Little Cigar and Cigarillo Warnings to Reduce Tobacco-Related Cancers and Disease: Randomized Controlled Trial among US Adults who use LCCs

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Version 1, 4/17/2023
Will be registered at ClinicalTrials.gov, will add registration number here: NCT05849051

Contents

Administrative Information

Trial Registration

Title: Little Cigar and Cigarillo Warnings to Reduce Tobacco-Related Cancers and Disease: Randomized Controlled Trial among US Adults who use LCCs

Short Title: Little Cigar and Cigarillo Warnings

ClinicalTrials.gov Registration: CT.gov link

Registration Date: TBD

Roles and Responsibilities

The research team below is responsible for the study design, management, analysis and interpretation of data; writing any reports or publications; and decision to submit any reports or publications. Participant recruitment and data collection will be completed through Qualtrics and their panel provider, with supervision by the study team.

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Funding Statement and Sponsors

Research reported in this publication was supported by grant number R01CA240732 from the National Cancer Institute (NCI) and the Food and Drug Administration (FDA) Center for Tobacco Products (CTP). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the Food and Drug Administration.

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Abbreviations and Definitions of Terms

Abbreviation	**Definition**
LCC	Little cigars and cigarillos
NIH	National Institutes of Health
NCI	National Cancer Institute
FDA	Food and Drug Administration
CTP	Center for Tobacco Products
UNC	University of North Carolina at Chapel Hill
HWL	Health warning labels
PME	Perceived message effectiveness
OTP	Other tobacco product (products other than little cigars and cigarillos)

Introduction

Background and Rationale

Over 4 million US adults regularly smoke cigars, which causes multiple cancers, including oral, esophageal, pancreatic, laryngeal, and lung cancer. (NCI ,1998; Chang, 2015) Even smoking 1-2 cigars per day is associated with elevated cancer risk. Though cigarette consumption decreased 39% from 2000 to 2015, cigar consumption increased 85%. (Wang, 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, Giovenco, 2017; Delnevo, Hrywna, 2017) 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.

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. (World Health Organization, 2008; Hammond, 2011; Noar, 2016) However, the evidence for cigarette warning labels cannot adequately inform implementation of improved LCC warnings for four reasons: 1) The FDA proposed cigar warnings differ from existing cigarette warnings; 2) there is no evidence on the effectiveness of the FDA proposed cigar warnings (i.e., behavioral intentions or outcomes)(Richardson, 2013; Sterling, 2013; Glasser, 2017) 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 v. FDA, 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, 2017), and African Americans, (Nyman, 2016; SAMHSA, 2017), and LCCs are used on fewer days per month)(Nyman, 2016; Jamal, 2018), which should be taken into account when developing improved warnings.

Gaps exist in understanding which LCC warning characteristics (i.e., content, format, size) are most influential in reducing LCC use, and how additional LCC policies, such as removal of flavor descriptors on packaging, influence the impact of LCC warnings. Our project will provide new data to fill these evidence gaps.

Our research on LCC warnings has found that the health effects included in warnings are the most important aspect of warning the warning statement text, and including multiple warnings can lead to stronger warnings, (Jarman, 2021) that that images paired with our warning statements that depict the internal harm or both internal and external harm of smoking LCCs were more effective. (Clark, 2022) In a 2x2 experiment to assess whether warning type (warning statement + image vs. warning statement only) and warning size (30% vs. 50%) were associated with perceived message effectiveness (PME), we found that the warnings that included images were higher in terms of PME than the warnings that were text-only, and that warning size were similar in terms of PME. (Goldstein, 2023)

Given the lack of research on LCC product warnings, our overarching goal is assess whether LCC warnings developed by the study team are more effective than the currently implemented health warnings on LCC products. Given this goal, the choice of comparators are: 1) Newly developed warnings (the six most effective warnings developed by the study team), 2) FDA proposed text-only warnings or 3) No warnings (control condition) in which participants will not see warnings.

Objectives and Hypotheses

Objectives

The proposed study will fill critical gaps regarding which characteristics make LCC warning most effective and provide needed evidence on how LCC warnings influence LCC behavioral intentions. Our overarching goal is to develop effective LCC warnings that reduce cancer and other health risks.

Hypotheses

- Newly developed warnings with images will increase LCC quit intentions more than FDA proposed text-only warnings and more than the control condition in which participants do not see packs or LCC warnings
- The FDA proposed text-only warnings will increase LCC quit intentions more than the control condition
- The warning conditions combined will increase LCC quit intentions more than the control condition
- Newly developed warnings with images will increase self-reported learning more than FDA proposed text-only warnings

Trial Design

The study is designed to be a parallel group trial, with participants evenly allocated to each study condition, using a superiority framework.

Methods: Participants, Interventions, and Outcomes

Methods Overview

We will conduct a 3-week web-based RCT of U.S. adults who currently use LCCs. In this study, LCC warnings on packs will be electronically presented to participants over time to determine if newly developed LCC warnings increase quit intentions compared to FDA proposed text-only warnings and a control condition (in which participants do not see LCC packs or warnings.) We will apply a daily diary methodology to present LCC warnings on packs to participants over time. Qualtrics will contact, screen, consent and administer the survey. To enroll participants, Qualtrics will screen participants using our inclusion criteria and measures and invite eligible participants to enroll in the study. To collect at least 750 quality completes we anticipate enrolling up to 3,000 people.

At the beginning of the baseline survey (day 0), participants will first consent to participate in the study and then complete a questionnaire about their tobacco use and behaviors (e.g., intentions and quit attempts) and other measures of interest. At the end of the baseline questionnaire, survey software will randomly assign participants to one of the 3 study conditions. The three study conditions are: 1) Newly developed warnings (the six most effective warnings developed by the study team), 2) FDA proposed text-only warnings or 3) No warnings (control condition) in which participants will not see warnings. Participants will be contacted via email each day (at approximately 6am) to invite them to complete the survey for that day of the study protocol.

For subsequent days (days 1-6, 8-13, 15-20) participants will be contacted and asked to complete a daily survey which will assess their previous day use of LCCs, as well as cigarettes and e-cigarettes. During these daily surveys, participants assigned to condition 1 or 2 (i.e., the warning conditions) will view an image of a little cigar and cigarillo package with a warning according to the participant's condition. Participants within each warning condition will view a total of 6 different warnings over the course of 6 days each week, this will be repeated 3 times during the study, resulting in a total of 18 exposures. Participants will be required to view the warning for at least 5 seconds before answering questions.

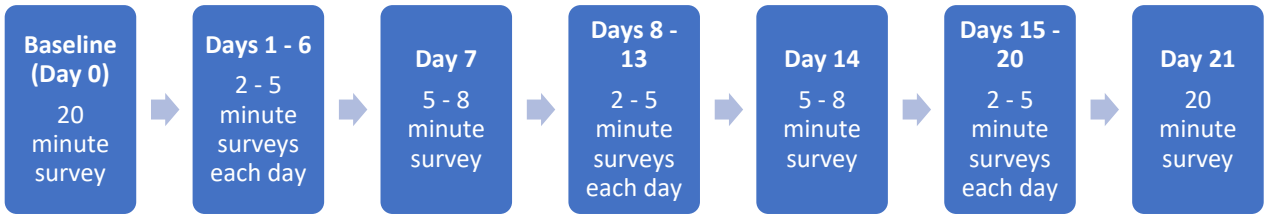
On days 7 and 14 participants will be asked to complete a slightly longer survey with questions about their LCC behaviors including: number of LCCs used in the past week, butted out because they wanted to smoke less, and forgone, other tobacco use, blunt use, and quit intentions and attempts.

For the post-test on day 21, participants will be asked to complete a longer questionnaire about their current tobacco use and behaviors including current LCC smoking behavior, LCC nicotine dependence, OTP use, LCC and OTP quit intentions, and LCC and OTP quit attempts.

Participant timeline

Potential participants will be invited to complete the screener, those who are eligible will be invited to participate in the study. On Day 0, participants will be asked to complete a baseline survey, then a survey every morning for days 1-6, 8-13, and 15-20 to deliver an LCC warning (stimuli shown only for conditions 1 and 2) and assess previous day behavior. Weekly behavior surveys will be completed on days 7 and 14. There is a final post-test on day 21.

Process:



Study Setting

The study will be conducted with online surveys, so participants can complete the surveys from wherever they are. As part of eligibility criteria, all participants will reside in the United States.

Participants

Eligibility criteria for participation in this study:

1. Members of the recruitment panel (we are partnering with a panel provider for recruitment of all participants)
2. Agree to provide their honest answers
3. Current little cigar and/or cigarillo every day or some day users
4. Over 21 years old
5. Currently living in US
6. Inclusion criteria based on the design of the study:
    a. Feel comfortable taking a survey in English without help
    b. Feel comfortable taking an online survey without help
    c. Have an email address that they check regularly
    d. Have access to the internet at work or home
    e. Able to read and respond to surveys delivered to their email
    f. Able to complete 2 surveys that take approximately 20 minutes
    g. Able to complete a 5 minute survey each day for 20 days
7. Inclusion criteria based on verifying real participants:
    a. Able to verify they are not a bot using CAPTCHA
    b. Able to answer a simple, random math question

Interventions

Experimental Conditions

1. Newly developed warnings: the six most effective warnings developed in Aim 1 at 30% size
2. FDA proposed text-only warnings: the six currently proposed warnings at 30% size
3. Control group: a control condition in which participants will not see warnings, but will be asked to complete daily surveys on previous-day LCC behaviors

Warning Stimuli

The stimuli for conditions 1 and 2 will vary based on the day of the protocol. The packages that the study warning labels will be shown on is standardized, warning labels will be shown on both a cigarillo and little cigar package (see table below: Stimuli Shown by Condition), and the packages will be purple and branded with the fictitious name "Brentfield" which has successfully been used in prior research to minimize the influence of brand loyalty and pre-existing brand perceptions. The warnings will be shown on the bottom 30% of the front of the package. Warning text for both warning conditions will be centered and the marker word "WARNING" was placed on a separate line. In accordance with FDA guidelines, warning text will be displayed in an arial bold type font. Across all warnings, the font in little cigar warnings was size 12 and in cigarillo packages, the font was size 14. (FDA, 2020)

For all warning conditions, LCC packages will be centered and placed on either a plain white background or light grey, blurred background. When present, background images will be consistent with locations where LCCs could be purchased (i.e., at a counter or in a grocery store, or blank). The background is used to give context to the stimuli that may help participants focus on it and give a more real world feeling.

Stimuli Shown by Condition:

Condition	Six Warning Messages Presented	Example LCC package depicted on each background		
		Transparent (White)	Grocery Store	Cigar Counter
Newly developed warnings (Condition 1)	WARNING: Cigar smoking causes pharyngeal and throat cancer.			
	WARNING: Cigar smoking causes stroke and blood clots.			
	WARNING: Cigar smoking causes colon cancer.			

	WARNING: Cigar smoking causes bladder cancer and blood in urine.			
	WARNING: Cigar smoking causes esophageal cancer.			
	WARNING: Cigar smoking causes lung cancer and lung disease.			
FDA proposed text-only warnings (Condition 2)	WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.			
	WARNING: Cigar smoking can cause lung cancer and heart disease.			
	WARNING: Cigars are not a safe alternative to cigarettes.			

	WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.			
	WARNING: Cigar use while pregnant can harm you and your baby.			
	WARNING: This product contains nicotine. Nicotine is an addictive chemical.			
No stimuli: Control (Condition 3)	For condition 3, the control, participants were not presented any stimuli.	N/A	N/A	N/A

Stimuli Order

Day	Message	Condition 1	Condition 2	Background
Day 1	A	Throat	Mouth	Plain
Day 2	B	Lung	Heart	Grocery
Day 3	F	Stroke	Nicotine	Counter
Day 4	C	Colon	Unsafe	Plain
Day 5	E	Bladder	Baby	Counter
Day 6	D	Esoph	SHS	Grocery
Day 8	B	Lung	Heart	Plain
Day 9	C	Colon	Unsafe	Grocery
Day 10	A	Throat	Mouth	Counter
Day 11	D	Esoph	SHS	Counter
Day 12	F	Stroke	Nicotine	Grocery
Day 13	E	Bladder	Baby	Plain
Day 15	C	Colon	Unsafe	Counter
Day 16	D	Esoph	SHS	Plain
Day 17	B	Lung	Heart	Counter
Day 18	E	Bladder	Baby	Grocery
Day 19	A	Throat	Mouth	Grocery
Day 20	F	Stroke	Nicotine	Plain

Condition 3 does not have a stimuli order because that condition does not see packages or warnings, their daily surveys are only to assess behavior

Message Order (based on Latin Square design)

- In week 1, participants see the following message order: A-B-F-C-E-D (sequence 1)
- In week 2, participants see the following message order: B-C-A-D-F-E (sequence 2)
- In week 3, participants see the following message order: C-D-B-E-A-F (sequence 3)

Message by Condition:

Message Letter	Condition 1: Text + Image Warning	Condition 2: FDA Text Only Warning
A	WARNING: Cigar smoking causes pharyngeal and throat cancer. (Throat1)	WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale. (Mouth2)
B	WARNING: Cigar smoking causes lung cancer and lung disease. (Lung1)	WARNING: Cigar smoking can cause lung cancer and heart disease. (Heart2)
C	WARNING: Cigar smoking causes colon cancer. (Colon1)	WARNING: Cigars are not a safe alternative to cigarettes. (Unsafe2)
D	WARNING: Cigar smoking causes esophageal cancer. (Esoph1)	WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers. (SHS2)
E	WARNING: Cigar smoking causes bladder cancer and blood in urine. (Bladder1)	WARNING: Cigar use while pregnant can harm you and your baby. (Baby2)

Message Letter	Condition 1: Text + Image Warning	Condition 2: FDA Text Only Warning
F	WARNING: Cigar smoking causes stroke and blood clots. (Stroke1)	WARNING: This product contains nicotine. Nicotine is an addictive chemical. (Nicotine2)

Background Order (based on Latin Square Design)

We will have 3 background options (A=Plain, B=Counter, C=Grocery), they will be counterbalanced in order based on day

- Message A will have background sequence: A, B, C (Sequence 1)
- Message B will have background sequence: C, A, B (Sequence 3)
- Message C will have background sequence: A, C, B (Sequence 2)
- Message D will have background sequence: C, B, A (Sequence 4)
- Message E will have background sequence: B, A, C (Sequence 6)
- Message F will have background sequence: B, C, A (Sequence 5)

Additional intervention details

Participants can withdraw from the study if they choose by no longer responding to the survey links and may withdraw their data by contacting the UNC study team.

Multiple strategies have been implemented to maximize adherence to the trial protocol, including reaching out to participants via email with invitations and reminders each day, compensating them based on completion of the most important questionnaires.

There is no relevant concomitant care or interventions that are permitted or prohibited during the trial.

Outcomes

Primary

- LCC quit intentions at post test (day 21)
    - Average quit intention score measured by survey, Quit intention measured with 3 questions, the final quit intention score is a mean of the response to the 3 questions, on a scale of 1 to 4, where 1 indicates low intention to quit, and 4 indicates a high intention to quit.

Secondary

- Number of LCCs smoked in past day (each day)
    - Measured daily by survey
- Number of days smoked LCCs in past week (days 7, 14, and 21)
    - Measured weekly by survey
- Number of LCCs smoked in the past week (days 7, 14, and 21)
    - Measured weekly by survey
- Butting out LCCs (days 7, 14, and 21)
    - Measured weekly by survey
- Forgoing LCCs (days 7, 14, and 21)
    - Measured weekly by survey
- LCC quit attempts (days 7, 14, and 21)
    - Measured weekly by survey
- LCC quit intentions (days 7 and 14)

- Average quit intention score measured by survey, Quit intention measured with 3 questions, the final quit intention score is a mean of the response to the 3 questions, on a scale of 1 to 4, where 1 indicates low intention to quit, and 4 indicates a high intention to quit.

- Self-reported learning (day 21) (only conditions 1 and 2)
  - Measured by survey. Self-reported learning measured with one item on a 1 to 5 scale, where 1 indicates no learning, and 5 indicates a great deal of learning from the warnings in the study.

Other

Sample Size

The sample size is based on quit intentions effect sizes from an RCT comparing graphic cigarette warnings to text only warnings (Brewer, 2016). Based on the effect size observed in that study, we would have 80% power at α=0.05 to detect a small change in differences between our groups (f=0.12).

Recruitment

We are working with Qualtrics research services to conduct this study and enroll participants from one of the panel providers that they work with. Qualtrics has access to high quality research panels across the US. They are able to leverage these panels to provide timely and reliable data collection to UNC and other research universities. We have high confidence that Qualtrics will be able to meet our recruitment goals.

Compensation Plan

Qualtrics will manage participant incentives. Participants in studies conducted by Qualtrics receive an incentive based on the length of the survey and their specific profile. The types of rewards vary and may include cash, airline miles, gift cards, redeemable points, sweepstakes entrance and vouchers. Participants who complete only the screening survey will receive a small incentive. For this study, participants who complete the baseline, 6 of the daily message surveys, at least one of the weekly surveys (day 7 or day 14), and day 21 will receive an incentive. Participants who complete only a few of the surveys but do not satisfy the criteria above will not receive an incentive.

Methods: Assignment of interventions

Allocation and Blinding

Participants will not be informed specifically about the possible interventions that they may be assigned to. Researchers will not be blinded to the condition that participants had been assigned to, however all outcome measures will be assessed via online survey. At the end of the baseline survey, survey software will randomly assign participants to one of the three study arms. Participants will have an equal chance of being randomized to each study arm.

Methods: Data collection management, and analysis

Data collection methods

Data collection will be conducted using Qualtrics web survey platform, questionnaires and references for measures can be found in the study measures document. Where possible, the measures used are previously developed and validated measures. Multiple strategies have been implemented to maximize adherence to the trial protocol, including reaching out to participants via email with invitations and reminders each day, and compensating them based on completion of the most important questionnaires.

Screener

Qualtrics will use invite potential participants to complete the screening survey and people who are eligible will be invited to complete the baseline survey. The screener is used to assess participant eligibility and collect demographic data.

Baseline Survey: Day 0

- Eligible participants will be invited to participate in the study and complete the baseline survey to enroll
- The first part of the baseline survey will be a consent form with an agreement to participate in the study
- The baseline survey contains baseline tobacco use questions (e.g., motivation to quit, previous year LCC quit attempts, nicotine dependence, etc.).

- At the end of the baseline questionnaire, survey software will randomly assign participants to one of the 3 study conditions

Daily Surveys: Days 1-6, 8-13, and 15-20

- There are 18 daily surveys, which align with each participant's condition. Participants in conditions 1 and 2 will be shown stimuli (in accordance with their assigned condition) and condition 3 will not see any stimuli. Participants will stay in their condition throughout the study. Depending on the day, participants will see a different message
- Daily surveys will be sent out at 6am EST and will close at 2am EST (gives west coast until 11pm to complete surveys). There will be a reminder email sent in the afternoon.

Weekly Surveys: Days 7, 14

- Weekly behavior surveys will include questions about LCC behaviors including: number of LCCs used in the past week, butted out because they wanted to smoke less, and forgone), other tobacco use (OTP), blunt use, and quit intentions and attempts.)
- The weekly surveys will be sent out at 6am EST and will close 48 hours later. There will be a reminder email sent in the afternoon, and the next day.

Post-Test Survey: Day 21

- For the post-test on day 21, participants will be asked to complete a longer questionnaire about their current tobacco use and behaviors including current LCC smoking behavior, LCC nicotine dependence, OTP use, LCC and OTP quit intentions, and LCC and OTP quit attempts.
- Participants in conditions 1 and 2 will be asked recognition questions to assess whether they can recognize warnings shown to them in their condition
- Participants will also be asked about their study experience
- The post-test surveys will be sent out at 6am EST and will close 48 hours later. There will be a reminder email sent in the afternoon, and the next day.

Data Management

Data management will be conducted by the study team. Multiple processes have been implemented to ensure high data quality, including internal pilots to test the protocol and ensure that data collection instruments are working properly, and ongoing data monitoring will be conducted during data collection to ensure that any issues with data quality are caught early and fixed. A pilot of the protocol with actual participants will be conducted before the full study is launched and participants will be asked about their experience in the study at the end of the pilot to further ensure that the protocol is working as intended and ensure a high quality data collection.

Statistical Methods

We will analyze the data using intention-to-treat analyses. Our primary outcome is LCC quit intention at post-test. We will model LCC quit intentions with message condition (warnings with images, FDA proposed text-only warnings, and a no warning control) as the between-participant predictor.

Analysis methods will depend on the time point that the outcome was measured. Post-test measures will be analyzed differently than repeated measures from the daily survey and weekly surveys, as outlined below. All models will include a categorical indicator of day to control for the durable linear effect of time.

Analysis methods for post-test measures will use linear regression for continuous outcomes, including the primary outcome of quit intentions, and logistic regression for dichotomous outcomes. Imputation will be used so that all participants who were randomized to an intervention and completed at least one daily survey will be included in the analysis, consistent with intention to treat practices.

Secondary models will examine differences between groups for items measured multiple times in either daily or weekly surveys (ex., LCC behavior measures). For these models, we will use linear mixed modeling to account for the repeated measure design. Mixed models are appropriate to use and robust to missing data, so we will be able to include everyone who completed at least 1 daily questionnaire, consistent with intention to treat practices.

Secondary models will also be run for the primary outcome as well as secondary outcomes that include the number of daily surveys completed (This is a measure that is equivalent to the dose of the stimuli for the active condition and also applies to the control condition)

LCC behavior is collected separately for cigarillos and little cigars and will be combined in the main analyses for these outcomes (ex. Number of cigarillos in past day and number of little cigars in past day combined for number of LCCs in past day). We also plan to run separate analyses for cigarillo behavior and little cigar behavior.

Additional information about the statistical analysis can be found in the Statistical Analysis Plan.

Methods: Monitoring

To ensure maximum protection of human subjects, we submitted our research project information to the School of Medicine Data Safety and Monitoring Board at the University of North Carolina at Chapel Hill and asked them to make the final decision regarding risk to participants and whether or not our studies should receive their supervision. A representative of the board agreed that given that the study involves a low risk behavioral intervention in a healthy population, that oversight by the board was not necessary.

Adverse events are not expected in this trial due to the minimal risks to participants, and no threat to participant health, so plans for collecting, assessing and reporting adverse events are not necessary.

We have no plans for auditing trial conduct.

Ethics and dissemination

This trial was granted an exemption by UNC's IRB under IRB # 22-2531.

All protocol changes will be communicated to the study team, and any change in participant interaction will be approved by UNC's IRB. Protocol changes will be tracked in an appendix table with new versions after initial approval including the date, version number, and a summary of changes.

Consent

Consent will be collected electronically as part of the baseline survey at the beginning of the study. At the beginning of the baseline survey, participants will view the consent form with an agreement to participate in the study. Participants will only be able to proceed with the study if they agree to participate in the study.

Confidentiality

We will take the following steps to minimize the risk to a breach of confidentiality via unauthorized access, use, disclosure, modification, loss or theft of participants' information: We will use and enforce appropriate security measures including physical, technical and administrative safeguards. Data will be stored on a university secure server that is password accessed and is only accessible to key research personnel. All study personnel are required to have valid training on ethics of research on human subjects and to complete confidentiality certification procedures upon employment. The research team will not have access to personal identifying information.

This study proposes research that has been determined to include Security Level 1 data security requirements. The PI has agreed to accept responsibility for managing these risks appropriately in consultation with departmental and/or

campus security personnel. The Data Security Requirements addendum can be reviewed here: https://guides.lib.unc.edu/datasecurity/irbis

Declaration of Interests

The study team declare that they have no competing interests.

Access to data

We will make data collection instruments available for public use after data collection and analyses are complete. On request, we will also make data sets available, stripped of individual identifiers, following publication of the relevant study's main findings. We may submit deidentified data collected in this study to a data repository, such as UNC Odum Institute's Dataverse (https://dataverse.unc.edu/dataverse/unc) to make our deidentified data publicly available. As part of submitting the data to a repository we will provide basic information about how the data was collected and upload a deidentified dataset to the repository.

Ancillary and post-trial care

This trial presents no more than minimal risk to participants, does not collect data on harms to participants or assess interim data during the trial. There is no need for ancillary or post-trail care.

Dissemination Plan

The study team plans to disseminate study findings via conference presentation and peer reviewed manuscripts in scientific journals. The study team will also share findings via ClinicalTrials.gov registration. We will follow authorship guidelines depending on the journal to which manuscripts are submitted. There are currently no plans to make a participant level dataset public.

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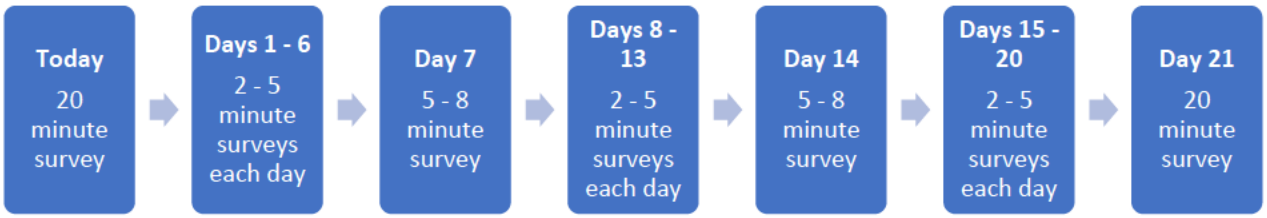
Appendix A: Trial Consent Form

University of North Carolina at Chapel Hill
Research Information Sheet
IRB Study #: 22-2531
Principal Investigator: Adam Goldstein, MD MPH

The purpose of this research study is to study tobacco use over a 3 week period of time. You are being asked to take part in this research study because you are an adult that uses little cigars or cigarillos.

Being in a research study is completely voluntary. You can choose not to be in this research study. You can also say yes now and change your mind later.

If you agree to take part in this research, you will be asked to complete a survey today, and then be asked to complete a survey every day for the next 3 weeks. Your participation in this study will take about 1.5 to 3 hours spread over today and the next 3 weeks.



We expect that 3,000 people will take part in this research study.

You can choose not to answer any question you do not wish to answer. You can also choose to stop taking the survey at any time. You must be at least 21 years old to participate. If you are younger than 21 years old, please stop now.

The possible risks to you in taking part in this research are:

- Statements or questions in the survey may make you feel uncomfortable or evoke emotional reactions. We anticipate this risk to be minimal and manageable.
- Survey questions may ask you about your opinions or behaviors that you would prefer to keep private. If you do not feel comfortable answering a question, you may skip it
- There is a risk of loss of confidentiality of the data, we will minimize these risks by using and enforcing appropriate data protection standards.

To protect your identity as a research subject, the research data will not be stored with your name, and the researcher(s) will not share your information with anyone. In any publication about this research, your name or other private information will not be used.

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one

person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

The de-identified data collected as part of this study may be used for additional research or included as part of a study data registry without additional consent.

If you complete this study, you will be given an incentive from the panel provider. To complete this study, you must complete the survey today, the surveys on day 7, 14, and on or within 48 hours after day 21, and at least 6 of the surveys on the other days.

If you have any questions about this research, please contact the study team by calling (919)966-3016 or emailing JKristen@email.unc.edu. If you have questions or concerns about your rights as a research subject, you may contact the UNC Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Do you agree to participate?
[ ] Yes, I agree to participate

Appendix B. List of Measures by Timeframe

Screener	Baseline	Daily (with messages)	Day 7 and 14 - **Weekly Behavior Assessment**	Post
Quality Participants • Quality Control • Captcha • Simple Math Problem Assess LCC use • Ever Cigarillo • Days per month smoked cigarillo • Every/some days cigarillo • Cigarillo brand • Ever little cigar • Days per month smoked little cigar • Every/some days little cigar • Little cigar brand Demographics • Age • Hispanic/Latino origin • Race • Gender • State Other inclusion criteria: • Comfort with survey in English • Comfort with survey on computer • Email access • Access to internet • Ability to complete emailed surveys	Consent Form **Weekly Behavior Assessment** Other tobacco use questions (14-28 items) • Cigarette use (2 items) • Motivation to quit smoking • Previous year LCC quit attempts • Nicotine Dependence (5 items) • Tripartite Risk (3 items) • Self-Efficacy • Response Efficacy • Open Mindedness • OTP Quit Intentions (0-7 items) • OTP Quit Attempts (0-7 items) Additional Demographics • Sexual orientation • Education • Household size • Income • Subjective Financial Status • Zip code	• Past day cigarillos • Past day little cigars • Past day cigarettes • Past day e-cigarettes • Warning/Study Stimuli • Attention to stimuli	LCC Behavior (5 – 9 items) • Memory Cue • Past week Cigarillos • Days smoked • Number smoked • Butting out cigarillos • Forgoing cigarillos • Past week little cigars • Days smoked • Number smoked • Butting out little cigars • Forgoing little cigars OTP (2-9 items) • Tobacco products used in past week • Past week large cigars • Past week cigarettes • Past week smokeless • Past week e-cigarettes • Past week hookah • Past week oral nicotine • Past week something else • Past week NRT Past day items (4 items) • Past day cigarillos • Past day little cigars • Past day cigarettes • Past day e-cigarettes Intentions, etc. (14 items)	**Weekly Behavior Assessment** Other tobacco use questions (12-26 items) • Motivation to quit smoking • Nicotine Dependence (5 items) • Tripartite Risk (3 items) • Self-Efficacy • Response Efficacy • OTP Quit Intentions (0-7 items) • OTP Quit Attempts (0-7 items) Stimuli Responses (11 items) • Reactance (3 items) • Self-reported learning • Recall • Recognition (6 items) Quality Control Questions (8-11 items) • See stimuli (+follow up) • Read text (+follow up) • Understand questions (+follow up) • Do study again • Recommend study to friend • Annoyed by study • Anything to share

• Ability to complete longer surveys • Ability to complete daily surveys			• Past week blunts (2 items) • LCC quit intentions (3 items) • LCC Quit attempts • Conversations (2 items) • Other LCC warnings • Cognitive elaboration (2 items) • Perceptions of recent LCCs smoked (3 items)	• Difficulty with behavior recall
Between 18 and 22 items – estimate about 5 – 6 minutes	Between 20 and 34 items + consent, + 25-36 from weekly behavior assessment. Estimate it will take 14 – 20 minutes when combined with screener and weekly behavior assessment	3 items or stimuli and 5 items – estimate about 2 minutes to complete	Between 25 and 36 items – estimate about 5 – 8 min	Between 31 and 48 items, plus 25-36 from weekly behavior assessment. Estimate it will take 15 – 22 minutes when combined with weekly behavior assessment