

STUDY PROTOCOL

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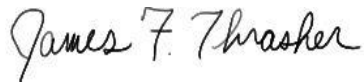
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INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study was conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance*.

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1 PROTOCOL SUMMARY

Title:	Evaluation of cigarette package inserts for enhanced communication with smokers
Grant Number:	R01 CA215466
Study Description:	<p>A randomized controlled trial was conducted to assess the influence of cigarette package inserts with messages about the benefits of cessation and tips for quitting on smoking cessation-related psychosocial and behavioral outcomes. We hypothesized that inserts would promote these outcomes and that these effects would be enhanced when cigarette packages included both inserts and pictorial warning labels. In this 2X2 between-subject trial (i.e., inserts with efficacy messages vs. no inserts; pictorial warnings vs. text-only warnings), participants received a 2-week supply of their preferred cigarette brand variety, with labeling to reflect their experimental condition.</p>
Objectives:	<p>To evaluate the impact of inserts on smoking cessation-related outcomes using a randomized controlled trial among adult smokers.</p>
Endpoints:	<p>Data were collected over 14 days using a study smartphone. Participants were instructed to log every cigarette they smoked during this period. Approximately 4-5 times a day, participants were prompted to complete a brief, 1-3 minute survey immediately after they indicated that they had smoked, with cigarette logs sampled using an algorithm based on self-reported baseline smoking frequency. Each evening, between 7 and midnight, participants were instructed to respond to an evening survey using the smartphone app, which took 1-3 minutes to complete.</p> <p><u>Primary Endpoints:</u> Self-efficacy to Quit Smoking; Self-efficacy to Cut Down on Smoking; Worry About Harms from Smoking; Strength of Feeling About Smoking; Extent of Motivation to Quit; Talk About Smoking Cessation or Harms; Foregoing or stubbing out a Cigarette</p> <p><u>Secondary Endpoints:</u> Strength of Hopefulness About Quitting; Satisfaction From Smoking; Cognitive Elaboration of Smoking Benefits; Cognitive Elaboration of Smoking Harms; Cognitive Elaboration of Cessation Benefits; Response Efficacy; Perceived Susceptibility to Smoking Harms; Cigarettes Per Day</p>

Study Population:	Adult smokers in South Carolina and New York were recruited, with efforts to recruit people from lower socioeconomic status groups. Of 1818 people screened, 602 were ineligible, 773 either declined to participate or were unable to be scheduled for orientation, and 443 were eligible and randomized. Of these, 56 did not attend the study orientation, and 20 did not complete minimum criteria to be included in the analytic sample. The final analytic sample involved 367 people.
Description of Study Intervention/Experimental Manipulation:	The 2X2 between subject intervention involved randomization to one of four groups: a) control; b) inserts only; c) pictorial warnings only; d) inserts and pictorial warnings. Insert conditions included four rotating messages, two about cessation benefits and two with cessation tips. Warning text for all conditions included four rotating messages, with the text-only “control” condition used the current warning size and placement (i.e., 50% of one pack side), whereas pictorial warnings covered approximately 50% of the lower half of both the front and back of packs.
Study Duration:	June 28, 2019 to June 29, 2021
Participant Duration:	Study participation involved a 45-minute study orientation where potential participants completed a baseline survey, received training in the 14-day study, and were provided the study materials (i.e., smartphone, cigarette packs). After the 14-day observation period, participants completed a final survey and interview and received compensation.

2.1 STUDY RATIONALE

Smoking is the leading cause of preventable disease in the US, killing 480,000 people a year.¹ Cigarette package labeling is a fundamental tobacco control policy^{2,3} that specifies how health messages are communicated to the 40 million people who smoke in the US.^{4,5} Smokers are exposed to their packs thousands of times a year, which makes packaging the most reliable, cost-effective vehicle for governments and industry to communicate with smokers. Reflecting this principle, the World Health Organization's Framework Convention on Tobacco Control (FCTC) recommends large, pictorial health warning labels (HWLs) printed on the exterior of cigarette packs to communicate about smoking-related risks.⁶ More than 100 countries have adopted pictorial HWLs,⁷ but only Canada uses inserts to enhance HWL effectiveness.

"Inserts" and "onserts" (hereafter "inserts") are small, printed leaflets that are removable material found inside or attached to the outside of product packaging (Figure 1). Tobacco companies have long used inserts to reach smokers with promotional materials and messaging (e.g., coupons, contests, product information).⁸⁻¹⁰ Smokers are exposed to inserts every time they open a new pack, which is much more often than inserts for pharmaceutical drugs that are purchased much less frequently than cigarettes. Because of their high exposure frequency, cigarette inserts need not include all pertinent information, allowing for rotating messages that address key limitations of drug inserts (e.g., concise, legible, use of imagery).¹¹⁻¹³ For example, Canada currently includes 8 different inserts that rotate across packs. One-third of Canadian smokers report reading inserts in the prior month,¹⁴ which would be equal to 12 million US smokers engaging with insert content each month. The US Food and Drug Administration (FDA) has regulatory authority to use inserts for communication with consumers¹⁵ and is developing pictorial HWL content for implementation in 4-5 years.^{16,17} The FDA can change its labeling policy to reflect scientific understanding, whether for upcoming or subsequent labels.¹⁸

Figure 1. Inserts in Canada



Studies of cigarette labeling have focused almost exclusively on HWLs about the negative consequences of smoking, generally finding that large pictorial HWLs promote smoking cessation.^{5,19,20} These studies have identified the central role of negative affect in mediating HWL effects on cessation-related intentions and behaviors.²¹⁻²⁶ However, some research and theory cautions that "fear appeals" – like HWLs that graphically portray negative health consequences from smoking – may be ineffective when people are scared but do not see an effective way to avoid the danger that the message highlights.²⁷⁻³⁶ Rather than quit smoking, smokers could deny the relevance of the message (denial), not attend to it (avoidance), or lash

out at it in anger (reactance). To minimize such defensive responses to HWLs and maximize their desirable effects, empirical evidence^{28 29} and diverse behavior change theories^{27 30 37-41} highlight the importance of efficacy messages like those that are included on Canadian inserts. However, almost no research has assessed whether efficacy messages on labels can promote smoking cessation. Our proposed study will fill this critical gap.

2.2 BACKGROUND

Scientific Premise & Conceptual Model

Our central hypothesis is that inserts with efficacy messages promote smoking cessation-related outcomes. Other primary hypotheses (Table 1) follow from our conceptual model (Figure 2). Figure 2 shows our synthesis of theory- and empirically-based propositions on which our study is based. We posit that insert exposure will increase efficacy beliefs that, in turn, increase quit motivation and quit behaviors. Prominent pictorial HWLs will increase quit motivation and behaviors primarily by generating negative affect around smoking, although some smokers will have defensive responses (e.g., avoidance, reactance) to HWLs. HWLs and inserts will interact synergistically. HWL-generated negative

Figure 2. Conceptual framework for health warning label (HWL) & insert influences on smoking cessation-related outcomes

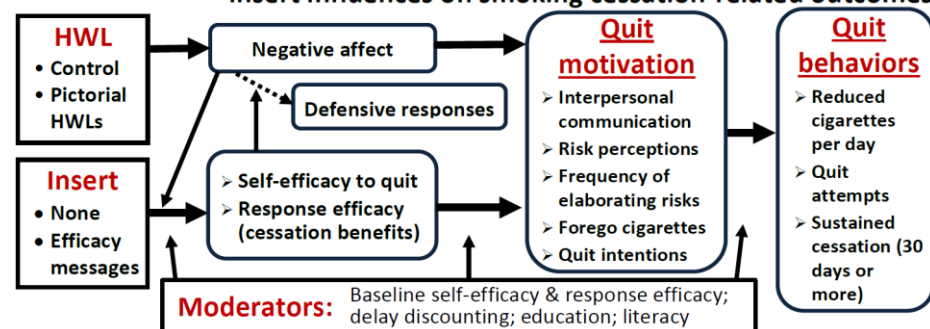


Table 1. Study 1 Hypotheses: EMA Randomized Controlled Trial

Main effects of condition on cessation-related outcomes & primary mediators
H1: Exposure to packs with inserts will result in stronger efficacy beliefs (e.g., self-efficacy, response efficacy) than packs without inserts, which, in turn, will lead to stronger cessation-related outcomes (e.g., interpersonal discussions about quitting, foregoing cigarettes, reduced consumption, intention to quit).
H2: Exposure to packs with large pictorial HWLs will produce stronger negative affective responses toward smoking than text-only HWLs, which, in turn, will lead to stronger cessation-related outcomes (see H1).
Interactions between inserts and HWLs & explanatory mechanisms
H3: Insert effects on cessation-related outcomes (see H1) will be stronger when accompanied by pictorial HWLs than by text-only HWLs, because pictorial HWLs will promote greater attention to inserts ("spotlight" effect of negative affect).
H4: Pictorial HWL effects (relative to text-only HWLs) on cessation-related outcomes (see H1) will be stronger when accompanied by inserts, because inserts will promote efficacy beliefs and thereby reduce defensive responding.
Interactions between condition & smoker characteristics
H5: Pictorial HWL effects (relative to text-only HWLs) on key outcomes (see H1) will be moderated by baseline self-efficacy to quit, such that the association will be stronger amongst smokers whose baseline self-efficacy is higher than lower (H5a). Moderation effects will be weaker when packs include inserts (H5b).
H6: Insert effects will be moderated by education, literacy, and delay discounting, such that the association with key outcomes (see H1) will be stronger for smokers with higher education, higher literacy, and lower delay discounting than for their counterparts (H6a). Moderation effects will be weaker when inserts are accompanied by pictorial HWLs due to because pictorial HWLs will have stronger effects among smokers with lower education and lower literacy (H6b).

affect will promote attention to and processing of insert messages (“spotlight” effect). Efficacy beliefs generated from inserts (or pre-existing efficacy beliefs) will reduce defensive responses to HWLs. Education will modify labeling effects given evidence of stronger responses to pictorial HWLs among smokers with lower education and literacy,⁴² although they face large barriers to cessation.^{43 44} Greater delayed discounting, or valuation of present rewards (e.g., nicotine administration) over future rewards (e.g., cessation benefits), is associated with failed cessation,^{45 46} and should reduce label effectiveness. Finally, labeling effects will vary over time, due to both message “wear out”⁴⁷⁻⁴⁹ and the dynamic nature of quit motivation.^{22 50 51}

Dual system model: We base our conceptual model in dual-system models of decision making, which posit that people process information using distinct but interacting modes of thinking.⁵²⁻⁵⁴ The “deliberative mode” is conscious, analytical, and slow, reflecting standard cognitive explanations of how people engage with information and make decisions.⁵⁵ By contrast, the “experiential mode” involves easier, more rapid and spontaneous feelings about information. The “affect heuristic,” wherein decision making is based on “gut” feelings, is based in this mode.^{56 57} Repeated exposures to information shape the feelings that make information meaningful and likely to influence people’s decisions.^{58 59} Deliberative and experiential modes are not mutually exclusive, and one may predominate over the other at any moment. In the context of repeated message exposures – as with cigarette labels – the relative prominence of either mode will vary over time because of situational and personal factors, including changes in motivation to process messages.

Studies support the central role of negative affect in explaining HWL effects on cessation-related intentions and behaviors. Compared to text-only warnings, prominent pictorial HWLs elicit more negative affect, including fear, sadness, and disgust,^{5 60} which are highly correlated in HWL studies that have considered them.^{26 61 62} These results support constructionist views of emotion that emphasize emotional valence and arousal⁶³ rather than differential effects of discrete emotions on intentions and behaviors.^{64 65} In explaining HWL effects on cessation-related outcomes, negative affect appears more important than cognitive risk perceptions.^{5 26 60}

Affective responses can function as: 1. information; 2. motivator; and 3. “spotlight”.^{22 53}^{58 59 66} As information, affective responses occur in the experiential mode, involving relatively rapid impressions of an object or information. As a motivator, positive affect prompts pleasant behaviors while negative affect inhibits behaviors that feel bad or could harm oneself. This “approach-avoidance” function to affect is central to implicit motivation models of HWL effects.^{67 68} As a spotlight, affect can lead to deliberative decision making by promoting greater scrutiny of information related to the source of the affective response.²² Prior HWL studies have found that affect functions as “information” (e.g., risk perception), “motivator” (interpersonal communication about HWLs;^{49 69 70} reduced smoking satisfaction;⁷¹ foregoing cigarettes;⁷²⁻⁷⁷ reduced cigarettes per day⁷⁸⁻⁸¹) and “spotlight” (e.g., frequency of thinking about risks^{72 76}), all of which can independently predict subsequent cessation behavior.⁴⁹ Our study

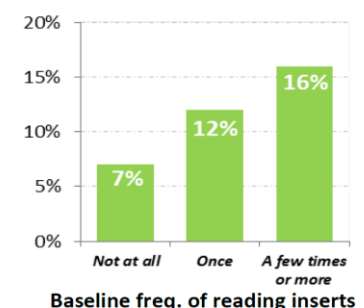
will provide a novel test of the “spotlight” function of negative affect, which we expect to promote processing of efficacy messages on inserts. This conceptualization is consistent with the “emotional flow” of persuasion,^{82 83} wherein fear appeals (e.g., HWLs encountered on the pack exterior) are most effective when followed by efficacy messages (e.g., inserts encountered after opening a pack) that generate hope about being able to escape the danger.

Defensive responses to HWLs: Fear arousing messages can produce “defensive responses” (e.g., avoidance, reactance) that, according to some theories, lead to message rejection.^{28 31-33 35} Eye-tracking research is mixed regarding whether smokers avoid HWLs by directing their attention more to branded parts of the pack than HWLs.^{84 85} Other experiments have found that fear arousing HWLs result in greater reactance (i.e., anger from perceived manipulation),^{35 36 86} which can lead to message rejection.^{88 89} Recent RCTs find that reactance offsets the effectiveness of pictorial HWLs for a subgroup of smokers, but these effects do not appear to outweigh the effectiveness of HWLs for smokers overall.^{26 77} No studies have examined whether efficacy messages enhance the effectiveness of HWLs by dampening defensive responses, as suggested by theory. The strongest critics of pictorial HWLs highlight the need for this research.³¹⁻³⁴

Efficacy beliefs and messages: Behavior change theories, such as the Extended Parallel Processing Model (EPPM)^{28 41} and Protection Motivation Theory (PMT),³⁰ posit that fear appeals will be most effective when message recipients believe the benefits of protective action (i.e., response efficacy) and are confident they can engage in this action (i.e., self-efficacy). Indeed, self-efficacy to quit predicts cessation behavior,^{14 73 77 90-94} and increasing self-efficacy to quit promotes smoking cessation.⁹⁵⁻⁹⁸ Fear appeals generally produce desired effects independent of efficacy beliefs,^{28 29 73 77} although HWLs can have weaker effects for smokers with lower self-efficacy.⁹⁹⁻¹⁰¹ No research, however, has examined whether including strong efficacy messages alongside fear-arousing HWLs will enhance desired outcomes, particularly for smokers with lower self-efficacy.

HWL messages that countries have adopted and that have been used in experimental research minimally address efficacy beliefs by including information about cessation resources (e.g., quitlines, websites).¹⁰²⁻¹⁰⁷ However, most smokers quit without using these resources,¹⁰⁸⁻¹¹¹ whose inclusion on new HWLs in Australia did not change smokers’ self-efficacy to quit.¹¹² To meaningfully change efficacy beliefs, labels likely require elaborated messages like those on Canadian inserts, which underscore cessation benefits and provide cessation tips that do not require cessation resource use. Our preliminary studies support this approach, including our post-implementation observational studies in Canada that found independent effects of reading inserts on subsequent sustained smoking cessation (Figure 3).^{14 113} No research has examined the conditions under which smokers are most likely to process efficacy messages

Figure 3. Quit for 30+ days at 4 month followup in Canada



and, thereby, increase their efficacy beliefs. Consistent with the “spotlight” function of affect⁵³ and theories of “emotional flow,”⁸² we hypothesize that efficacy messages on inserts will most influence cessation-related outcomes among smokers exposed to fear arousing pictorial HWLs on packs.

3 STUDY DESIGN

This study builds on tobacco labeling research that has focused almost exclusively on fear arousing HWLs for cigarette pack exteriors. Our assessment of efficacy messages on package inserts involves a 2X2 between-subject prospective randomized controlled trial (RCT) in the US, in which we will evaluate: a) inserts with efficacy messages vs no inserts; and b) fear arousing pictorial HWLs vs text-only HWLs.

4 STUDY POPULATION

Participant eligibility:

- Legal age to purchase cigarettes, which started at 18 but was changed to 21 years old (December 20, 2019) after the federal government increased the legal age of tobacco purchase;
- Smoked at least 100 cigarettes in their life;
- Smoked at least 10 cigarettes per day, to ensure exposure to four rotating labels in each treatment condition;
- Exhaled carbon monoxide of at least 8ppm to confirm smoking status, using COVITA. After the onset of COVID-19, this criterion was eliminated due to concerns about COVID transmission while using the COVITA device.

Participant ineligibility:

- Use of e-cigarettes, other forms of smoked tobacco (cigars, water pipe, hookah, cigarillos, little cigars, pipe), or smokeless tobacco products (chewing tobacco, snuff, dip) in the last month to minimize issues of cross-product substitution, as the study was not designed to address this issue;
- Living with someone else who has participated in or was currently participating in this two-week study, in order to prevent exposure to the study stimuli;
- Pregnant or considering becoming pregnant;
- After the onset of COVID-19 data collection, participants who reported having experienced symptoms or having been exposed to COVID-19 in the prior 30 days.

4.1 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment and training differed somewhat across the two recruitment sites: University of South Carolina (UofSC) and Cornell University. Furthermore, after the onset of COVID-19, these methods changed to ensure the safety of participants and study personnel. The information below describes these differences by site and time period.

To enhance protocol compliance and retention, check in calls were scheduled for three days after orientation and another call six days after orientation across sites and recruitment periods. Text reminders were set up for 24 hours before all calls and check ins. Before these calls, cigarette log and evening survey data were checked to assess compliance with study protocols. During the calls issues with compliance were discussed, any participant questions were answered, and participants were reminded of the date and time of the next call and follow up. After the second follow up call, participants who logged less than 50% of their baseline cigarettes per day or who missed more than one evening report received a third check in call.

Pre-COVID

UofSC: From June 28, 2019 to March 5, 2020, participants in Columbia, SC, were recruited through advertisements on social media (e.g., Facebook, Craigslist) and flyers, which directed participants to a screening survey hosted on RedCap. Eligible participants were called to confirm eligibility, interest in participating, preferred cigarette brand variety, and to schedule a date and time to attend an in-person study orientation at a UofSC lab. Prior to participants' arrival at the lab, packs of the participant's preferred brand of cigarette were purchased based on the number of cigarettes they smoked per day. These packs were then prepared according to their randomized condition with appropriate labels and inserts. Additionally, all cigarette packs were labeled on the bottom with the number of packs (i.e., if a person received 7 packs, they were labeled 1-7) and placed in a Ziplock bag to maintain freshness.

Cornell University: From July 6, 2019 to December 3, 2019, participants were recruited through intercept at smoke shops in 6 locations: Binghamton, Cortland, Ithaca, Newark, Oswego, Syracuse. Census data (54) were used to identify areas with lower median household income (ranged=\$34K - \$44K) than the state median (\$68K). Sites were selected from the list of candidates based the presence of smoke shops that were willing and able to host the mobile lab (i.e., had sufficient adjacent parking). Flyers were posted outside of the smoke shops approximately one week in advance of recruitment, with onsite signage was visible to participants at the time of recruitment. The intercept recruitment efforts occurred on weekends. At these recruitment efforts, a Cornell University-branded mobile lab (i.e., Ford Van) with five private research stations and 4-5 research staff went to recruit participants, to prepare study cigarette packs, and to conduct protocol orientation. After participants were screened for eligibility, they commenced with the baseline survey and study orientation inside the mobile lab, while study personnel purchased and prepared the cigarette packs for their preferred brand variety with labels reflecting their condition. We limited the number of

cigarette packs that participants in NY could receive to 14 packs due to the extremely high price of cigarettes in NY (i.e., the highest price in the US at \$11.96 on average). We were concerned that this high price would lead to differential participant compensation across study sites and potentially promote over-reporting of baseline smoking among NY participants.

Both Sites: At both sites, the in-person study orientation lasted approximately one hour and included:

- Eligibility confirmation with a brief survey and expired CO (≥ 8 ppm) using Covita
- Study consent
- Baseline survey (e.g., smoking behaviors, demographics)
- Baseline interview (social network data, health literacy assessment)
- Training in use of the study phone and the protocols, including how to log cigarettes, the timing of cigarette and evening surveys, what to do if participants missed logs and surveys, review of the EMA survey items, and a short quiz on the study protocol. Provision of packs modified to reflect experimental condition.
- Schedule date and time for check-in calls (3 and 6 days after orientation) and 15 days later for the follow-up survey and study debriefing.

Post-COVID onset

After the onset of COVID, we adjusted the study protocols to minimize in-person contact with study participants. Recruitment was done only through Facebook ads, and the eligibility survey integrated new questions on their availability for meeting in designated locations to receive study materials (i.e., study phone and cigarette packs) and about their ability to participate in video calls (Skype or Zoom), and COVID-19 exposures. Calls to screen for eligibility and to confirm interest in participation were the same as during the pre-COVID period with the addition of scheduling a study material pick up date and time before the virtual orientation. The social network questions were also moved to this call so the study phones could be programmed with named network members integrated into the data collection platform prior to giving the participant the materials. The baseline survey and a COVID-19 screener were also scheduled to be emailed to the participant on the morning of their materials pick up and orientation. During this period, we stopped using CO levels for determining eligibility due to concerns about COVID transmission. To meet sampling quotas, we prioritized recruitment of smokers who indicated they were male or intending to quit within six months.

UofSC: From August 12, 2020 to June 15, 2021, participants were recruited through Facebook ads, expanding the ad reach to include Columbia SC, Greenville SC, and Charlotte NC. For the material pick up and drop off, participants in Columbia briefly met staff on the UofSC campus. These participants were oriented via Zoom once home. For Greenville and Charlotte participants, a staff member traveled to the city to hand off materials while other staff conducted the Zoom orientations. Staff members wore masks and participants remained in

their cars and were encouraged to also wear masks. Participants from Greenville and Charlotte also received mailing materials to use for returning the phone after the study, whereas Columbia participants arranged to drop off the phone with study staff. The final study debrief took place on June 29, 2021.

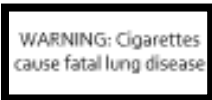
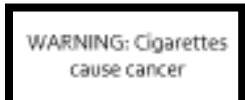
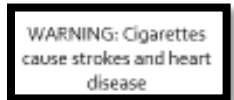
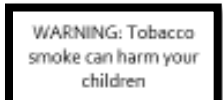









Cornell University: From December 1, 2020 to April 29, 2021, participants were recruited using the same protocols as for UofSC, including Facebook targeting of specific cities (i.e., Binghamton, Elmira, Syracuse, Rochester, Utica, and Cortland) and calling respondents to confirm eligibility and schedule meeting dates, times, and locations where they could pick up study materials. Additionally, participants at Cornell completed the orientation activities over Zoom prior to picking up the study materials.

5 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

All labeling stimuli associated with each of the four intervention groups are shown in Table 1.

- The text-only warnings were stickers that covered the existing Surgeon General's warning on the side of cigarette packs, covering approximately 50% of one side of packs. Four different text messages were selected from the 2009 Family Smoking Prevention and Tobacco Control Act that gave FDA regulatory authority over tobacco products:
 - WARNING: Cigarettes cause fatal lung disease
 - WARNING: Cigarettes cause cancer
 - WARNING: Cigarettes cause strokes and heart disease
 - WARNING: Tobacco smoke can harm your children
- The pictorial warnings were 2" x 1.75" stickers that covered approximately 50% of the bottom half of the front and back of cigarette packs. The text was the same as for the text-only warnings but with accompanying imagery selected from the FDA's originally proposed graphic warnings (2011) or for which prior research indicated effectiveness.
- The four insert messages were printed on 16 pt. matte cardstock and trimmed to 2" x 3.5". The four different messages selected based on our prior research to identify two effective messages to promote self-efficacy (i.e., tips to quit) (Loud et al., 2021) and two messages to promote response efficacy (i.e., cessation benefits) (Thrasher et al., 2018). All four inserts were designed with contrasting color schemes to help increase the likelihood that participants would recognize that the inserts included multiple messages. All four inserts included the same cessation resource information on the back. Reading levels ranged from 3.6-6.9th grade. Word counts ranged from 25-65 words.
- Participants assigned to groups that did not receive inserts received no inserts or accompanying control messages. The control group received packs labeled with just the text-only warnings.

Table 1. Stimuli Images and Sources

Text only warnings				
				
Pictorial warnings				
				
Inserts				
 <p>Dealing with Cravings</p> <p>Cravings can make quitting hard, but cravings only last 5 to 10 minutes.</p> <p>Some ways to deal with cravings:</p> <ul style="list-style-type: none"> • Breathe Deeply – Take 10 slow, deep breaths • Clean – Distract yourself by cleaning your car, desk, or junk drawer • Keep Your Hands Busy – Play with a coin, ring, or pen • Hydrate – Drink water when cravings come <p>Grade Level: 6.7 Word Count: 57</p>	 <p>Delaying a Cigarette is Practice for Quitting</p> <p>Choose one cigarette you normally smoke, like after a meal or at a work break.</p> <p>Delay smoking that cigarette for 2 hours. Make a plan for what to do during that time, and stick to it.</p> <p>Practice different types of distractions to get through the cravings.</p> <p>Learn what works for you.</p> <p>Grade Level: 3.8 Word Count: 58</p>	 <p>Good Things Happen When You Quit</p> <p>When you quit, in . . .</p> <ul style="list-style-type: none"> 20 Minutes - Your heart rate and blood pressure will drop. 2 Weeks - 3 Months - Your blood circulation and lung function improve. 1 Year - Your risk of heart disease is half of someone who still smokes. Your risk of a heart attack drops dramatically. 5 - 10 Years - Your risk of lung cancer is cut in half. <p>Grade Level: 3.6 Word Count: 65</p>	 <p>Quitting Saves Money</p> <p>For the pack-a-day smokers, quitting saves thousands of \$ each year.</p> <p>Quitting leaves more money for paying bills, buying necessities, and doing fun things.</p> <p>Grade Level: 6.9 Word Count: 25</p>	 <p>Delaying a Cigarette is Practice for Quitting</p> <p>If you want information about quitting, call</p> <p>1-800-784-8669</p> <p>or visit</p> <p>EveryTryCounts.gov</p> <p>From the U.S. Food & Drug Administration</p> <p>Word Count: 11</p>

All participants were provided with a supply of their preferred cigarette brand variety with packs modified to reflect their experimental condition. Study personnel double-checked participant assignment to experimental condition at baseline. At the end of study participation, all participants were asked to report on the labeling of the cigarettes that they received.

6 PARTICIPANT DISCONTINUATION/WITHDRAWAL

Participants could discontinue participation at any time. Clinically relevant findings were reported as an adverse event (AE). We discontinued participation for the following reasons:

- Significant study intervention non-compliance, as indicated by not logging any cigarettes or evening reports;
- Unable to contact study participant during any scheduled followup calls;
- Any event or medical condition or situation occurred such that continued collection of follow-up study data were not in the best interest of the participant or might have required an additional treatment that would confound the interpretation of the study.

The reason for participant discontinuation or withdrawal from the study were recorded. Those who signed the informed consent form and were randomized but did not receive the study intervention were replaced. Participants were also replaced if they signed the informed consent form, were randomized, received the study intervention, and subsequently withdraw, or if they were discontinued from the study.

A participant was considered lost to follow-up if study personnel were unable to contact the participant after at least 3 attempts. If the participant continued to be unreachable, he or she was considered to have withdrawn from the study with a primary reason of lost to follow-up.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Participant data were collected in three phases: the baseline survey, which included measurement of potential moderators of intervention effects (H5 & H6); ecological momentary assessments across the 2-week study period, including data collected around smoking sessions and through daily evening surveys; the final followup survey. Specifics on each of these are provided below.

Baseline survey:

Participants with confirmed eligibility who consented to participate answered a baseline survey on sociodemographics (i.e., sex, education, income), a 1-minute validated task to assess

delay discounting,^{45 46} a health literacy assessment,¹¹⁴ and smoking-related perceptions and behavior (e.g., time to first cigarette; preferred brand; risk perceptions; quit intentions; readiness to quit; self-efficacy to quit) using validated questions.¹¹⁵⁻¹¹⁸ Participants were then trained in the EMA protocol and given a 14-day supply of their preferred brand of cigarettes with packs modified to reflect their experimental condition.

Ecological Momentary Assessment (EMA) protocol:

EMA data were collected from participants over 14 days using a study smartphone (Android, Samsung Galaxy J3 and Samsung Galaxy A10e) for which all functions were disabled except for the app used for entering data. Participants were asked to use the app to log every cigarette they smoked during this period. Approximately 4-5 times a day, participants were prompted to complete a brief, 1-3 minute survey immediately after they indicated that they had smoked, with cigarette logs sampled using an algorithm based on self-reported baseline smoking frequency to reduce participant burden. Each day, between 7 and midnight, an evening survey was available in the smartphone app, which took 1-3 minutes to complete. Participants received an alert on the study phone to complete this report at 9pm if they had not already completed it by that time. The app was programmed by Col Ferguson's team at [HBART](#) and uploaded to the cloud in real time, which allowed for monitoring of participant compliance.

Follow-up survey and study debrief:

The conclusion of the study included a self-administered survey and study debrief, both which were scheduled for 15 days after the orientation. The survey took approximately 15 minutes and assessed: smoking behaviors and beliefs measured at baseline; reactance to health warning labels; reactions to the inserts and labels on their packs, depending on their condition. After completing the survey, participants completed a 30-minute debrief, which included: Aided and unaided recall of warnings and inserts to which participants were exposed; discussion of study protocol issues and suggestions to improve them in the future.

The location and timing of the followup survey and debrief were different between UofSC and Cornell University both before and after COVID-19, described as follows:

Pre-COVID UofSC: Participants received a text reminder the morning of their scheduled follow-up. Participants arrived at the UofSC campus and first completed the survey in a private room. Then, participants completed the debrief with a UofSC staff member. For the recall component of the debrief, participants viewed the stimuli on a computer screen. At the end, participants turned in their phone and charger and received their \$150 VISA gift card in person.

Pre-COVID Cornell University: Participants completed the follow up remotely with an online survey and debrief phone call. They received a text reminder and an email with the survey link the morning of their scheduled follow up. They were instructed to complete the survey on their own before their debrief call. Once they were on the phone, the staff member conducting the interview sent the participant an email with a link to an online presentation of the study stimuli for the recall component of the debrief and instructed to advance through the presentation

only when instructed during the call. If participants had not yet completed the follow-up survey, they were instructed to complete the survey and were called again once it was completed. At the end, participants were instructed to mail their phone and charger in the pre-addressed and stamped envelopes they had received during orientation. Once the phone and charger were received, their \$150 visa gift card was mailed to their home address.

Post-COVID onset UofSC: Participants received a text reminder and email with the survey link the morning of their scheduled follow up. They were instructed to complete the survey on their own before their debrief meeting. Prior to the debrief meeting, the staff member conducting the interview sent the participant a Zoom link. The debrief occurred via Zoom with audio and video sharing when possible. For the recall component of the debrief, the staff member shared their screen and showed the participants the stimuli. Columbia participants returned to the USC campus to return their cell phone and charger and receive their \$150 visa gift card. Greenville and Charlotte participants received a prepaid shipping envelope to mail their phone and charger. Once the phone and charger were received, their \$150 visa gift card was mailed to their home address.

Post-COVID-onset Cornell University: After the onset of COVID-19, the debrief occurred via Zoom with audio and video sharing when possible. For the recall component of the debrief, the staff member shared their screen and showed the participants the stimuli. If screen sharing was not possible, participants were sent the link and instructions for the online presentation of stimuli as was done during the pre-COVID period. All other aspects of the follow up protocol were the same as during the pre-COVID period.

7.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

7.2.1 DEFINITION OF ADVERSE EVENTS

This protocol used the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, ***whether or not considered intervention-related***.

Study participation involved receipt of information about the harms of smoking and the benefits of smoking cessation via cigarette package labeling. All participants were adults who smoked frequently, with their smoking status confirmed using standard protocols (COVITA ≥ 8 ppm). Study personnel monitored protocol adherence in real time, and followed up with participants, as necessary, over the 2-week study period to trouble shoot and resolve any issues related to adherence. This allowed identification of events that could be characterized as adverse events. However, we did not consider these events to be intervention-related given that the intervention consisted of the provision of information over a brief, 2-week period. Because participants were established, frequent smokers, we expected that we might detect

some adverse events over the period of observation that would be potentially related to their history of smoking, though not to study participation, per se.

The following guidelines were used to describe severity of events:

- **Mild** – Events require minimal or no treatment and do not interfere with the participant’s daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious”.

8 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

8.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

8.1.1 INFORMED CONSENT PROCESS

The UofSC IRB considered the study to be Expedited given that research activities were determined to (i) present no more than minimal risk to human subjects, and (ii) involve only procedures listed in one or more of the categories authorized by 45 CFR 46.110 and 21 CFR 56.10.

After initial screening for eligibility, potential participants were directed to a survey with the informed consent document that describes the study procedures and potential risks. When the potential participant finished reading this document, study personnel responded to any questions they had about the study. Those who were still interested in participating electronically signed the informed consent document prior to starting study participation. Consent documents are submitted to clinicaltrials.gov as separate supplementary material.

8.1.2 CONFIDENTIALITY AND PRIVACY

All study personnel were trained in human subjects research ethics, including the importance of maintaining confidentiality of research participants. Research activities were conducted in settings that were as private as possible. De-identified data from all surveys are stored on password-protected computers and associated with a unique identifying number, without any personal information attached. In one file, participants' names were associated with this unique identification number. We kept this information in a locked office and on password protected network storage for three months after study participation has ended, in

case we had any further questions around the data a particular participant provided. After that period lapsed, we destroyed this file with personal information for all participants who indicated that they were uninterested in being contacted about opportunities to participate in future research studies for which they may be eligible.

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EMA Insert Study – Baseline Survey: July 10, 2020

NOTE: After the onset of COVID-19, the questionnaire was modified to include additional questions related to COVID (shown below) but was otherwise the same as the survey used before COVID-19 onset.

Part 1: Online survey (self-administered online)

Var ID	Eligibility
DE01	How old are you? [Enter age] _____ [If <21, NOT ELIGIBLE]
SB01	Have you smoked at least 100 cigarettes in your life? 1. Yes 2. No
SB02	In the past 30 days, did you smoke every day, some days, or not at all? 1. Every day 2. Some days [NOT ELIGIBLE] 3. Did not smoke [NOT ELIGIBLE]
ND04	On average, how many cigarettes do you smoke each day, including both factory-made and roll-your-own cigarettes? [Enter number of cigarettes] _____ [If <10, NOT ELIGIBLE]
NP01	<p>Vaping products (often called e-cigarettes) are devices that heat a liquid only, but do NOT contain any actual tobacco. The liquid often contains nicotine and may be tobacco-flavored or many other flavors. The liquid that the vaping device heats may be in a cartridge or pod, or it may come separately in a bottle.</p> <p>Examples include: Juul, blu and NJOY].</p> <div style="text-align: center;">      </div> <p>During the past 30 days, did you use a vaping product or e-cigarette?</p> <p>1, Yes [NOT ELIGIBLE]</p> <p>2, No</p>
NP02	During the past 30 days, did you use any form of smoked tobacco products other than cigarettes (e.g. cigars, water pipe, hookah, cigarillos, little cigars, pipe)? 1. Yes [NOT ELIGIBLE] 2. No
NP03	During the past 30 days, did you use any form of smokeless tobacco products (e.g. chewing tobacco, snuff, dip)? 1. Yes [NOT ELIGIBLE]

	2. No
COVID-19*	<p>Have you or anyone in your household tested positive for COVID-19 in the last 30 days?</p> <p>1. Yes [NOT ELIGIBLE]</p> <p>2. No</p>
COVID-19*	<p>Have you or anyone in your household had any of the following symptoms in the last 30 days: sore throat, cough, chills, body aches for unknown reasons, shortness of breath for unknown reasons, loss of smell, loss of taste, fever at or greater than 100 degrees Fahrenheit?</p> <p>1. Yes [NOT ELIGIBLE]</p> <p>2. No</p>
COVID-19*	<p>Have you or anyone in your household visited or received treatment in a hospital, nursing home, long-term care, or other health care facility in the past 30 days</p> <p>1. Yes [NOT ELIGIBLE]</p> <p>2. No</p>
COVID-19*	<p>Have you or anyone in your household cared for an individual who is in quarantine or is suspected positive or has tested positive for COVID-19?</p> <p>1. Yes [NOT ELIGIBLE]</p> <p>2. No</p>
COVID-19*	<p>Do you have any reason to believe you or anyone in your household has been exposed to or acquired COVID-19?</p> <p>1. Yes [NOT ELIGIBLE]</p> <p>2. No</p>
COVID-19*	<p>To the best of your knowledge, have you been in close proximity to any individual who tested positive for COVID-19?</p> <p>1. Yes [NOT ELIGIBLE]</p> <p>2. No</p>
<p>* COVID-19 questions were originally developed by the American Medical Association (https://www.ama-assn.org/practice-management/sustainability/use-covid-19-screening-script-when-reopening-your-practice)</p> <p>-End of eligibility section-</p>	
WISDM (smoking dependence)	
Intro	<p>Below are a series of statements about cigarette smoking. Please rate your level of agreement for each using the following scale:</p> <p>1. Not true of me at all</p> <p>2.</p> <p>3.</p> <p>4.</p> <p>5.</p> <p>6.</p>

	7. Extremely true of me
	THE QUESTIONS ARE SHOWN IN A MATRIX WITH THE SAME SCALE PRESENT FOR EACH QUESTION.
WIS1	I often smoke without thinking about it.
WIS2	I smoke without deciding to.
WIS3	I frequently light cigarettes without thinking about it.
WIS4	I find myself reaching for cigarettes without thinking about it.
WIS5	Cigarettes control me.
WIS6	Sometimes I feel like cigarettes rule my life.
WIS7	I'm really hooked on cigarettes.
WIS8	My smoking is out of control.
WIS9	It's hard to ignore an urge to smoke.
WIS10	I frequently crave cigarettes.
WIS11	My urges to smoke keep getting stronger if I don't smoke.
WIS12	I usually want to smoke right after I wake up.
WIS13	Other smokers would consider me a heavy smoker.
WIS14	I smoke within the first 30 minutes of awakening in the morning.
WIS15	I consider myself a heavy smoker.
FTND/QA (smoking dependence)	
ND01	How soon <u>after waking up</u> do you usually have your first cigarette? 1. within the first 5 minutes 2. 6-30 minutes 3. 31-60 minutes 4. more than 60 minutes 9. Don't know
ND02	Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema)? 1. Yes 2. No
ND03	Which cigarette would you hate most to give up? 1. The first one in the morning 2. Any other
ND05	Do you smoke more frequently during the first hours after waking than during the rest of the day? 1. Yes 2. No
ND06	Do you smoke when you are so ill that you are in bed most of the day? 1. Yes 2. Yes
QA01	Are you planning to quit smoking . . . 1 Within the next month 2 Within the next 6 months 3 Sometime in the future, beyond 6 months 4 Or are you not planning to quit? 9. Don't know
QA02b	Have you made any attempts to stop smoking in the past 12 months? 1. Yes 2. No [Go to QA04] 9. Don't know [Go to QA04]
QA03b	What is your best estimate of the longest time that you went without smoking during the last 12 months? 1. Less than 24 hours

	2. Less than 30 days, but more than 24 hours 3. Between 1 month and 4 months 4. Between 4 months and 8 months 5. Between 8 months and 1 year 6. More than 1 year 9. Don't know
QA04	How much do you want to quit smoking? 1. Not at all 2. A little 3. Moderately 4. Very much 5. Extremely 99. Don't know
QA05	If you decided to quit smoking, how likely would you be to visit a website or call a telephone number that provides help for people who want to quit? 1. Not at all 2. A little 3. Moderately 4. Very 5. Extremely 99. Don't know
Response Efficacy	
RE01	How much do you think <u>you would benefit</u> from health and other gains <u>if you were to quit</u> smoking permanently? 1. Not at all 2. A little 3. Moderately 4. Very much 5. Extremely 99. Don't know
RE01b	How much would quitting smoking now reduce your chances of getting a serious disease? 1. Not at all 2. A little 3. Moderately 4. Very much 5. Extremely 99. Don't know
RE02	Please indicate how much you agree or disagree with each of the following statements. If you quit smoking, you are less likely to have a heart attack. 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know
RE03	If you quit smoking, you are less likely to get lung cancer. 1. Strongly disagree 2. Disagree 3. Neutral

	4. Agree 5. Strongly agree 9. Don't know
RE04	If you quit smoking, you are less likely to get diabetes. 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know
RE05	If you quit smoking, you would save a lot of money. 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know
RE06	If you quit smoking, you are less likely to get osteoporosis. 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know
Perceived Risk	
PR02	You will quit long before you need to worry about getting a serious disease from smoking 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know
PR01	How worried are you, if at all, that smoking will damage your health in the future? 1. Not at all 2. A little 3. Moderately 4. Very 5. Extremely 99. Don't know
Experiential Perceptions	
Intro	<i>-The following questions (EP01, EP02, and EP04) will be asked for each of the following diseases: cancer, heart disease, diabetes, and lung disease. Repeat all questions for each disease before asking about the next disease.</i>

EP01	<p>How concerned are you, if at all, about getting [disease] in your lifetime?</p> <ol style="list-style-type: none"> 1. Not at all 2. A little 3. Moderately 4. Very 5. Extremely <p>99. Don't know</p>
EP02	<p>How easy is it for you to imagine yourself getting [disease] in the future?</p> <ol style="list-style-type: none"> 1. Not at all 2. A little 3. Moderately 4. Very 5. Extremely <p>99. Don't know</p>
EP03	<p>How confident are you that you will NOT get [disease]?</p> <ol style="list-style-type: none"> 1. Not at all 2. A little 3. Moderately 4. Very 5. Extremely <p>99. Don't know</p>
Self-efficacy	
SE01	<p>If you decided to give up smoking completely how certain are you that you would succeed?</p> <ol style="list-style-type: none"> 1. Not at all 2. A little 3. Moderately 4. Very 5. Extremely <p>99. Don't know</p>
SE02	<p>If you decided to quit smoking, how certain are you that you could find the help you need to quit?</p> <ol style="list-style-type: none"> 1. Not at all 2. A little 3. Moderately 4. Very 5. Extremely <p>99. Don't know</p>
SE03	<p>Overall, how confident are you that you can stop smoking altogether right now?</p> <ol style="list-style-type: none"> 1. Not at all 2. A little 3. Moderately 4. Very 5. Extremely <p>99. Don't know</p>
SE04	<p>How confident are you that you can completely avoid smoking in the future?</p> <ol style="list-style-type: none"> 1. Not at all

	2. A little 3. Moderately 4. Very 5. Extremely 99. Don't know
Intro	Please indicate how much you agree or disagree with each of the following statements.
SE05	You know how to fight the cravings that come with quitting smoking. 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know
SE06	If you tried to quit smoking, it would be easy to fight the cravings to smoke. 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know
SE07	If you wanted to, you could delay a cigarette that you would normally smoke for at least two hours. 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know
SE08	If you decided to quit smoking, you would be able to get the support from family and friends that you need to quit. 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know
SE09	You are able to set a quit date to quit smoking. 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree 9. Don't know

Var ID	Health warnings
	The next set of questions asks about the health warnings on cigarette packages, which contain information about the health risks of smoking.
WL01	In the last 2 weeks, how often, if at all, <u>have you noticed</u> health warnings on cigarette packages? 1. Never 2. Rarely 3. Sometimes

	4. Often 5. Very often 9. Don't know
WL02	In the last 2 weeks, how often, if at all, <u>have you read or looked closely</u> at the health warnings on cigarette packages? 1. Never 2. Rarely 3. Sometimes 4. Often 5. Very often 9. Don't know
WL03	In the last 2 weeks, have the health warnings <u>stopped you from having a cigarette</u> when you were about to smoke one? Would you say . . . 1. Never 2. Once 3. A few times 4. Many times 9. Don't know
WL03A	In the last 2 weeks, how much did the health warnings make you feel angry? 1. No at all 2. A little 3. Moderately 4. Very much 5. Extremely 6. Don't know
WL03B	In the last 2 weeks, how much did the health warnings make you feel annoyed? 1. 1. No at all 2. A little 3. Moderately 4. Very much 5. Extremely 6. Don't know
WL03C	In the last 2 weeks, how much did the health warnings make you feel irritated? 1. 1. No at all 2. A little 3. Moderately 4. Very much 5. Extremely 6. Don't know
WL04	In the last 2 weeks, how often have you <u>talked with others</u> about the health warnings on cigarette packs? 1. Not at all 2. Once 3. A few times 4. Often 5. Very often 9. Don't know

WL05	How much do the health warnings <u>make you think about the health risks</u> of smoking? 1. Not at all 2. A little 3. Moderately 4. Very much 5. Extremely 9. Don't know
WL06	How much do the health warnings on cigarette packs <u>make you more likely to quit</u> smoking? 1. Not at all 2. A little 3. Moderately 4. Very much 5. Extremely 9. Don't know
WL07	How much do the health warnings <u>help people</u> who want to quit? 1. Not at all 2. A little 3. Moderately 4. Very much 5. Extremely 99. Don't know
WL08	How much do the health warnings make you feel like you would be <u>better off without smoking?</u> 1. Not at all 2. A little 3. Moderately 4. Very much 5. Extremely 99. Don't know

Var ID	Delay Discounting Task
DD100	<p>For the next 5 questions, you will be asked to choose between receiving different amounts of money at different points in time.</p> <p>You will see two options. You are requested to choose one of them. There are no right or wrong answers, but please take your time, answer thoughtfully, and pay careful attention to each of the options.</p> <p>We are NOT providing you with any additional money. Instead, we are interested in your responses to these hypothetical questions about what you would prefer if someone was to offer you money.</p> <p>Would you rather have \$500 <u>now</u> or \$1000 in <u>3 weeks</u>?</p> <p>0 - \$500 now 1 - \$1000 in 3 weeks [Ask If response=0, go to 396a/DD200a If response=1, go to 396b/DD200b]</p>
DD20 0a	<p>[Ask if 395/DD100=0.]</p> <p>Would you rather have \$500 <u>now</u> or \$1000 in <u>1 day</u>?</p> <p>0 - \$500 now 1 - \$1000 in 1 day</p>

	<p>[If response=0, go to 397a/DD300a. If response=1, go to 397b/DD300b.]</p>
DD20 0b	<p>[Ask if 395/DD100=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>2 years</u>? 0 - \$500 now 1 - \$1000 in 2 years</p> <p>[If response=0, go to 397c/DD300c. If response=1, go to 397d/DD300d.]</p>
DD30 0a	<p>[Ask if 396a/DD200a=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>4 hours</u>? 0 - \$ 500 now 1 - \$ 1000 in 4 hours</p> <p>[If response=0, go to 398a/DD400a. If response=1, go to 398b/DD400b.]</p>
DD30 0b	<p>[Ask if 396a/DD200a=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>4 days</u>? 0 - \$500 now 1 - \$1000 in 4 days</p> <p>[If response=0, go to 398c/DD400c. If response=1, go to 398d/DD400d.]</p>
DD30 0c	<p>[Ask if 396b/DD200b=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>4 months</u>? 0 - \$500 now 1 - \$1000 in 4 months</p> <p>[If response=0, go to 398e/DD400e. If response=1, go to 398f/DD400f.]</p>
DD30 0d	<p>[Ask if 396b/DD200b=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>8 years</u>? 0 - \$500 now 1 - \$1000 in 8 years</p> <p>[If response=0, go to 398g/DD400g. If response=1, go to 398h/DD400h.]</p>
DD40 0a	<p>[Ask if 397a/DD300a=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>2 hours</u>? 0 - \$500 now 1 - \$1000 in 2 hours</p> <p>[If response=0, go to 399a/DD500a. If response=1, go to 399b/DD500b.]</p>
DD40 0b	<p>Ask if 397a/DD300a=1. Would you rather have \$500 <u>now</u> or \$1000 in <u>9 hours</u>? 0 - \$500 now 1 - \$1000 in 9 hours</p> <p>[If response=0, go to 399c/DD500c. If response=1, go to 399d/DD500d.]</p>

DD40 0c	<p>[Ask if 397b/DD300b=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>2 days</u>? 0 - \$500 now 1 - \$1000 in 2 days</p> <p>[If response=0, go to 399e/DD500e. If response=1, go to 399f/DD500f.]</p>
DD40 0d	<p>[Ask if 397b/DD300b=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>1.5 weeks</u>? 0 - \$500 now 1 - \$1000 in 1.5 weeks</p> <p>[If response=0, go to 399g/DD500g. If response=1, go to 399h/DD500h.]</p>
DD40 0e	<p>[Ask if 397c/DD300c=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>2 months</u>? 0 - \$500 now 1 - \$1000 in 2 months</p> <p>[If response=0, go to 399i/DD500i. If response=1, go to 399j/DD500j.]</p>
DD40 0f	<p>[Ask if 397c/DD300c=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>8 months</u>? 0 - \$500 now 1 - \$1000 in 8 months</p> <p>[If response=0, go to 399k/DD500k. If response=1, go to 399l/DD500l.]</p>
DD40 0g	<p>[Ask if 397d/DD300d=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>4 years</u>? 0 - \$500 now 1 - \$1000 in 4 years</p> <p>[If response=0, go to 399m/DD500m. If response=1, go to 399n/DD500n.]</p>
DD40 0h	<p>[Ask if 397d/DD300d=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>18 years</u>? 0 - \$500 now 1 - \$1000 in 18 years</p> <p>[If response=0, go to 399o/DD500o. If response=1, go to 399p/DD500p.]</p>
DD50 0a	<p>[Ask if 398a/DD400a=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>1 hour</u>? 0 - \$500 now 1 - \$1000 in 1 hour</p> <p>[go to part 5, sociodemographics]</p>
DD50 0b	<p>[Ask if 398a/DD400a=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>3 hours</u>? 0 - \$500 now 1 - \$1000 in 3 hours</p>

	[go to part 5, sociodemographics]
DD50 0c	[Ask if 398b/DD400b=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>6 hours</u> ? 0 - \$500 now 1 - \$1000 in 6 hours [go to part 5, sociodemographics]
DD50 0d	[Ask if 398b/DD400b=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>12 hours</u> ? 0 - \$500 now 1 - \$1000 in 12 hours [go to part 5, sociodemographics]
DD50 0e	[Ask if 398c/DD400c=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>1.5 days</u> ? 0 - \$500 now 1 - \$1000 in 1.5 days [go to part 5, sociodemographics]
DD50 0f	[Ask if 398c/DD400c=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>3 days</u> ? 0 - \$500 now 1 - \$1000 in 3 days [go to part 5, sociodemographics]
DD50 0g	[Ask if 398d/DD400d=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>1 week</u> ? 0 - \$500 now 1 - \$1000 in 1 week [go to part 5, sociodemographics]
DD50 0h	[Ask if 398d/DD400d=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>2 weeks</u> ? 0 - \$500 now 1 - \$1000 in 2 weeks [go to part 5, sociodemographics]
DD50 0i	[Ask if 398e/DD400e=0.] Would you rather have \$500 <u>now</u> or \$1000 in <u>1 month</u> ? 0 - \$500 now 1 - \$1000 in 1 month [go to part 5, sociodemographics]
DD50 0j	[Ask if 398e/DD400e=1.] Would you rather have \$500 <u>now</u> or \$1000 in <u>3 months</u> ? 0 - \$500 now 1 - \$1000 in 3 months [go to part 5, sociodemographics]
DD50	[Ask if 398f/DD400f=0.]

0k	<p>Would you rather have \$500 <u>now</u> or \$1000 in <u>6 months</u>?</p> <p>0 - \$500 now 1 - \$1000 in 6 months</p> <p>[go to part 5, sociodemographics]</p>
DD50 0l	<p>[Ask if 398f/DD400f=1.]</p> <p>Would you rather have \$500 <u>now</u> or \$1000 in <u>1 year</u>?</p> <p>0 - \$500 now 1 - \$1000 in 1 year</p> <p>[go to part 5, sociodemographics]</p>
DD50 0m	<p>[Ask if 398g/DD400g=0.]</p> <p>Would you rather have \$500 <u>now</u> or \$1000 in <u>3 years</u>?</p> <p>0 - \$500 now 1 - \$1000 in 3 years</p> <p>[go to part 5, sociodemographics]</p>
DD50 0n	<p>[Ask if 398g/DD400g=1.]</p> <p>Would you rather have \$500 <u>now</u> or \$1000 in <u>5 years</u>?</p> <p>0 - \$500 now 1 - \$1000 in 5 years</p> <p>[go to part 5, sociodemographics]</p>
DD50 0o	<p>[Ask if 398h/DD400h=0.]</p> <p>Would you rather have \$500 <u>now</u> or \$1000 in <u>12 years</u>?</p> <p>0 - \$500 now 1 - \$1000 in 12 years</p> <p>[go to part 5, sociodemographics]</p>
DD50 0p	<p>[Ask if 398h/DD400h=1.]</p> <p>Would you rather have \$500 <u>now</u> or \$1000 in <u>25 years</u>?</p> <p>0 - \$500 now 1 - \$1000 in 25 years</p> <p>[go to part 5, sociodemographics]</p>

Var ID	Socio-demographics
DE02A	<p>What was your sex at birth?</p> <ol style="list-style-type: none"> 1. Male 2. Female 3. Intersex
DE02B	<p>Do you think of yourself as...</p> <ol style="list-style-type: none"> 1. Man 2. Woman 3. Transgender man/trans man/female-to-male (FTM) 4. Transgender woman/trans woman/male-to-female (MTF) 5. Non-binary 6. Not listed 9. Prefer not to answer
DE02C	<p>Do you think of yourself as...</p> <ol style="list-style-type: none"> 1. Straight/heterosexual

	<ul style="list-style-type: none"> 2. Lesbian/gay/homosexual 3. Bisexual 4. Queer 5. Pansexual 6. Asexual 7. Not listed 99. Prefer not to answer
DE03	<p>What is the highest level of formal education that you have completed?</p> <ul style="list-style-type: none"> 1. Grade school or some high school 2. Completed high school 3. Technical / trade school or community college 4. Some university, no degree 5. Completed university degree 6. Post-graduate degree
DE05	<p>Which racial or ethnic group best describes you? Select all that apply.</p> <ul style="list-style-type: none"> 1. White 2. Black or African American 3. Latino/Latina/Latinx 4. Asian 5. Native Hawaiian or Pacific Islander 6. American Indian or Alaska Native 7. Not listed (Please specify)
DE06	<p>Are you currently ... ?</p> <ul style="list-style-type: none"> 1 - employed for wages – full time 2 - employed for wages – part time 3 - self-employed 4 - unemployed 5 - homemaker 6 - student 7 - retired 8 - unable to work 9. Don't know
DE07	<p>Which of the following categories best describes your ANNUAL household income, that is the total income before taxes, or gross income, of all persons in your household combined, for one year?</p> <ul style="list-style-type: none"> 1 Under \$10,000 2 \$10,000-29,999 3 \$30,000-44,999 4 \$45,000-59,999 5 \$60,000-74,999 6 \$75,000-99,999 7 \$100,000-149,999 8 \$150,000 and over 9 Prefer not to answer
	<p><i>End of online baseline survey. (Participants will be prompted to call staff member to complete the baseline interview.)</i></p>

Part 2: Baseline interview

These items will be interviewer-administered either in person (pre-COVID) or over the phone (post-COVID), immediately after the online baseline survey is completed.

VAR ID	Health literacy assessment																												
	<p>(The staff interviewer will email the participant a link to view this image online)</p> <p>Figure 1A. The newest vital sign — English.</p> <table> <tr> <th colspan="2">Nutrition Facts</th></tr> <tr> <td>Serving Size</td><td>1/2 cup</td></tr> <tr> <td>Servings per container</td><td>4</td></tr> <tr> <td colspan="2">Amount per serving</td></tr> <tr> <td>Calories 250</td><td>Fat Cal 120</td></tr> <tr> <td colspan="2">%DV</td></tr> <tr> <td>Total Fat 13g</td><td>20%</td></tr> <tr> <td>Sat Fat 9g</td><td>40%</td></tr> <tr> <td>Cholesterol 28mg</td><td>12%</td></tr> <tr> <td>Sodium 55mg</td><td>2%</td></tr> <tr> <td>Total Carbohydrate 30g</td><td>12%</td></tr> <tr> <td>Dietary Fiber 2g</td><td></td></tr> <tr> <td>Sugars 23g</td><td></td></tr> <tr> <td>Protein 4g</td><td>8%</td></tr> </table> <p>* Percent Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.</p> <p>Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.</p>	Nutrition Facts		Serving Size	1/2 cup	Servings per container	4	Amount per serving		Calories 250	Fat Cal 120	%DV		Total Fat 13g	20%	Sat Fat 9g	40%	Cholesterol 28mg	12%	Sodium 55mg	2%	Total Carbohydrate 30g	12%	Dietary Fiber 2g		Sugars 23g		Protein 4g	8%
Nutrition Facts																													
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Total Fat 13g	20%																												
Sat Fat 9g	40%																												
Cholesterol 28mg	12%																												
Sodium 55mg	2%																												
Total Carbohydrate 30g	12%																												
Dietary Fiber 2g																													
Sugars 23g																													
Protein 4g	8%																												
	<p>This next section will involve reading a nutrition label and answering questions about it. First, I will give you the label to look at, and you can refer back to it whenever you need to. When you are ready, I will ask 6 questions about the nutrition label, which is printed on a pint of ice cream. Please let me know if you need me to repeat any of the questions, and feel free to use this pen and paper if necessary. The purpose of this section is to see how you interpret a nutrition label.</p> <p>[NOTE: Do not let participant see response options]</p> <p>If you eat all of the ice cream in the container, how many calories will you eat?</p> <ol style="list-style-type: none"> 1 Correct response (i.e., 1000 calories) 2. Incorrect response 																												
	<p>If you were allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you eat?</p> <p>[Note: If patient answers “2 servings,” ask “How much ice cream would that be if you were to measure it into a bowl?”]</p> <ol style="list-style-type: none"> 1 Correct response (i.e., 1 cup; any amount up to 1 cup; or Half the container) 2 Incorrect response 																												
	<p>Imagine that your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes 1 serving of ice cream.</p> <p>If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?</p> <ol style="list-style-type: none"> 1 Correct response (i.e., 33 grams) 2 Incorrect response 																												

	<p>If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving of ice cream?</p> <p>1 Correct response (i.e., 10%) 2 Incorrect response</p>
	<p>Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves, and bee stings. Is it safe for you to eat this ice cream?</p> <p>1 Correct response (i.e., No) 2 Incorrect response (Skip to income question)</p>
	<p>[NOTE: Ask only if the patient correctly responds “No” to the previous question]:</p> <p>Why would it not be safe to eat this ice cream?</p> <p>1. Correct response (i.e., because it contains peanut oil.) 2. Incorrect response</p>

Var ID	Social network items [Interviewer administered]
Intro_SN	<p>In the next section, we will ask you to name several people that you know and tell us a few things about them. Over the two-week study period, we will continue to ask about your interactions with these people.</p>
SN_01	<p>Of the people with whom you are closest, who have you spent the most time with in the past two weeks? You can name up to five people.</p> <p>1. (SN_01A) 2. (SN_01B) 3. (SN_01C) 4. (SN_01D) 5. (SN_01E)</p> <p>[PROBE: It does not have to be someone you see in person, and it cannot be a child under 3.]</p> <p>[IF THEY PROVIDE TWO ALTERS WITH THE SAME FIRST NAME, ASK THEM TO PROVIDE SOME ADDITIONAL DISTINGUISHING LABEL (E.G., INITIAL OF LAST NAME).]</p> <p>[ASK PARTICIPANTS TO NAME ALL ALTERS BEFORE PROBING WITH COGNITIVE INTERVIEW ITEMS]</p>
	<p>[EACH OF THE SUBSEQUENT QUESTIONS WILL BE ASKED FOR EACH ALTER (SN_01A-SN_01E) WITH THE PARTICIPANT’S RESPONSE APPEARING IN THE BLANK SPACES. THERE WILL ALSO BE A TEXT BOX AFTER EACH</p>

	QUESTION FOR THE INTERVIEWER TO TYPE IN ANY ADDITIONAL INFORMATION PROVIDED BY THE RESPONDENT.]
SN_02	<p>What is your relationship with _____?</p> <ol style="list-style-type: none"> 1. Spouse 2. Partner or significant other 3. Child 4. Other Family 5. Friend 6. Work Colleague 7. Neighbor 8. Acquaintance <p>Other [specify]</p>
SN_03	<p>To the best of your knowledge, how old is _____?</p> <p>[Exclude children 3 years and younger from the EMA analysis]</p>
SN_04	<p>How close do you feel to _____?</p> <ol style="list-style-type: none"> 1. Not at all 2. A little 3. Moderately 4. Very 9. Extremely
SN_05	<p>How often do you talk to _____?</p> <ol style="list-style-type: none"> 1. Every day 2. Several times a week 3. Once a week 4. Once every two weeks 5. Once a month or less 9. Don't know
Sn_06	<p>To the best of your knowledge, does _____ smoke cigarettes?</p> <ol style="list-style-type: none"> 1. No 2. Not now, but used to smoke 3. Yes 5. 9. Don't know
SN_07	<p>What does _____ think about your smoking?</p> <ol style="list-style-type: none"> 1. Strongly disapproves 2. Disapproves 3. Neutral 4. Approves 5. Strongly approves 9. Don't know

Ecological Momentary Assessment Questionnaires
Participant entered data on provided smartphone app - June 18, 2019

Cigarette log participant enters each time they smokes a cigarette				
Construct	var_id	Text	Response	Response type
<i>Smoking log</i>	log	Are you sure you want to log a cigarette?	Yes, No	Push Button (pick one)
<i>New Pack</i>	newpack	Is this the first cigarette from a new pack?	Yes, No	Push Button (pick one)
<i>Pack picture</i>	pic	[If New pack= Yes] Please take a picture of the bottom of your pack	[picture]	Image

Event based random assessment – CIGARETTE SURVEY: EVERY time the participant indicates first cigarette from a pack AND about 3-4 additional times per day				
Construct	var_id	Text	Response	Response type
<i>Affect</i>	feeling	How are you feeling right now?	1 (Very BAD!!) - 7 (Very GOOD!!)	Graduated slider
	rp_satisfy	How SATISFYING is/was the cigarette?	1 (not at all) – 7 (extremely)	
	attitude	Right now, you feel like smoking is	1 (Very BAD!!) - 7 (Very GOOD!!)	
	rp_vuln3	How WORRIED are you about getting a serious disease from smoking?	1 (not at all) - 7 (extremely)	Graduated slider
<i>Motivation</i>	motivation 2comply	How MOTIVATED are you to quit smoking?	1 (not at all) - 7 (extremely)	Graduated slider

<i>Efficacy</i>	rp_se1	How EASY would it be to cut down on the number of cigarettes you smoke?	1 (not at all) – 7 (extremely)	Graduated slider
	self-efficacy	How CONFIDENT are you that you could quit smoking altogether right now?	1 (not at all) - 7 (extremely)	Graduated slider
Hope	Hope stopping	How HOPEFUL do you feel about quitting smoking?	1 (not at all) - 7 (extremely)	Graduated slider

Evening survey Participant to answer at the end of each day				
Construct	var_id	Text	Response	Response type
<i>Reminder</i>	reminder	[An alarm with this message will appear every night at 9pm] Don't forget to fill out your evening report!		
<i>Availability</i>	cig_stock	How many cigarettes are still in your pack?	0-20	Spinner
<i>Compliance with logs</i>	missed	Did you miss logging any cigarettes today?	0-20	Spinner
	Stub	In the last 24 hours, have you stubbed out a cigarette before finishing it?	Yes, No	Push Button (pick one)
	forgo	In the last 24 hours, did you choose to skip any cigarettes that you normally would have smoked?	Yes, No	Push Button (pick one)
	Talk_alter	In the last 24 hours, have you talked with any of these people about good or bad things about smoking or quitting?	No, no one [Alter 1] [Alter 2] [Alter 3] [Alter 4] [Alter 5]	Push Button (select all that apply)
	Talk	In the last 24 hours, have you talked with anyone ELSE about good or bad things about smoking or quitting?	[check all that apply] No, no one Spouse or partner	Check box (select all that apply)

			Other family member Friend Coworker Someone else	
	Talk_cont ent	[If “yes” to Talk_alter or Talk] What did you talk about?	[check all that apply] How much you like smoking Dangers of smoking to you Benefits of quitting smoking Cigarette pack health messages are informative Cigarette pack health messages are NOT believable Cigarette pack health messages are useless Other topics [specify] _____	Check Box (all that apply, but see note)
<i>Positive cognitive elaboration</i>	Neg_Cog_ elab	In the last 24 hours, How often have you thought about the things you enjoy about smoking?	1 (not at all) - 7 (All the time)	Graduated slider
<i>Harm Cognitive elaboration</i>	Harm_Cog_ _elab	In the last 24 hours, How often have you thought about the harms from smoking?	1 (not at all) - 7 (All the time)	Graduated slider
<i>Cessation Cognitive elaboration</i>	Ces_Cog_ elab	In the last 24 hours, How often have you thought about the potential benefits from quitting smoking?	1 (not at all) - 7 (All the time)	Graduated slider
<i>Response efficacy</i>	response_ efficacy	How much would quitting smoking now reduce your chances of getting a serious disease?	1 (no chance) - 7 (certain to happen)	Graduated slider

<i>Perceived susceptibility</i>	Perceived _suscept	How likely are you to get a serious disease if you continue smoking the same amount?	1 (no chance) - 7 (certain to happen)	Graduated slider
<i>Charge reminder</i>	charge	Please remember to charge your phone tonight. Thank you.		