STATISTICAL ANALYSIS PLAN

Evaluation of cigarette package inserts for enhanced communication with smokers

Principal Investigator James F. Thrasher, MA, MS, PhD

Professor, Department of Health Promotion Education & Behavior

Arnold School of Public Health University of South Carolina

Columbia, SC, USA

Clinicaltrials.gov identifier NCT04075682

Funding: National Cancer Institute/NIH (R01 CA215466)

Author James W. Hardin, PhD

Professor, Department of Epidemiology & Biostatistics

Arnold School of Public Health University of South Carolina

Columbia, SC, USA

Version December 13, 2022

SIGNATURE PAGE

Principle Investigator	James F. Thrasher (12/13/2022)				
Author	James W. Hardin				
	James W. Hardin (12/13/2022)				

Table of Contents

1.	Study design overview	4
	Study hypotheses and outcomes	
	Assumptions for calculating power	
	Statistical design	
	Missing data	
	Sensitivity analyses	

This document is updated from the originally submitted version. Edits have been made to clarify which outcomes are associated with each hypothesis (Table 3), as this was not clearly indicated in the original submission. Also, we have revised the description of models for testing Hypotheses 5 and 6, whose original specification did not capture the contrasts intended in the original hypothesis wording (e.g., they evaluated differences in outcomes by participant characteristics but not moderation of treatment effects by participant characteristics). Why sensitivity analyses were limited to only one data type is also described.

Study design overview:

<u>Experimental protocol</u>: The basic design of the randomized controlled trial described as Study 1 follows a 2x2 between-subject treatment randomized assignment across whether there is an insert in the cigarette pack, and whether the health warning label includes pictures. We aimed to enroll a total of 380 persons to be randomly

assigned to the four treatment conditions. Given the expectation that 85% would complete the trial and provide adequate data for inclusion in the analyses, we expected to analyze data from 80 participants in each of the 2x2 treatment combinations (See Table 1).

 Table 1. Study 1 RCT design & sample allocation

 Randomized Participants
 Health warning label (HWL)

 Text only
 Text and Picture

 Yes
 80

 No
 80

 80
 80

<u>Data types</u>: Two types of data were collected, with different implications for power calculations due to the number of observations associated with each one:

- Type 1 data (daily log data) were collected from each person across a 2-week period yielding up to 14 repeated measures per person. Daily log data include a range of primary outcomes (e.g., foregoing cigarettes, talk about cessation) and secondary outcomes (e.g., cognitive elaboration of cessation benefits, perceived susceptibility) that encompass binary, ordinal and continuous variables.
- Type 2 data (event-based EMA) were collected approximately 4 additional occasions per day per person, yielding an average of 56 repeated measures of event-related data per person. Event-related data include both primary outcomes (e.g., feeling about smoking, self-efficacy to quit smoking, motivation to quit smoking) and secondary outcomes (e.g., hopefulness about quitting, satisfaction from smoking) measured as ordinal and continuous variables.

<u>Study hypotheses and outcomes</u> <u>of interest:</u>

Table 2 shows the study hypotheses. The outcomes evaluated depended on the specific hypothesis. Behavioral and psychosocial outcomes that are more proximal to cessation behaviors (e.g., foregoing/stubbing out cigarettes;

Table 2. 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).

motivation to quit) were assessed for all hypotheses. Other outcomes are specific to pathways of influence for insert effects or, separately, for pictorial HWL effects; hence, some outcomes were assessed only when they were relevant to the labeling effect (insert vs. pictorial HWL) evaluated in the hypothesis. Similarly, the proxy measure of "reactance" (i.e., expressed reactance) was only assessed for hypotheses assessing whether insert effects reduce defensive responding (i.e., H1, H4). Finally, the two outcomes involving positive smoking experiences (i.e., satisfaction, cognitive elaboration of smoking benefits) were only relevant to the main effects of pictorial HWLs (H2). Table 3 lists all primary and secondary outcomes, showing which were assessed for each hypothesis. Appendix 1 includes results for outcomes that are not specific to hypotheses (i.e., do not have an X in the table below). Details on the specific measures used and frequency of assessment are provided in the outcomes and results section of clinicaltrials.gov.

Table 3. Outcomes assessed for each hypothesis

Outcome type	Outcome Variable name		H2	НЗ	H4	Н5а	H5b	Н6а	H6b
Primary	Self-efficacy to Quit Smoking	Χ		Χ	Х			Χ	Х
Primary	Self-efficacy to Cut Down on Smoking	Χ		Χ	Χ			Χ	Χ
Primary	Worry About Harms from Smoking		Χ			Χ	Χ		
Primary	Strength of Feeling About Smoking		Χ			Χ	Χ		
Primary	Extent of Motivation to Quit	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ
Primary	Talk About Smoking Cessation or Harms	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ
Primary	Foregoing/stubbing out a Cigarette	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ
Secondary	Strength of Hopefulness About Quitting	Χ		Χ	Χ			Χ	Χ
Secondary	Satisfaction From Smoking		Χ						
Secondary	Cognitive Elaboration of Smoking Benefits		Χ						
Secondary	Cognitive Elaboration of Smoking Harms		Χ			Χ	Χ		
Secondary	Cognitive Elaboration of Cessation Benefits	Χ		Χ	Χ			Χ	Χ
Secondary	Response Efficacy	Χ		Χ	Χ			Χ	Χ
Secondary	Perceived Susceptibility to Smoking Harms		Χ			Χ	Χ		
Secondary	Expressed Reactance Against Messages	Χ	Χ		Χ	Χ	Χ		
Secondary	Cigarettes Per Day (number of cig logs)	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Х

X=included in the results data tables; results for outcomes that are not specific to hypotheses (i.e., no "X" in table above) are presented in data tables at the end of this document (see Appendix 1).

Assumptions for calculating power:

This section describes our assumptions regarding power before we collected our data. Throughout our discussion of power related to the statistical tests to evaluate our hypotheses of interest, we assume a moderate within-person autocorrelation of ρ = 0.40 for repeated measures. This estimate was lower than in the data we collected for this project (mean ICC=0.73) and in our re-assessment of preliminary data (mean ICC=0.72). Instead of running simulation programs to estimate power for mixed effects generalized linear models, we calculate the effective number of independent observations and use power for independence models.

<u>Effective sample size</u>: The effective number of independent observations $N_{\rm eff}$ is related to the number of correlated observations $N_{\rm eff}$ and the autocorrelation of correlated observations ρ as $N_{\rm eff} = N(1-\rho)/(1+\rho)$. Thus, our power calculations are derived using independence models with $N_{\rm eff} = 3N/7$ observations. Table 4 shows the effective sample for each hypothesis and data type, including adjustment for 10% and 20% missing data.

Table 4. Effective sample size for each hypothesis and data type, including missing data effects

				$N_{ m eff}$			
	Rep.			0% missing 10% missing 20% miss			
Data	Measures	Hypotheses	N	data	data	data	
Type 1	14	H1/H2	2,240=160*14	960	864	768	
	14	H3 ^{a-b} /H4 ^{a-b} /H5 ^{a-b} /H6 ^{a-b}	1,120=80*14	480	432	384	
Type 2	56	H1/H2	8,960=160*56	3,840	3,456	3,072	
	56	H3 ^{a-b} /H4 ^{a-b} /H5 ^{a-b} /H6 ^{a-b}	4,480=80*56	1,920	1,728	1,536	

We use the numbers in Table 4 as inputs for independent observations in deriving the detectable effect. In what follows, we report ranges of detectable effect sizes from 0% to 20% missing data in complete-case analyses. This presentation notwithstanding, our data analysis will employ multiple imputation methods to replace missing data, and we will investigate sensitivity models to determine whether missingness is related to any of the outcomes or covariates (See **Missing Data**, below).

<u>Alpha</u>: Modifications of the level of significance are considered using Bonferroni adjustment to maintain an overall 0.05 level of significance. As most of our hypotheses involve assessing 6 primary outcomes for each of the two data types, we use a Bonferroni-corrected $\alpha = 0.05/6 = 0.0083$.

<u>Effects size referents</u>: We follow Cohen's standardized effect sizes of small=0.20, medium=0.50, and large=0.80.¹ Standardized effect sizes are absolute differences divided by the standard deviation.

<u>Power</u>: Power was fixed to 80% in all analyses.

<u>Analyses</u>: Most detectable effect sizes were calculated using PASS 2012 software from NCSS (Kayesville, Utah). The only exception is for a hypothesis of mediation. In that case, we used the *powerMediation* package for *R* software. Specifically, we utilized the *minEffect.SLR* method to determine the minimum detectable slope (effect).

All detectable effect sizes were calculated for power=80% and stated level of significance. Furthermore, we assessed detectable effect sizes for the planned data collection design, up to 10% missing data, and up to 20% missing data (see Table 4).

Statistical design:

To test our study hypotheses (see Table 2, from Research Plan), we estimated a series of mixed effects generalized linear models, adjusting for repeated measures. The specific model we used depended on the type of dependent variable in the model. For each hypothesis, we estimated mixed effect generalized linear model of the outcome as a function of the inverse link: mixed-effects ordered logistic regression with inverse logit link for continuous/ordinal measures; mixed-effects regression with identity link for continuous/ordinal measures; negative binomial regression with log link for count measures; and mixed-effects logistic regression with inverse logit link for binary measures. Also, for outcomes with response options from 1 to 7, we estimated both mixed effects linear regression and ordered logistic regression models; however, we only report the results for the ordered logistic regression due to concerns about the distribution of responses and because the results are consistent across models. Note that the one count measure that we evaluate (i.e., cigarettes per day) is a single measure for each person and so there are no repeated measures. Evaluation of hypotheses will involve inference from Wald tests of associated regression parameters. We present power calculations for each hypothesis along with the model used to conduct the statistical tests. Subsequently, we discuss missing data and sensitivity analyses.

Throughout the following sections, we present models using the following indicator variables:

InsY _i	Person <i>i</i> has cigarette packages with inserts
$PicY_i$	Person <i>i</i> has cigarette packages with HWLs that include text and pictures
SeHi _i	Person <i>i</i> has a high baseline self-efficacy measure
EdHi _i	Person <i>i</i> has a high baseline education measure
$LtHi_i$	Person <i>i</i> has a high baseline literacy measure

Similarly, we also use the following indicator variables:

InsN _i	Person <i>i</i> has cigarette packages without inserts
$PicN_i$	Person <i>i</i> has cigarette packages with HWLs that include text only
$SeLo_i$	Person <i>i</i> has a low baseline self-efficacy measure
$EdLo_i$	Person <i>i</i> has a low baseline education measure
$LtLo_i$	Person <i>i</i> has a low baseline literacy measure

Model 1:

$$y_{ij} = g^{-1} \big[\beta_0 + (InsN_i \times PicN_i)\beta_1 + (InsN_i \times PicY_i)\beta_2 + (InsY_i \times PicN_i)\beta_3 + (InsY_i \times PicY_i)\beta_4 + Z_{ij}\tau + \gamma_i + \epsilon_{ij} \big]$$

where g^{-1} is the inverse link function (identity for continuous measures, log for count measures, and inverse logit for binary and ordinal measures), Z_{ij} is a possibly time-varying vector of covariates (e.g., sex, race, age, nicotine dependence, quit intentions), and y_{ij} is the outcome for the ith person at the jth repeated measure. This model will be used for evaluating Hypotheses 1 ($\mu_{InsN} = \mu_{InsY}$), 2 ($\mu_{PicN} = \mu_{PicY}$), 3a ($\mu_{PicN,InsY} = \mu_{PicY,InsY}$) & 4a ($\mu_{PicY,InsY} = \mu_{PicY,InsY}$) as shown in Table 5.

Table 5. Hypotheses evaluated using Model 1 and associated tests

Hypothesis	Test
Hypothesis 1	$H_0^1: \beta_1 + \beta_2 = \beta_3 + \beta_4$
Hypothesis 2	$H_0^2: \beta_1 + \beta_3 = \beta_2 + \beta_4$
Hypothesis 3a	$H_0^{3a}: \beta_3 = \beta_4$
Hypothesis 4a	$H_0^{4a}: \beta_4 = \beta_2$

Allowing up to 20% missing data, the range of effect sizes for which we will have 80% power to reject hypotheses are given by the values in Table 6 for the data type outcomes and specified level of significance.

Table 6. Level of significance and detectable effect sizes for all hypotheses

Hypotheses	Outcome	Level of significance	Range of effects*
H1 & H2	Type 1	$\alpha = 0.05/6 = 0.0083$	0.15 - 0.17
	Type 2	$\alpha = 0.05/6 = 0.0083$	0.07 - 0.08
H3a, H3b, H4a, H4b, H5a, H5b, H6a, H6b	Type 1	$\alpha = 0.05/6 = 0.0083$	0.22 - 0.24
	Type 2	$\alpha = 0.05/6 = 0.0083$	0.10 - 0.11

^{*}range of effects is for the different amounts of missing data (i.e., 0% - 20%)

Model 2a and Model 2b:

$$y_{ij} = g^{-1} \big[\beta_0 + InsN_i \beta_1 + \, InsY_i \beta_2 + Z_{ij} \tau + \, \gamma_i + \epsilon_{ij} \big]$$

Where g^{-1} is the inverse link function (identity for continuous measures, and inverse logit for binary and ordinal measures), Z_{ij} is a possibly time-varying vector of covariates (e.g., sex, race, age, nicotine dependence, quit intentions), and y_{ij} is the outcome for the ith person at the jth repeated measure. The 2a and 2b models are stratified over whether pictures were included (2a) or not (2b). This model will be used to assess Hypothesis

 $3b - H_0^{3b}$: $\mu_{InsN} = \mu_{InsY}$. Associated power is shown in Table 6. Note that the stratified analyses in Models 2a and 2b are investigated only if H_0^{3a} is rejected.

Note: H_0^{3a} was never rejected.

Model 3a and Model 3b:

$$y_{ij} = g^{-1} [\beta_0 + PicN_i\beta_1 + PicY_i\beta_2 + Z_{ij}\tau + \gamma_i + \epsilon_{ij}]$$

Where g^{-1} is the inverse link function (identity for continuous measures, and inverse logit for binary and ordinal measures), Z_{ij} is a possibly time-varying vector of covariates (e.g., sex, race, age, nicotine dependence, quit intentions), and y_{ij} is the outcome for the ith person at the jth repeated measure. The 3a and 3b models are stratified over whether pictures were included (3a) in the warning labels or not (3b). This model will be used to assess Hypothesis 4B $-H_0^{4b}$: $\mu_{PicN}=\mu_{PicY}$. Associated power is shown in Table 6. Note that the stratified analyses in Models 3a and 3b are investigated only if H_0^{4a} is rejected. Note: H_0^{4a} was never rejected.

Model 4:

$$\begin{aligned} y_{ij} &= g^{-1} \big[\beta_0 + (InsN_i \times PicN_i \times SeLo_i) \beta_1 + (InsN_i \times PicY_i \times SeLo_i) \beta_2 + (InsY_i \times PicN_i \times SeLo_i) \beta_3 \\ &+ (InsY_i \times PicY_i \times SeLo_i) \beta_4 \\ &+ (InsN_i \times PicN_i \times SeHi_i) \beta_5 + (InsN_i \times PicY_i \times SeHi_i) \beta_6 + (InsY_i \times PicN_i \times SeHi_i) \beta_7 \\ &+ (InsY_i \times PicY_i \times SeHi_i) \beta_8 + Z_{ij}\tau + \gamma_i + \epsilon_{ij} \big] \end{aligned}$$

where g^{-1} is the inverse link function (identity for continuous measures, and inverse logit for binary and ordinal measures), Z_{ij} is a possibly time-varying vector of covariates (e.g., sex, race, age, nicotine dependence, quit intentions), and y_{ij} is the outcome for the ith person at the jth repeated measure. This model will be used to assess Hypothesis 5 – using H_0^{5a} : $\mu_{PicY,SeHi} - \mu_{PicN,SeHi} = \mu_{PicY,SeLo} - \mu_{PicN,SeLo}$, and H_0^{5b} : $(\mu_{PicY,InsN,SeHi} - \mu_{PicN,InsN,SeHi}) - (\mu_{PicY,InsN,SeLo} - \mu_{PicN,InsN,SeHi}) - (\mu_{PicY,InsN,SeLo} - \mu_{PicN,InsN,SeLo}) = (\mu_{PicY,InsY,SeHi} - \mu_{PicN,InsN,SeHi}) - (\mu_{PicY,InsY,SeLo} - \mu_{PicN,InsN,SeLo})$. Associated power is shown in Table 6.

Model 5:

$$\begin{aligned} y_{ij} &= g^{-1} \big[\beta_0 + (InsN_i \times PicN_i \times EdLo_i) \beta_1 + (InsN_i \times PicY_i \times EdLo_i) \beta_2 + (InsY_i \times PicN_i \times EdHi) \beta_3 \\ &+ (InsY_i \times PicY_i \times EdHi_i) \beta_4 \\ &+ (InsN_i \times PicN_i \times EdLo_i) \beta_5 + (InsN_i \times PicY_i \times EdLo_i) \beta_6 + (InsY_i \times PicN_i \times EdHi_i) \beta_7 \\ &+ (InsY_i \times PicY_i \times EdHi_i) \beta_8 + Z_{ij}\tau + \gamma_i + \epsilon_{ij} \big] \end{aligned}$$

where g^{-1} is the inverse link function (identity for continuous measures, and inverse logit for binary and ordinal measures), Z_{ij} is a possibly time-varying vector of covariates (e.g., sex, race, age, nicotine dependence, quit intentions), and y_{ij} is the outcome for the ith person at the jth repeated measure. This model will be used to assess Hypothesis 6 – using H_0^{6a} : $\mu_{InsY,EdHi} - \mu_{InsN,EdHi} = \mu_{InsY,EdLo} - \mu_{InsN,EdLo}$ and H_0^{6b} : $(\mu_{InsY,PicN,EdHi} - \mu_{InsN,PicN,EdHi}) - (\mu_{InsY,PicN,EdHi}) - (\mu_{InsY,PicY,EdHi}) - (\mu_{InsY,PicY,EdLo} - \mu_{InsN,PicN,EdLo})$. Associated power is shown in Table 6.

Table 7 shows the H5 and H6 hypothesis specifications that were assessed and for which results are reported. The pre-specified hypothesis shown in the original Statistical Design and Power document were incorrectly specified for these hypotheses (though not for H1-H4). These new, intended specifications represent the two-part nature of the hypotheses (see Table 2).

Table 7. Hypotheses evaluated using Models 4/5 and associated tests

Model	Hypothesis	Test
4	Hypothesis 5a	H_0^{5a} : $\beta_1 + \beta_3 + \beta_6 + \beta_8 = \beta_2 + \beta_4 + \beta_5 + \beta_7$
4	Hypothesis 5b	H_0^{5b} : $\beta_6 - \beta_2 = \beta_8 - \beta_4$

5	Hypothesis 6a	H_0^{6a} : $\beta_1 + \beta_2 - \beta_3 - \beta_4 = \beta_5 + \beta_6 - \beta_7 - \beta_8$
5	Hypothesis 6b	H_0^{6b} : $\beta_4 - \beta_8 = \beta_3 - \beta_7$

Missing Data

While we have presented ranges of detectable effect sizes for our models even accounting for 20% missing data, we will investigate all missing data. Initially, the likelihood of missingness will be checked to see whether it is associated with any of the covariates or outcomes. Missing data are usually categorized as missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR). Complete case analysis assumes that data are MCAR, though it is rare that data really are MCAR. Missing data can potentially weaken the validity of results and conclusions. A number of methods have been developed for dealing with missing data. Multiple imputation is a method to deal with missing data, which accounts for the uncertainty associated with missing data. Multiple imputation is implemented in our statistical software (SAS and Stata) under the MAR assumption and provides unbiased and valid estimates of associations based on information from the available data. The method affects the coefficient estimates for variables with missing data and also the estimates for other variables with no missing data. We will investigate the nature of our missing data, and if an assumption of MCAR is invalid, we will utilize multiple imputation methods.

Complete datasets will be created using the multiple imputation by chained equations method, and results across imputed datasets will be combined using Rubin's method.² Results from this approach will be compared with those that obtain when we use only observations with complete data. This was done only for outcomes assessed in evening report surveys because those provided known missing data (i.e., people did not file a report). We were unable to do this for cigarette survey data that required participants to indicate when they were smoking; hence, the missingness of these observations was not known (i.e., we could not determine whether data were "missing" because people did not smoke vs. because they did not report a smoking session). Consistency of results across these approaches will be interpreted as providing stronger evidence of the model results found than in the case of the results depending on the approach used. We will report results of these additional analyses (see following tables, below) and our interpretation of them in our papers.

Sensitivity Analysis

In addition to imputing missing data, we will also investigate the sensitivity of models to weighted analyses. Probability weights will be generated to allow inference from our samples that will be valid for the general population of smokers across the United States. Comparisons of results and inference for weighted and unweighted analyses will allow us to discuss any limitations of our sample, and what differences might exist between our sample and the general population of interest.

REFERENCES

- 1. Cohen J. A power primer. Psychological Bulletin 1992;112(1):155-59.
- 2. Rubin D. Multiple imputation after 18+ years. Journal of the American Statistical Association 1996;**91**:473-89.

Appendix 1. Results for primary and secondary outcomes that are not specific to hypothesized effects and, therefore, not in the data tables

Table 1. Hypothesis 1: Results for outcomes not specific to hypothesized effects

Outcome Variable name	Coef*	SE	95% CI LB	95% CI UB	p-value
Worry About Harms from Smoking ¹	0.77	0.59	-0.38	1.92	0.19
Strength of Feeling About Smoking ²	-0.70	0.48	-1.64	0.23	0.14
Satisfaction From Smoking ¹	-0.38	0.39	-1.15	0.39	0.33
Cognitive Elaboration of Smoking Benefits ³	-0.09	0.30	-0.68	0.49	0.76
Cognitive Elaboration of Smoking Harms ³	0.59	0.34	-0.08	1.26	0.08
Perceived Susceptibility to Smoking Harms ⁴	0.71	0.46	-0.19	1.61	0.12

^{*}All results from ordered logistic regression mixed effects models

Table 2. Hypothesis 2: Results for outcomes not specific to hypothesized effects

Outcome Variable name	Coef*	SE	95% CI LB	95% CI UB	p-value
Self-efficacy to Quit Smoking ¹	-0.26	0.51	-1.25	0.73	0.60
Self-efficacy to Cut Down on Smoking ¹	-0.37	0.49	-1.33	0.59	0.45
Strength of Hopefulness About Quitting ¹	-0.55	0.66	-1.85	0.75	0.41
Cognitive Elaboration of Cessation Benefits ²	-0.40	0.34	-1.08	0.27	0.24
Response Efficacy ³	0.09	0.39	-0.67	0.85	0.82

^{*}All results from ordered logistic regression mixed effects models

Table 3. Hypothesis 3. Results for outcomes not specific to hypothesized effects

Outcome Variable name	Coef*	SE	95% CI LB	95% CI UB	p-value
Worry About Harms from Smoking ¹	-1.22	0.85	-2.89	0.44	0.15
Strength of Feeling About Smoking ²	0.23	0.69	-1.12	1.57	0.74
Satisfaction From Smoking ¹	-0.04	0.57	-1.16	1.07	0.94
Cognitive Elaboration of Smoking Benefits ³	-0.20	0.43	-1.04	0.65	0.65
Cognitive Elaboration of Smoking Harms ³	-0.72	0.49	-1.69	0.25	0.15
Perceived Susceptibility to Smoking Harms ⁴	-1.12	0.66	-2.40	0.17	0.09
Expressed Reactance Against Messages ⁵	1.21	0.78	0.35	4.25	0.76

^{*}All results from ordered logistic regression mixed effects models except for "Expressed reactance" which shows Odds Ratio for logistic regression mixed effects model.

^{1.} response options=1 Not at all – 7 Extremely; 2. response options=1 very BAD – 7 Very GOOD; 3. response options=1 Not at all – 7 All the time; 4. 1 No chance – 7 Certain to happen.

^{1.} response options=1 Not at all -7 Extremely; 2. response options= 1 Not at all -7 All the time; 3. 1 No chance -7 Certain to happen.

^{1.} response options=1 Not at all - 7 Extremely; 2. response options=1 very BAD - 7 Very GOOD; 3. response options=1 Not at all - 7 All the time; 4. 1 No chance - 7 Certain to happen. 5. Response options=yes, no

Table 4. Hypothesis 4. Results for outcomes not specific to hypothesized effects

Outcome Variable name	Coef*	SE	95% CI LB	95% CI UB	p-value
Worry About Harms from Smoking ¹	-0.12	0.84	-1.77	1.53	0.88
Strength of Feeling About Smoking ²	-0.08	0.68	-1.41	1.26	0.91
Satisfaction From Smoking ¹	-0.07	0.56	-1.17	1.03	0.90
Cognitive Elaboration of Smoking Benefits ³	0.23	0.49	-0.74	1.19	0.65
Cognitive Elaboration of Smoking Harms ³	0.18	0.49	-0.78	1.14	0.71
Perceived Susceptibility to Smoking Harms ⁴	-0.15	0.66	-1.45	1.15	0.82

^{*}All results from ordered logistic regression mixed effects models

Table 5a. Hypothesis 5a. Results for outcomes not specific to hypothesized effects

Outcome Variable name	Coef*	SE	95% CI LB	95% CI UB	p-value
Self-efficacy to Quit Smoking ¹	0.50	0.97	-1.41	2.41	0.61
Self-efficacy to Cut Down on Smoking ¹	0.35	0.95	-1.50	2.21	0.71
Strength of Hopefulness About Quitting ¹	1.18	1.25	-1.27	3.62	0.35
Satisfaction From Smoking ¹	-0.31	0.79	-1.85	1.24	0.70
Cognitive Elaboration of Smoking Benefits ²	0.54	0.60	-0.64	1.72	0.37
Cognitive Elaboration of Cessation Benefits ²	0.37	0.67	-0.94	1.69	0.58
Response Efficacy ³	-0.42	0.77	-1.92	1.09	0.59

^{*}All results from ordered logistic regression mixed effects models

Table 5b. Hypothesis 5b. Results for outcomes not specific to hypothesized effects

Outcome Variable name	Coef*	SE	95% CI LB	95% CI UB	p-value
Self-efficacy to Quit Smoking ¹	0.57	1.38	-2.15	3.28	0.68
Self-efficacy to Cut Down on Smoking ¹	0.08	1.35	-2.56	2.73	0.95
Strength of Hopefulness About Quitting ¹	-1.38	1.77	-4.84	2.09	0.44
Satisfaction From Smoking ¹	-0.05	1.12	-2.25	2.15	0.97
Cognitive Elaboration of Smoking Benefits ²	1.67	0.86	-0.01	3.35	0.05
Cognitive Elaboration of Cessation Benefits ²	0.88	0.96	-1.00	2.75	0.36
Response Efficacy ³	1.45	1.10	-0.70	3.60	0.19

^{*}All results from ordered logistic regression mixed effects models

^{1.} response options=1 Not at all -7 Extremely; 2. response options=1 very BAD -7 Very GOOD; 3. response options= 1 Not at all -7 All the time; 4. 1 No chance -7 Certain to happen.

^{1.} response options=1 Not at all -7 Extremely; 2. response options= 1 Not at all -7 All the time; 3. 1 No chance -7 Certain to happen.

^{1.} response options=1 Not at all $-\overline{7}$ Extremely; 2. response options=1 Not at all $-\overline{7}$ All the time; 3. 1 No chance $-\overline{7}$ Certain to happen.

Table 6a-Edu. Hypothesis 6a (moderation by education): Results for outcomes not specific to hypothesized effects

Outcome Variable name	В	SE	95% CI LB	95% CI UB	p-value
Worry About Harms from Smoking ¹	1.30	1.19	-1.04	3.65	0.27
Strength of Feeling About Smoking ²	-0.89	0.96	-2.78	1.00	0.35
Satisfaction From Smoking ¹	-0.61	0.81	-2.19	0.97	0.45
Cognitive Elaboration of Smoking Benefits ³	0.16	0.61	-1.02	1.35	0.79
Cognitive Elaboration of Smoking Harms ³	1.01	0.70	-0.36	2.38	0.15
Perceived Susceptibility to Smoking Harms ⁴	0.75	0.93	-1.07	2.56	0.42
Expressed Reactance Against Messages ⁵	3.52	3.44	0.52	23.95	0.20

^{*}All results from ordered logistic regression mixed effects models except for "Expressed reactance" which shows Odds Ratio for logistic regression mixed effects model.

Table 6a-Lit. Hypothesis 6a (moderation by health literacy): Results for outcomes not specific to hypothesized effects

Outcome Variable name	В	SE	95% CI LB	95% CI UB	p-value
Worry About Harms from Smoking ¹	0.25	1.27	-2.25	2.75	0.84
Strength of Feeling About Smoking ²	0.63	1.03	-1.39	2.64	0.54
Satisfaction From Smoking ¹	0.91	0.85	-0.75	2.58	0.28
Cognitive Elaboration of Smoking Benefits ³	-0.03	0.66	-1.32	1.26	0.97
Cognitive Elaboration of Smoking Harms ³	0.35	0.75	-1.12	1.82	0.64
Perceived Susceptibility to Smoking Harms ⁴	0.16	1.00	-1.80	2.12	0.87
Expressed Reactance Against Messages ⁵	6.78	7.25	0.83	55.10	0.07

^{*}All results from ordered logistic regression mixed effects models except for "Expressed reactance" which shows Odds Ratio for logistic regression mixed effects model.

Table 6a-DD. Hypothesis 6a (moderation by delayed discounting): Results for outcomes not specific to hypothesized effects

Outcome Variable name	В	SE	95% CI LB	95% CI UB	p-value
Worry About Harms from Smoking ¹	2.71	1.19	0.39	5.04	0.02
Strength of Feeling About Smoking ²	-1.11	0.95	-2.96	0.74	0.24
Satisfaction From Smoking ¹	-2.03	0.78	-3.57	-0.49	0.01
Cognitive Elaboration of Smoking Benefits ³	0.06	0.60	-1.12	1.23	0.92
Cognitive Elaboration of Smoking Harms ³	1.61	0.69	0.26	2.95	0.69
Perceived Susceptibility to Smoking Harms ⁴	2.38	0.92	0.58	4.18	0.01
Expressed Reactance Against Messages ⁵	2.10	2.13	0.29	15.26	0.46

^{*}All results from ordered logistic regression mixed effects models except for "Expressed reactance" which shows Odds Ratio for logistic regression mixed effects model.

^{1.} response options=1 Not at all - 7 Extremely; 2. response options=1 very BAD - 7 Very GOOD; 3. response options=1 Not at all - 7 All the time; 4. 1 No chance - 7 Certain to happen. 5. Response options=yes, no

^{1.} response options=1 Not at all – 7 Extremely; 2. response options=1 very BAD – 7 Very GOOD; 3. response options= 1 Not at all – 7 All the time; 4. 1 No chance – 7 Certain to happen. 5. Response options=yes, no

^{1.} response options=1 Not at all - 7 Extremely; 2. response options=1 very BAD - 7 Very GOOD; 3. response options= 1 Not at all - 7 All the time; 4. 1 No chance - 7 Certain to happen. 5. Response options=yes, no

Table 6b-Edu. Hypothesis 6b (moderation by education): Results for outcomes not specific to hypothesized effects

Outcome Variable name	В	SE	95% CI LB	95% CI UB	p-value
Worry About Harms from Smoking ¹	1.22	1.71	-2.14	4.58	0.48
Strength of Feeling About Smoking ²	-0.79	1.38	-3.51	1.92	0.57
Satisfaction From Smoking ¹	-0.51	1.16	-2.78	1.76	0.66
Cognitive Elaboration of Smoking Benefits ³	-1.30	0.86	-2.99	0.39	0.13
Cognitive Elaboration of Smoking Harms ³	-0.15	0.99	-2.10	1.79	0.88
Perceived Susceptibility to Smoking Harms ⁴	0.95	1.32	-1.64	3.54	0.47
Expressed Reactance Against Messages ⁵	0.81	1.15	0.05	12.96	0.88

^{*}All results from ordered logistic regression mixed effects models except for "Expressed reactance" which shows Odds Ratio for logistic regression mixed effects model.

Table 6b-Lit. Hypothesis 6b (moderation by health literacy): Results for outcomes not specific to hypothesized effects

Outcome Variable name	В	SE	95% CI LB	95% CI UB	p-value
Worry About Harms from Smoking ¹	-0.48	1.86	-4.12	3.15	0.79
Strength of Feeling About Smoking ²	-0.39	1.50	-3.32	2.55	0.80
Satisfaction From Smoking ¹	-1.27	1.24	-3.70	1.15	0.30
Cognitive Elaboration of Smoking Benefits ³	-0.33	0.95	-2.18	1.53	0.73
Cognitive Elaboration of Smoking Harms ³	-0.73	1.08	-2.85	1.39	0.50
Perceived Susceptibility to Smoking Harms ⁴	-0.38	1.44	-3.20	2.45	0.79
Expressed Reactance Against Messages ⁵	2.05	3.40	0.08	52.63	0.66

^{*}All results from ordered logistic regression mixed effects models except for "Expressed reactance" which shows Odds Ratio for logistic regression mixed effects model.

Table 6b-DD. Hypothesis 6b (moderation by delayed discounting): Results for outcomes not specific to hypothesized effects

Outcome Variable name	В	SE	95% CI LB	95% CI UB	p-value	1
Worry About Harms from Smoking ¹	-0.05	1.71	-3.41	3.31	0.98	
Strength of Feeling About Smoking ²	3.76	1.37	1.08	6.45	0.01	
Satisfaction From Smoking ¹	2.52	1.13	0.30	4.75	0.03	
Cognitive Elaboration of Smoking Benefits ³	1.03	0.86	-0.67	2.72	0.23	
Cognitive Elaboration of Smoking Harms ³	-0.60	0.99	-2.54	1.34	0.54	
Perceived Susceptibility to Smoking Harms ⁴	-0.17	1.32	-2.76	2.41	0.89	
Expressed Reactance Against Messages ⁵	0.12	0.19	0.01	2.54	0.17	

^{*}All results from ordered logistic regression mixed effects models except for "Expressed reactance" which shows Odds Ratio for logistic regression mixed effects model.

^{1.} response options=1 Not at all - 7 Extremely; 2. response options=1 very BAD - 7 Very GOOD; 3. response options=1 Not at all - 7 All the time; 4. 1 No chance - 7 Certain to happen. 5. Response options=yes, no

^{1.} response options=1 Not at all – 7 Extremely; 2. response options=1 very BAD – 7 Very GOOD; 3. response options= 1 Not at all – 7 All the time; 4. 1 No chance – 7 Certain to happen. 5. Response options=yes, no

^{1.} response options=1 Not at all - 7 Extremely; 2. response options=1 very BAD - 7 Very GOOD; 3. response options=1 Not at all - 7 All the time; 4. 1 No chance - 7 Certain to happen. 5. Response options=yes, no