Official Title: Comparison of Text and Pictorial Waterpipe Tobacco Warnings Among Young Adults

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Protocol

Comparison of Text and Pictorial Waterpipe Tobacco Warnings among Young Adults

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Background, Rationale, and Context
Young adults have the highest prevalence of waterpipe tobacco smoking (WTS) of any age group in the U.S. Extensive evidence shows that they consistently misperceive WTS as less harmful and less addictive than cigarette smoking, and these misperceptions are positively associated with WTS. Despite these widely held misperceptions, WTS is associated with serious acute and chronic harms, even among infrequent users. In addition, WTS is prospectively associated with cigarette smoking initiation putting young adults at greater risk for cancer. Considerable evidence shows that *cigarette warnings* effectively convey health information to consumers, resulting in increased motivation to quit and quit attempts. Waterpipe warnings have the potential to convey accurate information about health harms to consumers, but the currently mandated text warning, focused solely on nicotine addiction, is likely to have limited impact. The goal of this project is to develop warnings to promote greater understanding of harms and to reduce WTS behavior among young adults. We will use a systematic, evidence-driven, rigorous approach to develop waterpipe warnings and test these newly developed warnings in two contexts: (1) on waterpipe tobacco packaging; and (2) in an ecologically valid waterpipe café setting. In Aim 1, we developed text and pictorial (text plus image) waterpipe tobacco warnings to effectively communicate a broad range of health harms. We developed 29 text warning statements across a variety of health harms (e.g., cardiovascular, cancer, addiction). We tested these warning statements and the mandated nicotine warning statement in a national survey to determine the five most effective text warnings (IRB00062703). We then paired the five most effective text warning statements and the mandated nicotine warning statement with three investigator-selected images to determine the most promising image for each text warning statement. The resulting six text and six corresponding pictorial warnings will be tested in this experiment.

Objective(s)
The primary objective of the survey is assess the effectiveness of package warning type (text-only, pictorial [text plus image], no warning control) on intentions to smoke waterpipe tobacco in the near future. The secondary objective is to assess the impact of text and pictorial warnings on other behavioral antecedents from the Message Impact Framework, creating generalizable knowledge about text and pictorial warnings and lay the groundwork for stronger policies. The tertiary objective is to identify the most effective individual

warnings for use in the Aim 3 trial, where consumers will be exposed to warnings at waterpipe cafés to test the warnings' impact on behavior in a real-world setting.

Study Roles

Wake Forest University Health Sciences
The Wake Forest team's role in this study will be to develop the study stimuli and survey questionnaire, oversee survey administration, maintain the study data, conduct analyses, and disseminate findings.

University of North Carolina at Chapel Hill and Boston University
Collaborators at UNC and BU will assist in developing the survey questionnaire and stimuli, and will assist with interpretation and dissemination of data.

NORC at the University of Chicago
NORC will program the survey, recruit participants, administer the survey, compensate participants, and assist with data quality review.

Design
We will contract with NORC at the University of Chicago to recruit 1,230 young adults (aged 18-29) from a combination of their AmeriSpeak panel (approximately N=1000) and a third-party opt-in panel (remainder). NORC will recruit participants, program the survey, administer the survey to eligible participants, and provide the Wake Forest team with a final dataset, where participants are weighted to create a nationally representative sample. Participants who complete the survey will receive a small incentive, as agreed up by their panel, generally worth a few dollars. Participants will complete demographics and tobacco use measures and then will be randomized to one of three conditions. One-third (about 410 participants) will be randomized to the pictorial warning intervention group, 410 to the text-only warning intervention group, and 410 to the no-warning control group. The two intervention groups will see six respective warnings on sample packaging, one at a time. The control group will see the sample packaging once, without a warning. Intervention group participants will respond to measures designed to assess their warning reactions (emotional and cognitive reactions, perceived message effectiveness), and appeal of each package. Control group participants will complete items on package appeal. After viewing all warnings, participants will complete items on behavioral intentions, perceived risks of waterpipe smoking, and knowledge of risks. After completing the study, participants will be provided with a link to the CDC fact sheet about waterpipe smoking and the tobacco quit line number.

Setting
Participants will complete the survey on a computer, tablet, or phone at a location of their choosing.

Subject Selection Criteria
We will conduct an online national probability-based survey with a sample of 1,230 US young adults (18-29 years old) using the AmeriSpeak panel at NORC and a third-party non-probability sample, weighted with the AmeriSpeak sample to be nationally representative.

NORC will send the screener to all panelists who are aged 18-29 and live in the United States, determined by their pre-administered demographic questionnaires. They will administer their standard demographic questionnaire to all 3rd party panelist, as well, and ask an additional item to determine location. All respondents who are within the age range and report residence in the United States will be able to complete the screener survey. The screener survey will ask participants about their past year waterpipe smoking and their susceptibility to smoking waterpipe in the future.

Respondents who report that they have smoked waterpipe in the past year and those who have not used in the past year but are susceptible to future use (using a 5-item measure) will be routed to the consent form

for the full survey. If they agree to complete the survey, they will be randomized to one of the three conditions and will begin the full survey.

Inclusion Criteria
- Aged 18-29, inclusive
- US resident
- Satisfies one of the following categories:
    1. Has used waterpipe tobacco in the past year
    2. Has not used waterpipe tobacco within the past year but is susceptible to future use

Exclusion Criteria
- Under the age of 18 or above 29
- Not a resident of the United States
- Has not used waterpipe tobacco within the past year and is not susceptible to future use

Sample Size: 1,230

Interventions and Interactions
We will measure waterpipe use with two items (ever use and use in the past year) and susceptibility to future use with a five-item scale. We anticipate that 30% of young adults aged 18-29 will be current waterpipe users and 42% will be susceptible non-users, based on a waterpipe survey fielded recently within this sample. Given the young adult sampling frame available and estimated response rate from NORC, we anticipate recruiting 512 current waterpipe users and 718 susceptible non-users. AmeriSpeak participants will receive points, worth approximately $5, for completing the survey. Third-party participants will receive compensation as agreed upon with their panel.

Participants will be randomized to one of three conditions: text-only warnings, pictorial warnings, no warning control. Participants in the two intervention conditions will be shown six waterpipe packages, each with a different warning corresponding to their condition, in random order, and will complete items on package appeal and warning perceptions. Participants in the control condition will be shown one waterpipe package with no warning on it and will complete items on package appeal. The waterpipe package is a fictitious brand created by the study team in a separate study. All elements of the waterpipe packaging will be the same across conditions and the only difference will be the presence and type of warning.

Outcome Measure(s)

PRIMARY
Behavioral Intentions. The primary outcome is intention to smoke tobacco in a waterpipe within the next year, measured by averaging three items adapted from research on cigarette smoking:
1. How interested are you in smoking hookah in the next year?
2. How likely are you to smoke hookah in the next year?
3. How much do you plan to smoke hookah in the next year?

Response scale: (1) Not at all / (2) Very little / (3) Somewhat / (4) Quite a bit / (5) Very

SECONDARY
None

OTHER
Product Appeal. Three items will be used to measure how appealing each waterpipe tobacco package is to respondents, how likely they would be to try the product, and how much the packaging makes the respondent think that the product is harmful.
1. How appealing is this product to you?

2. How likely would you be to try this product?
3. How much does this packaging make you think this product is harmful?

Response scale: (1) Not at all / (2) A little / (3) Somewhat / (4) A lot

Mean Perceived Message Effectiveness (PME). This outcome will be measured using the 3-item Perceived Measured Effectiveness scale created by Noar and colleagues that includes items on attitudes, risk beliefs, and intentions. Overall scores are determined by summing the scores of the three items and dividing by three.

1. How much does this warning make smoking hookah seem unpleasant to you?
2. How much does this warning make you concerned about the health effects of smoking hookah?
3. How much does this warning discourage you from wanting to smoke hookah?

Response scale: (1) Not at all / (2) Very little / (3) Somewhat / (4) Quite a bit / (5) A great deal

Attention. One item to measure self-reported attention to the warning.

1. How much does this warning grab your attention?

Response scale: (1) Not at all / (2) Very little / (3) Somewhat / (4) Quite a bit / (5) A great deal

Emotional Reactions. Three items to measure negative emotional reactions to the warning that the participant saw. Overall scale scores are determined by summing the scores of the three items and dividing by three.

1. How much does this warning make you feel anxious?
2. How much does this warning make you feel disgusted?
3. How much does this warning make you feel scared?

Response scale: (1) Not at all / (2) Very little / (3) Somewhat / (4) Quite a bit / (5) A great deal

Cognitive Elaboration. One item to measure the extent to which a participant reports the warning making them think about the risks of hookah smoking.

1. How much does this warning make you think about the health effects of smoking hookah?

Response scale: (1) Not at all / (2) Very little / (3) Somewhat / (4) Quite a bit / (5) A great deal

Self-reported Learning. One item to measure the extent to which respondents learned something new from the warning.

1. To what extent did you learn something new from this warning that you did not already know?

Response Scale: (1) Not at all / (2) Very little / (3) Somewhat / (4) Quite a bit / (5) A great deal

Social Interactions. One item to measure self-reported likelihood of discussing the warning shown with one's social contacts within the week following the survey.

1. How likely are you to talk about this warning with others in the next week?

Response Scale: (1) Not at all / (2) Very little / (3) Somewhat / (4) Quite a bit / (5) A great deal

Knowledge. Six items to measure knowledge of the potential health harms described by the warnings.

1. Hookah smoking causes heart damage.
2. Hookah smoking causes lung damage.
3. Hookah smoking causes mouth cancer.
4. Hookah smoking causes carbon monoxide poisoning.
5. Hookah smoking during pregnancy stunts fetal growth.
6. Hookah smoking causes nicotine addiction.

Response scale: (1) True / (2) False / (3) I don't know

Beliefs. Five items to measure the respondent's belief of their own risk of experiencing each of the warning health harms. One item measures risk to pregnant people, rather than the self, since this item will be administered to all participants.

1. If I smoke hookah, I will damage my heart.

2. If I smoke hookah, I will damage my lungs.
3. If I smoke hookah, I will get mouth cancer.
4. If I smoke hookah, I will get carbon monoxide poisoning.
5. If a person smokes hookah during pregnancy, it will stunt fetal growth.
6. If I smoke hookah, I will become addicted.

Response scale: (1) Strongly disagree / (2) Somewhat disagree / (3) Neither disagree nor agree / (4) Somewhat agree / (5) Strongly agree

Worry. Five/six items measuring a respondent's concern about their risk of warning health effects. Damage to fetuses will only be asked of respondents who report female sex at birth.

1. If you smoke hookah, how much would you worry about getting mouth cancer?
2. If you smoke hookah, how much would you worry about damaging your heart?
3. If you smoke hookah, how much would you worry about damaging your lungs?
4. If you smoke hookah, how much would you worry about getting carbon monoxide poisoning?
5. If you smoke hookah, how much would you worry about stunting fetal growth, if you were pregnant?
6. If you smoke hookah, how much would you worry about becoming addicted?

Response scale: (1) Not at all / (2) A little / (3) Somewhat / (4) A lot

Motivation to quit. We will use a 1-10 scale to determine how motivated the participant feels they are to quit smoking. This item is only asked of those who reported past year hookah use.

Analytical Plan

There are three goals for the analysis. First, compare WTS intentions between those exposed to text versus pictorial waterpipe warnings. We hypothesize that those exposed to pictorial warnings will have lower WTS intentions than those exposed to text warnings. To test the differences in warnings format on WTS intentions, we will fit a linear regression model using PROC MIXED in SAS to account for the sampling design features (e.g., sample weights, repeated measures). We will then examine experimental condition as a fixed effect with and without adjustment for potential confounders (e.g. sex, race/ethnicity, age, SES, WTS, use of other tobacco products). All tests will be two-sided. For a sample of 400 participants per condition, we will have 80% power to detect differences between the text only and pictorial conditions in waterpipe intentions of 0.24 or greater (corresponding to an effect size 0.16) in a design with 6 repeated measurements having a compound symmetry covariance structure when the standard deviation is 1.5, based on Lipkus & Mays (2018). For comparisons between the text or pictorial warnings and the control condition (which does not have repeated measures), we will have 80% power to detect differences of 0.27 or greater, corresponding to an effect size of 0.18., For all comparison, the correlation between repeated observations on the same subject is 0.6 and the alpha level is 0.05. As a sensitivity analysis, we will perform a subgroup analysis restricted to those reporting that they have not participated in a tobacco study in the past year to examine whether prior participation influences our findings. Second, we will assess the impact of warnings on behavioral antecedents, such as negative affect, cognitive elaboration, perceived risks, and knowledge using separate models, similar to those described above for WTS intentions. Third, we will select four coordinating warnings from each condition (same text in both), with the highest PME scores for use in Aim 3. We will assess the rank order of warnings based on PME scores for the sample as a whole and for subgroups, based on sex, race/ethnicity, sexual orientation, and WTS behavior to determine whether the rankings remain consistent. Ultimately, we will select four text and four pictorial warnings (that match) and are consistently ranked high on PME across subgroups.

Human Subjects Protection

Subject Recruitment Methods

NORC will recruit and administer the survey to eligible participants from their AmeriSpeak panel and will contract with a third-party convenience sample administrator to obtain any additional participants needed to achieve the desired sample size. Interested participants will be contacted using methods typical of survey panels, including email and mobile application notifications. They will gain access to the survey through the manner in which they agree to be contacted by the survey panel administrators.

Informed Consent

This study protocol includes a request for a waiver of signed consent. This is an online survey and individual participation involves providing voluntary responses to questionnaires. The research presents no more than minimal risk of harm to subjects. Consent language will be included in the introduction to the survey and participants will be asked to check a box to indicate that they agree to participate.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and by maintaining all study information in a secure manner. A data use agreement is included in the subcontract with NORC detailing their access to and storage of any study-related data. No individual data will be shared with co-investigators at Boston University or the University of North Carolina at Chapel Hill.

Data and Safety Monitoring

The principal investigator, Dr. Sutfin, will be responsible for the overall monitoring of the data and safety of study participants. Dr. Sutfin will be assisted by other members of the study staff, as appropriate. The data will also be monitored closely by the Wake Forest School of Medicine IRB.

Reporting of Unanticipated Problems, Adverse Events, or Deviations

Any unanticipated problems, serious and unexpected adverse events, and protocol deviations or changes will be reported promptly by the principal investigator or designated member of the research team to the IRB and sponsor and/or appropriate government agency.