FULL PROTOCOL TITLE:

Palliative Care Consultations for Persons with Alzheimer's Disease and Related Dementia and Cognitive Impairment in the Medicare Skilled Nursing Facility (SNF) Setting

SHORT TITLE:

Palliative Care for Persons with ADRD in SNF

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Under the project manager and PI direction, the research assistant is responsible for developing and executing procedures and processes of study implementation, recruitment and retention, data collection, preparing Data/Safety monitoring reports, and regulatory processes.

1 STUDY OBJECTIVES

1.1 Primary Objectives (1a and 1b)

This study will examine the feasibility of a SNF-PC intervention in persons with Alzheimer's and related dementias (ADRD) and cognitive impairment (MCI) and address patient/caregiver reported outcomes including quality of life, symptom management, and satisfaction.

1a: Establish the feasibility of the SNF-Palliative Care (PC) intervention, determined by: (1) percentage of all post-acute SNF patients with ADRD/CI who meet eligibility criteria; (2) percentage of eligible patients with ADRD/CI and legally authorized representatives (LAR)/surrogate decision makers (also called a caregiver) who participate in the study; (3) percentage of participating patients with ADRD/CI who receive the SNF-PC and from whom all data are collected; and (4) clinician fidelity to the SNF-PC protocol (defined as 90% adherence to protocol elements).

1b: Measure patient/caregiver reported quality of life, symptom management, and satisfaction with care post SNF-PC in a two-arm non-randomized controlled pilot clinical trial among 50 patients with ADRD/CI.

1.2 Secondary Objectives (2)

This study will compare the demographics, clinical characteristics, and palliative (PC) needs of people with ADRD/CI versus non ADRD/CI serious illnesses during post-acute SNF care in NHs.

2 BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Alzheimer's disease and related dementias (ADRD) are serious, life limiting illnesses with no known cure. ADRD are often underdiagnosed in older adults yet cognitive impairment (CI) is often an early/middle stage of the dementia continuum with about one third of older adults with mild cognitive impairment developing dementia within 5 years.[1] Dementia is the fifth-leading cause of death in older adults [2] and the majority of people with advanced dementia die in nursing homes (NHs). [3] Miller et al reported that 40% of U.S. NH residents dying with advanced dementia received Skilled Nursing Facility (SNF) care in the last 90 days of life, and receipt of this care was associated significantly with poorer end-of-life outcomes, including a higher risk of dying in a hospital, compared to decedents with no SNF care. [4] SNF care is a Medicare post-acute rehabilitation service delivered in NHs focused on intense rehabilitation and/or aggressive, disease-modifying therapies. Regardless of life expectancy, use of SNF care precludes access to Hospice services. [5,6] Palliative care (PC) offers an evidence-based alternative. [7]

2.2 Study Rationale

PC offers an approach to improve care for older adults with ADRD in SNFs. [7,8] Key components of PC are: 1) open discussion of illness trajectories, and establishment and communication of patient- and family- directed goals that guide health care; 2) aggressive prevention, early identification and treatment of illness-related symptoms; and 3) identification of psycho-spiritual needs and approaches to mitigating suffering. [9,10] PC interventions are associated with improvements in patient quality of life and symptom burden. [9-12] There is evidence that PC for persons with ADRD can increase advance care planning and improve patient and caregiver satisfaction. [12]

The evidence-based SNF-PC encounter is a multi-component non-pharmacologic primary care provider delivered intervention designed to meet the PC needs of persons living with dementia (PLWD) receiving post-acute care in NHs. Components focus on assessing and managing symptoms, conducting and documenting goals of care conversations, communicating needs, recommendations, and treatment preferences of the NH team members.

3 STUDY DESIGN AND DURATION

3.1 Design

The study team will conduct a two-arm non-randomized controlled pilot clinical trial enrolling 50 persons with ADRD/CI who are in post-acute SNF NH care to meet the study objectives.

3.2 Enrollment Numbers

We anticipate screening up to 150 participants. Up to 50 patients with ADRD/CI admitted to 11 SNF NHs owned and/or operated by Acts Retirement Life Communities ("Acts") will be enrolled.

3.3 Study Duration

Participants will be enrolled in the study for up to a total of 21 days.

3.4 Compensation

N/A

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Key Inclusion Criteria

Patients: 1) admitted for SNF post-acute care at a participating NHs following a recent hospitalization, **2)** age ≥ 60 years old, **3)** speaks English (if verbal), **4)** if non-verbal/unable to participate in a conversation and/or unable to make decisions, has a legally authorized representative (LAR)/surrogate decision maker who can make decisions for the patient as determined by Acts staff, **5)** documented ADRD or CI (BIMS ≤ 12) diagnosis in the medical record, **6)** at least one global indicator for PC at SNF admission (provider would not be surprised if patient died within 1 year, believes the patient would benefit from advance care planning or symptom management; frequent hospital or NH SNF admissions; complex care requirements; decline in function; feeding intolerance; unintended decline in weight; or previous hospice assessment or enrollment and subsequent discharge).

Surrogate/LAR: 1) ≥ 18 years old; **2)** family member or friend of an eligible patient as determined by Acts staff; **3)** speaks English

4.2 Key Exclusion Criteria

Patients: 1) who have previously received or are referred for PC by their primary care team, **2)** with a discharge plan within 48 hours of screening, **3)** currently receiving hospice care, **4)** who do not have one global indicator of need, **5)** not recently hospitalized, **6)** not diagnosed with ADRD/CI (BIMS ≤ 12), **7)** <60 years of age, **8)** that are non-English speaking, (if verbal) and **9)** if unable to make decisions, do not have an LAR/surrogate decision maker.

Surrogate/LAR: 1) < 18 years of age, **2)** not a family Member or friend of an eligible patient, **3)** non-English speaking

4.3 Study Enrollment Procedures

UMB study team members will email designated points of contact at Acts at designated times that are predetermined and convenient for Acts staff weekly (this will vary based on their schedules). Study team members will then call the designated points of contact at each Acts site to receive new SNF unit admissions each week using the Screening Script for Acts. The study team will attempt to recruit all residents who meet inclusion criteria. The study team member will then contact designated Acts staff to screen and review medical records using the inclusion criteria to determine eligibility remotely. The research staff will not be cold calling potential participants. Acts staff will not be engaged in the research.

Global indicator of need: Acts staff will be given a copy of these forms to review medical records remotely with research staff. The purpose of this form is to confirm if the resident has at least one global indicator of need. If the resident is found to not have a global indicator of need, they will be excluded from the study. Those who meet these criteria will be contacted for enrollment into the study.

Once the study team has the list of eligible residents from the facility, they will contact potential participants (eligible patients or the LAR/surrogate decision makers of eligible patients) by phone and read the broadcast notification with the option to opt out. If they decide they want to enroll, study team members will arrange a convenient time to administer the baseline Palliative Care Outcome Scale version 2 (POSv2), Satisfaction with Care at the End of Life in Dementia (SWC-EOLD, and the Symptom Management at the End of Life in Dementia (SM-EOLD) with each patient or LAR/surrogate decision maker.

If patient names are provided by Acts, study staff will ensure they are recorded separate from the primary database and are used only for the necessary amount of time to complete enrollment after which the record will be erased/destroyed.

5 INTERVENTION

5.1 Palliative Care Encounter Intervention (STANDARD OF CARE)

Subjects will receive usual care plus a SNF-PC Encounter (intervention) by existing Acts providers who have been provided evidence-based PC focused training that includes ADRD/CI components. The goal of the intervention, the SNF-PC Encounter, is to evaluate illness understanding, symptom assessment and management, goals of care conversations, documentation, communication, and implementation recommendations. While the intervention is not specifically designed for patients diagnosed with ADRD/CI, all components are consistent with appropriate care for persons with cognitive impairment and their LAR/surrogate decision maker and include some ADRD/CI specific components. The intervention will be administered by Acts providers who have been trained to conduct the SNF-PC Encounter.

5.2 Handling of Study Interventions

A standardized treatment manual will guide the general approach for the Acts providers delivering the SNF-PC Encounter.

6 STUDY PROCEDURES

6.1 Research Procedures

In this pragmatic clinical trial, broadcast notification will be utilized to inform all newly admitted patients at each study site of their participation in this trial. During the admission process, potential subjects will be provided with a 1-page summary sheet (Broadcast notification) detailing their participation in this study that will include contact information for the study team, should the subject or their LAR/surrogate decision maker elect to opt-out of participating. Baseline data will be collected virtually via telephone by asking each newly admitted patient or their surrogate to complete the Patient Outcomes Scale (POSv2), the Satisfaction with Care at the End of Life in Dementia (SWC-EOLD), and the Symptom Management at the End of Life in Dementia (SM-EOLD).

Between 14 days and 21 days after the baseline POSv2, SWC-EOLD, and the SM-EOLD are administered, all subjects will be asked to complete the POSv2, SWC-EOLD, and the SM-EOLD again virtually via telephone. The POSv2, SWC-EOLD, and the SM-EOLD will be given a total of two times to those in the INTERVENTION and CONTROL groups (at baseline and follow up (14-21 days later)).

Deidentified subject demographics will be collected on all participants in the following way: Study team members will review subject's medical records and enter de-identified data into a Research Electronic Data Capture (REDCap) database (Acts staff assists with the study team’s access to subject's medical record).

The goal of the intervention is to prevent, identify and treat symptoms early during SNF care, establish goal directed treatment decisions, and support the patient and family in decision making. We anticipate that many Palliative Care encounters involve a single encounter with the patient and/or LAR/surrogate decision maker, but we have made allowances for follow up visits depending on individual patient and family needs (e.g., symptom management, continuing goals of care discussions). We will use usual care as the control condition. Usual care consists of traditional resources focused on skilled nursing care without services to support specialty palliative care. A usual care comparison will test whether the Palliative Care Encounter improves patient/family reported outcomes compared to traditional services. We have chosen to not use an attention control condition because the goal of this pilot clinical trial is to assess feasibility and determine the effect size of the intervention on the primary outcome.

Study team members will collect measures via phone or through a secured online template to minimize missing data at two time points (baseline and 14-21 days later) during the study. All data will be entered and managed in REDCap by the RA, project manager, or the PI.

Patient/Caregiver Quality of Life: Measured at baseline and follow-up (14-21 days later), the Palliative Outcomes Scale version 2 (POSv2) is a 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. (RESEARCH PROCEDURE)

Satisfaction With Care at the End of Life in Dementia (SWC-EOLD): Measured at baseline and follow-up (14-21 days later), the SWC-EOLD is a validated, 10-item scale that measures satisfaction with care for PLWD. Each item is measured on a 4-point Likert scale ranging from 1 ("strongly disagree") to 4 ("strongly agree") and uses a "prior 90 days" timeframe. Specific elements include satisfaction with medical and nursing care, decision-making, and their understanding of illness. All items are summed, yielding a range of scores of 10-40. Higher scores indicate greater satisfaction. (RESEARCH PROCEDURE)

Symptom Management at the End of Life in Dementia (SM-EOLD): Measured at baseline and follow-up (14-21 days later), the SM-EOLD is a valid and reliable 9-item scale that measures PLWD physical and psychological symptoms over the previous 90 days. Each item is rated on a 6-point Likert scale ranging from 0 to 5 (0 = "daily", 1 = "several days a week", 2 = "once per week", 3 = "2 or 3 days a month", 4 = "once a month", 5 = "never"). Scores are summed and range from 0 to 45 (higher scores indicate better symptom management). (RESEARCH PROCEDURE)

Palliative Care Encounter: Trained provider will discuss illness trajectories, establish, and communicate patient-directed goals that guide health care decisions, identify and treat illness-related symptoms, and identify psycho-spiritual needs and approaches to mitigate suffering. (STANDARD OF CARE)

6.2 Consenting Procedures

The study team will broadcast the study notification to all new admissions by placing a poster at the common areas of the facility as well as a copy of the broadcast study notification within the standard admissions paperwork (this provides a way for the patient or their legally authorized representative to receive a written statement of the research). The use of the broadcast study notification as well as the proposed broadcast study notification statement/flyer (included in this submission) has been approved by Acts (the participating nursing home). The broadcast notification will serve both as an advertisement and information sheet.

Study team members will consult virtually with Acts staff to determine eligibility and contact recently admitted potential participants via telephone. If the potential participant meets eligibility criteria, study team members will contact potential participants (eligible patients or the LAR/surrogate decision makers of eligible patients) by phone to explain the purpose of the study. The study team members will read the broadcast study notification to all subjects with the option to opt out.

Study team members can confirm that the individual is the LAR because we have been given the contact information by a designated Acts staff member who is involved in the resident's admission and overall care. The study team member asks the designated person at Acts if the resident can make their own decisions.

6.3 Data Collection

Baseline data will be collected virtually via telephone by asking each newly admitted patient or their LAR/surrogate to complete the Patient Outcomes Scale (POSv2) as well as two ADRD specific evaluations: the Satisfaction with Care at the End of Life in Dementia (SWC-EOLD) and the Symptom Management at the End of Life in Dementia (SM-EOLD).

Follow-up visit data will be collected virtually via telephone as well. The patient or surrogate/LAR will complete the POSv2, SWC-EOLD, and SM-EOLD 14-21 days post baseline measures.

6.4 Measures and Instruments

To establish feasibility, benchmarks for success will be measured. To measure quality of life, the Palliative Outcomes Scale (POSv2) will be used. To assess care satisfaction and symptom management, the Satisfaction with Care at the End of Life in Dementia (SWC-EOLD) and the Symptom Management at the End of Life in Dementia (SM-EOLD) surveys will be used.

Table 3 provides an outline of the outcome measures.

6.5 Table 3 Study Measures

Construct	**Measure/ Description**
Primary Outcomes: Baseline, 14-21 days	
Patient/Caregiver Quality of Life	**Palliative Outcomes Scale version 2 (POSv2):** A 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).
Secondary Outcome: Baseline, 14-21 days	

Satisfaction with Care	**Satisfaction with Care at the End of Life in Dementia (SWC-EOLD):** A validated, 10-item scale that measures caregiver satisfaction with care for persons with dementia. Each item is measured on a 4-point Likert scale ranging from 1 ("strongly disagree") to 4 ("strongly agree"). Specific elements include satisfaction with medical and nursing care, decision-making, and their understanding of the persons with dementia illness. All items are summed, yielding a range of scores of 10-40. Higher scores indicate greater satisfaction.
Symptom Management	**Symptom Management at the End of Life in Dementia (SM-EOLD):** A valid and reliable 9 item scale administered to a caregiver that measures persons with dementia physical and psychological symptoms. Each item is rated on a 6-point Likert scale ranging from 0 to 5 (0 = "daily", 1 = "several days a week", 2 = "once per week", 3 = "2 or 3 days a month", 4 = "once a month", 5 = "never"). Scores are summed and range from 0 to 45. Higher scores indicate better symptom management.

7 SAFETY MONITORING

7.1 Data Safety Monitoring Plan

The investigator will permit all study-related monitoring, audits, and inspections by the IRB and regulatory bodies. Participation as an investigator in this study implies acceptance of potential inspection by regulatory authorities. The PI will ensure the trial is conducted according to the approved protocol and be responsible for carrying out the DSM Plan. The PI will monitor the data safety monitoring plan and will submit an annual report to the UMB IRB.

7.2 Adverse Events and Serious Adverse Events

The study is low risk because it reflects current best practices for palliative care in the nursing home setting. We do not anticipate any adverse reactions to the intervention and therefore minimal risks to participants is expected. For Acts staff participating in the palliative care encounter training there is no risk. Adverse events (AEs) are defined as "unanticipated problems" involving risks to study participants or others (https://grants.nih.gov/grants/guide/notice-files/not99-107.html). AEs will be identified by study staff through participant self-report, routine study assessments, or through interactions with participants or SNF nursing home staff. Because this proposal involves an evidence-based palliative care intervention provided by specialty trained Nurse Practitioners, no serious adverse events are expected to occur. However, the following may occur and expected in persons with serious illness:

- Death, Hospitalization, Change in clinical status

Adverse Event (AE): AE is any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

Serious Adverse Event (SAE): SAEs consist of any adverse event that results in death; is life threatening or places the participant at immediate risk of death from the event as it occurred;

requires or prolongs hospitalization; causes persistent or significant disability or incapacity; results in congenital anomalies or birth defects; is another condition which investigators judge to represent significant hazards

Any SAE will be reported to the IRB as soon as possible but no later than 5 calendar days. If AEs or SAEs are identified or reported, the PI will convene an immediate (within 48 hours) ad hoc meeting with the study team. During this meeting, we will determine the relevance and significance of the AE to the study, including an aggregate analysis of other occurrences of the same (or similar) event. Then we will determine if the AE can be determined to be an anticipated or unanticipated problem (evaluate whether or not the event would have likely happened regardless of participation in the study) involving risk to human subjects or a serious adverse event and determine what, if any, follow-up is needed with the participant/family surrogate, participant's primary care team, and the nursing facility leadership and staff. AEs will be monitored on an ongoing basis by the research assistant and/or the project manager. A listing of AEs and their attribution (e.g., level of probability of being study related, intervention related, or unrelated to study or treatment) will be recorded and reviewed with each AE.

Data needing to be reported:

- The date the adverse event occurred
- The adverse event
- Relationship of the adverse event to intervention
- If the AE was expected
- The severity of the AE
- The intervention
- Detailed text that includes the following information:
    - An explanation of how the AE was handled
    - A description of the subject's condition
    - Indication if the subject remains on the study
    - If an amendment will need to be made to the protocol and/or consent form
    - If an amendment will need to be made to the protocol and/or consent form

The PI's signature and the date it was signed are required on the completed report.

7.3 Assessment of External Factors Related to AEs

The study team will track literature reports, developments in palliative care, and results of related studies that may have an impact on the safety of participants or on the ethics for this research study.

8 PARTICIPANT WITHDRAW/DISCONTINUATION

Subjects remain free to refuse the Palliative Care encounter (e.g.," SNF-PC") and/or any care or therapies offered because of said consultation. Subjects may withdraw voluntarily from participation in the study at any time and for any reason. Participants should continue to be followed for 30 days, with their permission, even if the study intervention is discontinued.

8.1 Study Discontinuation

The study may be discontinued at any time by the IRB, the NINR, the OHRP, or other government agencies as part of their duties to ensure that research participants are protected.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

N/A

9.2 Sample Size and Randomization

The primary outcome is to establish the feasibility of the post-acute Skilled Nursing Facility (SNF) Palliative Care (PC) intervention for patients with Alzheimer's disease and related dementias (ADRD) and cognitive impairment (CI). Following guidelines on sample size selection for pilot studies we focused on the corresponding precision (widths of confidence intervals [CIs]) of our estimates of feasibility to assess sample size. With 25 participants per group, 90% CIs for proportions will be ± 10-16% for within-group proportions between 10-90%, which is sufficient precision for a pilot under a wide range of possible outcomes. Another primary outcome of the study is to estimate effect sizes for the SNF-PC intervention on patient/family caregiver reported satisfaction with care, symptom management, and quality of life. Based on our current experience in the parent study, we anticipate up to 10% of participants will not have outcomes available (e.g., missing data or dropout).

Based on prior results and a conservative assumption of a modest correlation ($r = 0.3$) between pre- and post-intervention values, we estimate the corresponding standard deviation (SD) of pre-post changes of the Satisfaction with Care at the End of Life in Dementia (SWC-EOLD) scale to be 4.9 units. With 25 participants enrolled per group (22 with complete data), we will have 80% power to detect a change in SWC-EOLD within the intervention group of 2.7 scale units at a two-sided significance level of $\alpha = 0.1$, which corresponds to a clinically significant change. The precision of the mean changes in SWC-EOLD within group and between groups (90% CIs) would be ± 1.0 and ± 2.5 scale units, respectively. Lastly, with this sample size, the upper bound of the one-sided 90% CI for the SD of each endpoint will be only 17% higher than the point estimate, so there will be limited sample size inflation needed when powering a follow up study based on the SD estimates from the proposed study

This is a non-randomized pragmatic clinical trial.

9.3 Interim analyses and Stopping Rules

An interim analysis is not planned.

9.4 Data Analyses

We will establish the feasibility of the SNF-PC intervention in persons with ADRD/CI using established benchmarks based on published recommendations for evaluating pilot studies. We will track the number of eligible patients, monitor follow-up, document rates of eligibility, enrollment, and completion of the intervention, and collect the outcome measures with <5% missing data. We will determine clinician fidelity to the SNF-PC protocol

We also will estimate the effect size of the SNF-PC intervention on pre-post changes in the POSv2, SWC-EOLD, and the SM-EOLD relative to the control group. These estimates will be summarized with two-sided 90% Confidence Intervals and p-values corresponding to tests against the null hypothesis of no (zero) difference.

We also will examine the demographics, clinical characteristics, and palliative care needs of people with ADRD/CI versus non ADRD/CI serious illnesses during post-acute SNF care. As the

comparisons will be made using baseline/pre-intervention information, all 50 participants enrolled in this study are potentially includable in the analysis.

The primary analysis will be to compare the mean pre-post changes in the POS v2 between the intervention and control arms. Linear regression models will be used to compare the two groups. The within-arm changes and differences 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, and race.

Other key parameters needed to plan a follow-up study will be estimated as well, including the standard deviation (SD) and intraclass correlation coefficient (ICC) of each endpoint. The ICC summarizes the degree of correlation of values among patients within a site, which is an important parameter when planning a future cluster randomized controlled trial.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection/Management

Study data will be entered and managed using REDCap (http://www.project-redcap.org) which is a secure, web-based application. The University of Maryland is a member of the REDCap consortium, and this application is freely available to consortium members. REDCap provides: 1) an intuitive interface for data entry (with data validation), 2) audit trails for tracking data entry and changes, 3) automated export procedures for seamless data downloads to common statistical packages, 4) procedures for importing data from external sources, and 5) advanced features, such as branching logic and calculated fields.

10.2 Quality Assurance

10.2.1 Training

To maximize quality control, the study team will be trained in all data collection and entry procedures. A designated study team member will monitor data collection by checking completed data fields.

10.2.2 Metrics

The study team will utilize double-data entry methods on a 10% random sample, with checks for discordant errors, and as data are entered into the REDCap system.

10.2.3 Protocol Deviation

Protocol deviations will be captured, documented, and reviewed by a member of the study team during interaction with Acts staff and/or participants/LARs. The PI will monitor deviations and the team will review each deviation for its root cause and assess whether a modification to the protocol is needed.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

Confidentiality will be maintained by adhering to HIPAA guidelines. The study team will keep all data confidential in accordance with state and federal laws. Data will not be linked to

participant identifying name in the study database. Any data, specimens, forms, reports, or audio recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) and stored in secure computer files and locked filing cabinets to maintain confidentiality. All computer entry and networking programs will be done using PIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the NIA, and the OHRP. The study team will destroy the records at the earliest opportunity following data analysis and study completion.

11.2 Ethical Considerations

The guiding ethical principles being followed by the study include the NIH Common Rule.

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