



## Treatment development, implementation, and participant baseline characteristics: A randomized pilot study of a tailored quitline intervention for individuals who smoke and vape

Katrina A. Vickerman<sup>a,\*</sup>, Kelly M. Carpenter<sup>a</sup>, Lyndsay N. Miles<sup>a</sup>, Johnathan M. Hsu<sup>c</sup>, Karen A. Watt<sup>a</sup>, Thomas H. Brandon<sup>b</sup>, Jonathan T. Hart<sup>c</sup>, Harold S. Javitz<sup>d</sup>, Theodore L. Wagener<sup>e,1</sup>

<sup>a</sup> Optum Health, 11000 Optum Circle, Eden Prairie, MN, 55344, USA

<sup>b</sup> H Lee Moffitt Cancer Center and Research Institute, 12902 Magnolia Drive, Tampa, FL, 33612-9497, USA

<sup>c</sup> TSET Health Promotion Research Center, University of Oklahoma Health Sciences Center, 655 Research Parkway, Suite 400, Oklahoma City, OK, 73104, USA

<sup>d</sup> SRI International, 333 Ravenswood Avenue, Menlo Park, CA, 94025, USA

<sup>e</sup> University of Oklahoma Health Sciences Center, 655 Research Parkway, Suite 400, Oklahoma City, OK, 73104, USA

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### ABSTRACT

**Background:** Approximately 57,000 dual users of cigarettes and e-cigarettes call state tobacco quitlines in the U.S. each year.

**Methods:** This paper describes a behavioral intervention for dual users of cigarettes and e-cigarettes designed to increase cigarette abstinence. It also presents baseline data from a randomized pilot comparing the Enhanced E-cigarette Coaching (EEC) intervention with quitline treatment as usual (TAU). Oklahoma Tobacco Helpline callers were recruited at registration and randomized to EEC ( $n = 46$ ) or TAU ( $n = 50$ ). Treatment included 5 coaching calls and free nicotine replacement therapy (NRT). EEC treatment included enhanced e-cigarette assessment, education, a shared decision-making quit plan development approach, and tailored behavioral support.

**Results:** Participants averaged 40.6 years of age and 19.2 cigarettes per day; 85% smoked daily, 48% vaped daily, and 53% reported medium to high e-cigarette dependence. Most reported using e-cigarettes to quit (43%) or to cut down (26%) on smoking. Most had previously tried to quit smoking (91%) and had tried FDA-approved cessation medications (79%). Beliefs about vaping, NRT, and smoking included misinformation. After discussing the relative risks of NRT, vaping, and smoking, most EEC participants (89%) selected a quit plan that incorporated both NRT and vaping.

**Conclusions:** At baseline, most participants reported a history of failed quit attempts with NRT and were vaping to quit or cut down on smoking, but they may need more support to completely quit smoking. If the EEC improves smoking outcomes, it would provide needed guidance on behavioral support best practices for individuals who vape and want to quit smoking.

### 1. Introduction

Smoking continues to be the leading preventable cause of death and morbidity for adults in the United States [1]. E-cigarettes, also known as Electronic Nicotine Delivery Systems (ENDS) and vaping devices, were used by 4.5% of US adults in 2019, most of whom were current or former

smokers, and many of whom used e-cigarettes to assist with quitting smoking [2–5]. Although e-cigarettes are not FDA approved for smoking cessation, they are commonly used by smokers in the US trying to quit [6] and are promoted as a cessation aid in the UK [7].

Randomized trials have produced preliminary evidence that vaping is generally safe in the short term, may be more effective than NRT in

\* Corresponding author.

E-mail addresses: [Katrina.vickerman@optum.com](mailto:Katrina.vickerman@optum.com) (K.A. Vickerman), [jonathan-hart@ouhsc.edu](mailto:jonathan-hart@ouhsc.edu) (J.M. Hsu), [Thomas.Brandon@moffitt.org](mailto:Thomas.Brandon@moffitt.org) (T.H. Brandon), [Harold.javitz@sri.com](mailto:Harold.javitz@sri.com) (H.S. Javitz), [Theodore.wagener@osumc.edu](mailto:Theodore.wagener@osumc.edu) (T.L. Wagener).

<sup>1</sup> Ohio State University Comprehensive Cancer Center (present address), Wexner Medical Center, 3650 Olentangy River Rd. Columbus, OH 43214.

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helping people quit smoking, that nicotine containing e-cigarettes are more helpful than no-nicotine e-cigarettes, and that vaping can be safely combined with NRT [8–10]. Although the research evidence is not substantial enough for US regulatory bodies to promote vaping as a smoking cessation tool, adults in the US are already using e-cigarettes to quit about as frequently as FDA-approved cessation medications [6]. Each year, approximately 57,000 adults (15% of callers) who call publicly funded tobacco quitlines for help quitting traditional cigarettes are dual users of e-cigarettes at program registration [11,12], and most of those users are vaping to quit or cut down on their smoking [11,13].

The literature is sparse with regard to how to help smokers best use e-cigarettes to completely quit smoking cigarettes. As with nicotine replacement therapy (NRT), individuals planning to quit smoking utilizing e-cigarettes may be more successful with empirically supported education and behavioral support. Qualitative interviews with quitline callers who both smoke and vape found misunderstandings about the relative risks of smoking, vaping and using NRTs [14]. Furthermore, despite stating that they want to use e-cigarettes to quit smoking, dual users may not utilize strategies that facilitate quitting smoking completely. Treatment recommendations from the U.S. Centers for Disease Control and Prevention advise educating smokers that e-cigarettes are not an empirically supported quitting aid and recommending use of FDA-approved cessation medications, such as NRT, as first line treatment [15]. However, for smokers who have tried FDA-approved cessation medications without success and/or are committed to using e-cigarettes for cessation, providers should support their quit attempt [16–18]. These recommendations need translation into practice and testing. Furthermore, although e-cigarettes are likely far less harmful than combustible cigarettes, they are not completely safe. Any plan to switch completely from smoking to vaping should also include support for a long-term goal to quit vaping.

The purpose of the present study was to develop and pilot test a novel behavioral intervention designed to be delivered by quit coaches at a publicly funded tobacco quitline. The target audience was quitline callers who were dual users (i.e., using both combustible cigarettes and e-cigarettes) at enrollment and who were interested in using e-cigarettes as part of their cessation plan. The present article outlines the development of the novel coaching intervention, including a 10-person proof-of-concept study, and describes baseline data collected from dual users recruited into the randomized pilot study.

## 2. Methods

### 2.1. Study design

In this 2-arm randomized controlled trial, individuals who contacted the Oklahoma Tobacco Helpline (OTH) and were both smoking cigarettes and vaping were randomized to receive helpline treatment as usual (TAU) or an Enhanced E-cigarette Coaching (EEC) intervention. We utilized an automated algorithm to allocate participants to a study group, using blocked randomization with stratification on gender to achieve a similar proportion of males and females in each treatment group.

The Western Institutional Review Board (WIRB) approved the study protocols. We transferred oversight to UnitedHealth Group's (UHG) Office of Human Research Affairs (OHRA) after recruitment was completed.

### 2.2. Participants

We recruited individuals who called the OTH between November 28, 2018 and March 31, 2020, and met the following criteria: 1) used e-cigarettes in the past 30 days; 2) smoked at least one cigarette per day; 3) eligible for a one or multiple call coaching program (eligibility was expanded to include participants eligible for a one-call program on August 15, 2019); 4) ready to quit smoking in the next 30 days; 5) not

pregnant or planning to become pregnant in the next 3 months; 6) at least 18 years old; 7) English speaking; and 8) did not report a diagnosis of schizophrenia during OTH enrollment. Individuals who met these initial criteria were presented with a brief study description and were invited to be screened for the study. Additional screening criteria included: 1) currently using e-cigarettes some days or every day; 2) possible or very likely to use e-cigarettes while trying to quit smoking (excluded 'not at all likely'); 3) access to an Android smartphone, operating system 6.0 or higher; 4) access to a phone and email; 5) willing and able to use a free study app to complete brief daily surveys for 12 weeks; 6) not currently taking Varenicline or Bupropion; 7) no heart attack, stroke, or TIA in past two weeks; 8) no serious or worsening angina or heart pain in the past 6 months; 9) no rapid or irregular heartbeat requiring a change in activity or medications in the past 6 months, and; 10) no other household members already enrolled in the study.

### 2.3. Procedures

After quitline enrollment and screening for study eligibility, eligible callers who were interested in participating in the study were transferred to a research trained Quit Coach to provide verbal informed consent. Those who provided consent then completed a baseline assessment and were randomized to TAU or EEC. Participants were required to complete their first coaching call to remain in the study. This decision was made to prioritize study resources on examining treatment impacts for individuals who received at least some treatment exposure. Participants were not informed of their group assignment at randomization; thus, we do not attribute loss between baseline and call 1 to participant group assignment. Both groups received 5 coaching calls and could contact the OTH for support as needed. The amount of NRT available to OTH callers was determined by their health insurance status. Depending on their coverage status, callers were eligible for either 8 weeks of combination NRT (patch plus gum or lozenge), or 2 weeks of mono-NRT.

We provided study incentives for completing the baseline survey (\$20), outcome survey (\$50), and biochemical quit status verification (\$50). For daily survey completion, we provided up to \$60 (\$5 for each week that participant completed 5 or more surveys or the longer weekly survey). Additionally, participants received a bonus of \$25 if they completed 60–79% of the daily surveys, and another \$25 if they complete 80% or more. Selected EEC participants also received \$50 for completing a qualitative interview about their experiences with the intervention and recommendations for improvement.

**Daily Surveys.** We asked participants to download the Insight™ mHealth app [19] onto their personal Android smartphone to complete daily surveys for 12 weeks. Participants were asked 3–4 questions daily about their tobacco and e-cigarette use, and a slightly longer survey once a week to collect additional details about products used. Participants' preferred time to receive reminder messages to complete their daily surveys was entered during app setup. The daily surveys took about 1 min and the weekly surveys about 3 min to complete. At week 4 and week 8, if a participant completed less than 5 daily surveys or did not complete the longer weekly survey, then a research assistant made up to 5 attempts to complete a Timeline Follow Back (TLFB) survey assessing product use via phone.

**Outcomes survey at 3 months.** Outcomes were assessed 3 months after study enrollment. Participants were emailed a link to a web-based survey and received a reminder email 3 days later. Participants who did not respond after a week were contacted by phone to complete the survey. Up to 11 attempts were made to reach the participant. Phone survey staff were not otherwise involved in the study and were blind to participant condition. If the participant did not complete the survey within a month, the research team sent a final email asking the participant to complete a brief outcomes survey with four questions about product use and satisfaction.

**Biochemical verification of smoking status.** If a participant self-reported being abstinent from tobacco for 7 or more days at the 3-month survey, we mailed them an iCO™ Smokerlyzer®. The iCO™ Smokerlyzer® is a breath carbon monoxide (CO) monitor that the participant plugs into their Android smartphone. The Insight study app provided step by step instructions for the participant to calibrate and breathe into the Smokerlyzer® to complete a reading. We asked participants to provide 1 reading each day for 3 consecutive days. Three readings of 6 parts per million (ppm) or lower confirmed the participant's smoking abstinence.

#### 2.4. Interventions

The OTH is operated by Optum, the largest provider of tobacco cessation quitline services in the US. Optum's Quit For Life® program is an evidence-based tobacco cessation treatment delivered over phone, web, and text, and is grounded in social cognitive theory and the US Public Health Service (PHS) clinical guidelines (Fiore et al., 2008). Phone counseling for tobacco cessation has been evaluated in randomized trials and real-world effectiveness studies [20–23].

**TAU.** The OTH standard quitline program was the control, treatment as usual (TAU) group. Treatment included 5 coaching calls to help the participant throughout their quit process, from setting a quit date to successfully quitting tobacco to relapse prevention. Mailed support materials and an interactive web-based program supplemented these coaching calls. The OTH offers participants free cessation medications such as nicotine patch, gum, lozenge, or a combination of these, depending on insurance coverage. Quit coaches tailor counseling content and call timing to the participant's availability, quit date, and support requested. In Call 1, coaches focus on assessing the participant's tobacco use, treatment needs, and NRT dosing. In Call 2, they support the participants near their quit date, and in calls 3–5, they provide ongoing support for tobacco cessation and relapse prevention. Given the extensive evidence base of FDA-approved quit medications [24] and lack of FDA approval for vaping as a quit aid, vaping is not encouraged by quit coaches. Individuals who vape are encouraged to switch to FDA-approved cessation aids, such as the NRT products provided by the OTH. While coaches encourage participants to use FDA-approved medications, they will support those who choose to use an e-cigarette as a quit aid. At the time of this study, e-cigarette use in the last 30 days was assessed at registration, and, unless the topic was initiated by a caller, vaping was not typically addressed in coaching calls.

**EEC.** The experimental group (EEC) received a new intervention based on the Quit For Life® program that incorporates strategies for dual users of cigarettes and e-cigarettes to support their cessation of all combustible and smokeless tobacco. Given the serious health impacts of smoking, evidence that vaping is less harmful than smoking, and randomized trials indicating that e-cigarettes may be an effective quitting aid for smoking [1,15,25], smoking cessation was the primary treatment target. Vaping cessation was not a primary treatment target: if callers were using an e-cigarette during their quit attempt, they were advised to quit vaping after they were confidently quit from smoking with the recognition that this may not be during the study timeframe. Callers were advised they could contact the OTH for help quitting vaping in the future if needed.

The EEC treatment focused on 3 key components: education, a shared decision making (SDM) model for quit plan development, and tailored behavioral support. Previous work indicated that there is widespread misinformation concerning the relative harm of cigarettes, e-cigarettes and NRT and that quitline callers trying to use e-cigarettes to quit smoking may not use the most effective strategies to completely switch [26]. Furthermore, individual differences in previous experiences with e-cigarettes and NRT suggest that a tailored approach involving education and SDM could increase success. SDM is a patient-centered approach to decision making recommended in healthcare situations where there is more than one reasonable treatment option [27,28].

Elywn et al. have detailed a 3-step model for implementing SDM in practice: (1) introducing choice, (2) describing options including education, discussion, and decision aids, and (3) discussing preferences and making an informed decision. Patient-centered techniques such as SDM have been associated with improved health self-management, adherence, and outcomes [29,30]. Although generally efficacious, the majority of NRT users do not successfully quit smoking [24], indicating the need for more cessation options. Quitline data suggested that participants using e-cigarettes during their quit attempt may not discuss this with their quit coaches, and they may continue to vape despite recommendations to switch to NRT [26]. Moreover, increasing evidence suggests switching from cigarettes to e-cigarettes is a promising harm reduction strategy [9]. Thus, the SDM paradigm was a good fit for systematically addressing options, offering education, and supporting an informed decision among quit plan choices for smokers already using e-cigarettes.

In the first EEC call, quit coaches assessed participants' previous history with quitting smoking, use of cessation medications, and e-cigarette use. Coaches then led the participants through an SDM discussion offering 4 alternatives for a quit plan: using NRT, using e-cigarettes, using both NRT and e-cigarettes, and using no nicotine replacement. During this discussion, coaches elicited beliefs about relative harms of nicotine, smoking cigarettes and vaping and offered targeted education. Educational information included: 1) low relative risk of using nicotine (as nicotine is not the element in cigarettes that causes disease and death); 2) NRT was highly recommended as the first line of treatment, particularly if it had never been tried, given the decades of research on effectiveness and safety and FDA approval for quitting; 3) using combination NRT (nicotine patch plus gum or lozenge) can increase chances of success over mono NRT; 4) less research on e-cigarettes (which are not FDA approved) but there are promising studies - some people say they are helpful for quitting; 5) vaping is considerably safer than smoking (but is not completely safe) and likely safe for short-term use and; 6) the importance of completely quitting smoking cigarettes. Participants who chose to use e-cigarettes as part of their quit plan were given tailored behavioral support with the goal of helping participants completely quit smoking. Suggestions focused on receiving sufficient nicotine replacement to effectively manage cravings, such as: using a nicotine-containing e-cigarette, vaping every day and frequently throughout the day, taking longer and slower puffs, and finding a device type and nicotine level that delivers sufficient nicotine to help conquer cravings. These suggestions were necessary at the time recruitment started when many participants were using devices that varied widely in their ability to deliver nicotine. Currently with nicotine salt devices, which deliver nicotine nearly as efficiently as cigarettes, used by the majority of e-cigarette users in the US, the final suggestion may not be as relevant. In calls 2–5, coaches assessed adherence to selected quit plan, current product use, and craving management, supported participants in their choice of quit aid and provided problem solving support. See [Table 1](#) for more information on how the EEC and TAU treatments compare.

**EEC Quit Guides.** We developed 2 tailored quit guides for dual users of cigarettes and e-cigarettes trying to quit smoking. The guides were sent to participants following calls 1 and 3. EEC quit guide 1 included education about e-cigarettes, quit medications, nicotine, and cigarettes; exercises to reflect on why, when, and how they vape; selecting one of the four quit plan options (NRT, vaping device, NRT plus vaping device, no nicotine replacement) and; behavioral support tips for those planning to vape while quitting smoking. EEC quit guide 2 included information about completely quitting smoking, staying quit, getting social support, and quitting vaping.

**EEC Coaching Training.** Four Bachelor's-level tobacco cessation quit coaches delivered the EEC intervention. They received 8 h of study training as well as feedback and support throughout the study. These coaches had previously received 240 h of tobacco cessation treatment training and ongoing supervision as part of their employment at the quitline, as well as human subjects training. Study training included

**Table 1**  
Quitline treatment as usual (TAU) and enhanced E-cigarette coaching (EEC) treatment elements.

Call Number	Quitline TAU (control)	Enhanced E-cigarette Coaching (EEC) Intervention
Every call	Intervention grounded in social cognitive theory and US PHS clinical guidelines. Assessment of current status and challenges. Modify medications or set new quit date if needed.	Quitline TAU components <i>PLUS</i> behavioral support and education regarding e-cigarette use, EEC educational booklets referenced.
Call 1: <i>Assessment &amp; Planning</i>	Program overview, assessment and planning with focus on setting a quit date, cessation medications, urge management, tobacco proofing and support. Quit Guide mailed.	(1) Assessment of e-cigarette use and intentions for use, (2) Education on relative harms of e-cigarettes, NRT and cigarettes, and (3) shared decision making (SDM) on use of e-cigarettes and FDA-approved cessation medications in quit plan. Tailored EEC educational booklet #1 mailed to participant.
Call 2: <i>Quit date</i>	Discuss quit date preparation, reinforce quit plan, set new quit date if needed.	Reinforce QP including use of e-cigarettes and/or medications. Tailored EEC educational booklet #2 mailed to participant.
Calls 3–5: <i>Quit date follow-up</i>	ACE model of relapse prevention (avoid, cope, escape), social support, tobacco proofing.	If currently using e-cigarettes: (1) behavioral coaching to use e-cigarettes/NRT to prevent relapse to smoking, (2) address intentions for long-term use of e-cigarettes.
NRT provision	Same for both groups. All are eligible for 2–8 weeks of NRT (depending on insurance status)	
NRT dosing	Typically based on CPD prior to start of dual use, but also utilizes quit coach judgement guided by an established dosing protocol. Strongly encourages stopping all non-NRT forms of nicotine (including e-cigarettes) on quit date.	Participants will work with coaches using SDM to determine plans for e-cigarettes and NRT use while quitting. NRT dosing will be adjusted if participants plan to continue e-cigarette use. Coaches will assess potential side effects and quit plan adherence on every call and make needed adjustments to the QP or NRT dosing.

information about e-cigarette products, safety, and regulation education; reviewing participant educational materials (EEC quit guides), the SDM model for quit plan development, examples of potentially adaptive and maladaptive e-cigarette use strategies for smoking cessation, and tailored behavioral support strategies. Quit coaches followed an unscripted EEC protocol, and the study team assessed their skill before and throughout treatment delivery.

**EEC Treatment Fidelity.** The study team reviewed 20% of participants' calls to ensure treatment fidelity. Calls were reviewed for eight call elements: (1) call introduction and agenda set, (2) e-cigarette use assessment, (3) shared decision making quit plan development (for calls 2–5: quit plan reviewed and adjusted, if needed), (4) accurate education about e-cigarettes, quit medications, and nicotine provided with attempts to elicit participant beliefs, (5) behavioral cessation support tailored to participant's chosen quit plan, (6) maintained focus on smoking cessation as primary intervention target, (7) matched participant's terminology for e-cigarettes, and (8) call close: action step review and program next steps.

**EEC Proof-of-Concept Study.** Prior to conducting the randomized pilot trial, we conducted a Phase IIa proof-of-concept study [31] with 10 participants to determine whether updates were needed to the developed treatment or study procedures. Participants were recruited in May and June of 2018 from the OTH. Individuals who had completed their

first coaching call in the standard OTH program were contacted by study staff to check eligibility, obtain consent, and complete the baseline survey. All 10 participants were contacted to complete additional EEC intervention content intended for Call 1 and received four additional outbound coaching calls. Outcome data was gathered after 2 months. Participants completed 3.4 out of 5 calls on average (SD = 1.3, range = 1–5). We reviewed 22 calls for EEC treatment fidelity. Across calls, 90.1% of treatment elements were rated as present. Eight of 10 participants chose to use both NRT and e-cigarettes while quitting smoking; two chose to use combination NRT (patch plus gum or lozenge). Among the 7 who completed a 2-month outcome survey (70% response rate), all 7 were "very satisfied" with treatment and were "very likely" to recommend the program to others who use e-cigarettes and want to quit smoking. Five of the 7 respondents had been cigarette abstinent for 7 or more days (50% of the Phase 1 sample; 71.4% of outcome survey respondents); 3 out of 7 had been smoking abstinent for 30 or more days. Five participants recommended using both NRT and vapes as the best strategy for quitting smoking and 1 recommended NRT (1 did not respond to this question). All participants reached for their outcome survey (n = 7) were then invited to participate in a qualitative interview; 5 completed these interviews.

Outcome data and fidelity monitoring indicated readiness to proceed to the randomized trial. Based on the proof-of-concept study, two eligibility questions were revised because two of the 10 participants reported some recent e-cigarette use, but use was not frequent, and they had no interest in continuing to vape. Because the treatment was created for individuals who were currently vaping and smoking, and were likely to do so during their smoking cessation process, we added an additional question on current e-cigarette use (the randomized trial excluded anyone who reported e-cigarette use in the last 30 days but reported current use was "not at all" versus some or every day) and likelihood of using e-cigarettes while quitting smoking (the randomized trial excluded those who said "not at all likely" rather than "possible" or "very likely").

## 2.5. Measures

During standard OTH program enrollment participants reported on demographics (age, gender, race, ethnicity, education, insurance status), behavioral health conditions (i.e., depression, anxiety, bipolar disorder, post-traumatic stress disorder (PTSD)), and chronic conditions (i.e., Chronic Obstructive Pulmonary Disease (COPD), Coronary Artery Disease (CAD), and Asthma). Enrollment data predominately included minimum dataset (MDS) variables recommended by the North American Quitline Consortium [13].

**Tobacco use history.** Standard OTH enrollment and the study baseline survey included assessment of tobacco use (types, number of cigarettes per day, frequency of use (every day vs. some days), time to first cigarette after waking), readiness to quit, and presence of other tobacco users at home, work, and in social network [13,32]. We also assessed participant's previous quit attempts and past use of FDA-approved quit medications.

**E-cigarette use, dependence, and beliefs.** At enrollment, we asked individuals about their e-cigarette use and frequency of use [33]. In the baseline survey, we further assessed frequency of use, length of use, whether they used a disposable, refillable and/or modular device, nicotine content, most frequently used flavor, primary reason for use [34], helpfulness with quitting smoking, and presence of other vapers at home, work, and in social network. Dependence on e-cigarettes was measured with the Penn State Electronic Cigarette Dependence Index [35].

**Psychosocial functioning and substance use.** To measure depression, anxiety, and stress, we used the 2-item Patient Health Questionnaire (PHQ-2; [36], the Generalized Anxiety Disorder 2-item (GAD-2; [37], and the 4-item Perceived Stress Scale [38,39], respectively. We completed an alcohol and drug screen to assess for binge

drinking in the past year [40], illegal drug use episodes in the past year [41,42], days of marijuana use in the last 30 days, and mode of use [43].

**Knowledge and Beliefs.** Using questions adapted from published surveys [32,34,44–46], we asked participants about: their knowledge and beliefs regarding the relative harm of cigarettes, e-cigarettes, and NRT; risk reduction from cutting down on smoking; utility of e-cigarettes and NRT for quitting smoking and; beliefs about the harmfulness and use of NRT and nicotine. These questions included items chosen to parallel education points in the EEC intervention in order to assess knowledge and beliefs as a secondary outcome measure. Coding of accuracy/inaccuracy of these items was based on publications from national institutions such as the National Academies of Sciences, Engineering, and Medicine [25]; systematic reviews (e.g., Ref. [47]); and public health guidelines such as those from the Surgeon General [1]. Not all items had specified right and wrong answers, but were offered for descriptive purposes.

2.6. Analysis

Participant baseline characteristics were summarized using

proportions (with 95% confidence intervals (CIs)) and means (with SEs). Differences between groups were examined using Fisher’s exact test, rank-sum tests (for all scale scores, number of quit attempts, number of friends who smoked/vaped) and t-tests (for age and cigarettes per day) with an alpha level of 0.05. Missing data were reported as a category included in p-value calculations for categorical variables and noted in table footnotes for continuous variables.

3. Results

The CONSORT diagram is presented in Fig. 1. From the 11,694 OTH callers who were eligible for a phone coaching program and planning to quit in the next 30 days, 17.9% (2100) were current users of cigarettes and e-cigarettes. Of these, 918 (43.7%) met initial eligibility criteria, were provided a brief description of the study, and were asked if they would like to be screened. Just over a third (36.4%, n = 334) declined to be screened, and 10.1% (n = 93) were not screened due to a human or technology error. A total of 486 were screened, and 68% did not meet additional inclusion criteria (n = 331). Participants were asked all screening questions and could screen out for multiple reasons. The most

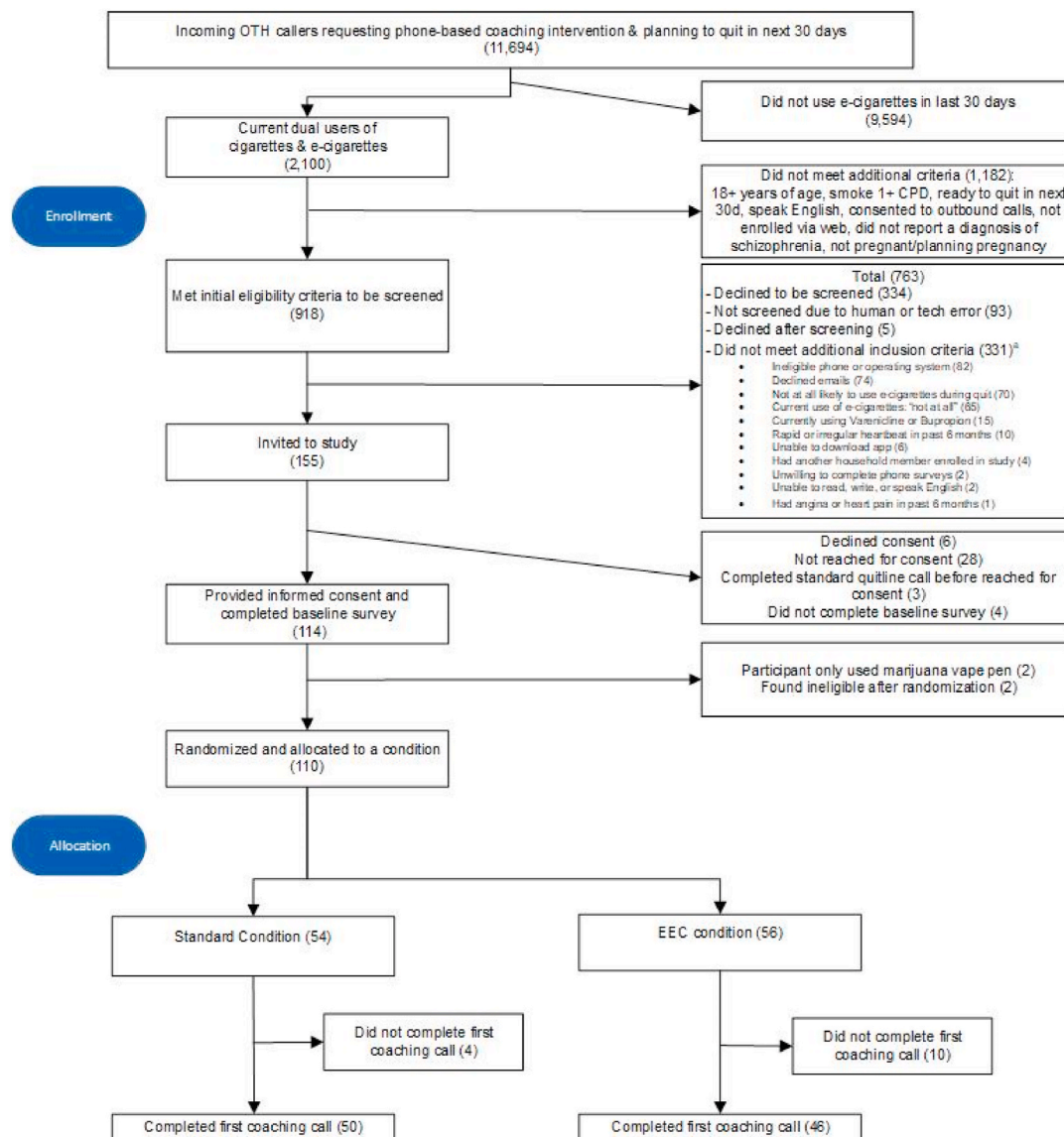


Fig. 1. Consort diagram

<sup>a</sup> Participants could have had one or more reasons that they “Did not meet additional inclusion criteria”. Numbers for specific reasons are not mutually exclusive and sum to more than 331.

frequent reasons included: ineligible smartphone ( $n = 82$ ), declining to receive emails ( $n = 74$ ), “not at all likely” to use e-cigarettes during their quit attempt ( $n = 70$ ), and reporting “not at all” about current use of e-cigarettes ( $n = 65$ ). This yielded 155 eligible callers, 114 of whom provided informed consent and completed the baseline survey. After the baseline survey, 4 additional participants were found to be ineligible, and were not randomized to a treatment group. Four TAU participants and 10 EEC participants did not complete their first coaching call and were removed from the study, as described during consent procedures.

Table 2 presents baseline data on demographics and psychosocial characteristics for the TAU and EEC groups. Table 3 presents smoking/tobacco and e-cigarette use, dependence, and medication use for the TAU and EEC groups. Table 4 presents beliefs related to vaping, smoking, quit medications, and nicotine for the TAU and EEC groups. There were no significant differences between the groups for any of these measures.

### 3.1. Demographics

The mean age for the study participants was 40.6 years. Most participants were female (61.5%), White or Caucasian (64.6%), and non-Hispanic (88.5%). However, a notable percent of participants self-reported as American Indian/Alaska Native (12.5%) or both American Indian/Alaska Native and White/Caucasian (11.5%), for a total of 24% reporting American Indian/Alaska Native ancestry. More than one third (37.5%) reported high school level education or less. One third (34.4%) reported having private or Medicare insurance, 20.8% reported Medicaid insurance, and 43.8% reported having no insurance. One fourth (24.0%) reported one or more chronic conditions, with asthma (16.7%) and COPD (8.3%) as the most commonly reported conditions.

**Table 2**  
Demographics and participant psychosocial characteristics at quitline enrollment and baseline survey.

Demographics	Total Sample ( $n = 96$ )			Enhanced E-cigarette Coaching (EEC) ( $n = 46, 48\%$ )			Quitline Treatment as Usual (TAU; control) ( $n = 50, 52\%$ )			p-value
	n	%	95% CI	n	%	95% CI	n	%	95% CI	
<b>Age (in years), Mean (SE)</b>	40.6 (1.4)		[37.9,43.4]	40.6 (2.2)		[36.2,44.9]	40.7 (1.8)		[37.1,44.3]	0.9679
18-24	16	16.7	[9.1,24.3]	10	21.7	[9.4,34.1]	6	12.0	[2.7,21.3]	0.2683
25-40	34	35.4	[25.7,45.2]	12	26.1	[12.9,39.3]	22	44.0	[29.7,58.3]	
41-60	40	41.7	[31.6,51.7]	21	45.7	[30.7,60.6]	19	38.0	[24.1,51.9]	
61+	6	6.3	[1.3,11.2]	3	6.5	[0.0,13.9]	3	6.0	[0.0,12.8]	
<b>Sex, Female</b>	59	61.5	[51.5,71.4]	30	65.2	[50.9,79.5]	29	58.0	[43.8,72.2]	0.5319
<b>Race</b>										
White or Caucasian	62	64.6	[54.8,74.3]	32	69.6	[55.8,83.4]	30	60.0	[45.9,74.1]	0.1910
Black or African American	7	7.3	[2.0,12.6]	5	10.9	[1.5,20.2]	2	4.0	[0.0,9.6]	
American Indian or Alaska Native	12	12.5	[5.8,19.2]	5	10.9	[1.5,20.2]	7	14.0	[4.0,24.0]	
American Indian or Alaska Native AND White/Caucasian	11	11.5	[5.0,17.9]	2	4.3	[0.0,10.5]	9	18.0	[7.0,29.0]	
More than One Race	4	4.2	[0.1,8.2]	2	4.3	[0.0,10.5]	2	4.0	[0.0,9.6]	
<b>Ethnicity<sup>a</sup></b>										
Hispanic	3	3.1	[0.0,6.7]	1	2.2	[0.0,6.6]	2	4.0	[0.0,9.6]	0.3152
Non-Hispanic	85	88.5	[82.1,95.0]	39	84.8	[74.0,95.6]	46	92.0	[84.2,100.0]	
No data	8	8.3	[2.7,14.0]	6	13.0	[2.9,23.2]	2	4.0	[0.0,9.6]	
<b>Education<sup>a</sup></b>										
Less than High School	7	7.3	[2.0,12.6]	4	8.7	[0.2,17.2]	3	6.0	[0.0,12.8]	0.1044
High school or GED	29	30.2	[20.9,39.6]	18	39.1	[24.5,53.8]	11	22.0	[10.1,33.9]	
Some college	29	30.2	[20.9,39.6]	8	17.4	[6.0,28.8]	21	42.0	[27.8,56.2]	
College graduate or more	21	21.9	[13.5,30.3]	11	23.9	[11.1,36.7]	10	20.0	[8.5,31.5]	
No data	10	10.4	[4.2,16.6]	5	10.9	[1.5,20.2]	5	10.0	[1.4,18.6]	
<b>Insurance Type<sup>a</sup></b>										
Uninsured	42	43.8	[33.6,53.9]	17	37.0	[22.5,51.4]	19	38.0	[24.1,51.9]	0.0777
Medicaid	20	20.8	[12.6,29.1]	14	30.4	[16.6,44.3]	6	12.0	[2.7,21.3]	
Insured + Medicare	33	34.4	[24.7,44.0]	14	30.4	[16.6,44.3]	25	50.0	[35.6,64.4]	
No data	1	1.0	[0.0,3.1]	1	2.2	[0.0,6.6]	0	–	–	
<b>Chronic Conditions, 1 +</b>	23	24.0	[15.3,32.7]	14	30.4	[16.6,44.3]	9	18.0	[7.0,29.0]	0.2311
Asthma	16	16.7	[9.1,24.3]	11	23.9	[11.1,36.7]	5	10.0	[1.4,18.6]	0.0994
Diabetes	5	5.2	[0.7,9.7]	1	2.2	[0.0,6.6]	4	8.0	[0.2,15.8]	0.3639
COPD	8	8.3	[2.7,14.0]	5	10.9	[1.5,20.2]	3	6.0	[0.0,12.8]	0.4740
Coronary Artery Disease	2	2.1	[0.0,5.0]	2	4.3	[0.0,10.5]	0	–	–	–
<b>Behavioral Health Condition<sup>b</sup></b>										
None	24	25.0	[16.2,33.8]	11	23.9	[11.1,36.7]	13	26.0	[13.4,38.6]	0.6284
1	20	20.8	[12.6,29.1]	8	17.4	[6.0,28.8]	12	24.0	[11.7,36.3]	
2+	52	54.2	[44.0,64.3]	27	58.7	[43.9,73.5]	25	50.0	[35.6,64.4]	
<b>Perceived Stress Scale-4 (PSS), Mean (SE)</b>	5.8 (0.4)		[5.1,6.6]	6.0 (0.5)		[5.0,7.0]	5.7 (0.5)		[4.6,6.7]	0.4484
<b>Anxiety (GAD-2), Mean (SE)</b>	2.9 (0.2)		[2.5,3.3]	2.6 (0.3)		[1.9,3.3]	3.2 (0.3)		[2.6,3.8]	0.1482
% 3+ (cutoff)	49	51.0	[40.9,61.2]	21	45.7	[30.7,60.6]	28	56.0	[41.7,70.3]	0.4139
<b>Depression (PHQ-2), Mean (SE)</b>	2.3 (0.2)		[1.8,2.7]	2.4 (0.3)		[1.8,3.0]	2.2 (0.3)		[1.6,2.7]	0.6300
% 2+ (cutoff)	54	56.3	[46.1,66.4]	27	58.7	[43.9,73.5]	27	54.0	[39.7,68.3]	0.6843
<b>Binge drinking 1+ times, past year<sup>c</sup></b>	41	42.7	[32.6,52.8]	18	39.1	[24.5,53.8]	23	46.0	[31.7,60.3]	0.5402
<b>Drug use 1+ times, past year<sup>d</sup></b>	15	15.6	[8.2,23.0]	7	15.2	[4.4,26.0]	8	16.0	[5.5,26.5]	0.9999
<b>Marijuana use, last 30 days</b>	38	39.6	[29.6,49.5]	19	41.3	[26.5,56.1]	19	38.0	[24.1,51.9]	0.8353
Daily MJ use, last 30 days	17	17.7	[9.9,25.5]	9	19.6	[7.7,31.5]	8	16.0	[5.5,26.5]	0.7902

<sup>a</sup> Missing responses and responses of “Refused,” “Do not know,” and “Not collected” are combined and reported as “No data”.

<sup>b</sup> Participants are asked if they have any of the following behavioral health conditions: attention-deficit/hyperactivity disorder (ADHD), bipolar disorder, depression, drug abuse disorder, gambling addiction, generalized anxiety disorder, post traumatic stress disorder (PTSD), and/or schizophrenia.

<sup>c</sup> Binge drinking defined as 4 or more drinks in a day for women and 5 or more drinks in a day for men.

<sup>d</sup> Drug use defined as using an illegal drug or using a prescription medication for non-medical reasons.

**Table 3**  
Tobacco, vaping, and quit medication use at quitline enrollment and baseline survey.

	Total Sample (n = 96)			Enhanced E-cigarette Coaching (EEC) (n = 46, 48%)			Quitline Treatment as Usual (TAU; control) (n = 50, 52%)			p-value
	n	%	95% CI	n	%	95% CI	n	%	95% CI	
<b>Multiple tobacco types, 2+</b>	21	21.9	[13.5,30.3]	10	21.7	[9.4,34.1]	11	22.0	[10.1,33.9]	0.9999
<b>Smoke daily (vs. nondaily)</b>	82	85.4	[78.2,92.6]	41	89.1	[79.8,98.5]	41	82.0	[71.0,93.0]	0.3932
<b>CPD, Mean (SE)</b>	19.2 (1.2)		[16.9,21.5]	19.2 (1.7)		[15.7,22.6]	19.2 (1.6)		[16.0,22.3]	0.9973
<b>Time to first cigarette - ≤ 5 min (vs. &gt; 5 min)</b>	42	43.8	[33.6,53.9]	21	45.7	[30.7,60.6]	21	42.0	[27.8,56.2]	0.8372
<b>Menthol cigarette use</b>										
None	59	61.5	[51.5,71.4]	31	67.4	[53.3,81.5]	28	56.0	[41.7,70.3]	0.1616
Some (both menthol & non-menthol)	13	13.5	[6.6,20.5]	3	6.5	[0.0,13.9]	10	20.0	[8.5,31.5]	
Mainly smoke menthol	24	25.0	[16.2,33.8]	12	26.1	[12.9,39.3]	12	24.0	[11.7,36.3]	
<b>Smoking environment – others smoke at home and/or work, yes</b>	70	72.9	[63.9,82.0]	33	71.7	[58.2,85.3]	37	74.0	[61.4,86.6]	0.8222
<b>Number of closest friends smoke (0–5), Mean (SE)</b>	2.9 (0.2)		[2.5,3.2]	3.2 (0.3)		[2.7,3.7]	2.6 (0.3)		[2.1,3.1]	0.1058
<b>Previous quit attempt, yes</b>	87	90.6	[84.7,96.6]	41	89.1	[79.8,98.5]	46	92.0	[84.2,99.8]	0.7333
<b># of previous quit attempts<sup>a</sup>, Mean (SE)</b>	7.9 (1.2)		[5.5,10.3]	9.0 (2.4)		[4.1,13.9]	6.9 (0.9)		[5.1,8.6]	0.7090
0	9	9.4	[3.4,15.3]	5	10.9	[1.5,20.2]	4	8.0	[0.2,15.8]	0.8611
1	5	5.2	[0.7,9.7]	2	4.3	[0.0,10.5]	3	6.0	[0.0,12.8]	
2-3	31	32.3	[22.8,41.8]	17	40.0	[22.5,51.4]	14	28.0	[15.1,40.9]	
4-5	19	19.8	[11.7,27.9]	8	17.4	[6.0,28.8]	11	22.0	[10.1,33.9]	
6+	32	33.3	[23.7,42.9]	14	30.4	[16.6,44.3]	18	36.0	[22.2,49.8]	
<b>Previously used FDA approved quit medication, yes any</b>	76	79.2	[70.9,87.4]	35	76.1	[63.3,88.9]	41	82.0	[71.0,93.0]	0.6159
NRT product, any of 5	71	74.0	[65.0,82.9]	34	73.9	[60.7,87.1]	37	74.0	[61.4,86.6]	0.9999
Combination NRT, yes	29	30.2	[20.9,39.6]	11	23.9	[11.1,36.7]	18	36.0	[22.2,49.8]	0.2664
Chantix or Bupropion, yes	39	40.6	[30.6,50.6]	17	40.0	[22.5,51.4]	22	44.0	[29.7,58.3]	0.5364
<b>Current quit medication use (any)</b>	7	7.3	[2.0,12.6]	4	8.7	[0.2,17.2]	3	6.0	[0.0,12.8]	0.7067
<b>Vape daily (vs. nondaily)</b>	46	47.9	[37.7,58.1]	20	43.5	[28.6,58.4]	26	52.0	[37.7,66.3]	0.4217
<b>Very likely to use vape while quitting smoking (vs. possible)</b>	46	47.9	[37.7,58.1]	21	45.7	[30.7,60.6]	25	50.0	[36.6,64.3]	0.6880
<b>Nicotine-containing vape, yes</b>	92	95.8	[91.8,99.9]	44	95.7	[89.5,100.0]	48	96.0	[90.4,100.0]	0.9999
<b>Device type</b>										
Disposable	17	17.9	[10.0,25.7]	9	19.6	[7.7,31.5]	8	16.0	[5.5,26.5]	0.1021
Cartridge	19	20.0	[11.8,28.2]	5	10.9	[1.5,20.2]	14	28.0	[15.1,40.9]	
Refill self	21	22.1	[13.6,30.6]	9	19.6	[7.7,31.5]	12	24.0	[11.7,36.3]	
Modular	38	40.0	[30.0,50.0]	23	50.0	[35.0,65.0]	15	30.0	[16.8,43.2]	
No data	1	1.0	[0.0,3.1]	–	–	–	1	2.0	[0.0,6.0]	
<b>Ecig Flavor</b>										
None	1	1.0	[0.0,3.1]	0	–	–	1	2.0	[0.0,6.0]	0.8004
Tobacco	10	10.4	[4.2,16.6]	4	8.7	[0.2,17.2]	6	12.0	[2.7,21.3]	
Menthol, mint, tobacco menthol	12	12.5	[5.8,19.2]	5	10.9	[1.5,20.2]	7	14.0	[4.0,24.0]	
Other (fruit, candy, etc)	73	76.0	[67.3,84.7]	37	80.4	[68.5,92.3]	36	72.0	[59.1,84.9]	
<b>Primary reason for Ecig use</b>										
To quit smoking	41	42.7	[32.6,52.8]	17	37.0	[22.5,51.4]	24	48.0	[33.7,62.3]	0.5610
To cut down smoking	25	26.0	[17.1,35.0]	15	32.6	[18.5,46.7]	10	20.0	[8.5,31.5]	
Use when cannot smoke	18	18.8	[10.8,26.7]	9	19.6	[7.7,31.5]	9	18.0	[7.0,29.0]	
Avoid returning to smoking	4	4.2	[0.1,8.2]	1	2.2	[0.0,6.6]	3	6.0	[0.0,12.8]	
Other	8	8.3	[2.7,14.0]	4	8.7	[0.2,17.2]	4	8.0	[0.2,15.8]	
<b>Vape environment – others vape at home and/or work, yes</b>	48	50.0	[39.8,60.2]	22	47.8	[32.8,62.8]	26	52.0	[37.7,66.3]	0.8383
<b>Number of closest friends vape (0–5), Mean (SE)</b>	1.6 (0.2)		[1.3,1.9]	1.5 (0.3)		[1.0,2.1]	1.6 (0.2)		[1.2,2.0]	0.3050
<b>Ecig helpfulness with smoking urges<sup>b</sup> (1–5), Mean (SE)</b>	3.6 (0.1)		[3.3,3.9]	3.5 (0.2)		[3.0,3.9]	3.7 (0.2)		[3.3,4.0]	0.5828
<b>How long vape used</b>										
Less than 1 month	5	5.2	[0.7,9.7]	3	6.5	[0.0,13.9]	2	4.0	[0.0,9.6]	0.6074
1- < 12 months	32	33.3	[23.7,42.9]	13	28.3	[14.7,41.8]	19	38.0	[24.1,51.9]	
12+ months	59	61.5	[51.5,71.4]	30	65.2	[50.9,79.5]	29	58.0	[43.8,72.2]	
<b>Ever daily vaper for 1+month</b>	58	60.4	[50.5,70.4]	28	60.9	[46.2,75.5]	30	60.0	[45.9,74.1]	0.9999
<b>Penn State E-cigarette dependence Questionnaire, Mean (SE)</b>	9.3 (0.4)		[8.5,10.2]	8.8 (0.7)		[7.5,10.2]	9.8 (0.6)		[8.6,11.0]	0.1864
Not dependent (0–3)	6	6.3	[1.3,11.2]	4	8.7	[0.2,17.2]	2	4.0	[0.0,9.6]	0.2092
Low dependence (4–8)	39	40.6	[30.6,50.6]	21	45.7	[30.7,60.6]	18	36.0	[22.2,49.8]	
Medium dependence (9–12)	26	27.1	[18.0,36.1]	10	21.7	[9.4,34.1]	16	32.0	[18.6,45.4]	
High dependence (13+)	25	26.0	[17.1,35.0]	11	23.9	[11.1,36.7]	14	28.0	[15.1,40.9]	

<sup>a</sup> Number of previous quit attempts asked of those who reported having a previous quit attempt.

<sup>b</sup> Ecig helpfulness with smoking urges asked of those who answered any of the following as their primary reason for ecig use: “To quit smoking”, “To cut down smoking”, “Use when cannot smoke”, “Avoid returning to smoking”. Out of the 88 respondents who provided one of these primary reasons for ecig use, 80 provided a valid response to ecig helpfulness with smoking urges.

### 3.2. Psychosocial characteristics

Three-fourths (75%) reported having one or more behavioral health condition diagnoses from a list of 8 conditions, and over half (54.2%) reported two or more behavioral health conditions. Participants’ mean score was 5.8 (out of 16) on the Perceived Stress Scale-4 (PSS). Results from the GAD-2 anxiety scale show that 51% of participants met or exceeded a cutoff score of 3, with a mean score of 2.9 (out of 6). More than half (56.3%) met or exceeded the cutoff score of 2 on the PHQ-2

depression score, with a mean score of 2.3 (out of 6).

Two fifths (42.7%) of participants reported binge drinking (1 or more times) in the past year. Two fifths (39.6%) reported marijuana use in the last 30 days, nearly one fifth (17.7%) reported daily use of marijuana, and 15.6% reported using other illegal or unprescribed drugs 1 or more times in the past year.

**Table 4**  
Beliefs about vaping, smoking, and quit medications at baseline.

	Total Sample (n = 96)			Enhanced E-cigarette Coaching (EEC) (n = 46, 48%)			Quitline Treatment as Usual (TAU; control) (n = 50, 52%)			p-value
	n	%	95% CI	n	%	95% CI	n	%	95% CI	
<b>“Compared to cigarettes, how harmful are e-cigarettes to a person’s health?”</b>										
Less harmful	59	61.5	[51.5,71.4]	33	71.7	[58.2,85.3]	26	52.0	[37.7,66.3]	0.1369
About the same	23	24.0	[15.3,32.7]	9	19.6	[7.7,31.5]	14	28.0	[15.1,40.9]	
More harmful	11	11.5	[5.0,17.9]	4	8.7	[0.2,17.2]	7	14.0	[4.0,24.0]	
I prefer not to answer	3	3.1	[0.0,6.7]	0	–	–	3	6.0	[0.0,12.8]	
<b>“Compared to cigarettes, how harmful are quit medications like the nicotine patch to a person’s health?”</b>										
Less harmful	85	88.5	[82.1,95.0]	40	87.0	[76.8,97.1]	45	90.0	[81.4,98.6]	0.2716
About the same	2	2.1	[0.0,5.0]	1	2.2	[0.0,6.6]	1	2.0	[0.0,6.0]	
More harmful	3	3.1	[0.0,6.7]	3	6.5	[0.0,13.9]	0	–	–	
I prefer not to answer	6	6.3	[1.3,11.2]	2	4.3	[0.0,10.5]	4	8	[0.2,15.8]	
<b>“Compared to quit medications like the nicotine patch, how harmful are e-cigarettes to a person’s health?”</b>										
Less harmful	22	22.9	[14.4,31.5]	13	28.3	[14.7,41.8]	9	18.0	[7.0,29.0]	0.1944
About the same	28	29.2	[19.9,38.4]	16	34.8	[20.5,49.1]	12	24.0	[11.7,36.3]	
More harmful	41	42.7	[32.6,52.8]	16	34.8	[20.5,49.1]	25	50.0	[35.6,64.4]	
I prefer not to answer	5	5.2	[0.7,9.7]	1	2.2	[0.0,6.6]	4	8.0	[0.2,15.8]	
<b>“How much do you think your risk of developing a smoking-related disease would decrease if you cut the amount that you smoke in half? Would you say ...”</b>										
Not at all	5	5.2	[0.7,9.7]	4	8.7	[0.2,17.2]	1	2.0	[0.0,6.0]	0.1698
A little	15	15.6	[8.2,23.0]	10	21.7	[9.4,34.1]	5	10.0	[1.4,18.6]	
Somewhat	21	21.9	[13.5,30.3]	9	19.6	[7.7,31.5]	12	24.0	[11.7,36.3]	
A lot	55	57.3	[47.2,67.4]	23	50.0	[35.0,65.0]	32	64.0	[50.2,77.8]	
<b>“Using an e-cigarette or vaping product can help a person quit smoking cigarettes.”</b>										
Disagree	11	11.5	[5.0,17.9]	4	8.7	[0.2,17.2]	7	14.0	[4.0,24.0]	0.8195
Neither	4	4.2	[0.1,8.2]	2	4.3	[0.0,10.5]	2	4.0	[0.0,9.6]	
Agree	81	84.4	[77.0,91.8]	40	87.0	[76.8,97.1]	41	82.0	[71.0,93.0]	
<b>“Using stop-smoking medications like the nicotine patch can help a person quit smoking cigarettes.”</b>										
Disagree	5	5.2	[0.7,9.7]	3	6.5	[0.0,13.9]	2	4.0	[0.0,9.6]	0.4866
Neither	8	8.3	[2.7,14.0]	2	4.3	[0.0,10.5]	6	12.0	[2.7,21.3]	
Agree	83	86.5	[79.5,93.4]	41	89.1	[79.8,98.5]	42	84.0	[73.5,94.5]	
<b>“Nicotine in cigarettes is the substance that causes most of the cancer caused by smoking.”</b>										
Disagree	38	39.6	[29.6,49.5]	15	32.6	[18.5,46.7]	23	46.0	[31.7,60.3]	0.3150
Neither	7	7.3	[2.0,12.6]	3	6.5	[0.0,13.9]	4	8.0	[0.2,15.8]	
Agree	51	53.1	[43.0,63.3]	28	60.9	[46.2,75.5]	23	46.0	[31.7,60.3]	
<b>“Nicotine is the main substance in tobacco that makes people want to smoke.”</b>										
Disagree	7	7.3	[2.0,12.6]	3	6.5	[0.0,13.9]	4	8.0	[0.2,15.8]	0.9999
Neither	6	6.3	[1.3,11.2]	3	6.5	[0.0,13.9]	3	6.0	[0.0,12.8]	
Agree	83	86.5	[79.5,93.4]	40	87.0	[76.8,97.1]	43	86.0	[76.0,96.0]	
<b>“Nicotine is something that I am concerned about.”</b>										
Disagree	11	11.5	[5.0,17.9]	6	13.0	[2.9,23.2]	5	10.0	[1.4,18.6]	0.9030
Neither	3	3.1	[0.0,6.7]	1	2.2	[0.0,6.6]	2	4.0	[0.0,9.6]	
Agree	82	85.4	[78.2,92.6]	39	84.8	[74.0,95.6]	43	86.0	[76.0,96.0]	
<b>“Stop-smoking medications might harm your health.”</b>										
Disagree	41	42.7	[32.6,52.8]	22	47.8	[32.8,62.8]	19	38.0	[24.1,51.9]	0.1036
Neither	19	19.8	[11.7,27.9]	5	10.9	[1.5,20.2]	14	28.0	[15.1,40.9]	
Agree	35	36.5	[26.7,42.3]	19	41.3	[26.5,56.1]	16	32.0	[18.6,45.4]	
I prefer not to answer	1	1.0	[0.0,3.1]	0	–	–	1	2.0	[0.0,6.0]	
<b>“Smoking while using the patch can lead to a heart attack.”</b>										
Disagree	10	10.4	[4.2,16.6]	5	10.9	[1.5,20.2]	5	10.0	[1.4,18.6]	0.9999
Neither	19	19.8	[11.7,27.9]	9	19.6	[7.7,31.5]	10	20.0	[8.5,31.5]	
Agree	65	67.7	[58.2,77.2]	31	67.4	[53.3,81.5]	34	68.0	[54.6,81.4]	
I prefer not to answer	2	2.1	[0.0,5.0]	1	2.2	[0.0,6.6]	1	2.0	[0.0,6.0]	
<b>“You should not use the nicotine patch or gum for longer than three months.”</b>										
Disagree	17	17.7	[9.9,25.5]	8	17.4	[6.0,28.8]	9	18.0	[7.0,29.0]	0.9682
Neither	22	22.9	[14.4,31.5]	10	21.7	[9.4,34.1]	12	24.0	[11.7,36.3]	
Agree	54	56.3	[46.1,66.4]	26	56.5	[41.6,71.4]	28	56.0	[41.7,70.3]	
I prefer not to answer	3	3.1	[0.0,6.7]	2	4.3	[0.0,10.5]	1	2.0	[0.0,6.0]	
<b>“Using two quit medications together at the same time, like the nicotine patch and gum, is safe.”</b>										
Disagree	43	44.8	[37.7,58.1]	22	47.8	[32.8,62.8]	21	42.0	[27.8,56.2]	0.9268
Neither	17	17.7	[9.9,25.5]	8	17.4	[6.0,28.8]	9	18.0	[7.0,29.0]	
Agree	35	36.5	[26.7,46.3]	16	34.8	[20.5,49.1]	19	38.0	[24.1,51.9]	
I prefer not to answer	1	1.0	[0.0,3.1]	0	–	–	1	2.0	[0.0,6.0]	

Note. “I prefer not to answer” category included in Fischer’s exact test calculation, alpha p.05.

### 3.3. Smoking/tobacco use

Participants smoked on average 19.2 cigarettes per day, with 85.4% smoking daily and 43.8% having their first cigarette within 5 min after waking. Over a fifth (21.9%) reported using another tobacco type in addition to cigarettes and vaping. About ninety percent (90.6%) had made a previous quit attempt, with a mean of 7.9 quit attempts. Nearly three quarters (72.9%) reported other smokers at home and/or work.

Over a third of participants (38.5%) reported smoking menthol cigarettes (25.0% mainly menthol; 13.5% both menthol and non-menthol).

### 3.4. FDA medication use

A fifth (20.8%) of participants had no previous use of FDA-approved cessation medications. Three quarters (74.0%) had tried NRT before, 30.2% had previously tried combination therapy (nicotine patch plus



gum or lozenge) and 40.6% had tried varenicline or bupropion. A minority (7.3%) of participants were currently using cessation medications at the time of the baseline survey.

### 3.5. E-cigarette use and dependence

Almost half of participants (47.9%) reported vaping daily, with about two-thirds (68.7%) noting that their primary reason for vaping was to quit (42.7%) or cut down on (26%) smoking. Nearly half (47.9%) reported they would be very likely to vape while quitting smoking. Most participants were experienced e-cigarette users: 61.5% reported vaping for 12 or more months, whereas only 5.2% reported vaping less than 1 month. Sixty percent reported having vaped daily for at least 1 month (ever). Almost all participants (95.8%) used a nicotine-containing vape. Forty percent of participants used a mod device, whereas 17.9% used a disposable e-cigarette. Flavors such as fruit or candy were the most common (76.0%), followed by menthol or mint (12.5%), and tobacco (10.4%). Of those who reported their primary reason for vaping was to quit, cut down, avoid, or temporarily replace smoking, the mean score for vaping helpfulness with smoking urges was 3.6 out of 5.

Results from the assessment of dependence on e-cigarettes indicate that participants were fairly split between no or low dependence (46.9%) and medium/high dependence (53.1%). The mean dependence score was 9.3 (out of 20).

### 3.6. Knowledge and beliefs

As shown in Table 4, participants answered questions about perceived harm and risks related to vaping, NRT, nicotine, and smoking on the baseline survey. Here we label answers to selected knowledge items “accurate” or “inaccurate” to describe relevant misconceptions. Responses to less clearly right or wrong items are also described, but not labeled as accurate or inaccurate. In the baseline survey only 61.5% of participants accurately answered that e-cigarettes were less harmful than cigarettes; one fourth (24.0%) reported that e-cigarettes were about as harmful as cigarettes, and 11.5% reported that e-cigarettes were more harmful. Nearly one fourth (22.9%) inaccurately believed e-cigarettes were less harmful than quit medications like the nicotine patch, and 29.2% believed e-cigarettes and quit medications were similar in harm. The majority (88.5%) accurately endorsed that quit medications were less harmful than cigarettes. More than half (57.3%) inaccurately believed their health risks would decrease ‘a lot’ by cutting down the amount they smoked by half. More than half (53.1%) inaccurately agreed that nicotine is the substance responsible for most of the cancer caused by smoking, but 86.5% accurately agreed that nicotine is the main substance that makes people want to smoke. More than a third (36.5%) inaccurately agreed stop smoking medications like the nicotine patch might harm one’s health; 19.8% neither agreed nor disagreed. Most were concerned that smoking while using the patch could lead to a heart attack (67.7% agreed; 19.8% neither agreed nor disagreed). More than half (56.3%) agreed you should not use the nicotine patch or gum for longer than three months. Just under half (44.8%) inaccurately disagreed that using combination NRT, like the nicotine patch and gum together at the same time, is safe; 17.7% neither agreed nor disagreed. Finally, most of the sample agreed that e-cigarettes (84.4%) and that quit medications (86.5%) can help someone quit smoking.

### 3.7. Selected quit plans and NRT provision

In the EEC group, 11% chose NRT alone and 89% chose NRT plus vaping for their quit plan. None chose vaping as a sole quit aid. In the TAU group, all but 3 participants were mailed NRT from the quitline (94%). Eligibility for type and number of weeks of NRT was based on insurance status. The majority were eligible for 8 weeks of combination NRT (nicotine patch plus gum or lozenge; 67.4% EEC vs 86% TAU,  $p = 0.0504$ ) rather than 2 weeks of mono NRT. Over half received shipments

of combination NRT (52.2% EEC vs 58.0% TAU,  $p = 0.20$ ).

## 4. Discussion

This article describes the treatment development of a tailored smoking cessation quitline intervention for dual users of cigarettes and e-cigarettes, outcomes from a 10-person proof of concept, and the baseline characteristics of dual users in a randomized pilot trial. Although e-cigarettes are used by some smokers in the United States for cessation, limited empirical data are available on smoking cessation behavioral interventions for dual users of cigarettes and e-cigarettes. The Enhanced E-cigarette Coaching intervention for state-funded quitline callers included enhanced education on e-cigarettes, smoking, and quit medications, a shared decision-making quit plan development approach, tailored behavioral support, and vaping assessment and support on every call. Standard quitline treatment at the time of the study involved limited assessment of e-cigarette use at enrollment; conversation about e-cigarette use during coaching calls was typically instigated by participants rather than coaches. The 3-month outcomes from this trial are intended to provide preliminary data on whether added vaping content may be impactful, and worthy of examination in a larger trial.

The 10-person proof-of-concept study revealed that the EEC intervention was feasible with respect to training coaches and implementation and was acceptable to participants. These results indicated readiness to proceed to the randomized pilot trial. In the randomized trial, no significant differences were identified between the two treatment groups, suggesting randomization was successful even with differential loss between randomization and the first coaching call for the two groups. Participants had tried and failed to quit smoking before—most had tried quitting multiple times and had tried FDA-approved quit medications during past quit attempts—indicating they may be ideal candidates for this behavioral intervention supporting their use of e-cigarettes to quit smoking. Data from the baseline survey, however, showed that although most were vaping to quit or cut down on their smoking, more than half had been vaping for 12 months or longer, highlighting the need for more support to successfully use vaping as a tool for completely quitting smoking.

Baseline survey belief data supported previous qualitative work [26] identifying knowledge gaps for state quitline callers regarding the relative harm of products, safety and use of quit medications like the nicotine patch or use of combination therapy (nicotine patch plus nicotine gum or lozenge), and concerns about nicotine that could influence use of NRT or vaping products containing nicotine for the purpose of quitting smoking, or duration of use. Existing evidence has shown that vaping products containing nicotine are more effective than no nicotine vaping products for smoking cessation [9]. Huang et al. [48] examined U.S. National Surveys from 2012 to 2017, and found a substantial increase in adult beliefs that e-cigarettes are as or more harmful than cigarettes; this points to a significant, growing problem of misinformation and the need for accurate communication of relative risk education. Still, the majority of the study sample agreed that quit medications like the nicotine patch can help people quit smoking, which has extensive research support [15], and that vaping products can help people quit smoking, which has promising evidence from existing RCTs [9,11]. Quit coaches were trained to educate participants that combination NRT (nicotine patch plus gum or lozenge) has been shown to be the most effective quit plan. After discussing the relative risks of NRT, vaping, and smoking, most EEC participants decided on a quit plan that incorporated both NRT and vaping. None chose vaping as a sole quit aid. The 3-month outcomes will elucidate actual NRT use and any changes in participants’ beliefs resulting from treatment.

There were several notable sample characteristics for these dual users who enrolled in a research study that could benefit from examination in future quitline samples. Approximately half of the sample screened positive on brief measures of depression and anxiety, and

three-fourths reported one or more mental health conditions, rates that are somewhat higher than expected. Previous reports found approximately half of state quitline callers report one or more current mental health conditions, including 32% reporting depression, and 21% reporting generalized anxiety disorder diagnoses [49]. Two in five participants reported using marijuana in addition to cigarettes and e-cigarettes in the last 30 days, and one in five were daily marijuana users. Data collected in three states with legal recreational marijuana in 2016 showed that one in four state quitline callers were using tobacco and marijuana at the time of quitline enrollment [43]. As regular marijuana use may negatively impact an individual's likelihood of success with quitting smoking [50–52], future investigations should consider marijuana use (smoked and/or vaped) and implications for smoking and vaping cessation.

Understanding nicotine dependence and dependence on smoking versus vaping in a sample of dual users at a specific time point during their quit process is complicated due to use of multiple sources of nicotine. All participants were using both cigarettes and e-cigarettes (most with nicotine). In addition, one fifth used another tobacco type (smokeless, pipe, little cigar or cigarillos, or cigars). The impact of use of multiple forms of nicotine on dependence measures is unclear. Further, the extent to which participants utilizing e-cigarettes to quit or cut down on cigarette smoking had already reduced their smoking, and potentially replaced smoking with vaping, was not assessed.

#### 4.1. Limitations

Limitations included that fewer EEC participants were reached to complete call 1 compared to the standard treatment arm. After completing baseline and randomization, participants were transferred to an EEC coach or any quitline coach, depending on their randomized arm. Call 1 completion was required to remain in the study, as the study goal was to examine the impact of exposure to the treatment conditions. The four EEC coaches were likely less available for immediate transfer resulting in more loss of EEC participants between randomization and call 1. We aimed to train enough coaches to have coaches available throughout the day, seven days per week, but few enough to allow coaches to regularly take calls to achieve competence with the new intervention. Testing differences in participant characteristics who completed versus did not complete call 1 for each group was not indicated due to small numbers; however, no important differences were noted from comparing descriptive data. Because participants were not informed of their group assignment, we do not attribute the differential loss of participants for call 1 to their randomization group.

Second, participants in this study were required to have an Android smartphone and be able and willing to download a study app for daily diary questions and biochemical verification of smoking quit status for those who self-reported 7-day abstinence at follow-up. Android phone ownership was the most frequent reason for study exclusion. This limited the generalizability of our study.

Third, participants were from one state quitline and may not be representative of all states, given policy and regional differences.

#### 5. Conclusion

State quitlines reach approximately 57,000 dual users of cigarettes and e-cigarettes at the time of program registration each year [11,13]. Tailored treatment for this population that effectively improves smoking cessation rates would have an important impact. Baseline data from this randomized pilot revealed that participants had tried and failed to quit smoking before, most with FDA-approved cessation medications. The majority were vaping to quit or cut down on smoking but nearly all had been doing so for over a month at the time of baseline, indicating they may need more behavioral support to completely quit successfully. The rates of marijuana use in this sample highlight the need to explore the impact of marijuana use on outcomes in future work with dual users.

Finally, after discussing the relative risks of NRT, vaping, and smoking, most EEC participants were interested in using both NRT and e-cigarettes during their smoking cessation attempt. The randomized pilot outcomes for this study will provide information on treatment acceptability and engagement, and, although not powered to test for significant differences in quit rates, will also provide information on smoking and vaping status at 3 months post-enrollment.

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#### Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: KV, KC, LM, JH, and KW are employees of Optum, the provider of quitline services for the Oklahoma Helpline in this study.

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