

BMJ Open Improving advance care planning for English-speaking and Spanish-speaking older adults: study protocol for the PREPARE randomised controlled trial

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ABSTRACT

Introduction: Advance care planning (ACP) is a process that allows patients to identify their goals for medical care. Traditionally, ACP has focused on completing advance directives; however, we have expanded the ACP paradigm to also prepare patients to communicate their wishes and make informed decisions. To this end, we created an ACP website called PREPARE (<http://www.prepareforyourcare.org>) to prepare diverse English-speaking and Spanish-speaking older adults for medical decision-making. Here, we describe the study protocol for a randomised controlled efficacy trial of PREPARE in a safety-net setting. The goal is to determine the efficacy of PREPARE to engage diverse English-speaking and Spanish-speaking older adults in a full spectrum of ACP behaviours.

Methods and analysis: We include English-speaking and Spanish-speaking adults from an urban public hospital who are ≥ 55 years old, have ≥ 2 chronic medical conditions and have seen a primary care physician ≥ 2 times in the last year. Participants are randomised to the PREPARE intervention (review PREPARE and an easy-to-read advance directive) or the control arm (only the easy-to-read advance directive). The primary outcome is documentation of an advance directive and/or ACP discussion. Secondary outcomes include ACP behaviour change processes measured with validated surveys (eg, self-efficacy, readiness) and a broad range of ACP actions (eg, choosing a surrogate, identifying goals for care, discussing ACP with clinicians and/or surrogates). Using blinded outcome ascertainment, outcomes will be measured at 1 week and at 3, 6 and 12 months, and compared between study arms using mixed-effects logistic regression and mixed-effects linear, Poisson or negative binomial regression.

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 and a data safety monitoring board. The results of this study will be disseminated to academic and community stakeholders.

Trial registration numbers: NCT01990235; NCT02072941; Pre-results.

Strengths and limitations of this study

- This study addresses gaps in advance care planning (ACP) for racially and ethnically diverse English-speaking and Spanish-speaking older adults based on a novel comprehensive ACP paradigm.
- The development of the PREPARE intervention was based on extensive published formative research in which the community, key stakeholders and the target population were included in the development of the website.
- This study measures the process of ACP and a full range of ACP outcomes including behaviour change and several ACP actions, such as discussions and documentation, over a 12-month follow-up period.
- Surrogate recruitment takes a great deal of time and may present obstacles in enrolling surrogate participants.
- This study is only occurring in four sites in the San Francisco Bay Area and may have limited generalisability.

INTRODUCTION

The population is ageing,^{1 2} and the prevalence of chronic disease is increasing, especially among underserved and vulnerable populations (ie, economically disadvantaged, racial and ethnic minorities, the uninsured, etc).³ A critical aspect of chronic and serious disease management is advance care planning (ACP), a process whereby patients plan for their future medical care. Traditionally, advance directives have been the main focus of ACP, but unfortunately, most are written in complex legal language.⁴ This lack of attention to limited health literacy and limited English proficiency may explain why advance directives are often not completed and may explain, in part, why <20% of racially and ethnically diverse, older adults engage in ACP by the end of life.⁵⁻⁸

Furthermore, for ethnic minorities, a population rapidly increasing in the USA, medical decisions are often complicated by a lack of trust and perceived racism.^{9–11} Ethnic minorities are also more likely to prefer aggressive treatment, mistrust advance directives and have non-autonomous views on decision-making (ie, prefer that family and doctors make medical decisions for them).^{9 12–16} Hispanics/Latinos account for 15% of the US population, a proportion projected to grow to 30% by 2050.^{1 2} Spanish-speaking patients face significant communication barriers, and literacy-appropriate and language-appropriate ACP tools that address unique aspects of Latino culture (eg, *familismo* or a strong commitment and orientation to the family) are lacking.¹⁰ In addition, the mean reading level in the USA is only at the eighth grade level, and for adults over 65 years of age it is only at the fifth grade level.^{17 18} Patients with limited literacy often lack self-efficacy to communicate their wishes or ask questions,¹⁹ and the combination of limited literacy and limited English proficiency results in low satisfaction with doctor–patient communication and decision-making.^{20–22} However, studies show that patients can be motivated to take action in response to culturally and linguistically appropriate information they trust and can understand.^{8 23}

To address these gaps in ACP and shortcomings of advance directives, we developed a novel comprehensive paradigm of ACP focused on preparing patients to identify their wishes, communicate with surrogate decision-makers and clinicians, and make complex decisions over the course of chronic and serious illness.²⁴ This approach recognises that patients' wishes change based on changing clinical contexts and that advance directives are but one tool to be used to inform in-the-moment decision-making.^{25 26} To address the gaps in ACP for racially and ethnically diverse older adults, and on the basis of the new comprehensive ACP paradigm, we created the interactive, patient-centred PREPARE website (prepareforyourcare.org) in English and Spanish that is culturally, linguistically and literacy appropriate. PREPARE has been shown in pilot studies among English speakers to help older adults engage in the ACP process, but it has yet to be tested in a randomised trial with English-speaking and Spanish-speaking older adults.²⁷ Both the new ACP paradigm and the PREPARE intervention have been described in detail elsewhere.^{27 28} In addition, a description of a related trial of the efficacy of PREPARE among US Veterans describes the theoretical framework underlying the PREPARE website.²⁸

METHODS AND ANALYSIS

Study overview

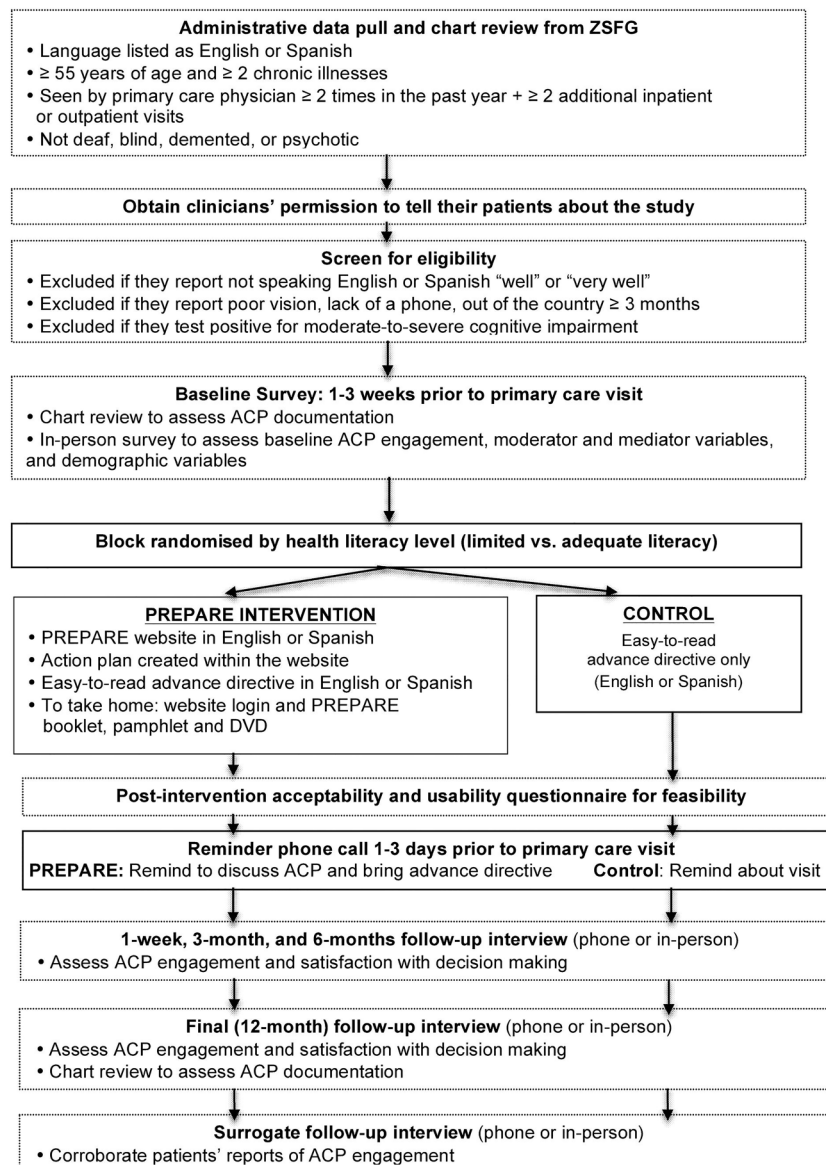
This study is a randomised controlled trial (RCT) that uses blinded outcome ascertainment to determine the efficacy of the ACP PREPARE website to engage ethnically diverse English-speaking and Spanish-speaking

older primary care patients in the ACP process. First, administrative data and chart review are used to determine potentially eligible patients (figure 1). Then primary care clinicians' permission is obtained to allow the study team to inform their patients about the study. Patients are then recruited, screened for eligibility and scheduled for a baseline interview 1–3 weeks before an upcoming primary care appointment. Next, informed consent is obtained, and those patients who provide consent are randomised to the PREPARE intervention arm (ie, the PREPARE website with action plan exercises plus an easy-to-read advance directive plus PREPARE materials to take home, which include a website login, and a PREPARE pamphlet, booklet and DVD) or the control arm (ie, an easy-to-read advance directive alone). See figure 1 and a full description of the intervention below. Blinded outcome ascertainment is then conducted at 1 week, and at 3, 6 and 12 months after the primary care appointment. At the end of the study, patients are asked if they are willing to refer their surrogate decision-makers to the study, if available, to corroborate patients' reports of engagement in ACP discussions and documentation. Chart review is also conducted at baseline and at the end of the study to determine ACP documentation. We chose an active control arm (ie, an easy-to-read advance directive) because we believe provision of an advance directive for chronically and seriously ill older patients should be the standard of care, even if it is not often 'usual' care in clinical practice.⁸ In addition, the easy-to-read advance directive used in this study has been adopted by the Zuckerberg San Francisco General Hospital (ZSFG) and is available in the primary care clinics.

Research aims and study hypotheses

The aims of this study are to (1) determine the efficacy of PREPARE to engage diverse English-speaking and Spanish-speaking older adults with chronic illness in ACP compared with controls (AD only) and (2) determine whether PREPARE efficacy varies by race/ethnicity, literacy, clinician–patient language concordance and patient's desired role in decision-making. Our primary hypothesis is that the PREPARE programme plus an easy-to-read advance directive will result in greater documentation of ACP wishes, including advance directives and documentation of ACP discussions in the medical record, than an easy-to-read advance directive alone in elderly populations with chronic illness. Our secondary hypotheses are that, compared with an advance directive alone, PREPARE will result in more engagement in behaviour change processes concerning ACP, including increased self-efficacy and readiness, as well as greater engagement in a full range of ACP actions, including discussions with surrogate decision-makers and other trusted family and friends. Secondary outcomes will be ascertained using validated surveys.^{29–31} We also hypothesise that PREPARE will result in improved satisfaction with patient–doctor communication and

Figure 1 PREPARE Study Flowchart Among English and Spanish-speaking Older Adults. ACP, advance care planning; ZSFG, Zuckerberg San Francisco General Hospital.



informed medical decision-making and that PREPARE efficacy may vary across moderator variables such as patient health literacy, clinician–patient language concordance and patients' desired role in decision-making.

Study setting

Recruitment for this randomised trial is occurring in four separate primary care clinics associated with ZSFG and the San Francisco Health Network (SFHN) in San Francisco, California. These four clinics are housed in three separate physical locations in San Francisco. ZSFG is an urban public hospital that, with the SFHN, serves racially and ethnically diverse, low-income and indigent patients; 30% of patients are Spanish-speaking.⁸

Eligibility criteria

Older adults are included in this study if they self-report speaking English or Spanish 'well' or 'very well'; are 55 years of age or older; have ≥ 2 chronic illnesses

determined by chart review; have seen a primary care clinician (physician, nurse practitioner or physician assistant) at ZSFG/SFHN-affiliated primary care clinics ≥ 2 times in the past year (an indication of established primary care); and have had ≥ 2 additional outpatient or inpatient visits in the past year (an indication of ongoing access to care and severity of illness). Their primary care clinician must also give us permission to contact them to tell them about the study (table 1). Patients will be excluded if they have medical record documentation of being deaf, blind, having dementia or being psychotic, or are deemed by their clinician to be too mentally or physically ill to participate. Through in-person or phone screening by study staff, patients are also excluded if they self-report vision too poor to read a newspaper, lack of a phone (needed for follow-up interviews and scheduling) or plans to be out of the country for ≥ 3 months; if they screen positive for moderate-to-severe cognitive impairment using the validated Short Portable Mental

Status Questionnaire followed by the Mini-Cog,^{32–34} or self-report or are determined by study staff to be blind, deaf, intoxicated or actively psychotic. Since ACP is an iterative process, participants with prior ACP experiences (eg, an advance directive) are not excluded.

We are also recruiting participants' self-identified surrogate decision-makers. Surrogates are included if the participant provides the surrogate's name and contact information and gives the study team permission to contact him or her. Through in-person or phone screening by study staff, surrogates are excluded if they self-report having dementia or test positive for moderate-to-severe cognitive impairment,^{32 33} or self-report or are determined by study staff to be blind, deaf, intoxicated or actively psychotic (table 1).

Recruitment and retention

To facilitate recruitment, 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, as well as dates of outpatient primary care clinic appointments in the past year and up to 3 months in the future, other appointments and hospitalisations and emergency room visits in the past year, and the name of patients' outpatient primary care providers. From these data, we obtain a list of potentially eligible patient participants and send a secure email to their primary care providers asking for permission for our study team to tell their patients about the study through a recruitment opt-out study letter, followed by phone or in-person recruitment. Clinicians can decline or approve

Table 1 Inclusion and exclusion criteria by type of study participant

Patient	
Inclusion criteria	55 years of age or older Obtains care in the primary care clinics at ZSFG Hospital Has been seen at least twice in the last year by a primary care provider (a measure of established primary care) and had at least 2 additional visits to ZSFG in the past year (a measure of frequent the medical centre)
Exclusion criteria	Dementia by ICD-9/ICD-10 codes, clinician assessment, chart review or self-report Blindness or poor vision by ICD-9/ICD-10 codes, clinician assessment, chart review, self-report of blindness or the inability to read print on a newspaper ⁵² Deafness by ICD-9/ICD-10 codes, clinician assessment, self-report, chart review or research staff assessment Cognitive impairment as assessed by research staff of any deficits on the validated SPMSQ ⁵³ and the Mini-Cog ^{32 54} Delirium or psychosis as assessed by a clinician or research staff Does not report speaking English or Spanish 'well' or 'very well' No phone for additional study contacts and follow-up interviews Active drug or alcohol abuse within the past 3 months determined by clinician assessment, self-report, chart review or research staff assessment Patients who report they will be out of town during their scheduled follow-up interview dates outside of a window of 3 months Patients who cannot answer consent teach-back questions after 3 attempts
Surrogate	
Inclusion criteria	18 years of age or older An enrolled patient must identify the surrogate as someone who could make medical decisions for him or her if needed An enrolled patient must provide the surrogate's contact information and give permission to contact their potential surrogate
Exclusion criteria	Self-reported dementia, blindness or deafness Cognitive impairment as assessed by research staff of any deficits on the validated SPMSQ ⁵³ and the Mini-Cog ^{32 54} Delirium or psychosis as assessed by research staff Does not report speaking English or Spanish 'well' or 'very well' No phone for screening and phone interviews Surrogates who report they will be out of town during their scheduled follow-up interview dates outside of a window of 3 months Surrogate for whom we cannot schedule an interview >6 months from the patient's final 6-month follow-up interview date Surrogates who we have attempted to contact 5 times or more without a response Surrogates who cannot answer consent teach-back questions after 3 attempts

ICD, International Classification of Diseases; SPMSQ, Short Portable Mental Status Questionnaire; ZSFG, Zuckerberg San Francisco General.

all of their patients or opt-out individual patients from the patient list provided in the secure email. Clinicians are informed that if they do not respond to our requests within three attempts, we will assume assent to contact their patients.

Study-related fliers written at a fifth grade reading level in English and Spanish are posted in approved areas in ZSFG/SFHN-affiliated primary care clinics. In addition, recruitment letters written at a fifth grade reading level in English and Spanish are mailed and describe the research study as well as provide a telephone number to either opt out or to hear more about the study. Although patients can opt-out at any time, those who do not call the study staff to decline participation within 1 week of the mailings are deemed eligible to be contacted to describe the study, assess willingness to participate and assess study eligibility. To standardise the timing between intervention exposure and primary care follow-up, we schedule patients for the baseline interview and exposure to PREPARE or the control intervention 1–3 weeks prior to their upcoming primary care appointment. Weekly administrative data pulls from the electronic health record identify patients with upcoming primary care appointments and are used to target patient recruitment efforts.

English-speaking and Spanish-speaking surrogates are recruited through enrolled patient referral after the patient has finished his or her 12-month interview. Depending on the information provided by the patient, we may contact the potential surrogate participant in the clinic, or by phone, email or postal mail.

Patients who consent and enrol are paid \$50 for the baseline interview and \$25 for each of the 1-week, 3-month, 6-month and 12-month interviews. All surrogates are paid \$25 for one interview at 12 months.

Diverse vulnerable populations are often difficult to recruit for research studies. We employed several strategies to enhance our recruitment. First, we attempted to hire individuals who had experience with diverse populations and individuals who were bilingual (native Spanish-speaking) and bicultural. Furthermore, we conduct extensive sensitivity training with all research staff and require staff to use approved study scripts when speaking to patients. These study scripts and all study materials used for recruitment have been vetted, updated and approved by our patient advisory and clinical advisory boards. All materials and study scripts are written at a fifth grade reading level and are provided to patients in their preferred language (ie, English or Spanish).

Consent procedures

We use a modified consent process that several co-authors designed for vulnerable populations.^{28–35} Consent forms written at the fifth grade reading level are provided and read to participants in English or Spanish. This review is then followed by standardised ‘teach-to-goal’ questions to ensure understanding.

If potential participants cannot correctly complete the teach-back process after three attempts, the patient is deemed ineligible. For surrogates, if they are available in person, written informed consent is also obtained using the teach-back method. Since some surrogates may live outside of the area, we have permission from the University of California, San Francisco (UCSF) Institutional Review Board (IRB) to obtain verbal consent by phone if the surrogate is able to accurately answer all consent verification questions on teach-back within three attempts.

The consent form has been approved by the UCSF and ZSFG IRBs, the patient/clinical advisory board and the Data Safety Monitory Board (DSMB). The consent form states the following for the purpose of the study: “Why is this study being done? Sometimes patients and their families have to make hard medical decisions. We want to design and test an easy-to-understand handout to help. This handout will help people think about their values, or what is most important to them in their life. It will also help prepare patients to make medical decisions.” We used the word ‘handout’ because, in pilot testing, both groups are given handout materials and written advance directives. For randomisation we explain, “We will ask you to look over a handout and answer some questions about your experience with making medical decisions. There will be two groups that will be given different handouts. You will have a 50/50 chance of being in either group.”

Intervention and control conditions

As previously described, PREPARE is an easy-to-use, patient-centred, interactive website that is available in English or Spanish, is written at a fifth grade reading level, includes voice-overs of all text for the reading-impaired and closed-captioning of all videos for the hearing impaired (<http://www.prepareforyourcare.org>).^{27–28} The conceptual framework for PREPARE has been previously published and is based on social cognitive and behavior change theories.²⁷ In the design of the PREPARE website, we included essential theory-based health education strategies, such as the use of video modelling of ACP behaviours, and tailored and interactive content based on patients’ values and decision preferences. To ensure that PREPARE was easy to read and understand, we used clear health communication principles (eg, targeting text to the fifth grade reading level) and used extensive formative research and cognitive interviewing with the target population (ie, racially and ethnically diverse older adults with limited health literacy and English proficiency) to ensure that the PREPARE content is acceptable to individuals from diverse cultural backgrounds.²⁷

The PREPARE website leads people through a five-step ACP process that ranges from choosing a surrogate decision-maker to asking their clinicians the right questions. While going through the website, PREPARE also helps individuals answer personal values questions about

their medical care and create an action plan to engage in some form of ACP. Patient-generated action plans have been shown to help patients engage in other preventative and disease management activities in the outpatient setting.³⁶

After the baseline interview, participants in the PREPARE arm review all five steps of the PREPARE website in English or Spanish in our research offices. They are asked to review PREPARE on their own and in its entirety. Research assistants are available to answer questions only if needed, but do not go through the website with the participants. At the end of the programme, a summary of the patient's medical wishes and action plan is automatically generated from the PREPARE website in written format. This information, along with the participant's PREPARE website login information, is included in a take-home folder that also contains PREPARE information in pamphlet, booklet and DVD format. We included PREPARE content in non-website formats because some patients may not have access to the internet at home. PREPARE arm participants are also given an easy-to-read advance directive in English or Spanish to review and consider completing.^{8 37} Participants are asked to review the advance directive form for at least 5 min and up to 15 min in research offices, and then to take the form home to discuss with their potential surrogates and/or their clinicians. The time frame of 5–15 min was chosen because our goal is only to introduce the advance directive and allow participants to ask questions. The goal is not to have patients complete the form on the day of the study, before potential discussions with clinicians or surrogates, unless the participant would like to do so. Participants in the control arm are only given the easy-to-read advance directive, are asked to review it for at least 5 min and up to 15 min, and to take the form home to discuss with their potential surrogates and clinicians. One to 3 days before the patient's next scheduled primary care appointment, research staff call the PREPARE arm participants to remind them to bring in their study materials (ie, action plan and advance directive) and to talk to their clinician about ACP. For the control arm, research staff members only remind patients about their upcoming appointment and do not provide additional encouragement about ACP.

Randomisation procedures

A statistician not involved in recruitment or data collection uses a computer-based random number generator to create a randomisation scheme using block randomisation by health literacy (adequate health literacy vs limited health literacy, as determined by a validated question concerning confidence with medical forms).³⁸ Random block sizes of 4, 6 and 8 are used to ensure an equal number of patients with limited health literacy in each group. Randomisation information is associated with a unique patient identification number and is kept separate from other patient data.

Blinding

Participants are told that each research participant will review one of two guides, but study participants are blinded as to which guide is the active intervention and which is the active control. Since each group obtains ACP materials, such as the easy-to-read advance directive, blinding is enhanced. To ensure blinding of all outcome assessments, research staff who conduct follow-up interviews are never the same staff member who completed the baseline interview and randomisation for that participant. At the start of all follow-up interviews, participants are reminded not to discuss the study materials they reviewed. If, however, during the follow-up interview, the research assistant becomes unblinded (eg, the participant mentions the PREPARE website), this information is noted in our database, and the participant is assigned to a new blinded research assistant for all subsequent interviews.

Intervention fidelity and data collection methods

All staff members are rigorously trained and are required to read and adhere to a standardised study protocol manual, standardised study scripts and standardised checklists for each contact and interview with participants. Several training videos have also been developed for staff. Research staff are not allowed to conduct study tasks independently until they have reviewed all written and video training materials and can demonstrate complete mastery of all scripts and checklist items. In addition, a 10% random sample of all interviews is observed by senior research staff to ensure study fidelity.

Research data are captured live and entered into a web-based software program called Research Electronic Data Capture (REDCap). REDCap is managed by the UCSF Academic Research Systems Team and is stored behind strong-string password-protected firewalls on UCSF servers, not on individual laptops or desktops. All patients are given a unique, non-identifying patient identification number that is removed from any personally identifying information (PII) or personal health information (PHI). All PII and PHI are stored in a Microsoft ACCESS database behind strong-string password-protected firewalls on UCSF and ZSFG servers. To reduce missing data, REDCap has been programmed to not allow study staff to progress if data fields are left blank.

MEASURES AND DATA COLLECTION

Primary and secondary outcomes

Since ACP ideally is a process that occurs over time, we felt it important to measure a full range of ACP measures including ACP documentation (primary outcome), as well as several behaviour change constructs and several additional ACP actions over a 12-month period (secondary outcomes). All study measures, including available validity and reliability information in English and Spanish, and the schedule of administration (ie, baseline, 1 week or 3, 6 or 12 months) are described in [table 2](#). The main outcome measures are also described in detail below.

Table 2 Longitudinal assessment of measures and constructs used to evaluate the efficacy of the PREPARE study

Construct	Measure	Number of items	English reliability/ validity	Spanish reliability/ validity	Screeener	Baseline	1 week	3 months	6 months	12 months
Cognitive impairment	<i>Eligibility screening</i> SPMSQ 0–2=eligible 3–7 moderate impairment → Mini-Cog ≥8 severe impairment=ineligible	7	Sensitivity 86.2%, specificity 99.0% ⁵³	–	X					
	Cognitive impairment (participants scoring 3–7 errors on SPMSQ) Mini-Cog (3-item recall as needed, if SPMSQ screen+for cognitive impairment) If recall ≥2 words=eligible	3	Sensitivity 76%, specificity 89% ³²	Sensitivity 99%, specificity 93% ⁵⁴	X					
Vision	Ability to see words on a newspaper ⁵²	1		–	X					
Health literacy screen for block randomisation (inadequate vs adequate)	‘How comfortable are you filling out medical forms by yourself?’ ‘Qué tan seguro(a) se siente al llenar formas usted solo(a)’	1	AUROC 0.80 (95% CI 0.67 to 0.93) for inadequate health literacy ⁵⁵	C-index=0.82, (0.77 to 0.87) for inadequate health literacy ⁵⁶	X					
ACP documentation	<i>Primary outcome</i> ACP Engagement Survey: ²⁷ self-report: ACP documentation	1	ICC*=0.87 ²⁷	–		X	X	X	X	X
ACP documentation	Chart review: ACP documentation					X				X
The full ACP Process	<i>Secondary outcomes</i> ACP Engagement Survey: ²⁷ behaviour change process measures (knowledge, contemplation, self-efficacy, readiness) Action measures: values identification and discussions	108	Process measures: Cronbach’s α =0.94 (0.91 to 0.96), ICC=0.70 (0.54 to 0.82) ²⁷ Action measures: ICC*=0.87 (0.79 to 0.92) ²⁷	–		X	X	X	X	X
Communication quality	CAHPS (eg, Did this provider explain things in a way that was easy to understand?)	13	Comparative Fit Index=0.98, Tucker Lewis Index=0.98 Cronbach’s α ≥0.70 for constructs ³⁹	Cronbach’s α ≥0.70 for constructs and associated with global physician rating ⁴⁰		X	X			

Continued



Table 2 Continued

Construct	Measure	Number of items	English reliability/ validity	Spanish reliability/ validity	Screener	Baseline	1 week	3 months	6 months	12 months
Satisfaction with communication	(i.e, How satisfied are you that you could share your most important concerns with X/ that X understood what was most important to you?)	8	–	–		X	X	X	X	X
Care consistent with current goals	Care consistent with goals: comparing 10-point scales of patient ratings about aggressiveness of care desired and care currently receiving	4	–	–		X			X	X
Satisfaction with decision-making	Decisional Conflict Scale	20	Test-retest coefficient=0.81 Cronbach's α : 0.78–0.92 for total scale ⁴¹	Cronbach's α =0.80 ⁵⁷			X	X	X	X
Depression	Patient Health Questionnaire-8	8	Scores ≥ 10 100% sensitive and 95% specific for major depressive disorder ^{42 43}	Scores ≥ 10 77% sensitive and 100% specific for major depressive disorder ⁵⁸		X	X	X	X	X
Anxiety	GAD-7 ⁴⁴	7	Cronbach's α =0.92 ⁴⁴ ICC*=0.83	Cronbach's α =0.88 ⁴⁵ ICC*=0.64		X	X	X	X	X
Barriers to ACP	Checkbox of common barriers and one open-ended question	13	Associated with ACP ⁵⁹	Associated with ACP ⁵⁹		X				X
Attitudes about ACP	Processes of change for ACP ³¹	34	Responsive to an ACP intervention ²⁷	–		X	X	X	X	X
Implementation: acceptability	Acceptability and usability		1 factor explained 81–85% of variance/scale.	1 factor explained 81–85% of variance/scale.		X				
	(1) Ease of use and understanding	8	Kuder-Richardson	Kuder-Richardson						
	(2) Usefulness in decisions and discussions	6	>0.75 ⁸	>0.75 ⁸						
Implementation: feasibility	(3) Attitudes about norms or expectations	6								
	Feasibility (both arms) (eg, when and where to review ACP materials)	7	–	–					X	X
	Feasibility (PREPARE only) (eg, when/where to review and which materials did you use and would recommend to others)	34								

Continued

Table 2 Continued

Construct	Measure	Number of items	English reliability/ validity	Spanish reliability/ validity	Screeener	Baseline	1 week	3 months	6 months	12 months
Surrogate reports of patient engagement in ACP	Modified from the ACP Engagement Survey, ²⁹ knowledge of patient's wishes, and confidence making decisions, 5-point Likert <i>Moderator variables</i>	47	–	–						X
Health literacy assessment	s-TOFHLA scores 0–36 ⁶⁰ Continuous and dichotomised to limited=0–22 and adequate=23–36	36	Cronbach's $\alpha=0.97$ Correlation coefficient with other literacy tests >0.80 ⁶⁰	Cronbach's $\alpha >0.95$ ⁶¹		X				
Patient–clinician language concordance	To clinicians: 'How well do you speak Spanish?' ⁶² Fluently, very well (concordant) vs well, fair or poor'	1	AUROC† 94% (CI 90% to 98%) ⁶²	AUROC† 94% (CI 90% to 98%) ⁶²		X				
Desired role in decision-making	CPS with clinicians and family ⁶³	2	Correlation between preferred and actual roles in decision-making ^{12 64 65}	Correlation between preferred and actual roles in decision-making ⁶⁶		X				X
US acculturation	Based on acculturation scale (USAS) 'How many years have you lived in the USA?' <i>Mediator variables</i> †	1	Cronbach's $\alpha=0.98$ Associated with desire to know prognosis ⁶⁷	–		X				
Baseline knowledge	Knowledge subscales of the ACP Engagement Survey ²⁷	6	Cronbach's $\alpha=0.84$ (0.76–0.90), ICC*=0.70 (0.50–0.82) ²⁷	–		X				
Baseline self-efficacy	Self-efficacy subscales of the ACP Engagement Survey ²⁷	6	Cronbach's $\alpha=0.83$ (0.75–0.89), ICC*=0.60 (0.41–0.76) ²⁷	–		X				
Baseline readiness	Readiness subscales of the ACP Engagement Survey ²⁷	10	Cronbach's $\alpha=0.92$ (0.88–0.95), ICC*=0.60 (0.53–0.81) ²⁷	–		X				
Baseline ACP barriers	Checkbox of 13 comment barriers ⁵⁹	13	Associated with ACP ⁵⁹	–		X				
Baseline attitudes about ACP	Processes of change for ACP ³¹	34	Responsive to ACP intervention ²⁷	–		X				

Continued

Table 2 Continued

Construct	Measure	Number of items	English reliability/ validity	Spanish reliability/ validity	Screeener	Baseline	1 week	3 months	6 months	12 months
<i>Potential confounders</i>										
Functional status	ADL and IADL measure (13-item) ^{68 69}	13	Morbidity/mortality correlation ^{68 69}	Cronbach's $\alpha=0.94$ ⁷⁰		X				
Self-rated health status	How would you rate your health? (5-point Likert) ^{71 72}	1	Cronbach $\alpha=0.80$ ⁷²	–	X					
Self-rated quality of life	How would you rate your quality of life? (5-point Likert) ^{72 73}	1	Test–retest coefficient=0.81 ⁷³	–	X					
Comorbid illness	Charlson comorbidity score ^{74 75} Elixhauser comorbidity score ^{76 77}	0	Mortality c-stat. ⁷⁸ Charlson=0.704 Elixhauser=0.793	– –		X				
Prior ACP experience	Prior ACP experiences (eg, (Ever had to make life-threatening medical decisions?)) ⁸	5		–		X				
Social support	mMOS-SS ⁷⁹	11	Cronbach's $\alpha=0.88$ –0.93 ⁷⁹	Cronbach's $\alpha=0.94$ ⁸⁰		X				
Major life changes	For example, 'In the past 12 months, have you or someone close to you been faced with a serious medical problem or diagnosis?'	4	–	–						X
<i>Demographic information</i>										
Demographic information	Age, gender, race/ethnicity, income, marital status and education ⁸¹				X	X				
Religion/spirituality	Self-reported extent of how spiritual/religious (five-point Likert) and role play in decision-making ⁸²	4	Spirituality associated with quality of life. Religiosity associated with wanting all measures to extend life ⁸²	–		X				
Finances	'In general, how do your finances usually work out at the end of the month?'	1	Associated with functional impairment and comorbidity ⁸³	–		X				

Continued

Table 2 Continued

Construct	Measure	Number of items	English reliability/ validity	Spanish reliability/ validity	1 week	3 months	6 months	12 months
Socioeconomic status and social standing	Social standing ladder (ie, place an 'x' where you think you stand relative to other people in society)	1	Associated with functional decline ⁸⁴	–				X

If a validated Spanish version of a survey was not available, we translated the English version into Spanish.
 *ICC=intraclass correlation.
 †Area under the receiver operating curve (AUROC).
 ‡While mediator variables, measured at baseline, may explain how or why a particular effect or relationship occurs, these variables may also be affected by the intervention and are therefore also considered secondary outcome variables measured over time (ie, knowledge, self-efficacy and readiness, as well as barriers and attitudes).
 ACP, advance care planning; ADL, activities of daily living; CAHPS, Consumer Assessment of Healthcare Providers and Systems; CPS, Control Preference Scale; GAD-7, Generalized Anxiety Disorder 7-Item Scale; IADL, instrumental activities of daily living; mMOS-SS, modified Medical Outcomes Study Social Support; SPMSQ, Short Portable Mental Status Questionnaire; s-TOFHLA, Short form Test of Functional Health Literacy in Adults; USAS, US Acculturation Scale.

The primary outcome is documentation of ACP wishes in the ZSFG/SFHN medical record (table 2). ACP documentation for the purposes of this study includes the easy-to-read advance directive or other valid advance directives or living wills, a durable power of attorney for healthcare document (DPOAHC), a physicians orders for life sustaining treatment (POLST) form, or other documentation of patients wishes for medical care (ie, documentation of oral directives by a physician, or code status, such as 'full code' or 'do not resuscitate' or 'do not intubate' orders or notes by a physician). We will assess baseline and 12-month documentation rates and the date of documentation to determine the length of time from study enrolment to subsequent documentation.

Secondary outcomes were chosen to measure the full process of ACP. Using validated questionnaires,²⁹ we will measure ACP behaviour change processes, such as knowledge, contemplation, self-efficacy and readiness, as well as several ACP actions, such as identifying a surrogate decision-maker, identifying values and goals for medical care, choosing the level of leeway in surrogate decision-making, discussing one's wishes with clinicians and surrogates, and documenting one's wishes in an advance directive (table 2). Validity and reliability of the ACP Engagement Questionnaire, as well as the questionnaire's ability to detect change in response to an ACP intervention, have been previously described.^{27–29}

Several additional secondary outcomes are included. Using validated surveys, we assess communication quality and satisfaction,^{39 40} care consistent with current goals, and satisfaction with decision-making.⁴¹ To ensure that the PREPARE programme does not cause undue harm, we will also assess both depression^{42 43} and anxiety^{44 45} (table 2). To evaluate whether and how PREPARE will be used in clinical practice and in the community, we also assess acceptability of the PREPARE website compared with an advance directive alone using validated scales from our prior work.⁸ For the PREPARE arm only, and at the end of the 12-month interview and after unblinding, we also ask how likely patients and surrogates are to recommend the PREPARE intervention to others,⁴⁶ and about usability, such as when and where to review ACP materials, and which PREPARE materials (ie, the website, pamphlet or DVD) they would recommend. We also obtain corroborating or conflicting information about patient engagement in ACP behaviours from their surrogate (table 2). Surrogates are also asked about their knowledge of the patient's wishes and confidence in making decisions on the patient's behalf, using a five-point Likert scale with response options from 'not at all' to 'extremely'.

On the basis of the previously published conceptual framework of PREPARE,²⁷ we also hypothesise that PREPARE efficacy may vary across several moderator variables (eg, health literacy, clinician–patient language concordance and patient's desired role in decision-making). We also hypothesise that the pathway from PREPARE to the primary and secondary outcomes may

be mediated by several baseline variables (eg, knowledge of ACP, perceived barriers to ACP), and that PREPARE efficacy may be affected by several confounding variables (eg, self-rated health, past experiences with ACP, social support (table 2)). We will also assess patient age, gender, finances, social standing, marital status, education and religiosity. In addition, we will assess clinicians' age, race/ethnicity and gender, as these factors may impact patient–clinician communication.^{20 47}

Analytic plan

Our primary analyses will compare change in engagement between study arms with respect to five ACP behaviours (yes/no and a five-point scale) and behaviour change scores (average five-point Likert scores) from baseline to 1 week, and at 3, 6 and 12 months. Baseline comparability will be assessed between groups using t-tests and χ^2 tests. To compare outcomes between the two arms longitudinally, we will use mixed-effects linear, Poisson or negative binomial regression for continuous measures and mixed-effects logistic regression for dichotomous measures. The mixed-effects models will include fixed effects for the primary modelling terms of time and arm; an interaction term of study arm and time; and a random effect for participants. We will treat the time variable in three ways: (1) we will encode the time variable as a dummy variable for baseline versus the postintervention time points; (2) we will next model time in a continuous linear fashion; (3) then consider an arbitrary time course by treating time as a categorical factor variable. We will adjust for the randomisation blocking factors limited versus adequate literacy,⁴⁸ and any predictor variables that differ between arms. We will also include random physician intercepts to account for nesting of patients within physicians and consider including random effects for the primary modelling terms of time, arm and their interaction. Stata V.12 will be used to fit the models using the xt routines. Mediation analyses will use Stata's mediation package.⁴⁹ For moderator analysis, we will stratify the outcomes (eg, health literacy (continuous score and limited vs adequate health literacy), control preferences for decision-making (three-item categorical and control vs lack of control), patient–clinician language concordance vs discordance) by the dichotomous forms of the three potential moderating factors. To make formal inference on the interaction effects, we will augment our mixed-effects regression models to include interaction terms of these potentially moderating variables.

Sample size

We will measure a full range of ACP behaviours including discussions. However, written advance directive completion is a primary outcome and is the one most well studied.⁵⁰ Power from longitudinal analyses with repeated measures will be stronger, but to be conservative we consider power for a single postintervention time point (eg, 12 months). A recent meta-analysis of written

advance directive documentation studies demonstrated a pooled effect size of 0.50 (95% CI 0.17 to 0.83),⁵⁰ as did an RCT of an ACP workbook that included both behaviour change constructs and a social work visit,⁵¹ and our prior RCT of an easy-to-read AD at ZSFG which showed an increased AD completion rate from 7% to 15%.⁸ Since both the intervention and control arms will receive the easy-to-read advance directive, we assume that both arms will have an advance directive completion rate of $\leq 15\%$. On the basis of prior studies, we assume PREPARE will result in additional benefit of advance directive completion with a minimum effect size of 0.5 (twofold increase) above 15%. A sample of 350 (175 per arm) will afford us 92% power (two-tailed α of 0.05) to detect a difference of advance directive completion rates of 15% in controls versus 30% in the PREPARE arm and 80% power to detect a difference of 15% vs 27%. Power is also expected to be strong for the ACP behavioural change scale outcomes (preliminary data demonstrated a pre-to-post improvement of 0.5 SD).²⁷ With a conservative assumption that controls will improve by 0.1–0.2 SD, we will have 85–98% power, respectively, to conclude that the improvement is better in the PREPARE arm. We expect a 15% dropout rate at 12 months based on our prior RCT at ZSFG,⁸ and will therefore attempt to recruit 402 patients, or 201 in each arm for each language (English and Spanish) for a total recruitment of 804 patients. On the basis of our prior experience recruiting surrogate decision-makers for a similar trial,²⁸ we plan to recruit 136 surrogates (68 in each arm) for English and Spanish speakers (total of 272), anticipating that 15% of patients will be lost to follow-up, 15% of patients will not have any potential surrogate decision-makers, 15% of patients will refuse permission for us to contact their surrogate and 25% of surrogates will refuse.

Our sample size will also allow adequate power to detect clinically important interactions based on potential moderators (literacy, control preferences, language concordance) for our outcomes. In a prior trial of an easy-to-read advance directive in the same patient population with only 200 patients, we found significant interactions for literacy.⁸ Thus, if we consider the power scenario of the control group advance directive documentation rate of 15% and the PREPARE group of 28%, and suppose the control group rate is the same (15%) for both levels of the moderating factor, then for a moderating factor split of 1:1 we would have 80% power to detect an interaction. If the PREPARE arm advance directive documentation rate was 18% for one level of the factor and 40% for the other, this corresponds to a relative rate of advance directive documentation of 2.2 times as high for one level of the factor compared with the other. A 2:1 split of the moderating factor still allows detection of a 2.4-fold increase in the relative rate of documentation. Power to detect interactions will most likely be stronger for continuous outcomes (eg, engagement/behavioural scales).

ETHICS AND DISSEMINATION

Ethics

This study is registered at ClinicalTrials.gov (NCT01990235 for English speakers and NCT02072941 for Spanish speakers). Recruitment of English-speaking older adults is funded through a National Institute on Aging R01 grant (R01 AG045043) and recruitment of Spanish-speaking older adults is funded through the Patient-Centered Outcomes Research Institute (CDR-1306-01500).

This study is guided by a patient and clinical advisory board comprising patients, patient advocates, surrogates, and ZSFG/SFHN primary care clinic staff and medical directors. It is also guided by a DSMB consisting of four experts in randomised trials, human participants research and consent, vulnerable populations, palliative care, ACP and biostatistics. Both advisory groups have reviewed and approved all study protocols and related materials. In addition, we continue to meet both groups every 4–6 months to review the progress of the trial, make suggestions for recruitment, review any potentially adverse events (until now, there have been none) and ensure that we are following our study protocols in a way that protects vulnerable patient populations.

Dissemination

For academic audiences, we will present our findings at scientific meetings and in peer-reviewed research journals. We have been working with our community and ZSFG/SFHN clinical and healthcare system partners throughout the development and implementation of the trial. Therefore, we will continue working with these key stakeholders to help us interpret our results and create appropriate messaging for the dissemination of our results to the community. We will also work with UCSF to create a press release for a lay audience and present our findings to our community and clinical partners through in-person lectures and discussions.

If PREPARE is found to be successful, our stakeholder partners will also help us determine how to replicate, refine and disseminate PREPARE in primary care clinics through the ZSFG/SFHN-affiliated system and other public healthcare systems.

DISCUSSION

This is the first study to test the efficacy of the new PREPARE website and its underlying ACP paradigm among diverse English-speaking and Spanish-speaking older adults from urban publicly run primary care clinics. If this trial demonstrates that PREPARE fosters diverse older adults' engagement in ACP and activates them to communicate and document their wishes in the medical record, then PREPARE would represent an efficient and effective strategy to ensure that patients' ongoing wishes are solicited and honoured. PREPARE could also decrease health disparities in ACP by providing ACP information to diverse English-speaking and Spanish-speaking older adults at a literacy level and in a

language and format that they can understand. Since PREPARE was designed to be used both inside and outside of the clinical setting, for resource-poor, urban, public hospital systems, future studies should evaluate whether PREPARE saves clinicians' time and is cost-effective.

If the results of this trial are positive, the next step will be to promote local uptake and widespread adoption. By including key patient, clinical and community partners in the design and ongoing conduct of the study and by eliciting suggestions for implementation and dissemination during the randomised trial phase, we are well positioned to move quickly to implementation and dissemination of PREPARE within ZSFG/SFHN-affiliated clinics and within the community.

Trial status

We started recruitment of English-speaking patient participants in March 2014 and will end recruitment in September 2016. We expect to complete recruitment of English-speaking surrogates in September of 2017. We started recruitment of Spanish-speaking patient participants in November 2014 and will end recruitment in March 2016. We expect to complete recruitment of Spanish-speaking surrogates in March 2017. At the time of this manuscript submission, 413 Spanish-speaking patients and 312 English-speaking patients from the ZSFG/SFHN primary care clinics have been enrolled. No surrogates have yet been recruited; surrogate recruitment and enrolment will start in March 2016.

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