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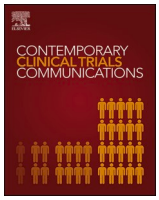

Protocol for the development of a vaping cessation intervention for young adult veterans

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ABSTRACT

The use of e-cigarettes ("vaping") by young adults has increased substantially in the past decade. Although health risks of long-term e-cigarette use remain unknown, there is evidence of acute physiological harms. Most young adults who vape report intent to quit, but little is known about effective interventions. This protocol paper reports on the development and design of a pilot trial of a vaping intervention for young military Veterans.

Young adult Veterans accessing VA healthcare (n = 20) who vape daily and have been referred for cessation services will be enrolled. To maximize accessibility the intervention will be delivered virtually; participants will be randomized to receive behavioral counseling by telephone or by video telehealth. The intervention was adapted from an existing program targeting young adult cigarette smokers and will include 6 individual counseling sessions delivered over 8 weeks. Assessment visits will occur at baseline, at end-of-treatment, and 4 weeks later.

Analyses will evaluate feasibility and acceptability of the intervention overall, and will compare telephone and video telehealth modalities. Longitudinal regression will be used to evaluate changes in vaping behavior and in nicotine dependence over time.

This study will provide assessment of a novel intervention adapted for Veterans who vape nicotine. The comparison of two modalities of virtual intervention delivery will increase knowledge and the potential to disseminate across VA and other healthcare systems. Findings from this pilot trial will inform the design of future, larger studies of vaping cessation interventions for younger Veterans.

1. Introduction

E-cigarette use (i.e, vaping nicotine) has increased dramatically in the past decade [1,2]. A variety of mechanisms are thought to have contributed to growth in use, including marketing, social pressures, and lower perceived risk relative to cigarettes [2]. Although it is too new for the consequences of chronic use to be well-understood, e-cigarette use has been linked to acute physiological harms [3,4]. E-cigarette use is also associated with risk of nicotine dependence, progression to use of combustible tobacco products, and other substance use [5,6]. Surveys suggest most young adults who use e-cigarettes have not attempted to quit or reduce vaping, but also that most report intent to quit in the long term [7,8]. Among young adults, military members and Veterans are at greater risk for nicotine and tobacco use, including vaping compared with the general population [9,10]. This discrepancy is likely at least partially due to the higher prevalence of vaping risk factors (e.g., male sex) compared to the general population. It may also be partly the result of e-cigarette manufacturers having followed the tobacco industry's longstanding pattern of targeting military and Veteran populations [11].

In light of the increasing prevalence and negative consequences of vaping in young adults, development of effective interventions is critical. More information is needed to inform intervention development.

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Key questions are not yet answered, including the extent to which interventions designed for combustible tobacco can be adapted to e-cigarettes; ideal intervention setting, modalities, and intensity; and whether there is a need to develop targeted interventions for specific subpopulations of individuals who vape nicotine.

On one hand, similarities to combustible tobacco products in terms of consumption of nicotine via a similar route of administration makes it plausible that interventions designed for combustible products could be readily adapted for e-cigarettes. However, recent studies suggest nicotine exposure may vary for young adults who use e-cigarettes compared with combustible users [12–14]. Young adults who vape nicotine are also more likely than not to use other nicotine/tobacco products and/or cannabis [15], potentially complicating intervention. Although many young adults who vape report interest in quitting, near-term intent to quit may be lower than it is for combustible product users [16]. Finally, although some motives for e-cigarette use overlap with motives for combustible use, others are distinct [17,18].

The existing literature includes only a handful of preliminary studies examining vaping interventions in this population, and none that focused on Veterans. Palmer et al. pilot-tested a four-week contingency management intervention delivered by a combination of a smartphone app and the Truth Initiative's *This is Quitting* text-messaging intervention [19]. Results indicated that most participants completed the intervention and rated it favorably. Graham and colleagues conducted a randomized, controlled trial of *This is Quitting* in more than 2500 young adults and found intervention group participants were more likely to be quit for 30+ days at 7 months post-baseline compared to an assessment-only control, though differences were modest (24 % vs. 18 %) [20]. While these and other interventions in the literature demonstrate some promise, they have generally been adapted from well-established interventions for cigarette smoking among older adults, as there are few examples of empirically supported interventions for young adult users of any nicotine or tobacco product [21]. As a result, that these interventions may lack key components that are relevant to young adults or important for cessation of vaping but not combustible tobacco products.

There is a need to develop effective, accessible interventions for vaping among young adults. The primary aim of this randomized, unblinded pilot study is to examine feasibility and acceptability of a virtual behavioral intervention for Veteran young adults who vape. Our assessment of feasibility will include the ease with which young adult vapers could be identified, and participant ratings of their ability to understand session modules and to access care virtually. Acceptability assessments will include participant ratings of the helpfulness of the material and whether they would recommend the protocol to their peers. We hypothesize that participants will generally rate the intervention as feasible and acceptable. Our primary secondary objective will be to evaluate whether participants are able to reduce or quit vaping, and we hypothesize that post-treatment descriptive statistics (quantity and frequency of vaping) will be lower than baseline.

1.1. Qualitative interviews to inform protocol content

Prior to the start of this feasibility study, a pilot was conducted to inform the adaptation of the intervention protocol. Ten Veterans with experience using e-cigarettes were recruited for participation in qualitative interviews regarding protocol content. The initial protocol was based on a 5-session American Cancer Society telephone program [22]. Inclusion criteria were 1) 18–25 years of age; 2) vaped some or all days for the past 6 months; and 3) owned a smart phone or computer or camera with internet connectivity.

Eligible individuals were scheduled for a qualitative interview either by phone or using an internet platform. Qualitative interviews were carried out between June and August 2022 at the VA San Diego. Interview guides were designed in a semi-structured open-ended format to increase potential for exploring participant viewpoints and personal experiences with e-cigarettes and commenting on the intervention and their preferred modality for receiving cessation counseling.

1.2. Participant feedback

Most participants were in favor of the intervention topics that were outlined for each of sessions about quitting vaping. Few expressed concerns or reservations about sharing personal experiences, and all described ways they could relate to the content. Feedback is summarized in Table 1.

The protocol was revised based on the qualitative data. Specifically, added attention to motivation was incorporated in the first and last sessions, mention of stress as a trigger led to adding a stress-management specific session, and responses reflecting mood and negative emotions as key challenges motivated the incorporation of cognitive restructuring skills to address negative thinking.

Table 1
Participant feedback from qualitative interviews.

Session focus	Participant Feedback	Incorporation into Protocol
Session 1. Value of support during quit process.	More than half of interviewees expressed strong interest and personal desire for strategies to create a support system during their quit attempt. A few interviewees specifically stated they wanted to have someone who would hold them accountable, as well as encourage them to stay in control of their cravings and triggers.	Added discussion and planning for obtaining social support.
Session 2. Identifying and coping with triggers.	Interviewees universally supported inclusion of this topic. Several interviewees added that learning the coping skills would be as important for them as learning to identify their triggers, which most believed were stress-related.	Session focuses on development and rehearsal of coping strategies.
Session 3. Creating a cessation plan.	A majority of interviewees perceived creating a plan as beneficial, but some also expressed apprehension about the efficacy of a plan in the moment that urges occur. A few interviewees suggested the content would demand keeping people engaged to prepare them for changed behavior.	Cessation plan development shifted to session 2 to allow more time for practice prior to quit date. Moved session 3 to within 72 h of quit to maximize engagement regardless of initial success.
Session 4. Positive aspects of quitting; surmounting barriers.	Most interviewees felt encouraged about this session and were hopeful to share their accomplishments.	Incorporated identifying successes into each of visits 4–6 to maintain motivation and increase self-efficacy.
Session 5. Planning for challenging situations.	More than half of the interviewees reacted to this session as potentially the most difficult, but no overt concerns were mentioned regarding their ability to participate. Most comments referred to interviewee stories about their own quit attempts and the difficult emotions that they grappled with in those moments.	Protocol was expanded to 6 sessions to permit additional time to identify and practice strategies for managing distress and cognitive distortions.

2. Methods

2.1. Study design and overview

Twenty young adults (aged 18–30) who are US military Veterans referred to the tobacco cessation clinic at VA San Diego Healthcare System (VASHS) will be recruited. Eligibility criteria will include daily nicotine vaping for at least the past 6 months. Individuals with a lifetime history of daily cigarette smoking for 6 months or more will be excluded, as will those who currently use recreational nicotine or tobacco products other than e-cigarettes more than 2 times per week. To reduce barriers to accessing care, the intervention will be delivered remotely. Participants will be randomized to participate via telephone or via video telehealth.

Participants will be enrolled in an 8 week, 6-session program designed to promote vaping cessation. The program was adapted and supplements a smoking cessation intervention developed by the American Cancer Society [22]. Intervention visits will take place 1, 2, 3, 4, 6 and 8 weeks after baseline. At baseline, end-of-treatment (eight weeks post-baseline) and follow-up (twelve weeks post-baseline), participants will complete quantitative measures of vaping quantity and frequency, vaping product(s) used, nicotine dependence, use of other nicotine and tobacco products including nicotine replacement, and use of alcohol and cannabis. Program factors (satisfaction, ease of access, length of visits, appropriateness of content) will be evaluated at the 8-week treatment visit, and at follow-up 4 weeks later using the 8-item Client Satisfaction Questionnaire [23], which has been shown to have high internal consistency and to predict treatment outcomes [24].

2.2. Procedure

Veterans referred to the VASDHS tobacco cessation program who appear to meet entry criteria will be given a brief description of the study and asked if they are interested in participating. Those who decline will be scheduled for cessation interventions as usual. Those who are interested in being screened will be referred to the study team.

Candidates will complete a screening visit, at which time they will provide informed consent. Interested and eligible participants will complete a baseline assessment of nicotine and tobacco history and related measures at this visit. Participant manuals will be provided at baseline to ensure access to content through the intervention. Enrolled participants will then be randomized to video or telephone conditions. Each participant will be assigned to a specific interventionist on the research team and will meet with the same interventionist for all sessions to maximize rapport.

2.3. Intervention content

The first intervention visit will be the longest. It will include an overview of the intervention schedule and a brief discussion of the benefits of including counseling in a cessation attempt. Other content will include mechanisms of nicotine addiction, including nicotine actions on the brain, withdrawal, and associations between vaping and environmental cues due to repeated pairing. The importance of social support will be reviewed briefly, and a plan for seeking support developed collaboratively. Information will be provided regarding nicotine replacement medications. Finally, participants will be introduced to a learning model, whereby past experience and repetition create triggers which lead to urges that lead to vaping. This model provides a framework for cognitive and behavioral strategies for coping with urges and changing vaping behaviors. Finally, the first visit will include teaching and in vivo rehearsal of cognitive and behavioral strategies for managing urges.

The second and third sessions focus on preparing for and attempting to quit. Visit two will include identifying and disrupting associations between specific environmental cues and vaping behaviors, as well as continued rehearsal of craving management (e.g., urge surfing). Participants and interventionists will collaboratively set a quit date and develop a behavioral cessation plan, with a focus on employing specific alternative behaviors at times and in situations when vaping is best-established.

Visit three will occur within 72 h after the quit date and focuses on reviewing the quit attempt. For successful quitters, content will focus on coping strategies employed, use of medications, experience of urges and temptations and introducing the notion of high risk for relapse situations. For those not meeting their quit goal, content will center on exploring and identifying barriers to abstinence, revisiting motivation to quit and setting new goals, including a new quit date if appropriate.

Visits four through six will focus on maintenance and avoiding relapse. Each will begin with a brief review of successes and challenges since last visit, including identifying alternative non-vaping strategies as needed. Visit four will include discussion of links between thoughts, emotions and behaviors and strategies for identifying and challenging maladaptive cognitions or negative emotions that trigger urges. Visit five will focus on stress management and will include practicing a relaxation exercise. Visit six will focus on planning for long-term abstinence.

2.4. Measurement

With participants' consent, demographic information will be obtained from the electronic medical record. At baseline, assessment will include measures of nicotine dependence adapted from the PATH study [25], current and past quantity/frequency of use of nicotine and tobacco products, and current use of alcohol and cannabis. Additionally, vaping device(s) used and frequency of replenishment will be assessed [26]. The assessment will also include participant ratings of motivation to quit, confidence in quitting, and perceived harm from vaping. Vaping expectancies will be assessed using the Electronic Nicotine Vaping Outcomes (ENVO) scale [27]. At each intervention visit, vaping quantity and frequency since the past visit will be re-assessed. Nicotine dependence will be re-assessed at visit 6. At the 12-week follow-up, assessment will include vaping quantity and frequency, nicotine dependence, and alcohol and cannabis use. Assessments at both visit 6 and 12-week follow-up will also include participant ratings of the intervention, including satisfaction, ease of access, length of visits, and helpfulness and appropriateness of content. Finally, at the 12-week follow-up research staff will interview participants to obtain qualitative information about potential protocol improvements.

2.5. Statistical analysis

Feasibility and acceptability. Descriptive statistics will be used to evaluate responses to questionnaire items. Sample means and standard deviations or percentages will be reported as appropriate. We plan to compare means at end of treatment to means at follow-up, and to compare the telephone and video groups, but given the small sample no inferential statistics will be used.

Vaping outcomes. Longitudinal regression models will be used to examine changes in vaping and nicotine dependence over time. Two separate models will evaluate vaping behavior over time; the first will evaluate change in vaping frequency, and the second will evaluate change in vaping status (i.e., vaped in the past week or not). Both models will include all timepoints (baseline and visits 1–6). The model of nicotine dependence will include all 3 timepoints at which dependence is evaluated (baseline, visit 6, follow-up). For all models, we expect significant associations between outcomes and linear time, suggesting vaping and dependence decline over the course of the intervention and follow-up.

3. Results

Recruitment began in the autumn of 2023, and we expect to

complete data collection in late spring 2024. Data analysis and interpretation are planned for completion in autumn 2024.

4. Discussion

4.1. Study overview

This project utilizes the academic and clinical expertise of the study team to adapt an existing intervention for use with Veterans who vape nicotine. This study will uniquely assess an intervention that has been adapted both for vaping and for a Veteran population. The study will also compare multiple remote delivery methods, increasing knowledge and the potential for dissemination across VHA and other healthcare systems.

4.2. Limitations

Some limitations are inherent in the study design. First, the small sample size may limit our ability to detect change over time. The longitudinal analytic approach will help to reduce the impact of this concern. Second, there is no clear standard in the field for capturing quantity and frequency of vaping. To account for this we will employ multiple assessments of these constructs, including vaping sessions per day, days of vaping per week, vaping product(s) used, and frequency of refilling/replenishing the product(s).

4.3. Future directions

If the pilot findings suggest that this intervention helped participants to quit or reduce vaping, we will seek funding to conduct a larger, well-powered efficacy trial based on these findings. In contrast, if initial findings suggest that the intervention was not effective, our next steps will focus on analysis of qualitative data gathered at follow-up to understand how the intervention could be adjusted to better meet the needs of younger Veterans who vape nicotine.

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CRediT authorship contribution statement

Neal Doran: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Samantha Hurst:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Jie Liu:** Writing – review & editing, Project administration, Methodology, Conceptualization. **Omar El-Shahawy:** Writing – review & editing, Conceptualization. **Mark Myers:** Writing – review & editing, Methodology, Conceptualization. **Paul Krebs:** Writing – review & editing, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Neal Doran and Paul Krebs report financial support was provided by University of California System (California Tobacco-Related Disease Research Program). If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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