Complete Title: UNC Tobacco Convenience Store

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Protocol Synopsis

Study title	UNC Tobacco Convenience Store Study
Funder	National Institute on Drug Abuse and US Food and Drug Administration
Study rationale	• The United States has proposed to ban menthol as a characterizing flavor in cigarettes (i.e., a menthol ban). • The benefits of a menthol ban could be amplified by a smoking cessation campaign that encourages people who smoke menthol cigarettes to quit smoking altogether, rather than switch to different cigarettes.
Study objectives	• Evaluate whether a menthol ban reduces purchases of combustible tobacco compared to no ban. • Evaluate whether a menthol ban paired with a smoking cessation campaign reduces purchases of combustible tobacco more than a menthol ban alone.
Study design	Randomized clinical trial
Number of participants	~1,185 participants
Study duration	Each participant is in the trial for ~1 week. The trial enrollment period is expected to last ~24 months.
Study phases	The trial will have two phases: (1) Screening: screening for eligibility and obtaining consent, and (2) Intervention: intervention/experimental treatment

Study protocol

This trial aims to determine whether a quit smoking campaign amplifies the impact of a simulated menthol cigarette ban. The trial will enroll ~1,185 adults ages 21 years and older who currently smoke menthol cigarettes. Participants will attend 2 in-person study visits at our experimental store, spaced approximately 1 week apart. The store will be stocked with a variety of tobacco products, food, non-alcoholic beverages, and household goods. At the first visit, participants will provide written informed consent and will be randomized to 1 of 3 trial arms, described further below. At both study visits, participants will shop for items in the store and complete computer surveys. Researchers will record in-store purchases and other self-reported measures will be assessed via the computer surveys. In between the in-person study visits, participants will receive ads via text message based on their trial arm.

Statistical analysis plan

Predictions

We predict that the likelihood of purchasing combustible tobacco will be lower in the menthol ban arm compared to the control arm. We predict that the likelihood of purchasing combustible tobacco will be lower in the menthol ban + campaign arm compared to the menthol ban arm.

In terms of secondary outcomes, we predict that expenditures on combustible tobacco products will be lower in the menthol ban arm compared to the control arm, and lower in the menthol ban + campaign arm compared to the menthol ban arm. Additionally, we predict that the

following secondary outcomes will be higher in the menthol ban arm compared to the control arm and higher in the menthol ban + campaign arm compared to the menthol ban arm: purchasing non-combustible tobacco products, attempting to quit smoking, forgoing cigarette use, intentions to quit smoking, injunctive norms for quitting smoking, and targeted benefits of quitting smoking. We do not have formal predictions about the following secondary outcomes (possible unintended consequences): reactance toward ads, reactance towards cigarette options, stigma from ads, and stigma from cigarette options.

Statistical methods

Analyses will be intent-to-treat, including all participants randomized at Visit 1. Inferential tests will use a critical alpha of 0.05 or 95% confidence intervals and two-tailed tests.

We will descriptively present demographic characteristics separately for each trial arm. We will not conduct statistical balance tests that compare trial arms on demographic characteristics, following CONSORT guidelines for randomized clinical trials. For multi-item measures completed by study participants, we will use the mean response to survey measures, assuming sufficient internal consistency reliability (Cronbach's alpha>=0.60). If internal consistency is lower, we will consider dropping items or analyzing individual items as separate constructs.

To examine the impact of trial arm on the primary outcome, we will use mixed-effects logistic regression. The repeated measures outcome will be whether participants purchased any combustible tobacco (no or yes) at each visit. The predictors will be trial arm (using the menthol ban arm as the reference group) and study visit (Visit 1 or 2). Analysis will treat the intercept as random.

We will explore whether the impact of trial arm on the primary outcome differs by the following potential moderator variables: race/ethnicity (Black vs. non-Black), sexual orientation (lesbian, gay, or bisexual vs. straight), proportion of cigarettes smoked that are menthol, and smoking frequency (daily vs. not daily). For each moderator, we will repeat the analyses, adding the variable and the interaction of the variable with trial arm as predictors. If the interaction term is significant, we will report the impact of trial arm on the primary outcome at each level of the moderator. We will adjust p-values for probing moderation analyses for multiple post-hoc tests using a Bonferroni-Holm correction.

Next, we will examine the impact of trial arm on secondary outcomes. We will use mixed-effects linear and logistic regression for outcomes with repeated measures, using the same predictors as in the primary outcome model. For smoking quit attempts and forgoing cigarette use (measured only once), we will use standard logistic and linear regression, respectively. For expenditures on combustible tobacco products, we will code people who did not buy combustible tobacco as $0. For all secondary outcomes, we will examine the distribution and adjust the modeling strategy as needed.

Sample size needs

To estimate sample size needs for analyses of the primary trial outcome, we assumed 2 repeated measures, 3 trial arms of equal size, an intraclass correlation of .50, and 80% retention between Visits 1 and 2. We assumed 60% of the control arm would purchase combustible tobacco, in line with two prior studies.[1,2] Power analyses were conducted used mixed-effects logistic regression in SAS. We estimated that enrolling ~1,185 people (~395 per arm) would provide 80% power to detect a difference of 9 percentage points between arms in participants who made purchases. This effect size is in line with prior studies of menthol ban effects and smoking cessation campaign effects.[3,4]

References

1. Shadel WG, Martino SC, Setodji C, et al. Placing antismoking graphic warning posters at retail point-of-sale locations increases some adolescents' susceptibility to future smoking. *Nicotine and Tobacco Research*. 2019;21(2):220-226.
2. Guillory J, Kim AE, Nonnemaker JM, et al. Effect of menthol cigarette and other menthol tobacco product bans on tobacco purchases in the RTI iShoppe virtual convenience store. *Tob Control*. 2020;29(4):452-459.
3. Guillory J, Curry L, Farrelly M, et al. Reach, receptivity, and beliefs associated with the Fresh Empire Campaign to prevent and reduce cigarette use among youth in the United States. *Am J Health Promot*. 2022;36(5):789-800.
4. Willoughby JF, Noar SM. Fifteen Years after a 10-year Retrospective: The State of Health Mass Mediated Campaigns. *J Health Commun*. 2022;27(6):362-374.