CPT-SMART for Treatment of PTSD and Cigarette Smoking

NCT03978442

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Verbal Consent Script

Before we begin this process, I need to ask you a couple of questions. Do you currently use tobacco? If yes, continue. **If no,** I am sorry this study is for Veterans who smoke cigarettes.

What forms of tobacco do you use? If Veteran endorses smoking cigarettes, continue. **If not,** I am sorry but this study is for Veterans who smoke cigarettes.

You are being asked to participate in a telehealth research study called "CPT-SMART for Treatment of PTSD and Cigarette Smoking" that is conducted by Dr. Eric Dedert at the Durham VA Health Care System. You are being asked to participate in this research study because you smoke cigarettes and you may have symptoms of posttraumatic stress disorder (PTSD). Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

Purpose and Duration

The purpose of the study is to evaluate the efficacy of a treatment that combines smoking cessation and Cognitive Processing Therapy (CPT) for PTSD. Your participation in this study will last about eight months. You are actively involved in treatment and study visits for about 14 weeks. We will continue to collect follow-up information for 6 months after your smoking quit attempt. All study procedures are completed via telehealth; you will not be asked to come to the Durham VA during your participation.

Study Procedures

If you agree to participate in this research study, you will attend a remote screening session in which you will be interviewed regarding PTSD symptoms and other psychiatric and substance use symptoms. For this session, and all other study sessions, we will ask you to refrain from alcohol or drug use prior to or during the visit(s). We will also ask you to complete some questionnaires about your mood, smoking, trauma history, substance use, and medical problems. This study session will take about five hours.

If you are eligible to participate in the study after the first session, you will be asked to attend twelve virtual treatment sessions (twice per week). At each treatment session, you will receive a therapy called Cognitive Processing Therapy, or CPT. In this therapy, you will talk with your therapist about traumatic events and how they have affected your beliefs and other aspects of your life. Also, at each treatment session, you will receive counseling designed to help you quit smoking and stay quit. You will be mailed a carbon monoxide, or CO monitor. CO is a measure of smoking. We will ask you to return this monitor when your study participation ends. Using these monitors is crucial to our research, and to helping other Veterans monitor their smoking. At each session, you will be asked to provide a breath CO sample. You will also be asked to complete some questionnaires at each therapy session. At session three, you will be asked to try to quit smoking. Each treatment session will take about one hour and 45 minutes.

If you are medically eligible, we will give you a medication to begin taking at your first counseling session. The medication is bupropion SR, an antidepressant medication that is FDA approved for treating depression and for helping smokers to stop smoking. You will not be allowed to participate in the research study if you are not medically eligible to take this medication. The study doctor will determine if you are medically eligible. He will work with your primary care physician or psychiatrist to determine eligibility. The study

doctor may also review your medical record to determine eligibility. If you have ever had seizures or currently have seizures, please tell the study coordinator. You should not take bupropion if you have uncontrolled diabetes, kidney impairment, current or past hepatitis, or current or past cirrhosis. You will take 150 mg each day for 3 days and then 300 mg each day and continue taking the medication until your 6-month study follow-up visit. We cannot guarantee that you will be able to continue receiving this medication after your final study visit. This will be up to your primary care provider or other treatment provider. We will ask you to bring your bupropion to each session so that we can count your remaining medication.

Using a procedure like flipping a coin, we will randomly assign you to one of two study groups. If you are assigned to the first study group, starting at session 3 (your quit smoking day), you will be paid money each time your CO readings or urine test results suggest that you haven't been smoking. The first payment is $30, and each week, this amount increases if your results continue to suggest that you haven't been smoking. Starting at session 5, you will be paid money each time you report that you have been abstinent from smoking and your urine test results confirm abstinence. By the final treatment session, you could be paid $75 for not smoking. If you do not attend an appointment once every eight days, or your results suggest that you have been smoking, you will not be paid. Your payment for the next time that your CO readings and urine test results suggest that you haven't been smoking will reset to $30. If you are one of the first four study participants who are eligible to participate, you will automatically be assigned to this group.

If you are assigned to the second study group, your payment for study participation is not related to your CO readings or urine test results. Each time that you provide a CO or urine sample, you may or may not be paid. You are "matched" to a participant in the first study group based on your gender and how much you smoke. Whether or not you are paid depends on whether your "match" was paid for the same reading. Whether or not you are paid will be completely irregular, and we cannot predict when you will receive payment or not. In fact, there is a small possibility that you will not be paid at all for any of these CO readings or urine test results.

After your 12 counseling sessions, you will participate in a remote post-treatment visit. In this visit, you will be asked to provide a CO breath sample. You will also be asked to complete some questionnaires about your mood, PTSD symptoms, and smoking. You will be asked to participate in an interview to see if your PTSD symptoms have changed as a result of treatment.

You will also be asked to participate in two study visits approximately 4 and 6 months after your smoking quit attempt. At each of these visits, you will complete some of the same questionnaires as in the screening visit, and you will be asked to provide breath samples. At the 6-month visit, you will also be interviewed regarding your PTSD symptoms.

Your study data may be stored and used for future studies without additional consent from you if identifiable private information, such as your name or medical record number, are removed.

If you have been referred to the study by your usual mental health clinical provider, we will contact your provider to let him/her know about your research participation. We will do this so that your clinical team can coordinate your mental health care.

The study team will ask you if you would like to receive email notifications regarding your study participation. If you would like, we can send you appointment reminders and other study correspondence this way.

Do you have any questions about the study so far? *(Address questions)*

Optional Study Procedures
If you consent to participate in this research study, we will collect information about how to contact you in the future. We will store this contact information along with your interview results in a database called "Contact Database." This information will be used to determine if you may be eligible for future studies run in our laboratory and to contact you about participation. These future studies include studies related to smoking, posttraumatic stress disorder (PTSD), and trauma. This permission is optional. Your choice to give permission to be re-contacted or not to give permission to be re-contacted will not affect your enrollment in the current study. If you do not wish for us to keep your information, we will not contact you in the future about other studies. *(Document yes/no response)*

Only if you grant permission, data collected from you during participation in this study may be entered into a large database called "Trauma Database." This data will be used for future research. Data will not include any identifying information, and will be stored at the DVAHCS. *(Document yes/no response)*

Risks and Discomforts
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Stopping smoking causes withdrawal symptoms. Symptoms can last for a few days to several weeks. These may include: headaches, dizziness, nausea, anxious or depressed mood, feelings of frustration and anger, trouble sleeping, bad dreams, trouble concentrating, restlessness, tiredness, increased appetite, weight gain, and craving for cigarettes.

There are no known risks associated with completing paper and pencil measures or electronic diary entries. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some questions asked as part of this study may make you feel uncomfortable or increase distress. This discomfort or increased distress is usually temporary and well tolerated. You do not have to answer questions and you can take a break at any time. You can call the study team at any time if you experience any discomfort related to the research.

Bupropion may cause some, all or none of these side effects:

More likely side effects include:

- dry mouth
- trouble sleeping
- nausea
- constipation
- headache
- shakiness or jitteriness
- skin rash

- sweating
- change in appetite
- weight loss
- dizziness
- tremor
- hot flashes
- ringing in the ears

Less Likely side effects include:

- unusual fatigue
- diarrhea or abdominal pain
- muscle or joint aches that last days
- yellowing of your skin
- seizures
- thinking abnormally

The Food and Drug Administration (FDA) has recommended that individuals taking certain medications including bupropion SR should watch out for worsening depression, or suicidal thoughts and behavior. You should also watch for sudden and severe changes in feelings such as: anxiety, agitation, feelings of panic, irritability, hostility, aggressiveness, impulsivity, severe restlessness, feeling overly excited or hyperactive, or not being able to sleep. In addition, you should tell family members or caregivers to watch out for these symptoms while you are taking the medicine. If you, your family members, or your caregivers notice any of these symptoms, you should notify the study doctor as soon as possible. If you are having suicidal thoughts or behaviors, you should go the nearest VHA emergency room.

You should avoid driving a car or operating heavy machinery until you know how the medications affect you.

Potential Benefits

You may benefit from stopping smoking, and you may have reduced PTSD symptoms as a result of the treatments in this study. However, these benefits are not guaranteed to you.

Confidentiality

The information collected for this study will be kept confidential. Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO).

Compensation

You will be reimbursed up to $810 for your participation in this study. You will be paid $50 for participating in the screening session, the posttreatment session, and the 4-month follow-up session. You will be paid $100 for the 6-month follow-up session. You may earn up to $525 for urine and breath samples. We will pay you $35 to return the study equipment.

Research Related Injury
The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAHCS or arrangements may be made for contracted care at another facility. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

Research Costs
There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Contact Information
If you have questions about the research or need to talk to the study team, you can contact Dr. Eric Dedert at (919) 286-0411 extension 134055 during the day, and at (919) 286-0411 (and ask the operator to call Dr. Dedert at home) at night. You may also contact the study coordinator at (919) 286-0411 extension 134059 during the day. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 177632. If you would like to check that this study is approved by the Durham VAHCS's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 176926.

Do you have any questions about anything? *(Address questions)*

Do you consent to participate in the study? (Document yes/no response.)
If yes: Great! I will send you a copy of the study consent form so that you can have it for your records. The consent form will include all of the information we've reviewed. (*Get mailing address, and schedule screening session*).

If no: Okay. Thank you so much for your time. Would you like a copy of the consent form that we reviewed? (*If indicated, get mailing address and send consent*).