A Multimethod Evaluation of Tobacco Treatment Trial Recruitment Messages for Current Smokers Recently Diagnosed With Cancer: Pilot Factorial Randomized Controlled Trial

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Recruitment messages using Vidscrip

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SPECIFIC AIMS

There is growing support for the delivery of evidence-based smoking cessation treatment at the time of cancer screening and/or after a patient receives a recent cancer diagnosis. However, there remain barriers to recruiting eligible patients to cessation trials in a cost-effective and scalable manner. One way to overcome these barriers is to employ digital recruitment strategies that utilize video-based recruitment messages to describe the benefits of participating in the trial. In order to determine the optimal components that should be included in these recruitment messages, rigorous formative evaluation must first be conducted. Therefore, this study will pilot test different components of study recruitment videos that will be employed in two future smoking cessation clinical trials.

Additionally, individuals who identify as Hispanic or Latino are historically underrepresented in smoking cessation clinical trials. Despite there being high levels of smoking among some sub-groups, engagement with smoking cessation remains low. We aim to test the most salient messages in informational recruitment videos for a smoking cessation clinical trial tailored for Hispanic/Latinos. We will refer to this as Survey 1a.

We propose to conduct an online survey experiment through Qualtrics Panels and Survey Sampling International (SSI), online panel companies. The survey will test a series of videos, delivered through the Vidscrip platform, to promote a smoking cessation trial (Smokefree Support 2.0) to patients who were recently diagnosed with cancer.

Broadly, the study aims are as follows:

> **Aim 1:** To determine the optimal recruitment video components for a smoking cessation trial for recently diagnosed cancer patients (Smokefree Support 2.0)
>
> **Aim 2:** To identify, qualitatively, aspects of each recruitment video that can be improved upon.

BACKGROUND AND SIGNIFICANCE

The study investigators have considerable experience in directing the successful execution of dissemination and implementation studies of evidence-based tobacco cessation treatments, as well designing and developing recruitment messages through online message experiments.

Dr. Park has extensive experience in integrating evidence-based tobacco treatments within the Partners HealthCare Network. She has completed a pilot tobacco non-randomized controlled clinical trial (5R03CA130722-02) which showed promising feasibility and efficacy for delivering an evidence-based intensive tobacco treatment (IT; 9 motivational coaching sessions plus varenicline) to lung cancer patients at Massachusetts General Hospital (MGH). Dr Park was a member of the committee to increase delivery of tobacco treatment at NCI-Designated Cancer Centers based on the 2008 Clinical Guidelines for Treating Tobacco Dependence. Dr. Park has directed multi-site tobacco treatment motivational trials among low income smokers as well as research examining cancer care in the setting of nicotine dependence. Dr. Park was also PI on a study involving the CanCORS cohort and factors associated with continued smoking

Dr. Haas is a licensed/credentialed general internist with research expertise in developing and evaluating clinical practice-based interventions, particularly using health IT. She recently completed an intervention for low income and minority smokers that included nicotine replacement, tobacco coaching and systematic screening and referral for social determinants of health. She collaborated with Drs. Park and Rigotti on this project. She is currently PI of an NCI-funded PROSPR grant that collaborates across 7 centers to define common data elements for screening and cancer outcomes.

Dr. Rigotti is a licensed/ credentialed general internist and has extensive experience integrating tobacco treatment into inpatient settings. She is currently PI of an NIH-funded comparative effectiveness trial of 2 post-discharge interventions for hospitalized smokers. Dr. Park oversees the motivational coaching design for this study. Dr. Rigotti has extensive experience testing pharmacological treatment for medical patients, including hospitalized smokers, and recently was site PI for an RCT that demonstrated the efficacy and safety of varenicline in patients with cardiovascular disease.

Dr. Neil is a postdoctoral research fellow and a health communication expert. He has extensive experience testing message design theories and utilizing persuasive message appeals to target behavior change and reduce cancer disparities. His recent publications in *Journal of Cancer Education, Journal of the National Cancer Institute,* and the *Oxford Research Encyclopaedia of Communication* focus on experimentally testing message strategies that encourage patient participation in cancer clinical trials, all of which have provided him with prior experience to help conduct this study.

RESEARCH DESIGN AND METHODS

Survey

A nationally representative sample of approximately 81 participants will be recruited from SSI. The survey will employ a 2^3 factorial design plus control condition, with participants randomized to one of 9 videos. The videos will consist of 9 intervention proportions, based on a 3-factor fully crossed factorial design to efficiently test components that vary on 1) threat of continuing to smoke (proximal vs. distal frame), 2) benefits of quitting (gain vs. loss frame), 3) benefits of participating in Screen ASSIST (gain vs. loss frame), and a kernel message control condition with no message factors included.

Survey inclusion and exclusion criteria:

Participants will be screened eligible if they meet the following criteria by self-reporting: language (English speaking), age (≥ 18), smoking status (puff within the past 30 days), and cancer status (diagnosed with cancer in the past 24 months).

Video development and recording

The videos for the surveys will be developed in collaboration with Deborah Kim, from MGH Marketing Dept. The approved script will be recorded in segments, in order to develop the differing video conditions. The videos for the survey will include an oncologist. Videos will be stored on a study-specific account on Vidscrip.com and the videos will be embedded into the survey platforms.

Video content

Participants will be prompted to review a study for an upcoming smoking cessation trial for patients who have similar characteristics and smoking and medical history as they do. The videos for survey will last approximately 3 minutes and introduce each respective cessation study, outlining the benefits of participating in the study.

Outcome Assessment

The survey employs an experimental design, in which participants will provide quantitative feedback through a series of survey responses, as well as qualitative feedback through open-ended questions. Both forms of data will be analyzed and merged to provide a holistic evaluation of the videos. There will be no follow-up data or connection to medical records. Survey responses will be completely de-identified. Please see survey instruments for full measures of data collection.

The study presents minimal risk to participants and does not expose participants to any unnecessary risk. To ensure participant understanding of the study prior to consenting, a description of the aims and length of the survey (approximately 15 minutes) will be detailed in the informed consent prior to beginning the survey. As with any behavioral research study, it is possible that participants may feel some psychological discomfort as they are presented with information about cessation within the video; however, we expect this likelihood of this to be minimal and the participant can stop participating in the survey at any time.

To ensure patient understanding of the study prior to consenting, there will be an explanation of the study on the initial screen of the survey. Subjects who wish to leave the study after enrolment may drop out at of the survey at time. MGH-directed research activities have been designed to carefully consider the safety of subjects, and all study staff have completed the requisite MGH/Partners human subjects trainings prior to being added as study staff.

FORESEEABLE RISKS AND DISCOMFORTS

Psychological Risks

Individuals may find it stressful to answer questions and discuss their smoking behaviors. The risks associated with these discussions are minimal, especially when compared to the benefits of smoking cessation. As with online video experiment, there is the small chance that a participant will be negatively affected by the content of the video. However, the script used for the video has been constructed in partner with, and vetted by, trained and certified tobacco treatment specialists and smoking cessation specialists.

EXPECTED BENEFITS

The expected benefits to the individual for participating in this study are that they will learn valuable information about the benefits of smoking cessation. They will be told about the benefits of cessation after a recent cancer diagnosis. At the end of the survey, they will also be offered the opportunity to click on a link that will direct them to clinicaltrials.gov to find a smoking cessation trial, if they wish. Therefore, the overall risk to benefit ratio for the participant is favorable. Furthermore, the results of the study will also benefit future patients who smoke, as the study determines the most effective messages to recruit patients to a smoking cessation study.

EQUITABLE SELECTION OF SUBJECTS

Patients will be recruited through Qualtrics panels and SSI and randomized to one of 9 videos. Built into the survey logic for the survey, each participant will have equal opportunity to be randomized to any one of the videos, respectively. The survey randomization will randomly assign each participant to a condition using a computer-generated program. The program will generate a schedule of randomization IDs and treatment assignments in balanced blocks.

Only English-speaking men and women will be recruited and enrolled as the videos are recorded in English. Children will not be enrolled because they are not eligible for lung cancer screening.

These surveys are pilot-testing the recruitment videos that will be used in the upcoming clinical trials. Only videos recorded in English will be tested in this study as we want to first evaluate the content of these videos to determine the most effective components for a recruitment video.

RECRUITMENT PROCEDURES

Participants will be recruited from Qualtrics Panels and Survey Sampling International, proprietary opt-in panel companies. Qualtrics and SSI recruit participants from various sources, including website intercept recruitment, member referrals, targeted email lists, gaming sites, customer loyalty web portals, permission-based networks, and social media, etc. Consumer panel members' names, addresses, and dates of birth are typically validated via third-party verification measures prior to their joining a panel. B2B participants are subject to additional quality control measures such as LinkedIn matching, phone calls to the participant's place of business, and other third-party verification methods (TrueSample, RelevantID, Verity, etc.). The study investigators pay Qualtrics and SSI to complete these procedures.

Qualtrics and SSI compensate patients based on how unique they are as a study participant (i.e., demographics, medical history, etc.). There official explanation reads: Our panelists join from a variety of sources. They may be airline customers who chose to join in reward for SkyMiles, retail customers who opted in to get points at their favorite retail outlet, or general consumers who participate for cash or gift cards, etc. When participants are invited to take a survey, they are informed what they will be compensated. Because each respondent is compensated differently, it would be inappropriate to provide a specific amount for how much they will be compensated in the informed consent document.

However, consultation with both companies has confirmed that the reimbursement value for completing the survey will be under $5.

CONSENT PROCEDURES

Patients will be presented with an initial 'Information Sheet' on the survey where they will read the details of the study. The survey will be administered online, and the patient must confirm that they have read and understand the text on the Information Sheet to move forward with the survey.

DATA AND SAFETY MONITORING

Data collection for this survey will be completed in approximately three weeks after launch, there will be a limited period data collection monitoring. In addition, there is minimal risk for participants and the study team will never have direct contact with the participants, so monitoring will primarily be conducted through as a means of data quality checks. However, throughout the study, if any adverse events or serious adverse events are reported as a result of responding to the survey, this information will be reported in a timely fashion to the IRB. The PIs are responsible for protecting the rights, safety, and welfare of the study patients and for ensuring that the study is conducted in accordance with the IRB-approved protocol and applicable regulations and requirements of the IRB.

Data monitoring plan: All study procedures and data collection will be piloted before the trial begins.This will firstly be done internally, then a 10% sample pilot launch will be conducted by Qualtrics and SSI externally to confirm that data is collected as expected. To further prevent the loss of confidentiality, all electronic information stored on the main database within the MGH/Partners Healthcare System, Inc. firewall, is password protected, and is protected by anti-virus software. Only study staff will have access to the study data on Shared File Areas. However, this data will not have Dr. Park will review the data for quality assurance and discuss data quality problems with the PIs. Data quality (including visits completed during the intervention window, data missingness, and recruitment rates) will be monitored monthly. Interim data analysis will be conducted throughout the trial and results will be reported in the annual NIH progress report. In addition, the RAs will participate in weekly study evaluation meetings to review any difficulties that arise with survey administration and the status of follow-up survey and biochemical collection.

The Principal Investigators will be responsible for the reporting of any adverse events to the Institutional Review Board. The Partners IRB requires that serious adverse events are to be reported to the IRB as soon as possible, within 5 working days/7 calendar days of the date the investigator first becomes aware of the problem. Non-serious adverse events are to be reported within 20 working days.

MONITORING AND QUALITY ASSURANCE

Data quality (including visits completed during intervention window, data missingness, and recruitment rates) will be monitored weekly by the Dr. Neil, and systemic data problems will be reported to the PIs. Dr. Park for adherence to the protocol. Data will be analyzed during the internal pilot, external pilot, and then upon completion of the survey. Interim data analysis after both pilots will reduce will be conducted halfway through the trial and results will be reported in the annual NIH progress report. Interim data analysis will be conducted halfway through the trial and results will be reported in the annual NIH progress report.

PRIVACY AND CONFIDENTIALITY

Qualtrics and SSI are extremely careful to protect participant privacy by providing no personally identifiable information. All survey materials and study data will be stored digitally on password protected computers to which only our study team has access. While researchers can never guarantee complete confidentiality of study data, we will take all efforts to prioritize the security of data. You will be assigned a study ID number to help protect your identity and to keep your responses confidential. You can also withdraw from the study at any time. If the results of this research study are published in a medical journal, they will not identify individual patients. Risks to subjects have been minimized wherever possible as participants will have the ability to end participation at any time and all activities will be directed or overseen by MGH research staff. All MGH components have been used successfully in previous trials overseen by Dr. Park.

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