Tech and Telephone Smoking Cessation Treatment for Young Veterans With PTSD

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Department of Veterans Affairs	INFORMED CONSENT FORM
Subject Name:	**Date:**
Title of Study: **TECH AND TELEPHONE SMOKING CESSATION TREATMENT FOR YOUNG VETERANS WITH PTSD**	
Principal Investigator: **Ellen Herbst, M.D.**	**San Francisco VAMC**

CONSENT TO PARTICIPATE IN RESEARCH

This is a medical research study funded by the University of California, San Francisco (UCSF). The principal investigator is Ellen Herbst, MD from the San Francisco VA Medical Center (SFVAMC) and UCSF Department of Psychiatry. The other researchers are Shannon McCaslin, PhD and Eric Kuhn, PhD, from the National Center for PTSD at the VA Palo Alto VA System. One of the study staff, supervised by these researchers, will explain the study to you.

1. What is an Informed Consent?

Medical research studies include only people who choose to take part. You are being asked to be in a research study. The purpose of this form is to give you the information you will need to help you decide if you want to be in this study. Read this form carefully and ask questions about anything you do not understand. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. When all your questions have been answered, you can decide if you want to be in this study. If you do decide to be in the study, you can request a copy of this signed and dated form to keep for your records.

2. Why am I being asked to take part in this study?

You are being asked to take part in this study because you may have current or past posttraumatic stress disorder (PTSD) and because you smoke cigarettes, and may use e-cigarettes, or chew tobacco in amounts that could pose a risk to your health. You have indicated a desire to stop smoking or reduce the amount of tobacco you consume with a possible long-term goal to stop.

3. Why is this study being done?

The purpose of this study is to find out if a combined treatment is a helpful and useful tool for people that are trying to quit smoking. The treatment includes (1) video/telephone coaching, (2) a smartphone application (app) called “Stay Quit Coach” (SQC) and (3) a mobile “Smokerlyzer” to measure carbon monoxide levels. We are trying to find out if this treatment helps veterans with PTSD quit smoking at higher rates, and if the intervention makes the process of quitting easier, compared with usual care (referral to the VA Telephone Quitline). We are also wanting to figure out if Veterans find the treatment helpful and convenient. Coaching will be conducted over the telephone and includes behavioral methods and stress reduction techniques.

4. How many people will take part in this study?

Up to 80 veterans will be in the study. Participants will be randomized (like a coin flip) into two groups. Half will receive the study treatment and half will receive usual care (VA Telephone Quitline). Participants in the treatment group will receive counseling sessions to help quit smoking, will be asked to use the smartphone

app, Stay Quit Coach, and a carbon monoxide monitor, iCO Mobile Smokerlyzer. The other participants will receive usual care, which means that they will be asked to use the VA Telephone Quitline if a need or concern around quitting comes up. Both groups will be offered nicotine replacement therapy (patches, gum, lozenge, inhaler and/ or nasal spray), which is optional and not required to participate.

5. Are there some people who should not be in this study?

The study doctor or a member of the study staff will talk with you about the requirements to be in this study. It is important that you are truthful with them about your history. You should not be in this study if you do not meet all the requirements of the study.

You should not be in this study if:

a. You are younger than 18 years of age or older than 45 years of age.
b. You are not comfortable using a smartphone.
c. You do not have a valid e-mail address.
d. You are experiencing severe medical problems, cognitive problems or severe mental health difficulties as determined by the Principal Investigator.
e. You are pregnant or plan to become pregnant in the next 6 months.
f. You are currently participating in similar research studies.

6. How long will I be in the study?

In total, you will be asked to commit approximately 13 -15 hours of your time over the course of 24 weeks.

The study can be divided into three phases:

Screening Phase (Week 0)
Treatment Phase (Weeks 1-8)
Follow-Up Phase (Measures at Weeks 8, 12, and 24)

At the **Screening Phase** (Week 0): You will answer questions about yourself through an interview with a study staff member and complete self-report questionnaires to determine if you are eligible for the study. All participants will attend 1 visit at the SF VA Medical Center or related clinic (Community-Based Outpatient Clinic), where you will be offered nicotine replacement therapy (NRT). You will also be asked to complete a urine pregnancy test if you are a woman of childbearing age. The entire screening process is estimated to take about 2 hours.

If you are eligible, you will participate in the **Treatment Phase** (Weeks 1-8) by phone, which is estimated to take 20-30 minutes per visit. During the Treatment Phase study visits you will be asked to:

- Half of the participants will receive 8 weekly video/telephone coaching sessions, with use of the SQC app or Smokerlyzer between sessions; the other half will receive a referral to the VA Quitline for 8 weekly sessions Regardless of the group, each session is 20-30 minutes. The final counseling session will occur at Week 8.
- All participants will receive monthly check-in calls with a study doctor to discuss NRT over the 24-week period, so 6 check-in calls total. Each phone call will be 10-15 minutes long.

In the **Follow-Up Phase,** you will be asked to complete 3 study visits by phone (Weeks 8, 12 and 24). Each study visit is estimated to take 2 hours. At the Follow-Up Phase study visits you will be asked to:

- Complete follow-up self-report questionnaires at Weeks 8, 12, and 24.
- Provide a saliva sample so that we can measure the amount of nicotine you are using.
- An interview or questionnaire at Week 8 visit to share your opinions about the treatment you received, either the VA Quitline or the coaching sessions, smartphone app, and carbon monoxide monitor.

7. What will happen if I take part in this study?

Both groups will receive:

- The option of receiving nicotine replacement therapy (NRT) once enrolled in the study (Week 0).
- Treatment that consists of either (1) eight weekly 20-30 minute coaching sessions, with use of the SQC app or Smokerlyzer between sessions; or (2) referral to the VA Quitline for eight 20-30 minute sessions. Weekly check-in Qualtrics surveys will be e-mailed out during the 8 treatment weeks as well to both groups.
- Monthly check-in calls with a study doctor to monitor nicotine replacement therapy (NRT) (patch, gum, etc.) throughout the 24-week period.

The group assigned to the coaching sessions, use of smartphone app and use of carbon monoxide monitor will receive:

- **VA Video Connect counseling sessions (or telephone sessions if out of wi-fi range)** that include:
  - questions to understand your smoking habits, attempts to quit, and reasons for quitting;
  - motivation techniques;
  - support and encouragement of your attempt to quit; setting up a plan with dates to stop quitting; identifying smoking triggers;
  - identifying sources of support;
  - working on coping skills and teaching controlled breathing;
  - and checking in on your progress at each meeting.
- Use of the **SQC app**, which provides messages, reminders and information to support your attempts to quit smoking.
- Use of the **iCO Smokerlyzer mobile carbon monoxide** monitor (compatible with smartphones).

7a. Screening Phase – 1-2 Visits

To see if you are eligible to participate in the study, the following will take place during the Screening Phase. Information will be kept confidential (as detailed later in this Consent Form).

- The study will be discussed with you, and you will be asked to sign this consent form.
- You will be asked to provide your contact information (preferred name, and phone numbers) and an alternate contact name and phone number to be called in case you miss a study appointment. You will also be asked to provide your e-mail address in order to receive the weekly online survey links as well as VA Video Connect (VVC) appointment invitation links if you are placed in the group assigned to video counseling. Research staff will confirm your personal contact information, as well as that of your alternate contact, before you can continue in the study.
- Medical chart review: Your medical chart will be reviewed by the study doctors.
- You will be asked how much you have been smoking and about any use of other substances (alcohol, marijuana, cocaine, etc). You will also use a Smokerlyzer to measure level of carbon monoxide (CO).
- You will be asked to answer questions about your military experience, psychiatric history, education, work, and other aspects of your life. These questions may include: specific information about any combat or stressful experiences you may have had as part of your military experience; specific questions to assess your mood, if you have ever felt suicidal, and questions about any anxiety you may experience; how much school you have completed and if you are currently a student; your work experience and where you see yourself continuing; and anything that arises due to your responses to these questions.
- You will fill out a questionnaire about the type, frequency, and intensity of your PTSD symptoms.
- You will be asked to complete a urine pregnancy test (for women of childbearing age).
- Lastly, you will fill out a questionnaire about your experiences with mobile phone interventions.

7b. Treatment Phase – 8 Weeks

After you have been deemed eligible based on the Principal Investigator's review of the screening tests, and you want to continue participating in the study, then you will enter the Treatment Phase of the study.

At each weekly visit, the following will take place:

- *Group assigned to the video/telephone counseling sessions, smartphone app and CO monitor*: You will meet with a study counselor by VA Video Connect for individual counseling sessions (or by telephone if out of wi-fi range). The sessions will follow the guidelines of a treatment manual that aims to help you quit smoking. There are 8 counseling sessions that are focused on tobacco use education, behavioral skills for quitting smoking, setting a quit date, and relapse prevention. These counseling sessions last about 20-30 minutes each and will be administered by a study counselor by video/telephone. All treatment sessions will be audio-recorded for later assessment of fidelity and adherence to the treatment protocol, which is associated with improved outcomes in both research and clinical implementation. You will be asked to complete a check-in survey every week that will be e-mailed to you as well.

- *Group assigned to the telephone helpline*: You will receive a referral to the VA Telephone Quitline, a toll-free service provided by the VA that allows Veterans to speak with a counselor specialized in helping people reduce or quit smoking. The Quitline is available Monday through Friday. The Quitline counselor may ask you specific questions about your tobacco use, quitting history, and motivations to quit to help create a quit plan. You will be asked to complete a check-in survey every week that will be e-mailed to you as well.

7c. Follow-Up Telephone Sessions (Weeks 8, 12 and 24)

- You will be asked to fill out more self-report questionnaires that are similar to questionnaires you completed during the screening phase of the study.

- You will also be asked a list of questions about your experience using the smartphone app (Stay Quit Coach), and carbon monoxide monitor (Smokerlyzer), the telephone helpline (VA Telephone Quitline) and your thoughts and feelings about the use of mobile phone interventions.

- If you are *assigned to the video/telephone counseling sessions, smartphone app and CO monitor*, you will be asked to participate in a 15-20 minute interview during which you will be asked about your thoughts about using mobile apps for health, whether or not you found the counseling sessions helpful, and whether or not you had any issues with using the app. This session will be audio-recorded for the research team to review your responses and feedback. You may opt out of this interview if you choose to.

- You will be asked how much you have been smoking and about any use of other substances (alcohol, marijuana, cocaine, etc).

- You will be asked to provide a saliva sample so that we may measure how much you are smoking. You will be mailed a saliva collection kit with detailed instructions on how to use it. First, use a funnel to collect your saliva in a tube, then invert the tube and place 8 drops of saliva on the test strip. After 15-30 minutes, the test will be complete, and you're asked to take a picture of your results and email them to quitsmoking@ncire.org. There is also a results card in the kit that allows you to interpret the results of your sample directly.

Study location: All study procedures will be done at the SFVAMC, an associated clinic, or by phone.

8. Can I stop being in the study?

Yes, you can decide to stop participating at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so that you and your doctor can discuss other treatment options.

The study doctor may stop you from taking part in this study at any time if the doctor believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

9. What risks can I expect from being in the study?

9a. Risk of Distress or Embarrassment: While completing questionnaires, some of the questions may be uncomfortable to answer, or they may upset you. You can refuse to answer any question, and you may stop at any time. Some of the evaluation questions, weekly interview questions, or questionnaires may involve talking or thinking about past traumatic events or other topics you may find emotionally upsetting. Should this occur, you can refuse to answer any question. You are free to stop the session at any time. In these cases, you will be able to stay in the study.

9b. Information on Illegal Drug Use: While we make every effort to maintain confidentiality, we will be asking many questions about the use of illegal substances. Given the event that confidentiality is breached and someone outside of the study finds out about a participant's illegal drug use, this can create issues in employment and benefits of a participant. Again, we will make every effort to ensure this information stays private amongst appropriate research staff.

***9c. Nicotine withdrawal symptoms*:** People who quit smoking may experience withdrawal symptoms, including occasional (1 to 10%) irritability, fatigue, dizziness, restlessness, insomnia, and increased cough. These symptoms are temporary and usually go away within 2-3 weeks. Participants will have access to nicotine replacement therapies (NRT) to minimize this risk.

***9d. Risk of use of nicotine replacement therapy (NRT*):** You will be given the option to receive nicotine replacement therapy (NRT). NRT will follow standard VA prescribing guidelines and will be based on (1) safety; (2) nicotine dependence level, and (3) participant preference. Receipt of medications in the study is optional and is not required for full participation in the trial. The potential risks of different formulations of NRT are summarized below.

- **Nicotine patches:** likely (> 10% risk): itching and redness of skin; less likely known risks (<10% risk): skin rash (swollen red skin under the patch), diarrhea, an upset stomach, muscle aches, increased blood pressure, trouble sleeping or nightmares.

- **Nicotine lozenges:** likely (> 10% risk): diarrhea, upset stomach, muscle aches, increased blood pressure, trouble sleeping or nightmares.

- **Nicotine gum:** likely (> 10% risk): hiccups, nausea, coughing, heartburn, headaches, flatulence, fast heart rate, increased blood pressure, trouble sleeping, flatulence (gas), occasional muscle ache in the jaw may occur due chewing the gum, occasional sore throat or sore mouth, or potential ulceration of the mouth.

- **Rare but serious risks of any NRT:** There may be an increase in the possibility of a heart attack or stroke if participants continue to smoke while using the nicotine patch, lozenges, or gum at the same time. For this reason, you should not smoke while using these NRT products.

- **Nicotine overdose symptoms:** less common (<10% risk) and may include very bad headache, confusion, dizziness, weakness, cold sweat, blurred vision, chest pain, and/ or vomiting.

- **Pregnancy:** NRT has not been deemed safe for use by pregnant women. The risks of using NRT during pregnancy are unknown.

- **Accidental poisoning:** NRT poisoning is a risk for participants with small children.

- **Potential drug-drug interactions or difficulty metabolizing NRT:** NRT may interact with the metabolism of other medications.

You may consult your healthcare provider for additional information on the risks of NRT.

9e. Unanticipated risks: You may experience side effects that we do not know about yet. If at any time during the study you observe any unusual or uncomfortable feelings, you should contact the research staff by coming in to the research office or calling the research staff during weekdays at the following numbers: 415-221-4810 x 24926.

10. Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. You may respond favorably to the counseling and phone application and reduce your smoking, but there is no guarantee that this will happen. Others may benefit in the future from the overall conclusions drawn from the results of this study.

11. What other choices do I have if I do not take part in this study?

You do not have to be in this study to be treated for PTSD or cigarette use. If you do not take part in this study you may continue to receive the usual treatment for PTSD and to help stop smoking.

You may obtain routine treatment for your cigarette use and PTSD symptoms at the SF VAMC Mental Health clinic, outside the context of the study; or pursue such treatment at another VA Mental Health or Primary Care clinic. The Stay Quit Coach app is free and available to download on the following VA website: https://mobile.va.gov/app/stay-quit-coach, so you may use if you choose not to participate in the study. You can also get additional help with a referral to the Telephone Quitline, referral to VA smoking cessation clinic or a referral to smoking cessation medications you're your primary care provider. You will also be free to obtain interventions outside the context of the SF VAMC, while participating in the study.

12. Will my medical information be kept private?

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. If you do not already have a medical record at the San Francisco VA Medical Center, one will be created because of your participation in this study.

A note about your study participation will be added to your medical record, that mentions your participation in the study but not the information you provide at study visits or during counseling sessions. Therefore, your other doctors in the VA health care system may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

Demographic information that will be collected from your medical record includes and during the study visit includes your name, address, age, date of birth, and social security number. Health information that will be collected from the medical record and during study visits includes your psychiatric, alcohol and illegal drug use, and medical information. You have the right, at any time, to take back the permission to use your personal health information for research purposes.

Every effort will be made to protect the confidential nature of your identifying information through the use of a unique study identification code, stored in an electronic database on a password-protected secure VA server behind a secure VA firewall at SFVAMC available to study staff only. The data manager will download study data from the server that will be needed for analysis and store it in a password-protected database. The log that connects your identification codes to the information you give us will be kept in a file separate from the collected data. This log will have restricted access and stored in locked cabinets when not in use. Data are not transmitted as an attachment to unprotected e-mail messages and data sent via mail or delivery service will be encrypted. Audio recordings will be stored on a secure, password protected VA web server.

Organizations that may look at and/or copy your research and medical records for research, quality assurance, and data analysis include:

- Department of Veterans Affairs
- University of California
- Study sponsor (Tobacco Related Diseases Research Program)

In this study, you will be asked questions about illegal drug use. On rare occasions, research records have been subpoenaed by a court. Should military command authorities request specific information about active duty service members (such as Reserve or National Guard), then such information will be provided in accordance with VA guidelines.

13. Will I be paid for taking part in this study?

You will be compensated in return for your time and effort to attend study visits in check.
Payment is also intended to cover, or partially cover, the cost of public transportation/gas/parking. Payment at screening depends on completion of tasks.

You will receive:

- $40 total for screening visit.
- $25 for the Week 8 Follow-Up Visit.
- $25 for the week 12 Follow-Up Visit.
- $30 for the week 24 Follow-Up Visit.
- $60 bonus for attending all and completing assessments administered at Baseline, Week 8, Week 12 and Week 24 as well as completing bio-verification if applicable.

If you attend all study visits, you will receive up to **$180.**

14. What happens if I am injured because I took part in this study?

It is important that you tell a study doctor if you feel that you have been injured because of taking part in this study. You can tell Dr. Herbst, the Principal Investigator, in person or call her at **(415) 221-4810 ext. 24926**. In the case of an emergency, Dr. Herbst can be reached 24 hours a day by work cell **(415) 559-8013.**

Treatment and Compensation for Injury: If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness as a result of being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available at a VA medical facility or non-VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by the VA or the study sponsor (if applicable) or may be billed to you or your insurer just like any other medical costs, depending on a number of factors. The VA and a study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided.

15. What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from the Department of Veterans Affairs health care system.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

16. Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. At San Francisco VA, please contact your study doctor Ellen Herbst, M.D. at 415-221-4810, ext. 24926 or call at 415-559-8013.

For questions about your rights while taking part in this study, call the office of the **UCSF Institutional Review Board** (a group of people who review the research to protect your rights) at **(415) 476-1814.**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

Optional Procedures: Please indicate if you agree to participate in the following optional procedures by placing your initials on the lines below:

_____I *agree* to be contacted after this study is done or to be asked to be in other studies.

_____I *do not agree* to be contacted after this study is done or to be asked to be in other studies.

If you wish to participate in this study, you should sign below.

_____

Signature of Participant Date

_____

Printed Name of Participant

_____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent