Official title: Engaging in Advance Care Planning Talks Group Visit Intervention

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Study Protocol

I. **Hypotheses and Specific Aims**: The main goal of the ENACT (**EN**gaging in **A**dvance **C**are planning **T**alks) Group Visit intervention is to integrate a patient-centered ACP process into primary care, ultimately helping patients to receive medical care that is aligned with their values. This study will determine: a) how the ENACT Group Visit intervention can be refined and adapted with input from patients, clinicians, staff, and healthcare system leaders to achieve high fidelity for essential components of the intervention while allowing adaptability to individual clinic settings and patients from diverse cultural backgrounds; b) meaningful ACP outcomes of the intervention to these key stakeholders; and c) feasibility, acceptability and preliminary efficacy of the ENACT Group Visit intervention compared to a comparison arm. We will pursue the following aims:

Aim 1: Develop and refine the ENACT Group Visit intervention prototype to have standardized essential components of the intervention, to be adaptable across clinic settings, and to prioritize ACP outcomes important to key primary care stakeholders (i.e., patients, clinicians, staff, and the healthcare system). We will conduct structured focus groups with stakeholders to answer key questions for intervention refinement:

Question 1a: What do patients identify as essential components of the intervention? What intervention changes do they suggest to address their ACP needs in the group visit context, including strategies to overcome common barriers to participation?

Question 1b: What do clinicians, staff, and system leaders identify as essential components of the ENACT Group Visit intervention and needed adaptations to promote implementation (e.g., clinician involvement, documentation, follow up)?

Question 1c: What do stakeholders identify as meaningful ACP outcomes for the ENACT Group Visit intervention (e.g., patient self-efficacy, readiness for ACP, clinician knowledge of patient's values, ACP documentation)?

Aim 2: Conduct a pilot randomized control trial (RCT) to test the feasibility, acceptability, and preliminary efficacy of the ENACT (ENgaging in Advance Care planning Talks) Group Visit intervention compared to a mailed advance directive (AD) arm.

Hypothesis 2a: It is feasible to recruit, randomize, and retain patients, with high intervention fidelity.

Hypothesis 2b: Patients and clinicians will rate ENACT Group Visit intervention as clinically appropriate, acceptable, and low burden.

Hypothesis 2c: Patients in the ENACT Group Visit intervention will have increased engagement in ACP outcomes, informed by aim 1 (i.e., primary outcome: documentation of surrogate decision maker; secondary outcomes: advance directive completion, readiness to complete ACP actions, ACP discussions), compared to a mailed AD arm.

II. **Background and Significance**:

Healthcare systems need interventions that promote integrated advance care planning (ACP) discussions for older adults in primary care. 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 wishes, yet most people, particularly poorer, minority, and less-educated individuals, do not have these conversations.[1-5] The report recommended that healthcare systems and payers 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, primary care settings face barriers that limit effective ACP.[6] Clinicians lack the time and training to have ACP conversations and lack clinic-based processes to facilitate ACP.(3) A novel ACP group visit in primary care may promote ACP for older adults by overcoming patient and clinician barriers to ACP.

ACP interventions in primary care settings to promote advance directive completion have a moderate overall effect size and the most effective approaches combined educational materials for patients coupled with a patient-healthcare provider interaction that was typically in a one-on-one setting.[7] However, implementation of ACP interventions into clinical care faces significant barriers such that many patients lack opportunities to discuss ACP with their healthcare provider.[8]

Group visits effectively engage patients in health care promotion and disease management, suggesting that an ACP group visit 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.[9] While group visits have inherent strengths that can be leveraged to improve ACP engagement, only 3 group visit interventions focusing on supporting ACP discussions have been published, all between 1993 and 2003.[10-12] 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.

To address the need for a disseminable patient-centered ACP model of care for older adults in primary care settings, we developed an Advance Care Planning Group Visit (ACP-GV) 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[13], 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[14] and The Conversation Project Starter Kit[15]) 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).[16] Ideally, this intervention will be able to be adapted to diverse patient populations and clinical settings. The current need is to refine and adapt the ACP-GV intervention for diverse patients and clinician stakeholders in preparation for implementation, and to test whether the ACP-GV intervention increases ACP outcomes compared to control conditions. **Moving forward, the refined intervention will be known as the ENACT (ENgaging in Advance Care planning Talks) Group Visit intervention.**

The ENACT Group Visit intervention is an innovative model of care that needs to be rigorously tested in a randomized controlled trial to determine whether it improves ACP documentation and informed discussions for older adults compared to usual care. Currently, 50% of UCHealth Denver Metro primary care patients over the age of 60 say they have an advance directive, though it is unknown what proportion of these patients have had detailed conversations with loved ones or healthcare providers (UCHealth Outpatient Advance Directives Report, Feb 2017). Additionally, the rate of advance directives available within the electronic medical record so that they are available during a medical episode is also less than 50%. To this end, the current research study will refine, adapt and test the ENACT Group Visit intervention, focusing on real-world clinical settings. Because the first ACP group visit prototype focused on engaging patients in primary care settings in a patient-centered ACP process, the proposed research project will extend this work by developingan effective healthcare model of care that can be implemented into practice. The need for new models that promote ACP is highly relevant given the approval by the Centers for Medicare and Medicaid Services of reimbursement for ACP counseling on January 1, 2016.[17]

III. Preliminary Studies:

Intervention Structure (COMIRB #13-2291) - At University of Colorado Hospital (UCH), we conducted the initial ACP-GV prototype intervention, which was named the “Conversation Group Medical Visit.” The intervention aims to engage patients in an interactive discussion of key ACP concepts and support patient-initiated ACP actions (i.e. choosing decision-maker(s), deciding on preferences during serious illness, discussing preferences with decision-makers and healthcare providers, and documenting advance directives). The group visits involve two 2-hour sessions, one month apart, facilitated by a geriatrician and a social worker or nurse. Table 1 provides an overview of the ENACT Group Visit intervention structure and facilitator considerations. The discussions include sharing experiences related to ACP, considering values related to serious illness, choosing a surrogate decision-maker(s), flexibility in decision making, and having conversations with decision-makers and healthcare providers.[18] The facilitators support an interactive discussion that promotes opportunities for patients to learn from others’ experiences.

Table 1. ENACT Group Visit Intervention

Overview of intervention	**Session format (2 hours)**	**Time**
Sessions: Two sessions, 1 month apart	Arrival, check-in, medical update	30 min
	Introductions and rapport building	20 min

Participants: 8-10 adults; option to bring a potential surrogate to the sessions Facilitators: Provider and social worker or RN Location: Clinic conference room	ACP discussion Discussion of individual ACP goals Opt.: Individual visits with clinician	60 min 10 min 10 min

Preliminary data - We implemented the prototype ACP-GV intervention for older adults (age 65+) in 3 UCHealth primary care clinics in 16 ACP-GV intervention cohorts (n=118) between Oct 2013-June 2015. This prior work and experience supports our ability to complete the current study. Compared to prior to participating, more patients reported having detailed ACP conversations with their loved ones about their wishes (19% to 42%, p<0.001). Medical record review showed increased rates of advance directives (20% to 57%, p<0.001) and documentation of a medical durable power of attorney [MDPOA] or medical proxy documentation (39% to 79%, p<0.001) (Table 2, McNemar's Test). While the intervention focuses on patient-initiated ACP goals and actions via education and support from the group, patients often chose to complete an advance directive.

Table 2. ACP-GV outcomes	Baseline, n (%)	3 month, n (%)	p-value
ACP documentation, n = 118			
Advance directive	23 (20)	67 (57)	<0.001
MDPOA or medical proxy	46 (39)	94 (79)	<0.001

Lessons learned and current gaps – From the initial quality improvement project, we identified specific intervention components of the ACP-GV intervention. These components are: patient and group characteristics, facilitator characteristics and communication skills, ACP resources, primary care provider integration, and clinic resources. Building on these preliminary insights, Aim 1 of this study will solicit key stakeholder input to identify essential and adaptable features of the ENACT Group Visit intervention and create an ENACT Group Visit intervention manual that can be used to adapt the intervention to individual clinic settings and populations. Aim 2 will conduct a pilot RCT of the ENACT Group Visit intervention

IV. Research Methods

A. Outcome Measure(s):

Aim 1: We have identified multiple potential outcomes for each key research question. In line with qualitative research methods, we anticipate that new outcomes of interest will be iteratively identified during the analytic process for each of the study questions.

Table 3. Intervention Components	**Potential Essential vs. Adaptable Features**

Patient and Group characteristics	Age; Gender; Interested in groups; Group size; Participation with spouse/partner; Patient cognitive status
Facilitator skills	Communication skills; Teaching skills; Medical and ACP knowledge
ACP resources	Conversation Starter Kit; PREPARE website; Colorado MDPOA
PCP integration	Desire for individualized follow up; Desire to share ACP with PCP
Clinic resources	Meeting space; Workflows; Staffing needs

1.1. What are essential/adaptable features of the ENACT Group Visit intervention? **Table 3**.

1.2. What are meaningful outcomes for the ENACT Group Visit intervention? **Table 4.**

Table 4. Potential Patient-centered Outcomes
ACP discussions, decisions, or documentation
ACP knowledge
Self-efficacy or patient readiness for ACP
Patient, clinician satisfaction
Knowledge of patient's wishes

Aim 2: Outcome measures for the pilot RCT of the ENACT Group Visit intervention include patient and implementation outcomes. These outcomes are guided by a Sudore et al conceptual framework of ACP engagement outcomes[14], the RE-AIM evaluation framework[19] and the Implementation Outcomes Framework[20], as described in **Table 5**. In this pilot study, we will focus on measures of Reach, Efficacy (Effectiveness) and Implementation.

Primary Outcome: Change in documentation of surrogate decision maker

Table 5. Patient-centered and implementation outcomes for Aim 2.

Aim 2 outcomes	Measure/Outcome	Data Sources	Time Point
2.1. Feasibility (Implementation outcome)			
Recruitment (related to Reach)	% individuals who participate of eligible patients by clinic-based screening	Demographics of participants and non-participants	After screening complete
Randomization	No difference in demographics across study arms (age, gender, racial composition, advance directive in EMR at baseline)	Demographics of participants	After randomization complete
Retention	% individuals who complete 6 month follow up; % who complete ENACT group visit intervention arm (both visits)	Participant database	0 to 6 months.
Intervention fidelity (ENACT group visit intervention arm only)	-Adherence to intervention manual -Quality of program delivery	Facilitator checklist; team notes	Post-intervention
2.2 Acceptability (Implementation outcome)			
Clinical appropriateness	Perceived fit or relevance	Patient survey after session A, , and patient/PCP interviews	Post-intervention (ENACT group visit intervention arm)
Acceptability	-Satisfaction with content; -Satisfaction with delivery		
Level of burden	Usefulness		

2.3 Advance Care Planning Outcomes (patient-reported effectiveness)

Primary Outcome Measure:

1. Change in documentation of the surrogate decision maker
Measure: An MDPOA form is in electronic medical chart
Time Frame: 0, 3, 6, 12 months
Secondary Outcome Measure:
2. Change in advance directive in medical record
Measure: Any advance directive is present in the medical chart
Time Frame: 0, 3, 6, 12 months
3. Change in readiness to engage in ACP
Measure: Four patient reported questions regarding readiness to engage in specific parts of the advance care planning process (i.e. signing official papers to name a medical decision maker; talking to the decision maker; talking to the doctor; signing official papers putting their wishes in writing)
Time Frame: 0, 6 months
4. Change in participant choice of a surrogate decision maker
Measure: Patient report - "Have you decided who you want your medical decision maker to be?"
Time Frame: 0, 6 months
5. Change in participant discussions of values and care preferences with surrogate decision maker
Measure: Patient report - "Have you talked with your decision maker about what kind of medical care you would want if you were very sick or near the end of life?"
Time Frame: 0, 6 months
Other Pre-specified Outcome Measures:
6. Percent of Recruitment (Reach)
Measure: Percent of individuals who participate of eligible patients, by clinic-based screening
Time Frame: From date of pre-screening until the date of participants' decision to enroll in study or not, up to 3 months
7. Percent of Retention
Measure: Percent of individuals who complete the intervention and the 6 month follow up
Time Frame: Enrollment thru 6 month follow up

B. Description of Population to be Enrolled:

Population and Setting: UCHealth patients and associated patient-invited observers, primary care providers (PCPs), clinical staff, and healthcare system leaders.

Aim 1 will enroll up to 42 individuals. Specifically, we will conduct 6 focus groups (5-6 participants each), including each of the following groups: patients (including those who participated in ACP GV prototype and those who did not), PCPs, and staff. Additionally, 4-6 healthcare system leaders will be interviewed.

Aim 2 will recruit up to 120 older adults (≥ age 50) from University of Colorado Hospital (UCH) primary care clinics and UCHealth Northern Colorado (Snow Mesa Internal Medicine). We will invite patients, observers, and patient's PCP. We will enroll 120 subjects to ensure that at least 100 subjects complete the study.

Inclusion Criteria:

Aim 1: Patients will be ages 65 or older. Clinicians will be PCPs, including physicians, advanced practice nurses, and/or physician assistants. Multidisciplinary staff members will include nurses, medical assistants, social workers, and/or schedulers who are members of primary care clinics teams. Healthcare system leaders related to UCHealth primary care practices will include medical directors, nurse managers, ambulatory service chiefs, and other administrative leaders.

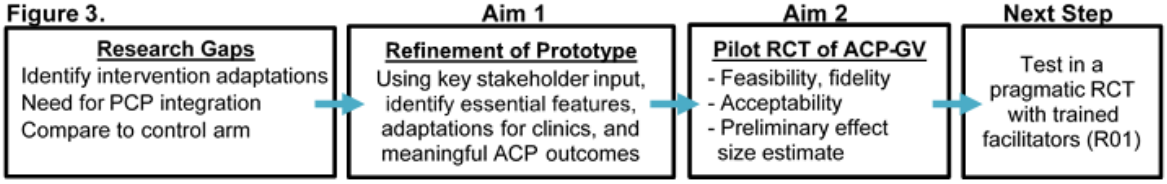
Aim 2: Patients will be ages 50 years and older, and receive primary care at UCHealth. Observers will be adults (>age 21) who are invited by patients who are randomized to the ENACT Group Visit intervention arm. PCPs can participate if at least one of their patients is enrolled in either study arm.

Exclusion Criteria:

Exclusion criteria for Aim 1 and Aim 2 patients include known prior diagnoses of dementia or deafness, as determined by ICD-10 codes, clinician identification or self-report, that limits ability to participate in group discussions. We will exclude participants who have cognitive impairment as assessed by inability to consent to the study and deficits on the validated Short Portable Mental Status Questionnaire (SPMSQ). We are assessing for memory impairment and dementia in order to exclude subjects who may have decision-making challenges. We will exclude individuals who do not have a phone, ability to travel to clinic, or someone who can assist with reading ACP materials if they are visually impaired. We will also exclude individuals planning to move in the next six months. Individuals who have a spouse or partner currently enrolled in the study will also be excluded in order to maintain independence of participants.

C. Study Design and Research Methods

This study will refine the ENACT Group Visit intervention using key stakeholder input to adapt the intervention to individual clinical settings and prioritize stakeholder outcomes for ACP (Aim 1), and conduct a pilot RCT of the ENACT Group Visit intervention (Aim 2) (Figure 3).



Aim 1: To develop and refine the ENACT Group Visit intervention prototype to have standardized essential components of the intervention, to be adaptable across clinic settings, and to prioritize ACP outcomes important to key primary care stakeholders (i.e., patients, clinicians, staff, and the healthcare system).

Recruitment:

Patients - Using existing clinical relationships (including through the ACP-GV quality improvement effort), we will recruit for focus groups (patients, clinicians, staff) and interviews (healthcare system leaders). We will also ask permission to recruit patients from the

UCHealth Patient Advisory Council. We will specifically recruit both men and women, ages 65 and older, and 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, if that is their preferred contact method) and/or up to 3 phone call attempts.

Clinicians, staff, healthcare system leaders- To gain broad perspectives on integration of the ENACT Group Visit intervention into clinical work flow, we will include clinicians from each discipline (MD, NP, PA) who had patients participate in the prototype, as well as University providers who did not have patients involved in the ACP-GV prototype. We will also invite clinical staff who were involved in the ACP-GV prototype and those who were not. Multidisciplinary staff members will include nurses, medical assistants, social workers, and/or schedulers. Healthcare system leaders will include medical directors, nurse managers, ambulatory service chiefs, and other administrative leaders. The study PI will contact clinicians, staff, and healthcare system leaders by email or in-person to recruit for the study.

All participants will be consented in person and provide written consent if they agree to participate. The consent process will take place immediately prior to the focus groups or interviews. See Table 6.

Research Methods: We will use a structured focus group process, Nominal Group Technique[22], to obtain qualitative data from patients, clinicians, and staff to answer key questions for intervention refinement. Like an in-person Delphi panel, Nominal Group Technique provides a structure to achieve prioritized recommendations from participants. By using this method, we will receive individual stakeholder and group-level input to reach consensus on how to refine the ENACT Group Visit intervention so that it has high fidelity to essential components, adaptability to clinic settings, and focuses on clinically meaningful ACP outcomes.

We will conduct focus groups with patients, clinicians, and staff (total of 6 groups). Each Nominal Group Technique Session will include 5-6 participants per group. To achieve input from health care system leaders while being respectful of their time and schedule constraints, we will conduct semi-structured 30-minute interviews in person or by phone based on the same topics with each leader (n=4-6). All groups and interviews will be conducted at a convenient location for participants.

Nominal Group Technique Sessions: Participants will be given a description of the purpose of the Nominal Group Technique session and how they will actively provide input as individuals and as a group. We will provide a description of the ENACT Group Visit intervention and its goals, the prototype intervention manual, and the key discussion questions. For each topic, individuals will first independently generate their own ideas. Then, the group will share ideas and engage in a discussion that refines the suggestion. Lastly, the group will rank ideas to provide prioritized input. The focus group/interview guides, including key discussion questions, will be updated iteratively based on emerging data and analysis.

For Topic 1, participants will review the intervention domains, including the potential essential components (Table 3), and identify areas that are unclear, poorly described, or missing. For Topic 2, participants will suggest adaptations or changes that are important to implementing the intervention into specific clinic settings or for individuals from diverse cultural backgrounds. We

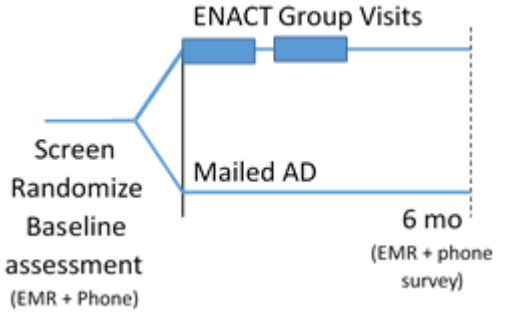
will solicit input related to the PCP's role in the intervention, clinical documentation, or subsequent follow up needs. For Topic 3, participants will describe meaningful outcomes from the ENACT Group Visit intervention. Potential outcomes include self-efficacy, readiness to engage in ACP, and values-based discussions, decisions, and ACP documentation. Clinicians and healthcare system leaders will be asked for input on "minimum clinically important differences" for each outcome. At the end of a session, we will summarize the ranked ideas for participants. We will incorporate input into subsequent sessions for iterative input. After all groups are completed, we will conduct a final combined session with patients, clinicians, staff or leaders (up to 10 total participants), as a form of member checking to assure that we have reached consensus on intervention refinements.

Aim 1 will lead to an ENACT Group Visit intervention that is refined for testing and implementation. Essential components will provide the basis for an intervention manual and fidelity checklist. Adaptable components will be included in the manual, as they outline how the intervention can be modified to a clinic setting or specific patient population.

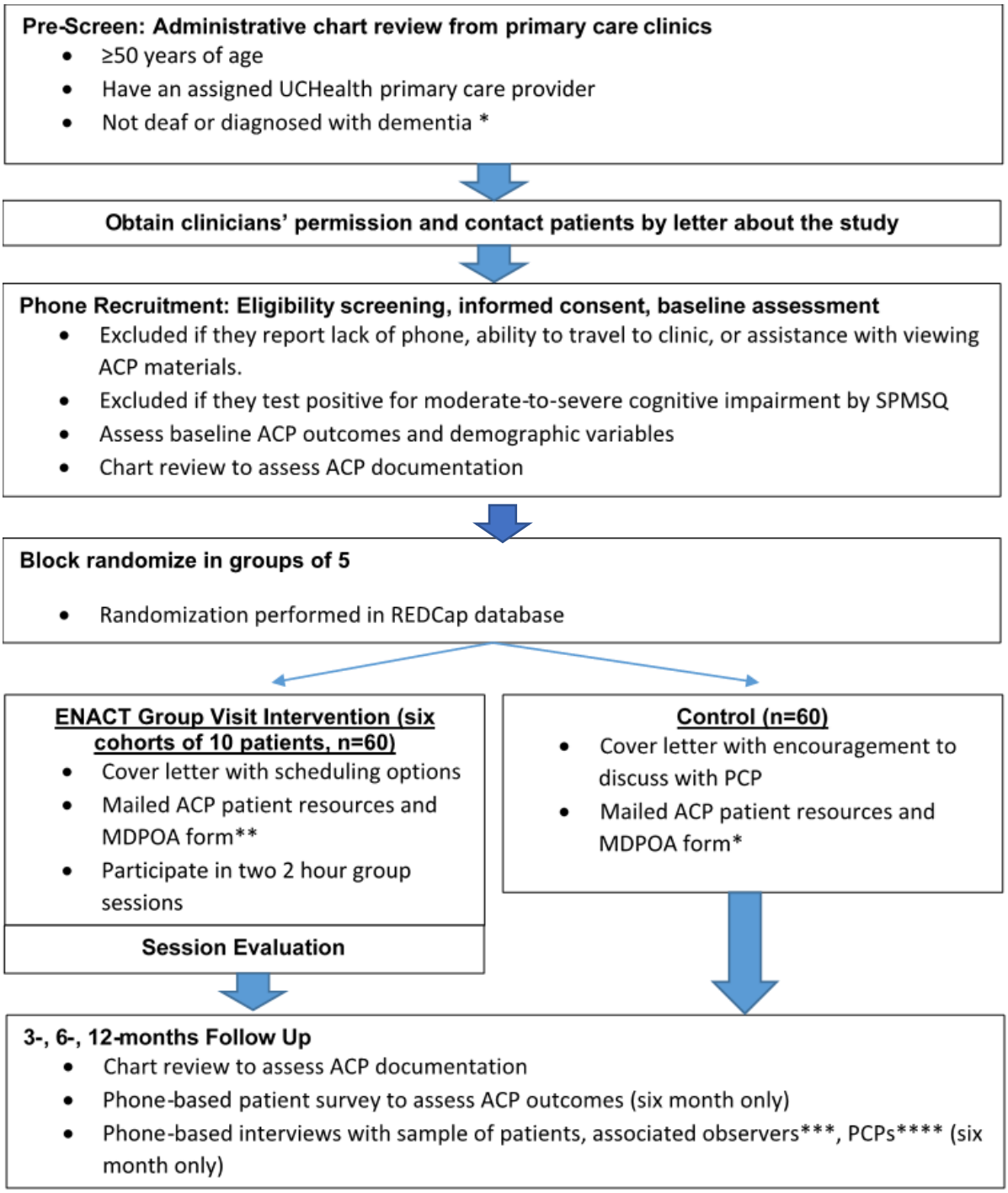
Aim 2: Conduct a pilot RCT to test the feasibility, acceptability, and preliminary efficacy of ENACT (ENgaging in Advance Care planning Talks) Group Visit intervention compared to a mailed advance directive (AD) arm.

Study design: We will conduct a pilot RCT of the ENACT Group Visit intervention vs. an AD-only control arm among older adults (≥ age 50) in a primary care clinic (**Schematic**). We will assess feasibility, patient and clinician acceptability, and preliminary efficacy on 3, 6, and 12-month ACP outcomes using validated instruments (i.e., primary outcome: MDPOA completion, secondary outcomes: advance directive completion, self-efficacy, readiness, ACP discussions [informed by Aim 1]).

Schematic for Aim 2:



ENACT (ENgaging in Advance Care planning Talks) Group Visit Intervention Study Flowchart.



*Short Portable Mental Status Questionnaire
**ACP resources include Conversation Starter Kit, PREPARE website pamphlet
*** Observers will be adults who are invited by patients who are randomized to the ENACT Group Visit intervention arm.
**** Primary care providers includes Physicians, advance practice nurses, and physician assistants.

Patient Pre-Screening – We will recruit patients from UCHealth primary care clinics, which are settings with which study team members have a treatment relationship. We will use chart review to screen potential patients for eligibility, with support from UCHealth Clinic personnel

who have access to population-health tools. We will ask for a list of patients who are 49 years of age or older, list a UCHealth clinician as their primary care provider. Although we will initially be recruiting patients 50 years of age and older, we will broaden the age range for the data extraction to age 49 because the recruitment phase may take more than 1 year and potential subjects may turn 50 during that time. This is an efficient use of clinical operations resources and avoids multiple data extractions.

Upon obtaining a list of potential patients from chart review, primary care clinicians 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 provide permission/endorsement for 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. Additionally, clinicians will be informed that if they do not respond one week after the 3rd attempt to contact them to review their patient list (including by email, phone, and/or in person), we will assume assent to contact their patients and a letter describing the study will be sent to patients on behalf of the study team. We will obtain permission from the Practice Directors before their clinicians are contacted.

In addition, we will also recruit patients directly from clinic by posting flyers in approved areas in the clinics, provider referral, and utilizing University of Colorado's free web-based advertisements, and local online community boards. 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 study consent, we will determine eligibility using the Pre-Screening template. Based on our preliminary experiences, around 25% will agree to participate and provide informed consent. To reach a goal of 120 enrolled subjects, we anticipate approaching 480 patients. We will over-enroll by 20% to reach the target study sample size of 100, allowing for individuals who chose not to complete the entire ENACT Group Visit intervention (both visits). We will monitor recruitment and retention to understand reasons for declining.

In total, this study will approach up to 660 subjects. For Aim 1, we anticipate screening up to 100 subjects (inclusive of patients, clinicians, staff, healthcare system leaders). For Aim 2, we will screen up to 480 patients, invite up to 60 observers and invite an estimated 20 primary care providers of enrolled patients. We estimate enrolling 200 subjects for study completion including 40 participants in Aim 1 and 120 patients, an estimated 20 observers (not required for study outcomes), and up to 20 primary care providers (not required for primary outcome assessment) in Aim 2.

<u>Recruitment, Screening and Consent Visit:</u>

Patients - Patients will be contacted by study personnel by letter (or up to 2 emails, if available in the EMR) and/or up to 3 phone call attempts. Patients will answer brief questions by telephone using the participant eligibility script to determine study eligibility (assessing for lack of phone, ability to travel to clinic, ability to view written ACP materials, plans to move if any, and current enrollment in the study of a spouse or partner). A waiver of HIPAA authorization has been requested for this telephone pre-screen.

Patients will then participate in a verbal consent process by phone. We will read the consent form to potential subjects, allowing time for questions and discussion, and then assess comprehension of the study using 5 true/false questions. (Supporting Materials: Consent Verification) If comprehension questions are not answered correctly, education and reassessment of comprehension are repeated. If subjects take more than two passes through the comprehension assessment, formal assessment for cognitive impairment will be completed using the Short Portal Mental Status Questionnaire. If patients are cognitively impaired they will be excluded. If they are not cognitively impaired, we will redo the teach-back one more time, after which the patient will be deemed ineligible for the study if they are unable to answer all comprehension questions correctly. Once complete comprehension is achieved, we will ask patients to provide verbal consent which will be documented. We are requesting a waiver of documentation of consent. A copy of the consent form detailing the date and time of consent will be provided to patients.

Observers - Once a patient has agreed to enroll in the study AND is randomized to the ENACT Group Visit intervention, we will ask patients if they want to include an "observer" to participate with them in the ENACT Group Visit intervention. We will obtain name and telephone contact information for the potential observer. Over the phone, we will describe the study, the dates of the patient's assigned ENACT Group Visit intervention sessions, and consent the observer for the study over the phone if they are interested in participating. We have requested a waiver of documentation of consent for this activity. Observers who agree to participate will attend the group visits and be invited to complete brief surveys and/or interviews. Observers themselves will not be registered as patients, so their insurance will not be billed and co-pays will not apply to observers. Although the personal health information is minimal (name, telephone number), we are requesting a waiver of HIPAA authorization.

Clinicians – For clinicians who have a patient enrolled in the study, study personnel will contact them by email about study participation after the 6 month patient-level outcomes have been collected to invite them to provide their perspective on the ACP intervention. If the clinician agrees, they will be consented by email and a waiver of documentation is requested. Clinicians will be asked to complete brief surveys (i.e. clinical relevance, acceptability, burden) and/or interviews to evaluate the potential impact of the study. This recruitment of PCPs is after the ENACT Group Visit intervention cohorts have been completed to limit PCP contamination, where PCP behavior may be directly influenced by reflecting on this ACP intervention study. Since the ENACT Group Visit intervention is medical care, we acknowledge that PCPs will be aware that their patients are involved in the study.

Table 6. Summary of methods of obtaining consent				
	Participant type	Method of consent	Consent type	Timing
Aim 1	Patient, clinicians, staff, healthcare system leaders	In person	Written	Immediately prior to focus group/interview
Aim 2	Patient: Pre-screen	By phone	Waiver of HIPAA authorization	After administrative selection, clinician permission, and outreach letter to patient.
	Patient: Eligibility, Consent, and Baseline Assessment		Telephone [Waiver of documentation of consent, with waiver of HIPAA authorization]	
	Observers	By phone	Telephone [Waiver of documentation of consent, with waiver of HIPAA authorization]	After a patient is randomized to the ENACT Group Visit intervention arm
	Clinicians	By email	Email [Waiver of documentation of consent]	After 6 month patient-outcomes are complete

Randomization: Patients will be randomized in blocks of 5 patients to maintain equal study arm size and gender balance. Based on pilot data, we will target scheduling 10 patients per ENACT Group Visit intervention cohort to achieve at 8-10 patients, allowing for cancellations. Patients randomized to the control arm will be offered the intervention after study completion. Offering the intervention to both arms limits dissatisfaction due to randomization to the control arm. In order to maintain independence, individuals with a spouse or partner consented to the study will be excluded. Prior to randomization, study personnel will conduct a chart review to assess ACP documentation and conduct a phone survey to assess ACP outcomes.

ENACT Group Visit Intervention Arm: We will implement the ENACT Group Visit intervention. It will consist of up to 10 patients meeting in two 2-hour group medical visit sessions, one month apart. Six cohorts will be conducted so that at least 50 patients receive the ENACT Group Visit intervention arm, allowing for patient cancellations. The intervention will be conducted based on an intervention manual that will be refined and adapted during Aim 1. Participants will receive the Colorado Medical Durable Power of Attorney (MDPOA) form and the Conversation Starter Kit by mail prior to the first session. An ENACT Group Visit intervention cohort will be started each month, with the goal of starting all cohorts within 6 months of starting Aim 2.

Intervention resources, which will be updated based on Aim 1 input, are included as an appendix to this protocol.

Control Arm: Patients randomized to the control arm will receive by mail a Colorado MDPOA, the Conversation Starter Kit, and a cover letter to encourage them to discuss ACP with their primary care provider. They will also receive the local standard of care, which includes opportunities to discuss ACP with their PCP during routine clinical one-on-one office visits. After collection of 6 month outcomes, control arm patients will be contacted and offered opportunity to be scheduled for a non-research ENACT Group Visit intervention cohort. While the ACP Group Visit is not systematically part of local standard of care, it has been previously offered at 3 UCHealth primary care clinics as part of a quality improvement initiative.

Follow up assessments:

Patient-centered and implementation measures will be collected as study outcomes as described previously in Table 5.

For Aim 2, after the 6 month patient-level outcomes have been collected, we will approach all PCPs who had a patient enrolled in the study (both ENACT Group Visit intervention or control arm) to invite them to provide PCP-level acceptability outcomes (i.e. clinical relevance, acceptability, burden) through brief interviews. We will recruit PCPs after the ENACT Group Visit intervention cohorts have been completed to limit PCP contamination, where PCP behavior may be directly influenced by reflecting on this ACP intervention study.

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

Aim 1 study procedures are focus group or interviews with up to 40 patients, clinicians, staff, or healthcare system leaders 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 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, 3, 6, and 12-months; d) ENACT Group Visit intervention evaluations after session 2; e) brief participant telephone interviews at 6 month follow up; f) group visit audio and video-recordings and study team de-briefing notes related to each ENACT Group Visit intervention; g) PCP interviews and clinic-level implementation measures. 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, in line with local standards of care for group medical visits practices at UCHealth, all participants will be asked to review and sign a standard clinical group visit consent form that outlines privacy guidelines including HIPAA and describes how standard medical visit insurance co-pays apply. The consent form from the ACP-GV prototype is provided as an example (supporting materials); in the quality improvement initiative, 100% of the participants signed this form. Although all participants will have already provided informed consent before arriving to the ENACT Group Visit intervention, this process will include a reminder that participants 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.

E. Potential Scientific Problems:

Aim 1: Potential problem - Patients and other key stakeholders may not be able to provide specific, actionable input to refine the ENACT Group Visit intervention.

Compared to a less structured focus group, Nominal Group Technique is an efficient method to achieve stakeholder consensus for intervention refinement. Overall feasibility is supported by the study team's experience using Nominal Group Technique and patient advisory boards are familiar with working with researchers, supporting the achievement of quality patient input. While stakeholders may not identify a "gold standard" ACP outcome for the intervention, the study team can suggest ACP outcomes from the literature. We desire stakeholder input on intervention outcomes to understand end-users' priorities. If stakeholder input diverges, or to improve generalizability for primary care settings that are not well represented by stakeholders, the study PI can re-convene an expert Advisory Panel from The Colorado Health Foundation prototype study to reach consensus.

Aim 2: Potential problem – Patient recruitment to a complex intervention related to advance care planning may be slow.

Our prior experience suggests that scheduled patients may cancel at the last minute. Thus, we have built in use of administrative searches to identify potentially eligible patients and will ask PCPs to endorse the study in a recruitment letter sent to patients on their behalf. We have allotted sufficient recruiting resources and multiple methods, and will over-schedule each ENACT Group Visit intervention cohort so that a goal of 10 patients per cohort is more likely.

F. Data Analysis Plan:

Aim 1: By design, initial data analysis occurs during the Nominal Group Technique sessions as participants generate ideas, refine ideas as a group, and rank ideas at the end of the session. A research assistant will create detailed field notes to outline this analysis and collect participants' written notes. All sessions (~2 hours each) will be audiotaped and transcribed. After each session, the study team will conduct a team-based, deductive content analysis[13,14] of transcripts and field notes to identify essential components for standardization, adaptable components that

can be changed to meet particular clinic setting needs, and prioritize ACP outcomes. Detailed logs of analysis and interpretation, transcripts, and coding will be maintained to ensure transparency. The focus group and interview guides will be updated iteratively based on emerging data and analysis to ensure data is rich and trustworthy, thereby reflecting key stakeholders' input.

Aim 2: To assess feasibility, we will track recruitment and participation rates, including reasons for not participating. We will compare patient demographics by study arm to assess randomization using t-test. We will assess intervention fidelity using a Fidelity Checklist that we develop in Aim 1, confirming with field notes and transcript analysis. Analyses will be intent-to-treat by assigned study arm. We will describe acceptability measures using means and standard deviations for 5-point Likert outcomes, and compare outcomes by study arm using t-test. The intervention will be a) feasible if ≥85% of intervention arm participants attend both sessions (retention rate) and b) acceptable if acceptability measure means are at least 4.0 out of 5. The proportion of MDPOA completion at 6 months will be compared by study arm to estimate effect sizes. Within arms, McNemar's test will be used to assess for pre- and post-study change in ACP outcomes at 6 months. To address potential missing, a secondary analysis using linear mixed models will be conducted using all available data collected at baseline and 6 months.

Power Calculation: While the proposed study is not powered to detect statistically significant differences for the ACP outcomes, we will compare 6 month ACP outcomes in the ENACT Group Visit intervention compared to the AD-only arm to provide preliminary estimates of effect sizes. The estimated effect sizes and stakeholder input on minimally clinically important differences in ACP outcomes will inform future trials. With a sample size of 50 patients per group and assuming a control arm advance directive completion rate of 20% based on pilot data, the detectable rate, with power=80% (alpha=0.05), in the ENACT Group Visit intervention arm will be 46% (26% increase). With power=90% (alpha=0.05), we can detect a 50% rate in the intervention arm.

G. Summarize Knowledge to be Gained:

This research study will clearly define the key intervention components, facilitator skills, and patient perspectives on feasibility, acceptability, and meaningful ACP outcomes for this novel ENACT Group Visit intervention. This study will provide rational and justification for and data to inform design of a future pragmatic trial of the ENACT Group Visit intervention in multiple clinics. 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.

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