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

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1. 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

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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) × 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.

2. Method

2.1. 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.

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