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Original Investigation

ACT on Vaping: Pilot Randomized Controlled Trial of a Novel Digital Health App With Text Messaging for Young Adult Vaping Cessation

Jaimee L. Heffner PhD[1], Kelsey Baker MS[1], Katerina Georgiou MS[2], Amanda L. Graham PhD[3], Megan M. Kelly PhD[4], Pinelopi Konstantinou PhD[2,5,6], Eleana Lamprou BA[2], Chinmaya Lele PhD[7], Kathleen Z. Lok JD[8], Maria Orzechowski MA[9], Raymond A. Ruiz PhD[10,11], Edit Serfozo MPH[1], Maria Karekla PhD[2]

[1]Fred Hutchinson Cancer Center, Seattle, WA, USA
[2]University of Cyprus, Nicosia, Cyprus
[3]Innovations Center, Truth Initiative, Washington, DC, USA
[4]University of Massachusetts Chan Medical School, Worcester, MA, USA
[5]Cyprus University of Technology, Limassol, Cyprus
[6]UCLan Cyprus, Larnaca, Cyprus
[7]Robert Morris University, Pittsburgh, PA, USA
[8]University of Michigan Law School, Ann Arbor, MI, USA
[9]Roosevelt University, Chicago, IL, USA
[10]Northwestern University Feinberg School of Medicine, Chicago, IL, USA
[11]Institute for Sexual and Gender Minority Health and Wellbeing, Chicago, IL, USA

Corresponding Author: Jaimee Heffner, PhD, Public Health Sciences, Fred Hutchinson Cancer Center, 1100 Fairview Ave N, M4-B204, PO Box 19024, Seattle, WA 98109, USA. Telephone: 206-667-7314; Fax: 206-667-5977; E-mail: jheffner@fredhutch.org

Abstract

Background: There is no published evidence to support the efficacy of any digital vaping cessation program for young adults (YAs) at differing levels of readiness to quit. In this pilot randomized controlled trial, we evaluated the preliminary acceptability and efficacy of a program for vaping cessation based on acceptance and commitment therapy (ACT on Vaping), delivered via a smartphone app and text messaging.

Methods: YAs aged 18–30 ($n = 61$) were randomized 1:1 to ACT on Vaping ($n = 31$) or incentivized text message control ($n = 30$). Outcome data were collected at 3 months post-randomization. Results were compared against a priori benchmarks for acceptability (satisfaction of ≥3.5 on 5-point scale) and efficacy relative to control (meeting at least one of three): ≥1-point difference in Contemplation Ladder change scores; ≥5 percentage difference in 24-hour quit attempts, ≥5 percentage difference in cotinine-confirmed 30-day point prevalence abstinence (PPA) from all non-therapeutic nicotine/tobacco.

Results: Satisfaction with ACT on Vaping averaged 3.8, exceeding the acceptability benchmark. A higher proportion of participants in the ACT on Vaping arm reported a 24-hour quit attempt (87.5% vs. 75.9%), exceeding the efficacy benchmark. Both changes in quit readiness (+0.96 in ACT on Vaping vs. +0.72 in control) and cotinine-confirmed 30-day PPA (4.2% in ACT on Vaping vs. 0% in control) were descriptively higher for ACT on Vaping but did not reach the benchmark level for efficacy.

Conclusions: ACT on Vaping had promising acceptability and preliminary efficacy. A fully powered trial of ACT on Vaping is warranted to evaluate its efficacy.

Implications: Digital interventions are a promising yet under-researched approach for reaching and supporting YAs to quit vaping. This proof-of-concept pilot randomized controlled trial evaluated a novel mobile health application and associated text messaging program (ACT on Vaping) for young adult vaping cessation and found preliminary evidence for acceptability and efficacy relative to an incentivized text message control arm, warranting evaluation in a fully powered trial as a next step.

Trial registration: NCT05897242

Introduction

Approximately 1 in 10 young adults (YAs) ages 18–24 in the United States uses electronic cigarettes (e-cigarettes),[1] placing them at risk of developing nicotine addiction and exposing them to heavy metals and other substances that are known to increase health risks, including risk of developing cardiovascular and respiratory diseases.[2,3] Effective and accessible cessation treatment is needed to support YA e-cigarette users to quit during a time of life when most tobacco-related harms can be avoided via cessation, based on evidence from the literature on cigarette smoking.[4] However, there are few options currently available that are specifically designed with the needs and preferences of YAs in mind and that have been

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empirically evaluated. Innovative approaches are needed to engage YA e-cigarette users, who tend to have minimal experience with trying to quit, low readiness to quit, and low use of traditional behavioral support tools like tobacco quitlines or group counseling.[2,5,6]

For smoking cessation, digital approaches to tobacco treatment delivery have been acceptable and effective for YAs[7,8] and are a recommended modality for cessation treatment.[9] Digital interventions have high reach,[10,11] and YAs in particular tend to use technology and the Internet in high numbers. Of YAs ages 18–29, 98% are smartphone users[12] and 99% use the Internet.[13] Data from Truth Initiative's *This is Quitting* text message program confirm that high numbers of YAs will use digital interventions for vaping cessation when they are well promoted.[14] *This is Quitting* was the first digital intervention to be evaluated in a randomized controlled trial for YA vaping cessation. In that trial,[14] 2588 YAs who were interested in quitting in the next month were randomized to either *This is Quitting* or to an assessment-only control group. Self-reported 30-day point prevalence abstinence (PPA) rates were compared at 7 months post-randomization under intent-to-treat analysis. Graham et al. found that 24.1% of the participants who received *This is Quitting* stopped vaping compared to 18.6% in the assessment-only arm, providing support for the effectiveness of a digital treatment approach using text messaging. The effects of the program among YAs not currently interested in quitting vaping are not yet known.

Although text messages for e-cigarette and other tobacco cessation have many benefits, YAs have expressed a preference for digital tobacco cessation programs that are app-based.[15] However, app-based programs for YA e-cigarette cessation remain in a nascent state. A 2025 Cochrane Review of interventions for e-cigarette cessation included only three studies of text-based interventions and no app-based interventions.[16] Further, smartphone apps are not yet a recommended modality even for smoking cessation,[9] where there have been several large-scale studies to date,[17,18] so well-designed trials are still needed to evaluate their efficacy.[8]

In addition to new modalities of treatment delivery, new treatment content may support YAs with vaping cessation. Acceptance and commitment therapy (ACT) focuses on the development of psychological flexibility as a means of quitting tobacco use, which is defined as a willingness to experience uncomfortable internal experiences (eg, anxiety, cravings) without trying to change them via the use of tobacco products.[19] ACT has been demonstrated to have greater efficacy for cigarette smoking cessation than standard care behavioral treatments in both digital and traditional modalities of treatment.[18,20] Prior studies have largely focused on people who smoke who were ready to quit, although there is some evidence for the acceptability and efficacy of digital ACT-based programs for YA tobacco users at all levels of quit readiness.[21,22]

The aim of this work was to evaluate the acceptability and preliminary efficacy of a mobile health (mHealth) program for YA vaping cessation (ACT on Vaping), based on ACT and delivered via a smartphone app and text messaging. Because the vast majority of YA e-cigarette users report not being ready to quit in the next 6 months,[23] the program was designed for YAs at all levels of readiness to quit vaping. Consistent with requirements from the funding agency as well as with CONSORT guidelines for pilot/feasibility trials,[24] the trial employed go/no-go criteria to determine whether the preliminary evidence of acceptability and efficacy from the pilot trial warranted continued development and evaluation in a larger trial.

Methods

Participants

Participants were recruited via the Facebook/Instagram advertising platform in January 2024. Inclusion criteria were (1) age 18–30 years, (2) current weekly user of e-cigarettes for the last 30 days, (3) has an Android (running version 10.1 or higher) or iPhone (running iOS version 13 or higher) or smartphone, (4) experience downloading and using one or more apps on their smartphone, (5) has a mobile data plan and/or access to WiFi to support the use of the ACT on Vaping app, (6) has access to text messaging, (7) has an email address, (8) US resident, with a US mailing address, (9) willing to complete all study procedures, and (10) comfortable reading and writing in English. Exclusion criteria were (1) currently using other tobacco cessation treatments at the time of screening, including pharmacotherapy or behavioral support (although use of these treatments was allowable if started during trial participation), (2) member of the same household as another research participant, (3) currently in prison, (4) Google voice number as sole phone number, due to its association with fraudulent study entry attempts, (5) ineligible per fraud prevention protocol, and (6) employees/family of investigator or study center.

Assessments

Primary Outcomes

Go criteria for the pilot trial were as follows: (1) overall satisfaction with ACT on Vaping averaging ≥3.5 on a 5-point Likert scale, and (2) ACT on Vaping showing evidence of better outcomes compared to the control arm on at least one of three efficacy endpoints: (1) change in readiness to quit (mean difference in Contemplation Ladder change scores ≥1, favoring ACT on Vaping), (2) 24-hour quit attempt (≥5 percentage difference), or (3) cotinine-confirmed 30-day PPA from all nicotine/tobacco products at 3 months (≥5 percentage difference).

Overall satisfaction was assessed with a 5-point Likert-type item on the 3-month follow-up survey, with response options ranging from (1) "not at all" to (5) "very much." The ACT on Vaping benchmark of 3.5 falls between ratings of (3) "somewhat" and (4) "mostly." Efficacy was assessed via (1) self-reported 24-hour quit attempt between baseline and 3-month follow-up, (2) self-reported change in readiness to quit vaping using the Contemplation Ladder score between baseline and 3-month follow-up, and (3) cotinine-confirmed 30-day PPA from all nicotine and tobacco use (excluding FDA-approved pharmacotherapies) at 3-month post-randomization, biochemically confirmed via saliva cotinine. The one-item Contemplation Ladder,[25] with scores ranging from 0 to 10, was used to assess readiness to quit using e-cigarettes. The Contemplation Ladder was chosen as an indicator of quit readiness because it has been demonstrated to predict smoking cessation attempts in previous work.[26] For comparability with the only previous trial of a digital intervention for YA vaping cessation,[14] 30-day PPA from vaping was assessed using the following item: ("In the past 30 days, did you vape at all, even a puff of someone else's?"), and item instructions encouraged

participants to focus on all nicotine-containing vaping devices when answering. Items assessing 30-day PPA from cigarette smoking and other tobacco use asked about frequency of use in the prior 30 days, with a response of "never" indicating abstinence. A staging question administered at 3 months ("Do you plan on quitting e-cigarette use entirely some day?") that included the response "I have already quit e-cigarette use" was also included as an exploratory measure of abstinence.

We biochemically confirmed self-reported abstinence from vaping and all other non-therapeutic nicotine and tobacco products at follow-up among those who reported 30-day PPA. Saliva cotinine tests (Alere iScreen) were sent to participants via mail, and they uploaded photos of the test results via a secure online study portal. Participants who reported using nicotine replacement therapy (NRT) for tobacco cessation within 7 days of the scheduled date of cotinine testing were considered abstinent without testing, since cotinine cannot distinguish e-cigarette and other tobacco use from NRT use and the only method that can potentially make this distinction—urinary analysis of minor tobacco alkaloids (eg, anatabine/anabasine)[27]—was not feasible in a remote trial design with national recruitment.

Efficacy benchmarks were based on clinically meaningful differences in readiness to quit (ie, ≥1-point change in average Contemplation Ladder score favoring ACT on Vaping) and behavior change outcomes (5 percentage difference between treatment arms in the proportion that reports making a 24-hour quit attempt and in 30-day PPA rates). As noted by West,[28] there is no universally agreed-upon definition of the minimal clinically significant difference in quit rates as a result of tobacco treatment, but definitions used in international guidelines and by licensing bodies have ranged between 2 and 9 percentage difference (number needed to treat [NNT] of 11–50). We chose a 5 percentage difference (NNT = 20) as a mid-range point, which is similar to the effect size of face-to-face counseling (4 percentage difference; NNT = 25),[28] as well as previous effect sizes for novel mHealth smoking and vaping cessation interventions when compared to assessment-only[14] or active treatment control groups.[18] Since a single effect size derived from a small sample is an inherently unreliable estimate of the true intervention effect size,[29] we aimed to reduce the likelihood of early abandonment of a potentially promising treatment by requiring evidence of a clinically meaningful effect on one of three cessation-related outcomes as the go criterion for efficacy.

Exploratory Acceptability and Efficacy Outcomes

In addition to measuring overall satisfaction (on a 5-point Likert-type scale), the eight-item treatment satisfaction questionnaire also included items assessing the perceived usefulness of the program and whether they would recommend the program to a friend. Participants completed the 10-item System Usability Scale[30] as a measure of the usability of their assigned program, and usage metrics (eg, number of ACT on Vaping sessions completed, proportion of participants stopping text messaging during the treatment period) were calculated to assess adherence to the program. For exploratory measures of efficacy, we assessed self-reported 30-day PPA from all nicotine/tobacco products at 3 months, self-reported 30-day PPA from vaping at 3 months, self-reported abstinence from vaping for at least a week at any time between baseline and 3 months (ie, floating 7-day abstinence), self-report of having quit vaping at 3 months (for an unspecified length of time, by indicating "I have already quit e-cigarette use"), reduced frequency of vaping between baseline and 3 months, and reduced frequency of other tobacco use between baseline and 3 months (based on frequency of use categories of daily, less than daily, or never in the past 30 days).

Baseline Demographics and Tobacco Use

Demographics assessed at baseline included age, assigned sex at birth, gender identity, sexual orientation, education, employment, income, number of dependents, and relationship status. The six-item E-cigarette Fagerström Test for Cigarette Dependence (e-FTCD),[31,32] with scores ranging from 0 to 10, was used to assess e-cigarette dependence. Nicotine and tobacco use history were assessed using items derived from major epidemiologic surveys.

ACT Process Measures

Assessment of intervention impact on ACT's theory-based mechanisms of change (ie, psychological flexibility, which includes both acceptance and valued living) occurred at baseline and the 3-month follow-up to evaluate changes in (1) acceptance of vaping-related triggers on the bodily sensations subscale of the modified Avoidance and Inflexibility Scale (AIS),[33,34] which measures physical urges or cravings to vape; and, (2) valued living on the 10-item Valuing Questionnaire,[35] which has two subscales representing values progress (with higher scores indicating greater enactment of values; 5 items) and values obstruction (with higher scores indicating greater challenges in living according to one's values; 5 items).

Other Assessments

Use of nonstudy cessation treatments was assessed at the 3-month follow-up. Adverse events were collected by a web-based survey (on days 21, 42, 63, and at the 3-month follow-up time point), and their relationship to the intervention was adjudicated by an independent medical monitor.

Interventions

Incentivized Text Message Control

The control condition was an assessment-only control that received incentivized text message check-ins.[14] Text message check-ins occurred at 2 weeks, 1 month, and 2 months post-randomization. At 2 weeks, participants received the following message: "Checking in: Have you cut down how much you vape nicotine in the past 2 weeks? Respond w/ letter: A = I still use the same amount, B = I use less, C = I don't use at all anymore. Make sure to respond in the next 24 hours to get your $5 incentive!" At 1 and 2 months, they received the following message: "How's it going? When was the last time you vaped nicotine, even a puff of someone else's? Respond w/ letter: A = in the past 7 days, B = 8–30 days ago, C = More than 30 days ago. Make sure to respond in the next 24 hours to get your $5 incentive!" Participants were compensated $5 for each message they responded to, for a maximum of $15 for responding to all three messages. In Graham et al.,[14] these text message check-ins were perceived as engaging and had placebo-like effects. Because of their perceived value in support of quitting, the use of the incentivized text messages as a control condition allowed for an estimate of the efficacy of the experimental ACT on Vaping intervention above and beyond any behavior changes caused by attention and expectancy effects alone. They were also designed to minimize attrition among participants assigned to the control arm. Participant

responses to text message check-ins were not analyzed as a study outcome. All participants assigned to the control condition were given access to the ACT on Vaping program after they completed their participation in the study.

ACT on Vaping

The ACT on Vaping program was created using a community-engaged, user-centered design approach, which involved a collaboration between researchers with expertise in ACT, digital interventions, and YA vaping cessation and a team of community advisors with project-relevant lived experience.

Participants assigned to the ACT on Vaping arm received the same incentivized text messages as the control condition. In addition, the ACT on Vaping app-based intervention contained six interactive sessions to be completed in order, with at least 3 days between sessions to allow for post-session practice. Each session took 10–20 minutes to complete and, once completed, remained available throughout the 12-week treatment period. After completing all sessions, users were emailed a copy of the session handouts. The content was ACT-based,[21,22,36,37] with major session content as follows: Session 1 introduces the avatar guide, who provides an overview of the program and shares their own story of quitting vaping. Participants complete an interactive game to identify personal values guiding quitting and review quit stories from other YAs. Session 2 focuses on trigger awareness through interactive questions, graphs, pictures, and experiential exercises and metaphors, and it introduces the ACT concept of creative hopelessness—recognizing that efforts to control thoughts, feelings, or sensations related to vaping (eg, urges to vape) can be counterproductive. Session 3 completes the topic of creative hopelessness and introduces cognitive defusion—that is, psychological distancing from thoughts—as an alternative to thought control as a strategy for coping with triggers. Session 4 completes the topic of cognitive defusion, encourages setting a practice quit date in the next week, and prompts participants to practice defusing thoughts that they will not be able to quit as part of quit planning. Session 5 starts with a reflection on recent successes and difficulties, introduces the acceptance strategy of willingness as a means of handling triggers, and covers relapse prevention via self-compassion and re-commitment to quitting. Session 6 starts with a reflection on recent successes and difficulties, reviews content from previous sessions, and ends with a video emphasizing the importance of letting go of the need to control feelings, sensations, and thoughts in order to follow one's valued life direction. Other sections of the app included: (1) the "My Triggers" tool to assist users with identifying vaping triggers and categorizing them as internal or external, and (2) the "Anytime Tools" section that included informational content about nicotine withdrawal, the health effects of vaping, and how vaping can impact mental health.

Short message service text messages were used to prompt completion of the next session and to push select intervention content to users. All messages in the 12-week program were automated, and users were able to choose what time of day the messages would be sent. The frequency of messages was once per day for weeks 1–5 and reduced to 3–5 messages per week for weeks 6–12. Both one-way and two-way messaging were included. One-way intervention messages included information about the adverse health effects of vaping (eg, "Although flavorings in food are often safe to digest, the chemicals that create vape flavors can harm your lungs when inhaled. That is because our intestines are much better at processing these things than our lungs are."), reminders of ACT-based strategies for handling vaping triggers and committing to values-based actions (eg, "Motivation to make change comes and goes like the weather. It can't be relied on to quit vaping. You can quit even if you don't feel motivated. Just take one small action at a time to move toward what matters most to you."), and brief personal narratives about the benefits of quitting vaping (eg, "One of the hardest parts of quitting for me was learning how to be intentional about the choices I was making rather than just vaping automatically. -Gavin, ex-vaper"). Two-way messages asked about readiness to quit and provided tailored responses, offered incentives for session completion by asking participants their preferred reward (which included a bank of reward messages representing jokes, fun facts, or inspirational quotes), and provided participants the choice of either getting advice for quitting or giving advice that might benefit others.

Procedure

Online study advertisements were linked to the study recruitment website, which provided basic information about the study and a portal to the online screening survey. Individuals who did not meet eligibility criteria were sent an email notifying them that they were not eligible for the study and providing other resources for cessation support.

Participants who screened eligible and provided their email addresses were sent an email invitation (and two reminders over a 7-day period) to provide informed consent and complete the baseline assessment. To address potential fraudulent responses to web-based screening surveys, we used a variety of recommended methods[38] including CAPTCHA verification, ineligibility if the IP address was previously used or suspicious (ie, flagged as potentially being a proxy IP address or VPN), and telephone contact by research staff if any aspect of automated data collection revealed suspicious activity (eg, very brief survey completion times or unusual patterns in email addresses). To further deter fraudulent attempts to enter the study, no compensation was provided for the completion of the brief (<10 minutes) screening and baseline surveys.

The study employed a parallel-groups design where enrolled participants were randomized 1:1 to either the ACT on Vaping app arm or the incentivized text message control arm. The randomization algorithm used a permuted-block design with random block sizes, with stratification by high (>5) versus low (5 or less) readiness to quit on the Contemplation Ladder. Only the unblinded study biostatistician, who generated the randomization sequence, had access to treatment assignment information. For participants assigned to the ACT on Vaping arm, an email and text message were sent to provide participants with a link to the login credentials of the ACT on Vaping program. If the participant did not log onto the app within 3 days, they received a text message reminder. If the participant still had not logged onto the app after 3 more days, study staff reached out by phone to check in and problem-solve any barriers to downloading and using the app.

The 3-month follow-up data collection protocol included a mailed reminder of the upcoming survey, with $2 pre-incentive included, up to three email requests to complete the survey, up to eight attempts by telephone if not completed using the link in the email, and a mailed survey if the participant did not respond to email or telephone prompts. Participants received

an incentive of $50 for the follow-up survey and an additional $25 for returning cotinine results if asked. In addition, an extra incentive of $10 was provided to participants who responded to the first invitation and completed the survey online within 24 hours. Research staff involved in outcomes surveys were blinded to treatment assignment.

Statistical Analysis

Sample Size Selection

We planned to accrue 60 participants in the pilot trial. A sample size of 30 per arm is consistent with the National Institute on Drug Abuse Stage Model of behavioral treatment development, which suggests that pilot trials should include approximately 15–30 participants per arm for preliminary evaluation of the intervention.[39]

Trial Outcome Analyses

We calculated descriptive statistics (eg, means, proportions) for the ACT on Vaping treatment group to evaluate the go/no-go criteria and to compare the two arms on other indicators of treatment acceptability and efficacy. Given that pilot and feasibility trials are not appropriate designs for testing hypotheses regarding the efficacy of interventions,[24,29] we focused on descriptive differences as an alternative to hypothesis testing. As specified in the protocol, because of differential attrition between arms, we used a complete case method of handling missing data rather than imputing all missing data as continued nicotine/tobacco use. All analyses were conducted using SAS Version 9.4 (SAS Institute Inc., Cary, NC).

Human Subjects Approval and Pre-registration

This study was reviewed and approved by the Fred Hutchinson Cancer Center Institutional Review Board (IRB). The trial was pre-registered on Clinicaltrials.gov (NCT#05897242), and a full trial protocol is available there.

Data Availability Statement

Data from the study are available from the corresponding author, upon reasonable request.

Results

The 61 participants for the trial were recruited over an approximately 1-week period in January 2024, with 3-month follow-ups completed during April 2024. In order to enroll 61 participants, we screened 285, of which 200 screened eligible, 83 consented to participate, and 75 completed the baseline survey (see Figure 1). Of those enrolled, 53 (86.9%: $n = 24$ Act on Vaping, $n = 29$ control) completed outcome surveys at the 3-month follow-up. Loss to follow-up differed by study arm (ie, 3.3% in the control arm vs. 22.6% in the ACT on Vaping arm). Demographic and tobacco-related characteristics of the sample, both overall and by assigned treatment arm, are presented in Table 1.

Acceptability

On the primary acceptability outcome (see Table 2), overall satisfaction with ACT on Vaping averaged 3.8 points (standard deviation [SD] = 1.3), which exceeded the acceptability benchmark of at least 3.5 on the 5-point rating scale.

We also examined several exploratory indicators of acceptability, including ratings of satisfaction and usability and program utilization. On the treatment satisfaction survey, mean satisfaction ratings (on a 1–5 scale) were all higher among those in the ACT on Vaping arm compared to the control arm for program usefulness, feeling more clear about how to quit vaping as a result of the program, having new ways of looking at quitting vaping as a result of the program, and feeling that the program will help them quit vaping when they are ready. Additionally, a greater proportion of participants in the ACT on Vaping arm than in the control arm said that they would recommend the program to a friend.

For participants assigned to the ACT on Vaping arm, the mean score on the System Usability Scale was 75.6 (SD = 16.9), exceeding the scale's benchmark usability score of 68. A total of 71.4% (15/23) of participants had SUS scores higher than the benchmark score of 68. The mean number of app sessions completed was 1.6 (SD = 2.4) out of 6, with $n = 6$ (19.4%) of participants completing all 6 sessions. Additionally, $n = 10$ participants (32.3%) discontinued the text messaging portion of the program before the end of the 12-week program ($n = 4$ within the first week). Of the interactive interventional text messages that requested a response, which were only included in the ACT on Vaping arm, 71% of participants responded to at least one message. The proportion of participants responding to at least one of the incentivized text messages, which were delivered on the same schedule in both arms, was descriptively lower in the ACT on Vaping arm (67.2%) compared with the control arm (91.8%).

Efficacy

The primary efficacy outcomes are shown in Table 3. The proportion of participants reporting a 24-hour quit attempt during the treatment period was 87.5% in the ACT on Vaping arm versus 75.9% in the control arm (an 11.6 percentage difference), which exceeds the benchmark of at least a 5 percentage difference. On the other primary efficacy endpoints, both the change in quit readiness (+0.96 in ACT on Vaping vs. +0.72 in control) and the complete case cotinine-confirmed abstinence from all non-therapeutic nicotine and tobacco products (4.2% in ACT on Vaping vs. 0% in control) were descriptively higher in the ACT on Vaping arm but did not exceed the pre-established benchmark for preliminary efficacy as defined in the go/no-go criteria (ie, ≥1-point difference in change scores for quit readiness, favoring ACT on Vaping, and ≥5 percentage point difference in 30-day biochemically confirmed PPA, favoring ACT on Vaping).

On the exploratory abstinence outcomes, the ACT on Vaping arm had descriptively higher rates on all outcomes: (1) self-reported 30-day PPA from all (non-therapeutic) nicotine and tobacco use (8.3% vs. 0%), (2) 30-day self-reported PPA from vaping (12.5% vs. 0%), (3) self-reported abstinence from vaping at any point in the trial that lasted longer than 1 week (33.3% vs. 17.2%), and (4) self-report of having quit vaping (for an unspecified time period) at 3-month follow-up (20.8% vs. 3.4%). On the reduction outcomes, a greater proportion of ACT on Vaping participants reported reduced frequency of vaping (54.2% vs. 31.0%), but a reduction in other tobacco use was similar (41.7% for ACT on Vaping, 41.4% for control).

Other Outcomes

On ACT process measures, change scores for the AIS bodily sensations subscale showed minimal decrease ($M = -0.1$, SD = 0.6; reflecting increased acceptance) in the ACT on Vaping arm and minimal increase in the control arm ($M =$

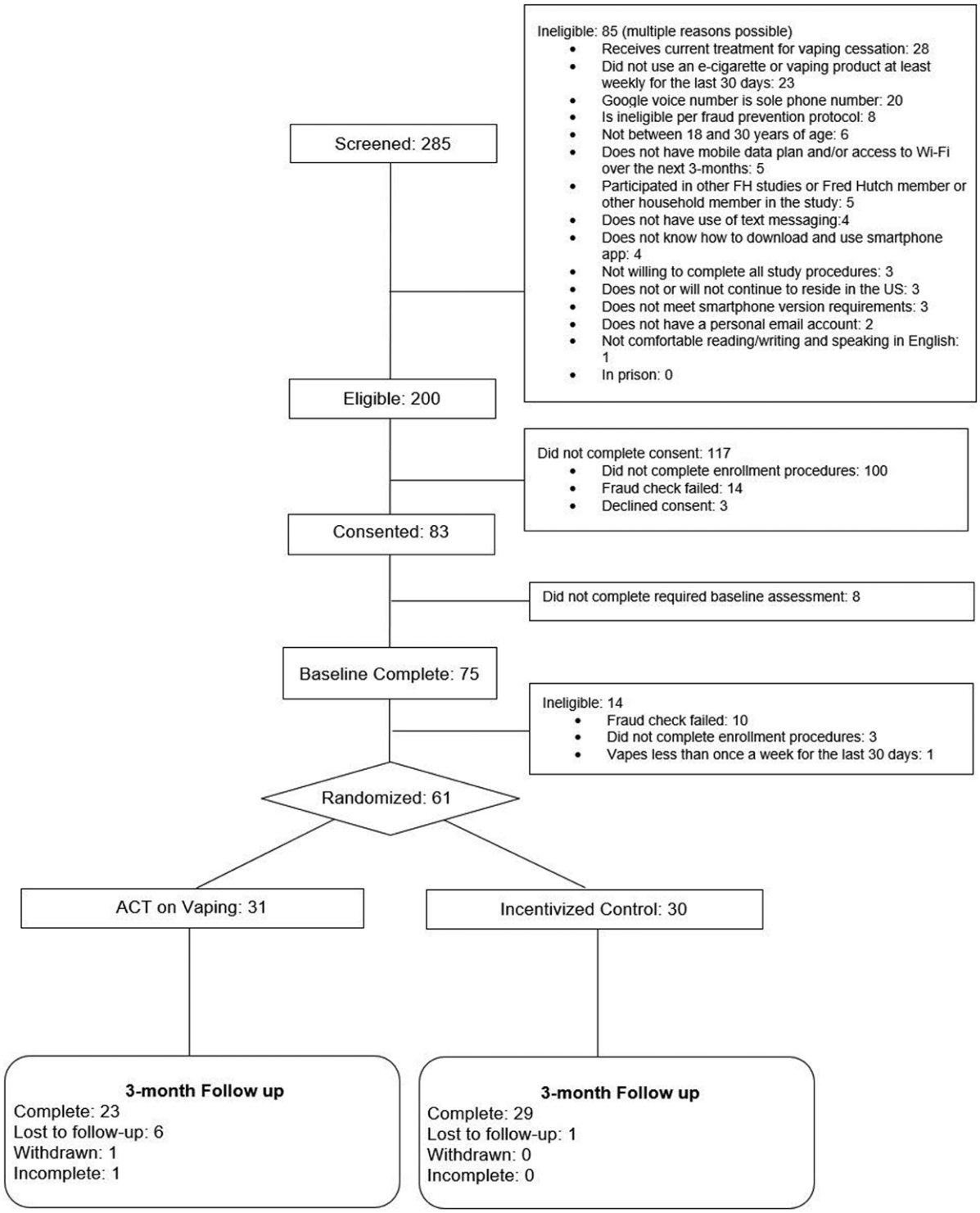

Figure 1. CONSORT diagram.

+0.6, SD = 0.5; reflecting decreased acceptance). On the Valuing Questionnaire, the ACT on Vaping arm showed an increase in values progress (M = +1.5, SD = 5.2) and a decrease in values obstruction (M = –1.3, SD = 5.0), whereas the control arm averaged a small decrease in values progress (M = –0.1, SD = 5.30) no change in values obstruction (M = 0.0, SD = 6.3).

The use of nonstudy behavioral treatments was reported by 4.2% of the ACT on Vaping arm and 0% of the control arm. Use of nonstudy medications was reported by 12.5% of the ACT on Vaping arm and 20.7% of the control arm. Of those reporting use of medications, one participant in the ACT on Vaping arm reported using bupropion and the remainder of those using medications in both arms used NRT.

Four adverse events were reported, two of which were categorized as "definitely unrelated" to the study and two of which were categorized as "possibly related." The two possibly related events were (1) a decreased resting heart rate

Table 1. Participant Characteristics at Baseline, Overall, and by Treatment Arm

	Overall (n = 61)		Control (n = 30)		ACT on Vaping (n = 31)	
	N or mean	(%) or SD	*N* or mean	(%) or SD	*N* or mean	(%) or SD
Age	21.8	3.4	22.0	3.6	21.5	3.2
Sex assigned at birth						
Male	26	(42.6)	17	(56.7)	9	(29.0)
Female	35	(57.4)	13	(43.3)	22	(71.0)
Gender identity						
Cisgender man	25	(41.0)	16	(53.3)	9	(29.0)
Cisgender woman	30	(49.2)	11	(36.7)	19	(61.3)
Transgender or gender non-conforming	6	(9.8)	3	(10.0)	3	(9.7)
Sexual orientation						
Lesbian, gay, bisexual, queer, pansexual, something else	25	(41.0)	11	(36.7)	14	(45.2)
Straight (heterosexual)	36	(59.0)	19	(63.3)	17	(54.8)
Ethnicity						
Not Hispanic or Latino	52	(85.2)	26	(86.7)	26	(83.9)
Hispanic or Latino	9	(14.8)	4	(13.3)	5	(16.1)
Race						
American Indian or Alaska Native	2	(3.3)	1	(3.3)	1	(3.2)
Asian	5	(8.2)	2	(6.7)	3	(9.7)
Multiracial	5	(8.2)	0	0	5	(16.1)
White	49	(80.3)	27	(90.0)	22	(71.0)
Highest Level of Education						
Greater than high school education	33	(54.1)	18	(60.0)	15	(48.4)
High school education or less	28	(45.9)	12	(40.0)	16	(51.6)
Employment Status						
Employed full or part time	39	(63.9)	21	(70.0)	18	(58.1)
Not employed full or part time	22	(36.1)	9	(30.0)	13	(41.9)
Family Income						
<$50,000/yr	33	(54.1)	19	(63.3)	14	(45.2)
≥$50,000/yr	28	(45.9)	11	(36.7)	17	(54.8)
Current vaping frequency						
Once a week or more, but not daily	6	(9.8)	0	0	6	(19.4)
At least daily	55	(90.2)	30	(100.0)	25	(80.6)
Current vaping intensity						
0–4 times/d	7	(11.5)	1	(3.3)	6	(19.4)
5–9 times/d	17	(27.9)	7	(23.3)	10	(32.3)
10–14 times/d	10	(16.4)	6	(20.0)	4	(12.9)
15–19 times/d	10	(16.4)	5	(16.7)	5	(16.1)
20–29 times/d	8	(13.1)	5	(16.7)	3	(9.7)
30+ times/d	9	(14.8)	6	(20.0)	3	(9.7)
Other tobacco product use in the past 30 d						
Not at all	28	(45.9)	13	(43.3)	15	(48.4)
Less than once a month	13	(21.3)	8	(26.7)	5	(16.1)
Once a month or more, but less than once a week	7	(11.5)	3	(10.0)	4	(12.9)
Once a week or more, but not daily	6	(9.8)	2	(6.7)	4	(12.9)
At least daily	7	(11.5)	4	(13.3)	3	(9.7)
24-h quit attempts in the past 12 mo						
At least 1 attempt	47	(77.0)	21	(70.0)	26	(83.9)
No attempts	14	(23.0)	9	(30.0)	5	(16.1)

Table 1. Continued

	Overall (n = 61)		Control (n = 30)		ACT on Vaping (n = 31)	
	N or mean	(%) or SD	*N* or mean	(%) or SD	*N* or mean	(%) or SD
Contemplation Ladder score						
Greater than 5	48	(78.7)	24	(80.0)	24	(77.4)
5 or less	13	(21.3)	6	(20.0)	7	(22.6)
e-FTCD score	5.2	2.3	5.4	2.5	5.0	2.2

The Contemplation Ladder is a single-item measure with scores ranging from 0 to 10. The anchor for the cutoff score of 5, indicating high versus low quit readiness, is "Think I should quit but not quite ready." e-FTCD = electronic Fagerström Test for Cigarette Dependence, with scores ranging from 0 to 10.

Table 2. Acceptability Outcomes by Treatment Arm

	Control (n = 30)			ACT on Vaping (n = 31)		
	N	Mean (or *n*)	SD (or %)	N	Mean (or *n*)	SD (or %)
Primary acceptability outcome						
Overall how satisfied were you with your assigned program?	27	3.1	1.4	21	3.8*	1.3
Exploratory acceptability outcomes						
Overall, how useful was the program?	26	3.0	1.3	21	3.5	1.1
The program felt like it was made for someone like me.	23	3.2	1.2	22	3.0	1.3
As a result of the program, I am clearer as to how I might be able to quit vaping if and when I am ready.	23	3.1	1.6	22	4.1	1.2
The program gave me new ways of looking at quitting e-cigarette use/vaping.	23	2.9	1.4	22	4.2	1.1
I feel that the things I did with the program will help me to quit e-cigarette use/vaping if and when I am ready.	23	3.0	1.5	22	4.1	1.2
Would you recommend the program to a friend? (yes)	29	(14)	(48.3%)	23	(18)	(78.3%)

With the exception of the item asking whether participants would recommend the program to a friend, all. acceptability items were rated on a 1 (not at all) to 5 (very much) scale. SD = standard deviation.
*Exceeded trial's "go" criterion of M = 3.5.

Table 3. Efficacy Outcomes by Treatment Arm

	Control (n = 29)		ACT on Vaping (n = 24)	
	N (or mean)	% (or SD)	*N* (or mean)	% (or SD)
Primary efficacy outcomes				
Change in readiness to quit between baseline and 3 months	(+ 0.72)	(1.7)	(+ 0.96)	(2.0)
24-h quit attempt between baseline and 3 months	22	75.9%	21	87.5%*
Cotinine-confirmed 30-d PPA at 3 mo	0	0%	1	4.2%
Exploratory efficacy outcomes				
30-d self-reported PPA from all (non-therapeutic) nicotine and tobacco use at 3 mo	0	0%	2	8.3%
30-d self-reported PPA from vaping at 3 mo	0	0%	3	12.5%
Went without vaping for more than a week at any time between baseline and 3 mo	5	17.2%	8	33.3%
Self-report of quitting vaping at 3 mo (for unspecified length of time)	1	3.4%	5	20.8%
Reduced frequency of vaping between baseline and 3 mo	9	31.0%	13	54.2%
Reduced frequency of other tobacco use between baseline and 3 mo	12	41.4%	10	41.7%

All abstinence outcomes are complete case. PPA = point prevalence abstinence; SD = standard deviation.
*Exceeded trial's go criterion of at least a 5 percentage point difference between arms favoring ACT on Vaping.

(ACT on Vaping arm participant) and (2) worsening of a pre-existing mental health condition (ie, depression and anxiety in one control arm participant). Both were categorized as moderate severity and neither caused the participant to withdraw from the study. No serious adverse events were reported.

Discussion

The results of this pilot trial of the ACT on Vaping program showed a promising signal for acceptability and preliminary efficacy, exceeding the preset benchmarks for overall satisfaction and the comparison of efficacy for motivating 24-hour quit attempts, which meets the trial's prespecified go criteria. The overall pattern of exploratory outcomes was also very promising, with ACT on Vaping exceeding the control arm descriptively on most indicators of acceptability and abstinence from vaping and other nicotine and tobacco products. Higher rates of abstinence in the ACT on Vaping arm are also noteworthy given that the control arm reported a descriptively higher rate of use of nonstudy pharmacotherapy for cessation.

Effect size estimates from this trial compare favorably to the limited number of studies that have been conducted to evaluate mobile health interventions for YA vaping cessation. On the outcome of self-reported vaping cessation, the difference between the ACT on Vaping and control arms in this trial was 12.5% versus 0% (12.5 percentage difference), which exceeds the differences in the trial of *This is Quitting* (5.5 percentage difference)[14] and a pilot study of app-delivered contingency management versus app-delivered monitoring (7.3 percentage difference).[40] Although findings from the present study are not entirely comparable to these previous studies that have focused on YAs who are motivated to quit vaping, the effect size of the current study using the same definition of abstinence (ie, self-reported abstinence from vaping only) and a similar control condition involving assessment or self-monitoring is very promising.

A limitation of this study is the small sample size, which, while appropriate for a pilot study, does not allow for a definitive evaluation of acceptability or efficacy and limits the generalizability of the findings. Additionally, the cotinine testing for biochemical verification of abstinence was not directly observed, leaving open the possibility that the test could have been completed by someone other than the participant. However, there is no reason to believe that the accuracy of biochemically verified abstinence would differ by arm, so the estimated effect size is unlikely to be impacted. Because the study attrition rate differed by arm (ie, ~3% in the control arm vs. ~23% in the ACT on Vaping arm), there is a possibility that the greater time commitment associated with the ACT on Vaping intervention reduced engagement in the study. A larger sample size would be needed to evaluate this hypothesis. Finally, although utilization of the ACT on Vaping app could be tracked via the software, the extent to which participants meaningfully engaged with the text messaging component of the program is unknown, with the exception of the rate of discontinuation.

Overall, the results of this study suggest that the ACT on Vaping program was acceptable and shows promise as a digital health intervention for vaping cessation among YAs at differing levels of readiness to quit. Using data from the present study, planned enhancements of the ACT on Vaping app will focus on improving engagement with core session content and reducing the rate of discontinuation of the text messaging component. A fully powered trial is then needed to evaluate the impact of the intervention on long-term abstinence from vaping and other commercial nicotine and tobacco products—work that will not only determine the efficacy of the ACT on Vaping app specifically, but will also expand the limited body of evidence examining the efficacy of smartphone apps for nicotine and tobacco cessation more broadly and for vaping cessation more specifically.

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Declaration of Interest

ALG is employed by Truth Initiative, a nonprofit public health foundation that sells digital tobacco cessation programs to support its mission-driven work. MMK and MK receive royalties from New Harbinger Publications for a book on Acceptance and Commitment Therapy for Cravings and Addictions. Other authors have no conflicts to disclose.

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Author Contributions

Jaimee Heffner (Conceptualization [Lead], Funding acquisition [Lead], Investigation [Lead], Methodology [Lead], Project administration [Lead], Supervision [Lead], Writing—original draft [Lead], Writing—review & editing [Lead]), Kelsey Baker (Conceptualization [Supporting], Data curation [Supporting], Formal analysis [Lead], Methodology [Supporting], Validation [Lead], Writing—review & editing [Supporting]), Katerina Georgiou (Software [Supporting], Writing—review & editing [Supporting]), Amanda Graham (Conceptualization [Supporting], Investigation [Supporting], Methodology [Supporting], Software [Supporting], Writing—review & editing [Supporting]), Megan M. Kelly (Conceptualization [Supporting], Investigation [Supporting], Methodology [Supporting], Software [Supporting], Writing—review & editing [Supporting]), Pinelopi Konstantinou (Investigation [Supporting], Software [Supporting], Writing—review & editing [Supporting]), Eleana Lamprou (Investigation [Supporting], Software [Supporting], Writing—review & editing [Supporting]), Chinmaya Lele (Software [Supporting], Writing—review & editing [Supporting]), Kathleen Z. Lok (Software [Supporting], Writing—review & editing [Supporting]), Maria Orzechowski (Software [Supporting], Writing—review & editing [Supporting]), Maria Karekla (Conceptualization [Supporting], Investigation [Supporting], Methodology [Supporting], Software [Supporting], Supervision [Supporting], Writing—review & editing [Supporting]), Raymond Ruiz (Investigation [Supporting], Software [Supporting], Writing—review & editing [Supporting]), and Edit Serfozo (Project administration [Supporting], Software [Supporting], Supervision [Supporting], Writing—review & editing [Supporting])

Data Availability

Deidentified data from this study are not available in a public archive. Deidentified data from this study will be made available (as allowable according to institutional IRB standards) by emailing the corresponding author.

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