Clinical Interventional Study

Protocol Template

PREFACE

The Clinical Intervention Study Protocol Template is a suggested format for clinical trials sponsored by the National Institute on Aging (NIA). Investigators are encouraged to use this format, as appropriate, when developing protocols for their studies. Large multi-site observational studies will also benefit from this protocol template.
Note that instructions and explanatory text are indicated by italics and should be replaced in your protocol with appropriate text. Section headings and template text formatted in regular type should be included in your protocol document as provided in the template.
The goal of this template is to provide a general format applicable to all single- and multicenter clinical intervention trials (e.g., drug, surgery, behavioral, nutritional, device, etc).
As you can see the version number and date are on the bottom of each page. When making changes to an approved and "final" protocol, please provide a summary of the changes, with the date, at the front of the protocol.

FULL PROTOCOL TITLE

Implementation of a Telehealth Palliative Care Model for Persons with Dementia

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Supported by:

The National Institute on Aging

IMPACT Collaboratory FY20_Pilot1_Carpenter

Study Intervention Provided by:

N/A

Sponsor of IND/IDE:

N/A

Version 1.9
September 21, 2022

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PRÉCIS

Study Title

Implementation of a Telehealth Palliative Care Model for Persons with Dementia

Objectives

1) Assess the reach of the Palliative Care Consultation in Post-Acute Care (PCC-PAC) intervention defined as acceptability and appropriateness through a Stakeholder Engagement Plan.
2) Assess Treatment Delivery Fidelity defined as a provider adherence to the PCC-PAC intervention protocol among 30 persons living with dementia (PLWD) in 1 nursing home (NH) with 2 providers.
3) Assess Intervention Implementation Fidelity defined as NH adherence to PCC-PAC recommendations among 30 PLWD in 1 NH with 2 providers

Design and Outcomes

Single arm pilot clinical trial to assess implementation outcomes of the PCC-PAC among 30 PLWD age 60 years or older newly admitted to a NH for post-acute care and their care partners.

Interventions and Duration

Subjects will receive usual care plus a telehealth palliative care consultation by specialty providers who will document their findings in the Electronic Health Record (EHR) and communicate their findings and recommendations to the clinical team.

Sample Size and Population

10 Stakeholders to meet objective 1

30 PLWD age 60 years or older newly admitted to a NH for post-acute care and their care partners to meet objectives 2 and 3.

STUDY TEAM ROSTER

Principal Investigator: **Joan G. Carpenter, PhD, CRNP**

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Supervise all aspects of this study's implementation including study start up, regulatory approvals, data collection, data management, all analyses, lead the drafting of primary manuscripts and conference abstracts.

Research Project Manager: **Jasmine A. Newman, B.S.**

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Manage all aspects of this study's implementation including study start up, regulatory approvals, data collection, data management, all analyses, lead the drafting of primary manuscripts and conference abstracts.

PARTICIPATING STUDY SITES

Site: UMB--The PI is engaged in research procedures at UMB including stakeholder engagement plan (focus groups and/or semi-structured interviews); assessment of nurse practitioner fidelity; assessment of nursing home implementation fidelity

Site: Collingswood Rehabilitation and Healthcare Center-- The telehealth palliative care consults are being implemented at this location; the site and staff are not engaged in research procedures. All activities at this location are 'standard care'.

1 STUDY OBJECTIVES

1.1 Primary Objective

Grounded in the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) Model, this study will assess the implementation outcomes of the provider delivered telehealth Palliative Care Consultation in Post-Acute Care (PCC-PAC) intervention for persons living with dementia (PLWD) and their care-partners newly admitted to nursing homes (NHs) for post-acute care.

1.2 Secondary Objectives

N/A

2 BACKGROUND AND RATIONALE

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

Dementia is the fifth-leading cause of death in older adults[1] and the majority of people with advanced dementia die in nursing homes (NHs).[2] Miller at al reported that 40% of U.S. nursing home (NH) residents dying with advanced dementia received post-acute 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 (EOL) outcomes, including a higher risk of dying in a hospital, compared to decedents with dementia and no SNF care.[3] SNF care is a Medicare post-acute rehabilitation service delivered in NHs focused on intense rehabilitation and disease-modifying therapies. Regardless of life expectancy, use of post-acute SNF care typically precludes access to hospice services. Palliative Care (PC) offers an approach to improve care for persons living with dementia (PLWD) in SNFs.[4,5] It incorporates symptom assessment and management and open communication and documentation of patients'/families' goals of care and treatment preferences.[6]

2.2 Study Rationale

Research demonstrates that PC consultations are associated with improved health-related quality of life and lower symptom burden.[7] Specifically, NH residents who receive PC consultations are significantly less likely to be hospitalized at the EOL compared with propensity-matched controls.[8,9] Studies have shown that PC delivered to PLWD increases advance care planning[10] improves patient and care partner satisfaction,[11] and reduces costs[12] and acute care use.[13, 14]

The evidence-based Palliative Care Consultation in Post-Acute Care (PCC-PAC) is a multi-component non-pharmacologic, nurse practitioner provider delivered intervention designed to meet the needs of PLWD receiving post-acute care in NHs. Components focus on assessing and managing symptoms; conducting and documenting goals of care conversations; and communicating needs, recommendations, and treatment preferences to the NH team members and primary care providers. PCC-PAC is well suited for telehealth delivery because care for PLWD often involves family care partners (e.g., caregivers, surrogate decision makers), many of whom are unable to visit inside the facility and thus rely on remote communication with providers.

3 STUDY DESIGN

Embedding complex interventions in NHs is challenging and requires addressing barriers to adopting new practices.[5,15] Well-established guidelines emphasize the need for conducting carefully designed pilot pragmatic studies to address effective implementation (defined as acceptability and appropriateness, treatment fidelity, and implementation fidelity).[16]

This single arm embedded pragmatic pilot clinical trial will provide data to assess the implementation outcomes of the provider delivered telehealth Palliative Care Consultation in Post-

Acute Care (PCC-PAC) intervention among 30 persons living with dementia (PLWD) and their care-partners newly admitted to one nursing homes (NH) for post-acute care.

To assess acceptability and appropriateness, we will engage approximately 10 stakeholders in a stakeholder engagement plan that include (1) PC providers; (2) Social Work (SW) NH champions; (3) post-acute care unit nursing staff and providers (including medial directors); (4) NH leadership, information technology staff; and (5) a PLWD and their care partners in focus groups and one on one semi structured interviews via phone or videoconference. Before, during, and after the study, we will invite stakeholders to join 8-10 regularly scheduled meetings to discuss different aspects of the PCC-PAC intervention and its implementation. Interview guides will be used to structure the meetings. Interview guides will be developed in an iterative fashion informed by the previous meetings and submitted to the institutional review board prior to being used. Note: a PLWD who receives the intervention will not be in the stakeholder engagement plan.

To assess Treatment Delivery Fidelity defined as providers adherence to the PCC-PAC intervention protocol among 30 PLWD in 1 NH with 2 providers.

To assess Intervention Implementation Fidelity defined as NH adherence to PCC-PAC recommendations among 30 PLWD in 1 NH with providers.

PCC-PAC Intervention Structure: The PC providers conducts the structured PCC-PAC via videoconference or telephone. The communication component includes documentation using a standardized template that is integrated into the electronic health record (EHR) PointClickCare® and direct contact with NH team members and primary care provider. New visits last approximately 45 minutes and follow up visits 20 minutes. Each PLWD and care partner receives at least 1-2 visits; follow up visits depend on their ongoing needs but no longer than 30 days after new visit.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

Stakeholders (1) PC providers; (2) Social Work (SW) NH champions; (3) post-acute care unit nursing staff and providers (including medical directors); (4) NH leadership, information technology staff; and (5) PLWD and their care partner(s).

PLWD: 1) documented dementia diagnosis, 2) admitted for post-acute care; 3) age ≥ 60 years; 4) if unable to participate in a conversation or lacking capacity to make healthcare decisions as determined by the NH staff/providers, a care partner who can act as a surrogate decision maker in the PCC-PAC.

4.2 Exclusion Criteria

Stakeholders: PLWD who receives the intervention

PLWD: All candidates meeting any of the exclusion criteria at baseline will be excluded from study participation: 1) planned discharge within 48 hours of screening, 2) currently receiving specialty palliative and/or hospice care

4.3 Study Enrollment Procedures

Stakeholders: Stakeholders will be identified by the participating NH leadership. We will invite stakeholders by phone or email to join regularly scheduled phone or video conference meetings to discuss different aspects of the intervention and its implementation. Using an interview guide we will conduct 8-10, 1-hour focus group and/or semi-structured interviews via phone or videoconference with different groups of stakeholders to encourage open communication and

identification of challenges and facilitators that are unique to each group. We will conduct the stakeholder engagement plan with an alteration (verbal) of standard informed consent.

PLWD screening/recruitment: With IRB and nursing facility approval, we will use a full waiver of HIPAA authorization to screen/recruit potential subjects. This pragmatic clinical trial involves minimal interaction between the research team and PLWD subjects; the PHI for identifying subject eligibility and contacting potential subjects is what is normally collected for usual clinical care by nursing facility social workers and consultants (palliative care nurse practitioners). Using the Electronic Health Record (EHR), participating sites Information Technology (IT) personnel or nursing home staff will identify PLWD over 60 years of age on post-acute care admission to a participating NH by an ICD 10 dementia diagnosis. They will generate a roster of potentially eligible PLWD which will be automatically delivered to the facility social work (SW) champion via secure email 2x/week.

PLWD enrollment: We will request a waiver of consent with an opt-out option to enroll partipants.[17] This is appropriate for IRB approved minimal risk interventions[18] of evidence based best practices and is consistent with clinical practice because PLWD or their care partner can opt-out of a palliative care consultation if it is not desired. In the PLWD and/or the care partner are non-English speaking, we will make interpreter services available and adhere to the nursing home site's procedures for interpreters.
We will maintain a deidentified screening log for ineligible candidate and for those who opt-out of PC consultation.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

The PC providers conducts the structured PCC-PAC (Table 1) via videoconference or telephone with the PLWD and/or their care partner and the social work (SW) champion in the NH. The SW and PC providers will set up a mutually agreed upon consultation day/time with the PLWD and/or care partner, within 5 business days of NH admission and follow up visits will occur no more than 30 days later (if needed). The PC provider will access the EHR PointClickCare® for clinical data and documentation. In keeping with a pragmatic trial, PC providers and NHs will have some flexibility implementing the protocol and this will be reviewed during stakeholder interviews. Because the trial is pragmatic, we expect the nurse practitioners and nursing home staff may make adaptations to tailor the protocol to their local context. All adaptations will be tracked and reported. providers and SWs also will provide feedback on the technical quality of the phone or videoconference via a technical quality form.
The potential risks associated with study participation are minimal because the study focuses on evidence-based assessment and management tools. Most of the data collected for the study is information that is similar to that which is already contained in the medical record. Patients who are able to self-report will be queried regarding their pain, function, and mood, but again, this information is not outside the realm of what is collected for clinical purposes.

Table 1. Telehealth PCC-PAC Encounter Protocol

Steps	Actions/Content	Materials
1. Gather Information	- Discuss progress since admission with facility social work champion (e.g. improvement, stabilization, decline) - Elicit patient/family/staff input	□ Electronic Health Record (EHR) PC note template □ Video/tele conference
2. Patient Assessment	- Examine patient assisted by facility social work champion (subjective, objective assessments) - Conduct a comprehensive pain and symptom assessment	□ EHR PC note template □ Primary team notes □ Video/tele conference

3. Goals of Care Conversation	- Determine illness understanding/ treatment expectations - Discuss initial transition planning after post-acute care - Elicit goals; explore preferences for type and site of care	□ Advance care planning education □ Communication scripts/guides □ EHR PC note template □ Video/tele conference
4. Document	- Symptom assessment/management - Propose treatment plan, ensure patient/family agreement	□ Symptom management protocols □ EHR PC note template
5. Communicate	- Communicate findings and recommendations to nursing and medical staff; determine agreement - Determine if additional visit or meeting is needed	□ Preferred communication with primary care provider and staff □ EHR PC note template
6. Follow up	- Decide based on continued need for symptom assessment and management and ongoing goals of care discussions	□EHR PC note template for follow up

5.2 Handling of Study Interventions

A standardized treatment manual will guide the general approach for the providers and SWs delivering the intervention.

5.3 Concomitant Interventions

5.3.1 Allowed Interventions

All

5.3.2 Required Interventions

None

5.3.3 Prohibited Interventions

None

5.4 Adherence Assessment

We will assess Treatment Delivery Fidelity to the 6 steps and corresponding content of the PCC-PAC encounter protocol (Table 1) on a 20% random sample of (n=3 per provider) by direct observation or an audio recording (with the provider and PLWD/care partners permission). The PI will conduct monthly (or more often as needed) calls with the providers who will present cases and discuss telehealth PCC-PAC encounter protocol issues or adaptations.

We will evaluate Intervention Implementation Fidelity, defined as evidence of collaboration between the PC provider and NH team members and primary care providers using a standardized chart audit tool. We will review the EHR PCC-PAC encounter note template and subsequent treatment/therapy orders and plan of care changes, and therapies actually administered in the medical administration record and treatment administration record to assess whether the PCC-PAC was accurately 'received' by the participant. Table 2 captures the 'mechanisms' of the intervention.

We will use outcomes of the treatment delivery and intervention implementation fidelity evaluations to provide additional context for stakeholder interviews and learn about adoption, acceptability, and provider/SW or facility adaptation of the intervention.

Table 2. Intervention implementation fidelity monitoring protocol

Component	*Complete*	*Partial*	*None*	*N/A* *	*Notes*
Goals of care:					
1. Recommend IDT meeting to discuss concerns					
2. Complete IDT meeting					
3. Recommend portable life sustaining treatment form or ADs					
4. Complete portable life sustaining treatment form or ADs					
5. Other (list):					
Symptom management:					
1. Recommended medications for symptoms are ordered					
2. Recommended medications for symptoms are administered					
3. Other (list):					
Recommended Referrals completed:					
1. Hospice					
2. Spiritual care					
3. Other (list):					

*no relevant recommendations; IDT- interdisciplinary team; ADs= Advance Directives

6 STUDY PROCEDURES

6.1 Schedule of Evaluation for Intervention

Assessment	*Screening: Visit (Day -14 to Day -1)*	*Baseline, Enrollment (Day 0)*	*Treatment Visit 1 Day 5 (±2 Days)*	*Follow-up Visits) by Day 20 (± 10 Days)*	*Post-completion*
Demographics	***X***				
Inclusion/Exclusion Criteria	***X***				
Enrollment		***X***			
Adverse Events			***X***	***X***	
Treatment Delivery Fidelity			***X***		
Intervention Implementation Fidelity					***X***

6.2 Description of Evaluations for the Intervention

6.2.1 Screening Evaluation

Screening

PLWD: Using the Electronic Health Record (EHR), participating sites Information Technology (IT) personnel to identify PLWD over 60 years of age on post-acute care admission to a participating NH by an ICD 10 dementia diagnosis. They will generate a roster of potentially eligible PLWD. SWs will review the roster of potentially eligible PLWD with the PC provider 2 times/week, including decision-making capacity, ability to participate in a goals of care discussion, and presence of care partner who can act as an LAR/surrogate if needed. The SW also will facilitate scheduling the PCC-PAC with the PLWD and/or care partner and supply additional clinical information if needed.

Consent Procedure

PLWD: We will seek a waiver of traditional informed consent for this study. A waiver of consent is permitted under 45 CFR provided the study meets the following requirements:

- The research involves no more than minimal risk to subjects;
- The waiver or alteration will not adversely affect the rights and welfare of subjects;
- The research could not practicably be carried out without the waiver or alteration;
- When appropriate, the subjects will be provided with additional pertinent information after participation

We will seek approval from the Institutional Review Board to conduct this pragmatic trial with a waiver of informed consent based on the following NIH Common Rule criteria: (1) palliative care consultation is standard of care and a low risk intervention; (2) the waiver will not adversely affect the rights and welfare of the subjects; hospice/palliative care and telehealth consults are already being offered in this site and this trial seeks to increase the opportunity for PLWD and their surrogates to benefit from telehealth palliative care consultation, while not restricting choice to forego it because it is not offered (3) The research cannot be practicably conducted without a waiver of the requirement for informed consent; the trial will evaluate system-level implementation of an evidence-based intervention; requiring prospective informed consent would introduce important selection biases greatly reducing the knowledge generated; and (4) to the extent possible, the subjects will be provided with pertinent information after participating in the trial.

Baseline Assessments (Self- Reported)

- Sex
- Race
- Ethnicity

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

PLWD: Despite seeking a waiver of consent, subjects still retain full autonomy over their healthcare decisions, including whether to participate in the telehealth palliative care consult. Subjects remain free to refuse the palliative care consultation and/or any care or therapies offered as a result of said consultation.

PLWD subjects will be informed by the provider/SW that they are receiving a clinical evaluation via telehealth to discuss goals of care, symptoms, and any unmet needs associated with their illness.

Baseline Assessments (from Electronic medical record)

- Age
- Sex
- Race
- Ethnicity
- Marital Status
- Diagnoses & Co-morbidities
- Brief Inventory of Mental Status
- Relationship of LAR/surrogate to subject
- Palliative Care Consult Notes
- Subsequent medical orders

Randomization

N/A

6.2.3 Follow-up Visit(s) Day 20 (± 10 Days)

- Adverse Events
- Palliative Care Consult Notes
- Subsequent medical orders
- Hospitalizations

6.2.4 Completion/Final Evaluation

N/A

7 SAFETY ASSESSMENTS ** NOTE: THIS PROJECT REQUIRES SAFETY OFFICER (SO) OVERSIGHT RATHER THAN A FULL DSMB**

7.1 Specification of Safety Parameters

The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. In addition, the NIA-appointed SO will oversee all data and safety monitoring activities for this study. This SO will act in an advisory capacity to the NIA Director to monitor participant safety, to evaluate the progress of the study, and to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. Advarra IRB will conduct the ethical review required for the protection of human subjects.

Refer to the NIA IMPACT Collaboratory Omnibus DSMB Charter for details.

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

Safety reports will be provided directly to the SO and NIA PO by the study team at the intervals described below. The SO will report on the status of pilot studies they are overseeing at the NIA IMPACT Collaboratory DSMB meetings.

For the pilot study, the frequency of DSM will proceed as follows: 1. Prior to the start of participant enrollment and data collection, the pilot study PI must submit a DSMP for approval by the SO and/or the NIA PO; 2. Four to six months after the initiation of participant enrollment and/or data collection, the pilot study PI must submit a DSM report to the SO. This interim report will be reviewed by the SO to determine whether there are any human subjects or data safety concerns; and 3. At the end of the pilot study, the PI must submit a final DSM report to the SO.
The content of the data and safety monitoring report will include: study status, subject descriptive demographics, any safety findings, actions taken, and plans to abate any potential risks identified during the course of the study.

7.3 Adverse Events and Serious Adverse Events

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.

- PLWD experiences inadequate symptom management or side effects from a therapy that is recommended by the PCC-PAC

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

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 in persons with serious illness:

- Death, Hospitalization, Change in clinical status

7.3.1 Reporting Procedures

Because this study involves minimal interaction between the research team and subjects, AEs and SAEs will most likely be identified through conversations with and reporting by clinical staff (providers & SWs) who provide direct care to enrolled subjects. Regular, monthly meetings with clinical staff will include dedicated questions to elicit whether any possible AEs or SAEs may have occurred.

AEs and SAE's will be recorded by the PI, research assistant immediately and the research team will conduct an analysis and determination of 1) whether or not the adverse event occurred, 2) the seriousness of the adverse event, 3) likelihood that the adverse event is associated with the intervention/study procedures; and 4) if necessary, preparation of report to the IRB and other entities.

Event	**Action**
Participant experiences inadequate symptom management or side effects from a therapy that is recommended by the PCC-PAC	**Primary care team will be advised to make therapeutic adjustments.** **Study team staff member completes alert form and provides to project manager and PI. A determination will be made by the person reporting the event, the PI**

	and the study team jointly as to the extent to which the event is a consequence of the intervention. **Study team staff member monitors series of events.**
Death **Hospitalization** **Change in clinical status**	**Study team staff member completes alert form and provides to project manager and PI.** **A determination will be made by the person reporting the event and the PI jointly as to the extent to which the event is a consequence of the intervention.** **Monitor series of events in both groups to determine if rate is higher in the either group**

- All adverse events that are both serious (SAE) and unexpected (i.e., have not been previously reported for the study's intervention) will be reported to the IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the IMPACT Collaboratory SO (Dr. Madhuri Reddy) within 48 hours of the study's knowledge of SAE.
- The summary of all other SAEs will be reported to IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the IMPACT Collaboratory SO (Dr. Madhuri Reddy) quarterly, unless otherwise requested by the SO.
- All deaths will be reported to IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the IMPACT Collaboratory SO (Dr. Madhuri Reddy) within 24 hours of study's knowledge of death.
- AEs will be reported per IRB policies and also to IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the SO (Dr. Madhuri Reddy) at minimum every 6 months, or at a frequency requested by NIA and/or by the SO.

  Severity

  • Mild: Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.

  • Moderate: Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities, but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning

  • Severe: Events interrupt the participant's normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating

  Relatedness

  • Definitely Related: The adverse event is clearly related to the investigational agent/procedure – i.e. an event that follows a reasonable temporal sequence from administration of the study intervention, follows a known or expected response pattern to the suspected

intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure and that could not be reasonably explained by the known characteristics of the subject's clinical state.

- Possibly Related: An adverse event that follows a reasonable temporal sequence from administration of the study intervention follows a known or expected response pattern to the suspected intervention, but that could readily have been produced by a number of other factors.

- Not Related: The adverse event is clearly not related to the investigational agent/procedure - i.e. another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event and the study intervention and/or a causal relationship is considered biologically implausible.

7.3.2 Follow-up for Adverse Events

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during conversations with providers/SWs.

All AEs not meeting the criteria for SAEs will be captured on the appropriate form. Information to be collected includes event description, time of onset, qualified medical professional's assessment of severity, relationship to (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE.

A study team member will record all reportable events with start dates occurring any time after study enrollment is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. Events will be followed for outcome information until resolution or stabilization.

7.4 Safety Monitoring

An NIA IMPACT safety officer will oversee study safety monitoring. The Principal Investigator will be responsible for ensuring participants' safety on a daily basis. In addition, the NIA-appointed SO will oversee all data and safety monitoring activities for this study. This SO will act in an advisory capacity to the NIA Director to monitor participant safety, to evaluate the progress of the study, and to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. Advarra IRB will conduct the ethical review required for the protection of human subjects.

8 INTERVENTION DISCONTINUATION

Subjects remain free to refuse the palliative care consultation and/or any care or therapies offered as a result 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.

If subject discontinued is due to an AE or SAE, every effort will be made to undertake protocol-specified safety follow-up procedures. If voluntary withdrawal occurs, the subject will be given appropriate care under medical supervision until the symptoms of any AE resolve or the subject's condition becomes stable.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

N/A

9.2 Sample Size and Randomization

As this is a pilot clinical trial, the primary objective is to study the implementation outcomes to inform refinement of the intervention and modifications for a large-scale effectiveness trial. We anticipate 8-10 stakeholders will be required to achieve an understanding of the acceptability and appropriateness of the telehealth PCC-PAC and 30 PLWD to assess intervention fidelity and NH adoption of the telehealth PCC-PAC.

9.2.1 Treatment Assignment Procedures

All PLWD subjects will be assigned to the intervention.

9.3 Interim analyses and Stopping Rules

An interim analysis is not planned.

9.4 Outcomes

9.4.1 Primary outcome

Implementation outcomes: acceptability, appropriateness, intervention fidelity, and NH adoption of the telehealth PCC-PAC

Clinical outcome:

Number of hospitalization(s)

9.4.2 Secondary outcomes

N/A

9.5 Data Analyses

Stakeholder Engagement: Interviews will be audiotaped and transcribed verbatim and managed and analyzed using NVivo 12.0. We will conduct initial descriptive data coding guided by directed content analysis techniques to describe the perceived most and least effective components of the intervention, barriers to implementation, and factors that facilitated the uptake, acceptance (adoption), and any adaptations of the intervention. We will then reorganize and condense coded data to compare similarities and differences and identify overarching categories. Categories will be grouped by their properties to develop themes. The study team will meet weekly during analysis to discuss codes, categories, and initial themes. The team will maintain a comprehensive audit trail, including methodological and analytic memos throughout the project.

PLWD: Intervention Implementation Fidelity (collaboration and implementation of findings from the PCC-PAC): Participating sites IT will provide deidentified reports to the study staff including each participants PCC-PAC notes and accompanying medical and treatment orders in the EHR. We

will quantitatively evaluate treatment delivery and treatment receipt using 90% adherence as a benchmark of success. Hospitalizations will be quantified for each participant

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

The project manager or research assistant will collect clinical and demographic variables for eligible subjects from the EHR.

10.2 Data Management

Study data will be entered and managed using NVivo 12.0 and 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.

10.3 Quality Assurance

10.3.1 Training

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

Quality Control Committee

N/A

10.3.2 Metrics

We 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.

10.3.3 Protocol Deviation

Protocol deviations will be captured, documented, and reviewed by a member of the study team during interaction with providers and SWs. 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. Of note: PCC-PAC Intervention protocol adaptations will be tracked using a standard form.

10.3.4 Monitoring

The PI will monitor protocol compliance and data quality monthly with the study team.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and any subsequent modifications will be reviewed and approved by the Advarra IRB who is responsible for oversight of the study.

Consent Procedure

Stakeholders: will provide verbal consent for participating in focus groups or semi-structured interviews using a script. The stakeholder who is a PLWD will be read the script for verbal consent to participate in the focus groups/semi structured interviews. The PLWD will then be asked what they understand about the purpose, the procedures, and the ability to refuse participation in the focus groups/semi structured interview at any time.

PLWD: We will seek a waiver of traditional informed consent for this study. A waiver of consent is permitted under 45 CFR provided the study meets the following requirements:

- The research involves no more than minimal risk to subjects;
- The waiver or alteration will not adversely affect the rights and welfare of subjects;
- The research could not practicably be carried out without the waiver or alteration;
- When appropriate, the subjects will be provided with additional pertinent information after participation

We will seek approval from the Institutional Review Board to conduct this pragmatic trial with a waiver of informed consent based on the following NIH Common Rule criteria: (1) palliative care consultation is standard of care and a low risk intervention; (2) the waiver will not adversely affect the rights and welfare of the subjects; hospice/palliative care and telehealth consults are already being offered in this site and this trial seeks to increase the opportunity for PLWD and their surrogates to benefit from telehealth palliative care consultation, while not restricting choice to forego it because it is not offered (3) The research cannot be practicably conducted without a waiver of the requirement for informed consent; the trial will evaluate system-level implementation of an evidence-based intervention; requiring prospective informed consent would introduce important selection biases greatly reducing the knowledge generated; and (4) to the extent possible, the subjects will be provided with pertinent information after participating in the trial.

PLWD subjects will be informed by the provider/SW that they are receiving a clinical evaluation via teleheath to discuss goals of care, symptoms, and any unmet needs associated with their illness. As this is a pragmatic clinical trial and the PCC-PAC is being integrated into the routine and usual care delivery of PLWD, the SW will use the same approach they use for other usual care delivery activities in the facility that address goals of care, symptoms, and unmet needs. Any of which the PLWD/surrogate decision maker will be informed that they can decline at any time.

INSERT HIPAA

11.2 Participant Confidentiality

We 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.

11.3 Study Discontinuation

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

12 COMPENSATION

Stakeholder subjects will be compensated **$50** per focus group or semi-structured interview that they participate in after providing verbal consent for a total of 8-10 focus group or semi-structured interviews over one year.
Subjects will be paid following each completed visit or at the end of their participation in the research study, whichever they prefer.

13 ETHICAL CONSIDERATIONS

The guiding ethical principles being followed by the study include the NIH Common Rule. [20]

14 COMMITTEES

N/A

15 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by the policies and procedures developed by the NIA IMPACT Collaboratory. Any presentation, abstract, or manuscript will be made available for review by the sponsor and the NIA prior to submission.

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17 SUPPLEMENTS/APPENDICES

Appendix I. Technical Quality Form

Phone/Video-call technical quality form

Type of Call: Zoom WebEx Skype FaceTime Phone
Other: _____
If the phone/video call did not take place, please indicate the reason:
subject didn't answer the call
connection could not be established
other, please indicate: _____
1) Did you at the central site experience any difficulties with:
Sound? Yes No
If Yes, please check one of the following in regard to the frequency of the experienced difficulty:
Once
A few times (2-3)
A lot (more than 3 times)
Visit was terminated due to this
Picture? Yes No
If Yes, please check one of the following in regard to the frequency of the experienced difficulty:
Once
A few times (2-3)
A lot (more than 3 times)
Visit was terminated due to this?
Other? Yes No
If Yes, please specify:_____
2) Did the patient/caregiver at seem to experience any difficulties with:
Sound? Yes No
If Yes, please check one of the following in regard to the frequency of the experienced difficulty:
Once
A few times (2-3)
A lot (more than 3 times)
Visit was terminated due to this
Picture? Yes No
If Yes, please check one of the following in regard to the frequency of the experienced difficulty:
Once
A few times (2-3)
A lot (more than 3 times)
Visit was terminated due to this
Other? Yes No
If Yes, please specify:_____
4) Would the conversation have been significantly better if it had been performed in person?
Yes No Don't know

5) Were there questions that you didn't ask today because of the phone/video that you would have asked in person?

Yes No Don't know

If Yes, please specify:_____

6) Did the patient/caregiver seem worried, concerned or generally in a bad mood today at the beginning of the video call?

Yes No Don't know

7) Overall, how would you rate the technical quality of today's phone/video call?

Excellent Good Acceptable Poor Unacceptable

8) Overall, how useful would you rate today's phone/video call for delivering the palliative care consult?

Very Useful Useful Neutral Not Useful
Interferes with the Consult

9) Please record any other thoughts or observations:

Appendix II. Adaptation Tracking Form

Date	
Description	
Reason	
By Whom?	
What is modified?	
At what level of delivery?	
Nature of modification (e.g., tailoring, refining)	
When during the project was the adaptation made?	
Why: purpose of the adaptation?	
Impact: short term results	
Notes	