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Increasing Engagement in Advance Care Planning Using a Behavior Change Model: Study Protocol for the STAMP Randomised Controlled Trials

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ABSTRACT

Introduction: Advance care planning (ACP) is a key component of high-quality end-of-life care but is underutilized. Interventions based on models of behavior change may fill an important gap in available programs to increase ACP engagement. Such interventions are designed for broad outreach and flexibility in delivery. The purpose of the STAMP (Sharing and Talking about My Preferences) study is to examine the efficacy of three behavior-change approaches to increasing ACP engagement through two related randomised controlled trials being conducted in different settings (Veterans Affairs [VA] medical center and community).

Methods and analysis: Eligible participants are 55 or older. Participants in the community are being recruited in person in primary care and specialty outpatient practices and senior living sites, and participants in the VA are recruited by telephone. In the community, randomization is at the level of the practice or site, with all persons at a given practice/site receiving either computer-tailored feedback with a behavior stage-matched brochure (CTI) or usual care. At the VA, randomization is at the level of the participant and is stratified by the number of ACP behaviors completed at baseline. Participants are randomised to one of four groups: CTI, motivational interviewing, motivational enhancement therapy, or usual care. The primary outcome is completion of four key ACP behaviors: identification of a surrogate decision maker, communication about goals, completing advance directives, and ensuring documents are in the medical record. Analysis will be conducted using mixed effects models, taking into account the clustered randomisation for the community study.

Ethics and randomization: The studies have been approved by the appropriate Institutional Review Boards and are being overseen by a Safety Monitoring Committee. The results of these studies will be disseminated to academic audiences and leadership in in the community and VA sites.

Trial registration numbers: NCT03137459, NCT03103828

Strengths and limitations of this study

- The intervention is based on a comprehensive model of advance care planning (ACP) that focuses on enhancing engagement and improving communication among patients, their surrogates, and their providers.
- The behavioral health approach to ACP provides a framework for practical interventions that can be implemented in a wide variety of settings.
- The interventions have been developed in English only, and the study therefore excludes individuals whose primary language is other than English.
- The study is being conducted in a single geographic region and therefore may have limited generalizability.

Key words: Advance care planning; health behavior; randomised controlled trial

INTRODUCTION

The Institute of Medicine (IOM) report, "Dying in America: Improving Quality and Honoring Individual Preferences near the End of Life" devotes an entire chapter to advance care planning (ACP), the process by which patients can plan for the care they will receive if they become incapable of participating in medical decision making.[1] The report endorses the promise of ACP to provide "a measure of control over the final phase of life" and to ensure that "patients' wishes are known and respected to the extent possible." ACP is also associated with improved caregiver outcomes.[2 3] However, as outlined in the IOM report chapter, ACP remains underutilized. A recent systematic review concluded that only approximately one-third of adults in the United States has completed advance directives (ADs).[4] Moreover, ADs alone are not sufficient in the absence of efforts to promote communication.[5]

Several intervention approaches have demonstrated efficacy in increasing engagement in ACP. Respecting Choices, consisting of facilitated discussions lasting between 60 and 90 minutes between patients and their surrogates, increased surrogates' knowledge of patients' preferences and reduced caregiver stress.[6,7] The PREPARE website, a self-administered tool providing step-by-step processes for ACP supplemented with video stories and modeling of behaviors, increased ACP documentation.[8] Additional approaches may be necessary to bridge the gap between intensive clinician-led and self-administered tools for ACP engagement. For example, efforts to replicate and disseminate the Respecting Choices program in a large metropolitan area required "concerted and sustained leadership," a prolonged planning phase and the subsidizing of salaries.[9] This experience suggests that intensive programs are best targeted to selected patients at high risk of facing difficult treatment choices. The IOM report supports such targeting, suggesting a lifespan approach to ACP, beginning early with broad considerations of wishes that become more clinical and detailed over time. This lifespan strategy is congruent with our approach, which is designed to promote widespread dissemination of material that engages individuals in mid-life and works to give them the tools to

help them reconsider their wishes over time as health challenges become clearer. While the PREPARE website provides a thorough introduction to ACP, over 50% of participants had no access to the internet, and the website was viewed in research offices,[8] suggesting that web-based materials may have limited outreach.

The STAMP (Sharing and Talking about My Preferences) study was designed to address gaps in the existing programs for promoting participation in ACP. The STAMP interventions are based on the conceptual model of ACP considered as a set of inter-related health behaviors.[10] Prior research has demonstrated that participants have variable readiness to engage in ACP behaviors,[10] and that this readiness can be represented and explained by constructs of the Transtheoretical Model (TTM), including stages of change, decisional balance (the pros and cons of behavior change) and processes of change.[11] Readiness is also explained by a construct of values/beliefs. Unlike the pros and cons, which are factually verifiable, values and beliefs consist of common misperceptions about ACP and religious values that can function as barriers to ACP.[11]

STAMP evaluates three behavior-change approaches to promoting ACP engagement. The first is the use of individualized feedback reports with stage-matched brochures.[12] The second is telephone-delivered motivational interviewing (MI), and the third is telephone-delivered motivational enhancement therapy (MET), a combination of written feedback and MI. The health behaviors consist of: a) identifying a trusted individual to act as a surrogate decision maker or healthcare agent; b) communicating with this person about goals, preferences, and values; c) completing advance directives (formal assignment of healthcare agent and living will); d) ensuring both that the physician is aware of documents and that documents are in the medical record. STAMP consists of two related randomised controlled trials (RCTs). The hypothesis is that individuals receiving each of the behavior change approaches will be more likely than individuals receiving usual care to complete all of the health behaviors.

METHODS AND ANALYSIS

Study overview:

STAMP consists of two related randomised controlled trials (RCTs), with shared inclusion and exclusion criteria for study participation, measures, outcomes, and analytic approaches but with enrollment procedures and interventions adapted for each of the two trials. Each RCT will test the efficacy of one or more interventions on the proportion of study participants who complete participation in ACP compared to usual care. One RCT is being conducted within the primary care clinics of the Veterans Affairs Connecticut Healthcare System (subsequently referred to as the VA study) and the second is in community-based primary care practices and senior living communities in the greater New Haven area (subsequently referred to as the community study). Trial registration data are provided in Table 1.

Participants, recruitment, and enrollment:

Inclusion criteria include: age 55 years or older, and, for participants recruited in the VA study, having a primary care clinic visit within the last twelve months. Exclusion criteria include: severe hearing or vision loss, moderate-to-severe cognitive impairment identified by chart review (VA study only), physician diagnosis, Brief Orientation Memory Concentration test score > 10[13] or inability to participate in the process of informed consent; primary language other than English; active psychiatric illness (current symptoms of depression, anxiety, substance abuse, or psychosis), no regular access to a telephone; no permanent mailing address; completion of all four ACP behaviors; or lack of physician permission for participation.

Screening, recruitment, and enrollment for participants differs according to study. In the VA study, potential participants are selected from a list obtained under a Health Insurance Portability and Accountability Act waiver of all persons age 55 and older who have had a primary care visit within the last year at VA Connecticut. This method of identifying participants accomplishes two objectives. First, it facilitates oversampling of women and minorities to ensure adequate representation in the study population. The study is aiming for 25% women and 40%

non-white participants. Second, it allows for all study procedures to be done by telephone. Veterans relying on public transportation face a significant barrier to access, with only 25% living within a 60-minute transit time from a VA medical facility.[14] The ability to identify individuals and deliver the intervention by telephone is in keeping with the VA's investment in telehealth to improve access to a variety of services.[15] Chart screens are performed to identify exclusion criteria. Potentially eligible participants are sent an opt-out letter. If they do not opt out, a research assistant calls the participant to explain the study and completes the screening for eligibility. If the participant is eligible and interested in participation, a process of verbal assent is obtained. Participants who are randomised to MI or MET are asked if they have a surrogate they would like to include in their MI/MET session. If they do, they are asked to provide the contact information for the surrogate, who must then provide verbal assent prior to inclusion in the session. All identifiable data are stored separately from study records, which are identified by code number, in access-restricted database files behind institutional firewalls. Printed records are kept in locked offices.

Recruitment in the community study is designed to encourage ACP as a part of routine healthcare. In community practices, the list of patients scheduled for either well patient or routine follow-up visits is reviewed prior to each clinic session to identify potentially eligible participants. These individuals are given an information sheet to read prior to the encounter. The clinician confirms patient interest in the study, and willing individuals meet with a research assistant at the end of the encounter to complete a process of written informed consent. In senior living communities, recruitment takes place both in the on-site medical clinics as described above and among the community as a whole. For the latter, the study is introduced in a talk given by the principal investigator, followed by the opportunity for volunteers to sign up for times to meet with the research assistant to complete written informed consent.

Intervention and control conditions

Similar to recruitment procedures, the intervention arms are tailored to take advantage of the opportunities offered by the different study settings. The availability of health psychologists and MI training at the VA supported the strategy of developing MI interventions to promote ACP engagement in addition to a computer-tailored intervention that generates printed feedback. Therefore, in the VA study, there are four arms: computer-tailored intervention (CTI), MI, MET, and control. In the community, there are two arms: CTI and control. All arms consist of contact at baseline, two months, and four months with delivery of the intervention according to assignment. There is a contact at six months for final assessment.

CTI

The development of the CTI has been previously described.[12] Briefly, it is an expert system (a software system consisting of an assessment battery, normative data to make comparisons, decision rules for delivering feedback, and feedback components) based on the TTM. TTM intervention principles include respecting and reflecting individuals' stages of change and their progress over time on each construct in individualized feedback reports. Such reports have been found to be effective across a wide range of other health behaviors.[16] The system assesses key constructs of the TTM, including stage of change (readiness to participate in each of the ACP behaviors), decisional balance, values/beliefs, and processes of change. The original system consisted of feedback paragraphs developed for each stage of the four ACP behaviors and for decisional balance, which are pulled into a templated cross-sectional, or "normative," report. For this study, the system was further developed in order to give feedback based on simultaneous consideration of stage for all four behaviors (referred to as stage pattern) as well as to give longitudinal feedback by comparing stage at follow-up to stage at baseline ("ipsative" reporting). Each feedback report consists of: 1) introduction to ACP (common across reports); 2) figure illustrating stage of change for each behavior (normative) and changes in stage at follow-up (ipsative) (see figure 1); 3) brief stage pattern-tailored

feedback; 4) feedback for up to three endorsed values/beliefs items; 5) decisional balance by stage pattern feedback; 6) processes/strategies/efficacy or “next steps” stage pattern-tailored feedback; 7) summary. For participants in the earliest stages of change for multiple behaviors, the report provides brief “next steps” focused on activities to help promote favorable attitudes toward ACP. For participants in later stages, the report provides suggestions for how the participant can go about engaging in the behavior. The “next steps” section also informs participants how completing one ACP behavior can help in the completion of others.

The feedback reports make reference to one of two stage-matched brochures. Each of these brochures provides additional details of ACP. The first brochure, provided to participants who have not yet completed any of the ACP behaviors, provides additional information promoting the reasons for engaging in ACP and addressing potential barriers. It also contains two stories describing families who did and did not engage in ACP. The second brochure, provided to participants who have completed at least one ACP behavior, also contains additional information about how to engage in each. In addition, this brochure contains either the VA or state of Connecticut Advance Directives Form. Finally, participants receive a four-fold pamphlet designed to be given to potential surrogate decision makers in order to explain their role in ACP.

For participants enrolled in the VA, the assessment occurs by telephone and the feedback report, brochure, and pamphlet are mailed. For participants enrolled in the community, the initial assessment is done in person in the clinician office or private space in the senior living community, and the report is printed using a portable printer. If the participant does not have sufficient time after his/her appointment but has provided informed consent, the assessment is done by telephone at a later time. All follow-up assessments are done by telephone, with reports mailed to participants.

MI

The development of the MI protocol has been previously described.[17] MI sessions are conducted by health psychologists and social workers who have received training by Dr. Martino, a member of the research team and of the Motivational Interviewing Network of Trainers, who is an expert in training clinicians in the conduct of MI for clinical trials.[18-20] The training consisted of a two-day experiential workshop and STAMP MI/MET manual review, followed by supervised practice cases, incorporating fidelity rating-based feedback and coaching based on the review of audio recorded telephone sessions using the Independent Tape Rater Scale.[21] Dr. Martino reviewed and rated all practice cases for initial certification. Initial certification was defined as at least adequate or average adherence and competence ratings on three consecutive practice sessions. If a clinician's performance later drifts below the initial certification level during the trial, then Dr. Martino will provide additional supervision and training and assign another practice case if necessary. The MI intervention consists of four steps: 1) elicitation and clarification of patient's understanding of and current engagement in ACP; 2) building motivation for ACP; 3) developing a change plan; and 4) summarizing the overall discussion. The first step involves understanding in what ways the patient thinks ACP is important and the patient's knowledge of the four key ACP behaviors. Consistent with MI, the Elicit-Provide-Elicit approach is used to deliver ACP. This approach involves inviting the patient to share his/her knowledge, asking the patient permission to provide additional information, and then eliciting the patient's reaction to this new information. The second step consists of four activities that are utilized as needed. The first activity is an enhanced discussion of reasons to engage in ACP, with attention paid to developing the discrepancies between the most important reasons for engagement and lack of ACP participation. The second is addressing beliefs that serve as barriers to ACP. The third is an exercise to help patients clarify their values regarding quality versus quantity of life. Understanding how patients view this trade-off is central to decision making about potentially

life-sustaining treatment[22] and is included in a number of ACP tools[23 24] as well as in the brochure provided with CTI. The fourth activity is a discussion of experiences that could help ACP engagement. If the participant has a surrogate who agrees to be part of the MI, the surrogate's perspectives are elicited in each of these steps. In pilot-testing, sessions lasted a mean (SD) of 34.9 (6.5) minutes.

MET

In the MET arm, participants are provided the CTI TTM-based feedback materials, and then engage in a MI interview as described above, with the addition of review of the materials with the clinician. Each component of the interview makes mention as appropriate to specific sections of the stage-matched brochures to address knowledge gaps and provide more information about reasons to engage in ACP and addressing ACP barriers. In an additional section of the interview specific to MET, the clinician reviews the personalized feedback report with the participant to facilitate the development of a change plan.

Control

Participants in the control arm receive assessments at baseline, two, and four months but do not receive any additional information about ACP, other than that potentially provided in usual care. In order to minimize the effect of asking about ACP behaviors on participants' engagement in these behaviors, the control assessments conclude with questions about readiness to engage in and pros and cons of physical activity.

Randomisation

Randomisation in the community trial is at the level of the practice/senior living community in order to avoid contamination. Contamination could occur if patients assigned to the intervention increased their clinicians' awareness of ACP, and then clinicians changed their behaviors towards other participants potentially assigned to the control group. Therefore, randomisation occurs within matched pairs of sites, instead of at the individual level. Sites are matched according to available data regarding characteristics most likely to be associated with ACP

participation. For clinical sites, this includes proportion of patients: age 55 years and older, non-white, and with Medicaid. For senior living communities, this includes type of community (e.g. continuing care retirement community) and, if applicable, type of contract (e.g. life care, fee-for-service). After matching, sites are randomised by means of computer-based random number generator.

Because participants at the VA belong to a very large panel of providers, each of whom would have only a small number of patients in the study, randomisation is at the level of the patient. Number of ACP behaviors completed at baseline may be the single variable most highly associated with the likelihood of full ACP engagement, since engagement is cross-sectionally related to attitudes, beliefs, and processes related to ACP[11] and to a number of sociodemographic characteristics[25] and life experiences.[26] Therefore, in order to ensure balanced representation of number of ACP activities completed at baseline across the four study arms, participants are assigned using stratified permuted block randomisation with a block length of eight via a customized computer program that provides the assignment at the time of randomisation.

Blinding

Participants are not blinded to their assignment. Research assistants are not blinded to participant assignment at interim time points since the assessment, as described below, differs slightly according to the assignment. However, blinded research assistants ascertain the primary study outcome at the six-month assessment.

Measures

The *primary outcome* is having completed, or being in the action/maintenance stage as specified in the TTM, for all of the four key ACP behaviors at six months. The designation of action and maintenance was originally designed for behaviors that required ongoing effort, such as smoking cessation and exercise, and refer to how long ago the behavior was initiated. While there are activities that an individual can and should be doing during the maintenance phase of

ACP, such as reviewing and updating documents, the focus for this study was on initial engagement in ACP. Therefore, these two stages were combined. The *secondary outcomes* are the stage of change for each of the behaviors. The stages of change prior to action/maintenance are: precontemplation, or not ready to take action within the next six months; contemplation, or thinking about taking action over the next six months; and preparation, or planning on taking action in the next thirty days. These variables are measured at each assessment: baseline, two months, four months, and six months.

Sociodemographic, health, and psychosocial status variables are assessed to describe the study population, test for the adequacy of randomisation, and use as covariates. The sociodemographic status variables include: age, gender, race/ethnicity, level of education, income, marital status, housing type, living alone or with others. The health status variables include: self-rated health,[27] self-rated quality of life, and variables included in a validated prognostic index for four-year mortality: current tobacco use, chronic conditions, and functional status.[28] The psychosocial status variables include: depression, measured using the PHQ-2;[29] and religion, measured using the Duke University Religion Index,[30] and experience with surrogate medical decision making.[26] These descriptive variables are measured at baseline only.

Additional constructs of the TTM are being assessed both as input for the expert system and as variables to be used in TTM-based models of ACP as behavior change. These constructs are posited to be mediation variables in the pathway of behavior change and include decisional balance, values/beliefs, confidence, and processes of change.[11] ACP knowledge is also assessed as a potential mediator.[25] These variables are measured at each assessment.

The final six-month assessment includes additional evaluation measures, asking participants how much participation in the study: increased their own interest in ACP, the interest of a significant other in ACP, and was responsible for their own and/or a significant other's movement forward with ACP.

In order to minimize missing data, a shortened form of the six-month assessment is available to those participants who do not want to complete a full assessment but are willing to answer an abbreviated set of items. This outcome assessment consists only of stage of change for the four ACP behaviors.

Participants recruited from community settings complete the baseline assessment as administered by a research assistant in person, unless they cannot stay after the appointment, in which case the assessment is completed by phone. They have the choice to complete follow-up assessments either by telephone or through self-administration. Both participants and research assistants access the assessment developed through the customization of TTMX, proprietary behavior change software licensed through Pro-Change Behavior Systems, Inc. The program is designed to support high-quality data collection by having respondents click on radio buttons next to responses to minimize data entry errors and not allowing respondents to leave a page until all questions are answered. Assessments can be completed up to seven days prior to or 30 days following the target date. Participants recruited from the VA complete all assessments by telephone.

Analytic Plan

The analysis for the community study is based on the study design of two groups (intervention, control) assessed on four occasions (baseline, 2, 4, 6 months) with sites nested in groups based on cluster randomization of matched pairs of sites. Baseline analyses will include examination of group differences to evaluate the success of the matched-pairs randomization procedure and examination of potential covariates to reduce the expected within-groups dependency resulting from cluster randomization.

The primary analysis will address the hypothesis that the proportion of participants in Action/Maintenance for the four ACP behaviors will be higher in the intervention group than in the control group at the six-month assessment. Several analytical approaches are available within a more general framework of random effects modeling incorporating both time and site

level effects in addition to potentially important covariates. The basic analytical approach will employ the generalized estimating equation (GEE) method to analyze intervention main effects and interaction (additive) effects.[31] Analytic models will include interaction terms for time point and site. This will permit an examination of the effect of the intervention not only at the primary endpoint of six months, but also at the intermediate time points of two and four months.

The analysis for the VA study is based on the study design of four groups assessed on four occasions. The primary analysis for this study will address the hypothesis that the proportions of participants in Action/Maintenance for the four ACP behaviors will be higher in each intervention group than in the control group at the six-month assessment. A logistic model that contains intervention group (CTI, MET, CTI+MET, with reference=control) as a categorical predictor will be utilized to analyze this outcome. The model will also control for the stratification variable (number of ACP activities completed at baseline) and for any factors found to be unbalanced across groups. Pre-specified subgroup analyses will be conducted by using the same logistic modeling approach within each of the strata. Although the study is not powered to find significant differences between intervention arms or within strata, the study will provide preliminary data for future studies regarding the effect sizes for each intervention arm and potential differences in effectiveness within subgroups.

Analytic approaches for secondary outcomes will follow the same plan in both studies and be similar to those employed for the primary outcome variable. Both categorical and continuous secondary outcomes will be examined, including specific behavioral and intermediate outcome measures, such as the number of ACP behaviors changed and ACP attitudes. For continuous measures, MANOVA, structural equation modeling, latent growth curve modeling, and GEE techniques will be utilized. For categorical measures, latent transition analysis, logistic regression, and GEE techniques will be used. For skewed frequency/count data, appropriate data transformation or Poisson regression approaches can be employed. Secondary analyses will also examine the nature of behavior change within and across groups over time within the

framework of multilevel structural equation modeling (SEM), including latent growth curve modeling, mediation modeling, cross-lagged panel designs, and model invariance testing.[32-36] These analyses will examine the relationships between intervention, mediator and moderator process measures. These analyses will provide considerable insight into how the interventions may be effecting change and will be especially helpful for continued development and refinement of the intervention. Mediation analysis in the control group will focus on how TTM constructs predict longitudinal adoption of ACP. Mediation analysis in the intervention group(s) will focus on how the TTM constructs and other sociodemographic factors compare as mediators of effective interventions. Because these modeling approaches can be complex, they will proceed in stepwise fashion systematically adding constructs and time points to more basic models to ensure model convergence. Models are built from the simplest to the most complex that the data and theory can support, using robust estimation methods and bias-corrected bootstrapping strategies for final model estimation and hypothesis testing.

Sample size

The sample size calculation for the community-based study was complicated by the use of practice site as the unit of treatment assignment and analysis, which introduces an unknown degree of dependency into the data. This dependency, or intraclass correlation (ICC) was conservatively assumed to be ICC = .05 based on existing cross-sectional data,[25] without covariate adjustment.

This cross-sectional data also provided an estimate of the prevalence of the primary outcome of between 4 and 8%.[25] We conservatively estimated that the prevalence of this outcome in the control group, which, because of our exclusion criteria, will be 0% at baseline, will be 5% at the six-month assessment. The sample size is based on the ability to detect an absolute increase of 10% for the primary outcome in the treatment group over the control group, consistent with effect sizes in previous TTM-tailored interventions and a judgment regarding a minimum clinically significant effect size. Sample size calculations assumed one-tailed

significance testing at alpha = .05 and were based on a one-way analysis of variance for proportions with arcsine transformation and nested random effects for sites to accommodate the cluster-randomised design.[37] Based on an enrollment of a minimum of 16 sites for the study (8 matched pairs), to achieve power of .80 for the primary outcome, a final sample size of 50 individuals per site is needed, resulting in a final study sample size of 800. Assuming 20% loss to follow-up, we estimate that a baseline sample size of 1000 for the community sample is required.

In the VA study, using the same estimates of 5% prevalence of the primary outcome in the control group, a sample size of 110 per group is required to detect an absolute increase of 10% for the primary outcome in each of the intervention groups to achieve a power of .80 with an alpha = .05. Based on prior experience within VA samples, a lower 10% loss to follow-up was assumed, resulting in a baseline sample size of 121 per group, for a total of 484.

ETHICS AND DISSEMINATION

Ethics

The protocol7 was reviewed and approved by the Institutional Review Boards of Bridgeport Hospital, which has governance over the majority of the community clinical sites participating in the study and the Yale School of Medicine, which has governance over the remaining community sites, and the Human Subjects Subcommittee of VA Connecticut Healthcare System. The study is being monitored with the use of a Safety Monitoring Committee. Members of this committee, with expertise in clinical geriatrics and study conduct, have reviewed and approved all study protocols and materials. Quarterly meetings occur to review any adverse events.

Dissemination

The results of the study will be presented to academic audiences through presentations at national meetings and publication in peer-reviewed journals. The principal investigator has

partnered with leadership in both the community and VA settings, with ongoing discussion of how the STAMP interventions can be implemented, if shown to be efficacious.

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AUTHORS' CONTRIBUTIONS

Study design: TRF, SM, CAR, AP, JSR Study conduct: TRF, SM, LI, MZ, LAB, JOL Development of interventions: TRF, SM, CAR, AP, LI, MZ, LAB, JOL Drafting of manuscript: TRF Review of manuscript for critical revisions: all authors Approval of final manuscript: all authors

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COMPETING INTERESTS:

None declared.

Table 1: Trial registration data

Category	STAMP (Community)	STAMP (VA)
Primary registry and trial identifying number	ClinicalTrials.gov NCT03103828	ClinicalTrials.gov NCT03137459
Date of registration in primary registry	04/27/2017	03/31/2017
Source(s) of monetary or material support	NIH/NINR NIH/NIA	VA HSR&D
Primary sponsor	NIH/NINR	VA HSR&D
Secondary sponsor	None	None
Contact for public queries	Lynne Iannone, MS: lynne.iannone@yale.edu	
Contact for scientific queries	Terri Fried, MD: terri.fried@yale.edu	
Public title	STAMP: Sharing and Talking about My Preferences	
Scientific title	STAMP: Sharing and Talking about My Preferences	
Countries of recruitment	USA	USA
Health condition(s) or problem(s) studied	Advance care planning (ACP)	
Intervention(s)	Active comparator: TTM-based CTI; No intervention: usual care	Active comparators: TTM-based CTI, MI, MET; No intervention: usual care
Key inclusion and exclusion criteria	Inclusion: age 55 and older and belonging to healthcare system or residential community. Exclusion: severe hearing impairment, severe visual, moderate to severe cognitive impairment, primary language other than English, active psychiatric illness, completion of all 4 key ACP behaviors	
Study type	Interventional; allocation: randomised; intervention model: parallel assignment; masking: single masking (outcomes assessor), primary purpose: health services research	
Date of first enrolment	July 2017	October 2017
Target sample size	1000	484
Recruitment status	Recruiting	
Primary outcome(s)	Completion of four key ACP behaviors	
Key secondary outcomes	Stage of change for each of the four key ACP behaviors	

NIH = National Institutes of Health; NINR = National Institute of Nursing Research; NIA = National Institute on Aging; VA = Veterans Affairs; HSR&D = Health Services Research and Delivery; TTM = Transtheoretical Model; CTI = computer-tailored intervention; MI = motivational interviewing; MET = motivational enhancement therapy

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	23
Protocol version	#3	Date and version identifier	NA
Funding	#4	Sources and types of financial, material, and other support	22
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	22
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	22

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
(Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5-6
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-10

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	NA
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	NA
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-14
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8, 10
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	16
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11-12
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	11-12

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11-12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-13
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-16
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	17
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	17
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	7
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
Data access	#29	Statement of who will have access to the final trial dataset,	NA

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17-18
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	NA
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

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Increasing Engagement in Advance Care Planning Using a Behavior Change Model: Study Protocol for the STAMP Randomised Controlled Trials

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Increasing Engagement in Advance Care Planning Using a Behavior Change Model: Study Protocol for the STAMP Randomised Controlled Trials

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ABSTRACT

Introduction: Advance care planning (ACP) is a key component of high-quality end-of-life care but is underutilized. Interventions based on models of behavior change may fill an important gap in available programs to increase ACP engagement. Such interventions are designed for broad outreach and flexibility in delivery. The purpose of the STAMP (Sharing and Talking about My Preferences) study is to examine the efficacy of three behavior-change approaches to increasing ACP engagement through two related randomised controlled trials being conducted in different settings (Veterans Affairs [VA] medical center and community).

Methods and analysis: Eligible participants are 55 or older. Participants in the community are being recruited in person in primary care and specialty outpatient practices and senior living sites, and participants in the VA are recruited by telephone. In the community, randomization is at the level of the practice or site, with all persons at a given practice/site receiving either computer-tailored feedback with a behavior stage-matched brochure (CTI) or usual care. At the VA, randomization is at the level of the participant and is stratified by the number of ACP behaviors completed at baseline. Participants are randomised to one of four groups: CTI, motivational interviewing, motivational enhancement therapy, or usual care. The primary outcome is completion of four key ACP behaviors: identification of a surrogate decision maker, communication about goals, completing advance directives, and ensuring documents are in the medical record. Analysis will be conducted using mixed effects models, taking into account the clustered randomisation for the community study.

Ethics and randomization: The studies have been approved by the appropriate Institutional Review Boards and are being overseen by a Safety Monitoring Committee. The results of these studies will be disseminated to academic audiences and leadership in in the community and VA sites.

Trial registration numbers: NCT03137459, NCT03103828

Strengths and limitations of this study

- The intervention is based on a comprehensive model of advance care planning (ACP) that focuses on enhancing engagement and improving communication among patients, their surrogates, and their providers.
- The behavioral health approach to ACP provides a framework for practical interventions that can be implemented in a wide variety of settings.
- The interventions have been developed in English only, and the study therefore excludes individuals whose primary language is other than English.
- The study is being conducted in a single geographic region and therefore may have limited generalizability.

Key words: Advance care planning; health behavior; randomised controlled trial

INTRODUCTION

The Institute of Medicine (IOM) report, "Dying in America: Improving Quality and Honoring Individual Preferences near the End of Life" devotes an entire chapter to advance care planning (ACP), the process by which patients can plan for the care they will receive if they become incapable of participating in medical decision making.[1] The report endorses the promise of ACP to provide "a measure of control over the final phase of life" and to ensure that "patients' wishes are known and respected to the extent possible." ACP is also associated with improved caregiver outcomes.[2 3] However, as outlined in the IOM report chapter, ACP remains underutilized. A recent systematic review concluded that only approximately one-third of adults in the United States has completed advance directives (ADs).[4] Moreover, ADs alone are not sufficient in the absence of efforts to promote communication.[5]

Several intervention approaches have demonstrated efficacy in increasing engagement in ACP. Respecting Choices, consisting of facilitated discussions lasting between 60 and 90 minutes between patients and their surrogates, increased surrogates' knowledge of patients' preferences and reduced caregiver stress.[6,7] The PREPARE website, a self-administered tool providing step-by-step processes for ACP supplemented with video stories and modeling of behaviors, increased ACP documentation.[8] Additional approaches may be necessary to bridge the gap between intensive clinician-led and self-administered tools for ACP engagement. For example, efforts to replicate and disseminate the Respecting Choices program in a large metropolitan area required "concerted and sustained leadership," a prolonged planning phase and the subsidizing of salaries.[9] This experience suggests that intensive programs are best targeted to selected patients at high risk of facing difficult treatment choices. The IOM report supports such targeting, suggesting a lifespan approach to ACP, beginning early with broad considerations of wishes that become more clinical and detailed over time. This lifespan strategy is congruent with our approach, which is designed to promote widespread dissemination of material that engages individuals in mid-life and works to give them the tools to

help them reconsider their wishes over time as health challenges become clearer. While the PREPARE website provides a thorough introduction to ACP, over 50% of participants had no access to the internet, and the website was viewed in research offices,[8] suggesting that web-based materials may have limited outreach.

The STAMP (Sharing and Talking about My Preferences) study was designed to address gaps in the existing programs for promoting participation in ACP. The STAMP interventions are based on the conceptual model of ACP considered as a set of inter-related health behaviors.[10] Prior research has demonstrated that participants have variable readiness to engage in ACP behaviors,[10] and that this readiness can be represented and explained by constructs of the Transtheoretical Model (TTM), including stages of change, decisional balance (the pros and cons of behavior change) and processes of change.[11] Readiness is also explained by a construct of values/beliefs. Unlike the pros and cons, which are factually verifiable, values and beliefs consist of common misperceptions about ACP and religious values that can function as barriers to ACP.[11]

STAMP evaluates three behavior-change approaches to promoting ACP engagement. The first is the use of individualized feedback reports with stage-matched brochures.[12] The second is telephone-delivered motivational interviewing (MI), and the third is telephone-delivered motivational enhancement therapy (MET), a combination of written feedback and MI. The health behaviors consist of: a) identifying a trusted individual to act as a surrogate decision maker or healthcare agent; b) communicating with this person about goals, preferences, and values; c) completing advance directives (formal assignment of healthcare agent and living will); d) ensuring both that the physician is aware of documents and that documents are in the medical record. STAMP consists of two related randomised controlled trials (RCTs). The hypothesis is that individuals receiving each of the behavior change approaches will be more likely than individuals receiving usual care to complete all of the health behaviors.

METHODS AND ANALYSIS

Study overview:

STAMP consists of two related randomised controlled trials (RCTs), with shared inclusion and exclusion criteria for study participation, measures, outcomes, and analytic approaches but with enrollment procedures and interventions adapted for each of the two trials. Each RCT will test the efficacy of one or more interventions on the proportion of study participants who complete participation in ACP compared to usual care. One RCT is being conducted within the primary care clinics of the Veterans Affairs Connecticut Healthcare System (subsequently referred to as the VA study) and the second is in community-based primary care practices and senior living communities in the greater New Haven area (subsequently referred to as the community study). Trial registration data are provided in Table 1.

Participants, recruitment, and enrollment:

Inclusion criteria include: age 55 years or older, and, for participants recruited in the VA study, having a primary care clinic visit within the last twelve months. Exclusion criteria include: severe hearing or vision loss, moderate-to-severe cognitive impairment identified by chart review (VA study only), physician diagnosis, Brief Orientation Memory Concentration test score > 10[13] or inability to participate in the process of informed consent; primary language other than English; active psychiatric illness (current symptoms of depression, anxiety, substance abuse, or psychosis), no regular access to a telephone; no permanent mailing address; completion of all four ACP behaviors; or lack of physician permission for participation.

Screening, recruitment, and enrollment for participants differs according to study. In the VA study, potential participants are selected from a list obtained under a Health Insurance Portability and Accountability Act waiver of all persons age 55 and older who have had a primary care visit within the last year at VA Connecticut. This method of identifying participants accomplishes two objectives. First, it facilitates oversampling of women and minorities to ensure adequate representation in the study population. The study is aiming for 25% women and 40%

non-white participants. Second, it allows for all study procedures to be done by telephone. Veterans relying on public transportation face a significant barrier to access, with only 25% living within a 60-minute transit time from a VA medical facility.[14] The ability to identify individuals and deliver the intervention by telephone is in keeping with the VA's investment in telehealth to improve access to a variety of services.[15] Chart screens are performed to identify exclusion criteria. Potentially eligible participants are sent an opt-out letter. If they do not opt out, a research assistant calls the participant to explain the study and completes the screening for eligibility. If the participant is eligible and interested in participation, a process of verbal assent is obtained. Participants who are randomised to MI or MET are asked if they have a surrogate they would like to include in their MI/MET session. If they do, they are asked to provide the contact information for the surrogate, who must then provide verbal assent prior to inclusion in the session. All identifiable data are stored separately from study records, which are identified by code number, in access-restricted database files behind institutional firewalls. Printed records are kept in locked offices.

Recruitment in the community study is designed to encourage ACP as a part of routine healthcare. In community practices, the list of patients scheduled for either well patient or routine follow-up visits is reviewed prior to each clinic session to identify potentially eligible participants. These individuals are given an information sheet to read prior to the encounter. The clinician confirms patient interest in the study, and willing individuals meet with a research assistant at the end of the encounter to complete a process of written informed consent. In senior living communities, recruitment takes place both in the on-site medical clinics as described above and among the community as a whole. For the latter, the study is introduced in a talk given by the principal investigator, followed by the opportunity for volunteers to sign up for times to meet with the research assistant to complete written informed consent.

Intervention and control conditions

Similar to recruitment procedures, the intervention arms are tailored to take advantage of the opportunities offered by the different study settings. The availability of health psychologists and MI training at the VA supported the strategy of developing MI interventions to promote ACP engagement in addition to a computer-tailored intervention that generates printed feedback. Therefore, in the VA study, there are four arms: computer-tailored intervention (CTI), MI, MET, and control. In the community, there are two arms: CTI and control. All arms consist of contact at baseline, two months, and four months with delivery of the intervention according to assignment. There is a contact at six months for final assessment.

CTI

The development of the CTI has been previously described.[12] Briefly, it is an expert system (a software system consisting of an assessment battery, normative data to make comparisons, decision rules for delivering feedback, and feedback components) based on the TTM. TTM intervention principles include respecting and reflecting individuals' stages of change and their progress over time on each construct in individualized feedback reports. Such reports have been found to be effective across a wide range of other health behaviors.[16] The system assesses key constructs of the TTM, including stage of change (readiness to participate in each of the ACP behaviors), decisional balance, values/beliefs, and processes of change. The original system consisted of feedback paragraphs developed for each stage of the four ACP behaviors and for decisional balance, which are pulled into a templated cross-sectional, or "normative," report. For this study, the system was further developed in order to give feedback based on simultaneous consideration of stage for all four behaviors (referred to as stage pattern) as well as to give longitudinal feedback by comparing stage at follow-up to stage at baseline ("ipsative" reporting). Each feedback report consists of: 1) introduction to ACP (common across reports); 2) figure illustrating stage of change for each behavior (normative) and changes in stage at follow-up (ipsative) (see figure 1); 3) brief stage pattern-tailored

feedback; 4) feedback for up to three endorsed values/beliefs items; 5) decisional balance by stage pattern feedback; 6) processes/strategies/efficacy or “next steps” stage pattern-tailored feedback; 7) summary. For participants in the earliest stages of change for multiple behaviors, the report provides brief “next steps” focused on activities to help promote favorable attitudes toward ACP. For participants in later stages, the report provides suggestions for how the participant can go about engaging in the behavior. The “next steps” section also informs participants how completing one ACP behavior can help in the completion of others.

The feedback reports make reference to one of two stage-matched brochures. Each of these brochures provides additional details of ACP. The first brochure, provided to participants who have not yet completed any of the ACP behaviors, provides additional information promoting the reasons for engaging in ACP and addressing potential barriers. It also contains two stories describing families who did and did not engage in ACP. The second brochure, provided to participants who have completed at least one ACP behavior, also contains additional information about how to engage in each. In addition, this brochure contains either the VA or state of Connecticut Advance Directives Form. Finally, participants receive a four-fold pamphlet designed to be given to potential surrogate decision makers in order to explain their role in ACP.

For participants enrolled in the VA, the assessment occurs by telephone and the feedback report, brochure, and pamphlet are mailed. For participants enrolled in the community, the initial assessment is done in person in the clinician office or private space in the senior living community, and the report is printed using a portable printer. If the participant does not have sufficient time after his/her appointment but has provided informed consent, the assessment is done by telephone at a later time. All follow-up assessments are done by telephone, with reports mailed to participants.

MI

The development of the MI protocol has been previously described.[17] MI sessions are conducted by health psychologists and social workers who have received training by Dr. Martino, a member of the research team and of the Motivational Interviewing Network of Trainers, who is an expert in training clinicians in the conduct of MI for clinical trials.[18-20] The training consisted of a two-day experiential workshop and STAMP MI/MET manual review, followed by supervised practice cases, incorporating fidelity rating-based feedback and coaching based on the review of audio recorded telephone sessions using the Independent Tape Rater Scale.[21] Dr. Martino reviewed and rated all practice cases for initial certification. Initial certification was defined as at least adequate or average adherence and competence ratings on three consecutive practice sessions. If a clinician's performance later drifts below the initial certification level during the trial, then Dr. Martino will provide additional supervision and training and assign another practice case if necessary. The MI intervention consists of four steps: 1) elicitation and clarification of patient's understanding of and current engagement in ACP; 2) building motivation for ACP; 3) developing a change plan; and 4) summarizing the overall discussion. The first step involves understanding in what ways the patient thinks ACP is important and the patient's knowledge of the four key ACP behaviors. Consistent with MI, the Elicit-Provide-Elicit approach is used to deliver ACP. This approach involves inviting the patient to share his/her knowledge, asking the patient permission to provide additional information, and then eliciting the patient's reaction to this new information. The second step consists of four activities that are utilized as needed. The first activity is an enhanced discussion of reasons to engage in ACP, with attention paid to developing the discrepancies between the most important reasons for engagement and lack of ACP participation. The second is addressing beliefs that serve as barriers to ACP. The third is an exercise to help patients clarify their values regarding quality versus quantity of life. Understanding how patients view this trade-off is central to decision making about potentially

life-sustaining treatment[22] and is included in a number of ACP tools[23 24] as well as in the brochure provided with CTI. The fourth activity is a discussion of experiences that could help ACP engagement. If the participant has a surrogate who agrees to be part of the MI, the surrogate's perspectives are elicited in each of these steps. In pilot-testing, sessions lasted a mean (SD) of 34.9 (6.5) minutes.

MET

In the MET arm, participants are provided the CTI TTM-based feedback materials, and then engage in a MI interview as described above, with the addition of review of the materials with the clinician. Each component of the interview makes mention as appropriate to specific sections of the stage-matched brochures to address knowledge gaps and provide more information about reasons to engage in ACP and addressing ACP barriers. In an additional section of the interview specific to MET, the clinician reviews the personalized feedback report with the participant to facilitate the development of a change plan.

Control

Participants in the control arm receive assessments at baseline, two, and four months but do not receive any additional information about ACP, other than that potentially provided in usual care. In order to minimize the effect of asking about ACP behaviors on participants' engagement in these behaviors, the control assessments conclude with questions about readiness to engage in and pros and cons of physical activity.

Randomisation

Randomisation in the community trial is at the level of the practice/senior living community in order to avoid contamination. Contamination could occur if patients assigned to the intervention increased their clinicians' awareness of ACP, and then clinicians changed their behaviors towards other participants potentially assigned to the control group. Therefore, randomisation occurs within matched pairs of sites, instead of at the individual level. Sites are matched according to available data regarding characteristics most likely to be associated with ACP

participation. For clinical sites, this includes proportion of patients: age 55 years and older, non-white, and with Medicaid. For senior living communities, this includes type of community (e.g. continuing care retirement community) and, if applicable, type of contract (e.g. life care, fee-for-service). After matching, sites are randomised by means of computer-based random number generator.

Because participants at the VA belong to a very large panel of providers, each of whom would have only a small number of patients in the study, randomisation is at the level of the patient. Number of ACP behaviors completed at baseline may be the single variable most highly associated with the likelihood of full ACP engagement, since engagement is cross-sectionally related to attitudes, beliefs, and processes related to ACP[11] and to a number of sociodemographic characteristics[25] and life experiences.[26] Therefore, in order to ensure balanced representation of number of ACP activities completed at baseline across the four study arms, participants are assigned using stratified permuted block randomisation with a block length of eight via a customized computer program that provides the assignment at the time of randomisation.

Blinding

Participants are not blinded to their assignment. Research assistants are not blinded to participant assignment at interim time points since the assessment, as described below, differs slightly according to the assignment. However, blinded research assistants ascertain the primary study outcome at the six-month assessment.

Measures

The *primary outcome* is having completed, or being in the action/maintenance stage as specified in the TTM, for all of the four key ACP behaviors at six months. The designation of action and maintenance was originally designed for behaviors that required ongoing effort, such as smoking cessation and exercise, and refer to how long ago the behavior was initiated. While there are activities that an individual can and should be doing during the maintenance phase of

ACP, such as reviewing and updating documents, the focus for this study was on initial engagement in ACP. Therefore, these two stages were combined. The *secondary outcomes* are the stage of change for each of the behaviors. The stages of change prior to action/maintenance are: precontemplation, or not ready to take action within the next six months; contemplation, or thinking about taking action over the next six months; and preparation, or planning on taking action in the next thirty days. These variables are measured at each assessment: baseline, two months, four months, and six months.

Sociodemographic, health, and psychosocial status variables are assessed to describe the study population, test for the adequacy of randomisation, and use as covariates. The sociodemographic status variables include: age, gender, race/ethnicity, level of education, income, marital status, housing type, living alone or with others. The health status variables include: self-rated health,[27] self-rated quality of life, and variables included in a validated prognostic index for four-year mortality: current tobacco use, chronic conditions, and functional status.[28] The psychosocial status variables include: depression, measured using the PHQ-2;[29] and religion, measured using the Duke University Religion Index,[30] and experience with surrogate medical decision making.[26] These descriptive variables are measured at baseline only.

Additional constructs of the TTM are being assessed both as input for the expert system and as variables to be used in TTM-based models of ACP as behavior change. These constructs are posited to be mediation variables in the pathway of behavior change and include decisional balance, values/beliefs, confidence, and processes of change.[11] ACP knowledge is also assessed as a potential mediator.[25] These variables are measured at each assessment.

The final six-month assessment includes additional evaluation measures, asking participants how much participation in the study: increased their own interest in ACP, the interest of a significant other in ACP, and was responsible for their own and/or a significant other's movement forward with ACP.

In order to minimize missing data, a shortened form of the six-month assessment is available to those participants who do not want to complete a full assessment but are willing to answer an abbreviated set of items. This outcome assessment consists only of stage of change for the four ACP behaviors.

Participants recruited from community settings complete the baseline assessment as administered by a research assistant in person, unless they cannot stay after the appointment, in which case the assessment is completed by phone. They have the choice to complete follow-up assessments either by telephone or through self-administration. Both participants and research assistants access the assessment developed through the customization of TTMX, proprietary behavior change software licensed through Pro-Change Behavior Systems, Inc. The program is designed to support high-quality data collection by having respondents click on radio buttons next to responses to minimize data entry errors and not allowing respondents to leave a page until all questions are answered. Assessments can be completed up to seven days prior to or 30 days following the target date. Participants recruited from the VA complete all assessments by telephone.

Analytic Plan

The analysis for the community study is based on the study design of two groups (intervention, control) assessed on four occasions (baseline, 2, 4, 6 months) with sites nested in groups based on cluster randomization of matched pairs of sites. Baseline analyses will include examination of group differences to evaluate the success of the matched-pairs randomization procedure and examination of potential covariates to reduce the expected within-groups dependency resulting from cluster randomization.

The primary analysis will address the hypothesis that the proportion of participants in Action/Maintenance for the four ACP behaviors will be higher in the intervention group than in the control group at the six-month assessment. Several analytical approaches are available within a more general framework of random effects modeling incorporating both time and site

level effects in addition to potentially important covariates. The basic analytical approach will employ the generalized estimating equation (GEE) method to analyze intervention main effects and interaction (additive) effects.[31] Analytic models will include interaction terms for time point and site. This will permit an examination of the effect of the intervention not only at the primary endpoint of six months, but also at the intermediate time points of two and four months.

The analysis for the VA study is based on the study design of four groups assessed on four occasions. The primary analysis for this study will address the hypothesis that the proportions of participants in Action/Maintenance for the four ACP behaviors will be higher in each intervention group than in the control group at the six-month assessment. A logistic model that contains intervention group (CTI, MET, CTI+MET, with reference=control) as a categorical predictor will be utilized to analyze this outcome. The model will also control for the stratification variable (number of ACP activities completed at baseline) and for any factors found to be unbalanced across groups. Pre-specified subgroup analyses will be conducted by using the same logistic modeling approach within each of the strata. Although the study is not powered to find significant differences between intervention arms or within strata, the study will provide preliminary data for future studies regarding the effect sizes for each intervention arm and potential differences in effectiveness within subgroups.

Analytic approaches for secondary outcomes will follow the same plan in both studies and be similar to those employed for the primary outcome variable. Both categorical and continuous secondary outcomes will be examined, including specific behavioral and intermediate outcome measures, such as the number of ACP behaviors changed and ACP attitudes. For continuous measures, MANOVA, structural equation modeling, latent growth curve modeling, and GEE techniques will be utilized. For categorical measures, latent transition analysis, logistic regression, and GEE techniques will be used. For skewed frequency/count data, appropriate data transformation or Poisson regression approaches can be employed. Secondary analyses will also examine the nature of behavior change within and across groups over time within the

framework of multilevel structural equation modeling (SEM), including latent growth curve modeling, mediation modeling, cross-lagged panel designs, and model invariance testing.[32-36] These analyses will examine the relationships between intervention, mediator and moderator process measures. These analyses will provide considerable insight into how the interventions may be effecting change and will be especially helpful for continued development and refinement of the intervention. Mediation analysis in the control group will focus on how TTM constructs predict longitudinal adoption of ACP. Mediation analysis in the intervention group(s) will focus on how the TTM constructs and other sociodemographic factors compare as mediators of effective interventions. Because these modeling approaches can be complex, they will proceed in stepwise fashion systematically adding constructs and time points to more basic models to ensure model convergence. Models are built from the simplest to the most complex that the data and theory can support, using robust estimation methods and bias-corrected bootstrapping strategies for final model estimation and hypothesis testing.

Sample size

The sample size calculation for the community-based study was complicated by the use of practice site as the unit of treatment assignment and analysis, which introduces an unknown degree of dependency into the data. This dependency, or intraclass correlation (ICC) was conservatively assumed to be ICC = .05 based on existing cross-sectional data,[25] without covariate adjustment.

This cross-sectional data also provided an estimate of the prevalence of the primary outcome of between 4 and 8%.[25] We conservatively estimated that the prevalence of this outcome in the control group, which, because of our exclusion criteria, will be 0% at baseline, will be 5% at the six-month assessment. The sample size is based on the ability to detect an absolute increase of 10% for the primary outcome in the treatment group over the control group, consistent with effect sizes in previous TTM-tailored interventions and a judgment regarding a minimum clinically significant effect size. Sample size calculations assumed one-tailed

significance testing at alpha = .05 and were based on a one-way analysis of variance for proportions with arcsine transformation and nested random effects for sites to accommodate the cluster-randomised design.[37] Based on an enrollment of a minimum of 16 sites for the study (8 matched pairs), to achieve power of .80 for the primary outcome, a final sample size of 50 individuals per site is needed, resulting in a final study sample size of 800. Assuming 20% loss to follow-up, we estimate that a baseline sample size of 1000 for the community sample is required.

In the VA study, using the same estimates of 5% prevalence of the primary outcome in the control group, a sample size of 110 per group is required to detect an absolute increase of 10% for the primary outcome in each of the intervention groups to achieve a power of .80 with an alpha = .05. Based on prior experience within VA samples, a lower 10% loss to follow-up was assumed, resulting in a baseline sample size of 121 per group, for a total of 484.

Patient and Public Involvement

The ACP behaviors that are both the targets of intervention and the outcome measures for the STAMP studies were developed based on the input of older persons, their surrogate decision makers, and bereaved caregivers obtained during focus groups[10] and individual interviews.[38] The assessment and printed intervention materials were pilot-tested and modified in response to participant feedback, both about the content of the feedback and also regarding the length and burden of the assessment items.[12] All procedures being utilized in the protocols were pilot-tested in two practices, and modifications were made in response to feedback both from patients and physicians. There are no plans to disseminate the study results to participants.

ETHICS AND DISSEMINATION

Ethics

The protocol7 was reviewed and approved by the Institutional Review Boards of Bridgeport Hospital, which has governance over the majority of the community clinical sites participating in

the study and the Yale School of Medicine, which has governance over the remaining community sites, and the Human Subjects Subcommittee of VA Connecticut Healthcare System. The study is being monitored with the use of a Safety Monitoring Committee. Members of this committee, with expertise in clinical geriatrics and study conduct, have reviewed and approved all study protocols and materials. Quarterly meetings occur to review any adverse events.

Dissemination

The results of the study will be presented to academic audiences through presentations at national meetings and publication in peer-reviewed journals. The principal investigator has partnered with leadership in both the community and VA settings, with ongoing discussion of how the STAMP interventions can be implemented, if shown to be efficacious.

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AUTHORS' CONTRIBUTIONS

Study design: TRF, SM, CAR, AP, JSR Study conduct: TRF, SM, LI, MZ, LAB, JOL Development of interventions: TRF, SM, CAR, AP, LI, MZ, LAB, JOL Drafting of manuscript: TRF Review of manuscript for critical revisions: all authors Approval of final manuscript: all authors

The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

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COMPETING INTERESTS:

None declared.

Table 1: Trial registration data

Category	STAMP (Community)	STAMP (VA)
Primary registry and trial identifying number	ClinicalTrials.gov NCT03103828	ClinicalTrials.gov NCT03137459
Date of registration in primary registry	04/27/2017	03/31/2017
Source(s) of monetary or material support	NIH/NINR NIH/NIA	VA HSR&D
Primary sponsor	NIH/NINR	VA HSR&D
Secondary sponsor	None	None
Contact for public queries	Lynne Iannone, MS: lynne.iannone@yale.edu	
Contact for scientific queries	Terri Fried, MD: terri.fried@yale.edu	
Public title	STAMP: Sharing and Talking about My Preferences	
Scientific title	STAMP: Sharing and Talking about My Preferences	
Countries of recruitment	USA	USA
Health condition(s) or problem(s) studied	Advance care planning (ACP)	
Intervention(s)	Active comparator: TTM-based CTI; No intervention: usual care	Active comparators: TTM-based CTI, MI, MET; No intervention: usual care
Key inclusion and exclusion criteria	Inclusion: age 55 and older and belonging to healthcare system or residential community. Exclusion: severe hearing impairment, severe visual, moderate to severe cognitive impairment, primary language other than English, active psychiatric illness, completion of all 4 key ACP behaviors	
Study type	Interventional; allocation: randomised; intervention model: parallel assignment; masking: single masking (outcomes assessor), primary purpose: health services research	
Date of first enrolment	July 2017	October 2017
Target sample size	1000	484
Recruitment status	Recruiting	
Primary outcome(s)	Completion of four key ACP behaviors	
Key secondary outcomes	Stage of change for each of the four key ACP behaviors	

NIH = National Institutes of Health; NINR = National Institute of Nursing Research; NIA = National Institute on Aging; VA = Veterans Affairs; HSR&D = Health Services Research and Delivery; TTM = Transtheoretical Model; CTI = computer-tailored intervention; MI = motivational interviewing; MET = motivational enhancement therapy

Figure 1 Legend: Example of figure included in follow-up feedback report illustrating change in readiness over time for the ACP behaviors.

How Ready Are You?

This figure shows you how ready you are to do each of these steps towards your Advance Care Plan.

Your forms are:	at MD Office	in Medical Record
Healthcare Agent	✓	-
Living Will	✓	-

You told us that you are:

- Just like last time, you have finished talking with your loved ones about quality versus quantity of life.
- Last time you were thinking about naming your healthcare agent, and now you have done this. That's great!
- Last time you were not ready to complete your living will, and now you have done this. Good step forward!

304x217mm (300 x 300 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

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

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

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

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

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

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	23
Protocol version	#3	Date and version identifier	NA
Funding	#4	Sources and types of financial, material, and other support	22
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	22
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	22

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
(Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5-6
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-10

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	NA
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	NA
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-14
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8, 10
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	16
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11-12
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	11-12

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11-12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-13
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-16
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	17
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	17
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	7
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
Data access	#29	Statement of who will have access to the final trial dataset,	NA

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17-18
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	NA
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA