Establishing the Effectiveness of Publicly Available Smoking Cessation Resource

Study Protocol and Data Analysis Plan

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ClinicalTrials.gov ID: NCT05055778

Funding: This study was funded by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number KL2TR003016. Dr. Wiseman was an iTHRIV Scholar during the completion of this work. The iTHRIV Scholars Program is supported in part by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Numbers UL1TR003015 and KL2TR003016.

List of Abbreviations

NCI: National Cancer Institute

SFTXT: Smokefree.gov Initiative SmokefreeTXT smoking cessation text message intervention

Study Overview

This project will recruit smokers from across Virginia with recruitment from rural and non-rural counties. All participants will be provided with access to a research version of the National Cancer Institute's SmokefreeTXT program (SFTXT). Cessation outcomes will be assessed at the end of program (7-weeks), and 3- and 6-months from enrollment. We will compare smoking abstinence by rurality. The project will be conducted remotely, using study-specific websites to complete all data collection, and using participants' own phones for intervention implementation.

Study Recruitment

Participants will be recruited using targeted (by location and likelihood of being a smoker) Google advertisements, social media (e.g. Facebook), and via introduction by a representative of a community partner organization. People interested in learning more about the study will be able to click through to a secure study-specific Qualtrics page which will serve as the study website. The website will include all information needed for informed consent and, for eligible participants, will serve as the consent form. It will provide an overview of the study and describe all aspects of study participation, risks, and benefits.

The information page will also serve as an eligibility screener. The screening component of the webpage will be divided into two parts. The first part will include items to assess eligibility and monitor demographic distribution of potentially interested participants. This includes assessing current smoking status, cell phone ownership, ability to read and speak English, current pregnancy status and planned pregnancies, date of birth, race, ethnicity, and gender identity. Individuals who do not meet initial study eligibility criteria will be informed that they do not qualify for the study. Interested participants who appear eligible at this stage will then be asked to provide additional contact information and will be asked to consent to participate in the study. The additional questions are, full name, home address, phone number, email address, and consent to be contacted via email. This information will be used for final eligibility determination. The age and identity of all individuals will also be confirmed using an online people search vendor. Individuals who do not meet study eligibility criteria due to non-Virginia residence or whose identities cannot be verified will be emailed to inform them they do not qualify for the study.

The inclusion criteria are:

- English speaking adult (18+ years old)
- Current cigarette smokers (at least 5 cigarettes per day)
- Residing in Virginia
- Owns a cell phone
- Is interested in quitting smoking but not currently undergoing a quit attempt

The exclusion criteria are:

- Being pregnant or anticipate becoming pregnant in the next 6 months

Rurality will be determined by utilizing Rural Urban Commuting Area codes. Rural counties have been identified by the Office of Rural Health policy, which takes into account areas

determined to be Metropolitan Areas based on the Office of Management and Budget as well as specific census-track levels areas based on RUCA codes 4-10.

If the participant is deemed 'not eligible' at any point they will be notified either via Qualtrics or via email and tagged as 'not eligible' and the reason why noted in our electronic database. All ineligible participants, regardless of reason for exclusion, will be given a list of alternative treatment resources (smokefree.gov online resources and information on 1-800-Quit-Now).

After the informed consent process is complete, participants will be sent an email link to collect additional baseline data (pre-assessment) and text message enrollment instructions.

Study Assessments

Pre-Assessment: This assessment questionnaire includes questions about tobacco use, readiness to quit smoking, motivation to quit smoking, confidence in quitting, mood, cessation techniques used in the past and planned for future quit attempts, as well as general information about themselves (age, gender, race, etc.), general health behaviors (e.g., alcohol use), cell phone and technology use questions (e.g., type of phone, carrier, frequency of voice calls, frequency of text messaging, perceived quality of signal quality, etc.), and measures of social cohesion and unmet needs. It is estimated that the Pre-Assessment Questionnaire will take 30 minutes. Participants will receive daily e-mail prompts to complete the Pre-Assessment Questionnaire until it is complete, or until three days have passed since their enrollment date.

After the Pre-Assessment Questionnaire is complete, the program automatically advances participants to text message enrollment instructions. Participants are instructed to text "JOIN" to the study text message platform via a study specific verified toll-free phone number. They will then complete the enrollment process through their own phones and begin receiving 3-5 messages a day for 7 weeks. Participants will be asked to sign up for the text messaging program within three days of completing the pre-assessment. All participants will receive reminder emails to complete text program enrollment for 3 days after the completion of the pre-assessment. Study staff will contact participants if they completed the baseline questionnaire but after three days have no record of completing the text program enrollment.

Post-baseline Assessments: At the end of the 7-week intervention, 3 months after the quit day, and 6 months after the quit day, participants will be instructed (by email) to

complete online follow-up assessments. The assessment questionnaires include questions about tobacco use, reasons for relapse (if relevant) motivation to quit smoking (if relevant), confidence in quitting (if relevant), mood, cessation techniques used in the previous assessment period, alcohol use, as well as satisfaction with the intervention and any changes in cell phone and technology use (e.g., type of phone, carrier, frequency of voice calls, frequency of text messaging, perceived quality of signal quality, etc.). The Post-Assessment Questionnaires are estimated to take no more than 20 minutes. As was true for the Pre-Assessment, participants will be able to complete the Post-Questionnaires in more than one sitting as the program auto saves where they are in the Questionnaire. Participants will be able to review and revise answers up until the point they select "Submit." Once the Questionnaire data is submitted, participants will no longer have access to their responses on the Questionnaire. All participants will receive reminder emails to complete the assessments daily for 3 days after the invitation to participate is sent.

Intervention

SFTXT is a six- to eight-week program that takes place entirely on a user's cellphone. Adults who interested in quitting smoking register for the program either online or by texting the program directly and select a quit day up to two weeks in the future. Between enrollment and the quit day, three to five messages are sent each day in preparation for the quit attempt. Starting on the quit day, users continue to receive multiple messages a day for six weeks. Within-program assessment questions texted to users measure smoking status, mood, and craving levels. Users are also able to request on-demand help using "keywords" related to smoking, mood, and cravings. Use of a keyword returns one of several preprogrammed responses. In practice, users are told about the keywords initially and are given reminders about some or all of the keywords within the program on Days 1,6, 10, 14, 17, 20, and 35. Users may opt out of the program at any time by texting "STOP" and can restart the program with a new quit date by texting "NEW". SFTXT is one of the most popular publicly available text-messaging cessation interventions, with more than 150,000 smokers having enrolled since 2011.

For the purposes of this study, all messages from SFTXT have been reprogrammed into a study specific account on a third party text message vendor, TextIT, and administered through a verified phone number via Twilio. This will allow better control of text message delivery and data by study staff, while maintaining all program functionality. For study participants, the initial quit date is set at one week after enrollment, but participants may change their quit date at any time by texting "NEW".

Study End

After completion of the 6-month survey, participants will be told that they have reached the end of the study. Participants who do not respond to the invitation to complete the 6-month post-assessment after four reminder emails will be sent an email informing them that they have reached the end of the study

Participant incentives

Participants will receive up to $100 for participating in the study in the form of e-gift cards sent at three time points:

- Up to $30 at the end of the intervention
    - $10 for completing the pre-cessation survey
    - $20 for completing the end of intervention survey
- $30 for completing the 3-month survey
- $40 for completing the 6-month survey

Data Analysis

This study was approved by the Social and Behavioral Sciences IRB at the University of Virginia (SBS IRB# 3928, clinicialtrials.gov identifier: NCT05055778).

Analysis of this study will be primarily descriptive in nature as there is only one intervention arm and no randomization

Outcomes of Interest

The post-intervention, three-, and six-month assessments measure the primary outcome of interest: 7-day smoking abstinence (responses to the question: “Have you smoked a cigarette (even a puff) in the past 7 days?”, with responses of ‘yes’, and ‘no’) measured at 7-weeks, 3-months, and 6-months. Secondary outcomes include continuous smoking abstinence (responses to the question: “In the last [6-weeks/3 months/6 months], have you smoked at all?”, with responses of ‘yes’, ‘no’, and ‘don’t know’). To provide the most conservative estimates of abstinence, missing responses for each assessment will be coded as continuing to smoke.

Statistical Analyses

Descriptive statistics will be used to characterize the population and describe primary and secondary cessation outcomes in the entire study population. All analyses will be conducted using SAS 9.4 (SAS Institute Inc., Cary, NC).