STAMP: Sharing and Talking about My Preferences
NCT: 03137459

Protocol: July, 2016

1. **Statement of Purpose:**

   This will be a randomized controlled trial examining the effect of an individually TTM-tailored intervention on the proportion of middle-age and older persons recruited from primary care practices and senior living communities who complete four ACP behaviors (completion of a living will, assignment of a health care proxy, and communication with loved ones and with their clinician about views on quality versus quantity of life) over six months, compared with usual care.

2. **Background:**

   Advance care planning (ACP), the process by which individuals and their healthcare surrogate can prepare for future treatment decisions, remains underutilized. 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. However, there are many emotional, cognitive, and practical barriers to engaging in ACP. 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. 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. 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 (AD), 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. This goal for ACP is best met by conceptualizing ACP as acts of communication, between patients and surrogates, and between patients and physicians, that focus not on preferences for specific treatments but rather on broader goals of care. Second, the intervention treats ACP as a health behavior utilizing the Transtheoretical Model (TTM) of health behavior change. 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-tailored expert system intervention with stage-targeted brochures and demonstrated the acceptability of these materials to a diverse cohort of older adults. The proposed study represents the

logical next steps in this work, by examining the efficacy of the intervention on increased engagement in ACP.

3. **Research Plan:**

Participants and Recruitment

Participants will be community-dwelling persons 55 years of age or older with an upcoming primary care visit in the NEMG practice or one of Yale New Haven Health System practices or individuals residing in senior living communities. Exclusion criteria include: a) severe hearing impairment, defined as being unable to participate in a telephone conversation; b) severe visual impairment, defined as being unable to read large-print materials; c) moderate to severe cognitive impairment, defined as either a diagnosis of dementia and/or short-term recall of <2/3 objects at 2 minutes d) primary language other than English, e) having completed all of the four ACP behaviors that are the focus of this study.

Participants will be recruited from eight pairs of primary care practices belonging to Northeast Medical Group, an accountable care organization that includes practices in New Haven and Fairfield counties, and Yale New Haven Health System, or located in senior living communities with each pair matched in terms of size, proportion of patients age 55 and older, and proportion of minority patients. Participants will also be recruited from similarly matched senior living communities. One site in each pair will serve as the intervention site, and the other as the control site.

Physicians will review lists of upcoming patients and asked to identify patients meeting eligibility criteria who do not meet exclusion criteria. Physicians and/or staff will give a flyer to eligible participants the day of their visit. For senior living communities, we will solicit volunteers following a presentation by the Principal Investigator performed in the facility providing general information about advance care planning.

Process of Consent/Assent

For individuals recruited from practices, clinicians will provide their consent for potentially eligible persons to participate. If clinician consent is granted, then the clinician will be alerted when he/she is scheduled to see a potentially eligible and asked to obtain the patient's assent to talk to the research associate about the study following the appointment. If the patient has the time, the research associate will explain the study and complete a process of written informed consent and HIPAA authorization. If the patient would like to participate but does not want to stay and would prefer to be contacted later by telephone, we will consent the participant in person and call them at the pre-arranged time. If participant does not want to sign at that time the patient will be given copies of the written documents to review with the research associated by telephone to complete the process of consent, sending in the signed forms using a self-addressed stamped envelope.

Individuals in senior living facilities will meet with the research assistant at the facility at a time of their choosing to complete the process of written informed consent and HIPAA authorization. The informed consent process will consist of the research associate and potential participant reading through the consent form together, with the research associate highlighting the study procedures, potential risks, and participants' ability to withdraw. The associate will ask if the participant has any questions, and then ask several open-ended questions to assess the potential participant's understanding.

Description of Intervention Group
Participants enrolled at the intervention site will receive four contacts, at baseline, two, four and six months. Each of the first three contacts 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.

The baseline assessment and feedback will occur in person, directly after a scheduled office visit. The assessment will be done through a face-to-face interview with a trained research associate, who will enter participants' responses into a laptop computer. The expert system feedback report will be delivered immediately via a portable color printer. The follow-up assessments will be conducted by telephone, with delivery of the feedback report and brochures by mail.

The baseline assessment will also include questions assessing sociodemographic status, health status, and psychosocial status (see below).

The six-month contact will assess participants for the outcome variables for the study, which is the stage of change for each of the four ACP behaviors. This contact will be performed by an interviewer who is blinded to the participant's group assignment.

Description of Control Group

Participants enrolled in control sites will receive four assessment contacts on the same schedule and in the same manner as the participants enrolled in intervention sites. Their assessments will include the TTM constructs of Stages of Change, DB, and V/B, using the same scales as administered to participants in the intervention group. However, 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 for several other behaviors that are relevant to the health of older persons, including a healthy diet, physical activity, and fall prevention.

Outcome Measures

The primary and secondary outcomes will be based on the participant's stage of behavior change for each of the four ACP behaviors targeted by the intervention materials (see **C.1.c.)** obtained at six months following the baseline assessment. The primary outcome will be the proportion of participants achieving the stage of action or maintenance for all four ACP behaviors. The secondary outcomes include the proportion of participants achieving each stage for each of the four ACP behaviors.

These outcomes will be obtained through participant self-report by an interviewer who is blinded to the participant's group assignment. Although there is a potential concern that social desirability bias could result in differential reporting by participants in the intervention and control groups, there are several reasons why self-report is the best way to ascertain outcomes. First, there is no gold-standard objective measure for these outcomes. There are no incentives for physicians to document communication with patients regarding values and goals, so that underreporting of this communication in the medical record is likely to be substantial. Physician and/or surrogate self-report of communication is subject to the same social desirability bias, especially for physicians in the practices randomized to the intervention. It would be possible to ask participants for copies of ADs, but, if the intervention is successful in increasing communication, these may be given to surrogates and not be immediately accessible. Second, the intervention minimizes the likelihood of social desirability bias. Because the feedback reports and brochures acknowledge the difficulties

associated with behavior change, they provide participants with the message of engaging in behaviors when they are ready to do so, rather than with a message of needing to accomplish a certain behavior. In addition to these outcomes, responses to the scales used for the assessment will be examined as secondary outcomes.

Independent Variables

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,[81] self-rated health,[82] and self-rated quality of life. Psychosocial status variables include: religion and religiosity, measured using the Duke University Religion Index[83]; instrumental and emotional support, measured using the EPESE social support items;[84] and depression, using the PHQ-2.[85] 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.[79] The independent variables will be obtained by self-report in the baseline assessment.

Power and Sample Size

Based on our cross-sectional data demonstrating a prevalence of between 4 and 8% for the primary outcome, we conservatively estimate 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 Month 6 assessment. The sample size is based on the ability to detect an absolute increase of 10% for ACP for the treatment group over the control group at Month 6, 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-randomized design.[86] Based on an enrollment 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, a baseline sample size of 1000 is required.

This sample size will also be sufficient for conducting process-to-outcome analyses assessing the effects of potential mediators and moderators of outcomes using multiple regression or structural equation modeling analyses.[87,88] For example, for structural models of reasonable size (e.g., df = 40–50), and assuming a close fit criterion (RMSEA = .05), power is at least .80 for groups of about 240.

Analysis

The analysis is based on the study design of two groups (intervention, control) X 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.

Primary Outcome

The main outcome hypothesis is that the proportion in Action/Maintenance for the four ACP behaviors is intervention group > control group at the final 6-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.[89] GEE enables use of linear, logistic and Poisson regression methods with repeated measures, providing consistent estimates of regression coefficients and robust variance estimates, even in the presence of unbalanced group data. It permits the clustering of sites by treatment condition and provides a direct estimate of the ICC.

Secondary Outcomes

Design and analysis approaches for secondary outcomes will be similar to those employed for the primary outcome variable. Subgroup analysis will explore the effects of the intervention according to demographic status, including age, gender, race/ethnicity, education, and according to the number of ACP behaviors completed at baseline.