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Planning Ahead: protocol for a randomised trial of advance care planning for community dwelling older adults at increased mortality risk

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ABSTRACT

Introduction An important goal of advance care planning (ACP) is ensuring that patients receive care concordant with their preferences. High-quality evidence is needed about the effect of ACP on this and other outcomes.

Methods and analysis Planning Ahead is a randomised controlled trial to test the effectiveness of facilitated ACP in community-dwelling older adults including those with normal cognition and those with Alzheimer's Disease and Related Dementias (ADRD) who are at high risk of death. The primary aim is to determine the effect of the intervention on discordance between preferences for medical treatments and the treatments received in the year after the intervention. Secondary outcomes include decision-making quality, care at the end of life and cost. Eligible patients have a primary care provider at one of two Midwest health systems, have an approximate 33% mortality risk and do not have a POLST form at baseline. Patients with capacity can invite the person they would choose to be their healthcare decision maker to participate as a study partner. A surrogate decision maker enrols and receives the intervention for patients who lack capacity due to ADRD. The intervention uses the Respecting Choices Advanced Steps (RCAS) model of ACP delivered by a registered nurse and includes identification of the patient's values and goals, education about ACP and the POLST form and the opportunity to complete a POLST form.

Ethics and dissemination The study is approved by the Indiana University Institutional Review Board. Primary and secondary analyses will be published in peer-reviewed journals. We also plan dissemination through the media. We will construct a deidentified data set that could be available to other researchers. Survey data will be preserved and shared via the NIH-supported National Archive of Computerised Data on Ageing's (NACDA) Open Ageing Repository (OAR).

Trial registration number NCT04070183.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study intervention is based on Respecting Choices, a rigorous, widely used approach to advance care planning.
⇒ Outcomes include an essential goal of advance care planning, providing care that is consistent with a person's goals and values.
⇒ Our analysis will include a mix of patient and surrogate decision makers. We made this decision to reflect the real world of clinical practice for older adults, where the need for surrogates is high due to Alzheimer's Disease and Related Dementias.
⇒ Although an eligibility criterion was that the participant did not have a POLST form at baseline, POLST utilisation is increasing, and we expect some utilisation in the control group. In our power calculations, we conservatively estimated a baseline rate of POLST completion at 0.10 for our control group. Based on our pilot, we anticipate we can increase this to at least 0.40 in the intervention group.

INTRODUCTION

Older adults with serious illness and multimorbidity often face decisions about their goals of care as the benefits of life-prolonging treatments decrease and burdens increase.[1 2] Advance care planning (ACP) is a multistep process that provides the opportunity to make decisions about goals and to record preferences in writing.[3] The objectives of ACP are to prepare patients and families for communication and decision-making, identify patient preferences and goals and ultimately ensure that the patient receives the care they prefer.[4–6]

ACP has been criticised by some who claim it fails to live up to its promise.[7] However, recent studies found that ACP affects a range of outcomes such as agreement between the patient/surrogate and physician, satisfaction with communication and reduction in surrogate distress.[8] Evidence shows that to be effective, ACP must incorporate high-quality communication, be facilitated by a skilled and trained clinician, include documentation of the outcome of the conversation, and be

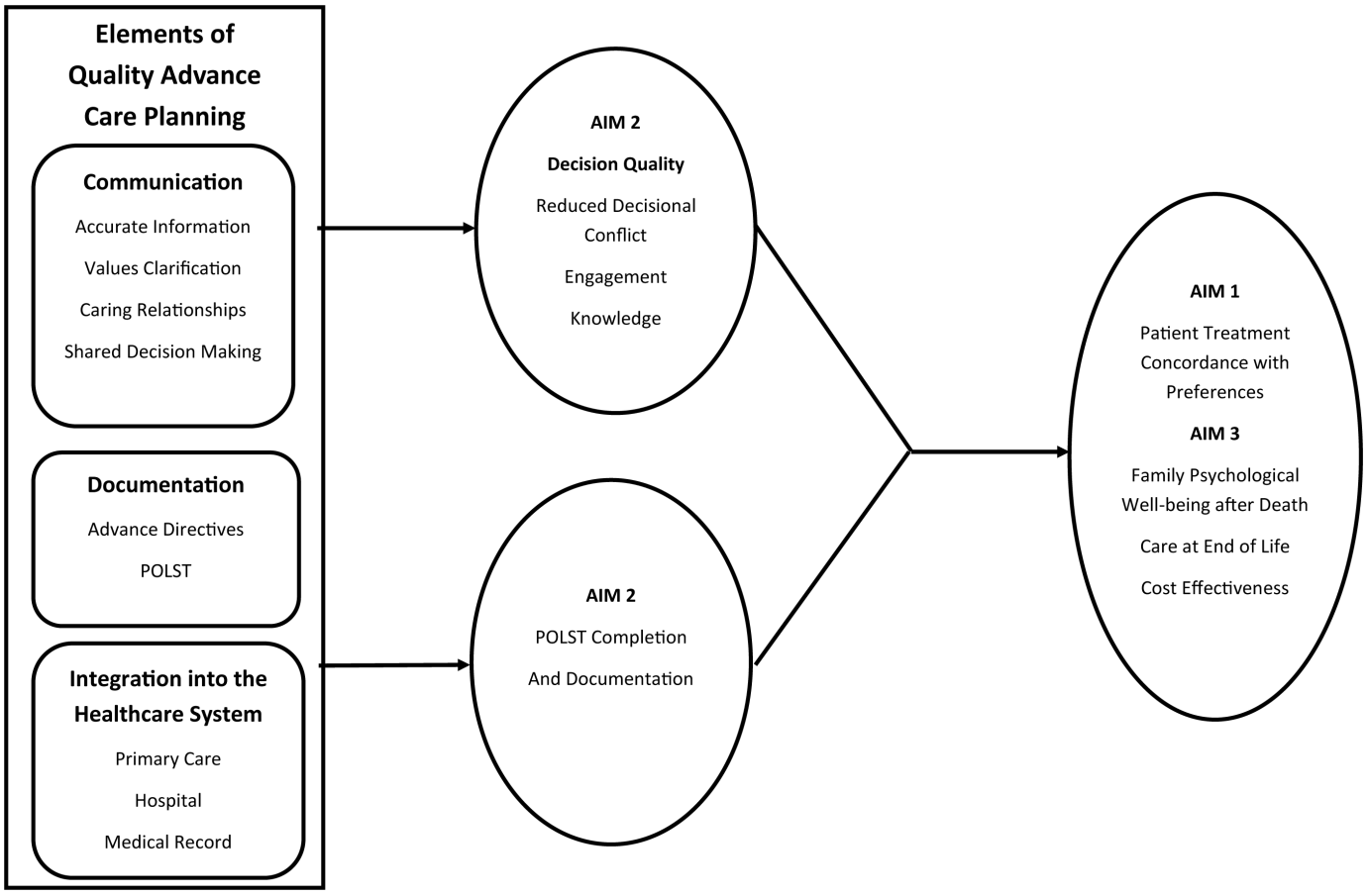

Figure 1 Elements and outcomes of advance care planning.

integrated into the healthcare system so the documentation is available when needed to make medical decisions (figure 1).[3 8 9]

POLST is an ACP tool that is widely used to document treatment preferences.[10] POLST results in medical orders valid throughout the healthcare system. However, the discussions necessary to support high-quality POLST decisions take time that is not easy to find in busy outpatient practices.[11] An alternative is to have the POLST conversation facilitated by a non-physician, followed by physician review. Training programmes such as the widely used *Respecting Choices Advanced Steps (RCAS)* were developed to ensure that facilitators are prepared to take on this role using a standardised, structured approach.[12] RCAS facilitators are trained to support patients in making decisions considering the patient's medical conditions and to document a surrogate decision maker if needed. Observational research indicates POLST affects delivery of medical interventions and improves concordance between patient preferences and care received.[13–16] However, there are no randomised, controlled trials of the impact of high-quality ACP models that include POLST facilitation such as RCAS.[15 17]

In summary, there is mounting evidence that ACP interventions are effective when they include a focus on high-quality communication with the patient, there is documentation of the preferences and there is integration into the health system so the information can be accessed when decisions are required (figure 1). These factors lead to better decision quality and higher documentation, which in turn reduce discordance between preferences and treatments and better outcomes at the end of life. We have pilot tested an approach to facilitate high-quality RCAS ACP conversations for community-dwelling older adults.[18] The goal of the Planning Ahead trial is to determine if this intervention improves ACP outcomes.

METHODS AND ANALYSIS

Planning Ahead is a randomised, parallel groups, attention-control trial of the RCAS model in community-dwelling older adults who qualify for POLST, including those with normal cognition and those with Alzheimer's Disease and Related Dementias (ADRD). We hypothesise that high-quality POLST facilitation will lead to lower discordance between the decision maker's (patient's or surrogate's) preferences for treatment compared with actual treatments received in the 12 months after the intervention (primary outcome), and will improve secondary outcomes including higher number of POLST forms completed and entered into the electronic medical record (EMR), higher decision quality, lower cost and better outcomes at the end of life for the subset of patients who die within 1 year. The study was funded on 1

September 2019 and began recruitment on 12 May 2020. Although we had planned for a 3 month startup, recruitment was delayed due to research restrictions during the early COVID pandemic. Enrolment and interventions have been completed, and we are currently collecting data for outcome measures.

Patient and public involvement

Patients or the public are not involved in the design, or conduct, or reporting of this research. However, we do intend to disseminate the results of this research to patients through the lay press and through ACP programmes at our participating hospitals.

Setting

The study is conducted in a Midwest metro area in primary care practices affiliated with a Federally Qualified Health Centre and a non-profit, statewide health system. The Indiana version of the National POLST (called Physician Orders for Scope of Treatment or POST) contains orders about four treatment categories: (1) cardiopulmonary resuscitation (CPR); (2) medical interventions; (3) antibiotics and (4) artificially administered nutrition. Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines were used in preparation of this manuscript.[19]

Participants

Participants are identified using International Classification of Disease-10 codes from the EMR that are used to determine the Gagne index, a validated mortality index.[20 21] Eligible participants are community-dwelling older adults who have not already completed a POLST form and who receive care at the participating primary care practices of the two health systems. Because RCAS and POLST are designed for patients with serious illness at increased risk of death, eligibility criteria include a 1 year estimate of mortality of about 33%, based on a score of 7 or higher on the Gagne Index[20] or a similar estimated 1 year mortality on one of several disease-specific indices designed for renal disease, heart failure, metastatic cancer, COPD and dementia (table 1). We selected the Gagne index because it is designed for community-dwelling older adults and can be calculated entirely from EMR data. This index is rated as 'good' by ePrognosis, a widely used repository of prognostic tools.[22] It has a c-statistic of 79% for predicting 1 year mortality.[20]

Both patients who can make their own medical decisions and those with impaired decision-making capacity due to ADRD and other causes are eligible. For those who lack capacity, an eligible surrogate must be available to participate in ACP facilitation on behalf of the patient. Study exclusion criteria include acute illness, current hospice enrolment, inability to complete study activities in English and for patients who lack decisional capacity, lack of a legal surrogate who is able to participate in ACP facilitation.

Table 1 Disease-specific indices used to determine patient eligibility

Condition	Index
End-stage renal disease	Liu Comorbidity Index[51]
Heart failure	Seattle Heart Failure Model[52]
Metastatic cancer	Eastern Cooperative Oncology Group Performance Status[53]
Chronic obstructive lung disease	The body mass index and blood results (B), age (A), respiratory variables (airflow obstruction, exacerbations and smoking) (R) and comorbidities (C) (BARC) scale[54]
Dementia	Functional assessment staging (FAST) in Alzheimer's disease[55]

Recruitment

The study began in May 2020 and is ongoing. Primary care providers (PCPs) are sent a list of potentially eligible patients identified through the EMR and asked to review the list to confirm eligibility. If the physician does not respond within 2 weeks, their patients are assumed to be eligible to approach for further screening. Those participants are then contacted by phone for further screening to determine eligibility and invite participation in the study (figure 2).

Because all interviews are conducted by phone, we received a waiver of written documentation of informed consent from the IRB. Research staff review a Study Information Sheet (see online supplemental materials) with each participant providing consent. Patients with decisional capacity provide informed consent and participate in all study activities. For these patients, we also attempt to enrol the person the patient would select (or has selected) as their legal representative. Including potential surrogates in the ACP process improves their ability to make decisions and reduces their decision-making-related distress.[23] Patients with decisional capacity but no available potential surrogate are still eligible to participate, which mirrors the real world of clinical medicine. For patients who lack capacity, we conduct ACP facilitation with the patient's authorised surrogate decision maker under Indiana law. To determine if the patient requires a surrogate, we first ask PCPs to indicate if the patient has capacity to consent for ACP and a POLST form. If the PCP indicates the patient lacks capacity, research staff call the appropriate surrogate decision maker. For all participants, research staff ask a brief, investigator-developed set of questions to determine if they understand the key elements of study enrolment, ACP and POLST completion. For patients who cannot answer the questions after further education and prompting, we ask permission to contact a surrogate decision maker for study enrolment. At the conclusion of the interview, participants undergo patient-level randomisation (figure 2) stratified by decision maker (patient or surrogate) using Research Electronic Data Capture (REDCap).

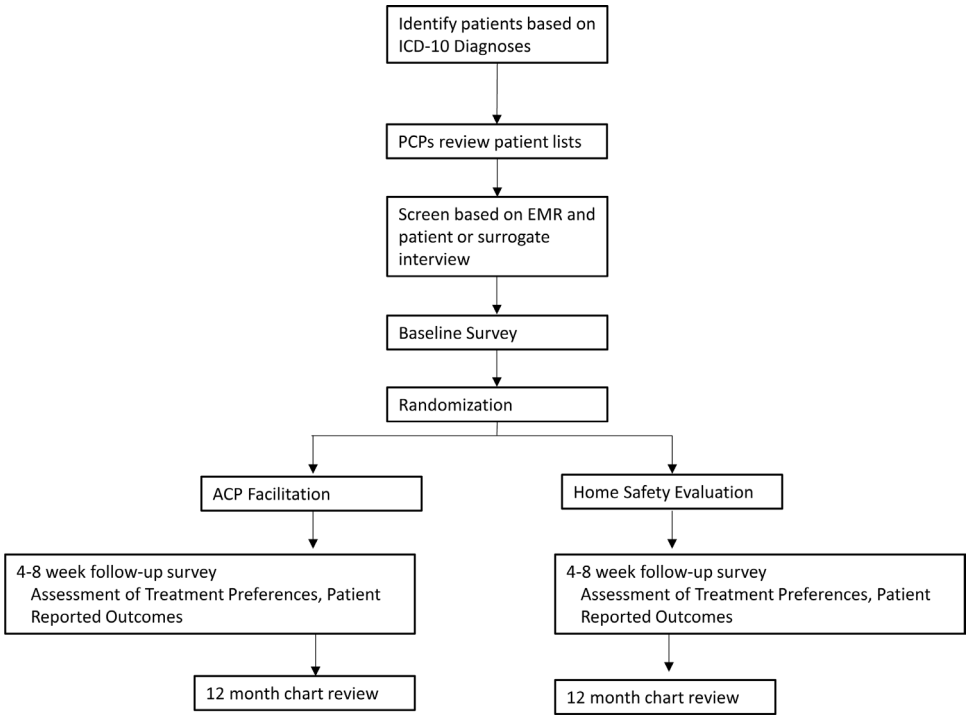

Figure 2 Study flow. ACP, advance care planning; EMR, electronic medical record; ICD-10, International Classification of Disease tenth revision; PCP, primary care provider.

The intervention

We selected registered nurses as ACP facilitators to ensure high familiarity with the interventions proposed in RCAS and POLST such as intubation and mechanical ventilation. The two facilitators underwent RCAS ACP Facilitator Certification, including six online educational modules that take 6–8 hours followed by 8 hours of in-person training including observed role play and a certification evaluation. In the intervention group, facilitators contact the decision maker (patient or surrogate) to schedule a dedicated visit for ACP facilitation within 3 months after enrolment, located in the patient's home, a neutral place of the patient's choosing, by telephone or by secure video conferencing. The conversation starts with an introduction to ACP and POLST, identifying a healthcare representative (for patients with decisional capacity), exploring understanding of medical condition and personal goals and discussing each section of the POLST form. The specific decision-making framework used to guide discussions about each section of POLST includes understanding of treatment decisions; benefits and burdens; goals for treatment and fears and concerns. Educational materials and decision aids available from the Respecting Choices programme are provided.

The facilitation process includes an opportunity to complete the POLST form if desired. After the visit, the facilitator completes a note in the appropriate EMR using a standard template developed for the study. If needed, the facilitator offers to complete a second visit to discuss the POLST form 1–2 weeks after the initial visit. If a POLST form is completed, the PCP is given the option of reviewing the form at a future visit with the patient and signing the form then or signing the form without further review. Forms are transported to the appropriate primary care site by study staff. Once forms are signed, the facilitator scans the form into the designated EMR.

Attention control

The control group receives a visit similar in duration to the intervention visit that consists of a home safety evaluation developed by the American Geriatrics Society Foundation for Health in Ageing.[24] These were conducted by the same two nurse facilitators.

Treatment fidelity strategies

We use treatment fidelity strategies consistent with the NIH Treatment Fidelity Working Group.[25] *Fidelity of facilitator training* is addressed by successful completion of RCAS facilitator certification and ensuring skill acquisition by observing the facilitators in standardised role plays during training using a standardised checklist developed by Respecting Choices (goal of >90% of required elements). *Drift in RCAS Facilitator skill* is monitored through self-assessment and review of intervention digital audio recordings by an investigator trained in RCAS (Dr Wocial), RCAS Faculty (Dr Hickman) or an RCAS Programme Leader (Ms. Ziemba) using the checklist. To establish inter-rater reliability, audio recordings of the first 17 RCAS conversations underwent review by two fidelity monitoring reviewers. Pairwise per cent agreement was calculated between Ms. Ziemba and each of the other raters, with a goal of achieving over 70% agreement among the raters for required items. For any items below

70%, an additional 12 recordings were reviewed, resulting in agreement above 70% for the previously low items.

Fidelity monitoring was then conducted for the first 25 interventions completed by each of two facilitators. The two facilitators achieved the goal of >90% of required elements in 23/25 interviews (facilitator 1) and 22/25 interviews (facilitator 2). The team had further discussion about any missed items prior to additional interventions. After the first 25 conversations, a random sample of 10% of all additional interventions is undergoing review by a single investigator. Finally, we assess *fidelity to treatment delivery* by measuring the percentage of eligible subjects completing the ACP facilitation visit, the number of POLST documents completed and the number scanned into the medical record.

Measures

Treatment discordance (primary outcome)

We developed two survey items to assess the decision maker's preferences for medical treatment before and after the intervention based on prior studies.[13 26–28] The items address preferences addressed in sections A (CPR) and B (medical interventions) of the POLST form (table 2).

Information about treatments received in the year after the intervention is obtained from the EMR supplemented with data from Indiana Health Information Exchange (IHIE), a large regional health exchange that provides data from other central Indiana health systems.[29 30] Chart reviews are conducted by the nurse facilitators and include data for 1 year after the study intervention. Each nurse

Table 2 Assessments of primary outcome of discordance between decision maker (patient or surrogate) preferences and treatment received in the year after the intervention

Survey question and responses	Medical interventions discordant with preferences
Code status There are a number of things doctors can do to try to revive someone whose heart has stopped beating. This usually includes pressing on the chest, shocks to the heart and use of a machine to help with breathing. This is called CPR. Some patients choose not to have CPR if their heart stops and die naturally. Patient: thinking of your current situation, would you want the doctors to use CPR to try to restart your heart? Surrogate: in the event (patient's) heart stopped beating, would you want the doctors to try to revive him/her?	
Yes (prefer full code status)	DNR order Death without CPR
No (prefer DNR status)	Full code order Cardiopulmonary resuscitation
Medical indications There are different preferences for medical treatment that may be considered for you if you are seriously ill. I will describe three possible choices. If you had to make a choice at this time, please tell me which of these options is the best choice for (you/patient name):	
Comfort measures Treatment is focused on relieving pain and discomfort as much as possible, but not getting other medical tests or treatments for illnesses or going to the hospital in the future unless it is necessary to provide comfort.	Chemotherapy Intubation/ventilation ICU admission Surgery* Procedures New dialysis/CVVH† Hospitalisation Emergency department visit
Limited additional interventions This care includes comfort measures as described in the first option as well as all other basic medical treatments. This would include going to the hospital if needed, medical tests to diagnose illness and treatments such as IV fluids or medicines. You would not receive life-sustaining treatments such as ventilators or breathing machines.	Hospice admission ICU admission Intubation/ventilation
Full intervention It includes treatments described in the first two options as well as full life support treatments, such as ventilators or breathing machines, with the goal of extending life as long as possible.	Hospice admission

*Excludes procedures indicated to be palliative.
†Excludes ongoing dialysis.
CPR, cardiopulmonary resuscitation; CVVH, continuous veno-venous hemofiltration; DNR, do not resuscitate; ICU, intensive care unit; IV, intravenous.

facilitator conducts reviews for the other nurses' patients while blinded to the patient's or surrogates' treatment preferences. Chart review accuracy was established by having the research nurses, the principal investigator (Dr Torke) and two research staff review 25 charts per nurse. Reviewers then held a consensus discussion resulting in final versions of each chart review. We then compared the nurses' initial, independent reviews to the training set and found there was 70% agreement or higher between the nurse reviews and the final consensus version for all chart review items.

After data are abstracted from the medical record, treatments received are compared with treatment preferences to determine whether treatments are discordant with preferences. For CPR, cases were judged to be discordant if the decision maker preferred full code status but the patient had a do not resuscitate (DNR) order written or the patient was not resuscitated during a cardiac arrest, or if the decision maker preferred DNR status but the patient had a full code order or underwent CPR (table 2). For medical interventions (section B), preferences for comfort-focused, limited additional or full interventions are compared with a previously published list of interventions to identify those that are discordant with each preference.[31] At study outset, there was discussion among investigators about whether surgery was potentially discordant with limited additional interventions, so surgeries in participants with limited interventions were reviewed. All were judged to be concordant with limited additional interventions, so surgery was removed from the list of treatments discordant with limited additional interventions. Because goals of care often change during a yearlong period, cases are not judged to be discordant if there was documentation of change in goals of care. All cases of discordance are reviewed by Dr Torke, and selected cases are reviewed by the investigator team to make a final determination of discordance.

POLST form completion

We track the number of patients with a completed POLST form in their primary health system's EMR by 3 months after POLST facilitation (table 3).

Decision quality

Participants respond to the Decisional Conflict Scale[32 33] regarding decisions about ACP. Participants completed the ACP Engagement Survey.[34] Knowledge was evaluated with the POLST Knowledge Scale.[35]

Care at the end of life

For patients who die during the year after enrolment, the EMR is reviewed to assess for life-sustaining treatments received within 30 days of death.

Psychological well-being

We administer measures of anxiety and depression[36 37] at baseline and postdeath (for those who enrolled with a study partner or surrogate). Post-traumatic stress is assessed in the postdeath interview (table 1).[38 39]

Cost

To examine the economic value of the intervention, we will compare delivery outcomes with the cost of the intervention using an ingredients methodology.[40 41] The ingredients approach entails: (1) systematically identifying the inputs necessary for the intervention; (2) pricing each ingredient to determine the total cost of the intervention in a given time frame and (3) analysing the costs. Costs captured in this analysis will include, but are not limited to: clinician time, recruitment and training costs and data transfer. We will then examine the cost needed to prevent (1) one intensive care unit (ICU) admission and (2) one hospitalisation.

Other variables

We measure biological and social variables that may be associated with ACP, including sex, age and mortality risk,[20] cognitive impairment, functional status,[42 43] health literacy, race, religion and socioeconomic status (SES).[44–46]

Data collection

Interviews are conducted by an RA blind to study group assignment via phone at baseline and 4–8 weeks after completion of the ACP facilitation intervention. The baseline interview includes patient and caregiver/surrogate demographics and assessments of decision maker treatment preferences, cognitive function, psychological distress, health literacy, religion, functional status, prior ACP and ACP engagement (table 2). Follow-up interviews assess treatment preferences, decisional conflict regarding ACP, ACP engagement and POLST knowledge. For patients who die within 1 year of enrolment and for whom a healthcare representative or surrogate is also enrolled with the patient, a bereavement interview is conducted with that person 2–4 months after death (or within 2 months of when we become aware of the death). Chart reviews to assess discordance between preferences and treatment for all patients and care in the 30 days before death are conducted 12 months after the intervention visit. All data are stored in a Health Insurance Portability and Accountability Act (HIPAA)-compliant, password-protected REDCap database.

Data analysis

Aim 1: to test the effect of high-quality POLST facilitation delivered in the home compared with attention control on discordance between preferences for treatment and treatments received in the subsequent 12 months (primary outcome)

Hypothesis 1

Discordance between preferences for medical intervention documented after the intervention compared with care received in the subsequent 12 months will be lower in the intervention compared with control group. The dichotomous outcome variable (discordance) will be created by coding for each patient whether one or more treatments were discordant with preferences for care. Logistic regression models will be used to compare groups on the odds of discordance,

Table 3 Study measures

Construct	Measure	Number of items	Reliability (Cronbach's alpha)	Source of data	Time of data collection
Baseline characteristics					
Patient demographics (age, sex, education, SES, race/ethnicity)	N/A	N/A	N/A	Decision maker	Enrolment
Cognitive impairment	Telephone Interview for Cognitive Status[42]	11	N/A	Patient or surrogate	Enrolment
Mortality risk	Gagne Mortality Index[20]	20	N/A	Chart review	Prior to enrolment
Surrogate/caregiver demographics (age, sex, education, income, race/ethnicity, relationship to patient)	N/A	N/A	N/A	Surrogate/caregiver	Enrolment
Health literacy	3-item telephone screen[56]	3	N/A	Decision maker	Enrolment
Religiosity	Duke University Religion Index[57]	5	0.75	Decision maker	Enrolment
Functional status	Katz Activities of Daily Living[43]	6	0.79	Patient or surrogate	Enrolment
Previous ACP	Investigator developed	3		Decision maker	Enrolment
Prior discussions					
Healthcare representative					
Living will					
Aim 1					
Treatment discordance with preferences	Based on Hickman *et al*,[13] refined by the investigators	N/A	N/A	Follow-up interview and chart review	12 months
Aim 2					
POLST completion/scanned into EMR	N/A	1		Chart review	3 months, 12 months
Decision quality, for ACP	Decisional Conflict Scale[58]	16	0.78	Decision maker	Follow-up
Engagement in ACP	ACP Engagement Survey[34]	6	0.94	Decision maker	Enrolment/follow-up
POLST knowledge	POLST Knowledge Survey[35]	21	0.072	Decision maker	Follow-up
Aim 3: surrogate/caregiver psychological outcomes (for patients who die)					
Treatment at end of life (for patients who die)	Chart review developed by the research team	N/A	N/A	Chart review	Postdeath
Post-traumatic stress	Horowitz Impact of Events Scale-Revised[38 39]	22	0.96	Surrogate/caregiver	Postdeath
Anxiety	Generalised Anxiety Disorder-7[37]	7	0.92	Surrogate/caregiver	Baseline, follow-up, postdeath
Depression	Patient Health Questionnaire-8[37]	8	0.86–0.89	Surrogate/caregiver	Baseline, follow-up, postdeath
Intervention cost	Cost-effectiveness ratio of intervention cost relative to 1. Hospitalisations 2. ICU admissions	N/A	N/A	Model implementation and operation, chart review	Ongoing

ACP, advance care planning; EMR, electronic medical record; ICU, intensive care unit; N/A, not applicable; SES, socioeconomic status.

while adjusting for potential covariates, which would include biologic variables, illness severity, health literacy and whether it is a patient or surrogate being interviewed. We will also conduct a mediation analysis based on our conceptual model, examining whether discordance is partially mediated by POLST form completion and/or each of the measures of decision quality as potential mediators. Path analysis will be used to estimate standardised coefficients (and 95% CIs) for direct, indirect and total effects of mediation models.

Although randomisation should minimise the likelihood of differences in demographic and clinical variables between treatment groups, t-tests and χ^2 tests will be performed to compare randomised groups on these baseline characteristics to ensure that this is the case and to determine if any characteristics should be included as covariates in the models. If t-test parametric assumptions are violated, non-parametric Wilcoxon rank sum tests or data transformations will be used on continuous variables. Fisher's Exact tests will be used instead of χ^2 tests

on categorical variables if 20% or more of cells contain expected cell counts less than 5.0.

Aim 2: to test the effect of POLST facilitation on intermediate outcomes

Hypothesis 2a

A significantly higher proportion of patients in the intervention group will have POLST forms in the EMR compared with patients in the attention control group. Logistic regression models will be used to determine if there are significant differences between study groups in the proportion of patients with any POLST form by 3 months after POLST facilitation, while adjusting for potential covariates that may affect approaches to ACP (sex, age, illness severity, religion, race and SES). We will also control for whether it is a patient or surrogate being interviewed. Adjusted ORs and 95% CIs will be reported.

Compared to the attention control group, patients in the intervention group will have better decisional quality regarding ACP, as measured by:

Hypothesis 2b

Lower scores on the Decisional Conflict Scale (DCS).

Hypothesis 2c

Higher ACP engagement, as measured by the ACP Engagement Survey.

Hypothesis 2d

Higher knowledge about the POLST programme, as measured by the POLST Knowledge Survey.

Linear regression models will be used to determine if there are significant differences in each of the three decision-making outcomes (decision quality, engagement and knowledge) between the treatments, while adjusting for potential covariates, including biologic variables, cognitive status, functional status, health literacy and decision maker. Standardised regression coefficients (effect size) and 95% CIs will be reported. All analyses will be conducted based on intention to treat.

Aim 3: to test the effect of POLST facilitation on secondary outcomes of end-of-life treatment, the psychological well-being of surrogates after the patient's death and cost

Hypothesis 3a

For the subset of patients who died in the 12 months after POLST facilitation, life-sustaining treatments received in the 30 days before death will be lower in the intervention compared with the control group.

Hypothesis 3b

For the subset of patients who died in the 12 months after enrolment, surrogate psychological distress including post-traumatic stress (Impact of Events Scale-Revised (IES-R)), anxiety (Generalized Anxiety Disorders-7 item (GAD-7)) and depression (Patient Heatlh Questionnaire-8 (PHQ-8)) will be lower in the intervention compared with the control group.

Logistic regression models will be used to determine if there are significant differences in these odds of receiving aggressive treatments in the 30 days before death, while adjusting for the covariates as described above. For H3b, linear regression models will be used to determine if there are significant differences in these three psychological outcomes (post-traumatic stress, anxiety and depression) between the treatments, adjusting for potential covariates. In addition, baseline values for distress outcomes will be included in the model.

The linear regression and logistic regression models will be estimated using the SAS PROC GENMOD procedure. PROC GENMOD allows for the specification of the appropriate link function (identity for linear regression, logit for logistic regression) and error distribution (normal for linear regression and binomial for logistic regression).

Hypothesis 3c

We will determine the programme cost associated with (1) the prevention of one ICU visit and (2) the prevention of one hospital admission. We will calculate the average cost-effectiveness ratio (ACER) of the intervention to reduce one ICU visit and one hospital admission based on the ingredient input quantities and costs of the intervention. These costs will be aggregated to calculate the total cost of the intervention and then compared directly with the change in hospital admissions and ICU admissions found earlier in aim 3a via the ACER, so we will ultimately know the cost per unit improvement in this outcome.

Non-linearity in regression models between continuous predictors and continuous outcomes or the logit of dichotomous outcomes will be handled with polynomial terms or indicator variables or data transformations. All analyses will be performed using SAS V.9.4 (SAS Institute, Cary, NC). All statistical tests will be two-sided and conducted at the 0.05 significance level.

Missing data

We will handle missing data by imputing the mean of available items for scale scores (for specific person and scale) if 50% or more items are not missing for that person and scale. We will examine differences between those who reported versus those missing the outcome to gauge potential bias due to cohort missingness, for which we will examine baseline demographics as well as interventionist, number of visits attended, type of visit and season or month of planned interview dates to determine the potential for time 'trends' to be associated with missingness.

Power and sample size

We conducted sample size calculations for the primary outcome of discordance. With 175 patients per group, or 350 patients total, our study will have a power=0.86, with an alpha level of 0.05, for a two-sided Wald test to detect a difference of 15% in treatment discordance rate between groups, assuming the treatment group lowering from 35% to 20% and the control group remaining at 35%.

We have powered the study to detect an effect size of 0.30 1-SD-unit difference in the DCS means with a power of 0.80. This requires 175 participants per group (350 total). Based on prior research and early implementation of the study,[47] we are experiencing a 10% loss to follow-up, so we will enrol 389 participants.

Ethics and dissemination

The study is approved by the Indiana University Institutional Review Board. Primary and secondary analyses will be published in peer-reviewed journals. We also plan dissemination through the media. We will construct a deidentified data set that could be available to other researchers. Survey data, technical appendix and statistical code will be preserved and shared via the NIH-supported National Archive of Computerised Data on Aging's (NACDA) Open Aging Repository (OAR). Data will be released 1 year after publication of prespecified study outcomes.

Adverse events are reported on the same day of occurrence by research assistants and ACP facilitators. The study is monitored by a Data Safety and Monitoring Board appointed by the NIA and overseen by an NIA Programme Officer. The Board includes a biostatistician and three additional scientists with expertise in ACP. It meets every 6 months during the study to review enrolment, follow-up, any protocol changes or deviations and adverse events. No interim analyses are planned.

DISCUSSION

Given recent controversy about the value of ACP, rigorous controlled trials are needed to establish whether ACP affects important patient and caregiver outcomes.[7 16] We selected discordance between care preferences and care received as the primary outcome because an important goal of ACP is to ensure that patient care is guided by the patient's own preferences. However, this outcome is challenging to assess as predicting one's future healthcare needs is difficult and preferences may change over the course of a year without being well documented.[48 49] We developed an approach to measuring discordance that includes two preference assessment questions that closely mirror the POLST form, followed by a chart review to determine if medical interventions occurred that conflict with preferences.[31] To account for changes in preferences, the chart is reviewed for goals of care conversations or new advance directives that indicate a change in goals. Such cases are judged to be concordant with preferences.

The study required several methodological decisions with potential limitations. Our analysis will include a mix of patient and surrogate decision-makers. We made this decision to reflect the real world of clinical practice for older adults, where the need for surrogates is high due to ADRD. Although we recognise that there are fundamental differences in decision making for oneself versus surrogates, the process of ACP facilitation has fundamental elements that are the same. We will address this by stratifying enrolment by decision maker (patient vs surrogate) and controlling for decision maker in the analysis. Second, although an eligibility criterion was that the participant did not have a POLST form at baseline, POLST utilisation is increasing, and we expect some utilisation in the control group.[50] In our power calculations, we conservatively estimated a baseline rate of POLST completion at 0.10 for our control group. Based on our pilot, we anticipate that we can increase this to at least 0.40 in the intervention group.[18] Because the study took place in one Midwestern city, it may not generalise to other locations. Furthermore, because the Hispanic population of Indiana is fairly young, we did not include Spanish speakers in the study.

The COVID pandemic posed additional challenges. The intervention was originally designed to be offered in person, generally in the home. At the onset of the pandemic, we developed alternative strategies to deliver the intervention by secure video platform or by phone. This provided additional challenges related to navigating technology and providing written materials to participants in advance of the visit.

In conclusion, this study of 389 community-dwelling older adults will test ACP facilitation, including the use of POLST, on outcomes important to patients and families. Findings can help The Centers for Medicare and Medicaid, policy makers and health systems to improve the ACP process. If successful, the POLST facilitation intervention can be widely implemented in community settings to improve the quality of ACP decision-making and treatment of older adults with serious and life-threatening illness.

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