Study Protocol, Including Statistical Analysis Plan

Study Title: Mobile Evidence-Based Smoking Cessation for Veterans Living With HIV (MESH)

NCT Number: NCT04135937

Document Date: 12/18/2020

Research Protocol: Smoking Cessation Treatment Preferences among Veteran Smokers Living with HIV
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PURPOSE

The overall goal of this study is to understand and improve tobacco abstinence rates among Veteran smokers living with HIV. The specific aims of the study are to:

AIM 1a: To qualitatively explore smoking cessation treatment preferences among Veteran smokers living with HIV, and to quantitatively evaluate perspectives on relapse-prevention messages among Veterans and smokers living with HIV.

AIM 1b: To quantitatively evaluate satisfaction with relapse-prevention messages among a de-identified online sample of Veterans and smokers living with HIV, and general-population smokers.

AIM 1c: To qualitatively explore smoking cessation treatment perspectives among ID health care staff who serve Veterans living with HIV.

AIM 2: To quantitatively examine trends and determine health disparities by HIV status and demographic characteristics in use of smoking cessation aids among patients receiving VHA clinical care.

AIM 3: To use a successive cohort design to develop a mobile health (mHealth) smoking cessation intervention tailored for Veterans living with HIV.

BACKGROUND AND SIGNIFICANCE

Among the over 1 million people living with HIV in the U.S., the smoking rate is two to three times higher than in the general U.S. population (Kariuki et al., 2016; Moscou-Jackson, Commodore-Mensah, Farley, & DiGiacomo, 2014). Population-based estimates indicate that roughly 2 of every 5 U.S. adults with HIV endorse current cigarette smoking, which far exceeds the 20% smoking prevalence rate in the general population (Mdodo et al., 2015). Furthermore, despite generally declining smoking rates in the U.S., rates of smoking among people living with HIV have remained virtually unchanged over the past 20 years (Cooperman, 2016). This is likely due to the fact that compared to the general adult population, individuals with HIV are less likely to quit (Mdodo et al., 2015).

Rates of current smoking are elevated in Veteran populations (Hoerster et al., 2012) as well as in HIV-positive populations (Mdodo et al., 2015). Estimates from a large cohort of VHA patients indicate that 63% of HIV-positive Veterans currently smoke cigarettes and 85% are lifetime smokers (Crothers et al., 2005). Data from national VA patient records indicates that 47% of HIV-positive VA users have a lifetime tobacco use diagnosis (Department of Veterans Affairs, 2012). Moreover, since tobacco dependence ICD codes in the VA EMR tend to underestimate use (McGinnis et al., 2011)), these data may actually underestimate smoking prevalence among HIV-positive VA patients.

Regardless of HIV serostatus, cigarette smoking generally increases risk of mortality and morbidity (Centers for Disease Control and Prevention, 2008). However, for those living with HIV, smoking is particularly deleterious to health (Lifson & Lando, 2012). Smoking disproportionately increases risk for myocardial infarction among those with HIV compared to their HIV-negative counterparts (Rasmussen et al., 2015). Smoking is also associated with the occurrence of HIV-related infections, such as oral and

esophageal candidiasis, bacterial and pneumocystis pneumonia, and tuberculosis (Lifson & Lando, 2012). For those living with HIV, cigarette smoking increases risk for cardiovascular disease, chronic obstructive pulmonary disease (COPD), and cancer (Lifson & Lando, 2012). In a longitudinal sample of Veterans living with HIV, current smoking was linked to all-cause mortality after controlling for the effects of HIV viral load, CD4 count, hazardous alcohol use, and use of antiretroviral treatment (ART; Crothers et al., 2005).

Few smoking cessation interventions have been rigorously tested in people living with HIV, and to date there have been no randomized controlled (RCT) trials of mHealth smoking cessation interventions for Veterans living with HIV. According to two recent systematic reviews, there are only five known large randomized smoking cessation trials among smokers with HIV (Moscou-Jackson et al., 2014; Cooperman, 2016). Of these trials, three yielded treatment effects on smoking abstinence with short-term abstinence odds ratios ranging from 2.0 to 5.6 (Vidrine, Arduino, Lazev, & Gritz, 2006; Vidrine, Marks, Arduino & Grits, 2012; Moadel et al., 2012), however, long-term abstinence rates were low. One of the most promising smoking cessation interventions for people living with HIV to date consisted of telehealth CBT (Vidrine, Marks et al., 2012), but did not show long-term efficacy. Despite a nearly 80% session completion rate (Vidrine, Marks et al., 2012), at 6-month follow-up, the smoking abstinence rate was only 5% (Gritz et al., 2013). (Gritz et al., 2013) [1] This high treatment uptake and low quit rate indicate that this population would likely benefit from an approach that is more accessible and more intensive. Thus, there is a need for novel, intensive mHealth approaches to smoking cessation in this population.

HIV patients face numerous barriers to both treatment access and smoking abstinence. Although most smokers with HIV receive advice to quit smoking, only a portion receive smoking cessation pharmacotherapy and even fewer are referred to intensive smoking cessation treatment (Tesoriero, Gieryic, Carrascal, & Lavingne, 2010). In vulnerable groups, common barriers to abstinence include lack of support for quitting from health care providers, high prevalence of smoking in the community, difficulties with stress management, and chronic pain (Twyman, Bonevski, Paul, & Bryant, 2014). For smokers with HIV specifically, barriers to abstinence include poor access to smoking cessation treatment, social networks that support smoking, alcohol and drug use, poor health, and mental health comorbidity (Karuiuki et al., 2016). Additionally, Veterans living with HIV have reported in qualitative interviews that referral to substance use treatment outside of the ID or primary care setting is burdensome (Minick et al., 2016). These patients further note that receiving HIV-specific care for addictions would help overcome this barrier (Minick et al., 2016). Additionally, mobile-delivered interventions can increase reach of smoking cessation services by circumventing time and travel barriers.

Beyond difficulties accessing cessation services, a large proportion of patients who are prescribed NRT or initiate behavioral treatment do not achieve initial abstinence (Piper, Vasilenk, Cook, & Lanza, 2016). Given the reality of treatment non-response, it could be immensely effective to offer smoking cessation treatment plans that can be personalized to patients as they progress through treatment. Use of mobile technology to personalize treatment has the potential to increase patient engagement and proactively address treatment non-response.

Furthermore, individually tailored and HIV-targeted approaches to follow-up messaging have been recommended in the literature (Moscou-Jackson et al., 2014; Pacek & Cioe, 2015), but are yet to be tested as part of a multi-component approach for smokers with HIV. There is strong meta-analytic evidence across studies that text-messaging programs for smoking cessation are generally efficacious

when compared to standard care or treatment-unrelated messaging programs (Scott-Sheldon et al., 2016). However, there is a lack of evidence of the feasibility of relapse prevention text messaging for smokers with HIV. This approach has only been tested once in HIV-positive smokers and yielded only short-term treatment effects (Shelley et al., 2015). Moreover, across studies for stand-alone text messaging interventions the effect size is small (Scott-Sheldon et al., 2016), which suggests that this approach may be most useful as part of a multi-component treatment. Given this project's emphasis on a personalized approach to smoking cessation, we expect that the addition of post-quit messaging support will maintain quit rates that are initialized by CBT and will additionally aid in prevention of relapse.

As a step toward refinement of the envisioned intervention, this study will elicit qualitative feedback to tailor the intervention to the population of Veteran smokers living with HIV and additionally generate new, specialized content for the relapse-prevention message library. Subsequently, this qualitative methodology will be supplemented with quantitative survey data gauging user satisfaction with the message library. Although SmokefreeVET has been evaluated in a one-group longitudinal design (Christofferson, Hertzberg, Beckham, Dennis, & Hamlett-Berry, 2016), no published research to date has utilized sequential qualitative and quantitative methods to evaluate perspectives on the program's message content. In quality improvement work with women veterans, some patients noted that they perceived medication adherence messages as mildly demanding. Patients also voiced a specific desire for messages with a friendly, informal tone without "text-speak" (e.g., "Did you smoke today?" instead of "r u smoking 2day"). It is currently unknown whether veterans living with HIV may express similar feedback, or have other perspectives on relapse-prevention messages.

The specific aims of this project are to: 1) qualitatively explore smoking cessation treatment preferences among Veteran smokers living with HIV, and to quantitatively evaluate perspectives on relapse-prevention messages among Veterans and smokers living with HIV, and general population smokers, and to qualitatively explore smoking cessation treatment perspectives among ID health care staff who serve Veterans living with HIV; 2) quantitatively examine trends and determine health disparities by HIV status and demographic characteristics in use of smoking cessation aids among patients receiving VHA clinical care; and 3) to use a successive cohort design to develop an mHealth smoking cessation intervention tailored for Veterans living with HIV.

AIM 1 METHODS

A qualitative patient sample (*N* = 20 or until saturation is reached) will include VHA patients with HIV who currently smoke or recently quit smoking. These patients will complete in-person qualitative interviews. A separate qualitative sample of ID health care staff who serve Veterans living with HIV will be collected (*N* = 15).

In qualitative coding and analysis, two complementary methodologies will be used: conventional content analysis (Hsieh & Shannon, 2005) and inductive thematic analysis (Braun & Clarke, 2006). Using these two sequential, complementary approaches will maximize the validity of findings and minimize researcher bias (Miles, Huberman, & Saldaña, 2014).

QUALITATIVE SAMPLE RECRUITMENT. Purposive sampling will be used to identify participants for the qualitative patient sample (*N* = 20). We anticipate that we will have to screen 30 participants to reach 20 completers. The sample will include 20 HIV-positive VHA patients who either currently smoke ≥ seven cigarettes per week or are lifetime smokers (smoked ≥ 100 lifetime cigarettes) who quit within the past 2 years. Veteran patients with an HIV diagnosis and documented tobacco use within the past 2 years will

be identified from patient records of the Durham VAHCS via a data pull from VA's Regional Data Warehouse. We will sample VHA patients with diverse backgrounds with respect to gender identity, sexual orientation, race/ethnicity, age, and medical/psychiatric comorbidities. Potential participants will be sent an introductory letter signed by the PI that describes the study and invites participation. Veterans who do not decline will be called to determine interest in the study and basic study eligibility. We will also recruit by presenting information about the study to clinicians throughout the medical center, who can then provide a referral to Dr. Wilson by adding her as a co-signer to CPRS notes. The third recruitment method will involve pre-screening potential participants who have clinic appointments in the Infectious Diseases clinic (8A). Study staff will monitor whether pre-screened patients have arrived in the clinic via VetLink. Study staff will indicate potential participants to 8A clinic staff, and clinic staff will inquire whether patients interested in hearing about an observational, single-visit research study about smoking. If a patient affirmatively indicates to their provider that they would like to hear about the study, they will be approached by a study staff member for screening and informed consent. The sample size has a high likelihood of reaching data saturation, which we define as the point in data collection when additional interviews do not result in new themes (Guest, Bunce, & Johnson, 2006). Guest et al. have experimentally demonstrated that after 12 interviews, there are diminishing returns on new themes; furthermore, at 18 interviews, 96% of themes are coded (Guest, Bunce, & Johnson, 2006).

A convenience sample of 15 local ID health care staff will be recruited from the Durham VA Health Care System. A wide variety of staff will be contacted in order to gather diverse opinions and perspectives regarding smoking cessation care, including physicians, nurse practitioners, physician assistants, social workers, psychologists, nurses, and pharmacists. A number of recruitment methods will be used: 1) recruitment email sent to clinic staff, 2) recruitment brochures and flyers displayed in the staff room in the 8A clinic, 3) announcements made during the ID clinic staff meeting, and 4) clinic staff will be approached during the 8A ID clinic (after receiving an email) to ascertain whether they would be willing to participate.

QUALITATIVE PROCEDURES. All interviews will be completed by either Dr. Wilson or trained study staff. For patients following informed consent, the interviewer will complete a 60-minute semi-structured interview with the participant. The format of the interview is funnel-shaped (Brinkman & Kvale, 2015), such that interview questions are initially broad and gradually narrow. An example of initial broad questions includes "For you personally, what would [be/have been] the best treatment to get to help you quit smoking?" Later interview questions will elicit feedback on specific examples of treatment options and relapse-prevention messages. For example, participants will be asked, "I'd like for you to tell me about the pros and cons of some different types of messages (I'll give examples of each type)." The qualitative interviewers will take notes during each interview, and all interviews will be audio recorded and transcribed by members of the study team at Durham. Veteran participants will be compensated $30 for completing the interview. Based on the first interview transcript, a codebook will be developed under the following categories: areas for expansion/tailoring for Veteran smokers with HIV; new themes for relapse-prevention messages; and reactions to messages. Following creation of the codebook, the coding scheme will be updated as necessary following each of the first three participant interviews. Once the final codebook is established, interview transcripts will be dually coded by the PI and another study staff member, with coding discrepancies resolved by consensus.

The medical records of participants will be reviewed to determine HIV disease status, use of smoking cessation medications and/or specialty clinic visits, comorbid diagnoses, and healthcare utilization patterns.

For clinic staff, documentation of informed consent will be waived. No HIPAA authorization will be collected, as no protected health information is being collected by clinicians. At the beginning of each interview, the interviewer will capture consent on the audio recording device. Interviews will last approximately 30 minutes, and will consist of questions derived from the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009). Questions will center on the following CFIR constructs: intervention characteristics, outer setting, and inner setting. Based on the first interview transcript, a codebook will be developed under the following categories: evidence strength and quality, relative advantage, adaptability, complexity, patient needs and resources, structural characteristics, tension for change, and compatibility. Once the final codebook is established, interview transcripts will be dually coded by the PI and another study staff member, with coding discrepancies resolved by consensus.

QUANTITATIVE PROCEDURES. The study team will receive a dataset from Duke University Health System, where Dr. Wilson will collect data from Amazon Mechanical Turk (MTURK; https://www.mturk.com). Data from MTurk will be collected by the Duke team via an anonymous survey hosted by Duke Qualtrics. Data will be moved to VA from Duke in accordance via a VA-owned thumbdrive. All data will be de-identified, such that the study team will neither collect nor retain any PII or PHI. Data will include: HIV, smoking, and veteran status; demographic information (age; race; ethnicity; relationship status; sexual orientation; gender identity; U.S. state/territory; education; income; VHA patient status); and for HIV-positive participants only, age at HIV diagnosis, last CD4 count, and last viral load). Data will also include participants' ratings of satisfaction with 148 relapse prevention text messages used in the SmokefreeVET library, as well as additional messages developed by the Duke research team.

AIM 2 METHODS

To identify potential treatment moderators and further understand current health services for smoking cessation among Veterans living with HIV, it is essential to determine existing health disparities in cessation treatment among VHA patients with and without HIV.

For this study aim, the data source will be a data request from Corporate Data Warehouse (CDW). Health data, which may include PHI (e.g., dates of care), will be gathered from 2014 to present. After requesting data access via the Data Access Request Tracker (DART) , Veterans with and without HIV (per ICD-9 and ICD-10 diagnosis codes) will be identified from VA's Regional and/or Corporate Data Warehouse. During the retrospective observation period, tobacco use will be determined annually (January 1 through December 31 for each year) for each patient based on a validated algorithm for identifying smoking status from the EMR (Calhoun et al., 2017; McGinnis et al., 2011). Data will be extracted on tobacco use health factors, pharmacy records of medications dispensed, primary care/ID clinic outpatient healthcare encounters, pain intensity vital sign data, patient demographics, and diagnosis codes for comorbid disorders of interest (Hepatitis C coinfection and psychiatric disorders). For each year in which patients are determined to be smoking, three outcomes will be assessed: pharmacy dispensation of NRT, bupropion, or any smoking cessation pharmacotherapy (NRT, bupropion, or varenicline). Specifically, pharmacotherapy dispensation will be coded dichotomously (yes/no) based on presence/absence of a pharmacy record within each 12-month observation period.

We will examine a range of variables to detect disparities in pharmacotherapy utilization. Demographic information will include age, race, and ethnicity. HIV, Hepatitis C, and psychiatric disorder will be based upon the ICD-9 and ICD-10 codes. Given previous work in the area of treatment access disparities, we will include the following psychiatric disorders as variables: psychotic disorder, bipolar disorder, PTSD,

other anxiety/mood disorder, and any substance use disorder (all time-invariant, coded in year 1). Pain is coded 0-10 at each VHA healthcare visit as the fifth vital sign, and will be averaged over each 12-month monitoring period and dichotomized as severe (≥ 7) vs. mild/moderate (0-6) (Volkman et al., 2015). Number of clinic visits attended each year will be collected to control for the likelihood that more clinic visits convey a higher probability of pharmacotherapy.

AIM 3 METHODS

We will use a successive cohort design to integrate and user-test the proposed intervention. The successive cohort design is an iterative process that is designed to refine behavioral treatments in the initial development stage (Epstein et al., 2007). This design involves multiple steps of development: 1) identifying theoretically-supported treatment models; 2) identifying key intervention elements; 3) developing preliminary intervention materials; and 4) revising the intervention iteratively based upon qualitative and quantitative data collected during successive patient cohorts. See below for proposed preliminary intervention methodology, as well as methodology for iteratively revising the intervention based upon patient qualitative feedback.

SAMPLE RECRUITMENT

A total of 3 cohorts of 5 patients each (*N* = 15) will complete the intervention and provide feedback after the treatment phase is complete. Participants will be recruited from the Durham VAHCS. Inclusion criteria are: VHA patient, HIV positive serostatus, currently smoking ≥ 7 cigarettes per week, and willing to complete study procedures. Exclusion criteria are: current hospitalization, acute risk for suicide documented in the medical record, or inability to complete study procedures.

We will primarily recruit by presenting information about the study to clinicians in the Infectious Disease (ID) Clinic, who can then provide a referral to Dr. Wilson by adding her as a co-signer to CPRS notes. In order to facilitate provider referral, Veteran patients with an HIV diagnosis and documented tobacco use within the past 2 years who have clinic appointments in the Infectious Diseases clinic (8A) will be identified from patient records of the Durham VAHCS via chart review in the Computerized Patient Reporting System (CPRS). Study staff will indicate potential participants to 8A clinic staff, and clinic staff will inquire whether patients interested in hearing about the study. If a patient affirmatively indicates to their provider that they would like to hear about the study, they will be approached by a study staff member for screening and informed consent. If an insufficient number of patients are recruited in this manner, potential participants with an HIV diagnosis and documented tobacco use within the past 2 years will be sent an introductory letter signed by the PI that describes the study and invites participation. Veterans who do not decline will be called to determine interest in the study and basic study eligibility.

PROCEDURES

Immediately following screening and informed consent (Session 0), patients will complete baseline measures and will begin the active treatment, Mobile Evidence-Based Smoking Cessation for Veterans Living with HIV (MESH). Table 2 describes the measures that will be used in Aim 3 as well as their administration schedule. Whenever possible, we have selected Common Data Elements from the PhenX Toolkit (Hamilton et al., 2011; Version 13.3) in order to maximize the impact of the proposed study.

Participants will then be scheduled for counseling session 1 with a stop smoking interventionist within 7 days of study enrollment. Participants enrolled in the first cohort will be invited to utilize SmokefreeVET, a mobile text messaging service for military Veterans trying to quit smoking. SmokefreeVET was developed by a joint effort of the National Cancer Institute and the U.S. Department of Veterans Affairs.

The program was created to provide 24/7 encouragement, advice, and tips to help smokers quit smoking and stay quit. It is a 6 to 8 week program, depending on when you set your quit date. Users will receive 1-5 messages per day and can receive additional quit support at critical points in the quit process by using one of SmokefreeVET's keywords (URGE, STRESS, or SMOKED). Participants can opt out of supportive text messaging at any time by sending the keyword STOP. Consistent with the structure of SmokefreeVET, participants interested in utilizing it will be assisted in signing up for the program within two weeks before their planned quit date. Participants will not be required to use the texting program. Participants of cohort 2 and 3 will be invited to sign up for personalized text messaging support (see details of this treatment component below) using the VA Annie app. Annie is an automated, short message service (SMS) text message system designed to promote Veteran self-care. At the baseline session, Veterans will be asked to complete an agreement to use Annie, and will be walked through the process of registering a personal phone number and setting message preferences. The SMS feature of Annie will function on either a basic cell phone or a smartphone. During this time, Veterans will be informed that Annie is not designed for direct communication with a provider, and should a medical emergency arise to contact their provider or emergency services through traditional means. If, however, Annie is not available, cohorts 2 and/or 3 will be invited to utilize SmokefreeVET.

Treatment sessions with the interventionist and the qualitative interview will be audio recorded. These recordings will be used to develop a fidelity system as a secondary goal of the cohort design.

Following completion of all intervention components (through end of treatment), each participant will complete a structured interview. Post-treatment interviews will include questions regarding strengths and weaknesses of the intervention as well as suggestions for ways to improve the overall treatment approach. See Data Analysis section for details on qualitative coding and analysis.

Participants will also be followed up at 3-months and at 6-months to assess clinical outcomes and treatment acceptability. Study measures are shown in Table 1. Secondary smoking outcomes will include 7- and 30-day point prevalence abstinence at each assessment. Abstinence will be verified by salivary cotinine assay (≤ 10 ng/ml), which improves self-report validity. When in-person visits are allowed post-COVID-19 pandemic, participants will also be asked to provide expired carbon monoxide (CO) breath readings at baseline, post-treatment, and 3- and 6-month follow-up. During the pandemic, participants will be mailed a CO monitor at three time points – post-treatment, and 3- and 6-month follow-ups. They will be paid $50 each time they return the CO monitor. Abstinence will be based on CO readings that are ≤4 ppm. Post-pandemic, for participants who are not able to complete an in-person visit, a breath CO monitor will be mailed to the participant. Participants will be compensated $50 for returning the CO monitor.

Following treatment completion for each cohort of *n* = 5 participants, qualitative data will be analyzed and based upon results, the intervention structure and content will be revised. Intervention content that may be subject to revision includes the computerized algorithms, CBT module content, and content and timing of SMS text messages.

Table 1. *Aim 3 Measures*

Measure	No. Items	Completed by	Month				Sessions
			0	Quit Date	3	6	
BACKGROUND AND PROCESS VARIABLES							
1. Demographics	32	Self-report	X	-	-	-	-

2. Smoking history/current smoking	6	Self-report	X	-	-	-	-
3. HIV Disease Progression – CD4, Viral Load (EMR)	-	Self-report	X	-	-	-	-
4. Fagerstrom Test for Nicotine Dependence	7	Self-report	X	-	-	-	-
5. Minnesota Withdrawal Scale	9	Self-report	X	X	X	X	-
6. The Everyday Discrimination Scale	10	Self-report	X	-	-	-	-
7. Pain, Enjoyment of Life, and General Activity (PEG) Scale	3	Self-report	X	-	X	X	-
8. Smoking and Nicotine Knowledge	14	Self-report	X	-	X	-	-
9. Non-VA Treatment Utilization	9	Self-report	X	-	X	X	-
TREATMENT PERSONALIZATION MEASURES							
10. Smoking Cessation Motivation	1	Self-report	X	X	X	X	-
11. Smoking Cessation Self-Efficacy	1	Self-report	X	X	X	X	-
12. Stages of Change	2	Self-report	X	-	X	X	-
13. PTSD Checklist of *DSM-5* (PCL-5)	20	Self-report	X	-	X	X	-
14. Patient Health Questionnaire (PHQ-9)	9	Self-report	X	-	X	X	-
15. Alcohol Use Disorders Identification Test (AUDIT-C)	3	Self-report	X	-	X	X	-
16. Non-Cigarette Smoking Behavior	6	Self-report	X	-	X	X	-
17. Smoking Cessation Weight-Grain Concerns	2	Self-report	X	-	-	-	-
18. Smoking to Cope with Pain	1	Self-report	X	-	-	-	-
19. Exposure to Smoking Cues	1	Self-report	X	-	-	-	-
20. Pharmacotherapy Adherence – Visual Analog Scale (personalized to pharmacotherapy use)	1-3	Self-report	-	X	X	X	-
21. Tobacco Exposure Questionnaire	6	Self-report	X	-	X	X	-
CLINICAL MEASURES							
22. 7-day, 30-day Point Prevalence Abstinence	2	Research Interventionist	X	X	X	X	-
23. Prolonged Abstinence	2	Research Interventionist	-	-	X	X	-
24. Timeline Follow-back (cigarettes per day)	1	Research Interventionist	-	-	X	X	-
OUTCOME MEASURES							
25. Patient Recruitment	-	Research Interventionist	X	-	-	-	-
26. Treatment Retention	-	Research Interventionist	-	X	X	X	-
27. Withdrawals	-	Research Interventionist	X	X	X	X	-
28. Patient Satisfaction – Treatment Acceptability	8	Self-report	-	X			X
29. Therapist Satisfaction – Treatment Feasibility	7	Research Interventionist's Self-report	-	X			X
30. Clinician Time	4	Research Interventionist	X	X	-	-	-

Treatment Components

Treatment Personalization Algorithm. During session 1, the interventionist will complete a treatment personalization algorithm with the participant. This algorithm requires participant self-report data in addition to data from the electronic health record. Data inputs are shown in Table 2.

Table 2. *Treatment Personalization Algorithm Components*

ALGORITHM	CONSTRUCT	MEASURE
Baseline CBT Algorithm	Motivation; Self-efficacy, Social influences; Substances and Alcohol; Mental Health; Pain; Pharmacotherapy	Smoking Cessation Motivation; Smoking Cessation Self-Efficacy; Stages of Change; PTSD Checklist of DSM-5 (PCL-5); Patient Health Questionnaire (PHQ-9); Alcohol Use Disorders Identification Test (AUDIT); Non-Cigarette Smoking Behavior; Smoking to Cope with Pain; Exposure to Smoking Cues
Quit Week CBT Algorithm	Relapse prevention; Weight gain; Self-efficacy; Motivation; Pharmacotherapy adherence;	Relapse Situation Efficacy Questionnaire (RSEQ); Smoking Cessation Weight-Grain Concerns; Pharmacotherapy Adherence – Visual Analog Scale (personalized to pharmacotherapy use); If necessary: Smoking Cessation Motivation; Smoking Cessation Self-Efficacy; Stages of Change
Post-Quit Relapse-Prevention Messaging Algorithm	Preferences regarding message type: Inspirational; Medication reminders; Help with lapses; Trigger information; Behavioral skills	Preference ratings
Baseline Pharmacotherapy	Willingness; Preference; Contraindications	Self-report
Quit Week Pharmacotherapy	Status; Adherence; Willingness	Self-report
Quit Week Algorithm for Revising Pharmacotherapy Regimen (Initially Prescribed Dual-NRT)	Willingness; Contraindications	Self-report
Quit Week Algorithm for Revising Pharmacotherapy Regimen (Initially Prescribed Varenicline)	Willingness; Preference	Self-report
Quit Week Algorithm for Revising Pharmacotherapy	Willingness; Preference	Self-report

Regimen (Initially Prescribed Bupropion)		
Quit Week Algorithm for Revising Pharmacotherapy Regimen (Initially Prescribed Single-Formulation NRT)	Willingness; Preference; Contraindications	Self-report

Personalized Smoking Cessation Counseling. Counseling session 1 will occur in person at the Durham VA Health Care System. For subsequent counseling sessions, participants will be offered the choice of whether to complete counseling sessions using a personal telephone, a personal digital device (i.e., tablet, laptop, or desktop computer with webcam), or a VA-issued digital device (i.e., 4G-enabled tablet with webcam). For those who request a VA-issued personal digital device, a consult will be placed to Prosthetics Service to issue the Veteran a 4G-enabled tablet in order to complete subsequent counseling sessions via VA Video Connect.

Core CBT modules include: identifying reasons for quitting, setting a quit date, breathing relaxation technique, identifying smoking triggers, identifying social support, and education about relapse prevention. We will also use the Session 1 treatment personalization algorithm to individually tailor counseling to provide an adaptable selection of discrete counseling modules in addition to core modules that all participants will receive. CBT treatment personalization algorithms are based upon the following assessments: self-efficacy, motivation for quitting, depression, PTSD, alcohol use, comorbid non-cigarette smoking, tobacco exposure, smoking to cope with pain, adherence to pharmacotherapy, and concerns about weight gain. Two to three of these 5- to 15-minute modules will be included in each session, and modules will focus on building each participant's skills that are needed to achieve cessation and long-term abstinence. Optional modules will address low motivation to quit, low self-efficacy for quitting and relapse prevention, comorbid psychiatric concerns, alcohol/drug use, tobacco exposure and poly-tobacco use, pain management, pharmacotherapy adherence, and healthy eating/exercise. Each session will last 30-60 minutes.

At Session 3 (1 week post-quit), the participant will be asked several treatment personalization questions (see measures section). These responses will be entered into the treatment personalization algorithm to determine additional post-quit modules depending on the following: self-reported quit status at Session 3 (defined as complete abstinence since most recent quit date), self-efficacy, motivation, pharmacotherapy adherence, and barriers to abstinence. Additional modules to be added to counseling include: relapse prevention, motivational interviewing, decisional balance, pharmacotherapy adherence (or pharmacotherapy motivational interviewing), and review of barriers and protective factors.

Personalized Smoking Cessation Pharmacotherapy. Participant pharmacotherapy recommendations will be based upon the study treatment personalization algorithm and will be sent to the participant's ID Clinic team. All pharmacotherapy prescriptions will be managed as part of routine clinical care by the participant's VA healthcare providers, who may choose to follow study pharmacotherapy recommendations at their discretion. At counseling Session 1, the study interventionist will ask questions regarding smoking cessation pharmacotherapy preferences and contraindications directly to the study participant. The interventionist will also review the participant's electronic medical record to note any additional potential contraindications to pharmacotherapy. Pharmacologic recommendations will be based upon a recent meta-analysis of smoking cessation pharmacotherapy as well as VA Pharmacy Benefits Management Services guidelines (Cahill et al., 2013). Similar to Cropsey et al.'s (2015)

algorithm methodology, participants will be followed 1 week post-quit to assess abstinence and pharmacotherapy adherence. If they are smoking and have poor adherence (<70% adherence) and are willing to increase pharmacotherapy use, then adherence will be more heavily targeted in CBT. If, however, they are smoking in the context of adherent use, the algorithm will suggest an alternative medication regimen if possible (e.g., switching from single-formulation NRT to dual-NRT).

Personalized Annie Messaging Support. If the participant has a working cell phone and is willing to receive SMS text messages, supportive SMS text messages will be sent to the participant starting after Session 1 and extending through 6 months post-quit. Individual tailoring of follow-up messages will be based upon the post-quit patient mHealth survey, which will measure the following: desired frequency of messages (1-3 per day); specific abstinence-related concerns (i.e., weight gain, difficulty coping with stress); preferred types of messages (skills-focused, health informational, encouragement); and personalized reasons for staying quit. Participants can opt out of follow-up messaging at any point. All messages will be sent via the VA Annie texting capability. As stated above, Annie is a standard VA SMS text message capability designed to promote Veteran self-care.

COVID-19 Temporary Study Procedures

Participants who are ongoing at the time of the COVID-19 crisis will complete future therapy and follow-up visits via phone, A VideoConnect (VVC), or another approved telehealth platform (http://vaww.telehealth.va.gov/technology/covid19-tech.asp). Questionnaires will be completed by mail, MyHealthyVet, or Azure RMS (in accordance with guidance issued in VA document "Use of Protected Health Information in Microsoft Office Applications"). If enrollment continues during the COVID-19 crisis, study procedures will be completed in the same manner. The consent process will take place by mail and phone.

PRIVACY, CONFIDENTIALITY, AND INFORMATION SECURITY

1. Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:

The Personal Health Information that will be obtained, used, and/or shared for this study includes:

Identifier(s)	Source(s) of Health Information
☒ Names	☒ Medical history & physical exam information
☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: Participants' addresses will be collected during the study in order to pay them for participation.	☒ Photographs, videotapes, audiotapes, or digital or other images
☒ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89, Describe: Date of participation will be collected. In addition, treatment records, laboratory results, etc. will be collected.	☒ Biologic specimens (e.g., blood, tissue, urine, saliva). Describe: Collection of saliva samples for salivary assay.
☒ Telephone numbers	☒ Progress notes
☐ Fax numbers	☒ Diagnostic / Laboratory test results
☒ Electronic mail addresses	☐ Operative reports

Identifier(s)	Source(s) of Health Information
☒ Social Security Numbers	☐ Imaging (x-ray, CT, MRI, etc.)
☒ Medical record numbers	☐ Discharge summaries
☐ Health plan beneficiary numbers	☒ Survey / Questionnaire responses
☒ Account numbers	☐ Billing records
☐ Certificate and/or license numbers	☒ HIV testing or infection records
☐ Vehicle identifiers and serial numbers, including license plate numbers	☐ Sickle cell anemia information
☐ Device identifiers and serial numbers	☒ Alcoholism or alcohol use information
☐ Web Universal Resource Locators (URLs)	☒ Drug abuse information
☐ Internet Protocol (IP) address numbers	☐ Mental health (not psychotherapy) notes
☐ Biometric identifiers, including finger & voice prints	☐ Psychological test results
☐ Full-face photographic images and any comparable images	☐ Genetic testing
☒ Any other unique identifying number, linked study ID, characteristic, or code, describe: study ID number	☐ Other, describe:

2. Data and/or Specimen Acquisition:

Data for this study will be collected through (*check all that apply*):

☒ Prospective data and/or specimen collection obtained from participants. Aim 1 patient data will be obtained through a 60-minute, semi-structured interview. Aim 1 VA staff data will be obtained through a 30-minute, structured interview. No data collection is involved in Aim 2.

☒ Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.):

Aim 1: In accordance with a Waiver or Alteration of HIPAA Authorization, names, addresses, telephone numbers, social security numbers, and diagnostic information of potential participants will be obtained from the VA's Regional Data Warehouse. For study Aim 2, health data will be obtained from VA's Corporate Data Warehouse.

☐ Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number: Aim 1b: Survey data from Duke University Health System will be shared with the VA team via a VA-owned thumbdrive.

Note: for data and/or specimens obtained from a VA approved data repository, a Data Use Agreement (DUA) must be executed prior to obtaining data and/or specimens. See VHA Handbook 1200.12 for further information.

3. Level of Data:

The following level(s) of data will be acquired/maintained for this study (*check all that apply*):

☒ Identified (e.g., names, addresses or other identifiers included)

☒ Coded (direct and/or all identifiers removed, but study code/ID included)

☒ De-Identified (all HIPAA 18 and study ID/code removed):

- ☐ Verified Statistically

  OR

- ☒ Verified by Absence or Removal of HIPAA 18 and study ID

☐ Limited Data Set
☐ Other: Describe:

4. Location of Data and/or Specimens, and Data Retention Plan:

A. Data and/or Specimen Location:

Aims 1 & 3:

Data will be stored electronically in \\vhadurhsmcifs01.v06.med.va.gov\Mesh. For Aim 1, data that will be stored electronically include name, address, phone number, social security number, amount of study payment earned, and date of visits (in Study Logbooks location). The study logbook will contain the key connecting PHI and the study identification number. Paper records of data include study consent form and HIPAA authorization (identified) and interview notes (coded); these will be stored in a locked filing cabinet in a locked office suite in Bldg. 1, Room C10006 or Building 8, Room 206 of the main Durham VA Health Care System campus. Audio recordings of qualitative interviews and to establish interrater reliability will be captured using an Olympus DM-620, which is a newer model of the Olympus DM-420 (see RBD 34), or will be captured using the Audacity program. When not in use, the audio recorder will be stored in a locked file cabinet in our study offices in Bldg. 1, C10006. Recordings will be moved from the audio recorder to the "Study Logbooks" location listed above; our laboratory has sanctuary exemption to allow these devices to plug into the network, as they are used in other current research projects. Audio recordings using Audacity will be immediately stored in the "Study Logbooks" location listed above. For long term storage, audio recordings may be moved to an encrypted DVD that is password-protected. Any encrypted DVDs will be stored in a locked filing cabinet in a locked office. Transcriptions from the study interviews will be stored electronically at the Study Logbooks location listed above. Data received from Duke University Health System will be moved to \\vhadurhsmcifs01.v06.med.va.gov\Mesh for storage and analysis.

Aim 2:

Data collected via a DART pull will be stored locally at \\v06.med.va.gov\DUR\Mesh.

☐ Data will be also be placed at the VA Informatics and Computing Interface (VINCI; http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx). The VA Informatics and Computing Infrastructure is a partnership between the VA Office of Information Technology and the Veterans' Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).

B. Data Retention Plan

☒ Research records will be maintained and destroyed according to the National Archives and Records Administration, Records Schedule Number: DAA-0015-2015-0004. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Currently, destruction of research records (see DAA-0015-2015-0004, section 7.6 "Research Investigator Files" for materials included in research records) is scheduled for 6 years after the cut-off (the cut-off is the completion of the research project) and may be retained longer if required by other federal agencies. Records will not be destroyed without pre-notification to the facility records manager.

☐ Other data retention plan, describe:

5. Data Access and Data Recipients:

Aims 1 & 3:

Only members of our DVAMC research team will have access to identifiers and coded data. All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one's password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins). Access to study data will be removed for all study personnel when they are no longer part of the research team.

Aim 2:
Only Dr. Wilson (PI) and study statistician will have access to identifiers and coded data. All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one's password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins). Access to study data will be removed for all study personnel when they are no longer part of the research team.

6. Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:

I. ☒ Data and/or specimens will not be transported or transmitted outside of Durham VAMC environment. Please note: Data will not be transported outside the Durham VA environment. Specimens will, see item IIIb below.

II. ☒ Data and/or specimens will be transported BETWEEN sites that are under the auspices of the Durham VA Medical Center. Please describe what is being transported, who will be responsible for transporting (study titles rather than names) how it will be secured during transport, and whether additional stops will be made while transporting the data/specimens. Study mail and correspondence will be moved from HSR&D space at Legacy Tower to DVAMC, Building 1, C10006. The study coordinator will be responsible for moving these documents. Data will be secured in a briefcase or lock bag with the notice below attached. No stops will be made while transporting the documents.

a. ☒ Local DVAMC memorandum "Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities" has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials.

b. ☒ Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container):

NOTICE!!!
Access to these records is limited to: AUTHORIZED PERSONS ONLY.
Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.

III. ☐ Data and/or specimens will be transmitted to other VA sites using the following method(s):

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted disk (encryption is optional).

☐ Data are coded or contain identifiers and thus will be sent

☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional).

☒ Specimens are coded or contain identifiers and thus will be sent via VA-authorized carrier with tracking.

☐ Other, describe:

IV. ☐ Data and/or specimens will be transported to non-VA/VHA sites (e.g., academic affiliates, laboratories, etc.) using the following method(s):

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted CD.

☐ Data are coded or contain identifiers and thus will be sent via <chose method of transfer such as FIPS 140-2 encrypted CD or FIPS 140-2 encrypted hard drive/flash drive> using VA—approved carrier with tracking.

☐ Data are coded or identified and will be uploaded to sponsor website using electronic case report form (eCRF) <insert information including sponsor name and URL and the encryption the site uses.>

☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional) or will be hand-delivered by research study personnel. Specify method of delivery:

☐ Specimens are coded and thus will be sent via VA-approved carrier with tracking or will be hand-delivered by research study personnel. Specify method of delivery:

In accordance with the HIPAA and the Privacy Act, for any coded or identifiable data or specimens released from the Durham VAMC (with the exception of Limited Data Sets), an Accounting of Disclosure (AOD) will be maintained (e.g., in a database or spreadsheet) that includes the participant's name, date of the disclosure, description of the nature of the Individually Identifiable Information (III) disclosed, purpose of each disclosure, and the name and address of the person/agency to whom the disclosure was made.

7. Risk Mitigation Strategies:

☐ Data are fully de-identified (stripped of HIPAA 18 and study ID/code) before being shared outside of Durham VAMC.
☐ Specimens are fully de-identified (stripped of HIPAA 18 and study ID/code before being shared outside of Durham VAMC.
☒ Direct identifiers will be maintained separately from data and or specimens by using a code to "identify" subjects. In a separate database (i.e., a "linking" or "cross-walk" database) this code will be linked to identifying subject information.
☐ Other, specify:

8. Suspected Loss of VA Information:
Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

9. Reporting of Results:
☒ Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published.
☐ Other results reporting plan, describe:

10. Future Use of Data:
☐ Data will be retained for future use. This is described elsewhere in the protocol and is noted in the HIPAA authorization.
- ☒ Future Use of data is optional (i.e., not required by the research subject).
- ☐ Future Use of data is required for participation in the study.

☐ No future use of data is currently planned.

11. Use of Mail Merge Technology
☒ Mail merge programs will be used to generate letters and/or address labels for mailings to potential or already enrolled research subjects. The study team is aware that to reduce risk of mail merge related privacy incidents, use of mail merge programs requires a 25% accuracy check to verify that (potential) research subject name and mailing address are properly "matched". If discrepancies are found, a 100% accuracy check is required before letters may be mailed.

DATA ANALYSES
Aim 1:
Sequential Exploratory Mixed Analysis. Qualitative data collection will constitute the initial idea-generation step in treatment development, and thus findings will be used to do the following: 1) conceptualize ways to adapt intervention content to increase its specificity and appropriateness for a population of Veteran smokers living with HIV; 2) identify additional CBT content needed to increase relevance to the population; and 3) generate relapse-prevention message content specifically needed for this population. After qualitative data collection and analysis are completed, appropriate updates will be made to the CBT treatment manual and relapse-prevention message library.

Qualitative Analysis. Data will be analyzed in two phases – an initial phase of conventional content analysis followed by an inductive, thematic approach to identify patterns in the data. Coded data will be analyzed for emergent patterns and themes that may adhere to or contradict the investigators'

expectations. Data management and coding will use NVivo8 software on VA VINCI website, or ATLAS.ti on a VA secured computer.

Quantitative Analysis. Regarding quantitative data received from Duke, data from veterans who smoke, people living with HIV who smoke, and members of the general public who smoke will be analyzed separately. First, data will be cleaned. Participants will be excluded from analysis if they meet any of the following criteria: greater than 2 endorsed bogus items, self-reported "very little" or "no" effort or attention, or a "no" response to the question "In your honest opinion, should we use your data in our analyses in this study?" After data cleaning, the following descriptive statistics will be calculated for satisfaction ratings on each SmokefreeVET message: range, mean, and standard deviation. Items falling below an 8 on mean satisfaction will be reviewed by the study staff in the context of qualitative findings to make final decisions regarding their inclusion in the final relapse-prevention message library.

Aim 2:
In order to examine disparities in healthcare delivery of smoking cessation prescriptions, we will use a longitudinal retrospective design. Generalized linear mixed modeling (GLMM) with a logit link and binomial variance will be used to determine differences by age, race, ethnicity, HIV, Hepatitis C, psychiatric disorder, and severe average pain in likelihood of pharmacotherapy dispensation during a given year. GLMMs appropriately accommodate multi-level data structures with unbalanced design for analyzing repeated observations across multiple individuals nested within clinics. Clinic- and person-level random effects will be included in statistical models to account for correlation among patients within the same clinic and repeated measurements on the same individual over time, respectively. Covariates will be assessed for collinearity before entering them simultaneously into the GLMM.

Aim 3:
We will use rapid qualitative analytic methods to analyze participant feedback from post-treatment qualitative interviews (Watkins, 2017). For each study cohort of 5 participants, study staff will complete written summaries of interview audio recordings, and will enter these summaries into a study database. Interview summaries across participants will be displayed by their structural content (i.e., intervention strength, intervention weaknesses, and areas for improvement). Then, thematic analysis will be used to code emergent themes and patterns within each content area. Given the sample size for this successive cohort study (N = 15), it is estimated that we will identify and be able to address 97% of usability problems in the treatment personalization program (Faulkner, 2003).

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