Protocol

Randomized Clinical Trial Evaluating the Impact of E-cigarette Device Warnings

NCT05714982

7/8/2025

Protocol Synopsis

Study Title	Randomized Clinical Trial Evaluating the Impact of E-cigarette Device Warnings
Funder	National Institute on Drug Abuse (NIDA)
Clinical Phase	N/A
Study Rationale	• The purpose of this randomized clinical trial is to determine whether e-cigarette warnings increase intentions to quit vaping without the unintended consequence of pushing users toward smoking. • This trial addresses these issues by evaluating the impact of e-cigarette warnings by randomly assigning vapers to have their devices and refills labeled with control messages, text warnings, or pictorial warnings.
Study Objective(s)	• This trial will assess the impact of e-cigarette warnings on vapers' devices and refills in a randomized clinical trial.
Study Design	Randomized experiment
Subject Population key criteria for and Exclusion:	Inclusion Criteria • Be 21 years or older • Currently vape every day or some days • Use an e-cigarette that contains nicotine • Be able to attend 2 in-person appointments • Be able to bring in e-cigarette device and 2 weeks' worth or refills to 2 in-person appointments • Be willing to let us apply a sticker to the device and refill materials • Be willing to use only the labeled e-cigarette during the study • Be able to complete 3 surveys online at home • Be able to read and speak English • Be able to complete a survey on a computer without help Exclusion Criteria • Pregnant people • If e-cigarette device cannot be labeled • Vapers concurrently enrolled in any research studies about vaping or using other tobacco products • Vapers who live in the same household as someone who has enrolled in the study
Number of Subjects	~1,200
Study Duration	Each subject's participation will last approximately 4 weeks.
Study Phases	There are two phases: (1) Screening: screening for eligibility and obtaining consent and (2) Intervention: study intervention/experimental treatment.
Efficacy Evaluations	The primary outcome is vaping quit intentions measured by 3 survey items at 5 time points: post-labeling (Visit 1) and at 1, 2, 3, and 4 weeks (Visits 2-5).
Statistical and Analytic Plan	• See document titled Statistical Analysis Plan.
Data and Safety Monitoring Plan	• The principal investigator is responsible for data quality management and ongoing assessment of safety.

Study Protocol

This trial will assess the impact of e-cigarette warnings on vapers' devices and refills in a randomized clinical trial.

Recruitment: Vapers will first undergo screening online or call the study center to complete the screening survey over the phone. Trial staff will schedule eligible vapers for 2 in-person visits. For each of the 2 visits, vapers will be asked to bring the vapes and refill materials they plan to use over the next 2 weeks.

Informed Consent: Prior to consenting vapers, trial staff will visually inspect photo identification of vapers to confirm that they are 21 years or older. At the beginning of the first appointment, trial staff will explain the consent form and ask the vaper to read the form. Once the participant has finished reading the form, the trial staff member will ask the participant if he or she has any questions. Then both parties will sign the consent form and the participant will receive a copy of the consent form.

Randomization: At the first visit, trial staff will randomly assign participants to one of the three trial arms by using Qualtrics software. Vapers have an equal chance of being randomized to have labels with control, text, or pictorial warnings.

Assessment: Participants will attend 2 in-person appointments at the study office (at Visit 1 and Visit 3 that are spaced 2 weeks apart). The visits will last about 45-60 minutes. At Visit 1 participants will take a survey, have their vape device and refills labeled based on their trial arm, and take another survey. At Visit 3, participants take a survey and have their vape device and refills labeled based on their trial arm. Participants will also be e-mailed 3 more surveys to complete online at home (taken at Visit 2, 4, and 5). Thus participants will take 5 weekly surveys overall.

Detailed description of the intervention: At each in-person appointment, participants will bring in the vapes and refills they plan to use over the next 2 weeks for labeling. While participants are taking the survey, trial staff will label the devices and refills based on their trial arm.

Participants randomized to the text warning arm will have labels with information about the health harms of vaping applied to their vapes and refills. Participants randomized to the pictorial arm will have labels with pictorial images and text about the health harms of vaping. Participants assigned to the control arm will have labels with neutral statements about vaping. Each trial arm will have four labels (two labels for Visit 1 and two additional labels for Visit 3). Trial staff will return labeled vapes and refills in a clear plastic bag with the e-cigarette warning labels applied to a card. Trial investigators developed the text, images, and design of these labels.

The trial staff will instruct participants in all trial arms to vape or not vape as they normally would. At the end of the trial, participants will receive a link to more information about the risks of vaping and tobacco use.