

Impact of E-Cigarette Prevention Messages on Adolescents

Study Protocol

NCT#05985538

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Participants

We recruited adolescents living in the United States (US) from a national probability-based panel administered by NORC. This panel consists of households randomly selected from a sample frame, with a known, non-zero probability of selection from NORC's National Frame. The frame provides at least 97% sample coverage of the US population by supplementing the US Postal Service Delivery Sequence File. To recruit adolescents aged 13-17, NORC first contacted a parent or guardian to obtain parental consent, followed by eligible adolescents being invited to participate in the study. Young adults aged 18-20 were invited directly to participate. The eligibility criteria included: being aged 13 to 20 years, possessing a phone capable of sending and receiving text messages, and either having used e-cigarettes or vapes in the past 30 days or being susceptible to vaping. Susceptibility was defined as answering anything other than "definitely not" or "not at all curious" to any of five susceptibility questions that were answered on four-point scales (1 = *Definitely not*, 4 = *Definitely yes*; 1 = *Not at all curious*, 4 = *Very curious*). An example item is, "Do you think you might use an e-cigarette or vape soon?" Our target sample size was 506, accounting for up to 20% loss to follow-up. The trial had 80% power to detect an effect size of $d=.28$ or larger between the intervention arm and the control arm.

Recruitment took place from February 5 to June 2 of 2024. For adolescents aged 13-17, legal parents or guardians provided informed parental consent online, and adolescents provided assent online before beginning the surveys. For young adults aged 18-20, participants provided informed consent online before beginning the surveys. Of the 733 adolescents and young adults screened, 183 were ineligible because they were not susceptible to vaping; 53 were ineligible because they did not have a phone that sends and receives text messages; 11 were ineligible because they lived in the same household as a current or prior study participant; and 6 met

criteria but declined to participate (Figure 1). This resulted in a total of $N=480$ adolescents and young adults enrolled in the trial. The trial was approved by the University of North Carolina Institutional Review Board and is registered at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/NCT05985538), identifier NCT05985538 (<https://www.clinicaltrials.gov/ct2/show/NCT05985538>). This paper follows CONSORT reporting guidelines for RCTs.

Procedures

Trial design and protocol. We conducted a two-arm randomized controlled trial (RCT) with parallel assignment. At the start of the trial, participants were randomly assigned to either *Breaking Vape*, a vaping prevention text message program (intervention arm) or to *Texting for Wellness*, a wellness text message program (attention control arm). Randomization was performed without replacement using simple randomization methods based on random numbers generated *R* Studio version 4.0.4. Due to the nature of the interventions being administered online, the research team was not blinded post-assignment.

Participants in both trial arms received at least one (but typically two) text messages per day over a 28-day period, with introductory messages sent on day 1 and concluding messages sent on day 28. The messages sent on days 2 – 27 focused on a series of topics in the intervention (negative consequences of using e-cigarettes and vaping) or attention control (wellness information) arms. To enhance engagement in both trial arms, some messages prompted replies from participants through multiple-choice quizzes and true/false questions (i.e., two-way messages). Additionally, some messages included website links to supplement the text message program information. For the intervention arm, we developed a website specifically for this study (<https://www.breakingvape.org>), while for the control arm, we provided links to existing teen wellness websites (e.g., <https://kidshealth.org/>). The structure of the intervention and control

arms were matched on the 28-day duration of the program and the number and types of two-way messages sent. In both intervention and control arms, messages were sent at approximately 4 p.m. local time. For multiple-choice quizzes and true/false questions, if participants did not respond, the correct answer was sent to them at approximately 7 p.m. local time. Consistent with the rules required by cell phone carriers, participants could opt out of receiving messages at any time by texting “Stop” and could rejoin the program by texting “Start.” A technical document describing the text messaging programs is included in the supplemental file.

To assess primary and secondary outcomes, participants completed four online surveys at four intervals: baseline, mid-intervention (2 weeks; survey was open from days 12 - 16), end of intervention (4 weeks; survey was open from days 29 - 36), and follow-up (8 weeks; survey was open from days 57 - 70). These surveys were sent by NORC via email, with text message reminders as needed (reminders were sent from a different number than the intervention messages). Incentives were offered in the form of points, redeemable for a total cash equivalent of up to \$120 upon completing the trial (\$20 for the first survey, \$25 for each of the second and third surveys, \$30 for the final survey, and \$1 for each text message response, up to \$20).

Intervention messages. Each vaping prevention text message in the *Breaking Vape* program focused on one of six topics. The program was designed so that messages about three topics were delivered before the wave 2 survey: nicotine addiction (days 2 – 5), monetary costs of vaping (days 6 – 8), chemical exposures from e-cigarette vapor (days 9 – 13); messages about the other three topics were delivered after the wave 2 but before wave 3 survey: cosmetic effects of vaping (days 14 – 16), mental and physical use symptoms of vaping (days 17 – 22), and health impact on organs from vaping (days 23 – 27). These topics were selected based on a series of studies that examined which vaping prevention content most resonated with youth.^{1,2} This

process culminated in the testing of a series of text statements that were subsequently adapted for the vaping prevention intervention.³ An example message from *Breaking Vape* is “True or false? Vaping is much less addictive than smoking cigarettes.” If a participant texted “True” (the incorrect answer), the program would respond with: “Actually, false is the right answer. Vaping can be as addictive as smoking cigarettes, and some vaping devices have even more nicotine than cigarettes. That’s why vaping is so easy to get hooked on.”

Attention control messages. Each wellness text message in the *Texting for Wellness* program focused on one of six topics, in the following order: sleep hygiene, safe driving, sun safety, study habits, nutrition, and exercise. These were chosen as they were relevant to youth but were unrelated to substance use behaviors, with content adapted from several youth-oriented wellness websites. An example message from *Texting for Wellness* is “True or false? People who eat breakfast do better in school.” If a participant texted “True” (the correct answer), the program would respond with: “You got it! Breakfast is an important part of your morning, and fueling your body before school can help you perform better.”

Text message delivery. A total of 27,840 text messages were intended to be sent out during the study. Because of intermittent technical issues in text message delivery, as well as a modest number of participants texting “stop” during the study (which halted all text message delivery unless participants texted restart), not all messages were delivered. In total, 26,100 messages were successfully delivered, representing a 93.8% fidelity rate (26,100/27,840). Text message delivery did not differ by trial arm, with a fidelity rate of 93.6% for *Breaking Vape* messages and 93.9% for attention control messages.

Intervention engagement. Of the text messages sent out, 20 of them asked for a response from the participant. Across all participants, the number of responses varied from 0 – 20 ($M=$

12.33, $SD=7.56$; $Median=16$). The number of responses was similar between *Breaking Vape* ($M=12.19$, $SD=7.71$, $Median=16$) and attention control ($M=12.46$, $SD=7.41$; $Median=16$) trial arms. Across conditions, a small proportion of participants did not respond to any messages, including 16.7% ($n=40$) in *Breaking Vape* and 12% ($n=29$) in the attention control group. In addition, we asked participants (in the 2 and 4-week surveys) how many of the text messages they read, on a 5-point response scale: 1 (none), 2 (a few), 3 (some), 4 (most), or 5 (all). In the first 2 weeks of the text-messaging, 88.1% in the *Breaking Vape* trial arm and 83.7% in the attention control arm reported reading “most” or “all” of the messages, while in the latter 2 weeks of the text-messaging, 85.5% in the *Breaking Vape* trial arm and 83.9% in the attention control arm reported reading “most” or “all” messages. We also asked participants how many of the weblinks in the text messages they visited. In the first 2 weeks of the text-messaging, 60.6% in the *Breaking Vape* trial arm and 47.2% in the attention control arm reported visiting at least one (of three possible) weblinks embedded in the text messages, while in the latter 2 weeks, 65.6% in the *Breaking Vape* trial arm and 57.6% in the attention control arm reported visiting at least one (of three) possible weblinks.

Measures

At baseline, participants reported vaping and smoking behaviors, susceptibility to vaping and smoking, vaping and smoking attitudes and beliefs, and demographic characteristics. At mid-intervention (wave 2 survey, at 2 weeks) and end of intervention (wave 3 survey, at 4 weeks), participants reported vaping and smoking behaviors, susceptibility to vaping and smoking, vaping and smoking attitudes and beliefs, and questions about reading and engaging with the text messages. At follow-up (wave 4 survey, 8 weeks after baseline), participants

reported vaping and smoking behaviors, susceptibility to vaping and smoking, and vaping and smoking attitudes and beliefs.

Primary outcome. Susceptibility to vaping at the end of text messaging (wave 3 survey, at 4 weeks) was the primary trial outcome. Susceptibility prospectively predicts vaping behavior,^{4,5} including when operationalized as a scaled score where higher values predict both greater initiation and current use of vapes.⁴ We assessed susceptibility with a 3-item susceptibility to vaping scale, similar to other studies.⁶⁻⁹ This scale assesses the extent to which adolescents are open to vaping, with a 4-point response scale ranging from “definitely not” (coded as 1) to “definitely yes” (coded as 4). We calculated a susceptibility score by averaging the 3 items, with higher scores representing higher susceptibility to vaping (Cronbach’s α at baseline =.94).

Secondary outcomes. The survey assessed several secondary outcomes hypothesized to elicit behavior change, according to the reasoned action approach¹⁰. Response scales for secondary outcomes had five points, coded such that higher scores represented a greater amount of the construct. For multi-item scales, overall scale scores were of the average of the items.

Vaping outcomes. Three-item scales assessed instrumental attitudes toward vaping ($\alpha=.89$), affective attitudes toward vaping ($\alpha=.89$), vaping addiction risk beliefs ($\alpha=.86$, vaping monetary cost beliefs ($\alpha=.94$), vaping chemical risk beliefs ($\alpha=.93$, vaping cosmetic risk beliefs ($\alpha=.90$), vaping physical symptoms of use beliefs ($\alpha=.85$), vaping mental health symptoms of use beliefs ($\alpha=.93$), vaping health organ risk beliefs ($\alpha=.91$), vaping injunctive norms ($\alpha=.92$), and vaping refusal self-efficacy beliefs ($\alpha=.91$),¹¹⁻¹⁶. Participants were also asked to report the number of days they vaped over the past 30 days. Higher scores indicated more positive attitudes towards vaping, greater belief in the harms of vaping, a stronger perception of others’ disapproval of vaping, and a greater belief in one’s ability to refuse vaping in social situations.

Smoking outcomes. Susceptibility to smoking cigarettes was assessed with a 3-item scale ($\alpha=.93$)¹⁷. Single items assessed smoking addiction risk belief, health harm risk belief, smoking instrumental attitudes and affective attitudes^{11,16}. Participants also reported the number of days they smoked cigarettes and used other tobacco products over the past 30 days.

Covariates. Adjusted models controlled for gender (male (ref), female, or other identity), age (13-15, 16-17 (ref), or 18-20), race (white (ref) or other race), ethnicity (Hispanic or not (ref)), sexual orientation (straight (ref) or LGBTQ), parental education (less than high school, high school/GED, some college (ref), bachelor's degree, or graduate school), and nicotine use in the home (no (ref) or yes).

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