Clinical Intervention Study Protocol

NCT05303194

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Version 3.0

FULL PROTOCOL TITLE

Patient Priorities Care for Hispanics with Dementia: adaptation and feasibility pilot study

FY20_Pilot8_Naik

Study Chairman or Principal Investigator:

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Supported by:

The National Institute on Aging

NIA IMPACT Collaboratory

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TABLE OF CONTENTS

Page

PRÉCIS

Study Title

Patient Priorities Care for Hispanics with Dementia: adaptation and feasibility pilot study

Objectives

Primary Objective: Adapt the Patient Priorities Care (PPC) approach (https://patientprioritiescare.org/) for Hispanics with multiple chronic conditions (MCC) and dementia.
Secondary Objective: Test feasibility of implementation of PPC in a sample of older Hispanics with MCC and dementia cared for at a Geriatrics Outpatient Clinic.

Design and Outcomes

Patient priorities care (PPC) will be initially incorporated in the workflow of a Geriatrics outpatient clinic at The University of Texas Medical Branch (UTMB). The PPC approach will be culturally adapted for older Hispanics in Texas through pilot testing with 5 subjects (Hispanics with multiple chronic conditions (MCC) and normal cognition). The study team will make clarifying edits to materials and processes to finalize adaptations to the 6-step toolkit for conducting PPC with Hispanics. Once the PPC team and the advisory team have completed all changes, a feasibility study with 20 Hispanics with cognitive impairment will be conducted in the same clinic at UTMB.

The primary objective of this pilot proposal is to adapt PPC for Hispanics. A secondary objective is to test the feasibility of using it on Hispanics with dementia. We will thus adapt and test PPC with 5 Hispanics and then test the adapted version with 20 Hispanics with dementia. One exploratory outcome is to determine if primary care providers use the identified priorities in the electronic medical record to guide changes in care aligned with priorities. The degree of alignment of care with priorities will be analyzed through chart reviews.

Interventions and Duration

Each participant will have one priority setting session with a PPC facilitator and one care alignment session with their PCP and will then have 1 interview with a research team member to evaluate the intervention.

Sample Size and Population

This pilot project is not intended to identify specific outcomes resulting from the PPC approach, thus no power calculations are needed. We will use descriptive statistics to examine frequency distributions and proportions for all quantitative variables. We will calculate effect sizes for changes in our exploratory outcome. Interviews with practice-based implementation team members will be performed by Dr. Samper-Ternent and analyzed using directed content analysis. Quantitative and qualitative findings will be triangulated using standard content

analysis methods to create meta-themes that synthesize the quantitative and qualitative findings. Inclusion of 20 subjects is therefore sufficient to directed content analysis with the expectation that we will obtain data saturation of each content area.

STUDY TEAM ROSTER

Principal Investigator: **Aanand Naik, MD**
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Role: PPC Content expert. He will oversee all research activities at UTMB and conduct quality control activities to make sure that adaptation and implementation of the PPC approach is done appropriately.

Co-Investigators: **Rafael Samper-Ternent, MD PhD**
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PARTICIPATING STUDY SITES

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Role: He will oversee implementation of the study at UTMB and will serve as the facilitator for all priority setting encounters in the study.

2 STUDY OBJECTIVES

2.1 Primary Objective

Adapt PPC to be culturally appropriate for Hispanics with dementia and test its feasibility in an outpatient setting.

2.2 Secondary Objectives

The adapted version of PPC will improve care by identifying the healthcare priorities of Hispanics with dementia and aligning them with the care they receive.

3 BACKGROUND AND RATIONALE

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

Most older adults with dementia have multiple chronic conditions (MCC),[1,2] experience difficulty managing their MCC, and have poorer outcomes.[3-6] Managing MCC typically involves adhering to single-disease clinical practice guidelines (CPG). This approach often results in burdensome care with outcomes that may not reflect what matters most to patients.[7-10] To address the challenges for caring for patients with MCC, we developed Patient Priorities Care (PPC) – an approach that aligns disease management with patient priorities rather than CPG, to improve care.[10-13] We demonstrated feasibility and effectiveness of PPC in a study embedded within a large primary and specialty care network.[14] Patients reported less burdensome treatment and had fewer medications and referrals.[14] A subsequent study found that PPC helped clinicians recommend home and community services aligned with patient priorities.[15] Focusing on patient priorities rather than CPG is a patient-centered approach that integrates well in routine clinic encounters.[16]

3.2 Study Rationale

Physical, emotional, and cognitive impairments related to dementia interfere with disease self-management.[17] Persons living with dementia (PlwD) therefore rely on caregivers for care and decision-making. Caregivers may add complexity to the patient-clinician interaction but are essential for translating 'what matters most' for PlwD into healthcare decisions.[18] Patient and caregiver involvement should include identifying outcome goals and care preferences (health priorities) as well as aligning care to meet those priorities. It is therefore important to integrate caregivers into the healthcare process to achieve high-quality, family-centered care.[19,20] In a feasibility study among Veterans with cognitive impairment and their caregivers, we demonstrated that PlwD and their caregivers are willing and able to identify health priorities. Clinicians could align care to achieve these priorities when placed in the electronic health record (EHR).

PlwD from minority groups experience more difficulties and poorer outcomes compared to their Non-Hispanic White (NHW) couterparts.[3-6] Hispanics are the fastest growing underrepresented population in the USA, and have 1.5 times higher risk of dementia compared to NHW.[21] Hispanics rely heavily on their families and there is a cultural

expectation of families to provide care to members in need.[22,23] Recent data report older Hispanics prefer care at home rather than professional care.[24] Cultural differences and language barriers play key roles in shaping healthcare priorities and how priorities impact outcomes among Hispanics.[25]

4 STUDY DESIGN

Figure 1. Conceptual Model of the Patient Priorities Care Approach

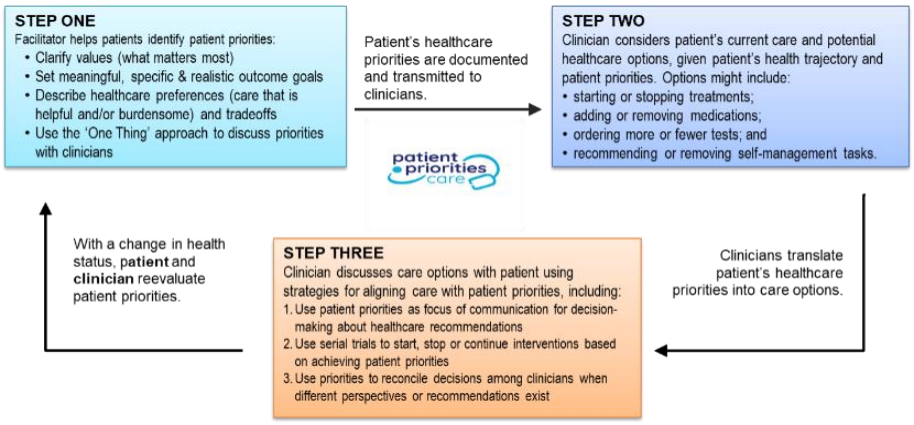

Figure 1 presents the main conceptual model of the PPC approach. For the adaptation 5 Hispanic patients will be included and for the feasibility test 20 Hispanic patients with cognitive impairment will be included.

The process will be as follows:

1) Eligible Hispanic patients will be identified through the patient roster of the Geriatrics Outpatient Clinic at UTMB.
2) Primary care providers will be asked to select patients they believe would not be good candidates for the study.
3) A research team member will contact the eligible patients and invite them to schedule the priority setting appointment (Step One). For those that agree she will obtain assent and/or consent and schedule the session.
4) The day of the session, the facilitator will use the PPC materials and identify the patient priorities and document them in the electronic health record. The visit will be audio recorded.
5) A research team member will schedule an appointment with the patient's primary care provider (PCP) within 2 weeks to conduct the alignment portion of the PPC approach (Steps two).
6) The primary care provider will discuss the patient priorities and the provider will align care to meet those priorities and document changes in care based on the discussion on the electronic health record (Step 3).
7) A research member will call the patient and assess their satisfaction with the PPC

approach 2 weeks after the visit with the primary care provider.

8) A research member will contact the primary care provider and assess their satisfaction with the PPC approach.
9) The PI, Co-PI and advisory team will review all the information and make adjustments to the protocol for the feasibility phase.
10) Steps 1-8 will be repeated with 20 Hispanic patients with dementia to test feasibility of the adapted PPC approach for Hispanics.

5 SELECTION AND ENROLLMENT OF PARTICIPANTS

The study has an initial adaptation phase and then a feasibility testing phase. For the adaptation phase 5 Hispanics with multiple chronic condition and without dementia will be invited to participate. These participants will need to consent to be part of the study. For the second phase, dementia can affect ability to consent. Thus, we will determine if participants with dementia have capacity by asking their primary care providers or by administering the telephone version of the Montreal Cognitive Assessment. If a score of less than 12 is obtained, the caregiver will be asked to consent for both participants.

5.1 Inclusion Criteria

For adaptation group (n=5)

- Patient's primary care provider is located in the UTMB Geriatrics Outpatient Clinic in Galveston.
- Patient identifies as Hispanic.
- Patient speaks English or Spanish.
- Patient has multiple chronic conditions listed as diagnoses in their electronic health record (3 or more chronic conditions).
- Consent to participate in all parts of the study.
- Primary care provider agrees with participation.

For feasibility testing (n=20)

- Patient's primary care provider is located in the UTMB Geriatrics Outpatient Clinic in Galveston.
- Patient identifies as Hispanic.
- Patient speaks English or Spanish.
- Patient has multiple chronic conditions listed as diagnoses in their electronic health record (3 or more chronic conditions).
- Patient has diagnosis of dementia.
- Have a caregiver willing to provide consent.

- Patient consent if he/she has capacity as deemed by their primary care provider or assent if he/she doesn't have capacity.

5.2 Exclusion Criteria

For adaptation group (n=5)

- Patient's primary care provider located at UTMB but not in the Geriatrics Outpatient Clinic.
- Non-Hispanic patients.
- Speaks language other than English or Spanish.
- Patient does not have multiple chronic conditions.
- Deemed ineligible by primary care provider.
- Patient has diagnosis of dementia.

For feasibility testing (n=20)

- Patient's primary care provider located at UTMB but not in the Geriatrics Outpatient Clinic.
- Non-Hispanic patients.
- Speaks language other than English or Spanish.
- Patient does not have multiple chronic conditions.
- Patient doesn't have diagnosis of dementia.
- Patient deemed ineligible by primary care provider.
- Patient doesn't provide consent or assent based on capacity.
- Caregiver doesn't provide consent.

5.3 Study Enrollment Procedures

The electronic health record at UTMB allows for selection of patients with different conditions that are cared for at specific clinics. For the adaptation part of the study we will select a list of Hispanics cared for at the UTMB Geriatrics Outpatient Clinic and ask primary care providers to exclude those that are not eligible for the study. For the feasibility part we will select Hispanic patients cared for at the UTMB Geriatrics Outpatient Clinic that are part of the dementia registry

in the electronic health record and have MCC. We will then ask their primary care providers to exclude those not eligible for the study.

6 STUDY INTERVENTIONS

6.1 Interventions, Administration, and Duration

For Step One of the PPC approach the priority setting session will take on average between 40-minutes and 60 minutes. Priority setting requires discussion of the patient's priorities and identifying what they are and are not willing to do to reach those priorities. Minimal risk is expected at this visit other than feeling uncomfortable with discussing their health related problems given that this is part of usual care.

7 STUDY PROCEDURES

Two clinic visits and one telephone follow-up comprise the entire intervention.

7.1 Description of Evaluations

7.1.1 Screening Evaluation

Consenting Procedure

Potential participants will be contacted over the phone by the research coordinator who will explain the project. A script will be available on Redcap for consent. Consenting will be performed once over the phone and verbal consent will be documented on the form. If the patient is deemed unable to consent in the pre-screening phase by the PCP or if they obtain a score less than 12 in the telephone version of the MoCA, a competent caregiver will be asked to consent and then the patient will provide assent.

Screening

The screening process will continue until all participants are included in the study.

7.1.2 Enrollment, Baseline, and/or Randomization

Enrollment

Enrollment will occur on the first visit where healthcare goals are identified.

Baseline Assessments

The visit where healthcare goals are identified is considered the baseline assessment.

Randomization

There will be no randomization.

7.1.3 Follow-up Visits

There will be one follow-up visit once healthcare goals are identified to conduct care alignment with the PCP. Once this step is completed there will be 1 follow-up call to evaluate the PPC process.

7.1.4 Completion/Final Evaluation

The care alignment visit is considered the final visit.

8 SAFETY ASSESSMENTS

A participant is enrolled if he/she completes the care alignment visit. No adverse events are expected given that only goal setting and care alignment will be performed as part of routine clinical visits.

8.1 Specification of Safety Parameters

We will monitor charts of enrolled subjects to track for any adverse events related to changes in care arising from care alignment procedures that differ from routine guidelines.

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

The proposed studies builds from prior published studies (Tinetti et al. JAMA Int Med 2019 and Freytag et al. JAGS 2020) using the Patient Priorities Care approach. These studies did not identify any significant AEs or SAEs related to the study protocols. Chart reviewers analyzed changes in care related to care alignment and attempted to attribute those care changes to any noted adverse events. No significant AEs or SAEs were identified.

8.3 Adverse Events and Serious Adverse Events

Adverse Event (AE): We will review charts from any potential AEs including urgent care visits, emergency department or hospital stays occurring after the care alignment step of PPC.

Serious Adverse Event (SAE): The intervention will not result in any of the following events, thus no SAE are expected. If a death occurs while the study participant is actively in the study this will be reported within 48 hours of occurrence or as soon as the study team finds out about the event.

8.3.1 Follow-up for Adverse Events

Rafael Samper-Ternent or Alejandra Mera will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigators will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.4 Safety Monitoring

We will follow NIA guidelines for data monitoring procedures and have developed a data safety monitoring plan that will be reviewed and approved by an appointed Safety Officer, Dr. Madhuri Reddy.

9 INTERVENTION DISCONTINUATION

There are no criteria for discontinuation at this point.

10 STATISTICAL CONSIDERATIONS

10.1 General Design Issues

This pilot project is not intended to identify specific outcomes resulting from the PPC approach, thus no power calculations are needed. We will use descriptive statistics to examine frequency distributions and proportions for all quantitative variables. We will calculate effect sizes for changes in our exploratory outcome. Interviews with practice-based implementation team members will be performed by Dr. Samper-Ternent and analyzed using directed content analysis. Quantitative and qualitative findings will be triangulated using standard content analysis methods to create meta-themes that synthesize the quantitative and qualitative findings. Inclusion of 20 subjects is therefore sufficient to directed content analysis with the expectation that we will obtain data saturation of each content area.

10.2 Sample Size and Randomization

Sample size is not required and there will be no randomization.

10.3 Outcomes

One exploratory outcome is to determine if primary care providers take priorities from the priority setting note on the electronic medical record and make changes in care as a result of the priorities. This will be analyzed through chart reviews.

11 DATA COLLECTION AND QUALITY ASSURANCE

11.1 Data Collection Forms

The PPC facilitator will use the PPC manual to facilitate goal setting with all patients. Goals will be documented in the patient form that the patients take home and will be added to the electronic medical record under the PPC heading for primary care providers to review.

11.2 Data Management

Data related to priorities identification and care alignment will be pulled from the electronic health record to evaluate the feasibility of the intervention.

We will use Redcap to conduct the patient and clinician evaluation of the PPC approach. These responses will be securely stored in the UTMB research server.

11.3 Quality Assurance

10.3.1 Training

The PPC facilitator is certified in the PPC approach. Dr. Naik and Dr. Samper-Ternent will use existing manuals to train clinicians on the PPC approach. Evaluations of fidelity will be conducted after 5 patients go through the PPC approach.

10.3.2 Metrics

We will conduct a chart review of all enrolled subjects and assess charts following care alignment steps for each of the following adverse events: urgent care visits, emergency department stays, and hospital admissions. If one of these events occurs, we will carefully review the charts to determine if any change in care results in clinical changes that contributed to the adverse event.

10.3.3 Protocol Deviations

Chart reviews of all enrolled subjects will focus on fidelity to the Patient Priorities Care processes. We will apply a PPC fidelity template to track any potential protocol deviations. We will also assess if these deviations resulted in any adverse events.

10.3.4 Monitoring

We will review charts on a monthly basis to ensure that the priorities identification process and the care alignment processes are occurring based on our established PPC fidelity rubric. We will also conduct a thorough chart review after any instance of an Adverse Event or SAE. The chart review will assess whether the AE/SAE occurred following any care alignment driven changes in treatment/care. AEs arising from a change in care will be reported to the IRB.

12 PARTICIPANT RIGHTS AND CONFIDENTIALITY

12.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document (Appendix 1) and any subsequent modifications will be reviewed and approved by the IRB responsible for oversight of the study. For participants with dementia unable to consent verbal assent will be obtained and the caregiver will provide consent.

12.2 Informed Consent Forms

Consent forms will be Institutional Review Board (IRB)-approved in English and Spanish and the participant will be asked to select language of preference and read and review the document. Consenting will be done over the phone by the research coordinator before scheduling the goal setting meeting. The investigator will explain the research study to the participant for the adaptation phase (n=5) and to the person with dementia in the second phase (n=20) and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will be informed that participation is voluntary and that they may withdraw

from the study at any time, without prejudice, and that the quality of their medical care will not be adversely affected if they decline to participate in this study. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants will be given a copy of the ICF so that they may discuss the study with their family or surrogates or think about it prior to agreeing to participate. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures. A copy of the signed informed consent document will be given to the participants for their records. For participants with dementia, PCP will be asked about decision capacity. If they are deemed unable to consent, verbal assent will be obtained and consent will be provided by the caregiver. Copy of the signed ICF will be provided to the caregiver.

12.3 Participant Confidentiality

Data, forms, recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All records will be kept in a locked file cabinet. 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.

12.4 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.

13 ETHICAL CONSIDERATIONS

The ethical principles of the current study are based largely on the recommendations of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (the Belmont Commission), established by the 1974 National Research Act, American regulations governing the conduct of biomedical research involving human participants were published in 1981 by the federal Department of Health and Human Services (DHHS) (at that time, the Department of Health, Education and Welfare). Most US health care institutions have adopted the DHHS regulations, as subsequently amended, as a Common Rule to protect human participants in any research protocol that those agencies sponsor.

PUBLICATION OF RESEARCH FINDINGS

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

14 REFERENCES

Tinetti ME, Costello DM, Naik AD, et al. Outcome Goals and Health Care Preferences of Older Adults With Multiple Chronic Conditions. JAMA Netw Open. 2021;4(3):e211271. doi:10.1001/jamanetworkopen.2021.1271

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Tinetti M, Dindo L, Smith CD, Blaum C, Costello D, Ouellet G, et al. Challenges and strategies in patients' health priorities-aligned decision-making for older adults with multiple chronic conditions. PLoS ONE. 2019; 14(6): e0218249.

Blaum CS, Rosen J, Naik AD, et al. Feasibility of Implementing Patient Priorities Care for Patients with Multiple Chronic Conditions Journal of the American Geriatrics Society. 2018;66(10):2009-2016.

Naik AD, Dindo LN, Van Liew JR, et al. Development of a Clinically-Feasible Process for Identifying Patient Health Priorities Journal of the American Geriatrics Society. 2018;66(10):1872-1879.

15 SUPPLEMENTS/APPENDICES

Statistical Analysis Plan

NCT05303194

2-24-2025

Patient priorities care (PPC) will be initially incorporated in the workflow of a Geriatrics outpatient clinic at The University of Texas Medical Branch (UTMB). The PPC approach will be culturally adapted for older Hispanics in Texas by testing it in 5 Hispanics with multiple chronic conditions (MCC) and normal cognition. Five patients will receive the intervention and then the study team will make clarifying edits to materials and processes to finalize adaptations to the 6-step toolkit for conducting PPC with Hispanics. Once the PPC team and the advisory team have completed all changes, a feasibility study with 20 Hispanics with cognitive impairment in the same clinic at UTMB.

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This pilot project is not intended to identify specific outcomes resulting from the PPC approach; thus, no power calculations are needed. We will use descriptive statistics to examine frequency distributions and proportions for all quantitative variables. We will calculate effect sizes for changes in our exploratory outcomes (changes in medications, changes in tests and other referrals, changes specifically aligned to an identified patient priority). Interviews with practice-based implementation team members will be performed by Dr. Samper-Ternent and analyzed using directed content analysis. Quantitative and qualitative findings will be triangulated using standard content analysis methods to create meta-themes that synthesize the quantitative and qualitative findings. The inclusion of 20 subjects is therefore sufficient to direct content analysis with the expectation that we will obtain data saturation of each content area.