TITLE: Translating Data Science to Palliative Care Practice for Persons Living with Dementia

IRB Protocol

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Statistical Analysis Plan listed under Section 9. Analytic Methods, pg. 11

Translating Data Science to Palliative Care Practice for Persons Living with Dementia
Research Protocol

1. PURPOSE.

This research study is intended to 1) better understand seriously ill adults' and their family care partners' (FCP), particularly persons living with dementia (PLwD), barriers to accepting community-based palliative care (CBPC); 2) develop an intervention to address barriers; and 3) pilot test whether the intervention has an impact on CBPC uptake among patients who previously refused CBPC. The intervention will consist of 1) a set of informational material describing the benefits of CBPC for the CBPC team to use when presenting CBPC to VNS Health Total (formerly VNS Choice) members and FCP; and 2) processes for tailoring information delivery so that eligible members and their FCP receive information about CBPC that is tailored to their individualized risk as identified by VNS Health's validated 12-month mortality risk algorithm.

2. SPECIFIC AIMS.

The specific Aims of the study are:
Aim 1: Engage FCPs and CBPC team members to identify barriers to CBPC. Aim 1 will incorporate the perspectives of 10 CBPC team members and 25 VNS Health Total members and FCPs of PLwD and those with other diagnoses who refused CBPC services.
Aim 2: Develop informational materials for CBPC team members to use when speaking with patients and FCPs about CBPC and process for tailoring information delivery based on patient's algorithm-identified risk profile. 10-15 persons from interested parties (CBPC team members, FCPs, content/research experts) will provide feedback on intervention materials. Most participants will be recruited from Aim 1 participants. Additional participants will be recruited as necessary.
Aim 3: Conduct a pre-post trial to determine the feasibility and acceptability of the materials and using them in existing clinical workflows for their 1) impact on CBPC enrollment for CBPC-eligible individuals, including PLwD, and 2) end-user satisfaction.

3. STUDY DESIGN

The study proposes to identify barriers to CBPC enrollment and develop ways to use the information from a valid, accurate data-drive algorithm to address barriers to enrollment. The study will 1) develop informational materials for CBPC team members that can be used to explain CBPC in a manner tailored to a patient's algorithm-identified risk profile (the intervention), and 2) pilot test whether the informational materials have an impact on CBPC uptake among patients who previously refused CBPC. This study will use a multi-methods design including data collection and pilot testing.
To achieve **Aim 1** focus groups and interviews with CBPC team members, VNS Health Total members, and FCP will be conducted to identify items important in accepting and refusing CBPC.

For **Aim 2** we will develop the intervention. The intervention is a set of information materials that address CBPC generally and challenges that CPBC can help manage. The materials will be tailored to patient needs based on their algorithm identified risk profile (e.g., disease progression, medication, and symptom management). The materials will be used by CBPC team members when introducing and describing the CBPC program to VNS Health Total members and FCP.
Aims 1 and 2 participants will not be offered any services. They will be asked about their understanding of palliative and why they chose not to accept it in the past. Their responses will be used to improve how palliative care services and programs are explained to others in the future.
For **Aim 3** we will compare intervention and usual care CBPC refusal rates and assess CBPC team member and FCP satisfaction with intervention materials using the End-User Satisfaction Tool. Because of the size of the CBPC clinical team and workflow structure, it is not feasible to randomize CBPC team members to intervention or control groups. As such, we will use a pre-post pilot clinical trial to test the feasibility and efficacy of the informational materials and process, compared to usual practice, on CBPC refusal rates. We will retrospectively examine CBPC refusal rates (CBPC refusals/CBPC eligible individuals) for a 6-month lookback

period prior to implementing the intervention (informational materials and process). We will compare this rate of refusal to the CBPC refusal rate for a 6-month period after implementing the intervention.

Measurements. All measures will be collected by study research team members via phone call or electronic survey. All participants will be assessed on the measures listed in Table 1 (see Appendix for more details). Aim 1 and 2 participants will be compensated $75 each time they participate, up to $150. Aim 3 CBPC team member participants will be compensated $25 each time they complete the feasibility and acceptability surveys, up to $75.

Table 1.

Domain	Proposed measure (items)	Aims	Schedule	Participants
Demographic and Health Information	Age, sex, race, ethnicity, education level, perceived discrimination in healthcare encounters (FCP only), relationship to VNS Health Total member (FCP only), role on CBPC team (CBPC team members only), etc.	1-2	Baseline (Aim 1)	VNS Health Total members, FCP, CBPC team members, research/content experts (Aim 2 only)
	Age, sex, race, ethnicity, date of CBPC eligibility determination, date of CBPC refusal, diagnoses, triggering events	3	As extracted from electronic health record for pilot clinical trial analysis	VNS Health Total CBPC-eligible members
Knowledge of Palliative and Hospice Care	Palliative Care Knowledge Survey[1] additional questions on palliative care knowledge and attitudes[9]/26/2025 8:41:00 PM	1-2	Baseline (Aim 1), following feedback on intervention materials (Aim 2)	VNS Health Total members, FCP
Intervention Development	Interview guides with questions about palliative care experiences, knowledge, barriers to participation in CBPC, including 5 rights framework (Aim 1); and user-centered design questions to solicit feedback on intervention materials (Aim 2)	1-2	1-time interview for Aim 1. 1-time think aloud session for Aim 2	VNS Health Total members, FCP, CBPC team members, research/content experts (Aim 2 only)
Intervention Feasibility and Acceptability	PC team member reports of use of intervention	3	1, 3, and 6 months into intervention delivery (Aim 3)	CBPC team members
	End-User Satisfaction Survey[3,4]	1, 3	Baseline (Aim 1); 1, 3, and 6 months into intervention delivery (Aim 3)	CBPC team members
Primary Endpoint	Number and rate of CBPC refusals (denominator=number of CBPC-eligible individuals)	3	As extracted from electronic health record for pilot clinical trial analysis	VNS Health Total CBPC-eligible members

Data Collection Protocol. Survey responses for Aims 1-3 will be collected in two ways: online or by telephone. Whenever possible, participants will be sent surveys to their preferred emails via REDCap, a password protected, HIPAA compliant data management system. Survey links will be unique to study

participants. If participants prefer to provide answers to survey questions over the phone or provide incomplete information in the online format, research staff will call the participant at the participant's preferred phone number to ask the questions. The research staff will record participants' answers in REDCap. Interviews and focus groups for Aims 1 and 2 will be conducted by phone or secure videoconference (e.g., Zoom, Teams). For videoconferences, study participants will be sent an encrypted link to their preferred email. Rutgers requires all Zoom users to use secure, up-to-date versions of the software. Zoom meetings cannot be accessed without the personalized link study staff will provide. Study team members have experience with or will be trained in obtaining answers to survey questions by phone and conducting interviews and focus groups by phone and videoconference (e.g., Zoom) including conducting the phone calls in a private area to protect participant confidentiality.

4. SAMPLE SELECTION / DATA SOURCES

Aim 1. Identify barriers to CBPC enrollment.
Sample. 10 CBPC team members and 25 VNS Health Total members and FCP.

Inclusion Criteria. VNS Health Total member who refused CBPC in the previous year or family care partner (including if they are paid for their caregiving) of a VNS Health Total member who refused CBPC services in the previous 12 months. VNS Health Total members and FCP must also be 18 years of age or older, English speaking and receive a score of 15 or higher on the one-minute animal fluency test. We will emphasize recruitment of FCP of PLwD. Although 75% of VNS Health Total CPBC participants have a dementia diagnosis, PLWD are not the only patient group served by the plan. As such, having a dementia diagnosis is not a requirement for participation. This will also allow us to compare refusal rates among PLWD and those without dementia in exploratory analyses.

CBPC team members must be a part of the VNS Health Total community-based palliative care team.

Exclusion Criteria. VNS Health Total members and FCP are excluded if they are: under the age of 18; do not speak English; FCP primary relationship to VNS Health Total member is employee or paid care partner (family members who are paid for their caregiving are eligible); VNS Health Total member or family member of FCP enrolled in VNS Health Total's CBPC in the previous 12 months.

PC team members are excluded if they are not a member of the palliative care team.

Aim 2. Develop informational materials and processes to support CBPC team member-FCP-PLwD conversations about CPBC.
Sample. 10-15 individuals from interested parties (PC team members, FCPs of PLwD, content/research experts). Most participants will be recruited from Aim 1 participants. Additional participants will be recruited as necessary.

Inclusion Criteria. Same for VNS Health Total members, FCP, and CBPC team members as Aim 1

Exclusion Criteria. Same for VNS Health Total members, FCP, and CBPC team members as Aim 1.

Research/Content experts will be identified and asked to participate based on expertise in areas of community-based palliative care, VNS Health care delivery, and/or data science.

Aim 3. Conduct a pre-post trial to determine the feasibility and acceptability of the materials and using them in existing clinical workflows for their impact on CBPC enrollment for PLwD and end-user satisfaction.
Sample. Based on 2022 identification, eligibility, and refusal data, we anticipate 500 VNS Health Total members will be identified as eligible for CBPC during the study period (250 control, 250 intervention) and that

80 individuals will refuse CBPC during the pre-test/control period. Of these, 365 CBPC-eligible and 60 refusals are expected to be PLwD.

Inclusion Criteria. All VNS Health Total members who were identified as eligible for CBPC in the 6-month period prior to the introduction of the intervention (tailored informational materials about benefits of palliative care) and in the 6-month period following the introduction of the intervention.

Exclusion Criteria. VNS Health Total members who were not identified as potentially eligible for CBPC services by the 12-month mortality risk algorithm or who were identified by the algorithm as potentially eligible for CBPC services but determined by the clinical team to be ineligible for CBPC. At times, individuals are flagged by the algorithm as potentially eligible for CPBC, but upon further assessment by the palliative care team, it is determined that CBPC is not appropriate at this time. For example, someone may be flagged because they are over 90 years old and recently visited the emergency department. However, upon further assessment, the clinical team determines that they are highly functional and independent, their chronic conditions are well-managed, and the emergency room visit was for a minor head wound or something similar that did not greatly impact the individual's functional or health status.

5. PROCEDURES FOR RECRUITING STUDY SUBJECTS.

Focus Groups and Interviews.

PC team member Recruitment. We will recruit 10 CBPC team members from the VNS Health Total's clinical team that supports the community-based palliative care services program. We will present the project at team meetings and reach out to potential participants by email and/or phone, using VNS Health Total staff directory information. We will explain that participation in the project consists of participating in a 30-60-minute interview or focus group about their existing job and answering questions about what formats they prefer for receiving information. We will explain that participants may also participate in a 30-60-minute follow-up session to provide feedback on intervention materials developed as a result of Aim 1 focus groups and interviews. Individuals will be given the opportunity to ask questions about the project.

Member and Family Care Partner Recruitment. We will recruit 25 VNS Health Total members and FCP of PLWD and with other diseases from a group of about 160 individuals who were eligible for, but refused, CBPC in the previous 12 months. A VNS Health research staff member experienced in recruiting family members to research studies will contact the VNS Health Total member or FCP by their preferred contact method (e.g., phone, email, mail) to tell them about the study. We will explain that participation in the project consists of participating a 30-60-minute interview or focus group about their knowledge of palliative care, attitudes towards it, and reasons for refusing palliative care for themselves or their loved one. We will explain that participants may also participate in a 30-60-minute follow-up session to provide feedback on intervention materials developed as a result of Aim 1 focus groups and interviews. Individuals will be given the opportunity to ask questions about the project.

Retention. Given the one- or two-time, one or two--hour nature of participation, we do not anticipate any issues with retention of CBPC team members, VNS Health Total members, or FCP.

Clinical Trial.

PC team member Recruitment. All of the CBPC team members who present the CBPC program to CBPC-eligible individuals and FCP will be asked to use the informational materials developed as part of this project when speaking with VNS Health Total members and FCP about the CBPC program. We will work with the CBPC leadership to identify effective ways to engage CBPC team members in the intervention while minimizing potential burden. CBPC team members who deliver the intervention (i.e., use the informational materials when explaining CBPC to eligible individuals and their FCP) will be asked to complete fidelity, feasibility, and acceptability measures (e.g., End User Satisfaction Survey) at 1, 3, and 6 months into intervention implementation.

VNS Health Total Member Recruitment. We plan to conduct a pilot clinical trial of integrating tailored informational materials on the benefits of community-based palliative care for eligible persons based on their individualized profile as identified by a validated 12-month mortality risk algorithm. Based on recent VNS Health Total data regarding the number of individuals identified as eligible for palliative care, we expect to run the pilot clinical trial with 500 eligible individuals over an enrollment period of 12 months. This sample of 500 individuals included in the Inclusion Enrollment Table represents all individuals expected to be identified as eligible for palliative care during the study period (250 prior to intervention implementation and 250 following intervention implementation).

All data collection from VNS Health Total members for the pilot trial will be taken from existing electronic health records and remotely collected. For the pilot trial, the study team will not interact directly with palliative care-eligible individuals, or their FCP. All outcomes for VNS Health Total members will be captured through an existing data source (the VNS Health Total electronic record) under a waiver of informed consent (see below).

Retention. To engage CBPC team members throughout the course of the intervention, we will present the informational materials at interdisciplinary team (IDT) and other team meetings prior to their introduction into clinical practice. We will also solicit feedback on introducing the intervention to the CBPC team members from the CBPC leadership team. Additionally, as part of the intervention development process, we will solicit feedback from CBPC team members about the best way to make the informational materials available and accessible to them. We will check in with CBPC team members monthly in order to ascertain how intervention use is progressing, troubleshooting issues, and responding to CBPC team member concerns regarding material content and or accessibility.

Recruitment Documents

For all VNS Health Total member and family care partner recruitment documents, we will use a patient-facing title ("Improving Patient Comfort and Care with Data") for the study to make it more accessible and understandable to these potential participants.

Aims 1 – Telephone script recruitment (VNS Health Total members, FCP and PC team members)

Greet person politely.

Introduce yourself and organization.

Ask to speak with person of interest.

Emphasis the purpose of the study:

[PC team member:] The purpose of the study is to improve the way we use health records and data to connect people with additional support services such as palliative care.

And/or

[VNS Health Total member, FCP:] Learn more about member interest in palliative care and improve how we explain our programming to people.

[VNS Health Total member, FCP:] *Explain that we are contacting them because they or their family member decided not to participate in palliative care in the last year or you provided support to VNS Health Total's palliative care team.*

Ask if they would you like to hear more about the second part of the study?

Let them know that their decision whether or not to participate will not affect their relationship {or employment} with VNS Health or Rutgers

If YES, continue.

If NO, thank the person for their time.

Explain what study participation involves:

- 30-60-minute interview or focus group to answer questions about
    - [PC team member:] how you use information from electronic health record data to refer enrollees to additional support programs.
      OR
    - [VNS Health Total member/FCP:] you will be asked about your interest in and experience with additional support programs that you Medicare advantage plan may provide. Your responses will be used to improve how services and programs are explained to others in the future.
- May also be asked to participate in a second 30-60-minute interview or focus group to provide feedback on informational materials we develop from your and others' feedback.
- Brief survey to provide demographic information and knowledge of palliative care (for VNS Health Total member/FCP) or experience with VNS Health algorithm (for PC team member)

Explain how study will be conducted:

- By VNS Health and Rutgers University
- At VNS Health headquarters, {PC team members: during IDT meetings}, by telephone, or by secure videoconference at your convenience.
- Focus groups and interviews take from 30-60 minutes (1-2 hours in total).
- Questions will focus on:
    - [PC team member] how you assess individuals as eligible for palliative care, reasons for refusal of palliative care, how health record data could be presented in a way that is useful for determining palliative care eligibility.
      OR
    - [VNS Health Total member/FCP] knowledge of palliative care, attitudes towards it, and reasons for refusing palliative care [FCP for their loved one].
- Surveys will take 10 minutes and be conducted online via a secure link or by telephone.
- Compensation: $75 for each round of feedback you provide during interviews or focus groups, up to $150.

Do you have any questions?

Answer all questions.

Are you interested in participating?

If YES, confirm contact information for mailing/emailing informed consent and schedule time to review it.

If NO, thank the person for their time.

<u>Aim 1 – Participant email/letter recruitment (VNS Health Total Members, FCP and PC team members)</u>

Subject: Research Study
Dear [Colleague / name of participant]:

We are contacting you to ask for your participation in an NIH-funded research study to improve the way we use health records and data to connect people with additional support services such as palliative care. The study is called - Improving Patient Comfort and Care with Data. We will be asking about your knowledge of palliative care, attitudes towards it, and reasons for refusing palliative care for [you/your loved one].

The study will be conducted by VNS Health and Rutgers University at VNS Health headquarters, {during IDT meetings}, by telephone, or by videoconference at your convenience and consist of 1 or 2 30-60-minute sessions. You will be compensated $75 for each session. If you are interested in participating, please reply to this email, or email or call [research assistant] at [email, phone number]. A research assistant may also follow up with you by phone to ask about participation.

This study is confidential, and participation is entirely voluntary. Your decision whether or not to participate will not affect your relationship {or employment} with VNS Health or Rutgers. Your response is an invaluable part of our research and will help us better understand how to improve care, including for people with dementia and their families. If you have any questions or comments about this work, please call or email at [phone number] eal133@ifh.rutgers.edu.

Thank you for your consideration.

Sincerely,
Elizabeth Luth, PhD

IRB# [IRB #]

NOTE: Language in {} will be included for CBPC team members only.

Aim 2 – Telephone script recruitment (VNS Health Total members, FCP and PC team members)

Greet person politely.

Introduce yourself and organization.

Ask to speak with person of interest.

Thank them for their prior participation in interview or focus group. (If they are recruited from Aim 1)

Let them know we are ready for the second step of the study and are reaching out to see if they are willing to help us out.

Emphasis the purpose of the study:

[PC team member:] The purpose of the study is to improve the way we use health records and data to connect people with additional support services such as palliative care. Your responses will be used to improve how palliative care services and programs are explained to others in the future.

And/or

[VNS Health Total member, FCP:] Learn more about member interest in palliative care and improve how we explain our programming to people.

Ask if they would you like to hear more about the second part of the study?

Let them know that their decision whether or not to participate will not affect their relationship {or employment} with VNS Health or Rutgers

If YES, continue.

If NO, thank the person for their time.

Explain what study participation involves:

- 30-60-minute interview or focus group to provide feedback on informational materials we develop from your and others' feedback.

Explain how study will be conducted:

- By VNS Health and Rutgers University
- At VNS Health headquarters, {PC team members: during IDT meetings}, by telephone, or by videoconference at your convenience.
- Focus groups and interviews take from 30-60 minutes.
- Participants will also be asked to complete a brief questionnaire with demographic information and their knowledge of palliative care.
- The questionnaire can be completed online via a unique link sent to their email or by telephone with study personnel.
- Compensation: $75

Do you have any questions?

Answer all questions.

Aim 2 – email/letter recruitment (VNS Health Total Members, FCP and PC team members)

Subject: Research Study
Dear [Colleague / name of participant]:

Thank you again for participating in the interview portion of our research study at VNS Health and Rutgers to improve the way we use health records and data to connect people with additional support services such as palliative care.

We are reaching out because it is time for the second part of the study to provide feedback on informational materials to improve how palliative care is explained to eligible individuals.

The study will be conducted by VNS Health and Rutgers University at VNS Health headquarters, {during IDT meetings}, by telephone, or by videoconference at your convenience and will last about 30-60 minutes. You will be compensated $75 as a thank you for your time. If you are interested in participating, please reply to this email, or email or call [research assistant] at [email, phone number]. A research assistant may also follow up with you by phone to ask about participation.

This study is confidential, and participation is entirely voluntary. Your decision whether or not to participate will not affect your relationship {or employment} with VNS Health or Rutgers. Your response is an invaluable part of our research and will help us better understand how to improve care, including for people with dementia and their families. If you have any questions or comments about this work, please call or email at [phone number] eal133@ifh.rutgers.edu

Thank you for your consideration.

Sincerely,
Elizabeth Luth, PhD

IRB# [IRB #]

NOTE: Language in {} will be included for CBPC team members only.

Aim 3 –email/letter recruitment (PC team members)

Subject: Research Study

Dear [Colleague / name of participant]:

[Thank you again for participating in the interview portion of our research study at VNS Health to develop informational materials about palliative care.] We are ready to implement the materials and are reaching out to see if you are interested in continuing to help with this project.

You will be asked to participate in completing three 5–10-minute surveys to answer questions about your experience using the informational materials to tell eligible individuals and their family members about palliative care.

The study will be conducted by VNS Health and Rutgers University at VNS Health headquarters, {during IDT meetings}, by phone, by teleconference, or electronically at your convenience and will last about 15-30 minutes over three survey sessions. You will be compensated $25 for each survey you complete. If you are interested in participating, please reply to this email, or email or call [research assistant] at [email, phone number]. A research assistant may also follow up with you by phone to ask about participation.

This study is confidential, and participation is entirely voluntary. Your decision whether or not to participate will not affect your relationship {or employment} with VNS Health or Rutgers. Your response is an invaluable part of our research and will help us better understand how to improve care for people with dementia and their families. If you have any questions or comments about this work, please call or email at [phone number] eal133@ifh.rutgers.edu

Thank you for your consideration.

Sincerely,
Elizabeth Luth, PhD

IRB# [IRB #]

NOTE: Language in {} will be included for CBPC team members only.

VNS Health Total Member or FCP screening questions (Aims 1 and 2)

1. Are you over 18 years of age?
2. Do you, or does a member of your family, receive health care from [VNS Health Total's/current plan name] Medicare Advantage plan?
3. Please name as many animals as you can in one minute. (Write down every animal mentioned. Must name 15 different animals)

6. CONSENT FORMS AND ADDITIONAL PHI AUTHORIZATIONS.

Prior to participating in any Aim (Aim 1, Aim 2, or Aim 3) study activities, all members, FCP, CBPC team member, and research/content expert participants will provide informed consent. Informed consent will be obtained by study personnel in person, by telephone, via oral consent. We are requesting this alteration of written consent in order to reduce the burden on participants of meeting in-person and to be able to include individuals in the study who may not have access to technology to provide e-consent. After obtaining oral consent over the phone, the study team will mail or email a copy of the form to the participant. Informed consent will be conducted by study personnel trained in consent procedures. Study personnel will review the study, allowing the participant to ask questions at any time during the discussion. The main points addressed by study personnel include explaining that participation is voluntary, why the study is being done, study procedures, potential risks and benefits of participation, and how participant confidentiality will be protected. Study team members will track oral consent in a secure, HIPAA compliant database such as REDCap that only authorized study personnel are able to access.

A copy of the study oral consent procedures are included in the application package.

7. Request for Waiver of Authorization

In addition to obtaining consent from FCP, CBPC team member and research/content expert participants, we are requesting a waiver of consent and HIPAA authorization to access VNS Health Total member electronic records for the following reasons.

Planning. We will extract information about refusals of CBPC in the electronic health record such as the number of individuals who refused CBPC, their demographics, and health information (e.g., key diagnoses, triggering events that made them eligible for CBPC). Analyzing this information will allow us to improve information about risk for CBPC and who is refusing services so that we can create information materials and process 1) to support CBPC enrollment, particularly for PLwD and 2) that can be tested in other healthcare settings. As this extraction will involve several hundred records, including for deceased individuals, it is not possible to obtain this information without a waiver of authorization.

Aims 1-2. We request the waiver for VNS Health study staff to view electronic records of VNS Health Total members to identify VNS Health Total members and FCP who are potentially eligible to participate in Aims 1 and 2 of the study. It is not possible to identify potentially eligible members or FCP without the waiver of authorization.

Aim 3. We request the waiver for VNS Health study staff to view identification, enrollment, and refusal data. The information will be used to calculate CBPC refusal rates before and after intervention delivery and to analyze factors associated with CBPC enrollment and refusal in multivariable statistical modeling (described below).

A Request for Waiver of Authorization Form is included in the appendix of this application.

8. Data to be employed

Please see Table 1 (above) and Appendix for data collection instruments at the end of the document. Data collection procedures will be conducted by trained research staff and done in-home, at VNS Health headquarters, at Rutgers University, by phone, by videoconference or online surveys as outlined in the protocol above. Data will be collected by research staff or online questionnaires and entered into and stored in a HIPAA compliant database such as REDCap.

9. Analytic Methods.

Feasibility/Acceptability.

We plan to conduct a pre/post pilot clinical trial to determine the feasibility and acceptability of an intervention to introduce tailored informational materials into clinician's discussions about community-based palliative care with VNS Health Total members who are eligible for the service. The informational materials will be tailored to the individual's risk profile as identified by a validated 12-month mortality risk algorithm. To establish feasibility and acceptability we will assess clinicians' and family care partners' assessments of the utility of the informational materials using the End-User Satisfaction Tool. End-User Satisfaction ratings for each concept are scored as 1 (almost never); 2 (some of the time); 3 (about half the time); 4 (most of the time); 5 (almost always). Minimum score is 12; maximum 60. Cumulative testing has produced percentile scores where a score of 54 corresponds to the 70th percentile. 57 = 80th and 59 = 90th. Short range test-retest scores for the overall score were .96 and the five subscales ranged from .80 to .95. Long range test-retest scores were .85 overall and .60 to .82 for the subscales. (Appendix). We will also assess whether and how the CBPC team members use the intervention (informational materials about palliative care) at regular intervals to assess fidelity and feasibility.

Qualitative analysis.

For Aims 1 and 2, We believe sample sizes will be sufficient to obtain thematic saturation in qualitative analyses. If needed, we will continue to collect data at all stages until achieving thematic saturation. Interview

and focus group data will be transcribed and imported into qualitative data analysis software for analysis (e.g., nVivo, Dedoose). Data coding and analysis will be informed by a responsive model in which blocks of information are combined based on the theme they represent. Trained raters will independently review the transcripts and identify passages that include suggestions for inclusion and/or modifications to the intervention. Raters will then organize these passages into categories reflecting single themes, discuss these themes, and revise themes until consensus is reached. Additionally, a study team member will take notes during stakeholder interviews and focus groups. Relevant notes and written feedback from stakeholders will be incorporated into developing a set of informational materials and process for individualizing information provision about potential benefits of CBPC, particularly for PLwD and FCPs.

Quantitative Analysis.
For Aim 3, based on 2022 identification, eligibility, and refusal data, we anticipate 500 individuals will be identified as eligible for CBPC during the study period (250 control, 250 intervention) and that 80 individuals will refuse CBPC during the pre-test/control period. Of these, 365 CBPC-eligible and 60 refusals are expected to be PLwD.

We will use descriptive statistics to describe the sample. End-user satisfaction results will be reported as mean ratings for each item and across all items as a composite score. Results will also be reported by percentages of respondents by Likert scale level, as well as grouped by percent favorable and unfavorable. Percentage of clinicians finding the intervention to be feasible and acceptable and the proportion reporting using the informational materials will be calculated.

Additionally, we will determine the association between the intervention and reductions in refusal of CBPC among eligible individuals. We will use a pre/post design for this pilot clinical trial. For the pre-intervention measurement, we will calculate the number of palliative care services refusals among all palliative care-eligible VNS Health Total members (expected n=250) for a 6-month lookback period prior to introducing the informational materials into clinical practice. For the post-intervention measurement, after incorporating the informational materials into clinical practice, we will observe palliative care refusals prospectively for 6 months among all palliative care-eligible VNS Health Total members (expected n=250). We hypothesize that the number of refusals will decrease during the 6-month intervention period.
We assume we will see approximately 80 refusals among the 250 pre-intervention patients, for a refusal rate of 80/250 = 0.32 (or 32%) or $H_0 = p_{pre} \geq p_{post}$, where p_{pre} and p_{post} are the pre and post intervention CBPC refusal rates, respectively.
The table below show the post-intervention CBPC refusal rates we will be able to detect, for different power levels, assuming a total of 500 patients (250 pre, 250 post) a significance level α = 0.05, and a pre-intervention CBPC refusal rate of 0.32.

Power	Pre-intervention CBPC refusal rate	Post-intervention CBPC refusal rate	Absolute rate reduction	Percent rate reduction
0.80	0.32	0.206	0.114	35.6%
0.85	0.32	0.199	0.121	37.8%
0.90	0.32	0.190	0.130	40.6%
0.95	0.32	0.178	0.142	44.4%

With 80% power, we will be able to detect a 11.4 percent points (or 35.6%) reduction of the CBPC refusal rate between pre and post intervention.

10. STATEMENT OF THE RISKS/BENEFITS FOR THE STUDY SUBJECTS.
This is a minimal risk study to develop and pilot test the feasibility and acceptability of an intervention consisting of informational materials and processes to encourage acceptance of CBPC services. We will also assess the extent to which using the informational materials is associated with reductions in rates of CBPC refusal.

Aim 1. Engage FCPs and CBPC team members to identify barriers to CBPC enrollment. We do not anticipate that participants will benefit directly from providing feedback. Risks to study participants are minimal

and may include FCP becoming distressed when discussing why they refused palliative care for themselves or their loved one or becoming fatigued when participating in a one-hour interview.

Aim 2. Develop informational materials for CBPC team members to use when speaking with patients and FCPs about CBPC and process for tailoring information delivery based on patient's algorithm-identified risk profile. The purpose of this aim is to develop a set of informational materials and process for individualizing information provision about potential benefits of CBPC to PLwD and other patient populations and FCPs (NIA model Stage 1A). We do not anticipate that participants will benefit directly from providing feedback. They may become fatigued when providing feedback on the materials.

Aim 3. Conduct a pre-post trial to determine the feasibility and acceptability of the materials and using them in existing clinical workflows for their impact on CBPC enrollment for PLwD and end-user satisfaction. Risks to study participants are minimal for VNS Health Total members. There is no anticipated risk resulting from providing additional information about benefits of CBPC. However, participants may experience stress if they have previously refused palliative care and are being reintroduced to the service again. It is worth noting, however, that the study does not change the current procedure for identifying and approaching individuals who previously were offered palliative care and become eligible for it again. The study only changes the information about palliative that is provided to these individuals, while remaining consistent with current standards of care. We do anticipate that VNS Health Total members and FCP may gain a better understanding of potential CBPC benefits and increased support provided by CBPC for individuals who accept the service. For CBPC team members we anticipate no risk. However, they may benefit from having additional resources and information about CBPC to make it easier for them to explain CBPC to eligible individuals.

Aims 1-3. All study subjects can refuse to answer any questions or to discontinue study participation at any time. As always, there is the possibility that participant confidentiality will be breached. We will take steps to minimize this possibility and protect participant confidentiality as outlined in the following section. The potential benefits of the study include the individualized materials on the benefits of palliative care that will be created, potentially benefitting VNS Health Total members and FCP, particularly of PLWD, by promoting and increasing enrollment in palliative care. Additionally, this research will generate generalizable knowledge essential to improving uptake of palliative care by VNS Health Total members, including PLWD, and their family members and inform VNS Health how they might better implement palliative care promotion processes within their care system.

11. Privacy / Confidentiality Protections.

To protect confidentiality, when analyzing outcomes data, identifying information such as (i.e., name, address contact information etc.) will not be extracted. Information will be extracted from VNS Health Total electronic health records using existing HIPAA compliant protocols and procedures. All study personnel will adhere to study protocols regarding data privacy, including collecting research data in a secure manner. When collecting data using videoconferences, study participants will be sent an encrypted link to their preferred email. Rutgers requires all Zoom users to use secure, up-to-date versions of the software. Zoom meetings cannot be accessed without the personalized link study staff will provide. Study team members have experience with or will be trained in obtaining answers to survey questions by phone and conducting interviews and focus groups by phone and videoconference (e.g., Zoom) including conducting the phone calls in a private area to protect participant confidentiality. Study personnel will also follow protocols regarding maintaining research data (transcriptions, audio recordings, demographic information) in a secure, password protected server that only authorized study personnel are credentialed to access. Paper records will not be created.

12. Data Use Agreement.

A data use agreement outlines the scope of work and research data to be shared between VNS Health and Rutgers (see "Data Use Agreement").

13. Rutgers IRB Approval.

Rutgers IRB approval is pending and will be submitted to the VNS Health IRB prior to data collection or sharing begins.

14. REPORTING.

The PI, Dr. Luth, will adhere to VNS Health IRB reporting requirements, including submitting a study closure report within 60 days of the end of primary data collection. The PI will also submit a summary of main project findings when available.