SHARE: Sharing Healthcare Wishes in Primary Care

Protocol Number: IRB00242431

National Clinical Trial (NCT) Identified Number: TBD

Principal Investigator: Jennifer Wolff, PhD

Sponsor: The National Institute on Aging

Grant Title: Involving Family to Improve Advance Care Planning for Primary Care Patients with ADRD

Grant Number: R01AG058671

Funded by: National Institute on Aging

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October 2023

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STATEMENT OF COMPLIANCE

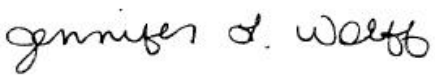
The study team and staff who are responsible for the conduct, management, or oversight of this protocol have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent script(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent script(s) will be obtained before any participant is consented. Any amendment to the protocol will be reviewed and approved by the IRB before the changes are implemented to the study.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: 7/10/2020

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Title: Eugene and Mildred Lipitz Professor

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[For multi-site studies, the protocol should be signed by the clinical site investigator who is responsible for the day to day study implementation at his/her specific clinical site.]

Signed: Date:

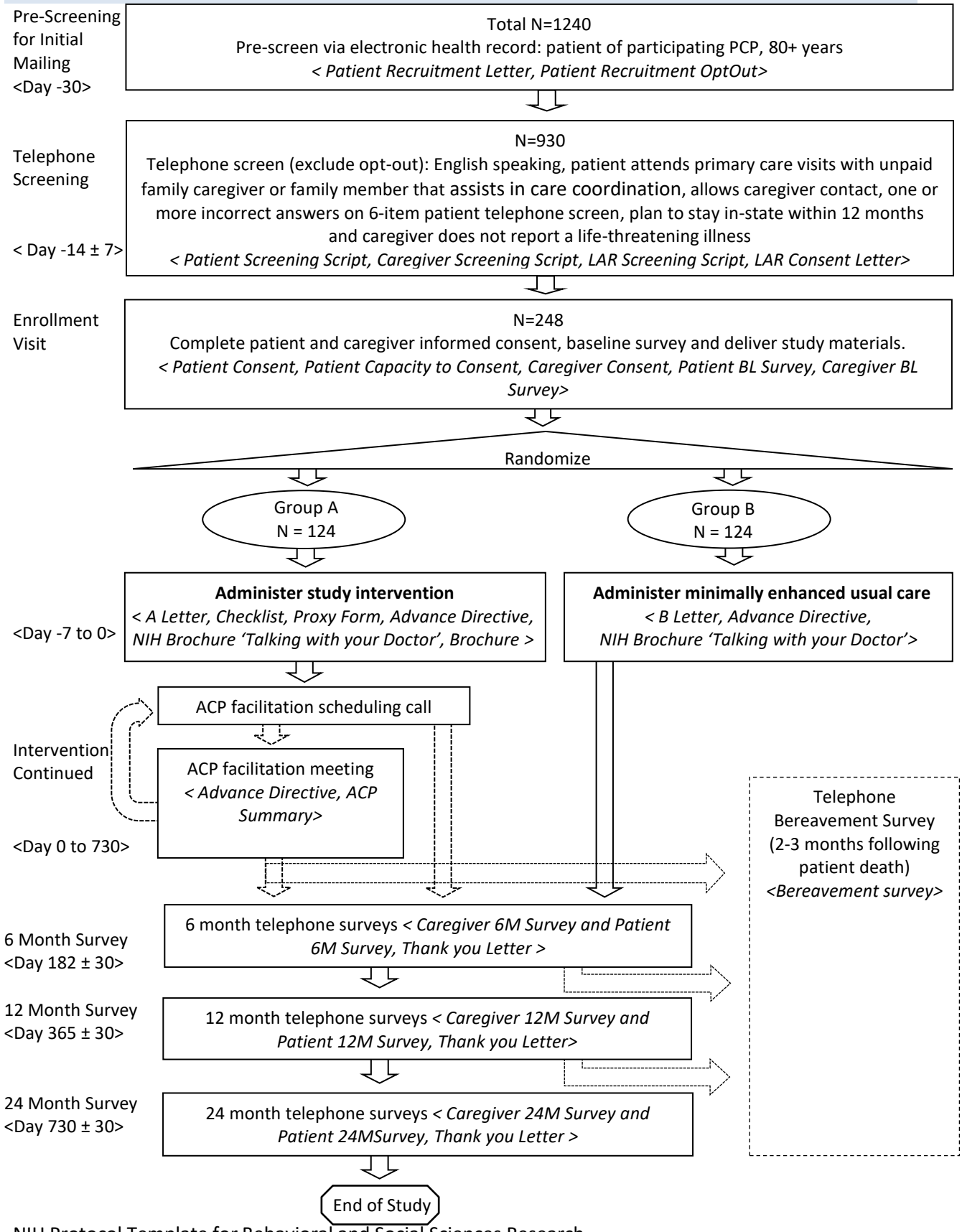
Name: Erin Giovannetti, PhD
Title: Scientific Director at MedStar Health Economics and Aging Research Institute
Affiliation: MedStar Health System

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	SHARE: Sharing Healthcare Wishes in Primary Care
Grant Number:	R01AG058671
Study Description:	This study will test a multicomponent communication intervention, referred to as SHARE, to proactively engage family members or friends (interchangeably referred to as "family" and/or "caregiver") and support advance care planning in primary care. We will conduct a two-group randomized trial at up to 10 primary care practices in which 124 dyads (+/- 10) will receive a control protocol of minimally enhanced usual care and 124 dyads (+/- 10) will receive the SHARE protocol. We test the efficacy of SHARE on quality of communication (primary outcome) and advance care planning processes (secondary outcomes) at 6 months among primary care patients with cognitive impairment (mild-severe) and family caregiver dyads. For patients who die by 24 months, we examine the quality of end of life care and bereaved family caregiver experiences with medical decision-making (secondary outcomes).
Objectives:	To test the efficacy of SHARE on improved quality of communication (primary outcome) and end-of-life experiences (secondary outcomes) of primary care patients with cognitive impairment (mild-severe) and family caregivers.
Endpoints:	Primary Endpoint: Quality of Communication and Quality of End of Life Care Secondary Endpoints: Advance care planning processes and bereaved family caregiver experiences with medical decision-making
Study Population:	We plan to enroll a sample of 248 (+/- 20) person-family dyads comprising primary care patients with cognitive impairment ages 80 years or older and the person who helps them the most with medical decision making, who we refer to as their caregiver. This study focuses on persons ages 80 and older with cognitive impairment (mild-severe) .
Stage:	Stage 1 Behavioral Intervention
Description of Sites:	We will conduct the trial at up to 10 primary care practices within two health systems (Johns Hopkins Community Physicians, and MedStar Health System) in the Baltimore/Washington area.
Description of Study Intervention/Experimental Manipulation:	SHARE encompasses the following four therapeutic elements: 1) a letter from the practice introducing the initiative, 2) access to a designated person (medical assistant, social worker, nurse, or lay person) trained to lead advance care planning discussions, 3) person-family agenda-setting to align perspectives about the role of the caregiver and stimulate discussion about goals of care, and 4) education about communication and available resources.
Study Duration:	The project period extends over four years.
Participant Duration:	Participants in both groups will be followed over a 24-month period.

1.2 SCHEMA


Pre-Screening for Initial Mailing <Day -30>
Total N=1240
Pre-screen via electronic health record: patient of participating PCP, 80+ years
< Patient Recruitment Letter, Patient Recruitment OptOut>
Telephone Screening
< Day -14 ± 7>
N=930
Telephone screen (exclude opt-out): English speaking, patient attends primary care visits with unpaid family caregiver or family member that assists in care coordination, allows caregiver contact, one or more incorrect answers on 6-item patient telephone screen, plan to stay in-state within 12 months and caregiver does not report a life-threatening illness
< Patient Screening Script, Caregiver Screening Script, LAR Screening Script, LAR Consent Letter>
Enrollment Visit
N=248
Complete patient and caregiver informed consent, baseline survey and deliver study materials.
< Patient Consent, Patient Capacity to Consent, Caregiver Consent, Patient BL Survey, Caregiver BL Survey>
Randomize
Group A
N = 124
Group B
N = 124
<Day -7 to 0>
Administer study intervention
< A Letter, Checklist, Proxy Form, Advance Directive, NIH Brochure 'Talking with your Doctor', Brochure >
Administer minimally enhanced usual care
< B Letter, Advance Directive, NIH Brochure 'Talking with your Doctor'>
ACP facilitation scheduling call
Intervention Continued
ACP facilitation meeting
< Advance Directive, ACP Summary>
<Day 0 to 730>
Telephone Bereavement Survey (2-3 months following patient death)
<Bereavement survey>
6 Month Survey
<Day 182 ± 30>
6 month telephone surveys < Caregiver 6M Survey and Patient 6M Survey, Thank you Letter >
12 Month Survey
<Day 365 ± 30>
12 month telephone surveys < Caregiver 12M Survey and Patient 12M Survey, Thank you Letter>
24 Month Survey
<Day 730 ± 30>
24 month telephone surveys < Caregiver 24M Survey and Patient 24MSurvey, Thank you Letter >
End of Study

1.3 SCHEDULE OF ACTIVITIES

Assessment	Screening Visit Day-30 to Day -1	Enrollment Day 1	Randomize	ACP, Patient Portal Use	6 Months Day 182 (±30 Days)	12 Months Day 365 (±30 Days)	24 Months Day 730 (±30 Days)	Bereavement Survey 60 to 90 Days After Death
Oral consent	X							
Informed consent		X						
Patient characteristics *		X			X	X	X	
Family characteristics & caregiving circumstances *		X			X	X	X	
Primary care interactions *		X			X	X	X	
Intervention processes *				X				
Patient, Family experiences *		X			X	X	X	
Outcomes at the end of life *								X
Alert Events **	X	X						
Adverse Events **		X	X	X	X	X	X	X
	Note: Enrollment visits and ACP discussions are in-person or remote. All other contacts involve telephone or electronic contacts. *See Section 9 for description of measures that are assessed. ** Section 8 for description of alert and adverse events.							

2 INTRODUCTION

2.1 STUDY RATIONALE

Advance care planning is a process that supports adults at any age or stage of health in understanding and sharing their personal values, life goals, and preferences regarding future medical care.[1] Early initiation of advance care planning is an imperative in ADRD care due to the long course of illness and its progressive and devastating effects on decision-making capacity. However, little attention has been directed at developing strategies to improve advance care planning for persons with ADRD and their family caregivers in primary care, which is the most common setting of initial diagnosis[2,3] and ongoing medical management.[4,5].

This study proposes to systematically develop and test a communication intervention, referred to as SHARE, to proactively engage family caregivers and normalize advance care planning in primary care. Our goal is to engage family caregivers in longitudinal interactions with primary care clinicians and stimulate and support advance care planning discussions in primary care. We focus on persons with mild, moderate, and severe cognitive impairment regardless of clinical diagnosis because of the importance of addressing

advance care planning early in the disease trajectory,[6,7] the under-diagnosis of ADRD[8-10] and because of the greater implementation potential of a protocol with broader applicability. We hypothesize that as compared with the minimally enhanced control care group, caregivers in the intervention group will report better quality of communication about end of life care with primary care clinicians at 6 months (primary outcome). We further examine the effects of the intervention on advance care planning processes (secondary outcomes) at 6 months. For patients who die by 24 months, we examine the quality of end of life care and bereaved family caregiver experiences with medical decision-making (secondary outcomes).

2.2 BACKGROUND

Alzheimer's Disease and Related Dementias (ADRD) are among the most profoundly disabling and costly of all health conditions[11] and the 5th leading cause of death.[12] Family caregivers are at the forefront of managing ADRD across the continuum of care. Clinicians rely on the substituted judgement of family for persons who lack decisional capacity toward the end of life.[13-15] However, family caregivers are not routinely included in discussions about prognosis[16,17] and are often poorly prepared to engage in surrogate decision-making.[15,18,19] Compared to persons without ADRD, persons living with ADRD are less likely to complete an advance directive or formally designate a surrogate decision-maker,[20] placing them at heightened risk for unnecessary suffering and high utilization of burdensome and costly end-of-life care.[21-23]

SHARE involves the following elements: 1) a letter from the practice introducing the initiative, to prepare persons and families to discuss goals of care,[24] 2) access to a designated staff member (e.g., medical assistant, social worker or nurse, lay person) trained to lead advance care planning discussions,[25-27] 3) person-family agenda-setting, to align perspectives about the role of family and stimulate discussion about goals of care,[28] and 4) education about communication and available resources, including a 44-page brochure developed by the National Institute on Aging entitled "A Guide for Older People: Talking with your Doctor", a blank easy to complete advance directive, and facilitated registration to the patient portal (for patient **and** family), to extend electronic interactions and information access to family.[29,30]

Each component has been found to improve a range of communication outcomes in other care contexts,[24-30] but have not previously been applied in this combination or examined with regard to advance care planning in persons with cognitive impairment, as we propose. SHARE is designed to be broadly scalable and widely relevant to diverse primary care patients and stakeholders. Our study is timely in light of newly available Medicare billing codes for advance care planning discussions with non-physicians,[31] recent recommendations of American Medical Association and National Quality Forum consensus committees emphasizing advance care planning in ADRD quality measurement,[32,33] National Alzheimer's Project Act Goal 3.C. to expand assistance for families in planning for future care needs,[34] and recommendations from a 2016 National Academies of Sciences, Engineering, and Medicine report calling for strategies to proactively engage and support families in care delivery.[35]

This study is guided by the patient-provider communication,[36-38] family caregiving,[39,40] health services,[41,42] and health informatics[43,44] literatures in acknowledging the multiple pathways by which interpersonal relationships influence treatment decisions and end-of-life care. We extend theory from the patient-provider communication literature[37,45] to include participation of a family caregiver.[38] Engaging family in primary care is particularly important in dementia care because of the influential role of family in medical

decision-making,[46-49] especially with disease progression at the end-of-life.[50-52] Our study seeks to improve communication for persons with cognitive impairment by establishing a structured protocol to proactively engage family caregivers in ongoing interactions with primary care clinicians and stimulate and support advance care planning in primary care throughout the disease trajectory. Our premise is that individuals and families expect clinicians to initiate advance care planning,[53] but that individual, family, and system factors including time, knowledge, and resources inhibit these conversations from occurring.[54] SHARE seeks to better equip persons with cognitive impairment and family caregivers with the knowledge, skills, and support to engage in effective communication and developing structured processes and enhancing capacity to engage in advance care planning. Our study is also guided by Normalization Process Theory, an applied theoretical model that articulates important contextual factors that promote or inhibit the routine incorporation of complex interventions into everyday practice.[55,56] As Normalization Process Theory stipulates the importance of implementation and sustainability from the outset, we propose to qualitatively examine a range of process and contextual measures that could affect the design of a subsequent trial and subsequent diffusion of SHARE.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The interventions are unlikely to pose harm or discomfort any greater than that ordinarily encountered in daily life or in obtaining routine medical care. Patient involvement in the study includes agenda-setting, engaging in goals of care discussion, and survey completion. There is low potential that agenda-setting between persons with cognitive impairment and family caregivers may lead to disagreement or interpersonal conflict. Completing some of the survey measures about attitudes, quality of life, and end-of-care preparations may involve some psychological discomfort. Some participants may become uneasy or fatigued during the interview process or may become slightly agitated when interacting with a stranger or by being asked to respond to questions about their memory. Some participants may be upset by the prospect or experience of goals of care discussions. Also, there is a low possibility that despite all protections, subject privacy and/or confidentiality may be breached. We believe the likelihood of such risks is low, that we have considered these risks, and that we have adequate protections in place. Our prior work we have found that these experiences are relatively rare. The main risks of participating in this study involve inconvenience, personal time, the potential for becoming upset or fatigued, and potential loss of confidentiality. Participants will be free to terminate their participation at any time and will be reminded of this during the consenting process.

2.3.2 KNOWN POTENTIAL BENEFITS

It is anticipated that persons with cognitive impairment and family caregivers will experience more benefit than risk from participation in this study and that risks associated with participation are reasonable in comparison to knowledge that may be gained. Benefits accrued by intervention study participants may include greater clarity regarding the patient's health and treatment preferences and the communication roles to be assumed by family caregivers during face-to-face medical visits, in electronic interactions with primary care providers, and in future medical decision-making. In addition to improving advance directive completion we hypothesize that the intervention might improve medical visit communication and satisfaction with care. Societal benefits will result from this study. We will test a scalable protocol to improve the quality of communication about end of life care in primary care, extending knowledge regarding the implementation and effects of advance care planning for persons with cognitive impairment outside of institutional settings. If this trial has a positive effect on communication, the methodology has

broad potential application to improve advance care planning and end of life care in primary care. Participants in the minimally enhanced care group will not directly benefit from participation.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

This is a Minimal Risk study of a behavioral intervention. The trial will be conducted in a population of older adults 80 years and older with cognitive impairment. The significance of our study rests in part on low completion of advance care planning in the target population despite high rates of mortality and adverse health events (e.g., hospitalization, emergency department visits). Advance care planning is already routinely offered in primary care and uptake of intervention processes will be at the discretion of patients and families. Based on our previous work and studies in this area by others, there is a small risk that participants will become anxious/agitated due to the prospect or experience of advance care planning. Adverse events that result from study participation are expected to be mild and psychological in nature. We will monitor rates of adverse health events by intervention group as a part of our analytic plan, but these events will not be systematically included in safety reporting as it is improbable that they will result from the intervention.

Individuals in the intervention and control groups may benefit from participation in this trial through improved communication between patients and caregivers, primary care providers, and family members regarding healthcare wishes, advance care directives, and the selection of decision makers for patient health. In addition, participants will benefit from the knowledge that participation in this trial may lead to improved outcomes for others in the future due to data gathered in this study. Potential societal benefits of this trial include a greater understanding of communication processes vital to advance care planning and a potential decrease in complicated or burdensome end-of-life care for older adults.

Several mechanisms to reduce the potential for psychological discomfort will be utilized. Interventionists and study interview staff will receive training in techniques for approaching older persons with cognitive impairment and family members, including sensitivity to discussing topics related to advance care planning and cultural competency for working with diverse populations. Intervention guides to help maintain these skills will be available as well as regular contacts, monitoring and feedback with the training team.

- This is a study about communication and ACP in primary care among older adults with cognitive impairment including ADRD. ADRD is a sensitive topic. Older adult participants will have a range of ADRD (from mild to severe) and not all older adults will be aware that they have ADRD or be in treatment for memory loss. Therefore, mention of cognitive impairment or ADRD in the recruitment materials or in the study title will be avoided.
- It will be emphasized in training interventionists that advance care planning is voluntary for patients, and that advance care planning sessions should not be initiated or be terminated if patients are not interested or do not wish to continue at that session.
- While it is possible that agenda-setting or advance care planning may introduce tension in the patient-caregiver relationship by acknowledging the distinct perspective of each individual, study staff will seek to mitigate associated risks by preparing interviewers and interventionists to anticipate concerns and mediate difficult discussions.
- Caregivers of older persons with significant health conditions, including those with Alzheimer's Disease and Related Dementias, are at heightened risk of depression and anxiety. During regular assessment for this study, participants will be screened for depressive symptoms or anxiety. Patients will be notified of scores above a pre-determined threshold and will be asked if they would like an educational brochure about depression or anxiety (as appropriate), or if they would like the

interventionist to notify the family's primary care clinician of this finding. Caregivers will also be encouraged to follow-up to discuss this with their health care clinician.

- In the event of extreme psychological discomfort among intervention patients or caregivers, interviewers and interventionists will be trained in procedures for ensuring necessary medical or professional intervention. Referral resource(s) will be identified for distressed family members within each health system. Primary care patients will be referred to their primary care clinician. Caregivers will be referred to the health system referral resource or to medical or psychological care (e.g., counseling, support, advocacy) as appropriate.

3 OBJECTIVES AND ENDPOINTS

3.1 PRIMARY OBJECTIVE

We test the efficacy of SHARE on quality of communication (primary outcome) and advance care planning processes (secondary outcomes) at 6 months among primary care patients with cognitive impairment (mild-severe) and family caregiver dyads. We hypothesize that as compared with the control group, caregivers in the intervention group will report better quality of communication about end of life care with primary care clinicians at 6 months (primary outcome).

3.2 SECONDARY OBJECTIVES

We further test the efficacy of SHARE on advance care planning processes at 6 months. We hypothesize that intervention caregivers will be more highly engaged in advance care planning than control caregivers as measured by caregiver-reported readiness to engage in advance care planning and having documented advance directive in the patient's electronic health record at 6 months. We expect patient-reported outcomes will mirror those reported by caregivers and that outcomes will be achieved without adversely affecting the therapeutic alliance with the primary care clinician or perceptions of shared decision-making with the primary care team.

For patients who die by 24 months, we examine the quality of end of life care and bereaved family caregiver experiences. Among patients who die between enrollment and 24 months, we hypothesize caregivers in the intervention group will report higher quality of end-of-life care than those in the control group as measured by the Satisfaction with Care at the End-of-Life in Dementia scale. We expect that that bereavement outcomes will be superior among intervention caregivers than control group caregivers as measured by less decisional conflict, less decisional regret, and fewer symptoms of anxiety and depression. Finally, we expect that decedents in the intervention group will be less likely to experience burdensome care at the end of life than decedents in the control group.

4 STUDY DESIGN

4.1 OVERALL DESIGN

This is a two-group single-blind randomized Phase 2 efficacy trial that will be conducted at up to 9 primary care practices in which 124 (+/- 10) dyads will receive a control protocol of minimally enhanced usual care and 124(+/- 10) dyads will receive usual care augmented with the SHARE protocol. We test the efficacy of multicomponent communication intervention, referred to as SHARE, on quality of communication (primary outcome) and advance care planning processes (secondary outcomes) at 6-, 12-, and 24-months

among primary care patients with cognitive impairment (mild-severe) and family caregiver dyads. For patients who die by 24 months, we examine the quality of end of life care (primary outcome) and bereaved family caregiver experiences with medical decision-making (secondary outcomes). Following enrollment and follow-up procedures, a small number of intervention group dyads will be selected to participate in a focus group interview to assess opinions and impressions of the SHARE experience. Primary care patients and family caregiver dyads will consent to being contacted for potential focus group participation.

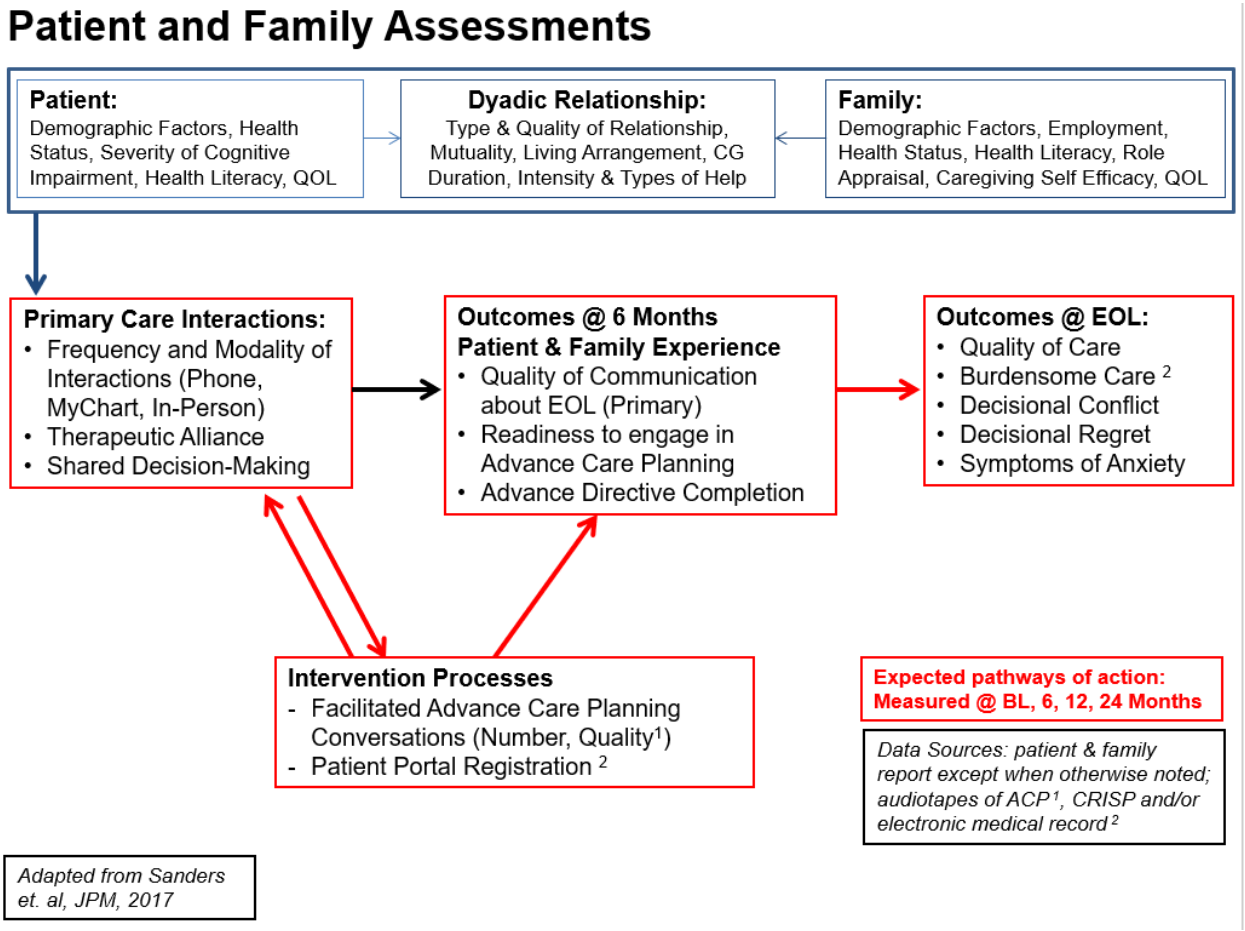
SHARE encompasses usual care, supplemented with the following four therapeutic elements: 1) a letter from the practice introducing the initiative, 2) access to a designated staff member (e.g., medical assistant, social worker or nurse, community health worker, or lay facilitator) trained to lead advance care planning discussions, 3) person-family agenda-setting to align perspectives about the role of the caregiver and stimulate discussion about goals of care, and 4) education about communication and available resources, including a 44-page brochure developed by the National Institute on Aging entitled "A Guide for Older People: Talking with your Doctor", a blank easy to complete advance directive, and facilitated registration to the patient portal (for patient and caregiver) to extend electronic interactions and information access to family. The control group will receive minimally enhanced usual care with print educational materials that include the 44-page brochure developed by the National Institute on Aging entitled "A Guide for Older People: Talking with your Doctor" and a blank easy to complete advance directive.

Person-family dyads assigned to the control group will receive a protocol of minimally enhanced usual care, encompassing a print educational brochure and blank easy to complete advance directive. The educational materials include a 44-page brochure developed by the National Institute on Aging entitled "A Guide for Older People: Talking with your Doctor" and an easy-to-read advance directive. Control dyads will be told that they are participating in a study about communication in primary care. We chose an active control arm for several reasons: 1.) because providing an advance directive should be the standard of care even if it is often not 'usual care', 2.) to ensure that positive results can be attributed to the effectiveness of the intervention, and 3.) to mitigate perceptions among dyads randomized to the control group that they are not being offered anything beyond usual care.

Participants will be randomized to treatment group at the level of the person-family dyad, following block randomization within primary care clinician. Participants in both groups will be followed over a 24-month period. Outcomes will be assessed from remote or in-person patient and caregiver interviews at enrollment and follow-up telephone or web surveys at 6, 12, and 24 months,; electronic health record portal activity; information about advance directive completion from electronic medical record; burdensome care at the end of life from family telephone or web survey and CRISP.

The below exhibit depicts the timing of assessments of intervention and control participants that will be conducted at baseline and at regularly scheduled intervals. The main pathways of interest (highlighted in red font) depict how advance care planning and clarifying the role of the family in primary care interactions affects patient and family experiences of care and quality of end-of-life care. These processes are relational in nature and we therefore assess constructs related to person-family mutuality, the patient-clinician therapeutic alliance, and shared decision-making at baseline and at all time points although these constructs are expected to be less responsive to change and less centrally aligned with the intervention pathway. We recognize feedback loops between primary care interactions, advance care planning, and patient and family experiences. These communication processes are hypothesized to affect outcomes at the end of life relating to quality of care, burdensome care, and surrogate decision-making. Recognizing that communication is affected by a wide range of individual and interpersonal characteristics, we comprehensively assess patient, family, and relational characteristics at baseline and

over time. Less mutable characteristics related to sociodemographic factors (age, gender, education, race/ethnicity, type of relationship, family function) are assessed at baseline only whereas more mutable factors relating to health status, quality of life, caregiving responsibilities, and caregiving appraisal are assessed at each time point. Patient TICS-m (Modified Telephone Interview for Cognitive Status) or AD-8 (Dementia Screening Interview) is assessed at baseline only at the time of enrollment, or at 6 month for those who were unable to communicate at baseline. Results from patient participant's completion of the TICS-m test of cognitive function at baseline will be shared with primary care clinicians for the purpose of providing the clinicians with the opportunity to follow-up as appropriate at their discretion (**A3**).



4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

This study proposes to systematically develop and test a communication intervention, referred to as SHARE, to proactively engage family caregivers and normalize advance care planning in primary care. SHARE involves the following elements: 1) a letter from the practice introducing the initiative, to prepare persons and families to discuss goals of care,[24] 2) access to a designated staff member (e.g., medical assistant, social worker or nurse, lay person) trained to lead advance care planning discussions,[25-27] 3) person-family agenda-setting, to align perspectives about the role of family and stimulate discussion about goals of care,[28] and 4) education about communication and available resources, including a 44-page brochure developed by the National Institute on Aging entitled "A Guide for Older People: Talking with

your Doctor", a blank easy to complete advance directive, and facilitated registration to the patient portal (for patient ***and*** family), to extend electronic interactions and information access to family.[29,30]

Each component has been found to improve a range of communication outcomes in other care contexts,[24-30] but have not previously been applied in this combination or examined with regard to advance care planning in persons with cognitive impairment, as we propose. SHARE is designed to be broadly scalable and widely relevant to diverse primary care patients and stakeholders. However, to facilitate examination of end-of-life endpoints, this study focuses on patients ages 80 and older who are at high risk of mortality.

Our goal is to engage family caregivers in longitudinal interactions with primary care clinicians and stimulate and support advance care planning discussions in primary care. We focus on persons with mild, moderate, and severe cognitive impairment regardless of clinical diagnosis because of the importance of addressing advance care planning early in the disease trajectory,[6,7] the under-diagnosis of ADRD[8-10] and because of the greater implementation potential of a protocol with broader applicability. Our study is timely in light of newly available Medicare billing codes for advance care planning discussions with non-physicians,[31] recent recommendations of American Medical Association and National Quality Forum consensus committees emphasizing advance care planning in ADRD quality measurement,[32,33] National Alzheimer's Project Act Goal 3.C. to expand assistance for families in planning for future care needs,[34] and recommendations from a 2016 National Academies of Sciences, Engineering, and Medicine report calling for strategies to proactively engage and support families in care delivery.[35]

This study is guided by the patient-provider communication,[36-38] family caregiving,[39,40] health services,[41,42] and health informatics[43,44] literatures in acknowledging the multiple pathways by which interpersonal relationships influence treatment decisions and end-of-life care. We extend theory from the patient-provider communication literature[37,45] to include participation of a family caregiver.[38] Engaging family in primary care is particularly important in dementia care because of the influential role of family in medical decision-making,[46-49] especially with disease progression at the end-of-life.[50-52] Our study seeks to improve communication for persons with cognitive impairment by establishing a structured protocol to proactively engage family caregivers in ongoing interactions with primary care clinicians and stimulate and support advance care planning in primary care throughout the disease trajectory. Our premise is that individuals and families expect clinicians to initiate advance care planning,[53] but that individual, family, and system factors including time, knowledge, and resources inhibit these conversations from occurring.[54] SHARE seeks to better equip persons with cognitive impairment and family caregivers with the knowledge, skills, and support to engage in effective communication and developing structured processes and enhancing capacity to engage in advance care planning. Our study is also guided by Normalization Process Theory, an applied theoretical model that articulates important contextual factors that promote or inhibit the routine incorporation of complex interventions into everyday practice.[55,56] As Normalization Process Theory stipulates the importance of implementation and sustainability from the outset, we propose to qualitatively examine a range of process and contextual measures that could affect the design of a subsequent trial and subsequent diffusion of SHARE.

4.3 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed the baseline, 6-month, 12-month, and 24-month assessments – or the bereavement survey, for family to patient participants who die prior to 24 months and/or completed a qualitative interview for those in the intervention. The Schedule of Activities (SoA) are shown in **Section 1.3**. If a patient/family dyad is lost to follow-up, we will

use all available data that are observed on that dyad in analyses. For patients who are lost to death, we will attempt bereavement surveys with family caregivers two to three months after death, following best practices.

5 STUDY POPULATION

We enroll a sample of 248 (+/- 20) person-family dyads comprising primary care patients with cognitive impairment ages 80 years or older and the person who helps them the most with medical decision making, who we refer to as their caregiver. This study focuses on persons ages 80 and older with cognitive impairment (mild-severe). We focus on this target population because persons living with (versus without) Alzheimer's Disease and Related Dementias are less likely to participate in advance care planning discussions, appoint surrogate decision-makers, or complete living wills,[20,21] and are consequently at greater risk for receiving unwanted aggressive care at the end-of-life.[17,21] We focus on persons with mild, moderate, and severe cognitive impairment regardless of clinical diagnosis because of the importance of addressing advance care planning early in the disease trajectory,[6,7] the under-diagnosis of Alzheimer's Disease and Related Dementias[8-10] and the greater implementation potential of a protocol with broad applicability. Advance care planning has been defined as a core element of high-quality dementia care but evidence-based primary care models do not exist. Although SHARE has been designed to be broadly applicable to all older primary care patients, we focus on those who are at high risk of mortality [25,57-59] so as to facilitate examination of end-of-life endpoints.

5.1 INCLUSION CRITERIA

In order to be eligible for this study, patients must meet all of the following criteria:

1. Under care of participating primary care clinician
2. 80 years or older
3. English speaking
4. Able to provide informed oral consent themselves or through a legally authorized representative
5. Can identify a family member or friend who assists in care coordination or accompanies them to some or all primary care visits
6. Cognitive impairment (mild-severe) as defined by having one or more incorrect answers or inability to respond to a validated 6-item phone screening instrument

In order to be eligible for this study, caregivers must meet all of the following criteria:

1. 18 years or older
2. English speaking
3. Able to hear well enough to communicate by telephone
4. Not planning to move out of state within the next 12 months
5. Do not report having a life-threatening illness
6. Family member or friend who assists in care coordination or attends at least some medical visits of an eligible patient with cognitive impairment
7. Does not have cognitive impairment, as defined by having fewer than two incorrect answers on a 6-item phone screening instrument

5.2 EXCLUSION CRITERIA

Potential patient participants who meet any of the following criteria will be excluded from participation in this study:

1. Younger than 80 years old
2. Does not speak English or requires an interpreter
3. Does not assist with care coordination or attend at least some primary care visits with a family member or friend
4. No willing/able legal guardian or representative to provide informed oral consent if the patient lacks capacity to do so for themselves
5. Plans to move out of the state in the next 12 months
6. Does not have cognitive impairment as defined by no incorrect answers on a 6-item phone screening instrument

Potential patient participants whose caregiver meets any of the following criteria will be excluded from participation in this study:

1. Younger than 18 years old
2. Does not speak English or requires an interpreter
3. Does not hear well enough to communicate by telephone
4. Reports a life-threatening illness
5. Cognitive impairment as defined by two or more incorrect answers or inability to respond to a validated 6-item phone screening instrument
6. Plans to move out of state within the next 12 months
7. Non-family member who is paid for their services

5.3 LIFESTYLE CONSIDERATIONS

N/A

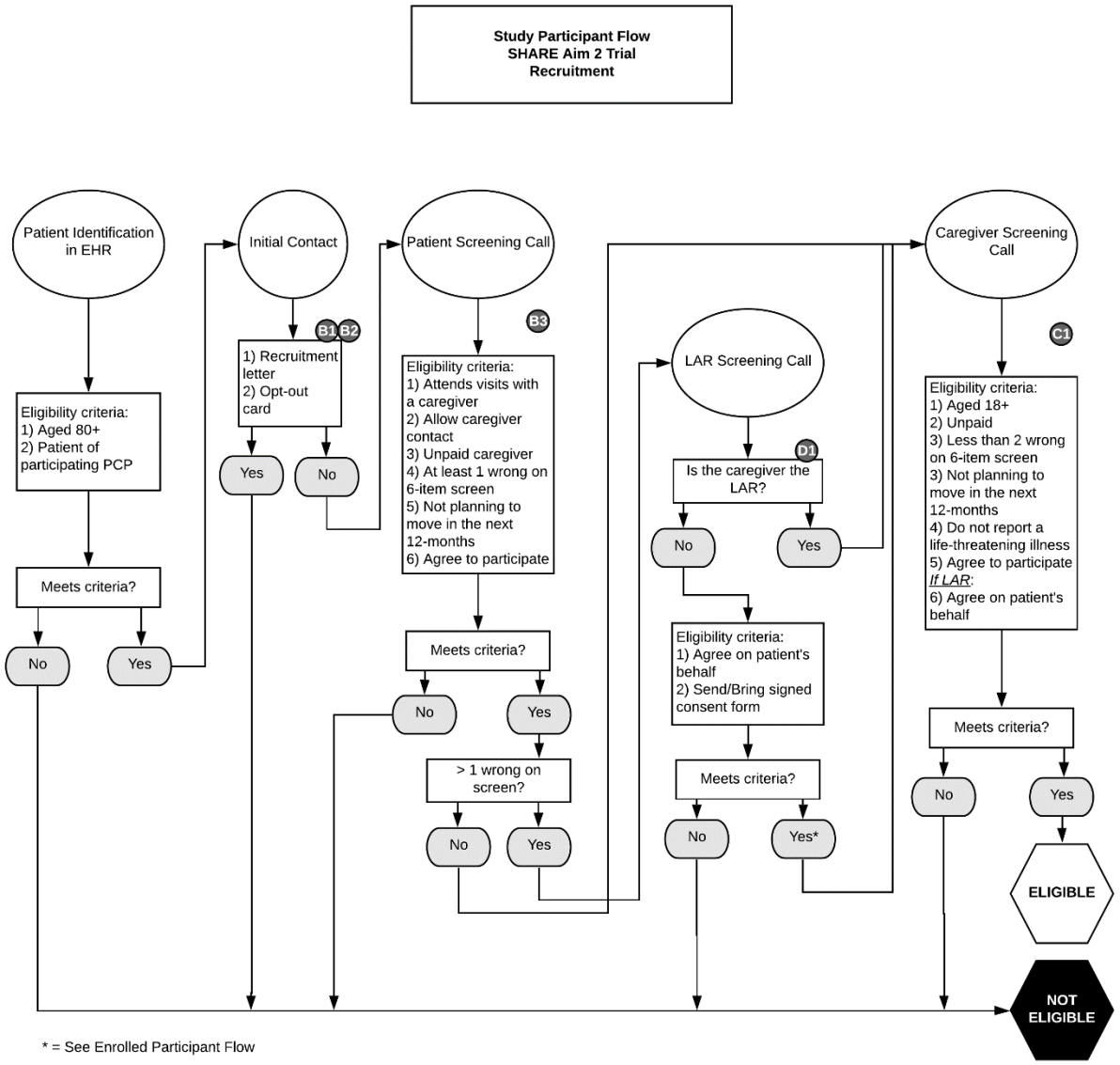
5.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate but are not subsequently assigned to the study intervention or entered in the study. Most exclusion criteria will be identified prior to consenting procedures during the telephone screen, however patients may reveal health concerns such as life-threatening illness or plans to move within the next 12 months during baseline enrollment procedures. Screen failures will be monitored and reported to the DSMB (see Table 3 of Open Tables).

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

5.5.1 SCREENING EVALUATION

We follow a phased approach to screening dyads for potential eligibility, as graphically depicted in the exhibit.



First, the PI will request access to records preparatory to research (**H1**). JHSPH staff working under the direction of a JHHS credentialed clinician to access the electronic medical record for recruitment purposes will complete a workforce member agreement co-signed by the JHHS credentialed clinician. (**H2**).

Second, we will invite primary care clinicians with an established patient panel at the participating practice(s) to provide informed consent (**A1, A5, A8**) and to participate in the trial by allowing research staff to contact their patient panel. Clinic staff at participating clinics may talk to their patients about the study, and may refer specific patients to our study, so that research staff may contact or recontact their patients.

Third, we will mail letters (**B1**) describing the study to patients ages 80 and older who are under the care of a participating primary care provider. The letter will state that patients will receive a call in about 10 days to explain the study in greater detail. The mailing will also include a pre-addressed (to the study office or PI's home address), pre-stamped postcard that the patient or the patient's caregiver may

return if they would like to "opt-out" from learning more about the study, or to indicate that they would be interested in learning more about the study at a later date (**B2**).

Fourth, patients who do not "opt out" by returning the postcard will be contacted via telephone by research staff who will further explain the study and answer questions. If patients indicate a date that they would like to be called on the postcard, research staff will contact them during that timeframe. Otherwise, patients will be contacted within two to four weeks of the initial mailing. Patients that may be newly eligible for the study (i.e. those that were not hospitalized in the past year, but fit the rest of the criteria) will be recontacted to be screened. Patients (or caregivers of patients who are unable to communicate) who are contacted by telephone and who express an interest in participating will be asked screening questions to determine eligibility. The results of the screening interview will be recorded in a REDCap data base so that the study can monitor reasons for ineligibility and nonparticipation of eligible candidates. (**B3**). Patients with at least one incorrect answer on the six-item telephone screening tool will be eligible to participate if they have an eligible caregiver who agrees to participate. For patients with two or more incorrect answers or who are not able to respond to a six-item telephone screening tool, we will determine eligibility by asking screening questions to the caregiver in order to identify a legally authorized representative according to Maryland law. We will ask the legally authorized representative to consent on behalf of patients who lack the capacity to do so (**D1**) as well as obtain assent (verbal, nonverbal) from the patient to participate.

Fifth, caregivers of eligible patients will be contacted by research staff who will introduce the study and answer questions. Caregivers who express interest in participating will be asked screening questions to determine eligibility. The results of the screening interview will be recorded in a REDCap database so that the study can monitor reasons for ineligibility and nonparticipation of eligible candidates. Caregivers with fewer than two incorrect answers on the six-item telephone screening tool will be eligible to participate if the patient is eligible and agrees to participate. (**C1**).

5.5.2 CONSENTING PROCEDURE

In order to minimize the need for research-only in-person visits, telemedicine visits may be substituted for in person clinical trial visits or portions of clinical trial visits where determined to be appropriate and where determined by the investigator not to increase the participants risks. Prior to initiating telemedicine for study visits the study team will explain to the participant, what a telemedicine visit entails and confirm that the study participant is in agreement and able to proceed with this method. Telemedicine acknowledgement will be obtained in accordance with the Guidance for Use of Telemedicine in Research. In the event telemedicine is not deemed feasible, the study visit will proceed as an in-person visit. Telemedicine visits will be conducted using HIPAA compliant method approved by the Health System and within licensing restrictions.

Primary Care Clinician Recruitment: Primary care clinicians with an established practice at participating primary care clinics who express a willingness to participate will be asked to provide written informed consent (**A1, A5, A8**) at the inception of the study prior to recruitment of older adults. Providers can either complete a remote e-consent process in REDCap or study staff will meet with providers to receive written consent at a location that is most convenient to them.

ACP Facilitator/ Interventionist Recruitment: Interventionist trained to guide ACP conversations will be invited to provide written informed consent (**E1, E8**). Prior to the initiation of intervention delivery, informed consent will be collected either remotely or in-person.

ACP Fidelity Rater/ ACP Facilitator for qualitative interviews: We will invite ACP Facilitators and those that have utilized our ACP conversation rating tool, to participate in a qualitative interview to help us

understand their experience with the intervention and tool. We will seek verbal consent from ACP Fidelity Raters/ ACP Facilitators who will be informed that their participation is confidential and completely voluntary.

Patient and Caregiver: During the telephone screen (**B3**, **C1**), we will seek verbal consent from patients and caregivers who will be informed that their participation is confidential and completely voluntary. The objectives, procedures, and a clear statement explaining risks and benefits of the study will be presented during the telephone screen. Patient-caregiver dyads who are determined to be eligible and who agree to participate will be asked to provide informed oral consent (**B4**, **C2**, **D4**). All consenting will be completed by research staff trained in human subject research and the study protocol. Research staff will be required to read the entirety of the oral consent scripts, allowing for any questions, comments, or concerns of prospective participants. Research staff will sign and date the oral consent script for study records within the REDCap study database to maintain detailed records of who administered the participant oral consent and when. Once oral consent is obtained, patients and caregivers will be mailed (via email or post) copies of the oral consent documents for their records.

For potential patient participants who complete the telephone screening interview and who make just 1 error on the six-item cognitive screen (indicative of very mild cognitive impairment) study eligibility will not be contingent on the availability of a legally authorized representative (LAR). For all other potentially eligible patient participants, if the caregiver is not the patient's LAR, we will seek to establish the identity (**D1**) and obtain the oral consent of the LAR (**D4**) prior to study enrollment. If a potential participant is suspected of moderate to severe cognitive impairment on the basis of 2 or more errors on the six-item cognitive screen and does not have a LAR or the LAR is unavailable or does not provide informed consent, then the patient will not be eligible to participate in the study.

Our approach to defining the patient's legally authorized representative is guided by the NIH Office of Extramural Research guidelines regarding Research Involving Individuals with Questionable Capacity to Consent and the JHMI Office of Human Subjects Research.

> *A legally authorized representative is an individual or other entity authorized under state law to consent on behalf of the research participant. Maryland law does not specify who may consent to research participation on behalf of an incompetent adult; however, Maryland law does indicate who may consent to medical care on behalf of an incompetent adult. For the purpose of determining who may serve as a legally authorized representative of an incompetent adult, investigators will follow the Maryland law applicable to surrogate decision-making for health care. This law specifies that the following categories of persons, in the specified order of priority, may make health care decisions for the incompetent adult: (1) a health care agent appointed by the adult before becoming incompetent; (2) a legal guardian appointed by the court; (3) a spouse; (4) an adult child; (5) a parent; (6) an adult sibling; or (7) a friend or other relative.*

During the administration of the informed oral consent protocol, we will evaluate capacity to give consent by asking potential participants about the study protocol **(B4)**. We will ask: *1) True or false, the main purpose of the study is to test a program called SHARE, to support communication between patients, families, and their primary care team, 2.) True or false, risks of the study include you may get bored, 3). True or false, a cure to cancer is a benefit of this study, 4.) True or false, my participation is voluntary, and 5.) True or false, I may never contact a member of the study team with questions*. If the patient provides an inaccurate answer, the study staff member will review that section and then re-ask the question. The study staff will then pose the question again to the patient. If the patient answers incorrectly a second time, then they are considered unable to provide informed consent. Research staff will document whether the person may provide oral consent. Among persons who are determined to

lack capacity to provide informed oral consent, we will seek to obtain oral assent from the person and oral proxy consent from their caregiver (if the legally authorized representative) or their legally authorized representative. We will ask the legally authorized representative to consent on behalf of patients who lack the capacity to do so (**D1**). We will obtain oral consent from the LAR prior to the initial enrollment meeting and send (via email or post) a paper copy of the patient and LAR oral consent script (**B4, D4)** to the legally authorized representative for their records. Patients and caregivers may consent to be recontacted for future studies. Collaborators at Hopkins, and collaborators at outside institutions will be able to contact patients who have agreed to recontact. Patient information shared with outside collaborators will be dependent on an established Data Use Agreement contracted between Johns Hopkins and the partner organization. As contact by outside investigators was not included in the original consent document, all participants who agreed to be contacted for future research will be reconsented (**R1)** by Hopkins staff prior to sharing information with external organizations. The reconsent process will only allow contact by Danielle Powell at UMD for her approved study (UMD IRB 2053970-1).

5.5.3 ENROLLMENT, BASELINE, AND/OR RANDOMIZATION

Enrollment officially occurs at the time of providing informed oral consent. See section 5.5.2 for more information about remote processes including enrollment and baseline assessment via telemedicine. For patient and family participants, enrollment occurs prior to completing the baseline assessment and randomization. The date of study enrollment will be tracked and documented for each participant.

Most intervention research in primary care has relied on cluster-randomization at the level of the clinic, which leads to challenges in the interpretation of results due to practice-level imbalances and unmeasured contextual differences.[60] This study randomizes at the level of person-family dyad, which may lead to between-group spillover and attenuate observed intervention effects. However, as 31 (+/-5) intervention dyads will be enrolled at each clinic (~4/month), we do not expect widespread changes to standard clinic workflows or practices. We believe the possibility of contamination is low as the intervention consists primarily of one-on-one contact between the interventionist and the person-family dyad, and there are no elements of the intervention that attempt to address clinicians' communication skill. Nevertheless, our analysis plan permits us to assess for the occurrence of contamination by evaluating whether there are changes over time in the control arm related to care processes, such as registration for shared access to the patient portal and advance directive completion. Dyad-level randomization will afford a more nuanced understanding of context and allow examination of group differences by primary care clinic.

Each person-family dyad will be randomized to treatment or control group in a 1:1 ratio using stratified, blocked randomization by doctor with alternating block sizes of 4 and 6 for each clinician. Randomization will utilize a statistical algorithm within REDCap developed by the project statistician that is unknown to study staff. The randomization module will generate random treatment group assignment of study participants for each participating clinician. Once patient and caregiver informed oral consent (**B4**, **C2**) have been received by study staff, research staff will initiate the randomization procedure within REDCap. Person-family dyads assigned to the treatment group will receive information about SHARE. Person-family dyads assigned to the control group will receive print materials about the control protocol (See 6.1.1).

Research staff responsible for the randomization protocol after the enrollment visit will be aware of participant assignment status after it occurs. Allocation concealment will be ensured by blinding the PI and research staff conducting follow-up assessments and those responsible for coding study outcomes throughout the study. Only the study statistician, selected unblinded staff (and REDCap administrator),

and members of the data and safety monitoring board (DSMB) will have access to unblinded data before study completion. As randomization occurs at the level of the person-family dyad, clinicians will care for patients in both groups. Clinicians will be blinded to group assignment.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

Person-family dyads assigned to both the intervention and control groups will receive usual care, comprising standard primary care at participating practices. Usual care involves following patients at variable intervals, with routine visits scheduled at 2 weeks-6 months, depending on the stability of health status. All patients may register for the patient portal, provide their primary care clinician / clinic with a completed advance directive to be uploaded in their electronic health record, or avail themselves of advance care planning with their primary care clinician or other clinic staff. However, these processes generally occur on an ad-hoc basis and do not involve a protocolized approach to engaging with family caregivers or advance care planning.

Person-family dyads assigned to the control group will receive a protocol of minimally enhanced usual care, encompassing an introductory letter (**F1B**), a print educational brochure (**F6**) and blank easy to complete advance directive (**F4**, **F5**). The educational materials include a 44-page brochure developed by the National Institute on Aging entitled "A Guide for Older People: Talking with your Doctor"(**F6**) [61] and an easy-to-read advance directive (**F4, F5**). Control dyads will be told that they are participating in a study about communication in primary care. We chose an active control arm for several reasons: 1.) because providing an advance directive should be the standard of care even if it is often not 'usual care', 2.) to ensure that positive results can be attributed to the effectiveness of the intervention, and 3.) to mitigate perceptions among dyads randomized to the control group that they are not being offered anything beyond usual care.

Person-family dyads assigned to the intervention protocol will receive usual care in addition to SHARE**,** encompassing the following four components (see exhibit below).

1. An invitation from the primary care clinic introducing the intervention to prepare patients and families to engage in advance care planning discussions (**F1A, F7**),[24]
2. Access to an ACP facilitator/ interventionist trained in the protocol and leading advance care planning for persons with cognitive impairment and their families,[26,27]
3. Person-family agenda-setting to align perspectives about the role of family and stimulate discussion about health care issues and advance care planning (**F2**),[28] and
4. Education about communication and available resources, including a 44-page brochure developed by the National Institute on Aging entitled "A Guide for Older People: Talking with your Doctor" (**F6**),[61] a blank advance directive (**F4**, **F5**, and information about and facilitated registration for the patient portal to enable and extend electronic interactions and information access to patients and family (**F3**).[29,30]

SHARE Therapeutic Components, Content, Rationale, Evidence of Effectiveness		
Content	**Rationale**	**Evidence of Effectiveness**

1. Primary care initiated voluntary ACP	Most patients expect primary care practices to initiate ACP.[53] Proactively introducing ACP normalizes these discussions.	Primary care initiatives to increase advance directive completion are effective and well-received.[24,62]
2. ACP education and availability of non-clinician led ACP discussions	ACP education and resources increase patient & family awareness, knowledge and skill. [50,51] Respecting Choices is a structured educational program to train facilitators to facilitate ACP discussions.[25,63]	ACP is associated with delivery of goal concordant care, greater confidence among surrogate decision-makers[13,64-66] & reduced EOL costs.[25-27,63]
3. Person-Family Agenda Setting	Individuals & families often have different concerns. Agenda-setting stimulates discussions about ACP & the role of family.	Agenda-setting helps clarify concerns, goals, and expectations, and increase engagement in care.[28,67,68]
4. Education about communication resources, including access to Electronic Health Record Via Patient Portal	The patient portal facilitates timely and accurate information about patient health, diagnoses, test results, & prescribed treatments. Families are provided their own identity credentials to access information and communicate with clinicians.	The patient portal operates through mechanisms of convenience, continuity, activation, and understanding.[43] Prior studies find clinical benefit of supporting family through technology.[69-73 30]
ACP=advance care planning; EOL=end-of-life; PCP=primary care practice		

6.1.2 ADMINISTRATION AND/OR DOSING

Staff at participating primary care clinics will be informed about the study objectives and how to respond to patient/family queries that may arise related to intervention processes such as how to facilitate registration to the patient portal for families, and where and how to upload a completed advance directive. Investigators will identify a liaison from each of the two partnering health systems to assist with the implementation of the intervention at participating clinics. Clinic staff at participating primary care clinics will be introduced to the study at monthly staff meetings.

Intervention and control dyads will be introduced to their respective protocol remotely (see section 5.5.2 for more information about telemedicine for remote processes) after randomization and completing the baseline enrollment survey. Study participants in both groups will be told they are participating in a study about communication in primary care and will be followed for up to 24 months. Research staff will provide person-family dyads in both groups with a letter from the primary care practice describing a new communication initiative.

Person-family dyads assigned to the ***control*** group will receive a protocol of minimally enhanced usual care, encompassing an introductory letter (**F1B**), print educational brochure (**F6**) and blank easy to complete advance directive (**F4, F5**).

Person-family dyads assigned to the intervention protocol will receive usual care in addition to SHARE. Research staff will provide patients with the contact information of the SHARE advance care planning facilitators (the interventionists) (**E9**), and will provide interventionists with the name, age, caregiving relationships, preferred communication modality, travel information/directions and safety concerns for potential home visits, and contact information of participants in the intervention group. The SHARE advance care planning facilitators will then contact person-family dyads using patient/family preferred mode of contact (e.g., by telephone or email) within 3 (+/- 3) business days of the enrollment visit to request either an in-person or remote meeting. Within 5 business days of receiving participant

information, the SHARE ACP facilitators/ interventionists will contact person-family dyads on their preferred mode of contact (e.g. by telephone or email) to request either a remote or in-person meeting. The meeting will ideally be scheduled within 4 weeks of the baseline assessment. The duration and nature of the conversation and the frequency and mode of subsequent contacts will be tailored to accommodate individual preferences. The initial advance care planning meeting is expected to be 45-60 minutes duration. In the initial meeting the facilitator will follow a semi-structured conversation guide and employ motivational interviewing techniques to stimulate interest, uptake, and adoption of SHARE components. Two copies of an ACP summary (F11) will be available via a letter delivered by post or email to patients assigned to the intervention for review at their leisure, and as a reminder of topics covered. From prior work [47,74] we expect most older adults and families will be receptive to SHARE but that older adults and family caregivers will vary in readiness and capacity to engage in elements of advance care planning. For example, prior studies find persons with severe cognitive impairment (TICS-m≤27) may have the capacity to name a surrogate decision-maker but that completing an instructional directive to specify preferences for medical treatments will likely exceed decision-making capacity.[75,76]

Existing asynchronous secure messaging features of the patient portal enable patients and individuals who have shared access to contribute to the electronic health record (e.g., to elaborate on meeting discussions, communicate emerging concerns, or summarize informal family conversations) to inform and stimulate ongoing discussions and documentation. This feature may be leveraged in communications with the interventionist. At the initial meeting the interventionist will clarify ongoing availability for follow-up meetings and seek patient and family input regarding the frequency (e.g., monthly, quarterly) and mode (by phone, via secure electronic messaging through the patient portal) of future "check-in" contacts to assess interest in scheduling future meetings. Subsequent in-person, telephone, or video conference meetings will occur as a result of "check-in" contacts initiated by the interventionist, ad-hoc requests by persons and/or family caregivers, or notable changes in health (e.g., unplanned hospitalization or emergency department visit, or notable change in health or function). SHARE interventionists will be expected to document the occurrence, content, and outcomes of advance care planning conversations after each ACP conversation (**E5**).

Participants may be asked to complete a brief questionnaire following all interventionist/facilitator meetings about their satisfaction with the conversation and their perception of its importance (**E6**, **E7**). Participants will be given the survey via web survey link or as a mailed paper form with a pre-addressed (to the study office or PI's home address), stamped envelope return to the study team once completed.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

Our approach to adherence assessment refers to how we monitor and maintain fidelity to the intervention protocol. Guided by the NIH Behavior Change Consortium[77] we address fidelity through a.) design, by selecting distinct therapeutic elements that are based on theory, b.) training, by relying on a protocolized curriculum to train interventionists in advance care planning and other elements of SHARE, c.) through multimodal assessment of the fidelity by which interventionists deliver the protocol, and d.) ongoing teleconferences at regular intervals (initially weekly, with less regular intervals over time as the interventionists gain competency) to monitor and support interventionists. All new interventionists will be required to present their first three cases during weekly case presentation meetings for discussion. The advance care planning facilitator (interventionist) will document all patient and family caregiver

contacts and advance care planning discussions in the patient's electronic health record and/or a REDCap data base (**E5**).

Interventionists will be nurse case managers, social workers, office medical assistants, community health workers who work 3 or more days per week and have been in their position for a minimum of one year, or trained lay facilitators hired by the study team. Training content will include all elements of SHARE, including: The Respecting Choices curriculum, documenting advance directives, facilitating family meetings, communicating difficult news, and assessing cognitive capacity. Training will be delivered and reinforced using traditional didactics, case scenarios and video conversations, and modeling and mentored role play. Dr. Cagle will supervise interventionists in weekly telephone meetings initially with monthly meetings after.

We rely on an established curriculum, Respecting Choices http:// respecting-choices.org, to train interventionists to lead advance care planning conversations. Respecting Choices includes patient and family education materials, a structured educational curriculum to train non-physicians in the competencies of advance care planning and standardization of policies for embedding ACP in routine care delivery. [26,27] The Respecting Choices program includes 6 online modules with scripted interview tools and communication techniques to facilitate understanding ACP, exploring personal values, identifying a health care decision-maker, and communicating preferences for end-of-life care. Respecting Choices has been successfully delivered by a range of non-physician interventionists, including nurses, social workers, and lay navigators[25,63] and has been well received in racially and ethnically diverse communities.[78,79] Prior studies that have demonstrated benefit for advance care planning outcomes and reductions in per-capita costs of end-of-life care,[25-27,63] have motivated the adoption of Respecting Choices by health care systems nationally and internationally.[78-81] However, Respecting Choices has not been specifically studied among persons with cognitive impairment or combined with strategies to proactively engage family caregivers in primary care, as we propose in this study.

Advance care planning facilitators will be either social workers, nurses, or medical assistants that are embedded in primary care as part of existing staff - or trained lay facilitators hired by the study team. Training will include all components of SHARE, including: certification in the Respecting Choices ACP curriculum, with specific attention to working with patients with cognitive impairment and families; documenting and uploading advance directives; resources specific to cognitive impairment and/or dementia. Training will be delivered and reinforced using traditional didactics, case scenarios and video conversations, and modeling and mentored role play.

6.3 MEASURES TO MINIMIZE BIAS

Most intervention research in primary care has relied on cluster-randomization at the level of the clinic, which leads to challenges in the interpretation of results due to practice-level imbalances and unmeasured contextual differences.[60] This study randomizes at the level of person-family dyad, which may lead to between-group spillover and attenuate observed intervention effects. However, as as many as 31 intervention dyads (+/- 5) will be enrolled at each clinic (~4/month), we do not expect widespread changes to standard clinic workflows or practices. We believe the possibility of contamination is low as the intervention consists primarily of one-on-one contact between the advance care planning facilitator and the person-family dyad, and there are no elements of the intervention that attempt to address clinicians' communication skill. Nevertheless, our analysis plan permits us to assess for the occurrence of contamination by evaluating whether there are changes over time in the control arm related to care processes, such as registration for shared access to the patient portal and advance directive completion.

Dyad-level randomization will afford a more nuanced understanding of context and allow examination of group differences by primary care clinic.

Each person-family dyad will be randomized to treatment or control group in a 1:1 ratio using stratified, blocked randomization by doctor with alternating block sizes of 4 and 6 for each clinician. A statistical program developed by the project statistician and unknown to study staff will be used to prospectively generate random treatment group assignment of study participants for each participating clinician. A set of opaque envelopes will be prepared for each clinician following the results of the statistical program. Upon providing informed oral consent (**B4, C2, D4**) and after completing the baseline enrollment survey (**B6**, **C3**), research staff will open the next sequentially ordered envelope specifying treatment group by clinician. Person-family dyads assigned to the treatment group will information about SHARE. Person-family dyads assigned to the control group will receive print materials about communicating with their doctor.

Research staff responsible for the randomization protocol after enrollment will be aware of participant assignment status after it occurs. Allocation concealment will be ensured by blinding the PI and research staff conducting follow-up assessments and those responsible for coding study outcomes throughout the study. Only the study statistician, selected unblinded staff (and REDCap administrator), and members of the data and safety monitoring board (DSMB) will have access to unblinded data before study completion. As randomization occurs at the level of the person-family dyad, clinicians will care for patients in both groups. Clinicians will be blinded to group assignment. Patient-family dyads will have knowledge of group assignment, but no delineation will be made between group assignment indicating which is treatment or control. We will use group naming conventions of (Group A and Group B) to describe group assignment.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

The approach to monitoring ongoing delivery of the intervention protocol will involve recording and auditing advance care planning sessions to determine the extent to which the protocol-based objectives are achieved. Following Vaccaro and Seaman, [82,83] we will implement a fidelity audit tool to assess the extent of adherence of advance care planning conversations to the curriculum, and the competence of its delivery (**E10**).

We will evaluate the extent to which patients and family caregivers avail themselves to therapeutic elements of the intervention relating to advance care planning conversations and interactions with primary care clinicians and their team about wishes for future medical care and goals of care. A monthly report will be generated to track the number, duration, and mode of all contacts with the advance care planning facilitator, the content of advance care planning discussions, as well as registration for the patient portal by the patient and the family caregiver. The report will produce information by interventionist and by clinic site. This level of detail will permit the team to identify areas where full implementation is not being achieved and enable corrective actions. If potentially problematic content during meetings is noted, it will be flagged for review during supervision meetings. This information will be used to descriptively characterize the intervention group at each data collection time point and as it relates to outcomes. In this study we endeavor to complete at least one advance care planning discussion for each person-family dyad assigned to the intervention group; ideally within 4 weeks of the enrollment.

6.5 CONCOMITANT THERAPY

N/A

6.5.1 RESCUE THERAPY

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

This is a Minimal Risk study of a behavioral intervention. The trial will be conducted in a population of older adults 80 years and older with cognitive impairment and the significance of our study rests in part on low completion of advance care planning in the target population despite high rates of mortality and adverse health events (e.g., hospitalization, emergency department visits). Advance care planning is already routinely offered in primary care and uptake of intervention processes will be at the discretion of patients and families. Participants will be free to terminate their participation at any time and will be reminded of this during the consenting process. Participants in the trial will be offered the intervention as a part of routine care and will be free to decline all aspects of intervention activities but will continue to be assessed according to intention to treat.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

We will monitor loss to follow up and discontinuation of participation in the study. Data from screening calls, intervention contacts and participant surveys will be entered into REDCap forms that the data manager will check for completion and accuracy. The data manager will provide semi-monthly reports of missing or inappropriate entries to the PI for clarification and resolution. Standardized electronic data validation checks will be developed within the database constructs using data entry discrepancy flags, programmed query rules, and in certain cases, external rules using SAS code. Monthly reports in aggregate and by study site will be generated summarizing accrual, completeness of follow-up, and study withdrawals. Periodic reports will be generated at the request of the Project Manager or the Principal Investigator. The Data Manager will generate all these reports, working collaboratively with the Biostatistician and study staff. The reason for participant discontinuation or withdrawal from the study will be recorded on the Case Report Form (CRF), tracked in REDCap, and reported to the DSMB. Subjects orally consent and are randomized but do not receive the study intervention may be replaced. Subjects who orally consent and are randomized and receive the study intervention, and subsequently withdraw, or are discontinued from the study will not be replaced.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if study staff are unable to contact the participant after at least 15 attempts for the 6-month, 12-month, or 24-month follow-up survey.
The following actions must be taken if a participant is unreachable by study staff:

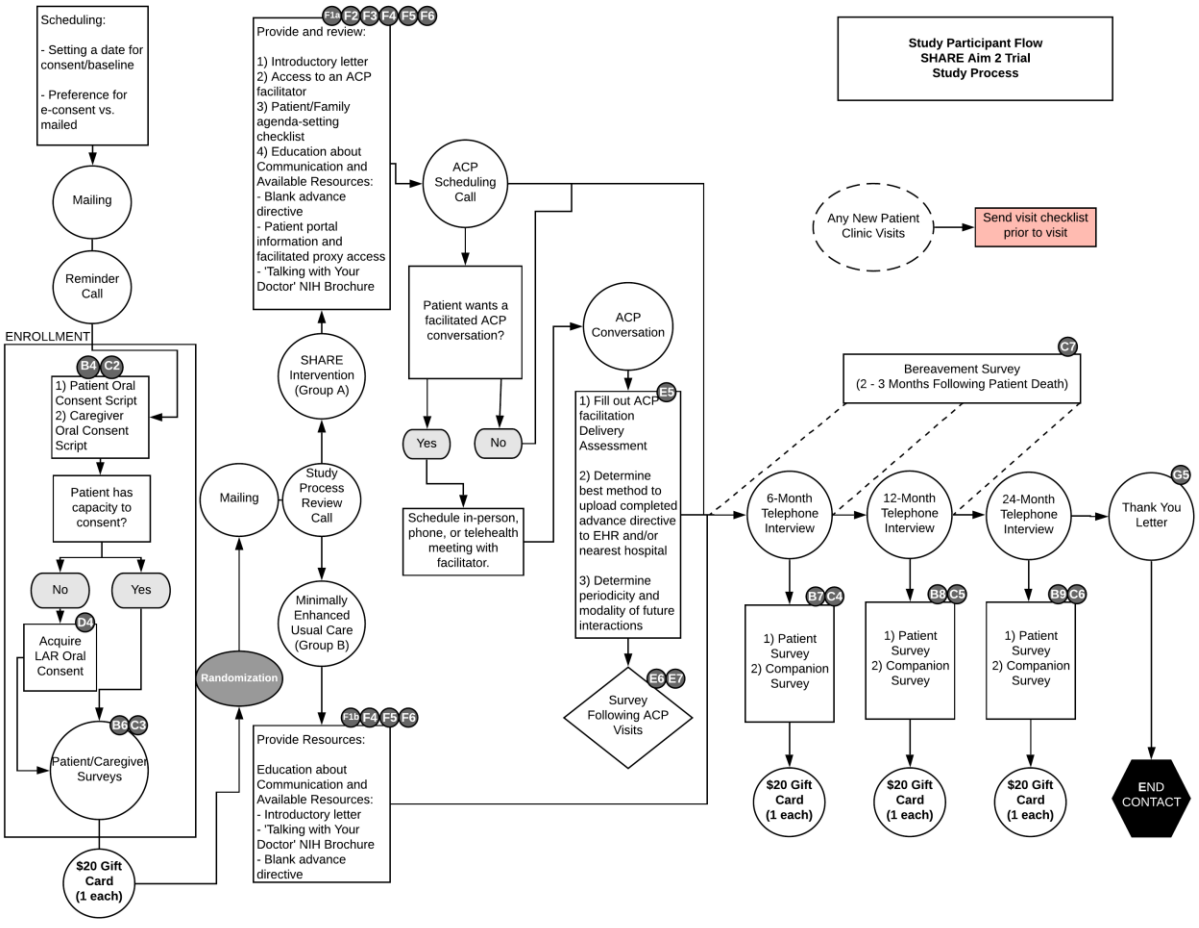
- Study staff will seek to contact family of an unreachable patient, or the patient of an unreachable family.
- Study staff will query the electronic health record or ask primary care clinic staff if the patient has moved or had a change in health status.
- If these efforts are not successful, the participant will be noted as having been lost to follow up.

If a patient/family dyad are lost to follow-up, we will use all available data that are observed on that dyad in analyses. For patients who are lost to death, we will attempt bereavement surveys with family caregivers two to three months after death, following best practices.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

A description of the screening and enrollment procedures is provided in section 5.5 of this protocol. Participants will be assessed at baseline (after consent and before randomization) (**B6**, **C3**), and 6 (**B7**, **C4**), 12 (**B8**, **C5**), and 24 months (**B9**, **C6**) post-randomization. Bereavement surveys will be administered via telphone or web survey to enrolled family caregivers two to three months after the death of the patient in lieu of subsequent assessments (**C7**). For the 6, 12, and 24- month surveys, the window for data collection will be +/- 30. We will attempt bereavement surveys with family caregivers two to three months after death, following best practices. A summary of information to be collected from participants at each assessment are further elaborated on in the text that follows and discussed in detail in section 9.0 of this protocol.



* = See Study Participant Flow Detailing Recruitment Process clarifying approach to recruiting patients with impaired capacity whose LAR is not the caregiver

Enrollment

Enrollment officially occurs at the time of providing informed oral consent (see exhibit, above), or at such a time that it is confirmed by study staff that both patient and caregiver have been administered the oral consent script with a research staff member and orally consented to participate. Enrollment occurs prior

to patient and caregiver participants' completion of the baseline assessment and randomization The date of study enrollment will be tracked and documented for each participant.

Baseline Assessments

Study staff will administer baseline patient surveys (**B6**). Caregivers will be given the option to self-administer the baseline survey on hard (paper) copy or using a REDCap survey link. The following information, further detailed in the Schedule of Evaluations (see 6.1 of our Manual of Procedures) will be collected during surveys at baseline:

- Patient characteristics (demographic factors, health status, interpersonal relationships with caregiver and family, quality of life)
- Family caregiver characteristics (demographic factors, health status, interpersonal relationship with patient and family, caregiving intensity and appraisal)
- Primary care interactions and communication (therapeutic alliance, shared decision-making, frequency and mode of contacts, use of patient portal)
- Patient and family experiences (quality of communication, engagement in advance care planning)
- Alert events, adverse events

After providing informed consent (**A1**), primary care clinicians will be asked to provide their demographic information and information about characteristics of their practice in a brief questionnaire (**A2**). Clinicians will be asked to allow research staff to identify potentially eligible established patients who are scheduled for an upcoming visit from the clinic's electronic scheduling system.

ACP facilitators/ interventionists will complete a baseline assessment prior to training (**E2, E3**) and a post-training survey (**E4**) upon completion of the training.

Follow-up Assessments

The window during which surveys are conducted will be +/- 90 days for each regularly scheduled follow-up assessment as noted in the Schedule of Evaluations. The following information, further detailed in the Schedule of Evaluations (see 6.1) will be collected at 6 (**B7**, **C4**), 12 (**B8**, **C5**), and 24 months (**B9**, **C6**) follow-up:

- Patient characteristics (health status, living arrangement, mutuality with family caregiver, quality of life)
- Family caregiver characteristics (health status, living arrangement, mutuality with older adult, caregiving intensity and appraisal)
- Primary care interactions and communication (therapeutic alliance, shared decision-making, frequency and mode of contacts, use of patient portal)
- Patient and family experiences (quality of communication, engagement in advance care planning)
- Alert events, adverse events

Should participants be screened positive for symptoms of depression or anxiety, they will be notified of this finding (**G1**). They will be asked if they would like an educational brochure about depression (**G4, G5**) or anxiety (**G3. G5**) (as appropriate), or if they would like the interventionist to notify their primary care clinician of this finding (**G2**).

Primary care clinicians will be asked to provide follow-up information about characteristics of their practice in a brief survey after all patients have been enrolled (**A4**).

Follow up assessments for ACP facilitators/ interventionists are detailed in section 6 of this protocol.

Completion/Final Evaluation

If a clinician drops out before randomization occurs, he/she will be replaced. If a clinician drops out after randomization, but patient/family dyads are evaluable, we will perform an intent-to-treat analysis for that dyad. If a patient/family dyad are lost to follow-up, we will use all available data that are observed on that dyad in analyses. For patients who are lost to death, we will attempt bereavement surveys (**C7**) with family caregivers two to three months after death, following best practices. Patients and/ or caregivers that are assigned to the intervention who have completed the study, including those who are lost to death, will be invited to share their experience with the intervention through a final qualitative telephone/ video interview. The following information, further detailed in the Schedule of Evaluations (see 6.1) will be collected:

- Quality of end-of-life care, receipt of burdensome care at the end of life
- Surrogate decision-making experience (decisional conflict, decisional regret)
- Family caregiver symptoms of anxiety and depression
- Adverse events

8.2 SAFETY ASSESSMENTS

Participant safety will be monitored following the protocol outlined in our Data and Safety Monitoring Plan and Manual of Procedures. We follow the Office of Human Research Protections' guidance in our approach to defining and identifying Serious Adverse Events, Adverse Events, and Unanticipated Problems. A description of safety assessments and reporting is further described in the following text.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

We follow the Office of Human Research Protections' guidance in our approach to defining and identifying Serious Adverse Events, Adverse Events, and Unanticipated Problems. **Adverse events** are any untoward or unfavorable medical occurrence, including any abnormal sign, symptom, or disease identified by any member of the research team that may occur at any time following consent of participants whether or not it is considered related to participation in the research. Advance care planning is already routinely offered in primary care and uptake of intervention processes will be at the discretion of patients and families. Based on our previous work and studies in this area by others, there is a small risk that participants will become anxious/agitated due to the prospect or experience of advance care planning. Adverse events that result from study participation are expected to be mild and psychological in nature. Interventionists will be trained to monitor, record, and manage such events and make effective referral.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

Serious adverse events are any adverse event temporally associated with research participation that: 1) results in death; 2) is life-threatening; 3) requires inpatient hospitalization or prolongation of existing hospitalization; 4) results in a persistent or significant disability/incapacity; 5) results in a congenital anomaly/birth defect; or 6) any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition. This is a minimal risk behavioral intervention and we do not anticipate any serious adverse events. The trial will be conducted in a population of older adults 80 years

and older with cognitive impairment and the significance of our study rests in part on low completion of advance care planning in the target population despite high rates of mortality and adverse health events (e.g., hospitalization, emergency department visits). We will monitor rates of serious adverse events by intervention group as a part of our analytic plan, but these events will not be systematically included in safety reporting as it is improbable that they will result from the intervention. If any deaths should occur, they will be reported by the principal investigator to the DSMB and National Institute on Aging Program Officer within 24 hours of initial notification.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

Relatedness of adverse events, serious adverse events, and unanticipated problems will be evaluated on the basis of temporality and relation to intervention processes. Specifically, we will determine whether the event occurred subsequent to the patient/family having engaged in an advance care planning and having been triggered or caused by the prospect or experience of engaging in an advance care planning discussion and/or other processes and activities related to the intervention protocol.

8.3.3.3 EXPECTEDNESS

Unanticipated problems are unexpected, related or possibly related to participation in research, and suggest that participating in research poses greater risk of physical, psychological, economic, or social harm than previously known or recognized. Given the minimal risk of the study, the voluntary nature of patient/family participation, and the availability of advance care planning in mainstream primary care, unexpected problems are unlikely. Nevertheless, we will monitor the emergence of any unanticipated problems in the Aim 2 trial through interviews with patients, families, and trained interventionists.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

Should a significant adverse event occur that is unanticipated and related to the intervention, it will be reported to NIA Program Officer and to the DSMB Chair or to the designated DSMB member within 48 hours of the study's knowledge of the significant adverse event. All other significant adverse events will be reported to the NIA Program Officer and to the DSMB (or a Safety Officer) quarterly. Given that some advance care planning visits may occur in people's homes, there is the potential that facilitators will encounter a potential emergency situation that is not related to study participation (e.g., dehydration, environmental risk, medical emergency). We refer to such events as **safety alerts** and have well developed procedures for monitoring and management (see adverse event reporting procedures below). All safety alerts will be reported to the NIA Program Office and DSMB semiannually.

8.3.5 ADVERSE EVENT REPORTING

Adverse events will be reported per IRB policies. All members of the DSMB will receive copies of all safety reports at the time of submission to the IRB of the Johns Hopkins Bloomberg School of Public Health. In addition, a listing of all adverse events and their attribution (e.g., study related, intervention related, or unrelated to study or treatment) will be provided to the DSMB biannually.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

Should a significant adverse event occur that is unanticipated and related to the intervention, it will be reported to NIA Program Officer and to the DSMB Chair or to the designated DSMB member within 48 hours of the study's knowledge of the significant adverse event. All other significant adverse events will be reported to the NIA Program Officer and to the DSMB (or a Safety Officer) quarterly.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

N/A

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

Unanticipated problems are unexpected, related or possibly related to participation in research, and suggest that participating in research poses greater risk of physical, psychological, economic, or social harm than previously known or recognized

8.4.2 UNANTICIPATED PROBLEMS REPORTING

Unanticipated problems are unexpected, related or possibly related to participation in research, and suggest that participating in research poses greater risk of physical, psychological, economic, or social harm than previously known or recognized. Given the minimal risk of the study, the voluntary nature of patient/family participation, and the availability of advance care planning in mainstream primary care, unexpected problems are unlikely. Nevertheless, we will monitor the emergence of any unanticipated problems in the Aim 2 trial through interviews with patients, families, and trained interventionists. Unanticipated problems that emerge will be reported by the principal investigators to the DSMB and National Institute on Aging Program Officer within 48 hours of initial notification to the project team.

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

Objectives and hypotheses related to primary outcomes are as follows:

We test the efficacy of SHARE on quality of communication (primary outcome) and advance care planning processes (secondary outcomes) at 6 months among primary care patients with cognitive impairment (mild-severe) and family caregiver dyads. We hypothesize that as compared with the control group, caregivers in the intervention group will report better quality of communication about end of life care with primary care clinicians at 6 months (primary outcome).

Objectives and hypotheses related to secondary outcomes are as follows:

We further test the efficacy of SHARE on advance care planning processes at 6 months. We hypothesize that intervention caregivers will be more highly engaged in advance care planning than control caregivers as measured by caregiver-reported readiness to engage in advance care planning and having documented advance directive in the patient's electronic health record at 6 months. We expect patient-reported outcomes will mirror those reported by caregivers and that outcomes will be achieved without adversely affecting the therapeutic alliance with the primary care clinician or perceptions of shared decision-making with the primary care team.

For patients who die by 24 months, we examine quality of end of life care and bereaved family caregiver experiences with medical decision-making. We hypothesize caregivers in the intervention group will report higher quality of end-of-life care than those in the control group as measured by the Satisfaction with Care at the End-of-Life in Dementia scale. We expect that bereavement outcomes will be superior among intervention caregivers than control group caregivers as measured by less decisional conflict, less decisional regret, and fewer symptoms of anxiety and depression. Finally, we expect that decedents in the intervention group will be less likely to experience burdensome care at the end of life than decedents in the control group.

We expect patient-reported outcomes will mirror those reported by caregivers and that outcomes will be achieved without adversely affecting the therapeutic alliance with the primary care clinician.

9.2 SAMPLE SIZE DETERMINATION

Sample size is based on our ability to detect a clinically meaningful effect for our primary outcome at 6 months, following intention to treat. Because we randomize at the individual level, clinic-level cluster effects are not included in power calculations. From prior trials we assume an unadjusted intervention effect of 0.30 standard deviation units (SDUs).[51,84] Incorporating baseline QOC scores as a covariate and assuming correlation of 0.65 between baseline and 6-month QOC scores yields a covariate-adjusted effect size of 0.39 SDUs. Based on an enrolled sample of about 248 dyads and attrition of 10%, a retained sample of 222 will provide more than 80% power to detect a covariate-adjusted effect of 0.39 using a two-sided test and a type 1 error rate of 0.05. For secondary outcomes, studies in similar samples[25,57-59] suggest 50% mortality by 24 months. With 124 observations, power exceeds 80% to detect decreases of 20% or more in burdensome care (e.g. 30% vs. 10%). Assuming 25% attrition, 92 surrogate responses will be sufficient to monitor the effects of SHARE on satisfaction with end-of-life care, surrogate decision-making, and bereaved family outcomes; measures that are essential to assessment of quality of end-of-life care, as well as provide effect sizes to guide future trials of advance care planning in primary care populations.

9.3 POPULATIONS FOR ANALYSES

The populations for analyses encompass a sample of about 248 person-family dyads who meet eligibility criteria specified in Section 5 of this protocol. The table below summarizes information that will be assessed from patient and family participants.

9.3 Table of Assessments											
Construct	**Measure**	**Items**	**Range**	**Validity**	**Source**	**Outcome**	**BL**	**6M**	**12M**	**24M**	**EOL**
Outcomes @ 6 Months, Patient and Family Experience											
QOC (Primary)	Quality of EOL Communication [51,84-87]; General QOC Subscale and Global (Secondary)	7 7	0-70	α=0.79 α=0.91	P, F	F@6M	X	X	X	X	
ACP (Secondary)	Sudore 4-item ACP engagement μ [88,89]	4	0-20	α=0.84	P, F	F@6M	X	X	X	X	
	Advance Directive Completion [20]	--	Y/N	--	EMR	E@6m		X	X	X	X
Outcomes @ EOL, Quality of Care and Surrogate Decision-Making Experience											
Quality of EOL (Primary)	Satisfaction w/ Care at the EOL in Dementia[51,90]	10	10-40	α=0.90	F	F@EOL					X
Surrogate Decision-Making (Secondary)	Decisional conflict scale [91-93]	16	0-100	α=0.78	F	F@EOL					X
	Decisional regret – Brehaut [94-96]	5	0-100	α=0.81-0.92	F	F@EOL					X
	Anxiety: GAD-7 [97,98]	7	0-21	α=>0.92	F	F@EOL	X	X	X	X	X
EOL care (Secondary)	Burdensome care				EMR/F	EMR@ EOL					X
Primary Care Interactions and Communication											
Therapeutic alliance	Human Connection Scale [99-103]	16	16-64	α=0.90 original	F	-	X	X	X	X	
Shared Decision-Making	CollaboRATE μ [104-107]	3	0-100	α=0.89; 0-9/item	P, F	-	X	X	X	X	
Primary Care Interactions	Frequency/Mode of Contacts [29,108,109] (IH)	5	--	Homegrown	F, E	-	X	X	X	X	X
	Use of patient portal	--	--	--	EMR	-	X	X	X	X	X
Implementation, Fidelity/Implementation Processes, Clinic Context (Note: these items will be limited to intervention participants)											
Acceptability	Acceptability: Recruitment & retention	Consort diagram				-				X	
Fidelity	Having had 1+ ACP discussion (ACP)	5	Y/N		P, F, I	-		X	X	X	
	Fidelity to Respecting Choices [82,110]				P,F,I,A	-		X	X	X	
	Registration for Patient Portal				F, E	-	X	X	X	X	
Sustainability	Clinic continues intervention [111]	Clinic/Health system leadership					X				
Patient and Family Characteristics, Caregiving Circumstances											

Demographic Factors	Age, Gender, Education, Race/Ethnicity, CG Work [112], P/CG type of relationship, Health literacy screen [113]	14			P/F, F	-	X				
	Living arrangement	1			P/F, F	-	X	X	X	X	
Interpersonal relationships	Caregiver/receiver Mutuality (Love, shared activities & values, reciprocity) [30,114]	15	0-4	α=0.93	P, F	-	X				
	Family Apgar (family function) [115,116]	5	0-20	α=0.94	P, F	-	X				
Health	Modified Telephone Interview for Cognitive Status	12	0-50		P	-	X				
	Self-rated health, PHQ-2, GAD2 (P) [117,118]	3	Likert		P/F, F	-	X	X	X	X	
Quality of Life	Quality of Life-AD [119-121]	13	13-52	α=0.84; ICC>0.75	P/F	-	X	X	X	X	
	EuroQOL-5D, [122,123]	6			F	-	X	X	X	X	
Caregiving Circumstances	Intensity: Frequency, Type of Help [124]	8		Homegrown	F	-	X	X	X	X	
	Caregiver self-efficacy [125,126]	4	5-20	Not reported[126]	F	-	X	X	X	X	
	12-Item Zarit Burden Int + 1 global [127-129]	13	0-60	0.87	F	-	X	X	X	X	
Source: P=patient; F=family caregiver; E=EMR; I=interventionist facilitator; A=audiotapes; C=clinic Note: µ=Modified to reflect family perspective.											

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

Quantitative Strand. The objective of this study is to test the efficacy of SHARE on quality of communication (QOC) at 6 months. Analyses will be performed using SAS statistical software, with each dyad as the unit of analysis. We will use intention-to-treat analyses as the primary method of analysis; data from all participants will be analyzed as members of their assigned study group. ***Primary outcome***: We will test the effects of SHARE on improved QOC compared to usual care at 6 months. We will use hierarchical analyses of covariance on the 6-month (**B7, C4**) QOC score with treatment group as the primary independent variable and baseline QOC score as the primary covariate. Other baseline characteristics (individual- or practice-level variables) will be covariates if there is imbalance on these measures by treatment group or if they are significantly correlated with 6-month QOC after adjusting for baseline QOC score. A multilevel design will be implemented using SAS Proc MIXED with dyads (level 1) nested within clinics (level 2) that will allow us to enter and control for clinic-level covariates (size and characteristics of patient panel, staff, location). ***Secondary outcomes and supplemental analyses*:** In addition to the primary outcome, numerous comparisons will be conducted for secondary outcomes, measures of implementation, and supplemental analyses for clinically relevant subgroups and maintenance of effects at 12 and 24 months. We will examine the maintenance of intervention effects at 12 (**B8, C6**) and 24-months (**B9, C7**) by extending the multilevel model to include a longitudinal or within-person level, and trajectories of treatment impact over time will be estimated with linear longitudinal models.

For dichotomous outcomes (e.g., newly documented advance directive; burdensome care) we will construct multilevel logistic regression models using SAS Proc GLIMMIX. We will compute the effect size of primary and secondary outcomes to assess SHARE effects relative to other treatment effect estimates for advance care planning interventions reported in the published literature. The multilevel model will also be used to examine potential intervention moderation effects by examining two-way interaction effects between intervention (SHARE vs. control) and either dyad (e.g., cognitive impairment, caregiving relationship) or clinic characteristics (e.g., size, urban vs. suburban/rural) in separate models. Given the relatively modest sample size available for some secondary analyses, careful attention must be given to potential problems such as over-parameterization; thus only a limited number of covariates will be included in these models and potential interactions will be examined in separate models. We will examine rates of recruitment and retention, the timeliness and completeness of collected data,[130] and relative attrition rates (SHARE versus control protocol).[60]

Qualitative Strand. At the end of the study, we will assess the acceptability of SHARE and the mechanism of observed effects.[131,132] From audio-recordings of advance care planning facilitation sessions we will examine the duration, content, and receptivity to components of SHARE. After the completion of 24-month interviews or at any point after enrollment, we will seek invite select group of 12-20 dyads, all ACP facilitators and ACP fidelity raters to complete post-intervention in-depth interviews. These interviews will be audio-recorded, transcribed verbatim, and entered into NVivo 9 textual data analysis software. Qualitative analyses will be conducted by the study team concurrent to data collection using a framework approach[132,133] involving familiarization with content, identification of a thematic analytic framework, data indexing, charting to abstract and distill key themes, and the mapping of charts to interpret themes and context-specific meaning. We will ensure rigor and minimize bias by comprehensively documenting data collection, regular study team debriefs, triangulation of diverse stakeholder perspectives and data

sources, attention to contradictory data elements, and reporting inter-rater agreement in data indexing.[131,134] Findings from qualitative analyses will be cross-tabulated with quantitative analyses of efficacy for convergence to clarify the mechanism by which SHARE effects were observed and to identify how SHARE might be further refined and improved.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

Our sample encompasses persons with cognitive impairment, some of whom may be unable to respond to study assessments. Therefore, primary outcomes at 6 months are assessed from the perspective of the family caregiver, although all measures are fielded in parallel to patient and analyses will be conducted in parallel to examine both perspectives. Baseline enrollment visits and assessments are conducted after obtaining informed oral consent. Follow-up assessments are conducted by telephone by study staff to afford greater flexibility and privacy. Caregivers are offered the opportunity to complete web-based follow-up assessments. Composite outcomes will be operationalized as previously described in source analyses of the psychometric properties of each battery. The outcomes that we assess have been identified as defining success in advance care planning and for which strong measures now exist. [135,136] We examine two primary outcomes, as follows:

Quality of Communication. We assess family caregiver-reported quality of communication at 6 months, using the end-of-life subscale (n=7 items) of the validated instrument.[137,138] The QOC has excellent internal consistency and strong evidence of reliability and validity: we focus on the end of life subscale which is most pertinent to advance care planning in the target population. We follow the question wording stipulated by Engelberg (2006), with two modifications. First, we have revised the question stem to reflect the perspective of the family. Second, we have revised the question stem to reflect our interest in communication with the primary care team as opposed to "their doctor".

Satisfaction with Care at the End-of-Life in Dementia (SWC-EOLD) is a 10-item instrument measured on a 4-point Likert scale that ranges from 1 "strongly disagree" to 4 "strongly agree" with a summary score ranging from 10-40 in which higher values indicate higher satisfaction.[90,139,140] We field this instruments as originally described by Volicer to bereaved family caregivers of patient participants who die by 24 months.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Two categories of secondary outcomes will be assessed: measures of patient and family experiences at six-months, and bereaved family caregiver experiences, for patients who die. Each are described in turn:

Patient and Family Experiences encompasses 3 metrics relating to advance care planning as follows.

1. **Readiness to engage in advance care planning.** The Advance Care Planning Engagement Survey is a validated patient-reported questionnaire that assesses advance care planning process measures (knowledge, contemplation, self-efficacy, and readiness) on a 5-point Likert scale, and action measures (discussing and documenting advance care planning) using dichotomous (yes/no) response categories.[141,142] The Survey has high internal consistency, test-retest reliability, and discriminant validity, and is responsive to change[141-143] but persons with cognitive impairment were excluded from its development and testing. In keeping with the developmental nature of the Aim 2 pilot[60] we will examine the feasibility and psychometric properties of the an abbreviated version of the survey in the target population. The original 82-item instrument took 49 minutes to administer, on average[141] and although we planned to field the abbreviated 15-item advance care planning engagement survey, [88] early work in a similar population suggested that respondents had a difficult

time differentiating between questions, and the battery was perceived by research staff as being unnecessarily long. In this study we therefore field the 4-item engagement instrument and draw on VanScoy's work (2019) which identifies a parallel survey for surrogate decision-makers involving 3 factors that pertain to shared decision-making (7 items), contemplation (4 items), and readiness (6 items). [89] Following the principal of fielding parallel questions to patients and families, we examined the Van Scoy 6-item readiness domain for potential inclusion on the family questionnaire and selected 4 items that most closely paralleled the patient version (items 12-14, and 16 from Van Scoy). We modify question stems for several items to replace "loved one" with "your RELATIONSHIP" so the items are neutral with respect to relational quality.

2. **Documentation of advance directive completion in the electronic health record** is defined as having a durable power of attorney or a living will documented in the primary care electronic health record.[51,144,145] We do not consider the Medical Order for Life Sustaining Treatment (MOLST) in inclusion/exclusion criteria for the study or as an outcome of advance directive completion as the completion of a Maryland MOLST is mandatory in certain situations (e.g., on transfer between settings of care) and is not indicative of having had an advance care planning discussion or naming a durable power of attorney; the Maryland MOLST does not conform to the National POLST Paradigm.[146,147]

Bereaved Family Caregiver Experiences. Among patients who die by 24 months, we assess 4 secondary outcomes relating to bereaved caregiver experiences with medical decision-making and burdensome care among older adults as follows.

1. **Decisional conflict.** The Decisional Conflict Scale is a 16-item instrument scored on a 5-point Likert scale ranging from 1 to 5.[91] Aggregate scores range from 0 (no conflict) to 100 (extremely high conflict). [91-93]
2. **Decisional regret** will be assessed using a 5-item instrument that assesses the extent to which decision-makers experience regret about care. Response options are assessed using a 5-item Likert scale in which scores of 1 indicate the least regret and 5 the most regret. Scores are then reduced by 1 point and multiplied by 25 for a scale that ranges in value from 0 to 100. Prior studies have categorized scores of 0 as no regret, 1 to 25 as mild regret, and more than 25 as heightened regret.[94-96]
3. **Symptoms of anxiety.** The Generalized Anxiety Disorder 7-item (GAD-7)[97] is a validated instrument that ask about symptoms of anxiety using a two-week recall period with response categories that vary from 0 ("not at all") to 3 ("nearly every day"). Item responses are summed to construct composite scores.
4. **Burdensome care.** Burdensome care will be measured by any intensive care unit use or life prolonging care (cardiopulmonary resuscitation, mechanical ventilation, tracheostomy, dialysis, artificial nutrition, chemotherapy) within 30 days of death[101,102] using dates and services abstracted from medical records and the Chesapeake Regional Information System (CRISP), Maryland's Health Information Exchange, which includes all hospital encounters.

9.4.4 SAFETY ANALYSES

N/A

9.4.5 BASELINE DESCRIPTIVE STATISTICS

Intervention groups will be compared on baseline demographic and health characteristics using descriptive statistics.

9.4.6 PLANNED INTERIM ANALYSES

N/A: none planned.

9.4.7 SUB-GROUP ANALYSES

We will examine the consistency of intervention effects on primary and secondary outcomes for subgroups identified a priori including gender, race, cognitive impairment severity (mild vs. moderate/severe), caregiving relationship (spouse vs. non-spouse), and by primary care clinic. We will use the Modified Telephone Interview for Cognitive Status to categorize Cognitively Normal (32-50), Mild Cognitive Impairment (28-31) and Severe Cognitive Impairment (0-27) (Knopman, 2009),[148] after adjusting for age and educational attainment.

Tabulation of Individual Participant Data

See Schedule of Assessments as described in 1.3 and 9.3.

9.4.8 EXPLORATORY ANALYSES

Supplemental analyses will examine the effects of SHARE for clinically-relevant subgroups of patients by severity of cognitive impairment as measured by baseline TICS-m score or AD-8 score, maintenance of effects on communication and advance care planning processes at 12 and 24 months, and contextual factors that may facilitate or impede the dissemination and sustainability of SHARE.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms and capacity assessment forms will be fielded to potential participants as follows: A1 Clinician Consent, B4 Patient Oral Consent Script, C2 Caregiver Oral Consent Script, E1 Facilitator Written Consent

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

See section 5.5.2 for a detailed description of the consenting procedures to be followed. Institutional Review Board (IRB)-approved oral consent scripts will be read to participants over the telephone or by video conference by a trained staff member. Copies will be shared with participants to keep for their records. Study staff will explain the research study to the participant 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 any questions or concerns with a staff member trained in human subjects research prior to providing oral consent during a phone or video call. The participants will be given a copy of the consent script for their records so that they may review the study with their family or surrogates. The informed oral consent process will be documented in REDCap (including the date) before the participant undergoes any study-specific

procedures. A copy of the oral consent script will be given to the participants (via email or post) for their records (**B4, C2**). Providers and facilitators will provide informed written consent. Consent documents will be signed and stored in secure locations by study staff. Individuals will be provided with copies of these documents for their records and review (**A1, A5, E1, E8**).

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This is a Minimal Risk study of a behavioral intervention. The trial will be conducted in a population of older adults 80 years and older with cognitive impairment and the significance of our study rests in part on low completion of advance care planning in the target population despite high rates of mortality and adverse health events (e.g., hospitalization, emergency department visits). Advance care planning is already routinely offered in primary care and uptake of intervention processes will be at the discretion of patients and families. Participants will be free to terminate their participation at any time and will be reminded of this during the consenting process. Participants in the trial will be offered the intervention as a part of routine care and will be free to decline all aspects of intervention activities but will continue to be assessed according to intention to treat.

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The DSMB and representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator. The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the Johns Hopkins University Center on Aging and Health, directed by Dr. David Roth. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived.

Multiple procedures will be instituted for protecting against and minimizing risks to privacy and confidentiality: Staff will be trained regarding HIPAA and human subjects' protections regulations and procedures (**H2**). When attempting to contact participants for follow-up telephone surveys, the nature and purpose of the phone call or letter will not be revealed. We seek to maintain privacy by asking sensitive questions related to assessment of the quality of the person-family relationship, appraisal of caregiver burden, and advance care planning in written surveys and surveys administered by telephone so that persons who are present are unable to hear the questions that are being asked. Information collected from patients and caregivers will not be shared with one another. All participant information

obtained as part of this study will be labeled with a unique participant identifier that does not reveal any personally identifying information. Data will be stored in a password protected secure REDCap database. As data capture will primarily occur through on-line questionnaires and direct data entry, we minimize paper copies with identifying information. No data will be stored on portable devices such as laptops, flash drives, smart phones, or personal digital assistants. Redacted (de-identified) versions of the data collection sheets will be used for coding and analysis. No personal identifiers will be included in the analytic database. No identifying information will be linked to audio-recordings from goals of care discussions, in-depth interviews, or focus group discussions, or transcripts. All identifiers will be stored separately from study data. No identifying information will be used in any publications. 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.

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

N/A

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator:	**Jennifer Wolff, PhD** 624 N Broadway, Room 692 Baltimore, MD 21117 (410) 502-0458 Jwolff2@jhu.edu
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Co-Investigators:	

Name	Organization	Expertise
Cynthia Boyd	JHU	Geriatrics, cognitive impairment and dementia
John Cagle	University of Maryland	Social work, advance care planning
Sydney Dy	JHU	Palliative care, advance care planning, quality of care
Erin Giovannetti	MedStar	Health services, implementation science
Naaz Hussain	JHCP	Primary care, advance care planning, geriatrics
David Roth	JHU	Statistician

Data Safety Monitoring Board Members (DSMB):

Abraham Brody, PhD, RN, FAAN, New York University
Joseph Gaugler, PhD, University of Minnesota School of Public Health
Ladson Hinton, MD, UC Davis Medical Center
Charles Henderson, PhD, Cornell University

Further details regarding DSMB processes and governance are detailed in the DSMB Charter.

10.1.6 SAFETY OVERSIGHT

Although this is a minimal risk study, it involves a vulnerable population. Following the guidance of NIA, we convene an independent Data and Safety Monitoring Board (DSMB) to assure subject safety and adherence to human subject protection policies. The Principal Investigator, Dr. Wolff is responsible for ensuring participants' safety on a daily basis, for distributing adverse event reports and coordination across multiple sites, as well as DSMB communications with local site PIs in advance of regularly scheduled study team meetings. The DSMB will act in an advisory capacity to the NIA Director to monitor participant safety, evaluate the progress of the study, to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. Further details regarding DSMB processes and governance are detailed in the DSMB Charter.

10.1.7 CLINICAL MONITORING

N/A.

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

Internal quality management of study conduct, data collection, documentation and completion will proceed as follows:

Oral consent

Study staff will record documentation of the consent process upon participant orally consenting for compliance with GCP, accuracy and completeness. Contextual information such as date and staff member administering consent will be stored electronically via REDCap (See 10.1.9.1 for specifics), and feedback will be provided to ensure proper consenting procedures are followed.

Informed consent

For providers and facilitators, study staff will review documentation of the consenting process upon participant consenting for compliance with GCP, accuracy and completeness. Consent forms will be reviewed upon storage of consent forms in a locked study cabinet or upon upload into OneDrive, and electronically via REDCap when electronic consent is completed (See 10.1.9.1 for specifics), and feedback will be provided to ensure proper consenting procedures are followed.

Metrics and Electronic Data

Study outcomes are primarily participant-reported. Participant preference for mode of data collection for surveys and consent completion will dictate collection of these items either electronically via REDCap links or via paper-pencil forms. All data will be entered and monitored via the REDCap data management system. Quality control metrics for study outcomes include the extent of missingness and item nonresponse. Baseline and follow-up telephone surveys will be audio-recorded. Documented responses in REDCap will be adjudicated by a study team member who did not administer the survey and who is blinded to treatment group.

Protocol Deviations
Protocol deviations will be tracked and documented by research staff via a protocol deviation tracking form. All protocol compliance related events will be reported to the PI immediately, and to the IRB and DSMB at the time of continuing review.

Monitoring and Fidelity
After each advance care planning meeting, interventionists will document their impressions of the meeting content and progress using a Meeting Summary form. The Meeting Summary form includes details about the structure of the meeting (individuals present, location, meeting duration, etc.) as well as a checklist of key fidelity components (**E5**).

Trained research staff will review all audio-recorded meetings to monitor adherence to the advance care planning protocol. Using the fidelity audit tool (**E10**), the rater will listen to the recording, integrate information found in the field notes, and determine the rating for content and quality elements of each session. Raters will monitor for the delivery of problematic content, such as interventionists offering pure opinion, displaying impatience, or failing to respect patient or family values. The study team will convene interventionists weekly during the first six months of the study, and then monthly thereafter. Additional elements of fidelity maintenance will include monitoring completion of field notes after each advance care planning session, holding weekly supervision sessions with interventionists (led by Dr. Cagle) with the opportunity to discuss concerns noted in the field notes and review of intervention fidelity monitoring reports, quarterly booster sessions with the interventionists to maintain delivery skill and identify potential drift, and remediation and retesting in response to identified deficiencies or drift in quality of intervention delivery.

We will evaluate the extent to which patients and family caregivers avail themselves to therapeutic elements of the intervention relating to advance care planning conversations and interactions with primary care clinicians and their team about wishes for future medical care and goals of care. A monthly report will be generated to track the number, duration, and mode of all contacts with the advance care planning facilitator/interventionist, the content of advance care planning discussions, as well as registration for the patient portal by the patient and the family caregiver. The report will produce information by interventionist and by clinic site. This level of detail will permit the team to identify areas where full implementation is not being achieved and enable corrective actions. If potentially problematic content during meetings is noted, it will be flagged for review during supervision meetings. This information will be used to descriptively characterize the intervention group at each data collection time point and as it relates to outcomes. In this study we endeavor to complete at least one advance care planning discussion for each person-family dyad assigned to the intervention group; ideally within 4 weeks of the enrollment visit. See **Section 6.2.1, Interventionist Training and Tracking** for further details regarding monitoring of interventionists.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

To minimize participant burden and disruption to primary care practices, the study team will obtain oral informed consent (**B4, C2, D4**) and conduct a written or electronic baseline survey (**B6**, **C3**) prior to randomization. Contextual information about how oral consent is obtained will be stored in REDCap. Follow-up and bereavement assessments will be conducted by telephone and web survey via by study staff masked to treatment group (**C7**). Follow-up and bereaved assessments obtained via web survey will be stored in REDCap. Measures of advance directive completion, use of the patient portal, and burdensome care will be extracted from the electronic health record and the Maryland CRISP by study staff masked to treatment group. Data collection will be the responsibility of research staff under the supervision of the research program manager and primary investigator.

All data will be maintained in confidentiality, and confidentiality protections will be included in study staff research training. Data collection will employ standardized data forms. Data from screening calls, intervention contacts and participant surveys will be entered into REDCap forms that the data manager will check for completion and accuracy. The data manager will provide semi-monthly reports of missing or inappropriate entries to the PI for clarification and resolution. Standardized electronic data validation checks will be developed within the database constructs using data entry discrepancy flags, programmed query rules, and in certain cases, external rules using SAS code. Monthly reports in aggregate and by study site will be generated summarizing accrual, completeness of follow-up, and study withdrawals. Periodic reports will be generated at the request of the Project Manager or the Principal Investigator. The Data Manager will generate all these reports, working collaboratively with the Biostatistician and study staff. The study database will comply with current data security standards, provide real-time data entry validation, and provide audit trails documenting changes or corrections of the study data. Data entry or review will require logging into a secure portal with a username and password. The database is hosted by the Johns Hopkins Bloomberg School of Public Health and is HIPAA-compliant.

10.1.9.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 7 years after the last subject has completed his or her participation in the study per the Record Retention guidelines on HIPAA Privacy Rule.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly. Protocol deviations will be tracked and documented by research staff via the protocol deviation tracking form attached. All protocol compliance related events will be reported to the PI immediately, and to the IRB and DSMB at the time of continuing review.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations. National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this

trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the National Institute on Aging has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS

Not applicable.

10.3 ABBREVIATIONS AND SPECIAL TERMS

ACP	Advance care planning
AE	Adverse Event
CFR	Code of Federal Regulations
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
FFR	Federal Financial Report
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event

SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale

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