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Abstinence Reinforcement Therapy (ART) for Rural Veterans: Methodology for an mHealth Smoking Cessation Intervention

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Abstract

Introduction—Smoking is the most preventable cause of morbidity and mortality in U.S. veterans. Rural veterans in particular have elevated risk for smoking and smoking-related illness. However, these veterans underutilize smoking cessation treatment, which suggests that interventions for rural veterans should optimize efficacy and reach.

Objective—The primary goal of the current study is to evaluate the effectiveness of an intervention that combines evidenced based treatment for smoking cessation with smart-phone based, portable contingency management on smoking rates compared to a contact control intervention in a randomized controlled trial among rural Veteran smokers. Specifically, Veterans will be randomized to receive Abstinence Reinforcement Therapy (ART) which combines evidenced based cognitive-behavioral telephone counseling (TC), a tele-medicine clinic for access to nicotine replacement (NRT), and mobile contingency management (*mCM*) or a control condition (i.e., TC and NRT alone) that will provide controls for therapist, medication, time and attention effects.

Methods—Smokers were identified using VHA electronic medical records and recruited proactively *via* telephone. Participants ($N = 310$) are randomized to either ART or a best practice control consisting of telephone counseling and telemedicine. Participating patients will be surveyed at 3-months, 6-months and 12-months post-randomization. The primary outcome measure is self-reported and biochemically validated prolonged abstinence at 6-month follow-up.

Discussion—This trial is designed to test the relative effectiveness of ART compared to a telehealth-only comparison group. Dissemination of this mHealth intervention for veterans in a

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variety of settings would be warranted if ART improves smoking outcomes for rural veterans and is cost-effective.

Keywords

mobile health=mHealth; eHealth; telehealth; financial incentives; smoking cessation; clinical trial

Introduction

Cigarette smoking is the most lethal substance use disorder in the United States in terms of morbidity and mortality [1], and it disproportionately affects U.S. veterans [2, 3] and individuals living in rural areas [4]. Compared to urban- and suburban-residing adults, rural adults have significantly higher rates of smoking, with nearly one quarter of rural adults endorsing current smoking [5]. Specifically, urban/rural differences in cigarette use are most pronounced in the South Atlantic region of the U.S. [6]. In the context of heightened smoking risk, rural veterans are also less likely to access healthcare services through the VHA or private sectors [7, 8]. Additionally, rural veterans are less likely to receive advice to quit from VHA providers, and are also less likely to receive important information about smoking cessation treatments [9]. Given the prevalence of smoking in rural veterans and their reduced access to VHA smoking cessation treatment, there is a need to develop smoking cessation interventions that are cost-effective and increase the reach of intensive smoking cessation services for rural veterans.

Although effective interventions for smoking cessation are available to veterans, treatment barriers attenuate the use and benefit of these treatments. Meta-analyses of existing smoking cessation interventions provide clear evidence that treatment intensity is associated with efficacy, such that longer and more intensive interventions are more efficacious [10]. VHA facilities often provide this type of intensive treatment through their specialty smoking cessation clinics, which combine multiple treatment formats, including self-help materials, group counseling, individual counseling, and telephone counseling [11]. However, attendance at these VHA specialty smoking cessation clinics among all veterans is as low as 13% [12]. For rural veterans, the following extrinsic factors may negatively affect access to smoking cessation treatment: distance from health services, lack of health care follow-up, and lack of knowledge about smoking cessation resources [13, 14].

Given that rural veterans underutilize smoking cessation services in VHA, they may benefit from an intervention that utilizes a public health model to maximize participation. While the traditional medical model focuses on content, i.e., developing the best possible program, relatively little attention has been paid to context, e.g., how to get people to participate [15]. From a public health perspective, impact has been defined as Reach (i.e., number of veterans who access/receive an intervention) $\times$ Efficacy (effect size of an intervention) [16]. Current VHA cessation interventions reflect a tradeoff between low reach/high efficacy (e.g., specialty care) and high reach/low efficacy (e.g., physician advice), ultimately affecting population impact. Improving reach of efficacious smoking cessation services and removing barriers that limit access and participation to effective interventions is critical in order to impact cessation rates on the population level.

To increase reach without decreasing efficacy, a combination of approaches may be indicated. First, reach can be broadened using intensive telephone counseling and telemedicine for smoking cessation rather than in-person, clinic-based specialty care [17]. Smoking cessation counseling alone or in combination with nicotine replacement therapy medication (NRT) has been shown to be highly cost effective [18]. However, there is still a need to optimize efficacy of intensive interventions to smoking cessation consumers. This may be especially true for rural veterans, as some data suggest that quit rates are lower among rural smokers compared to their urban counterparts [19]. To have a significant impact on smoking rates among rural veterans, there is a need to develop and implement interventions that both extend reach beyond clinic-based treatment approaches and provide more intensive treatment than currently available through telehealth or web-based approaches.

The addition of contingency management (CM) to existing evidence-based telehealth smoking cessation is hypothesized to be a cost-effective way to increase the efficacy of intensive telephone counseling and telemedicine. CM provides positive reinforcements contingent upon objective evidence of abstinence. There is considerable evidence for the efficacy of CM in reducing smoking in difficult-to-treat populations including individuals with low motivation to quit, individuals with psychiatric comorbidity, drug dependent individuals, and adolescents [20–22]. Despite evidence for its efficacy, implementation of CM has been limited because of the need to verify abstinence multiple times daily with a clinic-based exhaled carbon monoxide (CO) monitor. Web-based contingency management approaches overcome the need for clinic monitoring and can be particularly useful for difficult-to-treat smokers, including rural populations [23].

While empirical research has shown the efficacy of web-based applications that allow verification of smoking abstinence using a home internet connection [24, 25], web-based CM for rural veteran smokers may be limited by a number of factors: 1) lower rates of internet access in rural areas, 2) inability to verify abstinence while away from home, and 3) dissipation of treatment effects after removal of incentives. Rural Americans are less likely to have internet access, and moreover those with internet have slower connection speeds [26, 27]. Additionally, home verification of abstinence may be less convenient for smokers who work, participate in childcare, or travel (e.g., long-distance drivers). Difficulties in internet access may present barriers to accessibility of web-based CM. Furthermore, while CM increases odds of quitting, many ex-smokers return to smoking after the removal of incentives [28]. While web-based CM interventions for rural smokers initially increase quit rates, these effects disappear as quickly as the 3-month follow-up [24]. In short, web-based CM for smoking cessation has not yet been delivered efficaciously for rural smokers.

The combination of emerging smartphone technology and intensive telehealth treatment, however, can overcome these barriers to abstinence for rural smokers. First, pooled data from smoking cessation interventions delivered via mobile phone has shown the efficacy of this general approach [29]. Moreover, preliminary data specifically suggests that CM delivered via smartphone technology (mobile CM, or *mCM*) has the potential to increase efficacy of smoking cessation treatment [30]. *mCM* uses an app to enable veterans to receive contingent monetary rewards for verifying smoking abstinence on a mobile device in a

variety of locations. Additionally, pairing *mCM* with efficacious telehealth treatment (including psychotherapy and nicotine replacement) has the potential to affect long-term quit rates once incentives are removed. This pairing may affect long-term quit rates by keeping participants engaged in treatment, improving NRT adherence, and increasing self-efficacy, all of which have been predictive of long-term abstinence [31–34].

The primary goal of this clinical trial is to evaluate the effectiveness of a combined telehealth intervention called Abstinence Reinforcement Therapy (ART), which is a treatment package that combines *mCM*, telephone counseling, and telemedicine for smoking cessation. The current project will examine whether ART for rural veterans demonstrates both greater efficacy in abstinence rates and increased cost effectiveness compared to a telehealth-only contact control condition. The proposed research is particularly novel because it will be the first evaluation of smartphone-based CM in conjunction with evidence-based smoking cessation treatment in veterans. Specific aims are to:

AIM 1: Evaluate the impact of ART on rates of abstinence from cigarettes as measured by biochemically verified, self-reported prolonged abstinence.

Hypothesis 1: Abstinence rates at 6 months will be significantly higher among veterans randomized to the ART intervention than those randomized to the telehealth-only condition.

AIM 2: Evaluate the relative cost-effectiveness of the ART intervention in quality adjusted life years (QALYs).

Hypothesis 2: ART treatment will result in greater cost-effectiveness compared to the telehealth-only condition as measured by the incremental cost-effectiveness ratio.

AIM 3: Evaluate potential treatment mediators, including self-efficacy-related mechanisms.

Hypothesis 3: The relationship between ART and increased abstinence will be mediated by increased self-efficacy.

Method

Participants & Procedure

Study intervention and follow-up are currently ongoing. All study procedures were approved by the Durham Veterans Affairs Medical Center (VAMC) Institutional Review Board. Veteran patients with current tobacco use will be identified from patient records at the Durham VAMC. Inclusion criteria for the study include: at least 18 years of age, enrolled at Durham VAMC for ongoing medical care, current smoker willing to make a quit attempt in the next 30 days, and English speaking. Exclusion criteria are: no access to telephone, severely impaired hearing or speech (i.e., inability to take part in telephone counseling), active diagnosis of a psychotic disorder, extended serious illness, and current hospitalization.

Potential participants are sent an introductory letter signed by the Principal Investigator. The letter describes the study and informed potential participants that they will be called to

complete a telephone survey unless they called a toll free number to opt out of screening. Seven business days after the mailing, veterans who have not called the toll free number to decline participation are called by a research assistant to invite participation in the research study. After screening into the study, veterans complete verbal informed consent for study participation. Immediately following enrollment and informed consent, participants answer baseline survey questions over the telephone. Screening, consent, and the baseline survey were conducted in the same telephone call.

Randomization—After completion of the baseline survey, participants are randomized to one of two treatment groups, ART (telehealth-based counseling + telemedicine + *mCM*) or the control condition (telehealth-based counseling + telemedicine). Randomization was stratified based on distance to the Durham VAMC or closest VA outpatient clinic that offered smoking cessation care (< 15 miles, 15–49 miles, ≥ 50 miles) and positive psychiatric screen. Distance is measured from the centroid of the participants' zip code of residence to the centroid of the zip code of the nearest VA facility. Positive psychiatric screen was defined by any of the following: a) Center for Epidemiologic Studies Depression Inventory (CES-D) [35] score > 8, b) Alcohol Use Disorders Identification Test (AUDIT-C) [36] score > 3, c) indication of heavy episodic drinking in the past year on the AUDIT-C, or d) Primary Care Posttraumatic Stress Disorder (PTSD) Screen (PC-PTSD) [37] score ≥ 3. Permuted block randomization is used within each stratum to ensure that the numbers of patients in each intervention arm within each stratum remains balanced. The complete randomization sequence was generated a priori using computerized methods, but was concealed from study staff for each participant until completion of baseline measures.

Experimental condition, ART

Intervention components: Smokers randomized to the experimental condition, ART, receive five sessions of cognitive-behavioral telephone counseling (described below), NRT telemedicine (described below), and mobile contingency management (*mCM* via a smartphone app). They are mailed the following: 1) a handout with information regarding compensation for reduced CO readings, 2) a handheld CO breath monitor, and 3) a smartphone with a high-definition webcam, 4G connectivity, and the *mCM* app installed. The CO monitor is a battery-operated instrument that measures CO in parts per million (ppm), and provides an LED reading of CO levels to indicate abstinence. Participants are trained over the telephone in use of the CO monitor and smartphone app.

***mCM* app:** After receiving materials in the mail, participants receive approximately 45 minutes of training over the telephone in how to use the *mCM* app including a) how to record CO readings, b) upload readings via the *mCM* app, and c) use the app to check receipt of compensation and abstinence incentives. CO monitoring for smoking abstinence lasts for seven weeks. Throughout the monitoring period, participants upload videos to confirm smoking abstinence, all of which are visually monitored by study staff through a centralized website (see below). For each video recording, participants are asked to 1) begin a recording using the smartphone; 2) show the initial zero CO reading to the camera; 3) video record him/herself holding his/her breath during the monitor's countdown; 4) blow into the CO monitor while on camera; 5) show the final CO reading to the camera; and 6)

use the *mCM* app to upload their video recording. The *mCM* app was coded for Android OS using Java and the Android Software Development Kit (SDK). It was tested for bugs and usability by study staff prior to participant use in the study. Smartphones supplied to participants are compliant with current VHA information security requirements [38]. For the purpose of the current trial, features on the smartphones are limited to the app only. Internet, wi-fi, and texting capabilities are disabled on study smartphones, as well as incoming/outgoing calls (except the Durham VAMC and 911). Issues with network connectivity are tracked (i.e., lack of or inconsistent network connection). If network connection problems arise, participants are given four options: a) record videos and travel to a location with a network signal daily to upload videos and compensation tracker, b) upload videos whenever they have a network signal, with the understanding that incentives will not escalate due to missed videos, c) opt out of video uploading with the understanding that they will not receive incentives, or d) have study staff enable wi-fi to upload videos via wireless internet connection.

mCM intervention: Participants complete four weeks of active *mCM* following one week of training during which they are compensated simply for uploading CO readings twice a day using the *mCM* software. After approximately 7 days of practice, participants make a quit attempt and receive active *mCM* (weeks 2–5), during which they receive compensation based upon smoking abstinence. During weeks 6 and 7, participants continue to monitor and provide CO readings twice a day, but compensation is no longer contingent on smoking abstinence.

Reinforcement of smoking abstinence occurs twice per day and is contingent upon an abstinence criterion of CO ≤ 6 ppm, which increases sensitivity while maintaining a low false positive rate [39]. Reinforcement follows an escalating schedule (see Table 1) because it has previously produced higher abstinence rates than fixed reinforcements [24, 40]. With this escalating reinforcement schedule, participants start earnings at \$1, with a 10¢ increase for each subsequent consecutive reading with CO ≤ 6 ppm. If a participant smokes (indicated by CO > 6 ppm) or misses a video then the compensation amount per reading resets to \$1. Participants can also receive \$5 bonus incentives every 5 days for continuous abstinence. Using the *mCM* app, participants can view their up-to-date total incentives. Incentives are shown as credits that lead to direct financial compensation at the end of the monitoring period. Payment through direct deposit or by a check is received after the equipment is returned (immediately following seven-week contingency period). In two previous pilot studies using a similar schedule of escalating incentives for abstinence, total participant incentives averaged \$314 and \$286, respectively [30, 41].

To increase compliance with monitoring outside of the 4-week *mCM* compensation period, participants are offered compensation for practice and follow-up CO readings (not contingent upon abstinence). See Table 1 for non-contingent compensation. During the week prior to the quit date (week 1), participants receive compensation of \$1 per CO reading, regardless of CO level. Additionally, after the 4-week *mCM* period (weeks 6–7) participants can receive up to \$51 for providing follow-up CO readings twice per day, regardless of CO level.

mCM monitoring website: To facilitate daily tracking of each participant's CO level during the monitoring period, the study team created a web application that is integrated with the smartphone app. Only study staff members have access to the web app, which allows study staff to view uploaded CO reading videos. Using the web interface, study staff can view each video, assign a CO reading to the video, and can leave troubleshooting feedback and notes for participants. For each possible video uploaded (twice per day), study staff can mark the video as *Verified* (CO $\leq$ 6 ppm), *Denied* (CO $>$ 6 ppm), or *Extenuating Circumstance* (missed due to emergency, lack of 4G connectivity, etc.), or they can mark a period with no video uploaded as *Missing Video*. In the case of extenuating circumstances, participants do not receive incentives, but their incentive level is not reset to \$1 for their next uploaded video.

The web interface contains algorithms that automatically calculate incentives and study compensation based upon the contingency table (see Table 1). The web app also displays each participant's 7-day abstinence status for each day of monitoring. The web app was coded using PHP, MySQL, Javascript, HTML, and CSS, and was tested for bugs and usability by study staff prior to use in this study. The website is hosted on a secure server and access to the site is only available over secured connections via password. The smartphone app uploads encrypted videos linked to their study ID to the web app over secured connections. Videos remain encrypted at rest and are only decrypted during viewing by a member of the study staff.

Control condition—Participants randomized to the control condition are offered smoking cessation telephone counseling and telemedicine (described below). The difference between the ART condition and the control condition is solely the inclusion of the *mCM* smartphone app and monitoring website.

Telephone counseling—Both intervention (ART) and control conditions receive cognitive-behavioral telephone counseling and a participant manual. The treatment manual and participant workbook are adapted from an empirically tested five-session telephone counseling intervention developed within VHA [42]. The telephone counseling protocol is based on standard cognitive-behavioral therapy techniques shown to be efficacious for smoking cessation and is informed by behavioral treatment principles [43], Social Cognitive Theory [44], Motivational Interviewing techniques [45], and the Transtheoretical Model of Behavior Change [46]. The treatment protocol is consistent with the Public Health Service Clinical Practice Guide [10] and is tailored to the veteran population. The five telephone treatment sessions emphasize acquisition of skills for stopping smoking and relapse prevention/management. Telephone counseling occurs approximately once per week (with some flexibility for scheduling purposes), with each session lasting approximately 25 minutes. All telephone counselors receive 5 hours of training by a Ph.D.-level clinical psychologist, and additionally attend monthly supervision meetings. In order to standardize counseling sessions, telephone counselors are provided with a computerized manual that contains a checklist of session objectives. For each treatment session, counselors click through the pages of the computerized manual and check off an objective only after

completing it with the participant. Sessions are also automatically timed using the computerized manual.

Telephone counseling fidelity assessment—In order to examine treatment fidelity and counselor competence, we will randomly select ten percent of all counseling sessions to be audio recorded. The recordings will be reviewed by a Ph.D. clinical psychologist using the Yale Adherence and Competence Scale system (YACS) [47].

NRT telemedicine clinic—In both experimental and control conditions, veterans are offered an 8-week course of NRT, including nicotine patches and up to two additional rescue methods (to be taken for breakthrough cravings; i.e., nicotine gum, lozenge, inhaler), with medications managed by the study physician. Participants are screened for suitability for NRT or other smoking cessation medication. For those veterans whose medical records indicate contraindications to NRT (i.e. high blood pressure not controlled by medication), the study physician obtains additional VA physician authorization in the medical record prior to prescribing NRT. Veterans receive tailored amount and delivery-type of NRT based on number of cigarettes smoked per day [48]. All NRT is mailed directly to veterans from the VHA pharmacy, so travel is not required. Instructions regarding NRT are mailed to participants and verbally reviewed over the telephone with their study counselor.

Measures

All surveys are conducted using computer-assisted telephone interviewing (CATI), which allows for standardized question sequencing, branching, and simultaneous data entry. Participants complete baseline measures prior to randomization and complete follow-up measures at 3-, 6-, and 12-months after the first smoking cessation counseling session (Table 2). For follow-ups, measures were collected within 35 days of the exact follow-up date. Starting at the exact follow-up date, participants were contacted by telephone up to 7 times in order to minimize missing data, utilizing all telephone numbers provided at baseline assessment (i.e., home, work, mobile) and varying day of week and time of day for call attempts. Additionally, if participants had not responded by telephone, their medical record was checked for a change in telephone number. If this still did not yield a response, then they were mailed a return envelope and paper survey with smoking outcome questions.

Background measures and covariates—General demographic measures include age, ethnicity, gender, marital status, employment, travel time/distance to the VA, cell phone and smartphone use, and home-based internet access. Mental health symptoms are measured with the following: the PC-PTSD [37], the PTSD Checklist (PCL; only for patients who score ≥ 3 on the PC-PTSD) [49], the CES-D [35], the Patient Health Questionnaire (PHQ-9; only for patients who score > 14 on the CES-D) [50], and the AUDIT-C [36]. Social support is measured with a single item from the NIH PROMISE Study, “Do you have someone you feel close to, someone you can trust and confide in?” [51]. Participants are also asked to complete the EuroQol 5D, a measure of five domains of quality of life (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) that quantifies utilities for use in cost-effectiveness analysis [52]. Health-related measures include the Insomnia Severity Index (ISI) [53] and the PEG (a measure of pain intensity and interference) [54].

Tobacco use measures—There are several measures of smoking behavior, nicotine dependence, smoker self-concept, perceived health risks of smoking, and self-efficacy in/ motivation for quitting. Smoking behavior measures include smoking history, current use patterns, and history of quit attempts. Nicotine dependence is assessed with the 6-item Fagerström Test for Nicotine Dependence (FTND) [55]. The Smoker Self-concept scale and the Abstainer Self-concept scale [56] are also administered. Perceived health risk of smoking is assessed with a seven-item scale with response choices ranging from 1=strongly disagree to 4 strongly agree [57]. Veterans also rate their desire to quit smoking in the next 6 months on a 7-point Likert scale [58], and using a four-question scale of desire/ determination to quit smoking [59]. Self-efficacy for quitting smoking is assessed in two ways. First, a single item asks “How confident are you that you will be able to quit smoking?” (1= Not at all confident to 4= Very confident) [60]. The use of a global measure of self-efficacy is supported by previous studies in which multiple-item self-efficacy questionnaires formed a unifactorial construct [61]. Additionally, self-efficacy assessment includes 9 items measuring the participant’s confidence (1= Not at all confident to 5= Extremely confident) in their ability to refrain from smoking in various situations, such as when encountering social pressure, having a craving, and experiencing negative emotion [62]. Veterans will also be asked four questions about their desire and determination to change smoking behavior ($\alpha = .81$; Crittenden, Manfredi, Lacey, Warnecke, & Parsons, 1994).

Treatment process measures—At 3-, 6-, and 12-month follow-up, participants will be asked the following several questions regarding their treatment. Participants indicate which smoking cessation aids they used (e.g., bupropion or type of NRT), and their medical charts are reviewed to examine their use of smoking cessation aides. Participants are also asked whether or not they shared information from their participant workbook with anyone in their household [63]. At the 3-month follow-up only, participants complete the Helping Alliance Questionnaire (HAQ), a measure of psychotherapy treatment alliance [64], as well as a measure of smoking cessation medication adherence [65].

Study outcomes – cessation, biochemical verification, and quit attempts—Repeated participant measurements of smoking abstinence are taken at 3-month follow-up, 6-month follow-up, and 12-month follow-up. Abstinence measures include prolonged abstinence, as well as 7-day and 30-day point prevalent abstinence. Participants indicate whether they smoked any cigarettes/cigars/pipes (“even a puff”) in the past 7 days and in the past 30 days. If they report abstinence for 30 days, then they are also asked how long it has been since they smoked. Prolonged abstinence is defined by the *absence* of both of the following: a) 7 consecutive days of tobacco use and b) tobacco use at least once a week for 2 consecutive weeks [42]. To improve the validity of self-report smoking cessation at each follow-up, self-reported prolonged abstinence will be verified by cotinine assay. Participants are asked to provide a saliva sample if they report abstinence from smoking and no other exposure to nicotine (i.e., no current use of NRT or smokeless tobacco). For participants who report abstinence at follow-up and verbally assent to provide biochemical verification, saliva samples are collected by mail within a 2-week window following the telephone interview [66]. Participants are sent instructions, saliva vials, a brief tobacco use assessment

(that includes use of nicotine replacement therapies in the prior week), and a postage-paid padded envelope for returning the sample. Saliva samples are analyzed for the presence of cotinine using a standard cutoff point 15 ng/ml to determine abstinence. A blind sample of 5% will be run again to assure test accuracy of saliva samples. At each follow-up point, participants also indicate approximate dates of all subsequent quit attempts using the timeline follow-back method [67]. The primary endpoint is self-reported, bioverified prolonged abstinence at 6-months post-randomization. This endpoint was chosen because it is generally recognized as the standard follow-up duration for reporting data from clinical trials [68, 69]. Secondary endpoints include 3- and 12-month prolonged abstinence.

Cost-effectiveness—Costs of three types are collected to inform the cost-effectiveness analysis: intervention delivery costs, participant time costs, and VA healthcare costs. Intervention delivery costs for both conditions are estimated using convenience sampling of support staff and our interventionists. The time it takes to prepare for and execute the telephone counseling will be assessed through a data tracking system, surveys, budget/expense reports, and counselor records, to validate these estimates. Similar methods will be used to estimate time spent in identifying smokers, contacting veterans, training veterans on the use of the *mCM* app, and administering NRT to participants. To reduce burden, we will collect a convenience sample of observations to account for the fact that there may be a learning curve effect. In addition to labor costs, materials costs, including the cost of *mCM* app development/maintenance, smartphones, data plans, and server space will be included. Average time costs for each intervention delivery activity in each arm will then be constructed and applied across all patients.

Participant time costs (i.e., the opportunity costs to participants) will include the time spent by smokers in using the intervention strategies (e.g., video-recording CO monitoring), techniques, or information. Time estimates will be combined with standard wage estimates adjusted for age, gender, and race, derived from the Statistical Abstract of the United States. As part of the 3-month follow-up, all participants will report time spent on the intervention materials outside of telephone sessions. For the ART intervention arm, the number of videos submitted will be used to assess the time involved in providing bioverification of abstinence.

VA healthcare costs for inpatient and outpatient services will be obtained from VA claims data because a VA payer perspective will be taken. The primary effectiveness outcome measure is QALYs, as measured by the EuroQol 5D-5L [70].

Data Analytic Plan

Power analysis—Sample size estimation is based on the primary hypothesis that ART will have greater effectiveness than the control condition as measured by self-reported, bioverified prolonged abstinence at 6 months post-randomization. Abstinence will be measured as a dichotomous variable indicating whether participants have been abstinent or not. We estimated that the quit rate (impact) in the control condition would be 10%. This estimate was based upon meta-analytic data examining similar proactive telephone counseling in non-veteran and non-rural populations [10], as well as evidence of lower quit rates in rural populations [19]. Given effect sizes from pilot studies of combined CM and

telephone counseling [30, 41], we estimated the intervention group quit rate to be higher than 23%. Using methods for a difference in proportions, 252 veterans (126 in each arm) would be needed to detect a differential quit rate of 13% with 80% power and a 5% two-sided type-I error rate. However, with a possible attrition rate of 15% as well as deviations from our assumptions, we planned for a sample of 310 to ensure sufficient power to detect the group differences between ART and the control condition.

Primary outcome analysis—Our primary hypothesis (group difference in abstinence rates at 6 months) will be analyzed using a repeated measures logistic regression model, in which the model parameters are estimated using generalized estimating equations methodology (GEE). GEE methodology allows the relationship between the response and explanatory variables to be modeled separately from the correlations resulting from clustering of repeated measurements within each subject [71]. The regression coefficients from a GEE model have essentially the same interpretation as those from a cross-sectional regression analysis (e.g. logistic regression) but are more appropriate as they properly incorporate the longitudinal structure of the data. The predictors in the model will include intervention arm (a 2-level variable), geographic distance (3-level stratification variable), and a time effect (categorical 3-level variable; 3 months, 6 months, and 12 months). We will explore whether an exchangeable, unstructured, or AR(1) correlation structure is most appropriate to take into account the within-patient correlation between the repeated measures over time. Linear contrasts within this model will be used to examine (1) early abstinence (3-months), (2) the difference between groups at the primary point of interest, 6 months follow-up, and (3) sustainability of the intervention compared between groups at the 12-month follow-up.

Cost-effectiveness analysis—Economic analysis will follow the guidelines developed by the Panel on Cost-Effectiveness in Health and Medicine [72]. We will employ the societal perspective (i.e., all costs incurred by and benefits accruing to the society in general, the VA health care system, and the individual participants, including medical, non-medical, productivity), with secondary analyses from the VA health care system perspective (i.e., excludes direct non-medical costs borne by Veterans). Data on the effects and costs of the interventions will be used to estimate the incremental cost-effectiveness, or ICER (US\$ per QALY) comparing ART to the control condition. The incremental cost-effectiveness ratio R is expressed as: $R = (\mu_{CT} - \mu_{CU}) / (\mu_{ET} - \mu_{EU})$, where μ denotes the estimated mean for CT (cost of ART, CU (cost of telehealth only), ET (effect of ART), and EU (effect of telehealth alone). The time horizon of the economic analysis will be 12 months.

To incorporate the uncertainty in the data into the cost-effectiveness analysis, we will develop a decision analytic model and conduct probabilistic sensitivity analysis (2nd order Monte Carlo simulation). Parameter estimate ranges with appropriate distributions will be used for intervention and participant times, wage rates, NRT costs, and QALY effectiveness measures in conducting the decision model simulation. We will present our results as means (with CIs), incremental cost-effectiveness analysis scatterplots, cost-effectiveness acceptability curves, and one-way sensitivity analysis of key variables [73, 74].

Mediation analyses—If there is a significant intervention effect at 6-month follow-up, then we also plan to examine whether change in self-efficacy mediates the impact of the intervention. We propose to conduct this mediation analysis using the MacArthur approach, a modification of the traditional Baron & Kenny criteria, developed for use specifically in randomized clinical trials [75]. By the MacArthur definition, the potential mediator must be evident during or post-treatment; therefore, the change in patient self-efficacy measures between baseline and 3-months will be considered as the potential mediator. The outcome will be patients' abstinence at 6-months. We will first fit a model to examine the relationship between change in self-efficacy and intervention arm. We also will fit a model that examines the relationship between changes in self-efficacy and 6-month abstinence rates. Improvements in patient self-efficacy will be considered to account for improvements in abstinence rates if there is evidence of both relationships (i.e., regression coefficients statistically significant from 0).

Missing data—Because the main predictors of interest are collected at baseline, we do not anticipate much missing data in these variables. We do, however, anticipate missing values in the longitudinal outcomes owing to dropout, death, an inability to reach the patient by phone, lack of response to the mailed survey, or item non-response. Given pilot data, we anticipate that the rate of loss to follow-up may be as high as 35% [41]. If the missing values are related to other measured patient factors, such as age, gender, or employment status, then multiple imputation (MI) provides a framework for incorporating information from these auxiliary variables while still preserving a parsimonious main treatment effect model [76]: this framework is described as a significant advantage in recommendations from the Panel on Handling Missing Data in Clinical Trials [77]. We will follow multiple imputation methods presented in Hedeker et al for missing abstinence outcomes [78]. Depending on the type and scope of missing data for other longitudinal variables, MI will be conducted via the SAS procedure PROC MI or the SAS macro IVEware (<http://www.isr.umich.edu/src/smp/ive/>).

Results

Recruitment

Study recruitment is complete, with 2,064 letters mailed to potential participants. Of these, 38 opted out upon receiving the initial recruitment letter and 162 were ineligible prior to phone screening (e.g., no longer live in North Carolina, not receiving care at DVAMC), 292 passive refusals, and 147 were not reached prior to study recruitment goals being reached. Telephone calls have been placed to 1,425 veterans, of whom 733 declined to complete the telephone screening. Among screens, 359 were deemed ineligible for participation at phone screening due to the following reasons: not currently smoking tobacco ($n = 46$), not smoking more than 7 cigarettes in the past 7 days ($n = 148$), and not willing to make a quit attempt ($n = 165$). Among those who screened into the study, 333 consented to study participation. Of those who consented, 310 have completed baseline measures and been randomized. Study follow-up is ongoing.

Participant Characteristics

Preliminary sample characteristics are shown in Table 3. Participants were on average 56.8 years of age ($SD = 10.8$), and most (92.9%) had at least high school/GED education. The majority of participants (64.8%) lived more than 20 miles from the nearest VHA facility. Women veterans comprised 11% of participants, and the sample was diverse with regards to race (56% Black/African American, 38% White, 5% Multiracial, and 1% American Indian/Alaska Native). Few participants in the sample were currently working; roughly one quarter of participants reported currently working, half indicated that they were disabled, and a quarter reported being retired.

With regards to nicotine dependence and smoking behavior, participants scored on average 4.8 ($SD = 1.9$) on the FTND, over half of participants smoked more than 10 cigarettes per day, and 15% of participants are heavy smokers (> 20 cigarettes per day). With regards to telecommunications, most participants (92%) had a cell phone, and nearly half indicated that they had a smartphone.

Discussion

This clinical trial will examine the efficacy and cost-effectiveness of ART, a multi-modal mHealth intervention that combines telephone counseling, smoking cessation telemedicine, and *mCM*, a contingency management smartphone app. Given rural veterans' high rates of smoking and their underutilization of smoking cessation resources [5, 8], this mHealth intervention has a high potential public health impact. Moreover, this intervention is being tested in the U.S. region with the highest documented rural/urban disparity in cigarette smoking [6]. Results from this trial could potentially inform smoking cessation dissemination efforts within the VHA, especially given the relatively low cost of abstinence incentives within *mCM* (anticipated at \$300 per participant), the decreasing cost of smartphone technology, and the increasing availability of smartphones [79, 80]. While this intervention was designed to address tobacco use in difficult-to-treat VHA populations (e.g., rural smokers, homeless smokers), it likely could be adapted for use within other healthcare systems, such as employee health programs, publicly funded healthcare programs, large health maintenance organizations, or as an add-on to preferred provider organizations.

If ART improves smoking outcomes and is cost-effective, it could potentially be disseminated more widely to reduce costs incurred by smoking-related morbidity and mortality. Although it was designed to treat rural veteran smokers, this mHealth intervention could likely generalize to other difficult-to-treat smoking populations, such as veteran smokers with psychiatric disorders (e.g., depression, PTSD, or psychotic disorders), comorbid substance use, and those who are homeless. We also expect that this treatment would be highly efficacious for veteran smokers with health comorbidities (e.g., pulmonary, cardiovascular, and infectious diseases). To that end, the components of ART (telemedicine, telehealth counseling, and mobile application) are consistent with VHA's mission to implement treatment models that respond directly to the needs of rural veterans by increasing access to efficacious behavioral interventions [81]. Additionally, this study will provide important data on the relative efficacy and cost-effectiveness of adding an intensive mHealth intervention, *mCM*, to other evidenced-based telehealth interventions for smoking

cessation. Overall, this clinical trial is a step towards integrating more mHealth interventions into patient-centered care for veterans, which may ultimately improve both access to care and patient health outcomes.

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Table 1

Compensation for Participants in the ART Condition.

	Days After Quitting	Escalating <i>mCM</i> Incentives for Abstinence		Bonuses for Continuous Abstinence	Non-contingent Monitoring Compensation *	Total Possible
		1 st CO	2 nd CO			
Week 1	Pre-Quit				\$14.00	\$14.00
QUIT DAY						
Week 2	1	\$1.00	\$1.10			\$16.10
	2	\$1.20	\$1.30			\$18.60
	3	\$1.40	\$1.50			\$21.50
	4	\$1.60	\$1.70			\$24.80
	5	\$1.80	\$1.90	\$5.00		\$33.50
	6	\$2.00	\$2.10			\$37.60
	7	\$2.20	\$2.30			\$42.10
Week 3	8	\$2.40	\$2.50			\$47.00
	9	\$2.60	\$2.70			\$52.30
	10	\$2.80	\$2.90	\$5.00		\$63.00
	11	\$3.00	\$3.10			\$69.10
	12	\$3.20	\$3.30			\$75.60
	13	\$3.40	\$3.50			\$82.50
	14	\$3.60	\$3.70			\$89.80
Week 4	15	\$3.80	\$3.90	\$5.00		\$102.50
	16	\$4.00	\$4.10			\$110.60
	17	\$4.20	\$4.30			\$119.10
	18	\$4.40	\$4.50			\$128.00
	19	\$4.60	\$4.70			\$137.30
	20	\$4.80	\$4.90	\$5.00		\$152.00
	21	\$5.00	\$5.10			\$162.10
Week 5	22	\$5.20	\$5.30			\$172.60
	23	\$5.40	\$5.50			\$183.50

Days After Quitting	Escalating <i>mCM</i> Incentives for Abstinence		Bonuses for Continuous Abstinence	Non-contingent Monitoring Compensation *	Total Possible
	1 st CO	2 nd CO			
24	\$5.60	\$5.70			\$194.80
25	\$5.80	\$5.90	\$5.00		\$211.50
26	\$6.00	\$6.10			\$223.60
27	\$6.20	\$6.30			\$236.10
28	\$6.40	\$6.50			\$249.00
<i>Week 6</i>	35	–		\$25.00	\$274.00
<i>Week 7</i>	42	–		\$26.00	\$300.00
<i>Equipment Return</i>				\$30	\$330.00

mCM = mobile contingency management.

* Compensation for uploading CO readings and returning equipment outside of *mCM* period, regardless of CO level.

Table 2**Study Measures Completed at Baseline and Follow-Ups**

	Month			
	Baseline	3	6	12
Background Measures				
Demographics	✓			
Mobile technology use	✓			
PC-PTSD	✓		✓	✓
PCL (if PC-PTSD = 3)	✓		✓	✓
CES-D	✓	✓	✓	✓
PHQ-9 (if CES-D > 14)	✓	✓	✓	✓
AUDIT-C	✓	✓	✓	✓
Social support	✓	✓	✓	✓
EuroQol 5D	✓	✓	✓	✓
Insomnia Severity Index	✓		✓	✓
PEG	✓	✓	✓	✓
Tobacco Use Measures				
Smoking history/current use	✓			
FTND	✓			
Smoker-Abstainer Self-Concept	✓			
Perceived risk	✓			
Perceived barriers	✓			
Motivational readiness	✓	✓	✓	✓
Global self-efficacy	✓	✓	✓	✓
Self-efficacy to personal barriers	✓	✓	✓	✓
Smoking status	✓	✓	✓	✓
Treatment Process Measures				
HAQ		✓		
Intervention		✓	✓	✓
Adherence to NRT/other pharmacotherapy		✓	✓	✓
Smoking cessation aids	✓	✓	✓	✓
Outcome Measures				
Prolonged abstinence		✓	✓	✓
7-day abstinence		✓	✓	✓
30-day abstinence		✓	✓	✓
Quit attempts (timeline follow-back)		✓	✓	✓
Costs (VHA databases & surveys)	✓	✓	✓	✓

PC-PTSD = Primary Care PTSD Screen; PCL = PTSD Checklist; CES-D = Center for Epidemiologic Studies Depression Screen; PHQ-9 = Patient Health Questionnaire; AUDIT-C = Alcohol Use Disorders Identification Test; FTND = Fagerström Test for Nicotine Dependence; HAQ = Helping Alliance Questionnaire; NRT = nicotine replacement therapy; VHA = Veterans Health Administration

Table 3Preliminary Sample Characteristics, $N = 310$.

Variable	<i>N/M</i>	<i>%/SD</i>
Female	34	11.0%
Race		
American Indian/Alaska Native	4	1.3%
Black/African American	175	56.5%
White	117	37.7%
Multiracial	14	4.5%
Hispanic/Latino Ethnicity	4	1.3%
Distance to Nearest VA Facility		
0–20 miles	109	35.2%
21–40 miles	115	37.1%
41–60 miles	56	18.1%
61 miles or more	30	9.7%
Education		
Less than high school	22	7.1%
High school/GED	84	27.1%
Some college or trade school	121	39.0%
Associate's degree or higher	83	26.8%
Employment Status [*]		
Disabled	156	51.8%
Retired	77	25.6%
Working Full-Time	51	16.5%
Working Part-Time	20	6.5%
Student	16	5.0%
Cigarettes per day		
10	138	44.5%
11–20	126	40.7%
> 20	46	15.3%
Personal cell phone	285	91.9%
Personal smartphone	138	44.5%

^{*} Percent total adds up to > 100 because participants were allowed to indicate more than one response.