the research will be of interest to NH leadership and policy makers, particularly in light of ongoing state and national initiatives to improve care in NHs. As in our previous work, we will employ various avenues to disseminate results, including refereed and practitioner publications, direct presentations to NH managers and staff, and collaboration with stakeholder organizations.