Title:
Young Adults' Responses to E-Cigarette Advertisement Features and the Effect of Restricting Features on Tobacco Use - Phase 2

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Study Protocol:
RESEARCH DESIGN
R00 Phase: Aim 2:

Participant Recruitment and Screening. We will recruit 150 young adults susceptible to EC use to complete the study. Participants will be recruited from the greater Worcester area using email, flyers, and social media, advertising an opportunity to participate in a health messaging study. Inclusion criteria are as follows: 1) 18 years old, 2) fluent in English (earn a score of at least 4 on the Rapid Estimate of Adult Literacy in Medicine), 3) biochemically confirmed abstinence of alcohol (breath alcohol concentration=.00) and combusted tobacco or marijuana (eCO: exhaled carbon monoxide <6 parts per million) at time of visit, and 4) reporting never trying an e-cigarette, not even a puff. Susceptibility to EC use, will be determined using the Susceptibility to Use Tobacco Products questionnaire.[13]

In the R00 Phase, I will use the knowledge gained in the K99 to determine the highest impact features of the selected EC ads. The highest impact features will be determined by a host of variables including features that receive the greatest visual attention (determined by eye-tracking), orienting response (determined by deceleration of heart rate), and arousal (determined by increased skin conductance). Self-report measures will be considered as well including ads associated with increased acceptance, higher positive attitudes, decreased EC severity, and increased behavioral intentions. From this information, I will create two conditions of advertisements: 1) regulated advertisements and 2) unregulated advertisements. Regulated advertisements will be the same 15 advertisements as Study 1 but with the omission of the high impact features as a way to simulate effects that may occur in young adults if these high impact features were restricted by the FDA. Unregulated advertisements will be kept in their true form with no manipulation. Using an RCT, I will track participant changes over 6 months in the following measures: susceptibility, severity, behavioral intentions, and actual tobacco use behavior following exposure to EC ads.

Participant Screening and Recruitment. Participants will be screened and recruited in the same fashion as Study 1. If participants meet eligibility, they will be scheduled for a visit. The inclusion criteria will remain the same as in Study 1. The sample will include young adults who are susceptible to using ECs.[20] To account for an anticipated attrition rate of 20%, 150 participants will be recruited to ensure a sample of 120 participants. *Note: Participants will be offered information about the Massachusetts Tobacco Cessation and Prevention Program (MTCP).*

Retention. All participants will receive $5 per visit to offset travel costs to and from the study site for a total of 4 visits ($20), $25 for each visit that they attend ($100), and an additional $1 for each time they open the online magazine and answer the survey questions ($24), for a total of $168. We will also facilitate study visits by offering evening and weekend appointments as well as additional retention strategies (e.g., multiple sources of contact, reminder calls/emails/texts). These methods are consistent with our team's previous studies and have resulted in excellent retention rates.

Procedures. Following confirmation of eligibility criteria and demonstration of participants' informed consent, participants will come to the lab for a baseline visit and complete sociodemographic questions and measures pertaining to tobacco use susceptibility,[20] perceived severity of using ECs,[21] motivations to avoid ECs,[22] behavioral intentions,[23] exposure to tobacco advertising,[24,25] and receptivity to tobacco advertising.[26] Participants will also receive a tutorial on how the online magazine will work. Then, participants will be randomized in a 1:1 ratio to one of two conditions using a computer-generated sequence: 1) Regulated condition in which all features that are highest impact have been removed or 2) Unregulated condition in which all features remain in the advertisements. Research staff will be blinded to condition allocation. Advertisements will be the same as in Study 1 but manipulated for the regulated condition. Every week, for 24 weeks, participants will be instructed to view a 10-page online magazine

delivered via email that includes content and articles aimed at young people from popular magazines among young adults, such as ESPN Magazine and Marie Claire that often contain EC ads.[7] Before viewing, participants will be asked about their exposure to tobacco advertising in the last week and their receptivity to advertising as well as other masking questions. Every magazine will also contain two EC ads and two ads for products other than tobacco. During viewing, time spent on the ad page will be recorded. Every week, the online magazine will contain different content. Additionally, EC ads will be repeated at times. Opening and reading of the online magazine will be validated using recall tasks and incentives. At the one month, three month, and six month marks, participants will come into the lab and be assessed for tobacco use susceptibility,[20] perceived severity,[21] motivations to avoid ECs,[22] behavioral intentions to use EC, and recall of the ads.[23] Participants will also be asked about their tobacco use, including ECs[24] and bio-markers of EC use, in addition to eCO to confirm self-reported combusted tobacco use status. See Study 2 Flow Chart.

Measures. Sociodemographic data will assess participant age, sex, marital status, ethnicity, employment status, occupation, years of education, and socioeconomic status. Time spent on ad will be measured by a timer that records the amount of seconds a participant spends on the EC ad through REDCap. Tobacco use questions including pictures to enhance recall will assess tobacco use across all tobacco products (i.e., cigarettes, cigars, cigarillos, little cigars, hookah, pipe tobacco) including ECs.[24] Tobacco use susceptibility, including ECs susceptibility of use will be measured using the 27-item measure.[20] Perceived severity of using ECs will be assessed by participants' perceived significance, severity, and seriousness of health threats from EC use.[21] Motivation to avoid ECs including importance, confidence, and readiness to avoid ECs will be collected to assess for changes in motivations.[22] Behavioral intentions[23] will be evaluated using questions like "How interested are you in trying ECs?" and "How willing are you to try ECs?" Participants will also complete the PhenX Toolkit measure of participants' exposure to tobacco advertising[24,25] and tobacco advertising receptivity, a validated measure of tobacco promotional product influence.[26] Biochemical confirmation of tobacco non-use will be conducted with salivary cotinine (~3 day nicotine biomarker).

Power Analysis. Trial of EC products is the primary outcome of the study; thus estimated power will be based on this outcome at the 6-month follow-up. No direct data is available on which to base sample size estimates. The closest estimates for the trial of EC products among unregulated and regulated groups are based on a study conducted by Dr. Villanti (co-mentor) examining EC trial rates at 6-month follow-up (7.9% vs. 4.7% respectively) among young adults who were exposed vs. not exposed to 4 EC ads at a single time point.[5] Since participants will be shown 24 ads over 6 months, we estimate that the trial of EC products after viewing EC advertisements over multiple time points will be higher in both the unregulated (24%) and regulated (6%) groups. As such, 150 participants (75/group) will be enrolled in the study. The sample size will provide 80% power to detect an 18% difference in increased trial of EC products between unregulated and regulated groups for a two-sided .05 level chi-squared test. Our estimates of sample size adjust for attrition rates of 20% in each arm. These attrition rates are a conservative estimate based on Dr. Wagener's (co-mentor) previous research. We are confident that with a total sample size of 150 participants (n = 120 after accounting for attrition), we will have adequate power to test our primary aim. It is important to note that this sample size is deliberately conservative, as it does not assume the availability of repeated outcome measures that will be taken throughout the study. By choosing models that utilize longitudinal data, we will be increasing the power to detect differences between arms. Note: We are currently running a trial that will help us work out any unforeseen issues with the study and sample size, but are basing these estimates on the best available data[5] and most conservative estimates.

Data Analytic Plan. Baseline demographics and EC attitudes, intentions, and use will be summarized by groups as appropriate. Continuous variables will be presented as mean±SD and

compared among the 2 groups using ANOVA test. Categorical variables will be presented as counts and proportions and compared among the 2 groups using the chi-squared test. EC trial and use, at baseline and 6-month follow-up, will be compared between the 2 groups using logistic regression analysis. The GEE model will be performed for the repeated measure analysis of EC attitudes, intentions, and use across multiple visits. Self-reported exposure and receptivity to other tobacco advertising will be used as a covariate in the analyses.