Impact of The Real Cost Vaping Prevention Advertisements on Adolescents

Protocol

NCT #04836455

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Participants

We recruited adolescents living in the United States (US) from online panels administered by Qualtrics. Eligibility criteria were: aged 13 through 17 years, able to read and speak in English, able to take an online survey in English, and susceptible to e-cigarette use as shown by an answer of 2 or greater on any of five e-cigarette susceptibility items.[24] The susceptibility items assessed the extent to which adolescents were open to vaping, with a 4-point response scale that ranged from "definitely not" (coded as 1) to "definitely yes" (4).

Our target sample size was 1,500, which accounted for up to 33% of participants dropping out during the trial. With an estimated intraclass correlation of .70, the trial had power to detect an effect size of d=.25 or larger between intervention arms (combined) and the control arm.[12]

Recruitment took place from September to November 2021. Legal parents or guardians provided informed parental consent online, and adolescents provided assent online before beginning the surveys. Of the 1,708 adolescents who met inclusion criteria, 151 declined to participate and 43 were screened but unable to enroll because the study quota had been met (Figure 1). This trial was approved by the University of North Carolina Institutional Review Board and is registered at clinicaltrials.gov, identifier NCT04836455 (https://www.clinicaltrials.gov/ct2/show/NCT04836455). This paper follows CONSORT reporting guidelines for RCTs.[25]

Procedures

Trial design and protocol. We conducted a three-arm RCT with parallel assignment. Adolescents participated in four weekly online visits over a three-week period, completing a survey at each visit. Exposures to campaign ads occurred at Visits 1, 2, and 3. At the start of the

trial (Visit 1), participants were randomized to see a series of ads from one of two FDA *Real Cost* vaping prevention ad trial arms (health harms or addiction) or to a control arm (investigator-created neutral videos about vaping). Qualtrics software used simple randomization based on a single allocation ratio. Participants were randomized without replacement to one of the three trial arms using the Qualtrics randomizer. In each trial arm, participants viewed the same three ads per session, in a random order, corresponding to the trial arm they were assigned. Participants were told they were going to view three short ads, but received no information on the content or number of arms. The research team was not blinded after assignment because interventions were administered online.

At each of the visits (Visits 1 – 4), participants completed surveys reporting primary and secondary outcomes. Participants received incentives in the form of points for taking the surveys, with a total cash equivalent of $35 after completing the trial ($5 for the first and second surveys, $10 for the third survey, and $15 for the final survey). A pilot study with 51 participants was conducted prior to the trial to test trial procedures.

Intervention messages. Participants in both intervention trial arms viewed three 30-second ads from the *Real Cost* campaign, corresponding to one of the two major themes of the campaign. Those in the health harms trial arm viewed ads about toxic substances and lung damage, while those in the addiction trial arm viewed ads about consequences of nicotine addiction. Those in the control arm viewed three 30-second investigator-created neutral videos about vaping consisting of black text on a white screen with a narrator reading the text. The content of these ads included product definitions, farming practices, and manufacturing practices adapted from Wikipedia and other sources (see the Table 1).

Measures

At the first session (Visit 1), each participant reported vaping and smoking behaviors in the survey, then viewed ads that corresponded to their trial arm. They completed measures assessing message reactions after viewing each ad, after which they completed measures of susceptibility to vaping and smoking, vaping and smoking beliefs, and demographics. For the subsequent weeks of the trial (Visits 2 and 3), participants completed surveys with measures of susceptibility to vaping and smoking, vaping and smoking beliefs, and vaping and smoking behavior. Then, they viewed the same three ads from their trial arm and completed the message reactions items. At Visit 4, participants completed surveys assessing susceptibility to vaping and smoking, vaping and smoking beliefs, and vaping and smoking behavior (eFigure 1 in the Supplement).

Primary outcome. Susceptibility to vaping at Visit 4 was the primary trial outcome. Susceptibility prospectively predicts vaping behavior,[26,27] including as a scaled score where higher values predict both greater initiation and current use of vapes.[27] We assessed susceptibility with a 3-item susceptibility to vaping scale, similar to other studies.[28-31] 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) (eTables 2 and 3 in the Supplement). We calculated a susceptibility score by averaging the 3 items, with higher scores representing higher susceptibility (Cronbach's α=.93). Susceptibility was measured *after* ad exposure at Visit 1 to capture immediate ad impact and *before* ad exposure at Visits 2-4 to capture ad impact over time.

Secondary outcomes. The survey assessed several secondary outcomes hypothesized to elicit behavior change. Response scales for most 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.

Message reactions. A single item assessed attention to the message[32] and a 3-item scale assessed negative affect (α=.83).[32] Message reactions were measured immediately following ad exposure. These measures were last assessed at Visit 3 because the ads were not shown at Visit 4.

Vaping outcomes. Three-item scales assessed cognitive elaboration (α=.92),[33] social interactions (α=.94),[34] vaping health harm risk beliefs (α=.92),[35] vaping addiction risk beliefs (α=.89),[35] and vaping attitudes (α=.91).[36] Participants reported the number of days they vaped over the past 7 days at each visit. These outcomes were measured *after* ad exposure at Visit 1 and *before* ad exposure at Visits 2-4, except for days vaped which was always measured before ad exposure.

Smoking outcomes. Single items assessed smoking health harm risk belief, addiction risk belief, and smoking attitude. Susceptibility to smoking was assessed with a 3-item scale (α=.95). Participants reported the number of days they smoked over the past 7 days at each visit. We chose to retain the continuous measures of number of days vaping and smoking rather than dichotomizing these outcomes (as proposed in our trial registration) because we found substantial variability in number of days that these products were used.

Table 1. Vaping Prevention Video Ads used in the Trial

Condition	Ads	Prior recall n(%)
Real Cost – **Health Harms**	Epidemic: https://vimeo.com/325055700	198 (39.3%)
	Facts of Vaping: https://vimeo.com/413710792	189 (37.5%)
	Toxic Metals: https://vimeo.com/413711298	185 (36.7%)
Real Cost – **Addiction**	Hacked: https://vimeo.com/325055712	191 (37.7%)
	Vaping Mistake – Danny: https://vimeo.com/413711020	186 (36.8%)
	Nicotine addiction isn't pretty – Bathroom:https://vimeo.com/520033399	187 (37%)
Control	Definition: https://vimeo.com/514315064	n/a
	Farming: https://vimeo.com/514315483	
	Manufacturing: https://vimeo.com/514315497	

Note. Prior recall refers to reporting in the Visit 1 survey that participants had seen one or more of the ads in their assigned trial arm previously.