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Advance Care Planning for Vulnerable Older Adults within an Accountable Care Organization (ACO): study protocol for the IMPACT randomized controlled trial.

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Keywords:	advance care planning, electronic health record, goals of care, end of life care, advance care directives

Title: **Advance Care Planning for Vulnerable Older Adults within an Accountable Care Organization (ACO): study protocol for the IMPACT randomized controlled trial.**

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Abstract:

Introduction: Patients with multimorbidity plus additional impairments (e.g. mobility limitations, disability, cognitive impairment, or frailty) are at the highest risk for poor healthcare outcomes. Advanced Care Planning (ACP) provides patients and their surrogates the opportunity to discuss their goals, values, and priorities for healthcare – particularly in the context of end-of-life care. ACP discussions promote more person-centered care, however currently are underutilized. There is a tremendous need for systematic, scalable approaches to individualized ACP that promote patient and family engagement. Here we describe the study protocol for a randomized effectiveness trial of a nurse navigator and informatics intervention designed to improve the utilization and quality of ACP discussions.

Methods and Analysis: This is a randomized, pragmatic, effectiveness trial; patients aged 65 years and older who have multimorbidity plus impairments in either physical function (e.g., mobility limitations or disability) or cognition, and/or frailty within an affiliated Accountable Care Organization (ACO) are eligible. The Electronic Health Record (EHR) was utilized to develop an automatic prescreening system for eligible patients and participants were randomized in a 1:1 ratio to either the Nurse Navigator led ACP pathway or usual care. Our primary outcomes are documentation of ACP discussions within the EHR along with qualitative assessments of the quality of ACP discussions. Secondary outcomes include a broad range of ACP actions (e.g. usage of ACP billing codes, choosing a surrogate decision maker, and advance directive documentation). Outcomes will be measured over 12 months of follow-up.

Ethics and Dissemination: This study has been approved by the appropriate Institutional Review Boards and is guided by input from patient and clinical advisory boards. The results of this study will be used to inform a scalable solution to ACP discussions throughout our health care system and state-wide.
Trials registration number: NCT03609658.

Keywords: advance care planning, electronic health record; goals of care, end-of-life care, advance care directives

Article Summary

Strengths and limitations of this Study
• This study addresses gaps in advance care planning (ACP) for at-risk, vulnerable older adults.
• An automatic prescreening system was designed to identify vulnerable older adults who have multimorbidity plus either impairment in function, cognition and/or frailty within the Electronic Health Record that eliminates workload on primary care providers for patient identification.
• The development of the Nurse Navigator led pathway utilizes Nurse Navigators embedded in primary care clinics to aid in priming and engaging patients prior to their provider visits, which serves as a natural extension of their role and empowers nurses to use their skills in a new capacity.
• This study developed an outpatient easy to use ACP documentation system within the Electronic Health Record with structured, discrete data elements that can be tracked which also serves as a conversational guide, to help ensure that patients' preferences are heard, documented, and hopefully followed at the end-of-life.
• This study is only occurring in eight sites within North Carolina, targeting an Accountable Care Organization population, and may have limited generalizability.

Introduction:

One-fifth of the total U.S. population will be over the age of 65 by 2050.[1,2] Inevitably, there will be a corresponding surge in those with multiple chronic conditions ("multimorbidity") along with an associated increase in health care expenditures.[1-6] Multimorbidity has been associated with (a) poor patient health outcomes, including depression, polypharmacy, socioeconomic deprivation, poorer quality of life, and decreased satisfaction with care; and (b) increased overall health system costs, primarily due to increased healthcare utilization and burdensome care. [7-16 17,18] Yet multimorbidity alone does not identify the subset of older adults at greatest need of assistance with care planning.[19,20] Evidence is emerging that persons with multimorbidity plus impairments in either function, cognition, and/or frailty are at the highest risk for poor outcomes with respect to disability and mortality, above and beyond the risk attributable to individual diseases.[2,18,20-25] Here, we label these patients as *"vulnerable older adults"*: adults 65 years and older who have multimorbidity plus impairments in either physical function (e.g., mobility disability), cognition, and/or frailty. At present, the care of vulnerable older adults is marked by fragmented health care focused on disease-based treatment, lengthy and recurrent hospital stays, and higher cost healthcare through the end of life.[26-29] Studies have shown that older adult's link preserved functional health status as a prerequisite for higher quality of life and that functional decline is a strong prognostic indicator.[25,30,31] As opposed to a disease-based approach to health care, a function and goal based approach for patients at risk for worse outcomes can help inform advance care planning in vulnerable older adults.[32]

The use of patient-level variables that are gathered during routine medical care within the EHR allows for easier patient identification for implementing pragmatic clinical trials.[33] Recruiting patients

directly from the EHR allows for prescreen eligibility prior to approaching potential participants to help facilitate patient recruitment.[34] Thus we propose to promote ACP conversations by first utilizing the Electronic Health Record (EHR) for automatic prescreening for vulnerable older adults and developing a new outpatient ACP documentation system that promotes easy documentation along with provides a central location for documented goals of care discussions with the EHR. Second, we will leverage Nurse Navigators as the first point of contact for ACP discussions to assist in patient engagement. Nurse Navigators already function well in engaging patients with care coordination, patient education, and connections to community-based resources. The proposed project is a natural extension of their role and empowers the nurses to use their skills in a new capacity. Studies have shown the use of Nurse Navigators in ACP is feasible.[35-37] To leverage these opportunities, our research will evaluate the effectiveness of enhancing patient and family engagement in ACP through a coupled informatics and nurse navigator led intervention. **Our overall hypothesis is that in a primary care setting, a coupled informatics and Nurse Navigator led ACP pathway will improve ACP documentation within the EHR as compared to usual care and will improve provider-patient communication about goals of care.**

Materials and analysis

Study Overview:

This study is a randomized, pragmatic, effectiveness trial for determining better ways to engage vulnerable older adults and their family members in ACP through a coupled informatics and Nurse Navigator led pathway versus usual care. A new ACP documentation system that allows for the use of discrete data elements was created into the EHR (Epic Systems Corporation) to allow for easy documentation and tracking of ACP discussions in an outpatient setting. A linkage to the advance directive tab within the EHR was also created along with a new visit type called advance care planning, [38,39] so that all documented goals of care discussions could be found easily with the EHR in a central location. Nurse Navigators were trained in ACP using Respecting Choices to help facilitate discussions.[40] An automated EHR screening system utilizing existing data within the EHR was created to prescreen eligible patients.

Eligible patients were randomized using a 1:1 ratio to either the nurse led ACP pathway or usual care (N=765). Permission from primary care providers was obtained to allow the study team to inform their patients about the study using an opt-out strategy. Only those who were randomized to the Nurse Navigator led pathway (intervention arm) will be approached for recruitment. Patients who agree to participate will be consented over the telephone and be screened for eligibility. Nurse Navigators will

complete a brief introductory ACP discussion with the patient over the telephone to help prime and better engage patients prior to their provider visit. The new ACP telephone documentation system will be used to document these discussions which will automatically generate a note that will be forwarded to the primary care provider. After completion of the telephone ACP discussion, patients will be mailed an ACP packet (which will include additional information about ACP and a copy of an advance directive to review) and scheduled for a dyad visit (patient and their surrogate decision maker or loved one) with their primary care provider. Primary care providers will then complete an ACP visit with their patient and their surrogate decision maker or loved one and document that discussion using the new ACP documentation system. After the visit, patients will asked to complete a patient engagement survey (see figure 1). In order to ensure transparency, ACP notes have been systematically programmed to be available to provider's in-line with the code status documentation and in the advance directive tab within the EHR.

Study Setting

The geographic region for our intervention is the Piedmont Triad area of North Carolina, which is the north-central part of the state and contains 12 counties.[41] The population is estimated at 1.69 million, making it the 30th largest metropolitan area in the U.S. In the region, 22.2% of residents are African American and 15.9% of the residents are aged 65 and older.[41] Wake Forest Baptist Health (WFBH) is the only academic medical center in this 12-county region. WFBH, having recently acquired Cornerstone Health Care, supports more than 200 clinical practices sites in 80 locations throughout central North Carolina. Since 2012, all WFBH locations utilize an Epic-based EHR, a single instance, enterprise-wide platform that supports integrated clinical, billing and ancillary applications. Recruitment for this trial occurred at eight separate primary care clinics associated with the WFBH network. Sites were selected in both urban and rural settings across five different counties in North Carolina to help with recruitment of racially and ethnically diverse and low-income populations.

Randomization Procedures

Patient were randomized using a 1:1 ratio to either the Nurse Navigator led ACP pathway or usual care (N=765). We utilized a Zelen's design[42-46]for this study, which is a pragmatic clinical trial design whereby all participants are randomized prior to informed consent, and then only patients randomized to the interventional arm will be approached for consent and subsequently enrolled in the intervention group. Note that patients that do not consent to the intervention will still be counted as part of the intervention group under an intent-to-treat paradigm, which necessitates passive ascertainment mechanisms for outcomes (i.e. administrative claims or the EHR). One appealing aspect of Zelen's design is that it facilitates estimating real-world effectiveness, as we will be able to estimate the rate at which patients

decline to consent for the study, or refuse the Nurse Navigator intervention, which then factors into overall estimates of effectiveness. In addition, others have pointed out that the Zelen's design is ethical and particularly useful within the context of trials of screening interventions, where the desire is to estimate an effect on the entire population of eligible patients. [43,44]

Eligibility criteria

Patients were eligible for this study if they were affiliated with an Accountable Care Organization, were aged 65 and older, had seen their primary care provider within the past twelve months, who had multimorbidity defined by Charlson Comorbidity Index (CCI) of three or higher,[47] plus impairments in either physical function (e.g., mobility limitation or disability), cognition, and/or frailty[48]. Their primary care provider gave permission to study staff to contact patients about the study. Patients will be excluded if they have moderate to severe hearing loss (due to use of a phone intervention), are non-English speaking (since not all navigators spoke a second language; subtleties may not have been conveyed effectively), if no phone number is available, and if they have moderate-severe dementia measured by the Short Portable Mental Status Questionnaire (SPMSQ).[49,50] Since ACP is an iterative process, participants with prior ACP experiences (e.g an advance directive found with the EHR) were excluded (Please see Table 1). Patients on hospice, in a long-term care facility, or who transferred care to a different primary care provider (PCP) will also excluded from the study.

Table 1: Inclusion and exclusion criteria of study participants

Patients	
Inclusion Criteria	1. Aged 65 or older patient within the Wake Forest Baptist Health ACO. 2. Have seen their primary care provider within the Wake Forest Baptist Health network in the past 12 months. 3. Charlson Comorbidity Index (CCI) of 3 or higher. 4. Impairments in either physical function, cognition, and/or frailty defined by: a. <u>Impairments in physical function</u> *i. ICD-10 Codes for:* 1. Falls = V00.141A, V00.312A, W01.110A, W01.198A, W03.XXXA, W05.0XXA, W05.1XXA, W05.2XXA, W06.XXXA, W07.XXXA, W08.XXXA, W10.1XXA, W10.8XXA, W17.81XA, W17.89XA, W18.11XA, W18.30XA, W19.XXXA, R29.6,z91.81 2. Muscular Deconditioning R29.898 3. Physical Deconditioning R53.81 4. Gait Abnormality R26.9, 26.89 5. Impaired physical mobility Z74.09

	6. Difficulty walking R26.2 7. Debility R53.81, R54, 8. Wheelchair bound Z99.3 *ii. Annual Wellness Visit:* 1. Positive Falls Assessment 2. Impairments in Activities of Daily Living, answer of yes needing assistance with any of the following: a. Feeding self, bathing self, dressing self, use of toilet, needing assistive device for walking or cannot walk. *b.* Impairments in Cognition: *i. ICD-10 Codes for:* 1. Impaired cognition R41.89 2. Dementia F01.50, F02.81,F03.90, G30.9, F02.80, G20, G31.83, G31.09, G30.0, G30.1, G30.8, G31.01, G31.09 3. Memory Change: R41.3, F06.8 4. MCI (mild cognitive impairment): G31.84 5. History of memory loss Z86.59 6. History of short-term memory loss Z87.898 ii. *Annual Wellness Visit*: 1. Answer of yes to either "has a diagnosis of dementia or cognitive impairment?" And/or "are there any memory concerns by the patient, others, or providers? c. Frailty: i. Electronic Frailty Index (eFI) score >0.21.[48,51,52] 5. English speaking. 6. No documented Advance Directive in the EHR.
Exclusion Criteria	1. Moderate to severe hearing loss (due to phone interventions). 2. Non-English speaking (not all navigators speak a second language; subtleties may not be conveyed effectively). 3. No phone number available for patient. 4. Moderate/Severe Cognitive Impairment assessed by validated Short Portable Mental Status Questionnaire (SPMSQ)[49,50] 5. Enrolled on Hospice, in a long-term care facility, or who transferred care to a different primary care provider (PCP)

Recruitment and retention

We obtained a Health Insurance Portability and Accountability Act waiver to access patients' names, age, race/ethnicity, gender, primary language, phone numbers, addresses, medical record numbers, diagnoses,

lab results, medication lists, payer source, as well as dates of outpatient primary care clinic appointments in the past two years, other appointments, hospitalizations and emergency room visits in the past two years, and the name of patients' outpatient primary care providers. From this data, an automated EHR screening system was created to prescreen eligible patients. This system then generated a list of patients who met our inclusion criteria. Prescreened eligible patients from our eight sites were then randomized using a 1:1 ratio to either the nurse led ACP pathway or usual care (N=765).

Nurse Navigators will be utilized to recruit eligible patients for the intervention arm. The Nurse Navigators were trained in Respecting Choices. Respecting Choices (RC) is an internationally recognized, evidence-based model of advance care planning (ACP) that creates a healthcare culture of person-centered care; care that honors an individual's goals and values for current and future healthcare.[53,54] In addition, Nurse Navigators received training in the Collaborative Institutional Training Initiative (CITI) and the protocol. They were added to the research team to recruit, consent patients and complete an initial Advance Care Planning discussion over the phone. The Nurse Navigators also will perform a Short Portable Mental Status Questionnaire (SPMSQ)[49] for patients that are flagged as having an impairment in cognition to rule out patients with moderate to severe dementia.

The Nurse Navigators will call up to three times to try and recruit a participant. Once a patient consents to participate, the nurse navigator will complete a telephone ACP visit and then schedule them to see their primary care provider for a dyad ACP in-person visit. Patients will receive a reminder call 1 week prior to their visit. Patients who either are no shows or cancelled their appointment will be called up to three times to try and reschedule their appointment. A missed appointment post card will be sent as a 4th attempt, and patients will be considered lost to follow up if after four attempts they cannot be reached. The study team will also be sending Thank You and Appointment Reminder post cards to all participants enrolled in the intervention arm. Participants who complete the ACP telephone discussion, the ACP dyad in-person visit, and the Patient Engagement survey will be given at $25 gift card as a token of appreciation for their participation.

Consent procedures

Our consent was designed to meet the understanding capabilities of our elderly population with a sixth-grade reading level. The patient and family advisory team reviewed our informed consent and revisions were made as needed. We received approval by our Institutional Review Board (IRB) to obtain verbal consent by phone for patients and a copy of this consent will be mailed to all enrolled participants in the intervention arm. In our consent we stated that the purpose of the study was to find better ways to engage patients in discussing their goals and values with their primary care provider (PCP) through ACP. We

stated that the study consists of three steps, 1) to review a few questions about ACP with the Nurse Navigator over the phone, 2) to meet with their primary care provider and their loved one to further discuss ACP, and 3) to complete a Patient Engagement survey to provide feedback about their ACP conversation with their provider.

Patient and Public Involvement

Our engagement plan calls for meaningful patient, family, and stakeholder involvement at every step of the research project—including analysis and dissemination. The research team includes three sets of stakeholders: (1) The *Patient and Family Advisory Panel*, which consist of 10 patients or family members/caregivers; (2) The *Research Support Team*, which consist of 4 nurse navigators and 8 site champions (MD, PA, or NP), one from each of the 8 community-based clinics participating in the study; and (3) The *Investigator Team*, made up of primary investigators, mentors, analysts, and research assistants. All dissemination activities will be led by a group that includes at least one member of each group. This process will ensure that all three sets of stakeholders can share learnings and successes from their own perspective, and that all three groups have buy-in and recognition for their role in the project. Our Engagement Plan is founded on the principle of meaningful participation. Engaging with key stakeholders can strengthen the understanding of real world concerns, identify knowledge gaps and barriers and improve knowledge of health inequities in a given community. Teams will meet 3 times per year and more if needed. Members of the *Patient and Family Advisory Panel* and *Research Support Team* will be compensated equally (annual honoraria of $100). Compensation demonstrates recognition of the value of everyone's time, and contributes to the attitude that all members of the research team are valued as contributors to the research project.

Table 2: Engagement Plan

Stage	Patients and Family Members	Research Support Team and Investigator Team
Barrier Assessment for ACP	Patients and Family members helped identify and prioritize the key barriers to effective ACP.	Teams helped identify and prioritize the key barriers to effective ACP from a Provider level.
Research Design	Draft Design was presented. Patients and Family members had opportunity to give feedback and reshape study design. They were involved in revising study materials and protocol to ensure feasibility for clinicians and patients.	Draft Design was presented. Teams did have the opportunity to give feedback and reshape study design. They were involved in revising study materials and protocol to ensure feasibility for clinicians and patients.
Survey Design	The investigator team presented our draft patient engagement survey. The patients and family members had final say in survey design	Teams gave suggested indicators for the survey, provide input and feedback on the draft survey.

Conducting the Study	Patients/Families will be involved in recruitment and implementation phase to increase sustain recruitment and ensure viability of study.	Teams will participate in data collection and analysis to lead unique and varied perspectives on interpretation of data.
Data Analysis and Interpretation	Patients/Families will be presented with preliminary analytic results. They will have the opportunity to suggest new analytic perspectives and to help translate results.	Teams will be presented with preliminary analytic results. They will have the opportunity to suggest new analytic perspectives and to help translate results.
Dissemination	Patients/Families identify opportunities to present and shape information about the study, to move away from traditional models of dissemination and think more creatively about how to get information into the hands of those who need it.	Participate in dissemination efforts, such as authoring manuscripts and presenting study findings to gain key stakeholders perspectives and reach new and different audiences.

Baseline Demographics

A total of 765 patients were randomized for this trial (Table 3). The mean age was 77 in both arms with the majority being 75 and older. The majority of the patients were Caucasian with 18% being African American. The patients were high health care utilizers with an average of 13 outpatient encounters over 2 years. The majority (82%) of these patients would be categorized as frail based on an electronic frailty index score>0.21,[48,51,52]which demonstrates the high vulnerability of these of patients. About 25% of patients had either physical or cognitive impairments; the most frequent comorbid conditions were pulmonary disease, diabetes, and renal disease.

Table 3: Baseline Demographic Data			
Characteristic	Nurse Navigator N=383	Usual Care N=382	P Value
Age, mean (SD), years	77.7 (7.5)	77.6 (7.4)	0.90
Age, No. (%)			0.82
65 to <75 years	151 (39.4)	157 (41.1)	
75 to <85 years	161 (42.0)	152 (39.8)	
85 years or more	71 (18.5)	73 (19.1)	
Male sex, No. (%)	155 (40.5)	152 (39.8)	0.91
Race/Ethnicity, No. (%)			0.25
White	304 (79.4)	319 (83.5)	
African-American	71 (18.5)	59 (15.4)	
Other	8 (2.1)	4 (1.0)	
No. of outpatient encounters in past 2 years, No. (%)	13 [10 to 19]	14 [10 to 19]	0.92
Had Annual Wellness Visit in past 2 years, No. (%)	281 (73.4)	265 (69.4)	0.25
Weighted Charlson Comorbidity Index, median [IQR]	4 [3 to 5]	4 [3 to 5]	0.86
Electronic Frailty Index (eFI), median [IQR]	0.25 [0.22, 0.29]	0.25 [0.22, 0.29]	0.93
eFI>0.21, No. (%)	315 (82.2)	315 (82.5)	0.90
Diagnosis code for impaired physical function, No. (%)	96 (25.1)	85 (22.3)	0.41
Diagnosis code for impaired cognitive function, No. (%)	92 (24.0)	76 (19.9)	0.20
Charlson Comorbidities, No. (%)			
Myocardial Infarction	53 (13.8)	46 (12.0)	0.53
Congestive Heart Failure	97 (25.3)	95 (24.9)	0.91
Peripheral Vascular Disease	97 (25.3)	113 (29.6)	0.21
Cerebrovascular Disease	127 (33.2)	119 (31.2)	0.61
Dementia	36 (9.4)	31 (8.1)	0.62
Pulmonary Disease	186 (48.6)	173 (45.3)	0.40
Mild Liver Disease	15 (3.9)	21 (5.5)	0.39
Diabetes without complications	159 (41.5)	157 (41.1)	0.97
Diabetes with complications	192 (50.1)	199 (52.1)	0.64
Renal Disease	212 (55.4)	204 (53.4)	0.64
Malignancy	101 (26.4)	105 (27.5)	0.79
Metastatic Disease	13 (3.4)	5 (1.3)	0.10

Measures and Data Collection

Primary and secondary outcomes

Our primary outcomes are documentation of advance care planning (ACP) discussions within the EHR and qualitative assessments of the quality of ACP discussions. For the purpose of this study, documentation of ACP discussions includes both nurse navigators and primary care provider's ACP discussion documentation within the EHR. We will measure quality of ACP discussions from two

different mechanisms. First, we will use the quality about end-of-life communication (QOC) [55] to assess quality of ACP discussion from the patient's perspective through a patient engagement survey. QOC is a 13-item instrument with an overall score and 2 subscale scores for "general communication skills" and "communication about end-of-life care."[55] scores range from 0 ("poor") to 10 ("absolutely perfect"). Higher scores determine better outcomes. Second, a scoring mechanism was created to measure quality of ACP discussions for both the telephone ACP discussion with the nurse navigator along with primary care provider's ACP visit discussion.

Secondary outcomes were chosen to measure the full process of ACP. We will measure ACP billing code usage (99497, 99498) to help assess ACP discussion rates. We will measure documentation of designated surrogate decision makers along with advance directive completion rates as another marker to assess ACP documentation rates within the EHR.

Our exploratory outcomes were chosen to measure additional ACP processes along with the impact of ACP. We will be measuring medical scope of treatment (MOST) completion rates, we will be assessing patient healthcare utilization rates (measured by the number of events: inpatient hospitalizations, emergency department (ED) visits, intensive care unit (ICU) admissions and length of stay, mechanical intubations rates, and in-hospital CPR rates measured in the EHR), along with quality of end-of-life care which will be measured by After-death bereaved family member interviews[56]. The interview provides an assessment of patient-focused, family-centered care and assesses overall quality of care received.

Analytic Plan

The primary statistical aim is the comparison of rate at which ACP discussions are documented with the EHR between the nurse-navigator and usual-care groups. We will use regression techniques for censored time-to-event outcomes to compare the time to documentation of an ACP discussion, including a frailty term (i.e. random effect, different from the clinical concept of frailty) to account for correlations between patients with the same primary care physician.[51] The advantage of a time-to-event analytic framework, versus treating documentation of an ACP discussion as a binary outcome, is that it can account for variable lengths of follow-up and account for the competing risk of death using extensions such as the popular proportional model of Fine and Gray.[57] Follow-up time for patients without documentation of an ACP discussion will be defined either as of the date of the last in-person encounter with the health system (outpatient, inpatient, or emergency department visit) or as the date of death. Analyses of secondary endpoints (completion of advanced directives, completion of Medical Orders of Scope treatment forms, utilization of ACP billing codes, and healthcare utilization) will similarly utilize a time-to-event analytic

framework. One additional statistical nuance, primarily with healthcare utilization, is the potential for recurrent events, i.e. a patient with multiple ED visits. We will use extensions for time-to-event analyses that can accommodate recurrent events, such as the Mean Cumulative Count estimator[58] and the regression approach of Prentice, Williams, and Peterson.[59]

Power and Sample Size Considerations

Our power estimates are based on standard calculations for time-to-event analyses.[60] The primary nuance for estimating statistical power is the use of Zelen's pre-randomization design, whereby only patients randomized to the nurse-navigator group will be approached for consent. This naturally attenuates any presumed effect of the intervention, as a proportion of patients who will not receive the intervention.[61] Based on a previous randomized trial of ACP strategies conducted within the Veterans Affairs system, we assumed that 44% of patients randomized to the nurse navigator group will consent to participate.[62] Furthermore, we assumed that incidence of documented ACP discussions would be 25% for patients that do not consent or those randomized to usual care. Finally, we assumed a follow-up period of 1 year, that 10% of patients would be lost to follow-up, and an alpha-level of 0.05. Based on these assumptions, our initial calculations indicated that a total sample size of 300 patients (150 per group) would provide >80% power. However, we subsequently realized a deficiency in these assumptions. Since patients will be randomized prior to consent to the intervention arm, there can be a time lag of up to ~3 months in between randomization and initial phone contact for consent. Patients could therefore become ineligible in the interim, for example, by having transitioned to a nursing home or by passing away. We therefore revised our power calculations including an expectation that 20% of patients in the nurse-navigator group would be found ineligible by the time they are contacted, and that the incidence of documented ACP discussions within this group would be at most 10%. With an increased sample size of 765, we expect that n=135 of those randomized to the intervention arm will consent to participate. We will have >80% power provided that the rate of documented ACP discussions is at least 70% for participants that consent to the nurse-navigator intervention (which implies an overall rate of ACP discussions of 38% in the nurse-navigator arm). If the rate of documented ACP discussions is 30% in patients that do not consent or are randomized to usual care, then at least 80% of participants that consent to the nurse navigator intervention will need to have an ACP discussion documented to have >80% power (implies an overall rate of ACP discussions of ~44% in patients randomized to the nurse-navigator group).

Ethics

This study was funded by the Duke Endowment and Wake Forest Center of Healthcare Innovation. This study was guided by a patient and family advisory committee comprising of patients, patient advocates, and surrogates; site champions consisting of primary care clinic providers, an internal research team, external advisory members, along with the Wake Forest Institutional Review Board (IRB). Participant confidentiality will be ensured, and anonymity guaranteed.

Trial Status

This study is registered at Clinicaltrials.gov (NCT03609658). Recruitment started on November 2, 2018 and we are currently still actively enrolling patients into the study.

Dissemination

For academic audiences, we will present our findings at scientific meetings and in peer-reviewed research journals. We will also present these results to our patient and family advisory panel. If this study is successful, we will work towards refining and disseminating our study to primary care clinics through the Wake Forest Network and other healthcare systems.

Authors' contributions: JG, NP, KC, and JW conceptualized this study. AJ and AM contributed in the clinical informatics component of this study. JG and NP drafted the manuscript. KC, AD, KC, KF, AM, CG, JM contributed in editing of the manuscript. All authors approved the final manuscript. We would also like to acknowledge our Patient and Family Advisory Panel and our Research Support Team for their assistance with study design and implementation.

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Conflicts of Interest Statement: None declared.

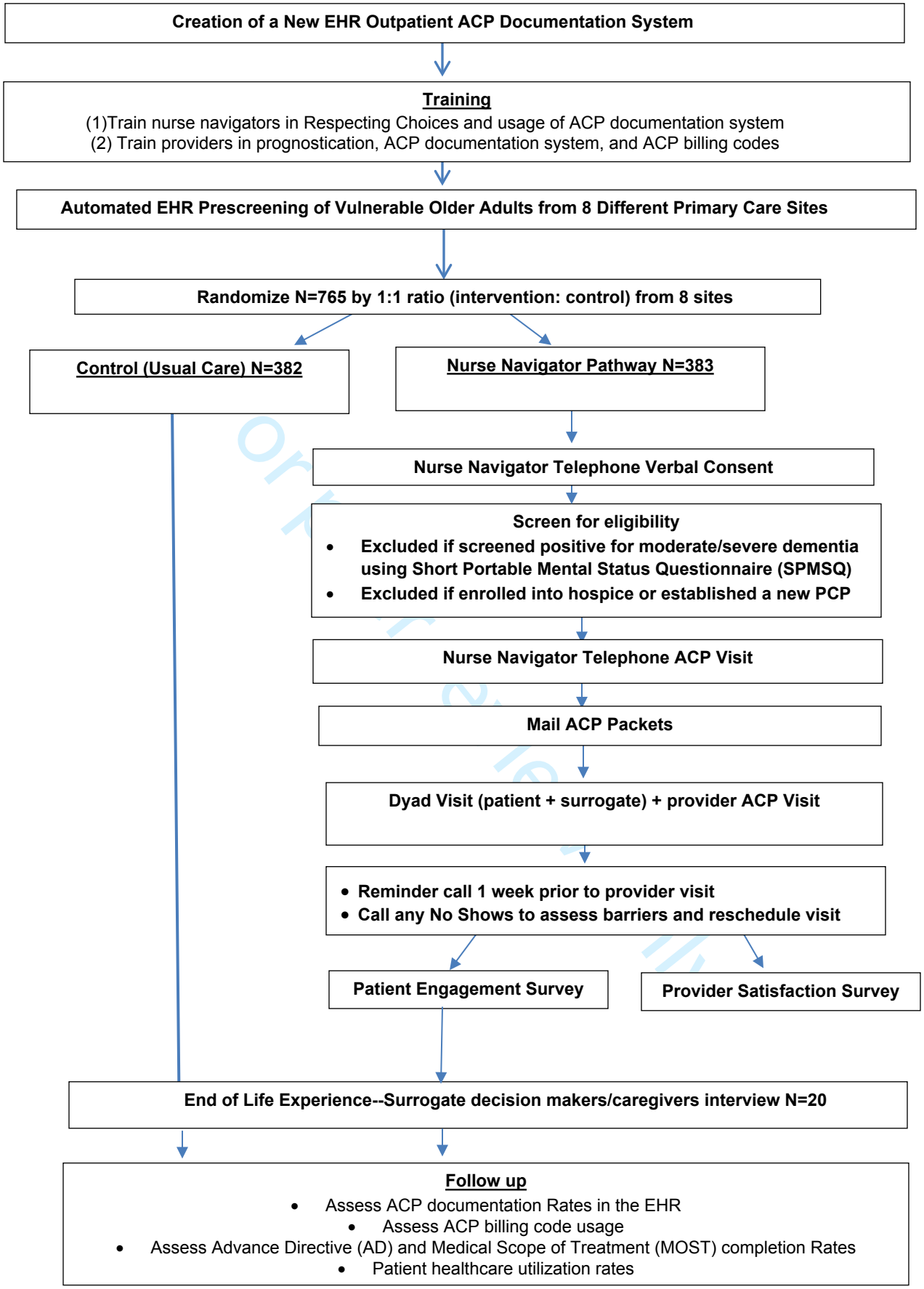

Figure 1: IMPACT STUDY Flowchart

References

1. U.S. Census Bureau. International database. Table 094. Midyear population, by age and sex. Available at http://www.census.gov/population/www/projections/natdet-D1A.htmlExternal Web Site Icon.
2. Gomez-Batiste X, Martinez-Munoz M, Blay C, et al. Prevalence and characteristics of patients with advanced chronic conditions in need of palliative care in the general population: a cross-sectional study. *Palliat Med.* 2014;28(4):302-311.
3. "Methods for Analysis of the Financing and Use of Long-Term Services and Supports," supplemental material for Rising Demand for Long-Term Services and Supports for Elderly People (June 2013), www.cbo.gov/publication/44370.
4. Schoenborn NL, Cayea D, McNabney M, Ray A, Boyd C. Prognosis Communication with Older Patients with Multimorbidity: Assessment after an Educational Intervention. *Gerontology & geriatrics education.* 2016.
5. Morrison RS. Research priorities in geriatric palliative care: an introduction to a new series. *J Palliat Med.* 2013;16(7):726-729.
6. Signorielli N: Physical disabilities, impairment and safety,mental illness, and death. In: Mass Media Images and Impact on Health: A Sourcebook. Westport, CT: Greenwood Press, 1993, pp. 37–42.
7. Fortin M, Bravo G, Hudon C, Vanasse A, Lapointe L. Prevalence of multimorbidity among adults seen in family practice. *Ann Fam Med.* 2005;3(3):223-228.
8. Fortin M, Soubhi H, Hudon C, Bayliss EA, van den Akker M. Multimorbidity's many challenges. *Bmj.* 2007;334(7602):1016-1017.
9. Marengoni A, Angleman S, Melis R, et al. Aging with multimorbidity: a systematic review of the literature. *Ageing research reviews.* 2011;10(4):430-439.
10. Smith SM, O'Dowd T. Chronic diseases: what happens when they come in multiples? *The British journal of general practice : the journal of the Royal College of General Practitioners.* 2007;57(537):268-270.
11. Taylor AW, Price K, Gill TK, et al. Multimorbidity - not just an older person's issue. Results from an Australian biomedical study. *BMC Public Health.* 2010;10:718.
12. Vogeli C, Shields AE, Lee TA, et al. Multiple chronic conditions: prevalence, health consequences, and implications for quality, care management, and costs. *J Gen Intern Med.* 2007;22 Suppl 3:391-395.
13. Menotti A, Mulder I, Nissinen A, Giampaoli S, Feskens EJ, Kromhout D. Prevalence of morbidity and multimorbidity in elderly male populations and their impact on 10-year all-cause mortality: The FINE study (Finland, Italy, Netherlands, Elderly). *J Clin Epidemiol.* 2001;54(7):680-686.
14. Fortin M, Lapointe L, Hudon C, Vanasse A, Ntetu AL, Maltais D. Multimorbidity and quality of life in primary care: a systematic review. *Health Qual Life Outcomes.* 2004;2:51.
15. Townsend A, Hunt K, Wyke S. Managing multiple morbidity in mid-life: a qualitative study of attitudes to drug use. *Bmj.* 2003;327(7419):837.
16. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *Lancet.* 2012;380(9836):37-43.
17. Smith SM, Soubhi H, Fortin M, Hudon C, O'Dowd T. Managing patients with multimorbidity: systematic review of interventions in primary care and community settings. *Bmj.* 2012;345:e5205.

18. Ryan A, Wallace E, O'Hara P, Smith SM. Multimorbidity and functional decline in community-dwelling adults: a systematic review. *Health Qual Life Outcomes.* 2015;13:168.
19. Iezzoni LI. Multiple chronic conditions and disabilities: implications for health services research and data demands. *Health Serv Res.* 2010;45(5 Pt 2):1523-1540.
20. Quinones AR, Markwardt S, Botoseneanu A. Multimorbidity Combinations and Disability in Older Adults. *J Gerontol A Biol Sci Med Sci.* 2016;71(6):823-830.
21. Kogan AC, Wilber K, Mosqueda L. Person-Centered Care for Older Adults with Chronic Conditions and Functional Impairment: A Systematic Literature Review. *Journal of the American Geriatrics Society.* 2016;64(1):e1-7.
22. Connors MH, Sachdev PS, Kochan NA, Xu J, Draper B, Brodaty H. Cognition and mortality in older people: the Sydney Memory and Ageing Study. *Age and ageing.* 2015;44(6):1049-1054.
23. Bunn F, Goodman C, Burn AM. Multimorbidity and frailty in people with dementia. *Nurs Stand.* 2015;30(1):45-50.
24. Bunn F, Burn AM, Goodman C, et al. Comorbidity and dementia: a scoping review of the literature. *BMC Med.* 2014;12:192.
25. Martin Lesende I, Mendibil Crespo LI, Castano Manzanares S, et al. Functional decline and associated factors in patients with multimorbidity at 8 months of follow-up in primary care: the functionality in pluripathological patients (FUNCIPLUR) longitudinal descriptive study. *BMJ Open.* 2018;8(7):e022377.
26. Campbell SE, Seymour DG, Primrose WR. A systematic literature review of factors affecting outcome in older medical patients admitted to hospital. *Age and ageing.* 2004;33(2):110-115.
27. Hagerty RG, Butow PN, Ellis PM, et al. Communicating with realism and hope: incurable cancer patients' views on the disclosure of prognosis. *J Clin Oncol.* 2005;23(6):1278-1288.
28. Guiding principles for the care of older adults with multimorbidity: an approach for clinicians: American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity. *Journal of the American Geriatrics Society.* 2012;60(10):E1-e25.
29. Herrin J, Harris KG, Kenward K, Hines S, Joshi MS, Frosch DL. Patient and family engagement: a survey of US hospital practices. *BMJ quality & safety.* 2016;25(3):182-189.
30. Asakawa T, Koyano W, Ando T, Shibata H. Effects of functional decline on quality of life among the Japanese elderly. *Int J Aging Hum Dev.* 2000;50(4):319-328.
31. Stineman MG, Xie D, Pan Q, et al. All-cause 1-, 5-, and 10-year mortality in elderly people according to activities of daily living stage. *Journal of the American Geriatrics Society.* 2012;60(3):485-492.
32. Kritchevsky SB, Williamson J. Putting function first. *The journal of nutrition, health & aging.* 2014;18(5):467-468.
33. Mc Cord KA, Ewald H, Ladanie A, et al. Current use and costs of electronic health records for clinical trial research: a descriptive study. *CMAJ open.* 2019;7(1):E23-e32.
34. Li G, Sajobi TT, Menon BK, et al. Registry-based randomized controlled trials- what are the advantages, challenges, and areas for future research? *J Clin Epidemiol.* 2016;80:16-24.
35. Rocque GB, Dionne-Odom JN, Sylvia Huang CH, et al. Implementation and Impact of Patient Lay Navigator-Led Advance Care Planning Conversations. *J Pain Symptom Manage.* 2017;53(4):682-692.
36. Niranjan SJ, Huang CS, Dionne-Odom JN, et al. Lay Patient Navigators' Perspectives of Barriers, Facilitators and Training Needs in Initiating Advance Care Planning Conversations With Older Patients With Cancer. *J Palliat Care.* 2018;33(2):70-78.
37. Rocque GB, Partridge EE, Pisu M, et al. The Patient Care Connect Program: Transforming Health Care Through Lay Navigation. *Journal of oncology practice / American Society of Clinical Oncology.* 2016;12(6):e633-642.

38. Turley M, Wang S, Meng D, Kanter M, Garrido T. Impact of a Care Directives Activity Tab in the Electronic Health Record on Documentation of Advance Care Planning. *Perm J.* 2016;20(2):43-48.
39. Huber MT, Highland JD, Krishnamoorthi VR, Tang JW. Utilizing the Electronic Health Record to Improve Advance Care Planning: A Systematic Review. *Am J Hosp Palliat Care.* 2018;35(3):532-541.
40. MacKenzie MA, Smith-Howell E, Bomba PA, Meghani SH. Respecting Choices and Related Models of Advance Care Planning: A Systematic Review of Published Evidence. *Am J Hosp Palliat Care.* 2018;35(6):897-907.
41. https://www.census.gov/quickfacts/fact/table/NC/PST045218 Accessed last 6/6/2019.
42. Zelen M. A new design for randomized clinical trials. *The New England journal of medicine.* 1979;300(22):1242-1245.
43. Torgerson DJ, Roland M. What is Zelen's design? *Bmj.* 1998;316(7131):606.
44. Torgerson D. The use of Zelen's design in randomised trials. *Bjog.* 2004;111(1):2.
45. House A, Knapp P. Informed consent. Trials that use Zelen's procedure should be acceptable. *Bmj.* 1997;315(7102):251.
46. Adamson J, Cockayne S, Puffer S, Torgerson DJ. Review of randomised trials using the post-randomised consent (Zelen's) design. *Contemp Clin Trials.* 2006;27(4):305-319.
47. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383.
48. Clegg A, Bates C, Young J, et al. Development and validation of an electronic frailty index using routine primary care electronic health record data. *Age and ageing.* 2016;45(3):353-360.
49. Erkinjuntti T, Sulkava R, Wikstrom J, Autio L. Short Portable Mental Status Questionnaire as a screening test for dementia and delirium among the elderly. *Journal of the American Geriatrics Society.* 1987;35(5):412-416.
50. Castanho TC, Amorim L, Zihl J, Palha JA, Sousa N, Santos NC. Telephone-based screening tools for mild cognitive impairment and dementia in aging studies: a review of validated instruments. *Front Aging Neurosci.* 2014;6:16.
51. Glidden DV, Vittinghoff E. Modelling clustered survival data from multicentre clinical trials. *Stat Med.* 2004;23(3):369-388.
52. Pajewski NM, Lenoir K, Wells BJ, Williamson JD, Callahan KE. Frailty Screening Using the Electronic Health Record within a Medicare Accountable Care Organization. *J Gerontol A Biol Sci Med Sci.* 2019.
53. Moorman SM, Carr D, Kirchhoff KT, Hammes BJ. An assessment of social diffusion in the Respecting Choices advance care planning program. *Death studies.* 2012;36(4):301-322.
54. Rietjens JA, Korfage IJ, Dunleavy L, et al. Advance care planning--a multi-centre cluster randomised clinical trial: the research protocol of the ACTION study. *BMC Cancer.* 2016;16:264.
55. Engelberg R, Downey L, Curtis JR. Psychometric characteristics of a quality of communication questionnaire assessing communication about end-of-life care. *J Palliat Med.* 2006;9(5):1086-1098.
56. Teno JM, Clarridge B, Casey V, Edgman-Levitan S, Fowler J. Validation of Toolkit After-Death Bereaved Family Member Interview. *J Pain Symptom Manage.* 2001;22(3):752-758.
57. Fine, J., & Gray, R. (1999). A Proportional Hazards Model for the Subdistribution of a Competing Risk. Journal of the American Statistical Association, 94(446), 496-509. doi:10.2307/2670170.
58. Dong H, Robison LL, Leisenring WM, Martin LJ, Armstrong GT, Yasui Y. Estimating the burden of recurrent events in the presence of competing risks: the method of mean cumulative count. *Am J Epidemiol.* 2015;181(7):532-540.

59. Prentice R, Williams B, and Peterson A. On the regression analysis of multivariate failure time data. Biometrika 1981;68:373-379. .
60. Julious SA. Sample Sizes for Clinical Trials. Chapman & Hall/CRC, Boca Raton, FL, 2010.
61. Reeves D, Howells K, Sidaway M, et al. The cohort multiple randomized controlled trial design was found to be highly susceptible to low statistical power and internal validity biases. *J Clin Epidemiol.* 2018;95:111-119.
62. Sudore RL, Boscardin J, Feuz MA, McMahan RD, Katen MT, Barnes DE. Effect of the PREPARE Website vs an Easy-to-Read Advance Directive on Advance Care Planning Documentation and Engagement Among Veterans: A Randomized Clinical Trial. *JAMA Intern Med.* 2017.

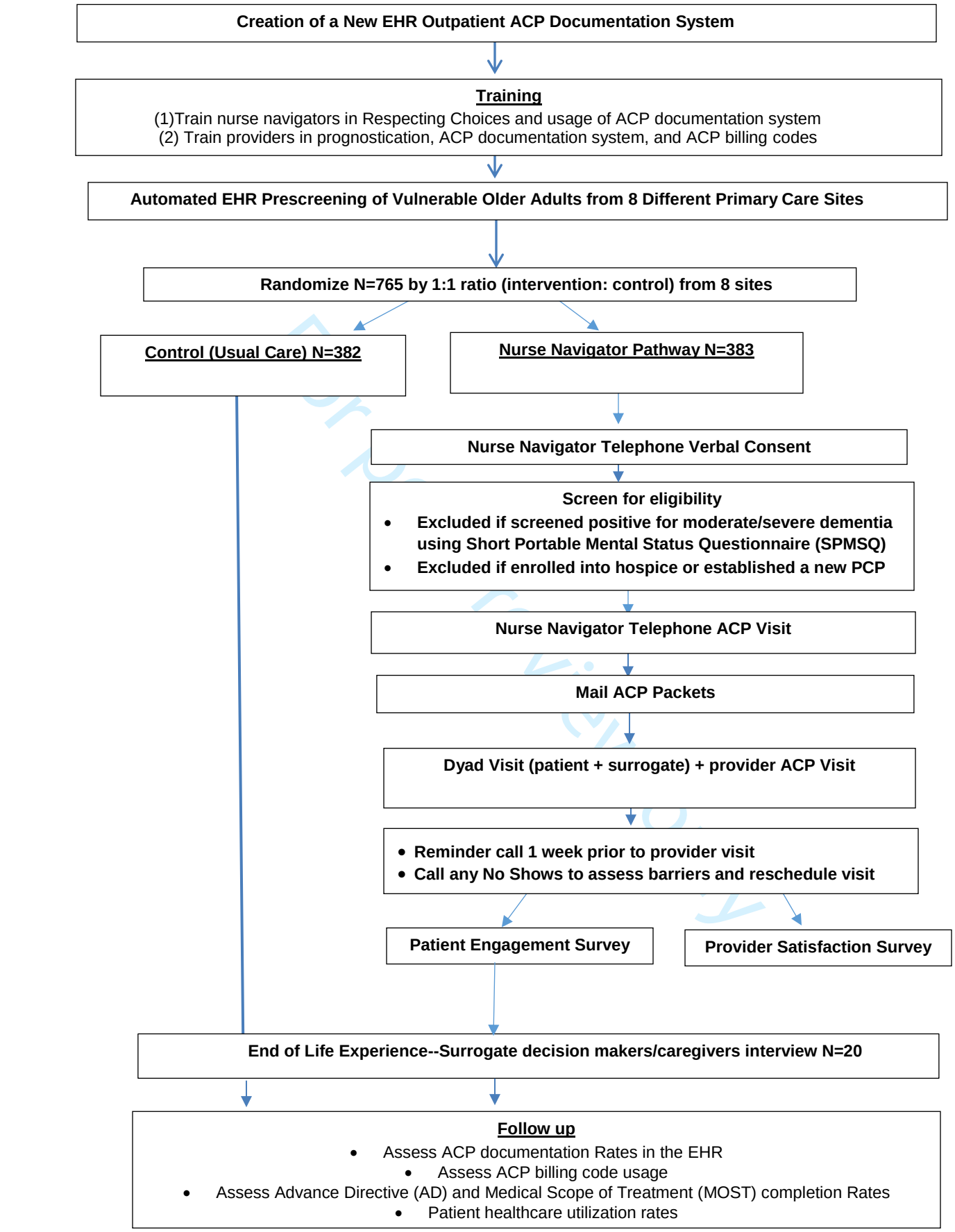

Figure 1: IMPACT STUDY Flowchart

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	10
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	10
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	10
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and	n/a

		other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	1, 2
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	1, 2
Objectives	#7	Specific objectives or hypotheses	2
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	2
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	3

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	2-3
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	3

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	3
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	3
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	3-4
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque,	n/a

		sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9

Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	5
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	n/a
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	8
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further	n/a

		details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	10
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6-7
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	1
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	10

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	10
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

Advance Care Planning for Vulnerable Older Adults within an Accountable Care Organization: study protocol for the IMPACT randomized controlled trial.

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Primary Subject Heading:	Palliative care
Secondary Subject Heading:	Geriatric medicine, Health informatics
Keywords:	advance care planning, electronic health record, goals of care, end of life care, advance care directives

Title: **Advance Care Planning for Vulnerable Older Adults within an Accountable Care Organization: study protocol for the IMPACT randomized controlled trial.**

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Word Count: 3,923

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Abstract:

Introduction: Patients with multimorbidity plus additional impairments (e.g. mobility limitations, disability, cognitive impairments, or frailty) are at the highest risk for poor healthcare outcomes. Advanced Care Planning (ACP) provides patients and their surrogates the opportunity to discuss their goals, values, and priorities for healthcare – particularly in the context of end-of-life care. ACP discussions promote more person-centered care; however, currently are underutilized. There is a tremendous need for systematic, scalable approaches to individualized ACP that promotes patient and family engagement. Here we describe the study protocol for a randomized effectiveness trial of a nurse navigator and informatics intervention designed to improve the utilization and quality of ACP discussions.

Methods and Analysis: This is a randomized, pragmatic, effectiveness trial; patients aged 65 years and older who have multimorbidity plus impairments in either physical function (e.g., mobility limitations or disability) or cognition, and/or frailty within an affiliated Accountable Care Organization (ACO) were eligible. The Electronic Health Record (EHR) was utilized to develop an automatic prescreening system for eligible patients (N=765) and participants were randomized in a 1:1 ratio to either the nurse navigator-led ACP pathway or usual care. Our primary outcomes are documentation of ACP discussions within the EHR along with qualitative assessments of the quality of ACP discussions. Secondary outcomes include a broad range of ACP actions (e.g. usage of ACP billing codes, choosing a surrogate decision maker, and advance directive documentation). Outcomes will be measured over 12 months of follow-up.

Ethics and Dissemination: This study has been approved by the appropriate Institutional Review Boards and is guided by input from patient and clinical advisory boards. The results of this study will inform a scalable solution to ACP discussions throughout our health care system and state-wide.
Trials registration number: NCT03609658.

Keywords: advance care planning, electronic health record; goals of care, end-of-life care, advance care directives

Article Summary

Strengths and limitations of this Study
• This study addresses gaps in advance care planning (ACP) for at-risk, vulnerable older adults.
• An automatic prescreening system was designed to identify vulnerable older adults who have multimorbidity plus either impairments in function, cognition and/or frailty within the Electronic Health Record that eliminates workload on primary care providers for patient identification.
• The development of the nurse navigator-led pathway utilizes nurse navigators embedded in primary care clinics to aid in priming and engaging patients prior to their provider visits, which serves as a natural extension of their role and empowers nurses to use their skills in a new capacity.
• This study developed an outpatient easy to use ACP documentation system within the Electronic Health Record with structured, discrete data elements that can be tracked, which also serves as a conversational guide to help ensure that patients' preferences are heard, documented, and hopefully followed at the end-of-life.
• This study is only occurring in eight sites within North Carolina, targeting an Accountable Care Organization population, and may have limited generalizability.

Introduction:

One-fifth of the total U.S. population will be over the age of 65 by 2050.[1,2] Inevitably, there will be a corresponding surge in those with multiple chronic conditions ("multimorbidity") along with an associated increase in health care expenditures.[1-6] Multimorbidity has been associated with (a) poor patient health outcomes, including depression, polypharmacy, socioeconomic deprivation, poorer quality of life, and decreased satisfaction with care; and (b) increased overall health system costs, primarily due to increased healthcare utilization and burdensome care. [7-16,17,18] Yet, multimorbidity alone does not identify the subset of older adults at greatest need of assistance with care planning.[19,20] Evidence is emerging that persons with multimorbidity plus impairments in either function, cognition, and/or frailty are at the highest risk for poor outcomes with respect to disability and mortality, above and beyond the risk attributable to individual diseases.[2,18,20-25] Here, we label these patients as *"vulnerable older adults"*: adults 65 years and older who have multimorbidity plus impairments in either physical function (e.g., mobility disability), cognition, and/or frailty. At present, the care of vulnerable older adults is marked by fragmented health care focused on disease-based treatments, lengthy and recurrent hospital stays, and higher healthcare cost through the end of life.[26-29] Studies have shown that older adult's preserved functional health status is a prerequisite for higher quality of life, and functional decline is a strong prognostic indicator.[25,30,31] As opposed to a disease-based approach to health care, a function- and goal-based approach for patients at risk for worse outcomes can help inform advance care planning in vulnerable older adults.[32]

The use of patient-level variables that are gathered during routine medical care within the Electronic Health Record (EHR) allows for easier patient identification for implementing pragmatic

clinical trials.[33] Recruiting patients directly from the EHR allows for prescreen eligibility prior to approaching potential participants to help facilitate patient recruitment.[34] Thus, we propose to promote advance care planning (ACP) conversations by first utilizing the EHR for automatic prescreening for vulnerable older adults, and then developing a new outpatient ACP documentation system that promotes easy documentation along with providing a central location for documented goals of care discussions within the EHR. Second, we will leverage nurse navigators as the first point of contact for ACP discussions to assist in patient engagement. Nurse navigators already function well in engaging patients with care coordination, patient education, and connections to community-based resources. The proposed project is a natural extension of their role and empowers the nurses to use their skills in a new capacity. Studies have shown that the use of nurse navigators in ACP is feasible.[35-37] To leverage these opportunities, our research will evaluate the effectiveness of enhancing patient and family engagement in ACP through a coupled informatics and nurse navigator-led intervention. **Our overall hypothesis is that in a primary care setting, a coupled informatics and nurse navigator-led ACP pathway will improve ACP documentation within the EHR as compared to usual care and will improve provider-patient communication about goals of care.**

Materials and analysis

Study Overview

This study is a randomized, pragmatic, effectiveness trial for determining better ways to engage vulnerable older adults and their family members in ACP through a coupled informatics and nurse navigator-led pathway (intervention arm) versus usual care (control arm). **(See figure 1).** A new ACP documentation system that allows for the use of discrete data elements was created into the EHR (Epic Systems Corporation) to allow for easy documentation and tracking of ACP discussions in an outpatient setting. A linkage to the advance directive tab within the EHR was also created along with a new visit type called ACP, [38,39] so that all documented goals of care discussions could be found easily in a central location within the EHR. Since nurse navigators were not involved in discussing ACP with patients prior to this study, they were trained in ACP by taking the "First Steps® ACP Facilitator Certification Course" training provided by Respecting Choices® to help facilitate discussions.[40,41] Respecting Choices® (RC) is an internationally recognized, evidence-based model of ACP that creates a healthcare culture of person-centered care: care that honors an individual's goals and values for current and future healthcare. Training consisted of one full day (8 hours) working with a trained facilitator to hone interviewing skills related to ACP, and included small group work, didactics, videos, case scenarios, role-playing, debriefing, and self-reflection. A pre- and post-test were also given. In addition, nurse navigators and providers completed a

one-hour training session to review the new ACP documentation program and observe a short role-play of a goals of care discussion. An automated EHR screening system utilizing existing data within the EHR was created to prescreen eligible patients.

Eligible patients (N=765) were randomized using a 1:1 ratio to either the nurse navigator-led ACP pathway (intervention arm) or usual care (control arm). Permission from primary care providers was obtained to allow the study team to inform their patients about the study using an opt-out strategy. Only those who were randomized to the nurse navigator-led pathway (intervention arm) will be approached for recruitment. Patients who agree to participate will be consented over the telephone and will be screened for eligibility. Nurse navigators will complete a brief introductory ACP discussion with the patient over the telephone to help prime and better engage patients prior to their provider visit. The new ACP telephone documentation system will be used to document these discussions, which will automatically generate a note that will be forwarded to the primary care provider. After completion of the telephone ACP discussion, patients will be mailed an ACP packet (which will include additional information about ACP and a copy of an advance directive to review) and scheduled for an in-person dyad visit (patient and their surrogate decision maker or loved one) with their primary care provider. All visits will be scheduled in conjugation to the patient's Medicare annual wellness visit, unless unable to occur (since can only occur once per year), and if so, will be scheduled as a separate ACP visit alone. Primary care providers will then complete an ACP visit with their patient and their surrogate decision maker or loved one and document that discussion using the new ACP documentation system. After the visit, patients will be asked to complete a patient engagement survey. In order to ensure transparency, ACP notes have been systematically programmed to be available to provider's in-line with the code status documentation and in the advance directive tab within the EHR.

<<Insert Figure 1>>

Study Setting

The geographic region for our intervention is the Piedmont Triad area of North Carolina, which is the north-central part of the state and contains 12 counties.[42] The population is estimated at 1.69 million, making it the 30th largest metropolitan area in the U.S. In the region, 22.2% of the residents are African American, and 15.9% of the residents are aged 65 and older.[42] Wake Forest Baptist Health (WFBH) is the only academic medical center in this 12-county region. WFBH, having recently acquired Cornerstone Health Care, supports more than 200 clinical practice sites in 80 locations throughout central North Carolina. Since 2012, all WFBH locations utilize an Epic-based EHR, which is a single instance, enterprise-wide platform that supports integrated clinical, billing and ancillary applications. Recruitment

for this trial occurred at eight separate primary care clinics associated with the WFBH network. Sites were selected in both urban and rural settings across five different counties in North Carolina to help with recruitment of racially and ethnically diverse and low-income populations.

Randomization Procedures

Patient were randomized (N=765) using a 1:1 ratio to either the nurse navigator-led ACP pathway (intervention arm) or usual care (control arm). We utilized a Zelen's design[43-47]for this study, which is a pragmatic clinical trial design whereby all participants are randomized prior to informed consent, and then only patients randomized to the interventional arm will be approached for consent and subsequently enrolled in the intervention group. Note that patients that do not consent to the intervention will still be counted as part of the intervention group under an intent-to-treat paradigm, which necessitates passive ascertainment mechanisms for outcomes (i.e. administrative claims or the EHR). One appealing aspect of Zelen's design is that it facilitates estimating real-world effectiveness, as we will be able to estimate the rate at which patients decline to consent for the study, or refuse the nurse navigator intervention, which then factors into overall estimates of effectiveness. In addition, others have pointed out that the Zelen's design is ethical and particularly useful within the context of trials of screening interventions, where the desire is to estimate an effect on the entire population of eligible patients. [44,45]

Eligibility criteria

Patients were eligible for this study if they were affiliated with an Accountable Care Organization, were aged 65 and older, had seen their primary care provider within the past twelve months, who had multimorbidity defined by Charlson Comorbidity Index (CCI) of three or higher,[48] plus impairments in either physical function (e.g., mobility limitation or disability), cognition, and/or frailty[49]. **(Please see Table 1).** Their primary care provider gave permission to study staff to contact patients about the study. Patients were excluded if they had moderate to severe hearing loss (due to use of a phone intervention), were non-English speakers (since not all navigators speak a second language, subtleties may have not been conveyed effectively), if no phone number was available, and if they had significant memory impairments based on a Short Portable Mental Status Questionnaire (SPMSQ) score of ≥ 5 or a score of ≥ 6 or higher for those with only a grade school education.[50,51] Since ACP is an iterative process, participants with prior ACP experiences (e.g. an advance directive found with the EHR) were excluded. Patients on hospice, in a long-term care facility, or who transferred care to a different primary care provider (PCP) were also excluded from the study.

Table 1: Inclusion and exclusion criteria of study participants

Patients	
Inclusion Criteria	1. Age 65 or older patients within the Wake Forest Baptist Health ACO. 2. Have seen their primary care provider within the Wake Forest Baptist Health network in the past 12 months. 3. Charlson Comorbidity Index (CCI) of 3 or higher. 4. Impairments in either physical function, cognition, and/or frailty defined by: a. <u>Impairments in physical function:</u> *i. ICD-10 Codes for:* 1. Falls: V00.141A, V00.312A, W01.110A, W01.198A, W03.XXXA, W05.0XXA, W05.1XXA, W05.2XXA, W06.XXXA, W07.XXXA, W08.XXXA, W10.1XXA, W10.8XXA, W17.81XA, W17.89XA, W18.11XA, W18.30XA, W19.XXXA, R29.6,z91.81 2. Muscular Deconditioning: R29.898 3. Physical Deconditioning: R53.81 4. Gait Abnormality: R26.9, 26.89 5. Impaired physical mobility: Z74.09 6. Difficulty walking: R26.2 7. Debility: R53.81, R54, 8. Wheelchair bound: Z99.3 *ii. Annual Wellness Visit:* 1. Positive Falls Assessment 2. Impairments in Activities of Daily Living, answer of "yes" for needing assistance with any of the following: a. Feeding self, bathing self, dressing self, use of toilet, needing assistive device for walking or cannot walk. *b.* <u>Impairments in Cognition:</u> *i. ICD-10 Codes for:* 1. Impaired cognition: R41.89 2. Dementia: F01.50, F02.81,F03.90, G30.9, F02.80, G20, G31.83, G31.09, G30.0, G30.1, G30.8, G31.01, G31.09 3. Memory Change: R41.3, F06.8 4. MCI (mild cognitive impairment): G31.84 5. History of memory loss: Z86.59 6. History of short-term memory loss: Z87.898 ii. *Annual Wellness Visit*: 1. Answer of "yes" to either "has a diagnosis of dementia or cognitive impairment?" and/or "are there any memory concerns by the patient, others, or providers?

	c. Frailty: i. Electronic Frailty Index (eFI) score >0.21.[49,52,53] 5. English-speaking. 6. No documented Advance Directive in the EHR.
Exclusion Criteria	1. Moderate to severe hearing loss (due to phone interventions). 2. Non-English-speaking (not all navigators speak a second language; subtleties may not be conveyed effectively). 3. No phone number available for patient. 4. Moderate/Severe Cognitive Impairment assessed by validated Short Portable Mental Status Questionnaire (SPMSQ)[50,51] 5. Enrolled on Hospice, in a long-term care facility, or who transferred care to a different primary care provider (PCP).

Table 1: Inclusion and exclusion criteria of study participants
Abbreviations: ACO, accountable care organization; EHR, electronic health record.

Recruitment and retention

We obtained a Health Insurance Portability and Accountability Act waiver to access patients' names, age, race/ethnicity, gender, primary language, phone numbers, addresses, medical record numbers, diagnoses, lab results, medication lists, payer source, as well as dates of outpatient primary care clinic appointments in the past two years, other appointments, hospitalizations and emergency room visits in the past two years, and the name of patients' outpatient primary care providers. From this data, an automated EHR screening system was created to prescreen eligible patients. This system then generated a list of patients who met our inclusion criteria. Prescreened eligible patients (N=765) from our eight sites were then randomized using a 1:1 ratio to either the nurse navigator-led ACP pathway (intervention arm) or usual care (control arm).

Nurse navigators will be utilized to recruit eligible patients for the intervention arm. The nurse navigators were trained in Respecting Choices® (RC), an internationally recognized, evidence-based model of ACP that creates a healthcare culture of person-centered care; care that honors an individual's goals and values for current and future healthcare.[40,41] In addition, nurse navigators received training in the Collaborative Institutional Training Initiative (CITI) and the protocol. They were added to the research team to recruit, consent patients and complete an initial ACP discussion over the phone. The nurse navigators also will perform a Short Portable Mental Status Questionnaire (SPMSQ)[50] for patients that are flagged as having an impairment in cognition to rule out patients with moderate to severe dementia.

The nurse navigators will call up to three times to try and recruit a participant. Once a patient consents to participate, the nurse navigator will complete a telephone ACP visit and then schedule them to see their primary care provider for a dyad ACP in-person visit. Patients will receive a reminder call one week prior to their visit. Patients who either are no shows or cancel their appointment will be called up to three times to try and reschedule their appointment. A missed appointment postcard will be sent as a 4th attempt, and patients will be considered lost to follow up if after four attempts they cannot be reached. The study team will also be sending "Thank You" and "Appointment Reminder" postcards to all participants enrolled in the intervention arm. Participants who complete the ACP telephone discussion, the ACP dyad in-person visit, and the Patient Engagement survey will be given a $25 gift card as a token of appreciation for their participation.

Consent procedures

Our consent was designed to meet the understanding capabilities of our elderly population with a sixth-grade reading level. The patient and family advisory team reviewed our informed consent and revisions were made as needed. We received approval by our Institutional Review Board (IRB) to obtain verbal consent by phone for patients and a copy of this consent will be mailed to all enrolled participants in the intervention arm. In our informed consent, we stated that the purpose of the study was to find better ways to engage patients in discussing their goals and values with their primary care provider (PCP) through ACP. We stated that the study would consist of three steps: 1) to review a few questions about ACP with the nurse navigator over the phone, 2) to meet with their primary care provider and their caregiver to further discuss ACP, and 3) to complete a Patient Engagement survey to provide feedback about their ACP conversation with their primary care provider.

Patient and Public Involvement

Our engagement plan calls for meaningful patient, family, and stakeholder involvement at every step of the research project—including analysis and dissemination. **(See Table 2).** The research team includes three sets of stakeholders: (1) The *Patient and Family Advisory Panel*, which consist of 10 patients or family members/caregivers; (2) The *Research Support Team*, which consist of four nurse navigators and eight site champions (MD, PA, or NP), one from each of the 8 community-based clinics participating in the study; and (3) The *Investigator Team*, made up of primary investigators, mentors, analysts, and research assistants. All dissemination activities will be led by a group that includes at least one member of each group. This process will ensure that all three sets of stakeholders can share learnings and successes from their own perspective, and that all three groups have buy-in and recognition for their role in the project. Our Engagement Plan is founded on the principle of meaningful participation.[54,55] Engaging with

key stakeholders can strengthen the understanding of real world concerns, identify knowledge gaps and barriers and improve knowledge of health inequities in a given community. Teams will meet 3 times per year and more if needed. Members of the *Patient and Family Advisory Panel* and *Research Support Team* will be compensated equally (annual honoraria of $100). Compensation demonstrates recognition of the value of everyone's time, and contributes to the attitude that all members of the research team are valued as contributors to the research project.

Table 2: Engagement Plan

Stage	Patients and Family Members	Research Support Team and Investigator Team
Barrier Assessment for ACP	Patients and Family members helped identify and prioritize the key barriers to effective ACP.	Teams helped identify and prioritize the key barriers to effective ACP from a provider level.
Research Design	Draft Design was presented. Patients and family members had opportunity to give feedback and reshape study design. They were involved in revising study materials and protocol to ensure feasibility for clinicians and patients.	Draft Design was presented. Teams did have the opportunity to give feedback and reshape study design. They were involved in revising study materials and protocol to ensure feasibility for clinicians and patients.
Survey Design	The investigator team presented our draft patient engagement survey. The patients and family members had final say in survey design.	Teams gave suggested indicators for the survey, provide input and feedback on the draft survey.
Conducting the Study	Patients/families will be involved in recruitment and implementation phase to increase sustained recruitment and ensure study viability.	Teams will participate in data collection and analysis to lead unique and varied perspectives on interpretation of data.
Data Analysis and Interpretation	Patients/families will be presented with preliminary analytic results. They will have the opportunity to suggest new analytic perspectives and to help translate results.	Teams will be presented with preliminary analytic results. They will have the opportunity to suggest new analytic perspectives and to help translate results.
Dissemination	Patients/families identify opportunities to present and shape information about the study, to move away from traditional models of dissemination and to think more creatively about how to get information into the hands of those who need it.	Team will participate in dissemination efforts, such as authoring manuscripts and presenting study findings to gain key stakeholders perspectives and reach new and different audiences.

Table 2: Engagement Plan

Abbreviations: ACP, advance care planning.

Measures and Data Collection

Primary and secondary outcomes

Our primary outcomes are documentation of ACP discussions within the EHR and the quality of ACP discussions. For the purpose of this study, documentation of ACP discussions includes both nurse navigators and primary care provider's ACP discussion documentation within the EHR. We will measure quality of ACP discussions from two different mechanisms. First, we will use the quality about end-of-life communication (QOC) [56] to assess quality of ACP discussion from the patient's perspective through a patient engagement survey. QOC is a 13-item instrument with an overall score and two subscale scores for "general communication skills" and "communication about end-of-life care."[56] Scores range from 0 ("poor") to 10 ("absolutely perfect"). Higher scores determine better outcomes. Second, a scoring mechanism was created to measure quality of ACP discussions for both the telephone ACP discussions with the nurse navigator along with primary care provider's ACP visit discussion. Each question listed in the new ACP documentation program was given a numerical score if the question was answered appropriately. Answers to these questions will be reviewed manually and scored. Telephone ACP discussions has scores ranging from 0 to 8 and provider ACP discussions has scores ranging from 0 to 15, with higher scores indicating better quality of discussion.

Secondary outcomes were chosen to measure the full process of ACP. We will measure ACP billing code usage (99497, 99498) to help assess ACP discussion rates. We will measure documentation of designated surrogate decision makers along with advance directive completion rates as another marker to assess ACP documentation rates within the EHR.

Our exploratory outcomes were chosen to measure additional ACP processes along with the impact of ACP. We will be measuring medical scope of treatment (MOST) completion rates. Patient healthcare utilization rates will be measured by the number of the following events: inpatient hospitalizations, emergency department (ED) visits, intensive care unit (ICU) admissions and length of stay, mechanical intubations rates, and in-hospital CPR rates measured in the EHR), along with quality of end-of-life care, which will be measured by after-death bereaved family member interviews[57]. The interview provides an assessment of patient-focused, family-centered care and assesses overall quality of care received.

Analytic Plan

The primary statistical aim is the comparison of rates at which ACP discussions are documented with the EHR between the nurse navigator and usual-care groups. We will use regression techniques for censored time-to-event outcomes to compare the time to documentation of an ACP discussion, including a frailty

term (i.e. random effect, different from the clinical concept of frailty) to account for correlations between patients with the same primary care physician.[52] The advantage of a time-to-event analytic framework, versus treating documentation of an ACP discussion as a binary outcome, is that it can account for variable lengths of follow-up and account for the competing risk of death using extensions such as the popular proportional model of Fine and Gray.[58] Follow-up time for patients without documentation of an ACP discussion will be defined either as of the date of the last in-person encounter within the health system (outpatient, inpatient, or emergency department visit) or as the date of death. Analyses of secondary endpoints (completion of advanced directives, completion of Medical Orders of Scope Treatment" forms, utilization of ACP billing codes, and healthcare utilization) will similarly utilize a time-to-event analytic framework. One additional statistical nuance, primarily with healthcare utilization, is the potential for recurrent events, i.e. a patient with multiple ED visits. We will use extensions for time-to-event analyses that can accommodate recurrent events, such as the Mean Cumulative Count estimator[59] and the regression approach of Prentice, Williams, and Peterson.[60]

Power and Sample Size Considerations

Our power estimates are based on standard calculations for time-to-event analyses.[61] The primary nuance for estimating statistical power is the use of Zelen's pre-randomization design, whereby only patients randomized to the nurse navigator group will be approached for consent. This naturally attenuates any presumed effect of the intervention, as a proportion of patients will not receive the intervention.[62] Based on a previous randomized trial of ACP strategies conducted within the Veterans Affairs system, we assumed that 44% of patients randomized to the nurse navigator group will consent to participate.[63] Furthermore, we assumed that incidence of documented ACP discussions would be 25% for patients that do not consent or those randomized to usual care. Finally, we assumed a follow-up period of 1 year, that 10% of patients would be lost to follow-up, and an alpha-level of 0.05. Based on these assumptions, our initial calculations indicated that a total sample size of 300 patients (150 per group) would provide >80% power. However, we subsequently realized a deficiency in these assumptions. Since patients will be randomized prior to consent to the intervention arm, there can be a time lag of up to ~3 months in between randomization and initial phone contact for consent. Patients could therefore become ineligible in the interim, for example, by having transitioned to a nursing home or by passing away. We therefore revised our power calculations including an expectation that 20% of patients in the nurse navigator group would be found ineligible by the time they are contacted, and that the incidence of documented ACP discussions within this group would be at most 10%. With an increased sample size of 765, we expect that n=135 of those randomized to the intervention arm will consent to participate. We will have >80% power provided that the rate of documented ACP discussions is at least 70% for participants that consent

to the nurse navigator intervention (which implies an overall rate of ACP discussions of 38% in the nurse navigator arm). If the rate of documented ACP discussions is 30% in patients that do not consent or are randomized to usual care, then at least 80% of participants that consent to the nurse navigator intervention will need to have an ACP discussion documented to have >80% power (implies an overall rate of ACP discussions of ~44% in patients randomized to the nurse navigator group).

Ethics

This study was funded by the Duke Endowment and Wake Forest Center of Healthcare Innovation. This study was guided by a patient and family advisory committee comprising of patients, patient advocates, and surrogates; site champions consisting of primary care clinic providers, an internal research team, external advisory members, along with the Wake Forest Institutional Review Board (IRB). Participant confidentiality will be ensured, and anonymity guaranteed.

Trial Status

This study is registered at Clinicaltrials.gov (NCT03609658). Recruitment started on November 2, 2018 and we are currently still actively enrolling patients into the study.

Dissemination

For academic audiences, we will present our findings at scientific meetings and in peer-reviewed research journals. We will also present these results to our patient and family advisory panel. If this study is successful, we will work towards refining and disseminating our study to primary care clinics through the Wake Forest Network and other healthcare systems.

Authors' contributions: JG, NP, KEC, and JW conceptualized this study. AD and AM contributed in the clinical informatics component of this study. JG and NP drafted the manuscript. KEC, AD, KF, KGF, AM, CG, JW contributed in editing of the manuscript. All authors approved the final manuscript.

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Conflicts of Interest Statement: None declared

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Family Advisory Panel and our Research Support Team for their assistance with study design and implementation.

Figure Legends:

Figure 1. IMPACT Study Flow Diagram

Abbreviations: ACP=Advance Care Planning, EHR= Electronic Health Record, PCP= Primary Care Doctor.

Tables

Table 1: Inclusion and exclusion criteria of study participants

Abbreviations: ACO, Accountable Care Organization; EHR, Electronic Health Record.

Table 2: Engagement Plan

Abbreviations: ACP=Advance Care Planning.

References

1. U.S. Census Bureau. International database. Table 094. Midyear population, by age and sex. Available at http://www.census.gov/population/www/projections/natdet-D1A.htmlExternal Web Site Icon.
2. Gomez-Batiste X, Martinez-Munoz M, Blay C, et al. Prevalence and characteristics of patients with advanced chronic conditions in need of palliative care in the general population: a cross-sectional study. *Palliat Med.* 2014;28(4):302-311.
3. "Methods for Analysis of the Financing and Use of Long-Term Services and Supports," supplemental material for Rising Demand for Long-Term Services and Supports for Elderly People (June 2013), www.cbo.gov/publication/44370.
4. Schoenborn NL, Cayea D, McNabney M, Ray A, Boyd C. Prognosis Communication with Older Patients with Multimorbidity: Assessment after an Educational Intervention. *Gerontol Geriatr Educ.* 2016.
5. Morrison RS. Research priorities in geriatric palliative care: an introduction to a new series. *J Palliat Med.* 2013;16(7):726-729.
6. Signorielli N: Physical disabilities, impairment and safety,mental illness, and death. In: Mass Media Images and Impact on Health: A Sourcebook. Westport, CT: Greenwood Press, 1993, pp. 37–42.
7. Fortin M, Bravo G, Hudon C, Vanasse A, Lapointe L. Prevalence of multimorbidity among adults seen in family practice. *Ann Fam Med.* 2005;3(3):223-228.
8. Fortin M, Soubhi H, Hudon C, Bayliss EA, van den Akker M. Multimorbidity's many challenges. *BMJ.* 2007;334(7602):1016-1017.
9. Marengoni A, Angleman S, Melis R, et al. Aging with multimorbidity: a systematic review of the literature. *Ageing research reviews.* 2011;10(4):430-439.
10. Smith SM, O'Dowd T. Chronic diseases: what happens when they come in multiples? *Br J Gen Pract.* 2007;57(537):268-270.
11. Taylor AW, Price K, Gill TK, et al. Multimorbidity - not just an older person's issue. Results from an Australian biomedical study. *BMC Public Health.* 2010;10:718.
12. Vogeli C, Shields AE, Lee TA, et al. Multiple chronic conditions: prevalence, health consequences, and implications for quality, care management, and costs. *J Gen Intern Med.* 2007;22 Suppl 3:391-395.
13. Menotti A, Mulder I, Nissinen A, Giampaoli S, Feskens EJ, Kromhout D. Prevalence of morbidity and multimorbidity in elderly male populations and their impact on 10-year all-cause mortality: The FINE study (Finland, Italy, Netherlands, Elderly). *J Clin Epidemiol.* 2001;54(7):680-686.
14. Fortin M, Lapointe L, Hudon C, Vanasse A, Ntetu AL, Maltais D. Multimorbidity and quality of life in primary care: a systematic review. *Health and quality of life outcomes.* 2004;2:51.
15. Townsend A, Hunt K, Wyke S. Managing multiple morbidity in mid-life: a qualitative study of attitudes to drug use. *BMJ.* 2003;327(7419):837.
16. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *Lancet.* 2012;380(9836):37-43.
17. Smith SM, Soubhi H, Fortin M, Hudon C, O'Dowd T. Managing patients with multimorbidity: systematic review of interventions in primary care and community settings. *BMJ.* 2012;345:e5205.
18. Ryan A, Wallace E, O'Hara P, Smith SM. Multimorbidity and functional decline in community-dwelling adults: a systematic review. *Health and quality of life outcomes.* 2015;13:168.

19. Iezzoni LI. Multiple chronic conditions and disabilities: implications for health services research and data demands. *Health Serv Res.* 2010;45(5 Pt 2):1523-1540.
20. Quinones AR, Markwardt S, Botoseneanu A. Multimorbidity Combinations and Disability in Older Adults. *J Gerontol A Biol Sci Med Sci.* 2016;71(6):823-830.
21. Kogan AC, Wilber K, Mosqueda L. Person-Centered Care for Older Adults with Chronic Conditions and Functional Impairment: A Systematic Literature Review. *J Am Geriatr Soc.* 2016;64(1):e1-7.
22. Connors MH, Sachdev PS, Kochan NA, Xu J, Draper B, Brodaty H. Cognition and mortality in older people: the Sydney Memory and Ageing Study. *Age Ageing.* 2015;44(6):1049-1054.
23. Bunn F, Goodman C, Burn AM. Multimorbidity and frailty in people with dementia. *Nurs Stand.* 2015;30(1):45-50.
24. Bunn F, Burn AM, Goodman C, et al. Comorbidity and dementia: a scoping review of the literature. *BMC Med.* 2014;12:192.
25. Martin Lesende I, Mendibil Crespo LI, Castano Manzanares S, et al. Functional decline and associated factors in patients with multimorbidity at 8 months of follow-up in primary care: the functionality in pluripathological patients (FUNCIPLUR) longitudinal descriptive study. *BMJ Open.* 2018;8(7):e022377.
26. Campbell SE, Seymour DG, Primrose WR. A systematic literature review of factors affecting outcome in older medical patients admitted to hospital. *Age Ageing.* 2004;33(2):110-115.
27. Hagerty RG, Butow PN, Ellis PM, et al. Communicating with realism and hope: incurable cancer patients' views on the disclosure of prognosis. *J Clin Oncol.* 2005;23(6):1278-1288.
28. Guiding principles for the care of older adults with multimorbidity: an approach for clinicians: American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity. *J Am Geriatr Soc.* 2012;60(10):E1-e25.
29. Herrin J, Harris KG, Kenward K, Hines S, Joshi MS, Frosch DL. Patient and family engagement: a survey of US hospital practices. *BMJ quality & safety.* 2016;25(3):182-189.
30. Asakawa T, Koyano W, Ando T, Shibata H. Effects of functional decline on quality of life among the Japanese elderly. *Int J Aging Hum Dev.* 2000;50(4):319-328.
31. Stineman MG, Xie D, Pan Q, et al. All-cause 1-, 5-, and 10-year mortality in elderly people according to activities of daily living stage. *J Am Geriatr Soc.* 2012;60(3):485-492.
32. Kritchevsky SB, Williamson J. Putting function first. *J Nutr Health Aging.* 2014;18(5):467-468.
33. Mc Cord KA, Ewald H, Ladanie A, et al. Current use and costs of electronic health records for clinical trial research: a descriptive study. *CMAJ open.* 2019;7(1):E23-e32.
34. Li G, Sajobi TT, Menon BK, et al. Registry-based randomized controlled trials- what are the advantages, challenges, and areas for future research? *J Clin Epidemiol.* 2016;80:16-24.
35. Rocque GB, Dionne-Odom JN, Sylvia Huang CH, et al. Implementation and Impact of Patient Lay Navigator-Led Advance Care Planning Conversations. *J Pain Symptom Manage.* 2017;53(4):682-692.
36. Niranjan SJ, Huang CS, Dionne-Odom JN, et al. Lay Patient Navigators' Perspectives of Barriers, Facilitators and Training Needs in Initiating Advance Care Planning Conversations With Older Patients With Cancer. *J Palliat Care.* 2018;33(2):70-78.
37. Rocque GB, Partridge EE, Pisu M, et al. The Patient Care Connect Program: Transforming Health Care Through Lay Navigation. *J Oncol Pract.* 2016;12(6):e633-642.
38. Turley M, Wang S, Meng D, Kanter M, Garrido T. Impact of a Care Directives Activity Tab in the Electronic Health Record on Documentation of Advance Care Planning. *The Permanente journal.* 2016;20(2):43-48.

39. Huber MT, Highland JD, Krishnamoorthi VR, Tang JW. Utilizing the Electronic Health Record to Improve Advance Care Planning: A Systematic Review. *Am J Hosp Palliat Care.* 2018;35(3):532-541.
40. Moorman SM, Carr D, Kirchhoff KT, Hammes BJ. An assessment of social diffusion in the Respecting Choices advance care planning program. *Death Stud.* 2012;36(4):301-322.
41. Rietjens JA, Korfage IJ, Dunleavy L, et al. Advance care planning--a multi-centre cluster randomised clinical trial: the research protocol of the ACTION study. *BMC Cancer.* 2016;16:264.
42. https://www.census.gov/quickfacts/fact/table/NC/PST045218 Accessed last 6/6/2019.
43. Zelen M. A new design for randomized clinical trials. *N Engl J Med.* 1979;300(22):1242-1245.
44. Torgerson DJ, Roland M. What is Zelen's design? *BMJ.* 1998;316(7131):606.
45. Torgerson D. The use of Zelen's design in randomised trials. *BJOG.* 2004;111(1):2.
46. House A, Knapp P. Informed consent. Trials that use Zelen's procedure should be acceptable. *BMJ.* 1997;315(7102):251.
47. Adamson J, Cockayne S, Puffer S, Torgerson DJ. Review of randomised trials using the post-randomised consent (Zelen's) design. *Contemp Clin Trials.* 2006;27(4):305-319.
48. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383.
49. Clegg A, Bates C, Young J, et al. Development and validation of an electronic frailty index using routine primary care electronic health record data. *Age Ageing.* 2016;45(3):353-360.
50. Erkinjuntti T, Sulkava R, Wikstrom J, Autio L. Short Portable Mental Status Questionnaire as a screening test for dementia and delirium among the elderly. *J Am Geriatr Soc.* 1987;35(5):412-416.
51. Castanho TC, Amorim L, Zihl J, Palha JA, Sousa N, Santos NC. Telephone-based screening tools for mild cognitive impairment and dementia in aging studies: a review of validated instruments. *Front Aging Neurosci.* 2014;6:16.
52. Glidden DV, Vittinghoff E. Modelling clustered survival data from multicentre clinical trials. *Stat Med.* 2004;23(3):369-388.
53. Pajewski NM, Lenoir K, Wells BJ, Williamson JD, Callahan KE. Frailty Screening Using the Electronic Health Record within a Medicare Accountable Care Organization. *J Gerontol A Biol Sci Med Sci.* 2019.
54. Higgins T, Larson E, Schnall R. Unraveling the meaning of patient engagement: A concept analysis. *Patient Educ Couns.* 2017;100(1):30-36.
55. de Wit M, Cooper C, Tugwell P, et al. Practical guidance for engaging patients in health research, treatment guidelines and regulatory processes: results of an expert group meeting organized by the World Health Organization (WHO) and the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO). *Aging Clin Exp Res.* 2019;31(7):905-915.
56. Engelberg R, Downey L, Curtis JR. Psychometric characteristics of a quality of communication questionnaire assessing communication about end-of-life care. *J Palliat Med.* 2006;9(5):1086-1098.
57. Teno JM, Clarridge B, Casey V, Edgman-Levitan S, Fowler J. Validation of Toolkit After-Death Bereaved Family Member Interview. *J Pain Symptom Manage.* 2001;22(3):752-758.
58. Fine, J., & Gray, R. (1999). A Proportional Hazards Model for the Subdistribution of a Competing Risk. Journal of the American Statistical Association, 94(446), 496-509. doi:10.2307/2670170.
59. Dong H, Robison LL, Leisenring WM, Martin LJ, Armstrong GT, Yasui Y. Estimating the burden of recurrent events in the presence of competing risks: the method of mean cumulative count. *Am J Epidemiol.* 2015;181(7):532-540.

60. Prentice R, Williams B, and Peterson A. On the regression analysis of multivariate failure time data. Biometrika 1981;68:373-379. .
61. Julious SA. Sample Sizes for Clinical Trials. Chapman & Hall/CRC, Boca Raton, FL, 2010.
62. Reeves D, Howells K, Sidaway M, et al. The cohort multiple randomized controlled trial design was found to be highly susceptible to low statistical power and internal validity biases. *J Clin Epidemiol.* 2018;95:111-119.
63. Sudore RL, Boscardin J, Feuz MA, McMahan RD, Katen MT, Barnes DE. Effect of the PREPARE Website vs an Easy-to-Read Advance Directive on Advance Care Planning Documentation and Engagement Among Veterans: A Randomized Clinical Trial. *JAMA Intern Med.* 2017.

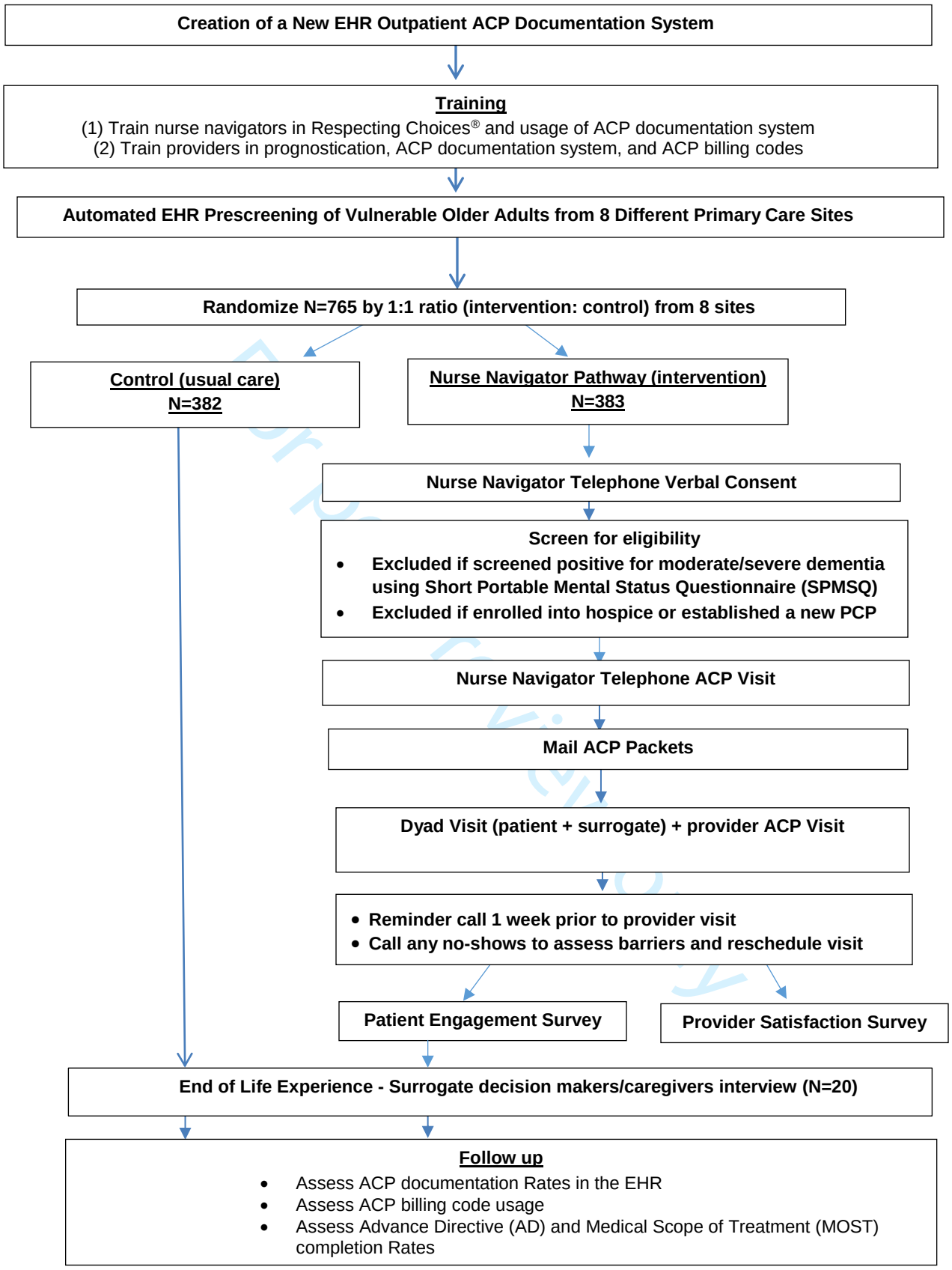

Figure 1. IMPACT Study Flow Diagram.

Abbreviations: ACP, advance care planning; EHR, electronic health record; PCP, primary care physician.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	10
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	10
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	10
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and	n/a

		other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	1, 2
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	1, 2
Objectives	#7	Specific objectives or hypotheses	2
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	2
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	3

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	2-3
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	3

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	3
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	3
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	3-4
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque,	n/a

		sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9

Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	5
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	n/a
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further	n/a

		details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	n/a
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6-7
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	1
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	10

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	10
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

Advance Care Planning for Vulnerable Older Adults within an Accountable Care Organization: study protocol for the IMPACT randomized controlled trial.

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Secondary Subject Heading:	Geriatric medicine, Health informatics
Keywords:	advance care planning, electronic health record, goals of care, end of life care, advance care directives

Title: **Advance Care Planning for Vulnerable Older Adults within an Accountable Care Organization: study protocol for the IMPACT randomized controlled trial.**

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Abstract:

Introduction: Patients with multimorbidity plus additional impairments (e.g. mobility limitations, disability, cognitive impairments, or frailty) are at the highest risk for poor healthcare outcomes. Advanced Care Planning (ACP) provides patients and their surrogates the opportunity to discuss their goals, values, and priorities for healthcare – particularly in the context of end-of-life care. ACP discussions promote more person-centered care; however, currently are underutilized. There is a tremendous need for systematic, scalable approaches to individualized ACP that promotes patient and family engagement. Here we describe the study protocol for a randomized effectiveness trial of a nurse navigator and informatics intervention designed to improve the documentation and quality of ACP discussions.

Methods and Analysis: This is a randomized, pragmatic, effectiveness trial; patients aged 65 years and older who have multimorbidity plus impairments in either physical function (e.g., mobility limitations or disability) or cognition, and/or frailty within an affiliated Accountable Care Organization (ACO) were eligible. The Electronic Health Record (EHR) was utilized to develop an automatic prescreening system for eligible patients (N=765) and participants were randomized in a 1:1 ratio to either the nurse navigator-led ACP pathway or usual care. Our primary outcomes are documentation of ACP discussions within the EHR along with the quality of ACP discussions. Secondary outcomes include a broad range of ACP actions (e.g. usage of ACP billing codes, choosing a surrogate decision maker, and advance directive documentation). Outcomes will be measured over 12 months of follow-up.

Ethics and Dissemination: This study has been approved by the appropriate Institutional Review Boards and is guided by input from patient and clinical advisory boards. The results of this study will inform a scalable solution to ACP discussions throughout our health care system and state-wide.
Trials registration number: NCT03609658.

Keywords: advance care planning, electronic health record; goals of care, end-of-life care, advance care directives

Article Summary

Strengths and Limitations of this Study
• This study addresses gaps in advance care planning (ACP) for at-risk, vulnerable older adults.
• An automatic prescreening system was designed to identify vulnerable older adults within the Electronic Health Record (EHR) to improve recruitment.
• Nurse Navigators are utilized in this study for ACP pre-visit planning over the telephone to improve patient engagement.
• Integrating Provider-Facing EHR ACP tools is an innovative method to improve ACP discussions, documentation, and promote engagement.
• This study is only occurring within an Accountable Care Organization population in North Carolina, thus may have limited generalizability.

Introduction:

One-fifth of the total U.S. population will be over the age of 65 by 2050.[1,2] Inevitably, there will be a corresponding surge in those with multiple chronic conditions ("multimorbidity") along with an associated increase in health care expenditures.[1-6] Multimorbidity has been associated with (a) poor patient health outcomes, including depression, polypharmacy, socioeconomic deprivation, poorer quality of life, and decreased satisfaction with care; and (b) increased overall health system costs, primarily due to increased healthcare utilization and burdensome care. [7-16] [17,18] Yet, multimorbidity alone does not identify the subset of older adults at greatest need of assistance with care planning.[19,20] Evidence is emerging that persons with multimorbidity plus impairments in either function, cognition, and/or frailty are at the highest risk for poor outcomes with respect to disability and mortality, above and beyond the risk attributable to individual diseases.[2,18,20-25] Here, we label these patients as *"vulnerable older adults"*: adults 65 years and older who have multimorbidity plus impairments in either physical function (e.g., mobility disability), cognition, and/or frailty. At present, the care of vulnerable older adults is marked by fragmented health care focused on disease-based treatments, lengthy and recurrent hospital stays, and higher healthcare cost through the end of life.[26-29] Studies have shown that older adult's preserved functional health status is a prerequisite for higher quality of life, and functional decline is a strong prognostic indicator.[25,30,31] As opposed to a disease-based approach to health care, a function- and goal-based approach for patients at risk for worse outcomes can help inform advance care planning in vulnerable older adults.[32]

The use of patient-level variables that are gathered during routine medical care within the Electronic Health Record (EHR) allows for easier patient identification for implementing pragmatic clinical trials.[33] Recruiting patients directly from the EHR allows for prescreen eligibility prior to approaching potential participants to help facilitate patient recruitment.[34] Thus, we propose to promote advance care planning (ACP) conversations by first utilizing the EHR for automatic prescreening for vulnerable older adults, and then developing a new outpatient ACP documentation system that promotes

easy documentation along with providing a central location for documented goals of care discussions within the EHR. Second, we will leverage nurse navigators as the first point of contact for ACP discussions to assist in patient engagement. Nurse navigators already function well in engaging patients with care coordination, patient education, and connections to community-based resources. The proposed project is a natural extension of their role and empowers the nurses to use their skills in a new capacity. Studies have shown that the use of nurse navigators in ACP is feasible.[35-37] Third, we will utilize the Medicare annual wellness visit to optimize ACP discussions between the patient and their provider care provider. **Our overall hypothesis is that in a primary care setting, a nurse navigator-led ACP pathway will improve ACP documentation within the EHR as compared to usual care and will improve provider-patient communication about goals of care.**

Materials and analysis

Study Overview

This study is a randomized, pragmatic, effectiveness trial for determining better ways to engage vulnerable older adults and their family members in ACP through a nurse navigator-led pathway (intervention arm) versus usual care (control arm). **(See figure 1).** A new ACP documentation system that allows for the use of discrete data elements was created into the EHR (Epic Systems Corporation) to allow for easy documentation and tracking of ACP discussions in an outpatient setting. A linkage to the advance directive tab within the EHR was also created along with a new visit type called ACP, [38,39] so that all documented goals of care discussions could be found easily in a central location within the EHR. Since nurse navigators were not involved in discussing ACP with patients prior to this study, they were trained in ACP by taking the "First Steps® ACP Facilitator Certification Course" training provided by Respecting Choices® to help facilitate discussions.[40,41] Respecting Choices® (RC) is an internationally recognized, evidence-based model of ACP that creates a healthcare culture of person-centered care: care that honors an individual's goals and values for current and future healthcare. Training consisted of one full day (8 hours) working with a trained facilitator to hone interviewing skills related to ACP, and included small group work, didactics, videos, case scenarios, role-playing, debriefing, and self-reflection. A pre- and post-test were also given. In addition, nurse navigators and providers completed a one-hour training session to review the new ACP documentation program and observe a short role-play of a goals of care discussion. An automated EHR screening system utilizing existing data within the EHR was created to prescreen eligible patients.

Eligible patients (N=765) were randomized using a 1:1 ratio to either the nurse navigator-led ACP pathway (intervention arm) or usual care (control arm). Permission from primary care providers was obtained to allow the study team to inform their patients about the study using an opt-out strategy. Only those who were randomized to the nurse navigator-led pathway (intervention arm) will be approached for recruitment. Patients who agree to participate will be consented over the telephone and will be screened for eligibility. Nurse navigators will complete a brief pre-visit ACP discussion with the patient over the telephone to help prime and better engage patients in ACP prior to their provider visit. The new ACP telephone documentation system will be used to document these discussions, which will automatically generate a note that will be forwarded to the primary care provider. After completion of the telephone ACP discussion, patients will be mailed an ACP packet (which will include additional information about ACP and a copy of an advance directive to review) and scheduled for an in-person dyad visit (patient and their surrogate decision maker or loved one) with their primary care provider. All visits will be scheduled in conjugation to the patient's Medicare annual wellness visit, unless unable to occur (since can only occur once per year), and if so, will be scheduled as a separate ACP visit alone. Primary care providers will then complete an ACP dyad-visit and document that discussion using the new ACP documentation system. After the visit, patients will be asked to complete a patient engagement survey[42]. In order to ensure transparency, ACP notes have been systematically programmed to be available to provider's in-line with the code status documentation and in the advance directive tab within the EHR.

<<Insert Figure 1>>

Study Setting

The geographic region for our intervention is the Piedmont Triad area of North Carolina, which is the north-central part of the state and contains 12 counties.[43] The population is estimated at 1.69 million, making it the 30th largest metropolitan area in the U.S. In the region, 22.2% of the residents are African American, and 15.9% of the residents are aged 65 and older.[43] Wake Forest Baptist Health (WFBH) is the only academic medical center in this 12-county region. WFBH, having recently acquired Cornerstone Health Care, supports more than 200 clinical practice sites in 80 locations throughout central North Carolina. Since 2012, all WFBH locations utilize an Epic-based EHR, which is a single instance, enterprise-wide platform that supports integrated clinical, billing and ancillary applications. Recruitment for this trial occurred at eight separate primary care clinics associated with the WFBH network. Sites were selected in both urban and rural settings across five different counties in North Carolina to help with recruitment of racially and ethnically diverse and low-income populations.

Randomization Procedures

Patient were randomized (N=765) using a 1:1 ratio to either the nurse navigator-led ACP pathway (intervention arm) or usual care (control arm). We utilized a Zelen's design[44-48]for this study, which is a pragmatic clinical trial design whereby all participants are randomized prior to informed consent, and then only patients randomized to the interventional arm will be approached for consent and subsequently enrolled in the intervention group. Note that patients that do not consent to the intervention will still be counted as part of the intervention group under an intent-to-treat paradigm, which necessitates passive ascertainment mechanisms for outcomes (i.e. administrative claims or the EHR). One appealing aspect of Zelen's design is that it facilitates estimating real-world effectiveness, as we will be able to estimate the rate at which patients decline to consent for the study, or refuse the nurse navigator intervention, which then factors into overall estimates of effectiveness. In addition, others have pointed out that the Zelen's design is ethical and particularly useful within the context of trials of screening interventions, where the desire is to estimate an effect on the entire population of eligible patients. [45,46]

Eligibility criteria

Patients were eligible for this study if they were affiliated with an Accountable Care Organization, were aged 65 and older, had seen their primary care provider within the past twelve months, who had multimorbidity defined by Charlson Comorbidity Index (CCI) of three or higher,[49] plus impairments in either physical function (e.g., mobility limitation or disability), cognition, and/or frailty[50]. **(Please see Table 1).** Their primary care provider gave permission to study staff to contact patients about the study. Patients were excluded if they had moderate to severe hearing loss (due to use of a phone intervention), were non-English speakers (since not all navigators speak a second language, subtleties may have not been conveyed effectively), if no phone number was available, and if they had significant memory impairments based on a Short Portable Mental Status Questionnaire (SPMSQ) score of ≥ 5 or a score of ≥ 6 or higher for those with only a grade school education.[51,52] Since ACP is an iterative process, participants with prior ACP experiences (e.g. an advance directive found with the EHR) were excluded. Patients on hospice, in a long-term care facility, or who transferred care to a different primary care provider (PCP) were also excluded from the study.

Table 1: Inclusion and exclusion criteria of study participants

Patients	
Inclusion Criteria	1. Age 65 or older patients within the Wake Forest Baptist Health ACO. 2. Have seen their primary care provider within the Wake Forest Baptist Health network in the past 12 months. 3. Charlson Comorbidity Index (CCI) of 3 or higher. 4. Impairments in either physical function, cognition, and/or frailty defined by: a. <u>Impairments in physical function:</u> *i. ICD-10 Codes for:* 1. Falls: V00.141A, V00.312A, W01.110A, W01.198A, W03.XXXA, W05.0XXA, W05.1XXA, W05.2XXA, W06.XXXA, W07.XXXA, W08.XXXA, W10.1XXA, W10.8XXA, W17.81XA, W17.89XA, W18.11XA, W18.30XA, W19.XXXA, R29.6,z91.81 2. Muscular Deconditioning: R29.898 3. Physical Deconditioning: R53.81 4. Gait Abnormality: R26.9, 26.89 5. Impaired physical mobility: Z74.09 6. Difficulty walking: R26.2 7. Debility: R53.81, R54, 8. Wheelchair bound: Z99.3 *ii. Annual Wellness Visit:* 1. Positive Falls Assessment 2. Impairments in Activities of Daily Living, answer of "yes" for needing assistance with any of the following: a. Feeding self, bathing self, dressing self, use of toilet, needing assistive device for walking or cannot walk. *b.* <u>Impairments in Cognition:</u> *i. ICD-10 Codes for:* 1. Impaired cognition: R41.89 2. Dementia: F01.50, F02.81,F03.90, G30.9, F02.80, G20, G31.83, G31.09, G30.0, G30.1, G30.8, G31.01, G31.09 3. Memory Change: R41.3, F06.8 4. MCI (mild cognitive impairment): G31.84 5. History of memory loss: Z86.59 6. History of short-term memory loss: Z87.898 ii. *Annual Wellness Visit*: 1. Answer of "yes" to either "has a diagnosis of dementia or cognitive impairment?" and/or "are there any memory concerns by the patient, others, or providers?

	c. Frailty: i. Electronic Frailty Index (eFI) score >0.21.[50,53,54] 5. English-speaking. 6. No documented Advance Directive in the EHR.
Exclusion Criteria	1. Moderate to severe hearing loss (due to phone interventions). 2. Non-English-speaking (not all navigators speak a second language; subtleties may not be conveyed effectively). 3. No phone number available for patient. 4. Moderate/Severe Cognitive Impairment assessed by validated Short Portable Mental Status Questionnaire (SPMSQ)[51,52] 5. Enrolled on Hospice, in a long-term care facility, or who transferred care to a different primary care provider (PCP).

Table 1: Inclusion and exclusion criteria of study participants
Abbreviations: ACO, accountable care organization; EHR, electronic health record.

Recruitment and retention

We obtained a Health Insurance Portability and Accountability Act waiver to access patients' names, age, race/ethnicity, gender, primary language, phone numbers, addresses, medical record numbers, diagnoses, lab results, medication lists, payer source, as well as dates of outpatient primary care clinic appointments in the past two years, other appointments, hospitalizations and emergency room visits in the past two years, and the name of patients' outpatient primary care providers. From this data, an automated EHR screening system was created to prescreen eligible patients. This system then generated a list of patients who met our inclusion criteria. Prescreened eligible patients (N=765) from our eight sites were then randomized using a 1:1 ratio to either the nurse navigator-led ACP pathway (intervention arm) or usual care (control arm).

Nurse navigators will be utilized to recruit eligible patients for the intervention arm. The nurse navigators were trained in Respecting Choices® (RC), an internationally recognized, evidence-based model of ACP that creates a healthcare culture of person-centered care; care that honors an individual's goals and values for current and future healthcare.[40,41] In addition, nurse navigators received training in the Collaborative Institutional Training Initiative (CITI) and the protocol. They were added to the research team to recruit, consent patients and complete an initial ACP discussion over the phone. The nurse navigators also will perform a Short Portable Mental Status Questionnaire (SPMSQ)[51] for patients that are flagged as having an impairment in cognition to rule out patients with moderate to severe dementia.

The nurse navigators will call up to three times to try and recruit a participant. Once a patient consents to participate, the nurse navigator will complete a telephone ACP visit and then schedule them to see their primary care provider for a dyad ACP in-person visit. Patients will receive a reminder call one week prior to their visit. Patients who either are no shows or cancel their appointment will be called up to three times to try and reschedule their appointment. A missed appointment postcard will be sent as a 4th attempt, and patients will be considered lost to follow up if after four attempts they cannot be reached. The study team will also be sending "Thank You" and "Appointment Reminder" postcards to all participants enrolled in the intervention arm. Participants who complete the ACP telephone discussion, the ACP dyad in-person visit, and the Patient Engagement survey will be given a $25 gift card as a token of appreciation for their participation.

Consent procedures

Our consent was designed to meet the understanding capabilities of our elderly population with a sixth-grade reading level. **(Supplement 1)** The patient and family advisory team reviewed our informed consent and revisions were made as needed. We received approval by our Institutional Review Board (IRB) to obtain verbal consent by phone for patients and a copy of this consent will be mailed to all enrolled participants in the intervention arm. In our informed consent, we stated that the purpose of the study was to find better ways to engage patients in discussing their goals and values with their primary care provider (PCP) through ACP. We stated that the study would consist of three steps: 1) to review a few questions about ACP with the nurse navigator over the phone, 2) to meet with their primary care provider and their caregiver to further discuss ACP, and 3) to complete a Patient Engagement survey to provide feedback about their ACP conversation with their primary care provider.

Patient and Public Involvement

Our engagement plan calls for meaningful patient, family, and stakeholder involvement at every step of the research project—including analysis and dissemination. **(See Table 2).** The research team includes three sets of stakeholders: (1) The *Patient and Family Advisory Panel*, which consist of 10 patients or family members/caregivers; (2) The *Research Support Team*, which consist of four nurse navigators and eight site champions (MD, PA, or NP), one from each of the 8 community-based clinics participating in the study; and (3) The *Investigator Team*, made up of primary investigators, mentors, analysts, and research assistants. All dissemination activities will be led by a group that includes at least one member of each group. This process will ensure that all three sets of stakeholders can share learnings and successes from their own perspective, and that all three groups have buy-in and recognition for their role in the project. Our Engagement Plan is founded on the principle of meaningful participation.[55,56] Engaging with

key stakeholders can strengthen the understanding of real world concerns, identify knowledge gaps and barriers and improve knowledge of health inequities in a given community. Teams will meet 3 times per year and more if needed. Members of the *Patient and Family Advisory Panel* and *Research Support Team* will be compensated equally (annual honoraria of $100). Compensation demonstrates recognition of the value of everyone's time, and contributes to the attitude that all members of the research team are valued as contributors to the research project.

Table 2: Engagement Plan

Stage	Patients and Family Members	Research Support Team and Investigator Team
Barrier Assessment for ACP	Patients and Family members helped identify and prioritize the key barriers to effective ACP.	Teams helped identify and prioritize the key barriers to effective ACP from a provider level.
Research Design	Draft Design was presented. Patients and family members had opportunity to give feedback and reshape study design. They were involved in revising study materials and protocol to ensure feasibility for clinicians and patients.	Draft Design was presented. Teams did have the opportunity to give feedback and reshape study design. They were involved in revising study materials and protocol to ensure feasibility for clinicians and patients.
Survey Design	The investigator team presented our draft patient engagement survey. The patients and family members had final say in survey design.	Teams gave suggested indicators for the survey, provide input and feedback on the draft survey.
Conducting the Study	Patients/families will be involved in recruitment and implementation phase to increase sustained recruitment and ensure study viability.	Teams will participate in data collection and analysis to lead unique and varied perspectives on interpretation of data.
Data Analysis and Interpretation	Patients/families will be presented with preliminary analytic results. They will have the opportunity to suggest new analytic perspectives and to help translate results.	Teams will be presented with preliminary analytic results. They will have the opportunity to suggest new analytic perspectives and to help translate results.
Dissemination	Patients/families identify opportunities to present and shape information about the study, to move away from traditional models of dissemination and to think more creatively about how to get information into the hands of those who need it.	Team will participate in dissemination efforts, such as authoring manuscripts and presenting study findings to gain key stakeholders perspectives and reach new and different audiences.

Table 2: Engagement Plan

Abbreviations: ACP, advance care planning.

Measures and Data Collection

Primary and secondary outcomes

Our primary outcomes are documentation of ACP discussions within the EHR and the quality of ACP discussions. For the purpose of this study, documentation of ACP discussions includes both nurse navigators and primary care provider's ACP discussion documentation within the EHR. We will measure quality of ACP discussions from two different mechanisms. First, we will use the quality about end-of-life communication (QOC) [57] to assess quality of ACP discussion from the patient's perspective through a patient engagement survey. QOC is a 13-item instrument with an overall score and two subscale scores for "general communication skills" and "communication about end-of-life care."[57] Scores range from 0 ("poor") to 10 ("absolutely perfect"). Higher scores determine better outcomes. Second, a scoring mechanism was created to measure quality of ACP discussions for both the telephone ACP discussions with the nurse navigator along with primary care provider's ACP visit discussion. Each question listed in the new ACP documentation program was given a numerical score if the question was answered appropriately. Answers to these questions will be reviewed manually and scored. Telephone ACP discussions has scores ranging from 0 to 8 and provider ACP discussions has scores ranging from 0 to 15, with higher scores indicating better quality of discussion.

Secondary outcomes were chosen to measure the full process of ACP. We will measure ACP billing code usage (99497, 99498) to help assess ACP discussion rates. We will measure documentation of designated surrogate decision makers along with advance directive completion rates as another marker to assess ACP documentation rates within the EHR.

Our exploratory outcomes were chosen to measure additional ACP processes along with the impact of ACP. We will be measuring medical scope of treatment (MOST) completion rates. Patient healthcare utilization rates will be measured by the number of the following events: inpatient hospitalizations, emergency department (ED) visits, intensive care unit (ICU) admissions and length of stay, mechanical intubations rates, and in-hospital CPR rates measured in the EHR), along with quality of end-of-life care, which will be measured by after-death bereaved family member interviews[58]. The interview provides an assessment of patient-focused, family-centered care and assesses overall quality of care received.

Analytic Plan

The primary statistical aim is the comparison of rates at which ACP discussions are documented with the EHR between the nurse navigator and usual-care groups. We will use regression techniques for censored time-to-event outcomes to compare the time to documentation of an ACP discussion, including a frailty

term (i.e. random effect, different from the clinical concept of frailty) to account for correlations between patients with the same primary care physician.[53] The advantage of a time-to-event analytic framework, versus treating documentation of an ACP discussion as a binary outcome, is that it can account for variable lengths of follow-up and account for the competing risk of death using extensions such as the popular proportional model of Fine and Gray.[59] Follow-up time for patients without documentation of an ACP discussion will be defined either as of the date of the last in-person encounter within the health system (outpatient, inpatient, or emergency department visit) or as the date of death. Analyses of secondary endpoints (completion of advanced directives, completion of Medical Orders of Scope Treatment" forms, utilization of ACP billing codes, and healthcare utilization) will similarly utilize a time-to-event analytic framework. One additional statistical nuance, primarily with healthcare utilization, is the potential for recurrent events, i.e. a patient with multiple ED visits. We will use extensions for time-to-event analyses that can accommodate recurrent events, such as the Mean Cumulative Count estimator[60] and the regression approach of Prentice, Williams, and Peterson.[61]

Power and Sample Size Considerations

Our power estimates are based on standard calculations for time-to-event analyses.[62] The primary nuance for estimating statistical power is the use of Zelen's pre-randomization design, whereby only patients randomized to the nurse navigator group will be approached for consent. This naturally attenuates any presumed effect of the intervention, as a proportion of patients will not receive the intervention.[63] Based on a previous randomized trial of ACP strategies conducted within the Veterans Affairs system, we assumed that 44% of patients randomized to the nurse navigator group will consent to participate.[64] Furthermore, we assumed that incidence of documented ACP discussions would be 25% for patients that do not consent or those randomized to usual care. Finally, we assumed a follow-up period of 1 year, that 10% of patients would be lost to follow-up, and an alpha-level of 0.05. Based on these assumptions, our initial calculations indicated that a total sample size of 300 patients (150 per group) would provide >80% power. However, we subsequently realized a deficiency in these assumptions. Since patients will be randomized prior to consent to the intervention arm, there can be a time lag of up to ~3 months in between randomization and initial phone contact for consent. Patients could therefore become ineligible in the interim, for example, by having transitioned to a nursing home or by passing away. We therefore revised our power calculations including an expectation that 20% of patients in the nurse navigator group would be found ineligible by the time they are contacted, and that the incidence of documented ACP discussions within this group would be at most 10%. With an increased sample size of 765, we expect that n=135 of those randomized to the intervention arm will consent to participate. We will have >80% power provided that the rate of documented ACP discussions is at least 70% for participants that consent

to the nurse navigator intervention (which implies an overall rate of ACP discussions of 38% in the nurse navigator arm). If the rate of documented ACP discussions is 30% in patients that do not consent or are randomized to usual care, then at least 80% of participants that consent to the nurse navigator intervention will need to have an ACP discussion documented to have >80% power (implies an overall rate of ACP discussions of ~44% in patients randomized to the nurse navigator group).

Ethics and Dissemination

This study was funded by the Duke Endowment and Wake Forest Center of Healthcare Innovation. This study was guided by a patient and family advisory committee comprising of patients, patient advocates, and surrogates; site champions consisting of primary care clinic providers, an internal research team, external advisory members, along with the Wake Forest Institutional Review Board (IRB). Participant confidentiality will be ensured, and anonymity guaranteed. For academic audiences, we will present our findings at scientific meetings and in peer-reviewed research journals. We will also present these results to our patient and family advisory panel. If this study is successful, we will work towards refining and disseminating our study to primary care clinics through the Wake Forest Network and other healthcare systems.

Trial Status

This study is registered at Clinicaltrials.gov (NCT03609658). Recruitment started on November 2, 2018 and we are currently still actively enrolling patients into the study.

Authors' contributions: JG, NP, KEC, and JW conceptualized this study. AD and AM contributed in the clinical informatics component of this study. JG and NP drafted the manuscript. KEC, AD, KF, KGF, AM, CG, JW contributed in editing of the manuscript. All authors approved the final manuscript.

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Conflicts of Interest Statement: None declared

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Figure Legends:

Figure 1. IMPACT Study Flow Diagram

Abbreviations: ACP=Advance Care Planning, EHR= Electronic Health Record, PCP= Primary Care Doctor.

Tables

Table 1: Inclusion and exclusion criteria of study participants

Abbreviations: ACO, Accountable Care Organization; EHR, Electronic Health Record.

Table 2: Engagement Plan

Abbreviations: ACP=Advance Care Planning.

Supplement 1: Patient Consent Form

References

1. U.S. Census Bureau. International database. Table 094. Midyear population, by age and sex. Available at http://www.census.gov/population/www/projections/natdet-D1A.htmlExternal Web Site Icon.
2. Gomez-Batiste X, Martinez-Munoz M, Blay C, et al. Prevalence and characteristics of patients with advanced chronic conditions in need of palliative care in the general population: a cross-sectional study. *Palliat Med.* 2014;28(4):302-311.
3. "Methods for Analysis of the Financing and Use of Long-Term Services and Supports," supplemental material for Rising Demand for Long-Term Services and Supports for Elderly People (June 2013), www.cbo.gov/publication/44370.
4. Schoenborn NL, Cayea D, McNabney M, Ray A, Boyd C. Prognosis Communication with Older Patients with Multimorbidity: Assessment after an Educational Intervention. *Gerontol Geriatr Educ.* 2016.
5. Morrison RS. Research priorities in geriatric palliative care: an introduction to a new series. *J Palliat Med.* 2013;16(7):726-729.
6. Signorielli N: Physical disabilities, impairment and safety,mental illness, and death. In: Mass Media Images and Impact on Health: A Sourcebook. Westport, CT: Greenwood Press, 1993, pp. 37–42.
7. Fortin M, Bravo G, Hudon C, Vanasse A, Lapointe L. Prevalence of multimorbidity among adults seen in family practice. *Ann Fam Med.* 2005;3(3):223-228.
8. Fortin M, Soubhi H, Hudon C, Bayliss EA, van den Akker M. Multimorbidity's many challenges. *BMJ.* 2007;334(7602):1016-1017.
9. Marengoni A, Angleman S, Melis R, et al. Aging with multimorbidity: a systematic review of the literature. *Ageing research reviews.* 2011;10(4):430-439.
10. Smith SM, O'Dowd T. Chronic diseases: what happens when they come in multiples? *Br J Gen Pract.* 2007;57(537):268-270.
11. Taylor AW, Price K, Gill TK, et al. Multimorbidity - not just an older person's issue. Results from an Australian biomedical study. *BMC Public Health.* 2010;10:718.
12. Vogeli C, Shields AE, Lee TA, et al. Multiple chronic conditions: prevalence, health consequences, and implications for quality, care management, and costs. *J Gen Intern Med.* 2007;22 Suppl 3:391-395.
13. Menotti A, Mulder I, Nissinen A, Giampaoli S, Feskens EJ, Kromhout D. Prevalence of morbidity and multimorbidity in elderly male populations and their impact on 10-year all-cause mortality: The FINE study (Finland, Italy, Netherlands, Elderly). *J Clin Epidemiol.* 2001;54(7):680-686.
14. Fortin M, Lapointe L, Hudon C, Vanasse A, Ntetu AL, Maltais D. Multimorbidity and quality of life in primary care: a systematic review. *Health and quality of life outcomes.* 2004;2:51.
15. Townsend A, Hunt K, Wyke S. Managing multiple morbidity in mid-life: a qualitative study of attitudes to drug use. *BMJ.* 2003;327(7419):837.
16. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *Lancet.* 2012;380(9836):37-43.
17. Smith SM, Soubhi H, Fortin M, Hudon C, O'Dowd T. Managing patients with multimorbidity: systematic review of interventions in primary care and community settings. *BMJ.* 2012;345:e5205.
18. Ryan A, Wallace E, O'Hara P, Smith SM. Multimorbidity and functional decline in community-dwelling adults: a systematic review. *Health and quality of life outcomes.* 2015;13:168.
19. Iezzoni LI. Multiple chronic conditions and disabilities: implications for health services research and data demands. *Health Serv Res.* 2010;45(5 Pt 2):1523-1540.

20. Quinones AR, Markwardt S, Botoseneanu A. Multimorbidity Combinations and Disability in Older Adults. *J Gerontol A Biol Sci Med Sci.* 2016;71(6):823-830.
21. Kogan AC, Wilber K, Mosqueda L. Person-Centered Care for Older Adults with Chronic Conditions and Functional Impairment: A Systematic Literature Review. *J Am Geriatr Soc.* 2016;64(1):e1-7.
22. Connors MH, Sachdev PS, Kochan NA, Xu J, Draper B, Brodaty H. Cognition and mortality in older people: the Sydney Memory and Ageing Study. *Age Ageing.* 2015;44(6):1049-1054.
23. Bunn F, Goodman C, Burn AM. Multimorbidity and frailty in people with dementia. *Nurs Stand.* 2015;30(1):45-50.
24. Bunn F, Burn AM, Goodman C, et al. Comorbidity and dementia: a scoping review of the literature. *BMC Med.* 2014;12:192.
25. Martin Lesende I, Mendibil Crespo LI, Castano Manzanares S, et al. Functional decline and associated factors in patients with multimorbidity at 8 months of follow-up in primary care: the functionality in pluripathological patients (FUNCIPLUR) longitudinal descriptive study. *BMJ Open.* 2018;8(7):e022377.
26. Campbell SE, Seymour DG, Primrose WR. A systematic literature review of factors affecting outcome in older medical patients admitted to hospital. *Age Ageing.* 2004;33(2):110-115.
27. Hagerty RG, Butow PN, Ellis PM, et al. Communicating with realism and hope: incurable cancer patients' views on the disclosure of prognosis. *J Clin Oncol.* 2005;23(6):1278-1288.
28. Guiding principles for the care of older adults with multimorbidity: an approach for clinicians: American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity. *J Am Geriatr Soc.* 2012;60(10):E1-e25.
29. Herrin J, Harris KG, Kenward K, Hines S, Joshi MS, Frosch DL. Patient and family engagement: a survey of US hospital practices. *BMJ quality & safety.* 2016;25(3):182-189.
30. Asakawa T, Koyano W, Ando T, Shibata H. Effects of functional decline on quality of life among the Japanese elderly. *Int J Aging Hum Dev.* 2000;50(4):319-328.
31. Stineman MG, Xie D, Pan Q, et al. All-cause 1-, 5-, and 10-year mortality in elderly people according to activities of daily living stage. *J Am Geriatr Soc.* 2012;60(3):485-492.
32. Kritchevsky SB, Williamson J. Putting function first. *J Nutr Health Aging.* 2014;18(5):467-468.
33. Mc Cord KA, Ewald H, Ladanie A, et al. Current use and costs of electronic health records for clinical trial research: a descriptive study. *CMAJ open.* 2019;7(1):E23-e32.
34. Li G, Sajobi TT, Menon BK, et al. Registry-based randomized controlled trials- what are the advantages, challenges, and areas for future research? *J Clin Epidemiol.* 2016;80:16-24.
35. Rocque GB, Dionne-Odom JN, Sylvia Huang CH, et al. Implementation and Impact of Patient Lay Navigator-Led Advance Care Planning Conversations. *J Pain Symptom Manage.* 2017;53(4):682-692.
36. Niranjan SJ, Huang CS, Dionne-Odom JN, et al. Lay Patient Navigators' Perspectives of Barriers, Facilitators and Training Needs in Initiating Advance Care Planning Conversations With Older Patients With Cancer. *J Palliat Care.* 2018;33(2):70-78.
37. Rocque GB, Partridge EE, Pisu M, et al. The Patient Care Connect Program: Transforming Health Care Through Lay Navigation. *J Oncol Pract.* 2016;12(6):e633-642.
38. Turley M, Wang S, Meng D, Kanter M, Garrido T. Impact of a Care Directives Activity Tab in the Electronic Health Record on Documentation of Advance Care Planning. *The Permanente journal.* 2016;20(2):43-48.
39. Huber MT, Highland JD, Krishnamoorthi VR, Tang JW. Utilizing the Electronic Health Record to Improve Advance Care Planning: A Systematic Review. *Am J Hosp Palliat Care.* 2018;35(3):532-541.

40. Moorman SM, Carr D, Kirchhoff KT, Hammes BJ. An assessment of social diffusion in the Respecting Choices advance care planning program. *Death Stud.* 2012;36(4):301-322.
41. Rietjens JA, Korfage IJ, Dunleavy L, et al. Advance care planning--a multi-centre cluster randomised clinical trial: the research protocol of the ACTION study. *BMC Cancer.* 2016;16:264.
42. Sudore RL, Heyland DK, Barnes DE, et al. Measuring Advance Care Planning: Optimizing the Advance Care Planning Engagement Survey. *J Pain Symptom Manage.* 2017;53(4):669-681.e668.
43. https://www.census.gov/quickfacts/fact/table/NC/PST045218 Accessed last 6/6/2019.
44. Zelen M. A new design for randomized clinical trials. *N Engl J Med.* 1979;300(22):1242-1245.
45. Torgerson DJ, Roland M. What is Zelen's design? *BMJ.* 1998;316(7131):606.
46. Torgerson D. The use of Zelen's design in randomised trials. *BJOG.* 2004;111(1):2.
47. House A, Knapp P. Informed consent. Trials that use Zelen's procedure should be acceptable. *BMJ.* 1997;315(7102):251.
48. Adamson J, Cockayne S, Puffer S, Torgerson DJ. Review of randomised trials using the post-randomised consent (Zelen's) design. *Contemp Clin Trials.* 2006;27(4):305-319.
49. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383.
50. Clegg A, Bates C, Young J, et al. Development and validation of an electronic frailty index using routine primary care electronic health record data. *Age Ageing.* 2016;45(3):353-360.
51. Erkinjuntti T, Sulkava R, Wikstrom J, Autio L. Short Portable Mental Status Questionnaire as a screening test for dementia and delirium among the elderly. *J Am Geriatr Soc.* 1987;35(5):412-416.
52. Castanho TC, Amorim L, Zihl J, Palha JA, Sousa N, Santos NC. Telephone-based screening tools for mild cognitive impairment and dementia in aging studies: a review of validated instruments. *Front Aging Neurosci.* 2014;6:16.
53. Glidden DV, Vittinghoff E. Modelling clustered survival data from multicentre clinical trials. *Stat Med.* 2004;23(3):369-388.
54. Pajewski NM, Lenoir K, Wells BJ, Williamson JD, Callahan KE. Frailty Screening Using the Electronic Health Record within a Medicare Accountable Care Organization. *J Gerontol A Biol Sci Med Sci.* 2019.
55. Higgins T, Larson E, Schnall R. Unraveling the meaning of patient engagement: A concept analysis. *Patient Educ Couns.* 2017;100(1):30-36.
56. de Wit M, Cooper C, Tugwell P, et al. Practical guidance for engaging patients in health research, treatment guidelines and regulatory processes: results of an expert group meeting organized by the World Health Organization (WHO) and the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO). *Aging Clin Exp Res.* 2019;31(7):905-915.
57. Engelberg R, Downey L, Curtis JR. Psychometric characteristics of a quality of communication questionnaire assessing communication about end-of-life care. *J Palliat Med.* 2006;9(5):1086-1098.
58. Teno JM, Clarridge B, Casey V, Edgman-Levitan S, Fowler J. Validation of Toolkit After-Death Bereaved Family Member Interview. *J Pain Symptom Manage.* 2001;22(3):752-758.
59. Fine, J., & Gray, R. (1999). A Proportional Hazards Model for the Subdistribution of a Competing Risk. Journal of the American Statistical Association, 94(446), 496-509. doi:10.2307/2670170.
60. Dong H, Robison LL, Leisenring WM, Martin LJ, Armstrong GT, Yasui Y. Estimating the burden of recurrent events in the presence of competing risks: the method of mean cumulative count. *Am J Epidemiol.* 2015;181(7):532-540.

61. Prentice R, Williams B, and Peterson A. On the regression analysis of multivariate failure time data. Biometrika 1981;68:373-379. .
62. Julious SA. Sample Sizes for Clinical Trials. Chapman & Hall/CRC, Boca Raton, FL, 2010.
63. Reeves D, Howells K, Sidaway M, et al. The cohort multiple randomized controlled trial design was found to be highly susceptible to low statistical power and internal validity biases. *J Clin Epidemiol.* 2018;95:111-119.
64. Sudore RL, Boscardin J, Feuz MA, McMahan RD, Katen MT, Barnes DE. Effect of the PREPARE Website vs an Easy-to-Read Advance Directive on Advance Care Planning Documentation and Engagement Among Veterans: A Randomized Clinical Trial. *JAMA Intern Med.* 2017.

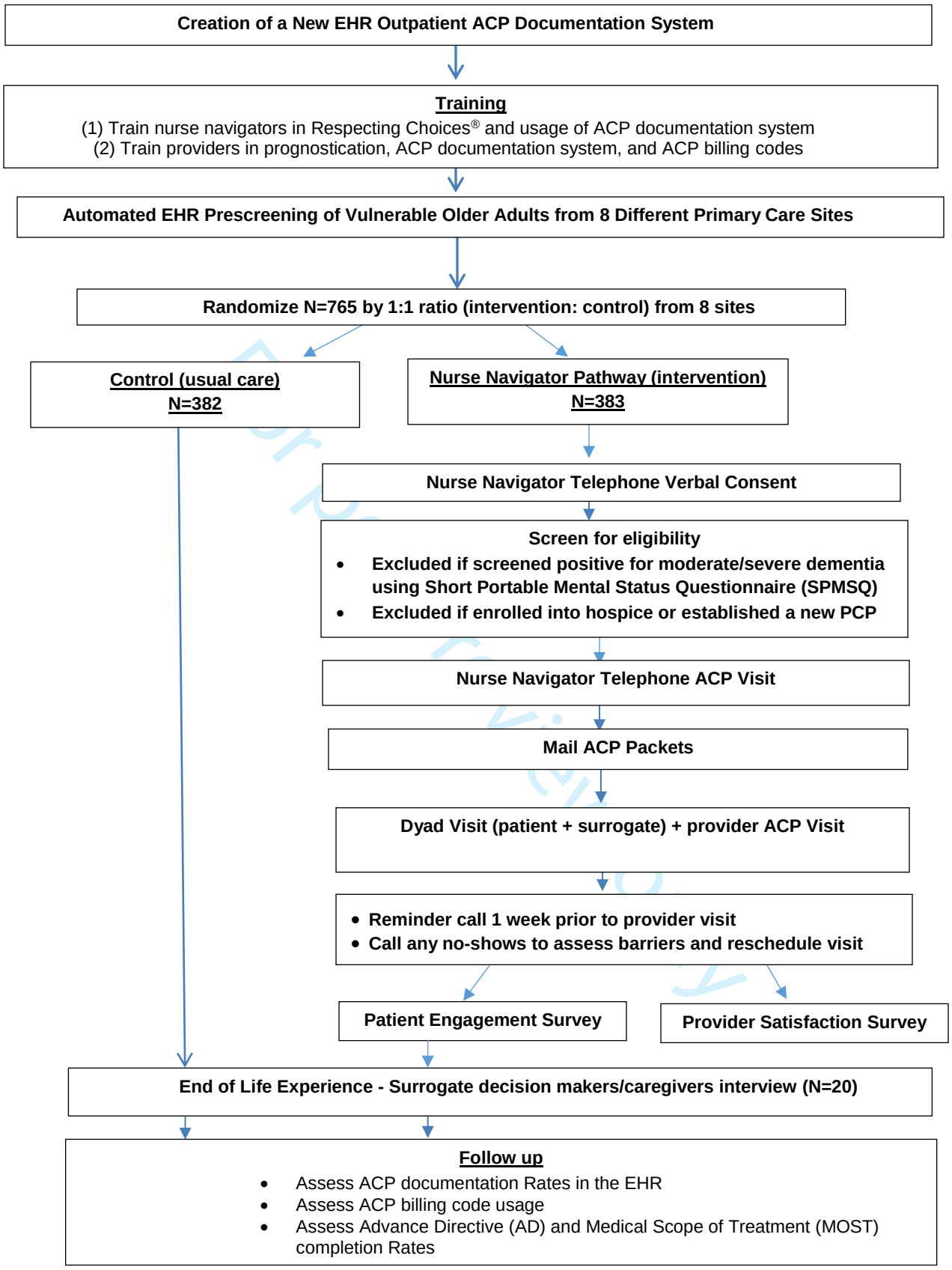

Figure 1. IMPACT Study Flow Diagram.

Abbreviations: ACP, advance care planning; EHR, electronic health record; PCP, primary care physician.

Wake Forest® School of Medicine

Integrated Multidisciplinary Patient and Famly Advance care Planning Trial for Vulernable Older Adults—IMPACT Study

Patient Telephone Script--Intervention

Hello, my name is_____ and I am a Nurse Navigator calling on behalf of Dr. _____ (name) to invite you to participate in a study conducted by Dr. Jennifer Gabbard. The study is call the IMPACT study and stands for Integrated Multidisciplinary Patient and Family Advance Care Planning Trial. This study is looking at finding better ways to engage older adults in advance care planning with their primary care providers using nurse navigators.

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.The goal of advance care planning is to help ensure that they receive medical care that is consistent with their values, goals, and preferences during serious or chronic illness. Thus it is important that your family and your health care providers know what your goals and values are so that care can be best aligned with that. For many people, this process also may include choosing and preparing another trusted person or persons to make medical decisions for them in the event they are unable to make their own decisions (example if they are too sick or if they are on life support) and completing what we call an advance directive.

You will receive a $25 gift card for participating. This phone call should not last longer than 30 minutes and an Advance Care Planning discussion with your primary care provider should not last more than 30 minutes.

Your participation in this study is completely voluntary. This means you do not have to participate if you don't want to. Our hope is that with your help we can continue to improve communication about your care with your provider and family member. Would you be willing to hear more information about this study?

(If yes, continue with below. If no, please ask, can you please tell me your reasons for not wanting to partipate? (e.g lack of time, lack of interest, perceived not important, etc and can you please also tell me if there are any ways that would have made this study more appealing/of interest to you?)

Thank you for agreeing to continue. Let me tell you more about this study and what will be required of you.

First, I will first ask you a couple of questions using the Short Portable mental Status Questionnaire (SPMSQ) to determine your elegibility. If you are eligible to participate in the study, I will briefly talk to you about Advance Care planning (ACP) and will ask you some questions about your overall goals and values. You have the right to stop participation at any point during this call if you choose. After this telephone call, I will then mail you more information to your home about Advance Care Planning.

Then I will schedule a visit for you to see your primary care provider and we ask that you to bring with you for that visit another trusted loved one, preferably whoever you think you would want to make medical decisions for you in the event they are unable to make their own decisions. (i.e if you ever become so sick you can't make your own decisions).

Please be aware that this type of visit will require a standard copayment as per your insurance requirements.

I will give you a call 5 days prior to your scheduled visit to remind you of your visit with your provider. At the end of the visit, we will ask you to complete a Patient Engagement Survey to give us feedback from the visit. You will receive a $25 gift card after you meet with your primary care provider and complete the Patient Engagement Survey.

You have the right to stop participation at any point in this study if you choose. No report generated by the study team will include your name or other identifying information. Refusal to participate will involve no penalty or loss of benefits to which you are entitled. The potential risks of this study are minimal and confidentiality of protected health information that you share with us will be maintained to the highest level. All information that we receive from you by phone and visit will be strictly confidential and will be kept under lock and key.

If you have questions or concerns regarding this study, you can contact Dr. Jennifer Gabbard at 336-716-8028 or the Wake Forest University Health Sciences Institutional Review Board (IRB) office at 336-716-4542. The IRB is a group of people who review the study to protect your rights and welfare.

Do you have any questions at this time?

By agreeing to participate in the study described above implies your consent to participate and your authorization to let Wake Forest School of Medicine use and share your health information as explainded above. If you don't agree to the use and sharing of your health information, you cannot participate in this study.

Would you like to participate in this study?

> If 'no', thank them for their time, please ask, can you please tell me your reasons for not wanting to partipate? (e.g lack of time, lack of interest, perceived not important, etc and can you please also tell me if there are any ways that would have made this study more appealing/of interest to you?) and then end the call.
>
> If 'yes', start discussion for Advance Care Planning and schedule a visit.

Thank you for agreeing to participate in this study.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	10
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	10
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	10
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and	n/a

		other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	1, 2
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	1, 2
Objectives	#7	Specific objectives or hypotheses	2
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	2
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	3

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	2-3
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	3
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	3
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	3-4
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque,	n/a

		sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9

Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	5
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	n/a
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	9
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further	n/a

		details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	n/a
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6-7
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	1
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	10

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	10
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a