STAMP-VA: Sharing and Talking about My Preferences

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PROJECT DESCRIPTION

1. **Principal Investigator:** Terri Fried, MD

2. **Project Title:** STAMP-VA: Sharing and Talking about My Preferences

3. **Purpose:** The purpose of this study is to examine the effects of two theory-based behavior interventions on engagement of Veterans in advance care planning (ACP) by means of the following specific aim:

   Primary Aim: To conduct a randomized controlled trial examining the effects of: a) usual care; b) computer-tailored intervention (CTI); c) motivational interviewing (MI); d) CTI + MI; otherwise known as Motivational Enhancement Therapy (MET) on the proportion of middle-age and older Veterans receiving primary care at the VA who complete the process of ACP, defined as completing a total of 4 key ACP behaviors, including selecting a health care proxy, communicating with the proxy about goals of care, communicating with the clinician about goals of care, and documenting proxy selection and goals.
   Primary Hypothesis: The proportion of Veterans completing ACP will be higher among those in each of the intervention groups compared to Veterans receiving usual care.

4. **Background:**
   ACP the process by which individuals and their healthcare surrogate can prepare for future treatment decisions, remains underutilized.[1] ACP addresses many of the issues that patients and their caregivers endorse as important in end-of-life care, including clear communication with loved ones, achieving closure, and remaining in control of medical decisions.[2] However, there are many emotional, cognitive, and practical barriers to engaging in ACP.[3] While it has been demonstrated that intervention can increase ACP engagement, this model requires a skilled, well-trained moderator meeting with patients and caregivers in lengthy encounters.[4] This type of intensive intervention may be best suited for patients with serious chronic illnesses who are ready to think about their specific disease trajectories and the decisions they are likely to face. The recent Institute of Medicine (IOM) report “Dying in America: Improving Quality and Honoring Individual Preferences near the End of Life” proposes a continuous process of ACP, starting earlier in the lifespan with individuals in good health and an initial focus on identification of a surrogate decision maker and general communication about patients’ goals with more in-depth and specific discussions coming later.[5] This proposal describes the evaluation of an intervention to promote initial engagement in ACP. Taking a public health approach to ACP engagement, the intervention is designed to be able to reach a broad cross-section of individuals at modest expense.

   The intervention builds upon the Principal Investigator (PI)’s long history of studying the process of ACP and several key insights provided by her past work. First, ACP has historically been conceptualized as the process by which patients could specify in advance the treatment they would want to receive if they became decisionally incapable. It consisted of completion of advance directives, which are documents such as living wills and health care proxies. However, it has been shown that this completion of documents, while most likely necessary, is not sufficient to improve end-of-life outcomes. The PI has argued that, instead of having patients make premature treatment decisions, which cannot take into account the specific details of future health scenarios and the clinical judgment of healthcare practitioners, ACP should instead be focused on preparing patients and their surrogates to make the best possible “in-the-moment” healthcare decisions.[2] This goal best met by conceptualizing ACP as acts of communication, between patients and surrogates, and

between patients and physicians. Second, the intervention considers ACP to be a group of health behaviors, to which the Transtheoretical Model (TTM) of health behavior change is applicable. The TTM provides a framework for the delivery of tailored intervention materials based on an assessment of an individual's readiness to engage in ACP along with the attitudes and beliefs influencing the desire, motivation, and ability to engage. The potential for this approach was recognized in the IOM report. The PI and her co-investigators have developed a TTM-based computer-tailored intervention (CTI) and demonstrated the acceptability of these materials to a diverse cohort of older adults. The proposed project adds a co-investigator with extensive experience in motivational interviewing/motivational enhancement therapy (MI/MET) to expand the approach to intervention. The proposed study takes the logical next steps in this work, by examining the ability of two theory-based interventions with empirical support in other areas.

5. **Signficance:**
The intensity of intervention required to increase early engagement in ACP is not yet known. One systematic review of ACP interventions concluded that, while more intensive interventions, involving repeated sessions with a health care professionals, had greater effect sizes, less intensive interventions were far more practical, but passive untailored education alone was not effective. While this review speculated that interventions grounded in a stages-of-change model would be a more effective method of providing a low-intensity intervention, there have been no trials of CTI in ACP to date. By including an MI/MET-based intervention arm, the proposed project will examine a "middle-ground" approach to increasing engagement in ACP between interventions requiring no clinical involvement and interventions requiring heavy involvement. While MI/MET requires a trained therapist, the training time is modest. Because the training is not specific to ACP, therapists who have experience using MI for other behaviors can readily adapt these techniques to ACP. In addition, the MI is delivered in brief sessions by telephone, an approach that maximizes clinical expertise at reduced cost compared to in-person sessions. The potential for MI to affect engagement in ACP was demonstrated in an intervention study conducted in the VA that included MI training for the social workers who met with Veterans in the intervention group. However, as a multicomponent study that also included written materials, the effect of each component alone could not be determined.

6. **Research Plan:**
Study participants: Participants will include Veterans age 55 years and older with a primary care visit within the VA Connecticut Healthcare System in the last 12 months. Exclusion criteria include: Severe hearing or vision loss, moderate-to-severe cognitive impairment, identified either by chart review or as determined by the Brief Orientation Memory Concentration (BOMC) test, primary language other than English, active psychiatric illness (current symptoms of depression, anxiety, substance abuse, psychosis), no regular access to a telephone, completion of all advance care planning activities. For Veterans who identify health care surrogates who are agreeable to participation, the surrogate will also be enrolled in the study.

Potential participants will be identified through a data query of the Regional Data Warehouse. This will allow us to oversample female and minority Veterans.

Recruitment and consent procedures: Chart review will be performed to identify exclusion criteria. Physicians of potential participants eligible after chart review will be asked to provide their permission to contact the Veteran by mail. Veterans will receive an opt-out letter, providing them with a brief description of the study and a number to call if they do not wish

to be contacted further. Veterans who do not opt out will receive a phone call from the research assistant to explain the study. Calls will never be made during the dinner hour, and no more than 3 attempts will be made to reach the Veteran. If the Veteran is eligible and is agreeable, then the Veteran will provide verbal assent as described in greater detail in the Initial Review Application and undergo cognitive screening. Participants who are randomized to MI or MET (see description below) will be asked if they have a surrogate who would agree to participation, and, if so, to provide the contact information for that person. If there is a surrogate who is willing to participate, then verbal assent will also be obtained from the surrogate prior to the MI/MET intervention. Surrogate assent is not required for the Veteran to participate; if the surrogate does not provide assent, the Veteran will undergo MI/MET without participation of the surrogate.

Procedures for randomization: Randomization will be at the level of the Veteran. Randomization will be stratified by two variables that may be particularly important effect modifiers of the intervention. The first of these variables is race/ethnicity. The evidence of substantive barriers to and lower participation in ACP among African-Americans is supportive of the effort to ensure that race/ethnicity is balanced among the groups. The second variable is number of ACP behaviors for which the Veteran is in the A/M stage at baseline. The randomization technique for the study will be stratified permuted block randomization.

Description of treatment groups:
CTI: Participants assigned to CTI will receive telephone contact at three time points: baseline, two, and four months. Each contact consists of an integrated assessment and intervention feedback report, using an expert system. This is a software system consisting of an assessment battery, normative data on which to base decision rules, and materials that can be assembled for feedback. The assessment battery includes the core TTM measures, including Stages of Change (how ready the participant is to engage), Decisional Balance (DB) (attitudes regarding the pros and cons of engagement), and Values/Beliefs (V/B) (medical and religious beliefs that can affect readiness to engage in ACP). Participants are assessed for four different behaviors that together represent complete ACP engagement: communication with loved ones about views on quality of life versus quantity of life, communication with clinicians about views on quality of life versus quantity of life, assignment of a health care surrogate, and completion of a living will. The system takes the results of the assessment and results in an individualized feedback report. For individuals in early stages of change for a given behavior, the feedback focuses on changing attitudes, a necessary prerequisite for changing behavior, by addressing common barriers and by reminding individuals, they can engage in small steps. For individuals in later stages of change, the feedback provides specific actions they can perform. In addition, if the participant has engaged in one ACP behavior but not another, the feedback provides information on how they can utilize what they have already accomplished in order to help them participate in any remaining ACP activities. Participants with a low pros score receive feedback suggesting additional pros they may not have realized, while participants with a high cons score receive feedback providing general strategies for overcoming the most common barriers to ACP. Participants also receive specific feedback for up to three items they endorsed on the V/B scale. A general introduction provides a common opening for the feedback report, briefly describing ACP, why it is necessary, and why individuals should engage in ACP even when it seems too difficult to plan for declines in health and dying. Whereas the baseline feedback report provides individualized normative feedback, the follow-up reports also provide ipsative feedback, in which the participants' current responses are compared to prior responses and feedback is provided on progress over time.

In addition to their tailored feedback report, participants will receive one of two brochures that provides stage-matched information for each of the three ACP behaviors. In comparison to the tailored feedback reports, the brochures contain information that is salient to participants in a given stage of behavior change regardless of their individual decisional balance or use of processes. The brochure for individuals who are not ready to engage in any ACP behavior is brief, focusing on descriptions of strategies to overcome attitudinal barriers to engagement in ACP and the positive consequences of engagement. The brochure also includes two stories, adapted from the PI's prior qualitative research. One illustrates the benefits to a spouse and children of her husband's engagement in ACP, and the second describes the regrets of a daughter whose mother did not engage in ACP. The second brochure, for individuals who are ready to engage in one or more ACP activities, provides strategies for participating in each activity. This brochure, for example, provides "words to use" to approach a health care proxy, and questions for individuals and their surrogates to discuss regarding goals of care. In addition, participants will receive a pamphlet developed for the individual to give to his/her (potential) surrogate. This pamphlet, written from the perspective of the individual, explains to the surrogate how he/she can help the individual engage in ACP. The time points for assessment were selected to provide sufficient time for the participant to reflect and act on the feedback received while maintaining the momentum to move forward by not waiting too long to provide follow-up.

*Please note that we have enclosed the brochures for review by the HSS. If approved, we would like to add the VA seal to the brochures.

MI: Participants assigned to MI will receive telephone contact at three time points: baseline, two, and four months. They will undergo the assessment as described above but will not receive the written tailored feedback materials. Instead, they will receive a second a telephone contact within two weeks of the assessment, which will consist of an MI session. In addition to utilizing the general interviewing techniques of MI, the delivery of MI includes the provision of individualized feedback based on the assessment. If the surrogate has been enrolled in the study, the MI will be conducted with both the Veteran and the surrogate in a dyadic telephone interview. The goal of the interview is to strengthen commitment to engage in ACP and promote self-efficacy. The general techniques utilized in the interview will include both the relational strategies (open questions, affirmations, reflections/summaries) and those used to evoke statements that favor ACP engagement. When surrogates are available to participate in the interview, the interviewer will also elicit the surrogate's perspectives on helping the Veteran engage in ACP and facilitate the resolution of discrepancies in the Veteran and surrogate perspectives. The interviewer will also help the Veteran to reflect on the pros and cons of ACP engagement as elicited in the assessment process, to understand how to build on ACP behaviors already engaged in, and, if appropriate, to help the Veteran create a change plan for further ACP engagement. Based on the open-ended interviews being conducted in our currently funded study, we anticipate the MI sessions will last between 30 and 45 minutes.

MET (CTI+MI): Participants assigned to MET will receive the CTI intervention at baseline, two months, and four months as described above. with a follow-up MI session as described above occurring within two weeks of each contact.
Because the MI/MET procedures are newly developed for this study, they require pilot-testing prior to the conduct of the full study. The pilot testing will be done to determine whether any changes to the MI manual are required and to examine adequacy of training of the interviewers in MI techniques. Up to 20 Veterans will participate in the pilot-testing

phase. In the first part of pilot testing, the participants will receive a single MET session. The interview will be recorded (see below for request for a waiver of HIPAA authorization, which will include voice recording) and rated for fidelity to MI criteria by Steve Martino, PhD, a co-investigator and expert in MI. In the second part of pilot testing, participants will receive the equivalent of the baseline telephone assessment. They will be mailed a feedback report, and then they will undergo a single MI session, which will be audiotaped, with the audiotape undergoing the same MI fidelity rating.

Both the MI and MET sessions in the main portion of the study will be audio recorded. There are two reasons for the audio recording. First, a random sample of audio files will be reviewed by Dr. Martino to ensure that fidelity to MI is maintained throughout the study. Second, the audio files will allow for more detailed secondary analysis examining associations between components of MI and MET and the outcome of ACP engagement.

Control: Participants assigned to the control group will receive three assessment contacts on the same schedule and in the same manner as the participants enrolled in the intervention groups. They will not receive any feedback. The purpose of this assessment is to control for historical trends and the potential reactivity of assessment alone. Apart from these assessments, participants enrolled in control sites will receive usual care. In order to minimize the effect of asking about ACP behaviors on participants' engagement in these behaviors, the assessments will be masked. This will be accomplished by assessing participants' Stages of Change and Decisional Balance for exercise as well as for ACP. At the end of their participation, Veterans assigned to this group will receive the CTI materials. In this way, we can provide the participants in the control group with information they may find helpful to engaging in ACP after their participation in the study has been completed.

All of these groups will receive their assessments and, if applicable, their interventions, by telephone and/or mail. Because the study will not require any face-to-face visits, we are requesting a waiver of written informed consent and a waiver of HIPAA authorization. We have chosen this mode of administration for several important reasons. First, telephone administration allows us to oversample women and minority Veterans. While it would not be feasible to staff all of the primary care clinics within the VA Connecticut Healthcare System for long enough to enroll large numbers of women and minority Veterans, it is feasible to identify such Veterans from the list of those enrolled in primary care. Telephone administration allows us to reach out to these Veterans regardless of whether they have an upcoming appointment. The inclusion of these Veterans will greatly enhance the generalizability of our results. Second, telephone administrative decreases the burden of participation, since we can be highly flexible in terms of when we speak to the Veterans. Third, telephone administration allows us to offer participation to surrogates who may not live locally. The participation of the surrogate is hypothesized to enhance the effect of the intervention, since the surrogate is an integral part of the ACP process. Finally, the interventions were designed with an eye toward ease of implementation if shown to be efficacious. Telephone administrative is highly cost-effective, and could be easily adopted by case management and social work for incorporation into their workload.

We will supplement the telephone assent procedure by mailing to the Veteran (and surrogate, if applicable) an information sheet based on the telephone script used to obtain verbal assent. This will both allow participants to refer to the sheet for information about the study and have written contact information should they have further questions about the study.

Measures: The primary outcome will be the proportion of participants completing all four ACP behaviors as measured at six months following the baseline assessment. The secondary outcome will be the proportion of participants achieving each stage of change for each of the four ACP behaviors. The primary and secondary outcomes will be obtained through participant self-report by an interviewer who is blinded to the participant's group assignment. The independent variables will be used to describe the study population and test for the adequacy of randomization. They will also be used as covariates in the models testing the study hypotheses. The independent variables will measure the constructs of sociodemographic status, health status, and psychosocial status. Sociodemographic variables include: age, gender, ethnicity, level of education, and income. Health status variables include: chronic conditions; functional status, measured using the instrumental activities of daily living scale, self-rated health, self-rated quality of life, number of hospitalizations and emergency room visits in the past year, and additional factors necessary to calculate 5-year mortality using a well-validated prediction tool for older community-dwelling persons. Psychosocial status variables include: religion and religiosity, measured using the Duke University Religion Index; instrumental and emotional support, measured using the Established Populations for Epidemiologic Studies of the Elderly social support items; and depression, using the PHQ-2. Participants will also be asked items taken from an earlier study on familial experiences with end-of-life decision making, as this has been demonstrated to be associated with readiness to engage in ACP. The independent variables will be obtained by self-report in the baseline assessment.

Power and sample size: To detect an absolute difference of 15% in the primary outcome between each of the intervention groups and the control group with 80% power and alpha = .05, the number of persons per group is 110, for a total of 440 subjects. To account for an estimated 10% loss to follow-up, the final sample size will be 121 per group, or a total of 484.

Analysis: The primary outcome is whether the subject completed all 4 ACP behaviors (binary outcome) at the final 6-month assessment. intervention group will be greater than the proportion in the control group. 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 stratification variables [race/ethnicity (white vs. nonwhite) and the number of ACP activities completed at baseline (0-3 range)] and for any factors found to be unbalanced among the intervention groups.

7. References:

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