Protocol and statistical analysis plan

Identifying effective ads to encourage quitting smoking among people who smoke menthol cigarettes

NCT06485479

8/13/2024

Protocol Synopsis

Study Title	Identifying effective ads to encourage quitting smoking among people who smoke menthol cigarettes
Funder	Food and Drug Administration (FDA) National Institute on Drug Abuse (NIDA)
Clinical Phase	N/A
Study Rationale	• Menthol cigarette use is an urgent public health problem and marked by stark disparities by race/ethnicity and sexual orientation. • This trial will identify ads that encourage quitting smoking among people who smoke menthol cigarettes.
Study Objective(s)	• To evaluate whether quit smoking ads elicit higher perceived message effectiveness than control messages.
Study Design	Randomized experiment
Subject Population key criteria for and Exclusion:	Inclusion Criteria • Currently smoke menthol cigarettes • Be a member of the AmeriSpeak online survey panel or their convenience sample • Live in the US • Be age 21 years or older • Read and speak English Exclusion Criteria 1. Not currently smoke menthol cigarettes 2. Not be a member of the AmeriSpeak online survey panel or their convenience sample 3. Not live in the US 4. Be younger than age 21 years 5. Not be able to read and speak English
Number of Subjects	~1,400
Study Duration	Each subject's participation will last approximately 15 minutes. The enrollment period is expected to last ~2-4 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 perceived message effectiveness for motivation of the ads at encouraging quitting smoking. It is measured with 1 survey item for each ad (6 items total). The secondary outcomes are perceived message effectiveness for response efficacy, perceived message effectiveness for self-efficacy, intentions to quit smoking, response efficacy, and self-efficacy.
Statistical and Analytic Plan	• See page 3 of this document.
Data and Safety Monitoring Plan	• The principal investigators are responsible for data quality management and ongoing assessment of safety.

Study Protocol
This trial will identify ads that encourage quitting among people who smoke menthol cigarettes by assigning them to 1 of 5 themes (3 intervention themes and 2 control themes). Each survey respondent will view 6 ads from one of the themes and respond to survey items about the ads. Thus, this is a 5 X 6 mixed-factorial design.

Participants will be recruited through the AmeriSpeak online survey panel or their convenience sample. Survey respondents will complete an online randomized experiment programmed in Qualtrics. After providing informed consent, survey respondents will view and rate 6 ads, shown in a random order, on perceived message effectiveness (PME) for motivation (primary outcome), PME for response efficacy (secondary outcome), and PME for self-efficacy (secondary outcome). After viewing the ads, respondents will provide ratings of intentions to quit smoking (secondary outcome), response efficacy (secondary outcome), and self-efficacy of quit smoking (secondary outcome). Participants will receive incentives in an amount agreed upon with the panel company.

We hypothesize that the intervention themes elicit higher PME scores than control themes.

Statistical analysis plan
To prepare for the analyses of the primary outcome, we will create a score for PME motivation by averaging responses to the 6 ads that each respondent views. If data are missing for one or more ads, we will take the average of the remaining responses. We will follow the same approach for the secondary outcomes.

To compare the intervention and control themes, we will use linear regression with theme as a two-level predictor and PME motivation as a continuous outcome. Exploratory analyses will examine moderation by race, sexual orientation, and nicotine addiction, adding these as main effects and moderator variables to the analysis. To compare the three individual intervention themes, we will use linear regression, with dummy coding comparing one theme to the other two on PME motivation. To compare the two control themes, we will again use linear regression, using PME motivation as the outcome.

We will also compare the themes on secondary outcomes using the same approach to compare intervention and control themes overall, and to look within intervention and control themes. Statistical analyses will use two-tailed tests with a critical alpha of .05. Analyses comparing conditions will not use survey weights.