Study Protocol and Statistical Analysis Plan

Official Title: Messages About Reduced Nicotine in Combusted Tobacco Products

NCT Number: NCT05506046

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Brief Title: Effects of messages about very low nicotine cigarettes

Sponsor: National Cancer Institute of the National Institutes of Health and the Food and Drug Administration Center for Tobacco Products

Information provided by (Responsible Party): Georgia State University

Collaborator: University of South Carolina

ClinicalTrials.gov Identifier: NCT05506046

Other Study ID Numbers: IRB: H22639
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Brief Summary

This randomized controlled trial aims to examine the effects of messages about very low nicotine cigarettes (VLNCs) alone and in combination with messages about e-cigarettes. Previous research on communications about VLNCs has primarily focused on the examination of various textual statements and message attributes rather than fully developed advertisements that are used in real-world communication campaigns. In addition, no research so far has examined the effects of VLNC messages in combination with messages about e-cigarettes, which are the two parallel components of the nicotine-focused regulatory approach. The present study accesses the effects of messages about VLNCs, e-cigarettes, and their combined messaging on perceptions, behavioral intentions, and behavioral outcomes among a nationally representative sample of different smoking status populations.

The study is a four-group RCT with parallel assignment that will be delivered through an online self-administered questionnaire, consisting of two sessions over a two-week period. Participants will be randomly assigned to one of one of four trial arms: 1) VLNC messages, 2) e-cigarette messages, 3) combination of VLNC and e-cigarette messages, and 4) control messages. They will be exposed to 2 messages corresponding to the assigned condition, and answer survey questions immediately after message exposure and two weeks after

Detailed description

The FDA proposed a nicotine-focused regulatory approach to reduce nicotine in cigarettes to non-addictive levels, coupled with advising those who are not ready to quit to obtain nicotine from alternative nicotine delivery products (e-cigarettes). The widespread misperception that very low nicotine cigarettes (VLNCs) are less harmful than regular cigarettes presents challenges in communicating about this policy to the public, especially in a landscape that involves e-cigarettes. This study tested messages about VLNCs alone and combined with e-cigarettes messages that may prepare key population segments for this groundbreaking regulation.

Setting: The trial will be an experiment delivered through an online self-administered questionnaire, consisting of two sessions over a two-week period.

Recruitment: Participants will be recruited through the research company Ipsos from its national research panel (KnowledgePanel).

Informed Consent: Participants will provide online consent prior to taking the survey.

Randomization: After providing informed consent and answer pre-exposure questions, Ipsos will randomize participants into one of the four trial conditions. The randomization will use least fill for the allocation of conditions. In least fill, the survey assigned the condition that had the lowest count. If the counts for the conditions were equal, the survey would assign the condition sequentially.

Assessment: Participants will take part in two sessions: in session 1 (estimated at about 15 min) participants will answer questions assessing smoking status, quit intentions and attempts (only asked adults who smoke exclusively and adults who dual use), e-cigarette use, other tobacco product use, and health literacy. They will then view the messages, and report immediate outcomes including perceptions and behavioral intentions. In session 2, which will take place 2 weeks after session 1, participants will complete a brief 5-minute survey measuring their recall of the messages and behaviors since message exposure.

Study Type: Interventional

Study Phase: N/A

Study Design

Allocation: Randomized

Endpoint Classification: Participant reported outcomes

Intervention Model: Parallel Assignment

Masking: None (open label)

Primary Purpose: Treatment

Condition: Smoking

Intervention

1. Behavioral: exposure to messages about very low nicotine cigarettes (VLNCs)

   Two VLNC messages will be drawn at random from a pool of five messages. The messages communicate that VLNCs contain other harmful chemicals and cause diseases just as regular cigarettes, but VLNCs would be easier to quit. Messages will be shown in a random order to participants in the corresponding trial arm in session 1.

2. Behavioral: messages about e-cigarettes

   Two e-cigarette messages will be drawn at random from a pool of five messages. The message describes that people who smoke and are not ready to quit could benefit from switching to e-cigarettes to reduce their health risks. They will be shown in a random order to participants in the corresponding trial arm in session 1.

3. Behavioral: combined messaging about VLNCs and e-cigarettes

   One message from the pool of VLNC messages and one from the pool of e-cigarette messages will be randomly drawn and shown to the participants during session 1.

4. Other: bottled water ads

   Two bottled water ads that have no smoking-related content will be randomly selected from a pool of five messages, and will be shown in a random order.

Study Arm(s)

1. Experimental: VLNC messages
2. Experimental: e-cigarette messages
3. Experimental: combined VLNC and e-cigarette messages
4. Other: control messages (bottled water ads)

Publications: N/A

Recruitment Information

Recruitment Status: Not active

Actual Enrollment: 1901

Actual Completion Date: February 28, 2023

Actual Primary Completion Date: February 28, 2023

Eligibility Criteria

Inclusion Criteria:

1. Being 18 years old or older;

2. Belonging to one of three groups of participants: current exclusive smokers (adults who had smoked at least 100 cigarettes in their lifetime, currently smoked cigarettes every day or some days, and did not use e-cigarettes), dual users (adults who dual use had smoked at least 100 cigarettes in their lifetime, currently smoked cigarettes every

day or some days, and had used e-cigarettes at least once in the past 30 days), and young adult non-smokers (adults aged 18-29 years who had not smoked 100 cigarettes in their lifetime)

3. Enrolled in existing nationally representative panel where recruitment is based

Exclusion Criteria: None

Gender: All

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Listed Location Countries: United States

Primary Outcome Measures:

Title	Definition	Time Frame
Perceived health risk of VLNCs (absolute)	Measured with a single item, assesses participant's perception of own risk of overall harm to health under conditions of smoking VLNCs every day. Response options range from 1 (Not at all likely) to 5 (Extremely likely) and include "Don't know"	Immediately after exposure

Secondary Outcome Measures:

Title	Definition	Time Frame
Perceived comparative harm of VLNCs	A single item measuring perceptions of comparative risk of smoking reduced nicotine cigarettes vs regular cigarettes. Response options are from 1 (Much less harmful) to 5 (Much more harmful) and include "Don't know.'	Immediately after exposure
Perceived absolute addictiveness of VLNCs	A single item measuring participants' perception of likelihood developing addiction to reduced nicotine cigarettes under conditions of smoking them every day. Response options are from 1 (Not at all likely) to 5 (Extremely likely) and include "Don't know.'	Immediately after exposure
Interest in trying VLNC	A single item measuring participants' interests in trying VLNC. Response options are from 1 (Not at all) to 7 (Extremely) and include "Don't know".	Immediately after exposure
Intention to switch completely to e-cigarettes	A single item measuring participants' intention to switch completely to e-cigarettes in the next 6 months. Response options are from 1 (Not at all) to 7 (Extremely) and include "Don't know".	Immediately after exposure
VLNC Policy Support	A single item measuring support for the policy to reduce nicotine by 95% in all cigarettes. Response options are from 1 (Strongly Oppose) to 5 (Strongly Support) and include "Don't know."	Immediately after exposure

Perceived Message Effectiveness	3-item scale measuring to what extent participants think the messages they saw discourage them from wanting to smoke, make smoking seem unpleasant, and make them concerned about health risks of smoking. Response options are from 1 (Strongly disagree) to 7 (Strongly agree) and include "Don't know.'	Immediately after exposure
Smoking behavior	Single item measuring the average number of cigarettes smoked per day in the past two weeks.	2 weeks after exposure
Perceived absolute health risks of VLNCs at post-test	A single item measuring participants' perception of likelihood developing addiction to regular cigarettes under conditions of smoking them every day. Response options are from 1 (Not at all likely) to 5 (Extremely likely) and include "Don't know.' Measured with a single item, assesses participant's perception of own risk of overall harm to health under conditions of smoking reduced nicotine cigarettes every day. Response options range from 1 (Not at all likely) to 5 (Extremely likely) and include "Don't know"	2 weeks after exposure

Analytic Plan

1. Continuous outcomes include the primary outcome (perceived absolute harm of VLNCs), as well as other VLNC-related perceptions and behavioral intentions. Univariate analyses of covariance (ANCOVA) will be used to examine message effects on continuous outcomes.

2. Binary outcomes include smoking and communication behaviors measured at the two-week follow-up survey, as well as quit attempt, cessation, and perceived relative harm of VLNCs. Logistic regression models will be fitted to test binary outcomes.

3. Interaction effects of message conditions and smoking status will be tested by adding interaction terms to the covariate-adjusted models.

Sample size and power

The study intends to recruit a total of 1,800 participants, including 450 participants in each trial condition. It is anticipated that approximately 80% of the participants in session 1 will be retained for the two-week follow-up survey. Give a power set at 80% and a significance level (alpha) of 0.05, the trial has adequate power to detect close to small sized effects, with effect sizes between 0.13-0.28 for continuous outcomes and effect sizes between 1.4-3.5 for binary outcomes.