COMIRB Protocol

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD
CAMPUS BOX F-490
TELEPHONE: 303-724-1055 Fax: 303-724-0990

Project Title: ENgaging in Advance Care Planning Talks (ENACT) Group Visit Intervention for individuals with amnestic Mild Cognitive Impairment

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I. Hypotheses and Specific Aims:

There are no group visit interventions designed to meet the advance care planning (ACP) needs of individuals affected by amnestic Mild Cognitive Impairment (aMCI). Given the likelihood of diminished capacity – and ultimately incapacity – to engage in meaningful ACP discussions in later stages of Alzheimer's disease dementia, a key question is whether the strengths of an Advance Care Planning Group Visit (ACP-GV) intervention can be tailored to support patients and loved ones in addressing ACP early in the disease process. In this study, we will adapt the ACP-GV for cognitively-impaired older adults with aMCI and their study partners (i.e., reliable partner, spouse, or friend who has frequent contact with the aMCI participant). We will use a human-centered design process, rapid-cycle prototyping, and qualitative methods to appropriately adapt the ACP-GV intervention, **also called ENACT (ENgaging in Advance Care planning Talks) Group Visit**, through the following specific aims:

Aim 1: **Identify appropriate ACP-GV intervention modifications for individuals with aMCI by convening a longitudinal cohort of affect patient-study partner stakeholders.** We will convene six patient-study partner dyads (12 people) for three focus groups to suggest and review ACP-GV adaptations.

Question 1a: What evidence-based ACP decision tools should be used in the adapted ACP-GV?

Question 1b: How should facilitation or other structural design aspects of the ACP-GV be adapted?

Question 1c: What are meaningful patient and caregiver outcomes in the context of the ACP-GV (e.g., patient readiness for ACP, caregiver preparedness, ACP documentation)?

Aim 2: **Conduct a single arm feasibility study of the ACP-GV with suggested adaptations from aMCI patient-study partner dyads.** We will conduct four cycles of n-of-1 iteratively adapted ACP-GV interventions involving up to five patient-study partner dyads per group (8-10 per group; 32-40 total participants)

using qualitative evaluation and rapid-cycle prototyping to inform intervention design.

Question 2a: Is it feasible to recruit aMCI patient-study partner dyads to the adapted ACP-GV and collect participant-reported meaningful outcomes (i.e., acceptability, appropriateness, and ACP outcomes)?

Questions 2b: In the context of the ACP-GV intervention, what are mechanisms of action for person-centered approaches for ACP-related decision making among individuals with aMCI?

II. **Background and Significance**:

The 2014 Institute of Medicine "Dying in America" report emphasized that ACP is essential to ensuring that patients receive care reflecting their values, goals, and preferences.[1] ACP discussions are associated with improved patient outcomes including satisfaction, quality of life, receipt of medical care aligned with their preferences, yet most people, do not have these conversations.[1-5] The report recommended that healthcare systems should encourage clinicians to initiate ACP conversations, integrate discussions into ongoing care, and facilitate communication across the healthcare system. Specific to the care of older adults, clinicians and primary care settings face barriers that limit effective ACP.[6] A novel ACP-GV in primary care may promote ACP for older adults by overcoming patient and clinician barriers to ACP.

Group visits effectively engage patients in health care promotion and disease management, suggesting that an ACP-GV may be feasible and effective. Older adults enrolled in chronic disease management group visits showed improved health status, satisfaction with care, and decreased healthcare utilization.[7, 8] While group visits have inherent strengths that can be leveraged to improve ACP engagement, only three group visit interventions focusing on supporting ACP discussions have been published, all between 1993 and 2003.[8-10] These studies have several limitations. First, the group visits focused on completion of advance directives instead of a broader, contemporary understanding of ACP as a patient-centered process that includes multiple steps such as choosing and preparing a surrogate decision maker and values-based discussions. Secondly, these studies were conducted in a single clinical setting and have not been effectively implemented into real-world clinical practice. Additionally, none of the group visits have been designed for individuals with cognitive impairment.

To address the need for a patient-centered ACP model of care for older adults, we developed an Advance Care Planning Group Visit intervention prototype at the University of Colorado Hospital to promote ACP engagement (e.g., discussing ACP) and documentation (e.g., surrogate decision makers, advance directives) in August 2013. This intervention is an innovative approach to promoting ACP in primary care settings by combining Collaborative Learning Theory,[10] the strengths of facilitated discussions within the group medical visit setting (i.e. group dynamics to promote behavior change), and ACP patient resources (e.g.,

PREPARE website[11] and The Conversation Project Starter Kit[12]) to facilitate effective communication and patient engagement related to ACP. The initial intervention prototype involved groups of older adults (age 65+) who participated in two sessions, one month apart, facilitated by a physician and social worker. Findings from the clinical demonstration quality improvement intervention (COMIRB #13-2291) suggested that older adults were willing to engage in ACP discussions and document their wishes (described below).[13] Ideally, this intervention will be able to be adapted to diverse patient populations and clinical settings, including individuals with early cognitive impairment.

The ACP-GV intervention, now called the ENACT Group Visit intervention (COMIRB #16-1922), is an innovative model of care that is being rigorously tested in a feasibility randomized clinical trial to determine whether it improves ACP documentation and informed discussions for older adults compared to usual care. Table 1 shows the current ACP group visit intervention (see Appendix for ENACT Implementation Manual for more details).

Table 1. Current ACP Group Visit Intervention Structure

Overview of intervention	Session format (2 hours)	Time	ACP resources
Sessions: Two sessions, 1 month apart Participants: 8-12 adults; option to bring a potential surrogate Facilitators: Provider and social worker Location: Clinic conference room	Vital signs, medication review Introductions and rapport building ACP discussion Discussion of individual ACP goals	30 min 20 min 60 min 10 min	Conversation Starter Kit[12]; PREPARE videos[11]; ACP forms (i.e. Medical Power of Attorney and advance directives)

We will adapt the ENACT intervention for patients with amnestic Mild Cognitive Impairment (aMCI) and test the feasibility in this patient population (Table 2). The need for new models of ACP in clinical care, especially among individuals with early cognitive impairment, is highly relevant the growing US population affected by early Alzheimer's disease.

Table 2. Potential adaptations of an ACP Group Visit Intervention for aMCI participants

Overview of intervention	Session format	Time	ACP resources
Sessions: Up to two sessions Participants: Up to 4 dyads (8 people) Facilitators: Provider and social worker Location: Clinic conference room	Vital signs, medication review Introductions and rapport building Modified ACP discussion Supported goal-setting discussion	30 min 20 min 60 min 10 min	Go Wish cards[14] PREPARE website videos[11] Easy to read ACP forms

III. Preliminary Studies/Progress Report:

Preliminary data: The initial two-year clinical demonstration project implemented the ACP-GV prototype for community-dwelling older adults (age 65+) in primary care clinics.[13, 15] **Table 3** shows patients who participated whom we perceived to

have cognitive impairment based on how they participated in group discussion and/or electronic health record-based diagnoses of cognitive impairment or dementia. Although these participants did not have formal cognitive assessment, these findings suggest that individuals with cognitive impairment can participate in a group-based intervention. Compared to baseline, electronic health record review showed increased rates of advance directive documentation.

Table 3. Individuals with perceived cognitive impairment in ACP-GV prototype

ACP-GV (16 cohorts)	**Patients** (n = 17), n (%)		**ACP Outcomes**	
Total Patients (n = 118)	Mean age (yrs)	78	Medical Power of Attorney	
Patients with perceived	Female gender	12 (71)	Baseline	5 (29)
cognitive impairment*:	Married	10 (59)	At 12 months	10 (59)
Session A patients (n=17)	Attended ACP-GV	9 (53)	Advance Directive in EHR	
Session B patients (n=14)	with a partner		Baseline	1 (5.9)
Retention rate = 82%			At 12 months	9 (53)
*Facilitators noted "perceived cognitive impairment" based on group participation or EHR diagnoses				

Existing aMCI longitudinal research cohort: Dr. Brianne Bettcher, PhD (Co-investigator) is Principal Investigator on a prospective study of aging and cognitive decline that is successfully recruiting subjects with aMCI between the ages of 65-89 at the Rocky Mountain Alzheimer's Disease Center: COMIRB number 15-1774, Rocky Mountain Alzheimer's Disease Center at the University of Colorado School of Medicine (RMADC at UCSOM) Longitudinal Biomarker and Clinical Phenotyping Study). Specifically, in the "Longitudinal Biomarker and Clinical Phenotyping" study (**Bio-AD**; PI: Bettcher), she has comprehensively assessed 32 aMCI patients (mean age: 72 years; 52% female), with a goal of recruiting at least 75 aMCI patients over two years. All aMCI patients enrolled in Bio-AD have a study partner who attends each visit and current retention rates are over 90% for the annual in-person visits. All Bio-AD participants have consented to be contacted about future studies.

This study will leverage Dr. Bettcher's study by inviting individuals with aMCI and study partners to participate. A key strength of this approach is that baseline measures of cognition and mood, as well as informant-based measures of everyday functioning will be completed through Dr. Bettcher's ongoing Bio-AD study, and all data will be available for the proposed study. For example, all aMCI individuals have completed cognitive testing (i.e., Spanish and English Neuropsychological Assessment Scales [SENAS] and National Alzheimer's Coordinating Center [NACC] measures) and mood assessment (i.e., Geriatric Depression Scale [GDS], perceived stress scale [PSS]). Study partners have completed measures of clinical severity (i.e., Clinical Dementia Rating [CDR; global severity] and NACC functional activities questionnaire [FAQ]).

There are five intervention domains that facilitate patient engagement in ACP decision making: group characteristics, facilitation approaches, ACP resources, primary care provider (PCP) integration, and clinic resources (**Table 4**). The ENACT Group Visits already incorporates reminder calls, written materials, and short videos, which we expect will promote participation in aMCI individuals.

Table 4. Intervention	Components in ENACT Intervention	Potential Adaptations Appropriate for ENACT Memory Group Visit
Group characteristics	Age; Gender; Group size	Smaller group sizes (up to 4 dyads, 8 total participants)
Facilitation approaches	Helpful phrases; Teaching skills; Medical and ACP topic discussion	Focus on story telling; emphasis on visual/written cues with simple language; encourage study partner to serve as "scribe" for goal-setting and ACP decisions
ACP resources	Folder of materials with goal-setting worksheet; Conversation Project;[12] PREPARE website;[11] advance directive forms	Go WISH visual cards (http://codaalliance.org/go-wish/) to facilitate values discussion;[14] easy-to-read advance directives[16]
PCP integration	Documentation; PCP follow up	Facilitate PCP follow up for other aMCI needs; initiate social worker referrals
Clinic resources	Meeting space; Reminder calls; Staffing	Shorter meeting time (1.5 hour total); Sessions closer together (two weeks apart) or only one session

IV. Research Methods

A. Outcome Measure(s):

Aim 1: We have identified multiple potential outcomes for each key research questions. In line with qualitative research methods, we anticipate that new outcomes of interest will be identified during the analytic process for each of the study questions. Table 4, above, describes anticipated outcomes related to adaptations to the ENACT Group Visit intervention to meet the needs for individuals with aMCI.

Aim 2: We will evaluate feasibility of participation including recruitment and retention of patient-study partner dyads, participant acceptability, and feasibility of measuring patient- and caregiver-reported outcomes (as selected in Aim 1) for each n-of-1 ENACT Memory Group Visit intervention cycle.

Quantifiable outcome measures for the ENACT Memory Group Visit prototypes are summarized in **Table 5:**

Table 5. Pilot ENACT Memory Group Visit Outcomes	Data Sources
2.1. Feasibility	
Recruitment, randomization, retention	Patient demographics
Intervention fidelity and adaptations	Fidelity checklist and field notes
2.2 Acceptability	
Clinical relevance, acceptability, burden	Patient, Study Partner surveys
2.3 Advance care planning outcomes	
Advance directive completion	Medical record
Self-efficacy, readiness for ACP	Patient survey
ACP discussions	Patient survey

Potential Modifiers of ACP Outcomes (Secondary Analysis): To identify aMCI participant characteristics that might influence feasibility and ACP outcomes, we will also examine the relationship between baseline cognitive function or mood symptoms (Table 6) and ACP outcomes. For example, we will examine whether better memory function or better executive functions are associated with advance directive completion. Cognitive, mood, and informant data from Bio-AD will be available for secondary analyses and will be referred to as their 'baseline' cognitive data. For participants who are not also participating in Bio-AD, we will a) offer participation in Bio-AD if they agree to participate in the recruitment data base, or b) not collect these baseline measures that are outlined in Table 6 due to the additional time requirements.

Table 6. Cognitive and Mood Measures Collected in Dr. Bettcher's Bio-AD Study

	Primary Variable	Description
Cognitive		
Memory	SENAS: Memory Composite	Learning and delayed recall performance on a word list task.
Executive Functions	SENAS: Working Memory Composite	Verbal and visual working memory performance
	NACC Trail Making Test B (Total Time)	Cognitive flexibility and switching performance
Mood		
Depression	Geriatric Depression Scale (Total Score)	30-item questionnaire of current mood
Stress	Perceived Stress Scale (Total Score)	10-item questionnaire of recent perceived stress

We will collect qualitative data on implementation process measures, including interviews with patients and study partners, to understand the ACP-GV intervention from multiple perspectives.

B. Description of Population to be Enrolled:

Population and Setting:
Individuals with amnestic Mild Cognitive Impairment and study partners from UCHealth settings: Memory Disorders Clinic, Seniors Clinics.

Aim 1 will recruit 6 older adults (≥ age 60) with aMCI and 6 associated study partners.

Aim 2 will recruit 20 older adults (≥ age 60) with aMCI and 20 associated study partners.

Inclusion criteria for the diagnosis of aMCI will be based on the National Institute on Aging and Alzheimer's Association workgroup *clinical* criteria for MCI,[17] but will depart from the core clinical criteria in that we will focus specifically on individuals with early memory impairment. The rationale for this decision is that our goal is to enrich our aMCI cohort for likely AD pathology and minimize the likelihood of a non-degenerative primary etiology. Study criteria will thus include the following clinical determinations: a) cognitive complaint that reflects a decline in cognition; b) preservation of independence in functional activities; and c) not meeting criteria for a dementia. Additionally, objective neuropsychological impairment in one or more domains, including memory, will be based on either 1) inclusion as aMCI in Dr. Bettcher's study which uses comprehensive criteria by Jak;[18], or 2) 0-2 errors (out of 10 questions) on the Short Portable Mental Status Questionnaire. Finally, the individual must be able to provide consent to participate in the study by demonstrating understanding.

Exclusion criteria will be: 3 or more errors on the Short Portable Mental Status Questionnaire; major psychiatric disorder, neurological or autoimmune conditions affecting cognition; systemic medical illnesses; substance abuse or dependence (DSM-V criteria); and current depression (defined as Geriatric Depression Scale [GDS][19] score > 15).

Recruitment:

For both Aim 1 and 2, participants with aMCI and their study partners will be recruited directly from Dr. Bettcher's ongoing longitudinal study (**Bio-AD**) at the Rocky Mountain Alzheimer's Disease Center. Dr. Bettcher will directly refer aMCI patients to our study who meet the specified criteria, who have undergone their Bio-AD assessments within the past 6 months, and who consented to be invited to other research studies. Additionally, after obtaining a Health Insurance Portability and Accountability Act (HIPAA) waiver from COMIRB, a list of potential participants (patients) will be obtained from the UCHealth Seniors Clinic clinical dementia outreach program. We will ask for a list of patients who are 60 years of age or older, have their preferred language listed as English, and do not have a diagnosis of moderate or severe dementia.

Upon completion of the administrative data pulls, Seniors Clinic primary care providers will be sent a letter/e-mail informing them about the study. We will ask them to review a list of their patients and to refer patient(s) who would be appropriate for the study based on their judgment that the patient is appropriate for a group visit (i.e. does not have severe cognitive impairment or hearing loss to make a group visit very difficult). Clinicians will be asked to provide

permission for the study team to contact their patients by letter to describe the research study and offer patients the opportunity to decline to be contacted by study staff. We will obtain permission from all of the Service Chief(s) before their clinicians are contacted.

We will specifically recruit both men and women, ages 60 and older, and purposefully invite individuals from diverse self-reported racial/ethnic backgrounds to maximize potential for generalizability. Patients will be contacted by study personnel by letter (or up to 2 emails through MyHealth Connection, if that is their preferred contact method) and/or up to 3 phone call attempts.

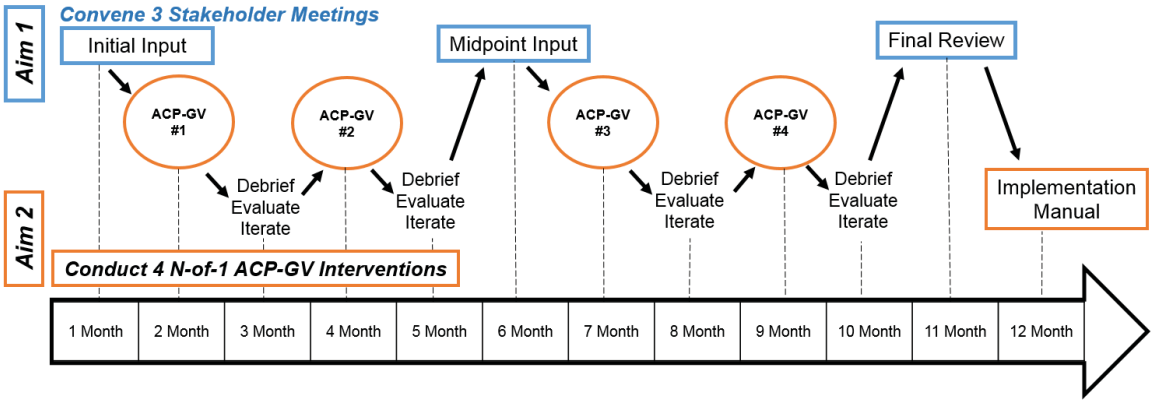
We will also recruit patients directly from clinic by posting flyers in approved areas in the clinics and utilizing University of Colorado's free web-based advertisements. Participants can contact study staff in person, by phone, or by email.

We expect that >90% of patients from the administrative data pull will be eligible based on study criteria. Prior to arranging for a study consent visit, we will determine eligibility using the pre-screening consent template. Based on our preliminary experiences, around 25% will agree to participate and provide informed consent. To reach a goal of 52 enrolled participants (including patients and study partners), we anticipate approaching up to 100 patients (and their associated study partner). We will slightly over-enroll the longitudinal focus group (recruiting 12 total participants) because we expect that some participants may not participate in all three focus groups over the one year study period. We will monitor recruitment and retention to understand reasons for declining. Additionally, we will recruit five patient-study partner dyads (10 participants) per ENACT Memory Group Visit n-of-1 prototype because we have had an at least 20% cancellation or no-show rate in our prior experience.

See supporting materials: Recruitment aMCI Correspondence Script, Flyer for Clinics, Patient/Observer Pre-screening Consent Template, Aim 1 consent form, and Aim 2 consent form. Note – UCDenver web-based advertisements will be submitted as an amendment for approval in the future.

C. Study Design and Research Methods

This study will prioritize stakeholder input to adapt the ACP-GV intervention for aMCI patient-study partner dyads, and identify mechanisms of action for ACP-related decision making. This study will provide necessary feasibility data conducting patient-centered ACP research among individuals with aMCI to inform pragmatic trials of ACP-related decision making strategies in aMCI. See **Figure** for an overview of activities.



Aim 1: Identify appropriate ACP-GV intervention modifications for individuals with aMCI by convening a longitudinal group of affected patient-study partner stakeholders.

Research Methods To design for patients and study partners, promote intervention feasibility, and actively return findings to participants, we will convene six aMCI patient-study partner dyads (12 people) for three focus group meetings over one year to suggest and review ACP-GV adaptations. In line with stakeholder engagement methods, we will solicit individual and group-level input to identify suggestions for adapting the ACP-GV intervention so that it is appropriate for individuals with aMCI, has defined intervention components (i.e., ACP decision tools, facilitation techniques, structural design aspects), and focuses on clinically meaningful ACP outcomes. Aim 1 activities will address the following questions:

Question 1a: What evidence-based ACP decision tools should be used in the adapted ACP-GV?

Question 1b: How should facilitation or other structural design aspects of the ACP-GV be adapted?

Question 1c: What are meaningful aMCI patient and caregiver outcomes in the context of the ACP-GV (e.g., patient readiness for ACP, caregiver preparedness, and ACP documentation)?

Longitudinal Focus Group Sessions: The stakeholder group will meet three times, aligned with Aim 2 activities as follows: beginning of the study, mid-point meeting after two cycles of the n-of-1 ACP-GV intervention, and final meeting after all four cycles of ACP-GV intervention rapid-prototyping process. To start, a brief description of the ACP-GV intervention and key discussion questions will be mailed prior to each meeting. At each meeting, we will review the overall purpose of achieving robust stakeholder input and introduce the ACP-related decision making topics for discussion. The group will share ideas, engage in a discussion about suggested adaptations, and personally use ACP decision tools to make recommendations for use. At all three meetings, participants will discuss person-centered support for ACP-related decision making in the context of cognitive impairment, including suggestions for evidence-based ACP decision tools, appropriate adaptations to the ACP-GV intervention, and meaningful outcomes for

individuals affected by aMCI. Potential outcomes include patient readiness for ACP, caregiver preparedness, and ACP documentation. At the end of each meeting, we will summarize the ideas for the participants, and we will incorporate input into the ACP-GV rapid-cycle prototyping process. The mid-point and final meetings will include detailed feedback and discussion of ACP-GV intervention experiences so that stakeholders can make new or updated suggestions to promote the feasibility and implementation related to ACP decision making. The final meeting will also function as a form of "member checking" to assure that we have reached consensus on the final ACP-GV adaptations, including ability for stakeholders to review and revise the online ACP-GV Implementation Manual.

Data Collection: All groups and interviews will be conducted at a convenient location for participants. A qualitative research assistant will create detailed field notes. All sessions (~1.5 hours each) will be audiotaped and transcribed. After each meeting, our multidisciplinary team will utilize iterative, inductive, and deductive analytical strategies including field notes and memos; qualitative content methods of analysis; and reflexive team analysis[20, 21] of transcriptions to identify suggested ACP decision tools (**Q1a**), appropriate facilitator or structural design adaptations (**Q1b)**, and meaningful patient and study partner/caregiver outcomes (**Q1c**). Detailed logs of analysis and interpretation, transcripts, and coding will be maintained to ensure transparency. ATLAS.ti will be used for data management.

Aim 2: Conduct a single arm feasibility study of the ACP-GV with suggested adaptations from aMCI patient-study partner dyads.

Research Methods: We will conduct four cycles of n-of-1 ACP-GV interventions involving up to five patient-study partner dyads per group (n=8-10 per cohort; n=32-40 total participants). Each cycle will use qualitative evaluations, human-centered design principles, and rapid prototyping to address the following ACP-GV intervention questions:

Question 2a: Is it feasible to recruit aMCI patient-partner dyads to the adapted ACP-GV and collect participant-reported meaningful outcomes (i.e., acceptability, appropriateness, beneficial or helpful)?

Question 2b: In the context of the ACP-GV intervention, what are mechanisms of action for ACP-related decision making in aMCI?

Intervention Development: The current ACP-GV intervention consists of up to 12 patients meeting in two 2-hour sessions, one month apart (see Appendix for ENACT Implementation Manual). In Aim 2, we will conduct four n-of-1 ACP-GV interventions with specific adaptations. To generate ideas for adaptations, we (researchers and patient-study partner stakeholders) will use rapid-prototyping methods guided by The Bootleg toolkit from the Institute of Design at Stanford.[22] This free, online, state-of-the-art resource outlines a human-centered design process and describe dozens of specific methods to support design thinking work. Each n-of-1 ACP-GV intervention will be guided by detailed suggestions from the

aMCI stakeholders, including potential changes to the Facilitator Guide, facilitation communication approaches, discussion topics, use of ACP decision tools, modified or new handouts, and other specific resources to meet the needs of individuals with aMCI. An n-of-1 ACP-GV intervention will be every two to three months, based on the evaluation, analysis, stakeholder focus groups, planning process for detailed suggestions to the next n-of-1 prototype, and recruitment of participants.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Aim 1 study procedures are focus group or interviews with up to 12 patients-study partner dyads and pose no more than minimal risk to subjects. The potential risks include breach of confidentiality and privacy. Information provided by subjects about the ENACT Memory Group Visit intervention will be beneficial to its refinement and implementation, and has very low potential for psychological distress related to discussing ACP and/or end-of-life issues.

Aim 2 study procedures include a) minimum necessary patient demographic information related to screening, recruitment and retention rates; b) participant self-reported demographics; c) advance care planning (ACP) outcomes (documentation of advance directives, documentation of medical durable power of attorney or medical proxy decision maker) at baseline and 3 months; d) ENACT Group Visit intervention evaluations after session(s); e) brief participant telephone surveys at 3 month follow up; f) group visit audio and video-recordings and study team de-briefing notes related to each ENACT Group Visit intervention. Data collection tools and request for audiovisual release have been included in this COMIRB application. The potential minimal risks include breach of confidentiality and privacy, which is not greater than the potential usual risk encountered through participating in routine medical care, and potential for psychological distress related to discussing advance care planning and/or end-of-life issues.

Plans to minimize risk related to psychological discomfort - The ENACT Group Visit intervention has been developed, and will be iteratively refined in Aim 1, to promote effective group dynamics and a supportive environment, while minimizing participants' discomfort. Research staff will be trained to address psychological distress and will follow standard procedures for referral for mental health evaluation. The mailed letter that the control group and the ENACT Group Visit intervention participants receive will include a healthcare provider contact whom they can contact for support or concerns related to ACP and/or end-of-life issues.

Plans to minimize risks related to loss of confidentiality - At the beginning of each ENACT Group Visit intervention, participants will be reminded that they are participating in a research study, participation is voluntary, and to maintain privacy and confidentiality. All written and audio/visual recordings and consent

materials will be in locked cabinets and on password-protected, encrypted computers.

See supporting materials: aMCI Focus Group Discussion Guide (n.b., this guide will be iteratively adapted and edited for best use), Aim 2 aMCI pre.post study partner survey, Aim 2 aMCI pre.post participant survey, Aim 2 Session evaluation, Aim 2 post group interview guide, Aim 2 Group Visit Field Notes, Aim 2 Session Evaluation, Aim 2 Demographic Survey

E. Potential Scientific Problems:

Potential Problem - It is possible the proposed n-of-1 ACP-GV prototypes in Aim 2 among individuals with aMCI will not be feasible, despite our prior exploratory activities. Therefore, Aim 1 is designed to capture qualitative input from aMCI individuals and study partners related to how best to facilitate ACP-related decision making and communication in real-world clinical settings.

Potential problem - If recruitment does not proceed as expected, other strategies include: 1) recruiting from the Memory Disorders Clinic, the University of Colorado Hospital, and Seniors Clinic, which have collectively evaluated more than 1,200 aMCI and ADRD patients in the past two years, and 2) partnering with the Department of Neurology's recruitment specialist to streamline recruitment.

F. Data Analysis Plan:

Aim 1: **Qualitative Analysis Plan:** Data analysis occurs longitudinally and begins at the time of the first focus group meeting as participants generate ideas and provide concrete suggestions for intervention adaptation. The words participants use, their beliefs, needs, and preferences will be described. The qualitative research analyst and I will initially code individually and then meet to discuss codes, establish inter-code reliability, and create an initial code list. The code list will be revisited and revised with each subsequent focus group meeting. Text within and between codes will be compared to develop themes. We will use observer triangulation (using the multidisciplinary team), participant triangulation (comparing patient and study partner perspectives) and member checking (eliciting feedback while returning results at the final meeting) to increase validity.

Aim 2: **Analysis Plan**: Data will be stored in a secure REDCap database.[23] For feasibility (**Q2a**), we will track recruitment and participation rates, including reasons for not participating. We will track the length of time to complete and completeness of participant-reported outcomes, as well as level of assistance provided by a research assistant (i.e. reading questions aloud; repeating questions; filling out responses). To address the question of mechanisms of action for ACP-related decision making (**Q2b**), each n-of-1 ACP-GV session will be audio

and video recorded, transcribed, observed by a research assistant who will create field notes, assessed for intervention fidelity to the planned adaptations, and formally de-briefed by the team to capture “what worked and what did not work?” Additionally, follow-up interviews will be conducted with more than half of participants after each session. The qualitative analysis will be conducted as outlined in Aim 1 to address feasibility, acceptability, and mechanisms of action for ACP-related decision making in aMCI.

Because this is a feasibility study that involves iterative development and refinement of the ENACT Memory Group Visit, a power calculation is not appropriate.

G. Summarize Knowledge to be Gained:

This research study will help define the key intervention components, facilitator skills, and patient perspectives on feasibility, for adapting the ENACT Group Visit intervention for individuals with aMCI. This study will provide rationale and justification to inform design of a future pragmatic trial of the ENACT Memory Group Visit intervention for efficacy with individuals with aMCI. Findings will enable the ENACT Group Visit intervention to be adapted to individual clinic and patient populations. This knowledge is critical to future efforts to refine the intervention, train facilitators, implement and test the intervention with high fidelity.

Appendix to this protocol:

I. ENACT Implementation Manual

H. References:

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