

Improving Aging in Place for Older Adults Living in Subsidized Housing

NCT04212442

July 1, 2020

Aim 3: Determine the feasibility and preliminary effectiveness of the adapted Function-Focused Care intervention in subsidized housing residents at high risk for nursing home admission. We will conduct a 2-month pilot test of the adapted Function-Focused Care intervention in 15 subsidized apartment buildings for older adults. We will use a pre-to-post study design to examine the change in outcome measures from baseline to 2 months. Implementation outcomes will include feasibility and acceptability. Preliminary effectiveness outcomes will include resident function (primary outcome), with secondary outcomes of quality of life and health care utilization. Because function declines over time, our design will incorporate a waitlist control, in which half of the sites are cluster randomized to receive the intervention in months 0-2 while the other sites are randomized to receive usual care. The waitlist sites will then receive the intervention in months 2-4. The waitlist period will provide a baseline rate of functional decline that will serve as a comparison for functional outcomes (see Figure 3 for study flow).

Study setting and population: We will pilot the intervention in 15 subsidized apartment buildings for older adults.

Eligibility: Residents living at any of the sites will be invited to participate. If a resident wishes to participate but does not pass consent verification,⁶⁷ they will be asked to sign an assent to participate, and a proxy will be contacted to complete the consent process. Residents will receive sequential \$50 incentives for participation at baseline, 3, and 6 months (i.e., up to \$150 total).

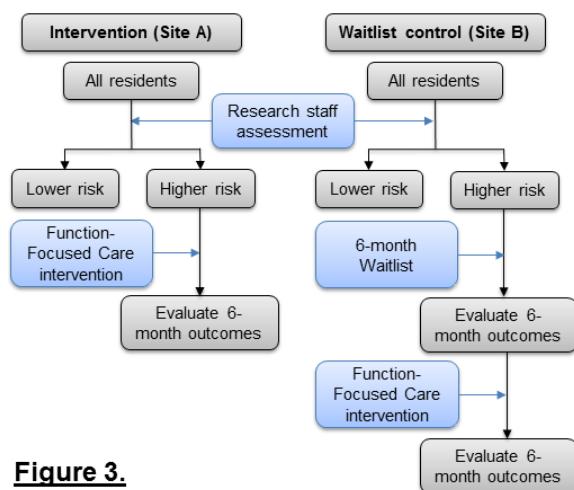


Figure 3.

resident-family caregiver dyads, among residents who have such support.

A research Function-Focused Care Nurse will coordinate and implement the intervention with support from our interdisciplinary research team. The nurse will receive extensive training in the intervention. This will include a 1-week in-person training with Dr. Resnick and her team at the University of Maryland in Year 1, followed by weekly web-based training during the first 6 months of Year 2 and as-needed check-ins in Years 2 and 3. Based on the successful implementation model for assisted living,³⁵ the nurse will work with each site 16 hours per week for the first 3 months of the intervention and 8 hours per week for the next 3 months. To ensure that the intervention can be sustained over time, we will work with each site to identify a staff “champion” who will work with the nurse to learn how to maintain this approach. Working with the champion, the nurse will implement the 4 steps of the intervention (Table 2). As noted above, the approach for each step may be adapted based on stakeholder feedback, e.g., to incorporate family caregivers. Steps will be implemented sequentially and continue throughout the intervention, including ongoing mentorship and motivation for residents and caregivers. This will include observing caregiver performance, giving positive encouragement for providing Function-Focused Care, and reinforcing benefits of the intervention. Mentorship will occur in-person.

Table 2. Component	Description of the intervention
I: Environmental and policy assessments	Site champion works with research nurse to complete assessments using standard evaluation forms. Findings are used to identify and recommend feasible interventions to alter the environment, policy, and procedures to optimize resident function and physical activity (e.g., make pleasant walking areas)
II: Education	Research nurse educates housing staff (e.g., service coordinators), residents, and families in principles of Function-Focused Care (FFC), using established materials and adult learning techniques.
III: Establishing goals	Research nurse works with residents to complete Capability Assessments/Goal Attainment Forms with eligible residents. Goals established based on assessments and resident input.
IV: Mentoring and motivating	Research nurse works to motivate residents to participate in FFC throughout study period by using evidence-based approaches (e.g., observing performance of caregivers and providing one-on-one mentoring to incorporate FFC into routine care; providing positive reinforcement for incorporating FFC)

Waitlist control: At the waitlist control site, residents will be screened for risk of nursing home admission and

enrolled as described in Aim 2. Residents will be referred for whatever services are customary per usual facility protocols based on results of these screenings, but for the next 2 months, will not be enrolled in the Function-Focused Care intervention.

Outcome measures: Outcomes are shown in Table 3. Measures will be collected at baseline and 2 months at both sites, and at 4 months at the waitlist control site (i.e., 2 months after intervention initiation at the control site). Measures correspond to the outcome domains assessed in the original Function-Focused Care trial³⁵ and were selected because they have well-established validity and reliability. Measures of feasibility will include standard measures of recruitment, retention, and refusal. We will assess intervention fidelity once per resident by evaluating home care workers during care interactions using a fidelity checklist.⁷⁹ Acceptability for residents, workers, and leaders will be assessed in both sites using similar approaches to Aim 2.⁷⁷

Table 3. Outcomes	Data source/measure
Feasibility	
Recruitment, retention, and refusal rates; intervention fidelity	Facility observations; Restorative Care Checklist ⁷⁹
Acceptability	
Satisfaction, usability, burden	Stakeholder interviews
Resident outcomes	
Function (co-primary outcomes)	SPPB, ⁸⁰ Yale ADL scale ⁶⁸⁻⁷¹
Quality of life, depression	QOL-AD, ⁸¹ PHQ-9 ⁸²
Health care utilization	No. hospital/nursing home admissions; length of stay
Adverse events	No. falls, fall-related injuries
Beliefs about function and physical activity	Self-efficacy/Expectations for Functional Activity Scales ⁸³⁻⁸⁷
Caregiver outcomes	
Knowledge of intervention	11-item scale ⁸⁸
Self-efficacy and outcome expectations	Self-efficacy/Expectations for Restorative Care Activities ⁸⁷
Job satisfaction	Job Attitude Scale ⁸⁹
Family caregivers: QOL, depression, caregiver burden	EQ-5D, ⁹⁰ PHQ-9, ⁸² brief Zarit Caregiver Burden scale ⁹¹

Resident outcomes include key factors that contribute to aging in place, including a primary outcome of functional status and secondary outcomes of quality of life, depression, and health care utilization. We will measure function using 2 measures. The Short Physical Performance Battery (SPPB) is an objective measure of lower extremity functioning in older adults which has excellent reliability, validity, and responsiveness (range, 0-12 points).^{80,92} We will also measure self-reported ability to perform 8 ADLs using the Yale ADL scale (range, 0-16).⁶⁸⁻⁷¹ We will assess quality of life using the Quality of Life in Alzheimer's Disease (QOL-AD) scale⁸¹ and depression using the Patient Health Questionnaire (PHQ-9).⁸² Health care utilization will be assessed by self-report. Other outcomes will include adverse events and attitudes about function and physical activity (see Table 3).⁸³⁻⁸⁷ Home care

worker outcomes will include knowledge⁸⁸ and attitudes about Function-Focused Care⁸⁷ and job satisfaction.⁸⁹ For family caregivers, outcomes will include quality of life,⁹⁰ depression,⁸² and caregiver burden.⁹¹

Analysis plan and power calculation: We will analyze measures of feasibility using similar methods to Aim 2. We will define the intervention as feasible if residents complete $\geq 75\%$ of checklist items. For other outcomes, we will assess change from baseline to 2 months and compare the changes between intervention and waitlist groups. For continuous outcomes, the change will also be continuous; for dichotomous outcomes, the change can be defined as a four-category variable (0-0, 0-1, 1-0, and 1-1 for pre and post outcomes). We will then compare the change between intervention and waitlist groups using the t-test or Wilcoxon signed rank sum test for continuous variables and Chi-square or Fischer's exact test for dichotomous variables.

Because this is a pilot feasibility study, the sample size need only be large enough to determine key parameters such as recruitment, retention, and refusal rates. Given the pool of potential participants, we are confident that we can recruit enough participants to not only determine feasibility but also determine point estimates and standard deviations for projected sample size for a follow-up randomized controlled trial. We plan to recruit a total of 70 participants in the overall study. To estimate preliminary effect sizes, the mean scores for continuous outcomes or proportions for dichotomous outcomes will be compared among participants in the intervention vs. waitlist control conditions. If we assume that the correlation between pre and post continuous measures from baseline to 6 months is 0.8, then the SD for the change is 0.6 SD for the continuous measures. With 70 residents, we will have 80% power (2-sided alpha of 0.05) to detect a 0.66 SD change in the mean of continuous measures from baseline to 2 months, assuming a 20% dropout. Thus, for our primary outcomes, we should have sufficient power to detect a mean 1.78-point increase in SPPB score (SD~2.7)⁹¹ and a mean 1.45-point increase in ADL/IADL score (SD~2.2).⁷⁶

Potential problems and alternative approaches: Potential problems include staff turnover, resident loss to follow-up, and a relatively limited sample size and follow-up period. We will train new staff and champions and use best practices to minimize loss to follow-up, including obtaining multiple types of contact information at baseline and providing sequential incentives for participation. Also, our implementation protocol will incorporate stakeholder input on barriers and facilitators to implementation identified in Aim 1. Although this pilot study has a limited sample size, it will provide preliminary data to support a definitive R01-level study.