

Little Cigar and Cigarillo Warnings to Reduce Tobacco-Related Cancers and Disease

Aim 3 Eye Tracking Protocol

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Rationale

Over 4 million US adults regularly smoke cigars, which causes multiple cancers, including oral, esophageal, pancreatic, laryngeal, and lung cancer (Chang et al., 2015; National Cancer Institute, 1998). Even smoking 1-2 cigars per day is associated with elevated cancer risk (Chang et al., 2015). Though cigarette consumption decreased 39% from 2000 to 2015, cigar consumption increased 85% (Wang et al., 2016). Of the three major types of cigars—large cigars, little cigars, and cigarillos—little cigars and cigarillos (LCC) are the most commonly used in the US (Delnevo et al., 2017a; Delnevo et al., 2017b). LCC use among adults has increased in part because LCCs are taxed at a lower rate than cigarettes, are subject to fewer regulations and marketing restrictions, can be purchased in small pack sizes, and are exempt from flavor bans that apply to cigarettes (Delnevo et al., 2017a; Delnevo et al., 2017b).

In May 2016, the Food and Drug Administration (FDA) required text-only warnings on LCC packs, rotating among six statements. Research on cigarettes suggests warnings on packs should have multiple rotating sets, contain images illustrating the negative health effects associated with LCC use, and be large (Noar et al., 2016; Hammond, 2011; WHO, 2008). However, the evidence for cigarette warning labels cannot adequately inform implementation of improved LCC warnings for four reasons: 1) The currently mandated cigar warnings differ from existing cigarette warnings; 2) there is no evidence on the effectiveness of the currently mandated cigar warnings (i.e., behavioral intentions or outcomes) (Glasser et al., 2017; Richardson et al., 2013; Sterling et al., 2013) or evidence on efforts that might improve LCC warnings (i.e., images, larger warning size, removal of LCC flavor descriptors on packaging); 3) Courts have ruled that one type of effective tobacco warning (i.e., for cigarettes) cannot be used to justify other types of tobacco warnings, such as those for LCCs; (R.J. Reynolds Tobacco Co. et al. v. U.S. Food & Drug Administration, 2012) and 4) LCC users have different demographic and consumption profiles than cigarette users (i.e., LCC users include a higher proportion of young adults (SAMHSA, 2016) and African Americans, (SAMHSA, 2016) and LCCs are used on fewer days per month (Jamal et al., 2018; Nyman et al., 2016)), which should be taken into account when developing improved warnings.

Gaps exist in understanding how LCC policies, such as removal of flavor descriptors on packaging, influence the impact of LCC warnings. Our eye tracking and psychophysiology project will provide new data to fill these evidence gaps and advance general scientific knowledge about elements of tobacco warnings research. We will employ a novel methodology by combining eye tracking and psychophysiology methods to study the impact of removing flavor descriptors on LCC health warnings, directly measuring visual attention and capturing emotional reactions (via survey) and arousal (perspiration via electrodermal activity (EDA) sensor).

This study can directly inform state and national cancer prevention and control actions around LCCs, and it addresses the “behavioral research in cancer prevention and control” in NCI’s Cancer Prevention and Control Program.

Objective(s)

Determine how warning images and LCC flavor descriptors on packaging impact attention and affective responses to LCC warnings.

Hypotheses

We hypothesize that:

1. Warnings with images will increase attention to the warning area of interest and increase negative affect
2. Packages with flavors will increase attention to the flavor and branding area of interest and increase positive affect

Methods and Measures

Design

We will conduct a within-participant eye tracking and psychophysiology experiment with 100 adult LCC users. The study will feature our newly developed graphic warnings and our text only LCC warnings, both with and without a sweet flavor descriptor. We will use a 2x2 design where participants will view 12 stimuli in random order and each condition is repeated three times with each warning featuring a different health effect.

Setting

Participants will complete the experiment in our office located in Carrboro, North Carolina.

Subjects Selection Criteria

Participants will be recruited through flyers, emails, and recruitment websites to identify potentially eligible participants local to our study location (Chapel Hill/Carrboro, NC)

Inclusion criteria

- Over 21 years old
- Pass quality/bot screening (will answer honestly, captcha, simple math question)
- Speak English
- Current every day or some day users of LCC products
- Able to come to an appointment in NC triangle area
- Do not have any eye conditions that prevent them from being eye tracked (e.g., glaucoma, lazy eye, bifocals)

Exclusion criteria

- Under 21 years old
- Do not speak English
- Unable to pass quality/bot screening
- Unable to come to an appointment
- Eye conditions that prevent eye tracking (e.g., glaucoma, lazy eye, bifocals)

Sample Size

Our goal is for at least 100 eligible participants to complete the study

Interventions and Interactions

After recruitment, potential participants will complete an online screening survey to determine their eligibility. Participants who meet the eligibility criteria will be contacted to set up an in-person study

appointment at our primary study location in Chapel Hill/Carrboro NC, or at another location in the Triangle area of NC.

After explaining the study protocol and obtaining consent, participants will be calibrated to the eye tracker and electrodes for the EDA data recording will be applied. Before participants are presented with stimuli, we will conduct a baseline assessment for two minutes in which participants' neutral EDA activity will be recorded (Jennings et al., 1992). This will allow us to detect within-participant changes in EDA outcomes after being exposed to LCC warnings on packs (Jennings et al., 1992).

We will then compare attention and affective responses to the two warning formats (pictorial warnings and text only warnings) in the presence and absence of flavor descriptors. Participants will see 12 LCC pack stimuli images presented in random order. 3 packs will feature pictorial LCC warnings and a "Sweet" flavor descriptor, and the same 3 warnings will be presented on packs without a flavor. The remaining 6 LCC packs will have 3 text-only warnings, with 3 images containing the "Sweet" flavor and 3 images without a flavor.

Participants can look at an image for as long as they want. After they view an image, they will be directed to a short Qualtrics survey featuring items from the Discrete Emotions Questionnaire (Harmon-Jones et al., 2016) to assess affective response to the pack image. When the survey is completed, participants will view the next randomly presented image, and the process will repeat until all 12 images are shown. At the end of the study, we will assess additional warning reaction measures and also debrief participants to explain the study purpose and provide tobacco quitting information. We will first pilot the protocol with 10 participants who currently use LCCs, and then launch the study with a goal of enrolling at least 100 participants who currently use LCCs.

At the end of the main study, participants will complete a short additional task of viewing LCC packages manipulated to include or not include blunt descriptors and flavors. Data on attention, affective response, and emotional arousal will be collected as well as measures of appeal, discouragement, and perceptions of nicotine, flavor, and taste.

Outcome Measures

- Attention to warning area of interest (e.g., dwell time to pre-defined areas of interest on the LCC package, total amount of time in milliseconds that people spend looking at warnings)
- Attention to flavor area of interest (e.g., dwell time to pre-defined areas of interest on the LCC package, total amount of time in milliseconds that people spend looking at the area where the flavor of the LCC is shown)
- Affective response to warnings using our abridged version of the Discrete Emotions Questionnaire (Harmon-Jones et al., 2016)
- Emotional arousal by Electrodermal Activity (EDA), measured by sweat on the hands (Ravaja, 2004)

Analytic Plan

We will use Tobii ProLab (Tobii, Danderyd, Sweden) to collect and analyze eye tracking and electrodermal activity outcomes and Qualtrics to collect survey measures. We will use SAS 9.4 (SAS, Cary, NC) as our primary data management and analysis software. Based on experimental design with 4 experimental conditions and 12 repeated measures, we will have 80% power to detect an $f=0.065$ effect size (comparable to $d=0.13$, for small effect size) at $\alpha=0.05$. No eye tracking studies within tobacco

control have examined the effect of flavor descriptors, however the effect size used is consistent with moderate changes in attention (Maynard et al., 2013; Maynard et al., 2014; Munafò et al., 2011; Shankleman et al., 2015). A sample size of 100 people in a within-participant eye tracking study is more than adequate to detect differences in visual attention; in a recent systematic review of eye tracking studies in tobacco control, the 4 studies with a within-design all included fewer than 35 participants.

Human Subjects Protection

Informed Consent

Potential participants will need to read and agree to an informed consent form before beginning their study appointment. Their agreement will be collected electronically and will be documented in a participant consent log.

Data and Safety Monitoring

The PI of the research project will be responsible for monitoring of the data and safety of their study participants. The proposed research will be monitored by the UNC IRB.

Reporting of Unanticipated Problems, Adverse Events, or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the PI to the IRB and sponsor agency, if appropriate.

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