

Study Protocol and Statistical Analysis Plan

Official Title: Correcting Public Misperceptions about Very Low Nicotine Content Cigarettes

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Study Protocol

Objective

The objective was to test whether communication messages can reduce the misperception that very low nicotine content (VLNC) cigarettes are less harmful than other cigarettes.

Design

In this between-subjects experiment, participants were recruited from a panel, screened, and then eligible participants were randomized to one of four study arms, each with different communication messages: 1) Emotion-based messages about VLNC, 2) Continued-harm-framed messages about VLNC, 3) Myth-refuting messages about VLNC, or 4) Control messages about littering. In each arm, participants were exposed to three messages, and then outcomes were assessed. The primary outcome was the VLNC misperception, and secondary outcomes included quit intentions, perceived message effectiveness, perceived understandability, attention, negative affect, cognitive reactions, social interactions, and reactance.

Methods

Participants were recruited and screened by the panel provider, and then eligible participants were directed to an online survey that included the experiment. Participants were compensated for their time by the panel provider. The study was reviewed and approved by the institutional review board of the University of North Carolina at Chapel Hill.

Scientific Background

Tobacco use is the leading preventable cause of cancer and cancer deaths in the US. While most (69%) smokers want to quit, only 6% succeed in doing so each year. For many smokers, the addictiveness of nicotine makes quitting very difficult. To reduce cigarette smoking and resulting harms, FDA recently announced a comprehensive approach to tobacco and nicotine regulation that includes moving toward a very low nicotine content (VLNC) standard for cigarettes. Greatly reduced nicotine levels would facilitate smoking cessation. However, smokers only benefit from a VLNC policy if they quit. The success of the policy may require public understanding that, although these new cigarettes are less addictive, their high toxicity and carcinogenicity are unchanged. Although communication research suggests it is challenging to change people's incorrect understanding, new communication techniques may help reduce the VLNC misperception.

Statistical Analysis Plan

1,253 participants completed the study questionnaire, and the panel provider determined that of those, 1,145 qualified participants completed the questionnaire. The panel provider removed 13 cases from the study who skipped half or more of the survey questions. The study team received data for 1,132 participants. For analysis purposes, we excluded anyone who did not complete the questions for the primary outcome ($n=79$), yielding a final analysis sample size of 1,053. For the analyses presented in on clinicaltrials.gov, we computed the outcome values for each study arm, including simple mean values for scale items. Responses from participants who did not complete all items within a scale were not included in the analyses for that scale. No

adjustments were made for testing multiple variables. Future analysis to examine statistically-significant difference between study arms for each outcome will be conducted under the supervision of a trained statistician and following best practices in statistical methods. Since the purpose of the experiment was to reduce the misperception that low nicotine cigarettes are less harmful, we may also dichotomize the outcome to determine the percentage of participants who hold the misperception in each study arm after the communication intervention.