Implementing Primary Palliative Care in Post-acute nursing home care: Protocol for an embedded pilot pragmatic trial

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ARTICLE INFO

ABSTRACT

Introduction: Older adults with serious illness frequently receive post-acute rehabilitative care in nursing homes (NH) under the Part A Medicare Skilled Nursing Facility (SNF) Benefit. Treatment is commonly focused on disease-modifying therapies with minimal consideration for goals of care, symptom relief, and other elements of palliative care.
Intervention: The evidence-based Primary Palliative Care in Post-Acute Care (PPC-PAC) intervention for older adults is delivered by nurse practitioners (NP). PPC-PAC NPs assess and manage symptoms, conduct goals of care discussions and assist with decision making; they communicate findings with NH staff and providers. Implementation of PPC-PAC includes online and face-to-face training of NPs, ongoing facilitation, and a template embedded in the NH electronic health record to document PPC-PAC.
Objectives: The objectives of this pilot pragmatic clinical trial are to assess the feasibility, acceptability, and preliminary effectiveness of the PPC-PAC intervention and its implementation for 80 seriously ill older adults newly admitted to a NH for post-acute care.
Methods: Design is a two-arm nonequivalent group multi-site pilot pragmatic clinical trial. The unit of assignment is at the NP and unit of analysis is NH patients. Recruitment occurs at NHs in Pennsylvania, New Jersey, Delaware, and Maryland. Effectiveness (patient quality of life) data are collected at two times points—baseline and 14–21 days.
Conclusion: This will be the first study to evaluate the implementation of an evidence-based primary palliative care intervention specifically designed for older adults with serious illness who are receiving post-acute NH care.

1. Introduction

Older adults with serious illness frequently receive post-acute care in nursing homes (NH) under the Part A Medicare Skilled Nursing Facility (SNF) Benefit in the six months prior to death [1]. However this care may not align with patient and family goals. Patients in SNF care have high rates of symptom distress and re-hospitalization [2–5]. In part, the poor outcomes occur because the focus of post-acute NH care is on disease-directed treatment and rehabilitation services [6], regardless of a patient's goals for care. This focus may prevent patients with serious illness from receiving care to address their complex physical symptoms and psychosocial needs [1].

In observational research, palliative care has been shown to reduce re-hospitalizations for seriously ill older adults in NHs, but has never been tested in a randomized trial to assess other outcomes [7]. Palliative care is patient- and family-centered care that focuses on the needs of people with serious, life-limiting illnesses. It includes establishment of patient- and family-directed goals that guide health care and identification and treatment of physical and psycho-spiritual symptoms to mitigate suffering [8]. Empirical evidence from acute care and outpatient settings demonstrates that palliative care is associated with improved

health-related quality of life, higher satisfaction with care, lower costs, less caregiver burden, and better symptom management [9–11].

The most widely used model of palliative care in nursing homes is hospice; however Medicare regulations generally do not allow patients to enroll in hospice while receiving post-acute NH care under the SNF Benefit [12]. Further, many older adults living with serious illness, particularly those with underlying neurocognitive disorders such as Alzheimer's disease and other progressive causes of dementia, fail to meet the 6-month prognosis as required for hospice. Primary palliative care (PPC) is defined as elements of palliative care delivered by the patient's primary provider, rather than a specialist trained in hospice and palliative clinician. It is a practical option for delivering palliative care to SNF patients because it is reimbursable by NH prescribing providers (e.g., physicians, nurse practitioners, physician assistants). In addition, it allows for the concurrent use of rehabilitation and disease directed treatment with palliative care strategies, thereby avoiding the "terrible choice" that confronts patients who choose hospice and are required to forgo "curative" treatment such as physical therapy or active treatment for infection [13]. Although PPC is a promising model, it is not widely available in US NHs and there is little research about the processes and outcomes of PPC [14].

To address these challenges, we developed a novel approach for PPC delivery in post-acute care (PAC). The PPC-PAC intervention integrates palliative care clinical practice guidelines and preferred practices [8] with elements that have been identified as important in the NH setting: symptom assessment and management among those with neurocognitive disorders and the need for enhanced family-staff-provider communication and collaboration [15]. Evidence suggests that earlier palliative care is associated with improved quality of life, better preparation for and experiences of end-of-life care, fewer burdensome transitions and lower healthcare costs [16–19]. Therefore, the intervention identifies seriously ill post-acute care patients upon NH admission to ensure timely access to palliative services [20,21].

The aims of this pilot clinical trial are to establish the feasibility, acceptability and preliminary effectiveness of the PPC-PAC intervention among 80 post-acute care NH patients [22]. The primary outcome is quality of life among five domains (physical, emotional, psychological, spiritual, and provision of support); secondary outcomes are patient satisfaction and staff adherence to PPC-PAC recommendations. This paper describes the intervention, study design, and baseline site and patient characteristics over the first 6 months of the trial.

2. Methods

2.1. Description of the intervention

The PPC-PAC intervention is a program designed to assist NH-based nurse practitioners (NPs) in providing effective PPC to people living with serious illness. It is specifically tailored toward post-acute care NH patients, although components can be applied to any NH resident with palliative care needs. The program implementation strategy consists of training and facilitation: (1) five 1-h self-paced online learning modules, (2) a day-long communication skills workshop using role play and simulation, and (3) ongoing monthly virtual meetings to support the online learning and communication workshop. Learners are given pocket-size serious illness conversation guides and scripts and access to symptom management tools. Details of the program training have been described elsewhere [23]. Upon completion of the program training, NPs are oriented to a template that is embedded in the NH electronic health record to document the palliative care encounter.

2.2. Conceptual framework

Fig. 1 outlines the study conceptual framework. The clear boxes on the bottom of the figure outline the overall sequence of study activities, including identifying persons with serious illness, the intervention itself, and measurement of outcomes. The RE-AIM Framework examines five factors— Reach, Effectiveness, Adoption, Implementation and Maintenance—to evaluate the impact of an intervention; it is a commonly used model to guide the design of all stages of biobehavioral clinical trial development, testing, and implementation [24,25]. The shaded boxes on the top of the figure link the study sequence, RE-AIM concepts and outcomes. The dashed boxes identify the study aims linked to the study activities.

The PPC-PAC intervention focuses on assessing and managing symptoms, conducting goals of care discussions, assisting with decision making and communicating findings with NH staff [8]. In previous qualitative work, we found a lack of communication between NH staff and care providers contributed to incongruous use of rehabilitation services that did not match palliative care recommendations or patient and family preferences for care [2,26]. Therefore, we incorporated standardized communication and documentation processes into the PPC-PAC intervention and follow up protocols to promote communication and implementation of recommendations.
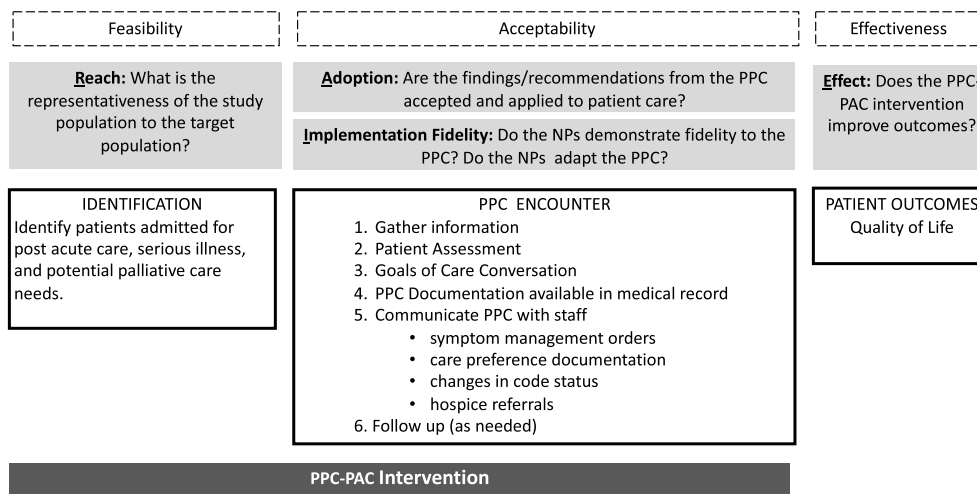

Fig. 1. Conceptual framework: Study design and integration with RE-AIM components.

2.3. Study design

This study is a two-arm pilot pragmatic clinical trial in a real-world practice setting using a nonequivalent group design; the unit of assignment is the NH NP. Study staff recruit newly admitted post-acute care NH patients after admission and collect data supporting the primary and secondary outcomes. The NPs who have been trained in the PCC-PAC intervention integrate its recommended palliative care practices into their daily clinical routines; they are not otherwise engaged in study activities.

2.4. Target population and study setting

Patients are recruited from 12 continuing care retirement communities with a NH post-acute care unit. Communities are located in Pennsylvania, Delaware, Maryland, and New Jersey. Each NH post-acute care unit has one unique NP on staff; patients in sites with an NP who has had full exposure to the intervention training are assigned intervention, all others are assigned to the control group (usual care). Assignment is not randomized. All NPs were offered training; NPs self-selected their participation in one of two training sessions offered over a one-year period. Convenience control sites were chosen after all training sessions were complete.

2.4.1. Inclusion criteria

Patients are eligible for the study if they meet the following criteria: 1) admitted to a participating NH for post-acute care following a recent hospitalization; 2) age ≥60 years; 3) English speaking; or 4) if non-verbal or unable to participate in a conversation, there is a legally authorized representative (LAR, also referred to as a surrogate decision maker) who can participate in the study on behalf of the patient; 5) have a diagnosis of one or more advanced serious illness using established criteria (Table 1); and 6) have at least one global indicator for palliative care at admission (Table 2). LARs who participate in the study on behalf of the patient must be: 1) at least 18 years old; 2) a family member or friend of an eligible patient who act as the surrogate decision maker; and 3) English speaking.

Table 1

Operationalization of advanced serious illness [20].

Dementia [44,45]	Brief Inventory of Mental Status (BIMS) ≤12 OR if unable to Complete BIMS, moderate/severe cognitive impairment
Cancer [17]	Stage III/IV lung, breast, gynecologic, gastrointestinal, genitourinary cancer, brain, melanoma, or hematologic malignancy
Advanced Cardiac Disease [46]	New York Heart Association Class III or IV heart failure; Use of an implantable defibrillator; Present or Past 2 years: planned or inoperable heart valve replacement or repair; heart artery bypass surgery; recurrent cardiac arrhythmias
Renal Failure [47]	Stage 4 and 5 Chronic Kidney Disease
Lung Disease [48]	Severe to Very Severe Pulmonary Disease (COPD, pulmonary fibrosis, acute respiratory distress syndrome in past year, pleural effusions in past year, oxygen dependence)
Neurological Disease [49]	Progressive neurological disease (motor neuron disease, parkinsonian syndromes/Parkinson's disease, cerebrovascular accident with hemiparesis, or dysphagia, or aphasia with/without need for medically administered nutrition OR recurrent cerebrovascular accident)
[a]Multiple Chronic Condition pairs [39,50]	Clinically active diagnoses at any stage: • Respiratory disease + cardiac disease • Dementia + cardiac disease • Dementia + respiratory disease • Cerebral Vascular Accident + cardiac disease

[a] Study modification in month 4.

Table 2

Global indicator for palliative care [20,51].

"Surprise question": Primary provider would not be surprised if patient died within 12 months and believes patient would benefit from advance care planning or has symptom management needs
Frequent hospital or SNF admissions (3 or more in the past year or 2 or more in the past 6 months)
Complex care requirements   • Wound care (wounds with one or more complicating factors such as exudate, infection)   • New feeding tube   • Total parenteral nutrition
Decline in function   • One or more falls in the past month   • Dependence in more than 3 ADLs   • Sleeping more than 50 % of awake time
Feeding intolerance   • Intake less than 50 % of usual for 2 or more meals/day on more than 4 days in the past week   • Excessive feeding tube residuals
Unintended decline in weight   • 10lbs over 6–12 months or less   • 5 % of body weight over 6–12 months or less   • Not due to fluid related to diuresis
previous hospice assessment or involvement[a]

[a] Study modification in month 4.

2.4.2. Exclusion criteria

Patients are not eligible if they: 1) have a discharge plan within 48 h of screening or 2) are referred for a specialty palliative care consult or are currently receiving hospice care at the NH.

2.4.3. Recruitment and informed consent

The study staff reviews the admission census once/week with the NH staff to identify eligible, newly admitted NH patients using post-acute care and attempts to recruit all patients who meet inclusion criteria, thus avoiding or minimizing selection bias. Confirmation of patients' decision-making capacity is made through thorough medical record review and discussion with NH providers. The LAR's legal authority to make healthcare decisions on behalf of the patient is verified by NH staff.

Patients or their LARs are approached for participation using broadcast notification, a form of alternative consent, which involves placing study-specific notices in prominent locations in a health care facility to inform patients they may be included in research as part of their ongoing care. Details about this approach have been documented elsewhere [27]. After determining eligibility, study staff approach the patient or the LAR, review with them the study notification document, and ask if they would like to 1) opt-out; 2) think about the study and contact study staff by phone or email to opt-out; or 3) decline from further contact with study staff. No data are collected until the patient/LAR confirm that they are aware of the study and are given the opportunity to opt-out. Patients/LARs are reminded that they can opt out at any time over the course of the study.

2.5. Outcome measures

2.5.1. Overview of data measurement

Several outcomes are used to assess the feasibility, acceptability, and effectiveness of the PPC-PAC intervention. NH census data and study recruitment and enrollment data are used to obtain measures on feasibility. Electronic medical record data and person-centered outcomes are used to assess acceptability. Person-centered outcomes also are used to assess the effect of the intervention on quality of life. These data are collected at 2 timepoints: baseline/study enrollment (day 1) and follow up (day 14–21). We attempt to collect data on all patients even if they are discharged from the NH. Additional demographic vari-

ables are collected from the medical record and used to describe the population in each arm and control for imbalances.

2.5.2. Feasibility

To assess feasibility, we collect the number of eligible patients at each site per number of admissions; contact rate; enrollment rate; intervention visit completion rates; follow-up data collection rates at 14–21 days; missing data rates; and percentage of completed assessment of primary and secondary outcome measures. Feasibility benchmarks for success include: (1) > 60 % of those eligible and approached enroll in the study, (2) there is successful enrollment of 80 participants, (3) > 70 % intervention visit completion rate among enrolled participants, and (4) collection of 95 % of the primary outcome data for 80 patients.

2.5.3. Acceptability

Acceptability is defined as (1) patient/LAR satisfaction with the palliative care encounter and (2) NP fidelity to the intervention and NH adherence to the PPC-PAC recommendations made by the NP. Satisfaction with the NP encounter is measured via the Consultation Satisfaction Questionnaire, an 18-item validated patient/caregiver-report instrument that measures communication and satisfaction of an encounter (1–5 scale; higher scores reflect greater satisfaction) at follow up [28]. Acceptability will be supported if the mean satisfaction with the consult is 4 or greater. We will explore NH adherence to the PPC-PAC recommendations made by the NP at follow up using electronic medical record data (see Table 3). We will assess overall adherence quantitatively for each participant as a percentage of all proposed recommendations that are implemented. NH adherence measures will contribute to our assessment of NH acceptability and adoption of the intervention.

2.5.4. Effectiveness: patient quality of life

The primary outcome for the study is the effectiveness of the PCC-PAC on patients' quality of life as measured by the Palliative Outcomes Scale (POS) Version 2, a brief validated tool to assess quality of life across five domains. Possible scores range from 0 to 40 with lower scores representing better quality of life [29]. The POS is collected from the patient/LAR at baseline and follow up.

2.5.5. Assessment of NP fidelity to the intervention

To enhance fidelity, the PI has incorporated strategies from the NIH Behavior Change Consortium including use of a treatment manual, regular contact (at least monthly) with the NPs who present cases and discuss protocol issues and modifications, and monitoring through direct observation [30]. The PI evaluates fidelity to the protocolized intervention through direct observation or an audio recording (with the patient/LAR's permission) of a random sample of 20 % of the PPC-PAC encounters using a standardized tool. The study team will quantitatively evaluate treatment delivery, including dose, intensity, and treatment receipt and use 80 % adherence to the six steps of the PCC encounter as a benchmark of success. Intervention adaptations are monitored using the Framework for Reporting Adaptations and Modifications Expanded (FRAME) model [31].

2.6. Patient assignment

Eight sites are assigned to the intervention and four sites are assigned as controls. The 2:1 ratio was selected for this pilot study to gain as much experience as possible implementing the intervention in different settings. Participants in the intervention group receive the PPC-PAC from NPs who have received the training and those in control receive usual care from an NP who has not received the training. The study team is not blinded to the assignment as they interact with the NPs at

Table 3
Measures assessed, tool used for measurement, source of assessment, time assessed and relation to RE-AIM.

Measures	Tool	Source	Collection Timepoint	RE-AIM Component
Effectiveness: Patient Quality of Life	Palliative Outcomes Scale version 2 (POSv2) [29] 12-item survey that measures quality of life in five dimensions: 1) physical; 2) emotional; 3) psychological; 4) spiritual needs, and 5) provision of information and support. Items scored on a 5-point Likert Scale (0 = not at all, 4 = overwhelmingly) based on symptom/need in the past week. Overall profile score is calculated by summing responses to the 10 questions (range 0–40). Time to complete: 5–7 min	NH patient or family caregiver	Baseline Follow-up	Effect
Acceptability: Encounter Satisfaction	Consultation Satisfaction Questionnaire (CSQ) [52] 18-item patient/caregiver-report instrument that measures communication and satisfaction of a consult in four domains 1) general satisfaction, 2) professional care, 3) depth of relationship, 4) perceived length of consultation (scale format: 5-point Likert, strongly agree to strongly disagree). Time to complete: 3–5 min	NH patient or family caregiver	Follow-up	Adoption
Acceptability: Fidelity to the intervention and adaptations	Evaluation of protocolized intervention through direct NP observation or an audio recording of a random 20 % sample of PPC-PAC encounter using a standardized tool.	Structured observation, monthly NP meetings	Ongoing	Implementation
Acceptability: Adherence to Recommendations	Adherence protocol Recommendation: completed, partially completed, not competed, N/A, notes) Time to complete: < 30 min	Medical record review and/or phone interview with NH patient/family caregiver	Follow-up	Adoption
Demographics /Covariates	Age Sex Race (White, Black or African American, Asian, Other) Ethnicity (Hispanic or Latino, Not Hispanic or Latino, Unknown/Not Reported) Advanced Serious Illness Diagnoses Palliative Care Indication Nursing Home Decision making capacity If surrogate/legally authorized representative, relationship	Medical record review	Baseline	Reach
Feasibility	Number of eligible patients at each site per number of admissions; contact rate; enrollment rate; intervention visit completion rates; follow-up data collection rates at 14–21 days; missing data rates; and percentage of completed assessment of primary and secondary outcome measures	Study sites, study database	Ongoing	Reach

the communities. However, the PI and Co-Is are not involved in individual data collection processes.

2.7. Data collection and management

A study team research assistant trained in data collection and management collects measures face-to-face or via phone, and if needed, mails study instruments to the patients/LARs with a self-addressed stamped envelope for return. Data is directly entered in a secured online template using a password protected tablet to minimize missing data during the study. All data, including recruitment and enrollment, is managed in a Research Electronic Data Capture (REDCap) [32] database. Quality checks are completed weekly by the study team project manager to identify data that appear incomplete.

2.8. Proposed data analysis

We will use descriptive statistics to evaluate our feasibility and acceptability benchmarks. We will calculate rates of eligible patients at each site per number of admissions; contact rate; enrollment rate; intervention visit completion rates; follow-up data collection rates at 14–21 days; missing data rates; and percentage of completed assessment of primary and secondary outcome measures. We will also calculate 90 % confidence intervals (CIs) for these metrics. To determine attrition, we will calculate how many participants leave the study (e.g., decline to continue, loss to follow-up) between data collection visits.

The primary analysis of effectiveness will be to compare the mean pre-post changes in POS between the intervention and control arms. While the intervention is assigned at the site-level, given the size of the pilot (8 intervention sites and 4 control sites), it is more feasible to perform the analysis at the individual-level. A linear regression model will be used to compare the two groups. The outcome variable will be pre-post change in POS score and the exposure variable will be an indicator for whether the patient was treated at an intervention site or control site. Additional relevant covariates will be adjusted for, including sex, age, and decision-making status. The within-arm changes in POS and differences in POS between arms will be summarized with two-sided 90 % CIs and p-values corresponding to tests against the null hypothesis of no (zero) change or difference. We will also explore subgroup effects of the intervention on endpoints by testing for statistical interactions between the binary group indicator and covariates of interest such as sex, age, race, and LAR participant on behalf of patient.

2.9. Power analysis

Following guidelines on sample size selection for pilot studies by Hertzog et al. [33], we focused on the corresponding precision (widths of confidence intervals [CIs]) of our estimates of feasibility to assess sample size. With 40 participants per group, the 90 % CIs for proportions (feasibility metrics) will be ±10–16 % for within-group propor-

tions, if the true proportions are between 10 and 90 %. This is sufficient precision for a pilot study under a wide range of possible outcomes.

For the comparison of pre-post changes in POS between intervention and control groups, we will have 80 % power to detect a difference between groups if the true difference is 0.56 standard deviation (SD) units and two-sided $\alpha = 0.1$. Assuming that POS (pre or post) has SD = 6, similar to values observed in previous studies [34–36],and that the correlation between pre- and post-POS values is between 0.3 and 0.7, the SD of the pre-post change in POS will be between 4.6 and 7.1. The effect size detectable with 80 % power is therefore between 2.6 and 4.0 on the POS scale (0.56 × 4.6 and 0.56 × 7.1).

Anticipating a 10 % rate of dropout or missing data over the 21-day study period will require a recruitment goals of 88 participants (NH patients). Sampling will occur at all sites until reaching 80 completed participants, 40 in each group.

3. Ethics considerations

The study protocol was reviewed and approved by the sponsor and University of Pennsylvania Institutional Review Board. The Review Board determined that the study constituted minimal risk to patient and LAR participants. All research protocols and forms are available on ClinicalTrials.gov #NCT03958552. In this study, a data safety monitoring plan was developed and approved by the NIH to ensure safety of participants.

4. Results

4.1. Preliminary feasibility

In the first six months of the study, the participating sites had a total of 287 unique post-acute patient admissions, of which 54 % (n = 156) were admitted using the Medicare post-acute care benefit. We were able to screen 70 % (n = 109); 43 % of those screened qualified for the trial (n = 47) and 66 % of those qualified ultimately enrolled (n = 31) —which allowed us to meet our eligible and approached to enrollment feasibility benchmark. Patients were not eligible for the trial because they had: no serious illness (n = 62) (as defined in Table 1), no global indicator for palliative care (n = 5) (Table 2), or inadequate decision-making capacity without an LAR (n = 1). Reasons eligible patients were not enrolled included: unable to be reached (n = 4), opted out (n = 4), advised not to approach by NH leadership (n = 3), discharge plan within 48 h (n = 2), and no reason (n = 3). At this time, other feasibility benchmarks are not available.

4.2. Study sites and baseline participant characteristics

Baseline characteristics of the study sites are listed below in Table 4. The structural characteristics of the study sites vary in terms of pres-

Table 4
Characteristics of study sites.

Site	A	B	C	D	E	F	G	H	I	J	K	L
Dementia Unit? (# of beds)	Yes (60)	Yes (61)	Yes (23)	Yes (20)	No	Yes (17)	No	No	Yes (16)	Yes (16)	Yes (16)	No
Post-acute care SNF Beds	120	88	92	73	82	60	60	34	40	45	41	38
Average Census	63	58	71	53	40	40	32	17	35	31	32	24
Mean (Range) SNF Admissions/month	15 (8–21)	12 (3–19)	6 (4–13)	6 (3–15)	8 (5–8)	6 (4–9)	8 (2–9)	6 (4–7)	1 (2–8)	5 (3–11)	6 (4–9)	5 (2–7)
Control (**Ctl**) or Intervention (**Int**)	Int	Int	Int	Ctl	Int	Ctl	Int	Int	Ctl	Int	Ctl	Int
State	PA	PA	PA	PA	PA	DE	PA	NJ	PA	DE	DE	MD
Urban/Rural	Urban	Urban	Urban	Urban	Urban	Rural	Urban	Urban	Urban	Rural	Rural	Rural
# of Hospice Agency contracts	1	1	1	1	1	4	1	2	1	1	2	1
Access to Spec PC Services	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	No	No
Proximity to Hospital	4.8 mi	6.1 mi	2.8 mi	4.2 mi	1.3 mi	0.3 mi	1.3 mi	7.0 mi	4.6 mi	8.3 mi	13.3 mi	0.7 mi

*All sites have Assisted Living services, on-site Nurse Practitioner.

ence of a dementia unit, number of NH post-acute care beds, monthly census, and mean admissions per month.

Baseline characteristics of the participants in the first 6 months of study enrollment are listed in Table 5. According to these data, most patients are female and over age 80 years. Slightly more than 70 % have decision making capacity. About one third of the sample is composed of people living with dementia, several (n = 3) of whom can make their own medical decisions (data not shown). In addition to dementia, the most common serious illnesses that qualify patients for the trial include advanced cardiac, respiratory, and neurological disease. The overwhelming majority of participants' indication for palliative care is a decline in function, followed by complex care requirements. The baseline average Palliative Outcome Scale score is 9 (range 2–19).

5. Discussion

Greater attention to seriously ill post-acute care NH patient's care goals, treatment preferences, and symptom management soon after admission is critical to ensuring high-quality palliative care. To date, there are no studies that have conducted a primary palliative care approach to improve care delivery among seriously ill post-acute care NH patients. The PPC-PAC intervention fills this gap; findings from this study will be used to inform a future, adequately powered, larger scale prag-

Table 5
Baseline characteristics of participants (N = 31).

Variable	Value[a]
Facility [b]	
A	16 (51.6)
B	5 (16.1)
C	3 (9.7)
D	1 (3.2)
E	3 (9.7)
F	1 (3.2)
G	1 (3.2)
H	1 (3.2)
Female sex[d]	24 (77.4)
Age	
70-79	5 (16.1)
80-89	15 (48.4)
90 +	11 (35.5)
Marital status	
Married or domestic partnership	13 (41.9)
Widowed or divorced	18 (58.1)
Decision-making capacity (yes)	22 (71.0)
Qualifying Diagnosis	
Dementia	7 (22.6)
Advanced Cardiac Disease	7 (22.6)
Neurological Disease	7 (22.6)
Respiratory Disease	6 (19.4)
Renal Failure	3 (9.7)
Advanced Cancer	1 (3.2)
PC indication	
Decline in function	19 (61.3)
Surprise Question	4 (12.9)
Complex care requirements	5 (16.1)
Frequent hospitalizations	3 (9.7)
Any Dementia diagnosis	10 (32.3)
Baseline POS (imputed)[c]	
Median (range)	9 (2–19)
Mean ± SD	9 ± 5

[a] Values are no. (%), median (range), or mean ± SD.

[b] 4 facilities did not enroll in the first 6 months.

[c] One subject did not respond to 4 POS items and was excluded from the summary; another subject did not response to 1 POS item, so the POS score was imputed by replacing the missing item rating with the average of the other ratings provided by that subject.

[d] All subjects were White Non-Hispanic/Latino.

matic clinical trial that includes diverse patients from a range of different races, social, economic, and ethnic backgrounds.

During the first six months of this pilot clinical trial, we learned that our trial is feasible and representative of several serious illness diagnoses and that for most, the global indicator for palliative care was functional decline (e.g., falls, dependence in daily activities, increase in sleep time during awake hours). However, the criteria we used to identify serious illness was based on diagnosis of one advanced illness, not the accumulating effects of multimorbidity resulting in serious illness and limited life expectancy [37]. By month four of study recruitment, it became apparent that we needed to broaden our inclusion criteria to represent the full spectrum of serious illness including multiple chronic conditions (MCCs). MCC is defined as two or more concurrent chronic conditions "that last a year or more and require ongoing medical attention and/or limit activities of daily living." [38] As MCCs increase, so does the risk of mortality [39].

In the report, *Multiple Chronic Conditions: A Strategic Framework,* the US Department of Health and Social Services outlines objectives for programs to address MCCs. Two strategies in this report to guide efforts to address MCC have a direct application to the current and future studies. One strategy is defining and identifying populations with MCC broadly and focusing care models on the subgroups at high risk of poor health outcomes [40]. Therefore, we added pairs of clinically active (i.e., currently being treated with therapies or interventions) MCCs that have demonstrated synergistic interactions to our inclusion criteria [39]. Another recommended strategy in the report emphasizes increased training and competency in palliative and patient-centered approaches in treating MCCs. The PPC-PAC training program addresses this strategy through the enhanced education and ongoing facilitation provided to the NPs; future work will incorporate education on palliative care and MCC to achieve this recommendation and support the intervention [15].

It is important to note that of the 31 participants, over 30 % are people living with dementia. We believe that their needs will be different enough from those with non-dementia serious illness to warrant additional investigation. Hermans et al. found greater psychosocial and spiritual PC needs among long-stay NH residents with dementia compared to those without dementia [41]. Further, NH residents living with neurocognitive impairment often have underrecognized physical symptoms such as pain [42]. Therefore, we plan to conduct a supplemental study that is focused on the unique needs of the population of people living with dementia and their care partners. The PPC-PAC will be modified using tools and evidence-based non-pharmacological practices specifically to address dementia serious illness and we will use dementia-specific outcome measures to measure its effectiveness.

To our knowledge, there are no studies that describe the demographic and clinical characteristics and associated palliative care needs of newly admitted post-acute care NH patients. While Stephens et al. evaluated potential palliative needs of NH residents in three northern California NHs [43], our work is unique as we are specifically studying post-acute care NH patients with serious illness. Using the POS, a multidimensional patient-reported palliative care assessment tool, we will assess different aspects of physical, psychological and supportive care needs [34]. As of now, it is difficult to confidently interpret and comment on the current sample baseline POS scores. However, the entire sample of baseline POS scores will be reported and stratified according to diagnosis and global indicator for palliative care to better understand the participants' needs on admission to post-acute care. The POS outcomes also will be used to further refine the PPC-PAC to meet patients' needs. For example, we may find that many patients or their care partners report unmet social or spiritual needs. In this case, we would adapt the PPC-PAC to more fully address these concerns.

In previous work, we found that several clinical trials testing complex palliative care interventions embedded into existing NH practices have showed no effect on patient outcomes [14]. One reason for this

could be inattention to intervention acceptability, fidelity monitoring, and/or implementation outcomes. Therefore, we will assess PCC-PAC intervention acceptability to different stakeholders (study participants, NPs, NH staff). Participant acceptability is measured via structured survey; if we find that this approach is not successful (e.g., due to non-response) we will engage patients and/or their care partners in interviews at the end of their study participation to provide feedback and guidance for future intervention refinement. In addition, this trial will provide essential fidelity data as well as information on adaptations that NPs make to the PPC-PAC. FRAME will be applied during observations and monthly meetings with the NPs to understand fidelity-consistent (i.e., preserve core PPC-PAC elements) and fidelity-inconsistent (i.e., do not preserve core elements) intervention modifications and their rationale [31]. These data will assist us in tailoring the PPC-PAC to different NH settings increasing its transferability in future large-scale testing. Lastly, NH adoption of the PPC-PAC recommendations will help us to assess if the intervention is accepted by NH staff. In future work, we will use the findings to assess why and how certain recommendations are or are not acted on as well as barriers to implementation.

Researchers and clinicians have widely documented the policy issues that create challenges to delivering palliative care in the NH setting [53,54]. Medicare paid post-acute care services are designed to maintain the patient's current condition or to prevent or slow further deterioration. How much a seriously ill patient's goals of care and expected illness trajectory match the basic purpose of the post-acute care benefit to promote improvement is uncertain [2,55]. Further, facilities with higher staffing of therapists compared to those with lower staffing are associated with high use of post-acute rehabilitative services in the last 30 days of life [56]. Medicare is currently structured to promote use of post-acute care because the facility receives a higher level of reimbursement. The benefit's payment structure favors rehabilitative or restorative care over comfort-focused care. Future work should focus on modifying current payment models for post-acute care to integrate high quality palliative services.

6. Conclusions

This will be the first study to evaluate an evidence-based palliative care intervention specifically designed for post-acute care NH patients diagnosed with serious illness. The goal of the PPC-PAC intervention is to assist NH based NPs in providing effective PPC to persons living with serious illness. Its purpose is to prevent, identify and treat symptoms early in the course of post-acute NH care, establish goal-directed treatment decisions, and support the patient and family in decision making. This pragmatic pilot clinical trial will provide essential data regarding the feasibility, acceptability, and preliminary effectiveness of the PPC-PAC vs usual care. If successful, it has profound implications for the quality of serious illness care in NHs.

Funding

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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