

Engaging Diverse English- and Spanish-Speaking Older Adults in Advance Care Planning: The PREPARE Randomized Clinical Trial

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[+ Supplemental content](#)

IMPORTANCE Advance care planning improves the receipt of medical care aligned with patients' values; however, it remains suboptimal among diverse patient populations. To mitigate literacy, cultural, and language barriers to advance care planning, easy-to-read advance directives and a patient-directed, online advance care planning program called PREPARE For Your Care (PREPARE) were created in English and Spanish.

OBJECTIVE To compare the efficacy of PREPARE plus an easy-to-read advance directive with an advance directive alone to increase advance care planning documentation and patient-reported engagement.

DESIGN, SETTING, AND PARTICIPANTS A comparative efficacy randomized clinical trial was conducted from February 1, 2014, to November 30, 2017, at 4 safety-net, primary-care clinics in San Francisco among 986 English-speaking or Spanish-speaking primary care patients 55 years or older with 2 or more chronic or serious illnesses.

INTERVENTIONS Participants were randomized to PREPARE plus an easy-to-read advance directive (PREPARE arm) or the advance directive alone. There were no clinician-level or system-level interventions. Staff were blinded for all follow-up measurements.

MAIN OUTCOMES AND MEASURES The primary outcome was documentation of new advance care planning (ie, legal forms and/or documented discussions) at 15 months. Patient-reported outcomes included advance care planning engagement at baseline, 1 week, 3 months, 6 months, and 12 months using validated surveys. Intention-to-treat analyses were performed using mixed-effects logistic and linear regression, controlling for time, health literacy, and baseline advance care planning, clustering by physician, and stratifying by language.

RESULTS Among the 986 participants (603 women and 383 men), the mean (SD) age was 63.3 (6.4) years, 387 of 975 (39.7%) had limited health literacy, and 445 (45.1%) were Spanish speaking. No participant characteristic differed between the 2 groups, and retention was 85.9% (832 of 969) among survivors. Compared with the advance directive alone, PREPARE resulted in a higher rate of advance care planning documentation (unadjusted, 43.0% [207 of 481] vs 33.1% [167 of 505]; $P < .001$; adjusted, 43.0% vs 32.0%; $P < .001$) and higher self-reported increased advance care planning engagement scores (98.1% vs 89.5%; $P < .001$). Results remained significant among English speakers and Spanish speakers.

CONCLUSIONS AND RELEVANCE The patient-facing PREPARE program and an easy-to-read advance directive, without clinician-level or system-level interventions, increased documentation of advance care planning and patient-reported engagement, with statistically higher gains for PREPARE vs advance directive alone. These tools may mitigate literacy and language barriers to advance care planning, allow patients to begin planning on their own, and could substantially improve the process for diverse English-speaking and Spanish-speaking populations.

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Advance care planning (ACP) improves the receipt of medical care aligned with patients' values and patient satisfaction.¹⁻³ Thus, ACP has recently been approved for reimbursement and recommended as a quality indicator in clinical guidelines.⁴⁻⁶ However, a majority of older adults, even those with serious illness, have not engaged in conversations about ACP, and patients' wishes about ACP are often not documented.^{4,7,8} Engagement in ACP remains especially low among minorities and patients with limited health literacy and limited English proficiency, and is less than 20% among Latinos.⁹⁻¹⁴ For health care systems and clinicians, barriers to ACP include time and resource constraints. For minorities, ACP is complicated by a lack of trust and prior experiences of racism,¹⁵ complex legal language in advance directives (ADs),¹⁶ and differing views on autonomy and decision making.¹⁷

To overcome these barriers and to address a lack of literacy-appropriate, culturally appropriate, and linguistically appropriate ACP materials, we created an easy-to-read AD and a patient-directed, interactive, online ACP program in English and Spanish called PREPARE For Your Care (PREPARE) (<https://prepareforyourcare.org/>).^{10,18} PREPARE is designed to be used at home, to prepare people for complex medical decision making,¹⁹ and incorporates several unique health communication elements. These elements include application of user-centered design principles in the co-creation of the program with and for diverse patients and surrogate decision makers; 5 modular skill-building steps based on social cognitive and behavior change theories that model how to engage in ACP through video stories; narratives and testimonials based on real scenarios to mitigate cultural barriers; video, audio, and closed-captioning in 2 languages to mitigate literacy, language, and hearing barriers; and encouragement to include family and loved ones.¹⁸ The AD has been shown to improve ACP engagement among English speakers and Spanish speakers,¹⁰ and PREPARE has been shown to improve engagement among English-speaking veterans.²⁰ However, to our knowledge, no prior study has compared these interventions among ethnically diverse English-speaking and Spanish-speaking older adults in a safety-net health care system. The objective of this trial was to compare the efficacy of PREPARE plus the easy-to-read AD vs the AD alone on ACP documentation in the medical record and patient-reported ACP engagement. We hypothesized that documentation and engagement would increase in both arms and be greater in the PREPARE arm.

Methods

This is a single-blind, parallel-group, comparative efficacy trial randomized at the patient level. Because of the benefits of ACP,¹⁻³ we chose not to have a control group and provided all participants with ACP materials. The conceptual framework of PREPARE, based on social cognitive and behavior change theories, and the trial protocol including inclusion and exclusion criteria, as well as the study flow diagram, recruitment procedures, sample size estimates, and validity, reliability, and response options of all outcome measures have been pre-

Key Points

Question Can a patient-facing, online program called PREPARE For Your Care plus an easy-to-read advance directive increase advance care planning documentation and engagement compared with the easy-to-read advance directive alone?

Findings In this randomized clinical trial of 986 English-speaking and Spanish-speaking older adults with chronic illness from 4 primary care clinics, PREPARE For Your Care plus an easy-to-read advance directive resulted in higher rates of advance care planning documentation (43.0% vs 32.0%) and engagement (98.1% vs 89.5%) compared with an advance directive alone.

Meaning Patient-facing tools, including an online advance care planning program and an easy-to-read advance directive, may enable diverse populations to engage in the advance care planning process without additional clinician-level or system-level interventions.

viously published and are included in the trial protocol in Supplement 1.^{18,21} This study was approved by the University of California, San Francisco Institutional Review Board; written informed consent was obtained using a teach-to-goal process in English and Spanish²²; and safety was overseen by a patient-clinician stakeholder advisory board and a data safety monitoring board. Although recruitment of English speakers and Spanish speakers was supported by 2 funders, this was 1 trial with 1 protocol.²¹

Recruitment and Data Collection

Study participants were enrolled from 4 primary care clinics within the San Francisco Health Network, a public-health delivery system, from February 1, 2014, to November 30, 2017. We obtained a Health Insurance Portability and Accountability Act waiver to identify individuals who met inclusion and exclusion criteria and had upcoming primary care appointments.²¹ After receiving clinician approval, we sent recruitment letters written at a 5th-grade reading level in English or Spanish. If patients did not opt out, staff called them to assess interest and eligibility.

Participants and Enrollment Criteria

Patients were eligible if they were 55 years or older, spoke English or Spanish well or very well, had 2 or more chronic medical conditions by medical record review, 2 or more visits with a primary care provider (ie, established care), and 2 or more additional outpatient, inpatient, or emergency department visits in the past year (ie, marker of illness). To standardize timing of the intervention to upcoming primary care visits, participants were enrolled 1 to 3 weeks prior to an upcoming appointment. Exclusion criteria included dementia, moderate to severe cognitive impairment, blindness, deafness, delirium, psychosis, active drug or alcohol abuse (determined by their clinician, *International Classification of Diseases, Ninth Revision* codes, medical record review, or in-person screening), lack of a telephone, or inability to answer consent teach-back questions within 3 attempts.²¹ Because ACP is a process,^{19,23} we did not exclude individuals who had previously engaged in ACP.

Randomization, Allocation Concealment, Blinding, and Fidelity

Because limited health literacy is associated with lower ACP engagement,^{10,24} participants were block randomized, in random block sizes of 4, 6, and 8, by adequate vs limited health literacy using a random number generator.²¹ Clinicians were blinded. Participants could not be blinded but were told during consent there was a “50-50 chance” of getting 1 of 2 ACP interventions, and the nonassigned intervention was not described. Research staff were blinded for all follow-up assessments. Staff followed standardized scripts, used checklists, and were observed for 10% of interviews to ensure protocol fidelity.²¹

Interventions

Online PREPARE Program Plus AD Intervention

In the PREPARE arm, participants were asked to review PREPARE in English or Spanish in research offices. Although the 5 steps of PREPARE were designed to be viewed individually (approximately 10 minutes per step),¹⁸ to standardize exposure, participants were asked to complete all steps in their entirety. Although all materials are designed to be reviewed on their own at home, we standardized procedures for this trial by asking participants to review the materials on their own in our research offices. Research staff were available to answer questions but did not facilitate viewing of the materials. PREPARE includes interactive online values questions that, when answered, generate a unique action plan and “Summary of My Wishes.” This summary was printed and given to participants. PREPARE participants were also asked to review the AD for 5 to 15 minutes. They were provided the AD, the PREPARE Summary of My Wishes, and website login to take home. Participants were called 1 to 3 days prior to their upcoming primary care visit and reminded to talk to their clinician about the PREPARE materials. No clinician-level or system-level interventions were included in either arm.²¹

AD-Only Intervention

In the AD-only arm, participants were asked to review the easy-to-read AD in English or Spanish for 5 to 15 minutes in research offices on their own and were provided the AD to take home. They were reminded of their upcoming primary care visit by telephone 1 to 3 days before the primary care visit.²¹

Outcomes

We administered baseline questionnaires in person and follow-up questionnaires in person or by telephone. Fluent English-speaking or Spanish-speaking staff asked survey questions while participants could follow along with a written copy. Validity, reliability, and scoring of all measures are included in the published and online trial protocol included in [Supplement 1](#).²¹ At baseline, we assessed self-reported participant characteristics including age, gender, race/ethnicity, income, marital status, and educational level.²¹ We also administered validated measures of health literacy, US acculturation, educational level, finances, religion or spirituality, social support, presence of a possible surrogate decision maker, self-rated health and functional status, desired role in decision making, prior plan-

ning (ie, burial or wills), internet access in the home, and, for Spanish speakers, patient-clinician language discordance.²¹ We determined documentation of ACP legal forms in the medical record at any time prior to enrollment and documented discussions about ACP within 5 years of enrollment. In addition, the baseline rate of documentation of ACP in the 12 months prior to enrollment was determined using a composite of legal forms or documented discussions about ACP.^{20,21}

Primary Outcome

Our primary outcome was new documentation of ACP in the medical record 15 months after enrollment. We used a composite variable of legal forms (ie, ADs, durable power of attorney for health care, and Physicians Orders for Life Sustaining Treatment) and documented discussions (ie, oral directives or goals of care noted in the medical record) because both may be used to direct medical care.²¹ Documented discussions included documentation of oral directives by a physician or clinician notes describing patients' surrogates or goals for medical care. All notes in the medical record were hand searched. We also assessed forms and discussions separately. All primary outcome data were double-coded by 2 independent, blinded reviewers as described in the trial protocol in [Supplement 1](#).^{20,21}

Secondary Patient-Reported Outcomes

The validated ACP Engagement Survey was used to measure engagement in the ACP process over time at baseline, 1 week, 3 months, 6 months, and 12 months.^{25,26} The Behavior Change Process subscales of knowledge, self-efficacy, and readiness included 5-point Likert response options of “not at all, a little, somewhat, fairly, and extremely” and the contemplation subscale included the 5-point response option of “never, once or twice, a few times, several times, and a lot.” The survey also includes a 0- to 25-item action score (eg, reported discussions and documentation of ACP wishes; yes or no).

Feasibility and Safety Outcomes

We measured ease of use on a scale of 1 (very hard) to 10 (very easy) points. Satisfaction was measured by asking about level of comfort, helpfulness, and likelihood of recommending the guide to others using a 5-point Likert scale (where 1 indicates not at all and 5 indicates extremely).²¹ To assess potential adverse outcomes, we measured depression and anxiety with the validated Patient Health Questionnaire-8²⁷ and Generalized Anxiety Disorder-7²⁸ questionnaires.

Sample Size

A sample of 350 in each arm allowed 92% power (2-tailed $\alpha = .05$) to detect a difference in documentation of ACP between arms of 15% vs 30%.²¹ With an expected 15% loss to follow-up, our recruitment target was 201 English speakers and 201 Spanish speakers per arm (804 total) (trial protocol in [Supplement 1](#)).²¹

Statistical Analysis

We compared baseline characteristics using unpaired *t* tests, χ^2 tests, or Fisher exact tests. We performed intention-to-

treat analyses using SAS, version 9.4 (SAS Institute Inc), and STATA, version 15.0 (Stata Corp). All *P* values were 2 tailed and set at *P* < .05 for the primary outcome and Bonferroni adjusted for secondary outcomes (*P* < .025). Because of differences in ACP engagement by language,¹⁰ and based on stakeholder and funding agency recommendations, we decided, a priori, to also stratify all analyses by English speakers and Spanish speakers. For our primary outcome of documentation of ACP, we used mixed-effects logistic regression with fixed effects for time (baseline and 15 months), group (PREPARE vs AD-only), and group-by-time interaction. For our secondary outcomes of ACP engagement scores, we used mixed-effects linear regression with fixed effects for time (baseline, 1 week, 3 months, 6 months, and 12 months, with time modeled using dummy variables to allow for nonlinearity), group, and group-by-time interaction. Mixed-effects models enable inclusion of all available data in intention-to-treat analyses while accounting for within-individual correlation over time. Because this was a comparative efficacy trial, we calculated within-group pre-post effect sizes using standard, clinically meaningful thresholds (ie, small, 0.20-0.49; medium, 0.50-0.79; and large, ≥0.80).²⁹ Per stakeholder request, we conducted post hoc mixed-effects regression to calculate the percentage of participants with increased behavior change or action scores from baseline (ie, estimated slope >0) by study arm. All models were adjusted for the blocking variable of health literacy (adequate or limited) and baseline documentation of ACP, and accounted for clustering by physician. *P* values were Bonferroni adjusted to *P* < .017.

We also explored effect modification by adding interaction terms to the group-by-time variable for language (English vs Spanish), health literacy (adequate vs limited), desired role in decision making (makes own decisions vs physicians decide), age (<65 years vs ≥65 years), gender (women vs men), race/ethnicity (white vs nonwhite), health status (good to excellent vs fair to poor), presence of a potential surrogate decision maker (yes vs no), internet access at home (yes vs no), and, for Spanish speakers, patient-clinician language discordance (concordant vs discordant); *P* < .05 was considered significant. Ease of use and satisfaction were assessed using the Wilcoxon rank-sum test, and depression and anxiety, adjusted for baseline scores, were assessed using analysis of variance. Definitions and references for all measures are in the trial protocol in Supplement 1.

Missing Data

There were no missing data for the primary outcome. For secondary outcomes, 920 of 986 participants (93.3%) had at least 1 follow-up interview, and all available data were included in the mixed-effects models.

Results

Of 1797 eligible patients, 986 (54.9%) enrolled; 481 were randomized to PREPARE and 505 to the AD-only group (Figure 1). The refusal rate was 30.1% (540 of 1797). Those who refused were older than those who enrolled (mean [SD] age, 66.9 [7.9]

vs 63.3 [6.4] years; *P* < .001), but the groups did not otherwise differ. Among enrolled participants, 387 of 975 (39.7%) had limited health literacy, 504 of 983 (51.3%) reported fair to poor health, 269 (27.3%) had any prior documentation of ACP, and 99 (10.0%) had documentation of ACP during the 12 months prior to the intervention (Table 1). Participant characteristics did not differ between arms, except a higher rate of prior documentation of ACP among Spanish speakers in the AD-only arm compared with Spanish speakers in the PREPARE arm (64 of 226 [28.3%] vs 44 of 219 [20.1%]; *P* = .04). Twelve-month retention was 85.9% (832 of 969) among survivors (Figure 1) and 89 (9.0%) withdrew, 56 of 481 in PREPARE (11.6%) and 33 of 505 in the AD-only arm (6.5%) (*P* = .04) (eTable 1 in Supplement 2). No staff became unblinded.

New overall documentation of ACP at 15 months was higher in the PREPARE vs AD-only arm (unadjusted, 43.0% [207 of 481] vs 33.1% [167 of 505]; *P* < .001; and adjusted, 43% vs 32%; *P* < .001). All differences were significant for English and Spanish speakers (Figure 2). When assessed separately, documentation of legal forms was higher in the PREPARE vs AD-only arm in adjusted analysis (26% vs 13%; *P* < .001), but did not differ between arms for documented discussions in adjusted analysis (31% vs 26%; *P* = .10). There were no significant interaction effects of any participant characteristics for documentation of ACP, including health literacy, desired role in decision making, and patient-clinician language concordance for Spanish speakers (eTable 2 in Supplement 2).

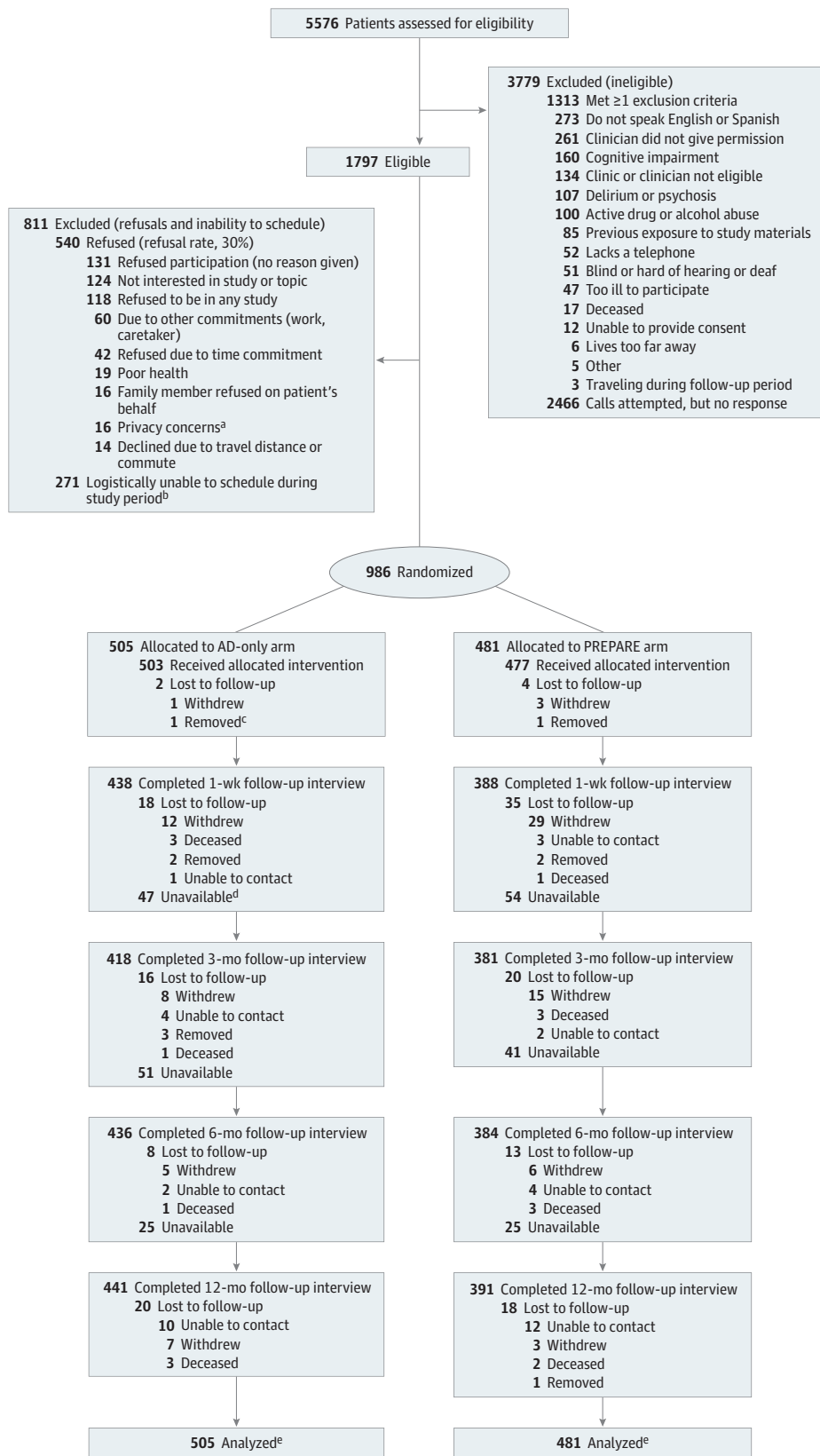
Mean ACP behavior change and action scores increased significantly more in the PREPARE vs AD-only arm overall and for English speakers and Spanish speakers for all time points (Figure 3). Effect sizes were medium to large for PREPARE and small to medium for the AD-only group (eTable 3 in Supplement 2).²⁹ In the PREPARE arm, 472 of 481 participants (98.1%) reported increased ACP engagement (behavior change or action) scores over time vs 452 of 505 participants (89.5%) for the AD-only arm (Table 2). When examined separately, behavior change scores (469 of 481 [97.5%] vs 441 of 505 [87.3%]; *P* < .001) and action scores (456 of 481 [94.8%] vs 396 of 505 [78.4%]; *P* < .001) were also higher for PREPARE vs the AD-only group (Table 2). Increases were significant for all types of ACP activities as well as for discussion-specific and documentation-specific ACP activities and among English speakers and Spanish speakers (Table 2).

Reported ease of use and satisfaction were high and did not differ between arms. However, PREPARE was perceived as significantly more helpful than the AD only overall and by English speakers and Spanish speakers (eTable 4 in Supplement 2). No adverse events were reported and adjusted mean depression and anxiety scores at 12 months did not differ between arms overall or for English speakers or Spanish speakers (eTable 5 in Supplement 2).

Discussion

In a diverse cohort of 986 English-speaking and Spanish-speaking older adults in a safety-net clinic setting, with high

Figure 1. CONSORT Diagram of Screening, Enrollment, and Follow-up of Trial Participants



AD indicates advance directive; and PREPARE, PREPARE For Your Care.

^a Concerns about privacy of medical information or distrust of the clinic or hospital.

^b Patient willing to participate, but logistical issues (eg, work, caretaking, travel, illness) prevented scheduling.

^c Removed from study for staff safety.

^d Unavailable participants completed subsequent interviews and were not lost to follow-up.

^e Total retention rate of survivors was 85.9% (832 of 969); there were 17 decedents. The AD-only retention rate was 88.7% (441 of 497); there were 8 decedents. The PREPARE arm retention rate was 82.8% (391 of 472); there were 9 decedents.

Table 1. Participant Characteristics^a

Characteristic ^b	All Participants (N = 986)		English Speakers (n = 541)		Spanish Speakers (n = 445)	
	AD-Only Arm (n = 505)	PREPARE Arm (n = 481)	AD-Only Arm (n = 279)	PREPARE Arm (n = 262)	AD-Only Arm (n = 226)	PREPARE Arm (n = 219)
Age, mean (SD), y	63 (6.3)	63 (6.4)	62 (5.4)	63 (6.1)	64 (7.2)	64 (6.8)
Women, No. (%)	314 (62.2)	289 (60.1)	151 (54.1)	132 (50.4)	163 (72.1)	157 (71.7)
Race/ethnicity, No. (%)						
White Latino or Hispanic	248 (49.1)	251 (52.2)	24 (8.6)	35 (13.4)	224 (99.1)	216 (98.6)
White non-Latino or Hispanic	104 (20.6)	85 (17.7)	104 (37.3)	84 (32.1)	0	1 (0.5)
African American	92 (18.2)	86 (17.9)	92 (33.0)	86 (32.8)	0	0
Asian or Pacific Islander	34 (6.7)	44 (9.1)	34 (12.2)	44 (16.8)	0	0
Multietnic or other	27 (5.3)	15 (3.1)	25 (9.0)	13 (5.0)	2 (0.9)	2 (0.9)
US acculturation						
Place of birth, No. (%)						
United States	219 (43.4)	193 (40.1)	216 (77.4)	192 (73.3)	3 (1.3)	1 (0.5)
South America	17 (3.4)	13 (2.7)	4 (1.4)	3 (1.1)	13 (5.8)	10 (4.6)
Central America	161 (31.9)	154 (32.1)	9 (3.2)	7 (2.7)	152 (67.3)	147 (67.1)
North American Latino Countries	63 (12.5)	67 (14.0)	5 (1.8)	6 (2.3)	58 (25.7)	61 (27.8)
Other	45 (8.9)	53 (11.0)	45 (16.1)	53 (20.2)	0	0
If born outside United States, years in the United States, mean (SD)	27 (13.3)	27 (13.3)	32 (16.5)	33 (16.5)	26 (11.9)	26 (11.7)
Educational level, No. (%)						
≤High school	287 (56.8)	289 (60.1)	102 (36.6)	102 (38.9)	185 (81.9)	187 (85.4)
Limited health literacy, No. (%)	202 (40.0)	185 (38.5)	60 (21.5)	56 (21.4)	142 (62.8)	129 (58.9)
Patient-clinician language discordance, No. (%)	NA	NA	NA	NA	86 (41.2)	65 (32.2)
Finances, No. (%)						
Not enough to make ends meet	124 (25.0)	119 (25.1)	65 (23.8)	56 (21.5)	59 (26.5)	63 (29.4)
Financial social standing, mean (SD)						
1-10 score	6.1 (7.7)	6.0 (6.9)	6.4 (7.3)	6.6 (9.1)	5.8 (8.1)	5.3 (2.3)
Religious						
Fairly to extremely, No. (%)	267 (53.4)	245 (51.6)	150 (54.6)	140 (54.3)	117 (52.0)	105 (48.4)
Spiritual, No. (%)						
Fairly to extremely	332 (66.3)	296 (62.1)	190 (68.8)	173 (66.8)	142 (63.1)	123 (56.4)
Social support						
Measure of social support score (total, 11-55), mean (SD)	38.3 (11.7)	37.9 (11.8)	39.8 (10.6)	38.6 (11.2)	36.5 (12.7)	37.0 (12.4)
In a married or long-term relationship, No. (%)	179 (35.5)	166 (34.7)	98 (35.1)	80 (30.7)	81 (35.8)	86 (39.5)
Have adult children, No. (%)	374 (74.2)	362 (75.4)	173 (62.2)	168 (64.4)	201 (88.9)	194 (88.6)
Have a potential surrogate, No. (%)	482 (95.5)	463 (96.5)	263 (94.3)	246 (93.9)	219 (96.9)	217 (99.5)
Health and functional status						
Self-rated health, fair to poor, No. (%)	249 (49.4)	255 (53.2)	122 (43.9)	128 (49.0)	127 (56.2)	127 (58.3)
Instrumental activities of daily living difficulty score (total, 0-16), mean (SD)	2.7 (3.8)	2.6 (3.5)	2.9 (3.9)	2.8 (3.6)	2.5 (3.6)	2.4 (3.4)
Activities of daily living difficulty score (total, 0-12), mean (SD)	1.8 (2.2)	1.7 (2.1)	1.8 (2.2)	1.8 (2.4)	1.9 (2.2)	1.6 (1.8)
Depression, moderate to severe, No. (%) ^c	64 (12.7)	60 (12.5)	35 (12.5)	33 (12.6)	29 (13.0)	27 (12.3)
Anxiety, moderate to severe, No. (%) ^c	61 (12.1)	42 (8.7)	35 (12.5)	21 (8.0)	26 (11.5)	21 (9.6)
Desired role in decision making						
Low decision control preference (ie, physicians make all medical decisions), No. (%)	44 (8.8)	52 (11.0)	11 (4.0)	19 (7.4)	33 (14.8)	33 (15.3)
Internet access						
Access to the internet in the home, No. (%)	265 (52.6)	228 (47.5)	187 (67.3)	171 (65.3)	78 (34.5)	57 (26.1)

(continued)

Table 1. Participant Characteristics^a (continued)

Characteristic ^b	All Participants (N = 986)		English Speakers (n = 541)		Spanish Speakers (n = 445)	
	AD-Only Arm (n = 505)	PREPARE Arm (n = 481)	AD-Only Arm (n = 279)	PREPARE Arm (n = 262)	AD-Only Arm (n = 226)	PREPARE Arm (n = 219)
Prior planning activities						
Completed a will, No. (%)	57 (11.4)	71 (14.8)	37 (13.3)	51 (19.5)	20 (8.9)	20 (9.2)
Made funeral arrangements, No. (%)	118 (23.7)	114 (23.8)	62 (22.6)	60 (23.1)	56 (25.1)	54 (24.7)
Any prior ACP documentation, No. (%) ^d	148 (29.3)	121 (25.2)	84 (30.1)	77 (29.4)	64 (28.3) ^e	44 (20.1) ^e
Legal forms, No. (%)	89 (17.6)	79 (16.4)	45 (16.1)	50 (19.1)	44 (19.5)	29 (13.2)
Documented discussions about ACP, No. (%)	81 (16.0)	64 (13.3)	52 (18.6)	43 (16.4)	29 (12.8)	21 (9.6)
Baseline ACP documentation rate 12 mo before intervention exposure, No. (%)	58 (11.5)	41 (8.5)	36 (12.9)	28 (10.7)	22 (9.7)	13 (5.9)

Abbreviations: ACP, advance care planning; AD, advance directive; NA, not applicable; PREPARE, PREPARE For Your Care.

^a Percentages reported in the table correspond to denominators that correct for missing data, overall less than 5% missing. The following data were missing: place of birth: 1 missing in PREPARE arm; years in United States: 5 missing in AD arm, 6 missing in PREPARE arm; limited health literacy: 4 missing in AD arm, 7 missing in PREPARE arm; patient-clinician language discordance: 17 missing in AD arm, 17 missing in PREPARE arm; finances: 9 missing in AD arm, 7 missing in PREPARE arm; financial social standing: 4 missing in AD arm, 3 missing in PREPARE arm; religious: 5 missing in AD arm, 6 missing in PREPARE arm; spiritual: 4 missing in AD arm, 4 missing in PREPARE arm; measure of social support score: 14 missing in AD arm, 15 missing in PREPARE arm; in a married or long-term relationship: 2 missing in PREPARE arm; have adult children: 1 missing in AD arm, 1 missing in PREPARE arm; have a potential surrogate: 1 missing in PREPARE arm; self-rated health: 1 missing in AD arm, 2 missing in PREPARE arm; instrumental activities of daily living difficulty score: 1 missing in PREPARE arm; activities of daily living difficulty score: 1 missing in PREPARE arm; depression: 3 missing in PREPARE arm; low decision

control preference: 6 missing in AD arm, 9 missing in PREPARE arm; internet access: 1 missing in AD arm, 1 missing in PREPARE arm; completed a will: 3 missing in AD arm, 2 missing in PREPARE arm; made funeral arrangements: 7 missing in AD arm, 2 missing in PREPARE arm.

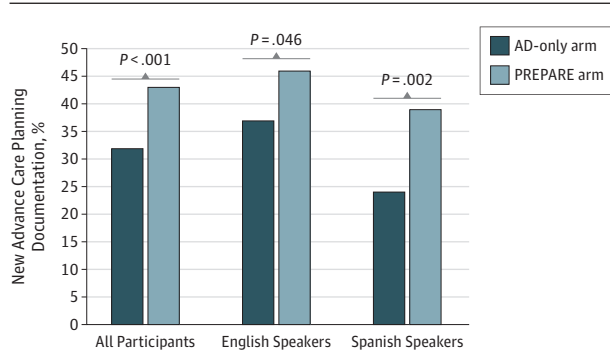
^b All variables are defined including reliability, validity, response options, scoring, and references in the online protocol and the published protocol.²¹

^c Depression is measured with the 8-item Patient Health Questionnaire (scores, 0-24) and anxiety is measured with the 7-item Generalized Anxiety Disorder screening measure (scores, 0-21). Moderate to severe depression or anxiety are defined by scores on both assessments of more than 10.²¹

^d Any prior ACP documentation includes any prior legal forms (ie, advance directives, durable power of attorney for health care, and Physicians Orders for Life Sustaining Treatment) and documented ACP discussions in the past 5 years (ie, oral directives or goals of care notes by clinicians).²¹

^e There were no significant between-group differences for any patient characteristic overall and for English speakers or Spanish speakers, except for any previous ACP documentation among Spanish speakers ($P = .04$).

Figure 2. New Advance Care Planning Documentation in the Medical Record



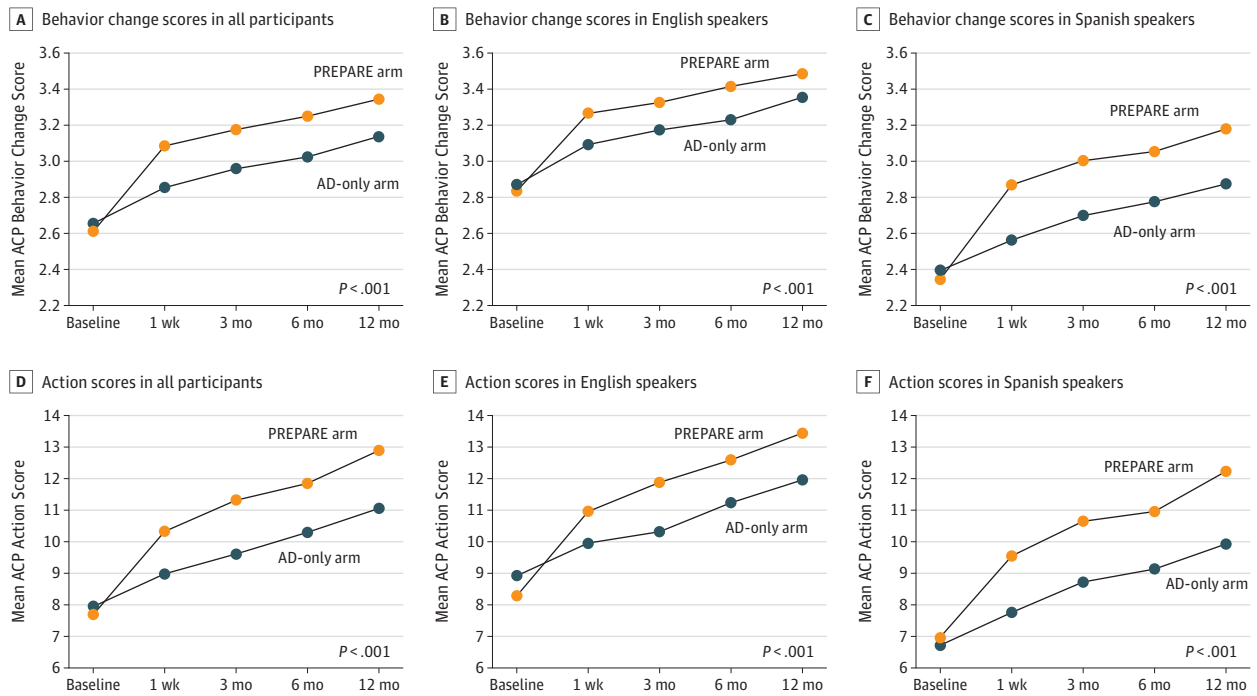
The PREPARE For Your Care (PREPARE) arm included the website (<http://www.prepareforyourcare.org>) plus an easy-to-read advance directive (AD). The AD-only arm included only the easy-to-read AD.

rates of chronic disease and limited health literacy, both the easy-to-read AD and the patient-directed, interactive online PREPARE program significantly increased documentation of ACP and patient-reported ACP engagement, with significantly greater gains in the PREPARE arm. This improvement was achieved without additional clinician-level or system-level interventions. To our knowledge, this is the largest, most culturally diverse trial of patient-facing ACP interventions.

These results are important because, historically, studies have demonstrated limited ACP engagement among low-income, diverse, Spanish-speaking older adults as well as a dearth of literacy-appropriate, culturally appropriate, and linguistically appropriate patient-facing ACP materials.^{9,14-16} The observed gains in documentation of ACP in this trial (43%) and a prior PREPARE trial among veterans (35%)²⁰ are likely the result of a combination of novel health communication components of the patient-directed, interactive, online PREPARE program. These include co-creation with and for diverse populations to mitigate literacy, cultural, and language barriers^{10,18}; theory-based content designed to enhance self-efficacy and readiness; and the use of narratives, testimonials, video stories, and modeling of behaviors, all of which are strategies demonstrated to help patients make decisions about ACP.³⁰ The magnitude of improvement in documentation is clinically meaningful given the known deficiencies in clinician documentation, especially documented discussions.³¹ The high proportion of patient-reported ACP engagement for both documentation (422 of 481 [87.7%]) and discussions (451 of 481 [93.8%]) in the PREPARE arm further validates our medical record findings and demonstrates that patients engage in a range of ACP behaviors, such as discussions with surrogates and clinicians, in addition to documentation.^{19,23,32}

Prior studies of patient-directed ACP tools in primary care have been less effective in increasing documentation of ACP (5%-23%) than coaching or facilitation.^{7,33,34} The use of trained

Figure 3. Advance Care Planning (ACP) Engagement Behavior Change and Action Scores



Behavior change was measured on a 5-point Likert scale. Action scores ranged from 0 to 25. *P* values reflect significance for overall group + time interactions using repeated measures, mixed-effects linear regression models adjusted for health literacy, baseline ACP documentation, and clustering by physician. Statistical significance set at *P* < .025 to account for multiple comparisons for the 2 outcomes of behavior change and action scores. No additional *P* value

adjustments were made for analyses stratified by language as these were prespecified. *P* values reflect group by time interactions. In addition, all *P* values for time were also less than .001 (ie, both PREPARE and AD-only arms increased significantly from baseline). AD indicates advance directive; and PREPARE, PREPARE For Your Care.

Table 2. Percentage of Participants With Increased ACP Behavior Change and Actions Scores Over Time

Participants	Improvement in Behavior Change and ACP Actions ^a			Improvement in ACP Behavior Change Only			Improvement in ACP Actions Only		
	AD-Only Arm, No. (%)	PREPARE Arm, No. (%)	<i>P</i> Value ^b	AD-Only Arm, No. (%)	PREPARE Arm, No. (%)	<i>P</i> Value ^b	AD-Only, No. (%)	PREPARE Arm, No. (%)	<i>P</i> Value ^b
All participants, No.	505	481		505	481		505	481	
All ACP activities ^c	452 (89.5)	472 (98.1)	<.001	441 (87.3)	469 (97.5)	<.001	396 (78.4)	456 (94.8)	<.001
Documentation	431 (85.3)	476 (99.0)	<.001	419 (83.0)	472 (98.1)	<.001	237 (46.9)	422 (87.7)	<.001
Discussions	453 (89.7)	474 (98.5)	<.001	430 (85.1)	464 (96.5)	<.001	397 (78.6)	451 (93.8)	<.001
English speakers, No.	279	262		279	262		279	262	
All ACP activities	263 (94.3)	259 (98.9)	.004	258 (92.5)	257 (98.1)	.002	223 (79.9)	250 (95.4)	<.001
Documentation	247 (88.5)	261 (99.6)	<.001	236 (84.6)	258 (98.5)	<.001	166 (59.5)	252 (96.2)	<.001
Discussions	257 (92.1)	258 (98.5)	<.001	249 (89.2)	255 (97.3)	<.001	212 (76.0)	248 (94.7)	<.001
Spanish speakers, No.	226	219		226	219		226	219	
All ACP activities	189 (83.6)	213 (97.3)	<.001	183 (81.0)	212 (96.8)	<.001	173 (76.5)	206 (94.1)	<.001
Documentation	184 (81.4)	215 (98.2)	<.001	183 (81.0)	214 (97.7)	<.001	71 (31.4)	170 (77.6)	<.001
Discussions	196 (86.7)	216 (98.6)	<.001	181 (80.1)	209 (95.4)	<.001	185 (81.9)	203 (92.7)	<.001

Abbreviations: ACP, advance care planning; AD, advance directive; PREPARE, PREPARE For Your Care.

^a The validated Advance Care Planning Engagement Survey includes both self-reported behavior change and action scores. Percentages reflects participants with positive slopes over time, adjusted for health literacy, baseline ACP documentation, and clustering by physician.

^b Statistical significance set at *P* = .017 to account for multiple comparisons for the 3 outcomes of improvement in behavior change or action, behavior change only, and action only. No additional *P* value adjustments were made for

analyses stratified by language as these were prespecified.

^c "All ACP Activities" is a composite measure of behavior change and action scores. We present slopes for all reported ACP activities as well as ACP documentation-specific and ACP discussion-specific activities. To specifically assess engagement in ACP discussions or documentation, we categorized Advance Care Planning Engagement Survey items into those related to discussions (ie, survey item referred to "ask" or "talk") and documentation (ie, survey item referred to "signing" or "documenting").

clinicians or ACP facilitators has shown improvements of 50% or more in documentation of ACP among English-speaking and Spanish-speaking patients.^{3,7,33-38} However, many health care organizations, especially public and safety-net settings, do not have the resources for dedicated, trained ACP facilitators. This study demonstrates that PREPARE and the easy-to-read AD enable many patients to initiate and engage in the ACP process on their own, without the need for trained facilitators. All care plans should be reviewed by a medical professional within the patient's clinical context. In addition, some individuals will need additional support to engage in ACP. Future research should explore whether PREPARE results in ACP quality comparable with that achieved by trained facilitators and whether combining PREPARE and the easy-to-read AD with other clinician-level or system-level interventions results in synergistic gains.

Limitations

This study has some limitations. Generalizability may be limited because participants were recruited from 1 integrated public-health delivery system in San Francisco; however, the sample was racially and ethnically diverse. It was not possible to blind participants; however, research staff were blinded for all follow-up assessments. Although limited staff support was provided, the interventions were viewed in research offices, and we do not have information concerning the questions asked of staff. Similarly, study interviews and reminder calls may have activated patients to engage in ACP. Additional studies are

needed to determine whether similar results may be obtained if the materials are viewed at home or without reminder calls, often a regular part of primary care. Alternatively, because PREPARE was compared with an evidence-based, easy-to-read AD, PREPARE's real-world effect compared with usual care may have been underestimated. Finally, we did not assess quality of ACP or longitudinal effects on the receipt of medical care aligned with patients' values or costs. Shorter versions of PREPARE are now available for home use and future longitudinal effectiveness trials are needed and are under way.

Conclusions

The patient-facing, easy-to-read AD and the patient-directed, interactive, online PREPARE program, without additional system or clinician interventions, can substantially increase ACP documentation and engagement. PREPARE plus an easy-to-read AD resulted in higher ACP documentation and engagement than the AD alone, an effect that remained across English speakers and Spanish speakers and participants with limited health literacy. This study suggests that PREPARE and the easy-to-read directive are useful and potentially scalable ACP interventions for diverse populations. These patient-directed interventions may mitigate literacy, cultural, and language barriers to ACP; allow patients to begin planning on their own; and could substantially improve the process for diverse, English-speaking and Spanish-speaking populations.

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