

Title: High Impact E-cigarette Advertisement Features

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NON-INTERVENTIONAL/METHODOLOGICAL RESEARCH PROTOCOL

(HRP-503b)

STUDY INFORMATION

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High Impact E-cigarette Ad Features and Claims
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1.0 Research Design

1.1 Purpose/Specific Aims

The overall purpose of this study is to assess the influence of e-cigarette advertisements (ads) and their high-impact ad features (flavor features, reduced exposure messages, and FDA-authorized claims) on perceptions and intentions of using e-cigarettes among young adults (ages 18-30). Using two randomized between-subject experiments in an online survey, the main goal of the first experiment is to examine the effect of viewing different flavor features (flavor name, product color that coincides with flavor name, flavor image, flavor sensation descriptor, and flavor choice claim) on self-reported e-cigarette use perceptions and use intentions. The main goal of the second experiment is to examine the effect of viewing different e-cigarette marketing claims suggesting harm reduction (reduced exposure claim, FDA-authorization claims) on self-reported e-cigarette use perceptions and use intentions.

A. Objectives

Objective 1: To assess if exposure to e-cigarette ads with flavor features and reduced harm claims will result in greater positive perceptions and increased e-cigarette use intentions than exposure to e-cigarette ads without these features.

B. Hypotheses / Research Question(s)

Hypothesis 1: Exposure to e-cigarette ads with flavor features and reduced harm claims will result in greater positive perceptions and increased e-cigarette use intentions than exposure to e-cigarette ads without these features.

Hypothesis 2: The positive effect of exposure to e-cigarette ads with flavor features on e-cigarette use intentions will be moderated by participants' tobacco-use status.

1.2 Research Significance

There has been a rise in e-cigarette use with nicotine among U.S. young adults in recent years.¹ Among those aged 19-30, past 12-month nicotine vaping increased from 13.7% in 2017 to 25.3% in 2023, while past 30-day nicotine vaping rose from 6.1% in 2017 to 18.7% in 2023.¹ This is concerning, given that e-cigarette use during young adulthood among those who are naïve to tobacco products can lead to nicotine addiction and may increase the risks of developing more harmful tobacco-use behaviors that can lead to respiratory diseases, cardiovascular diseases, and cancer later in life.^{2,3} On the other hand, young adults who smoke cigarettes may benefit from using e-cigarettes to quit smoking, as switching from cigarettes to e-cigarettes could reduce their exposure to harmful chemicals before they become vulnerable to the severe health effects of long-term cigarette smoking.⁴ E-cigarette marketing plays a key role in shaping the perceptions and use intentions of e-cigarette products among young adults of varying tobacco use behaviors.⁵⁻⁷ In our previous research, we found that exposure to flavor features, such as fruit flavor names, images, etc., is influential in increasing positive product perceptions and use interests.⁸⁻¹¹ This is unsurprising considering the availability of e-cigarettes in non-tobacco flavors is commonly cited as a key reason for e-cigarette initiation and use among young people.¹² However, it is unclear which specific flavor features (e.g., flavor names, colorful product packing that coincide with the product flavor [e.g., red for strawberry, green for apple], flavor images, flavor sensation claims) may be particularly appealing to young adults. It is also unknown which combinations of various flavor features appearing on an ad together are especially influential in changing perceptions and use intentions. In addition, various potential marketing claims related to reduced harm from e-cigarette use, including reduced exposure claim and FDA-authorized claims may also alter the perceptions and use intentions of the products. Additional research is needed to address significant gaps regarding which the impact of those features and claims used in e-cigarette ads among young adults with varying tobacco use behaviors and to inform regulatory decision-making. Regulatory decision-making related to e-cigarette flavor features on ads is important for helping to reduce the use of e-cigarettes with non-tobacco flavorings that may expose young people to aerosols containing compounds of respiratory toxicity.¹³

1.3 Research Design and Methods

To assess the impact of those features and claims, we will administer two separate randomized experiments through this online survey project where subjects will be assigned to one of six e-cigarette ad conditions (experiment 1) and one of the six e-cigarette ad conditions (experiment 2). The survey will include a series of questions about subjects' sociodemographic backgrounds, health

conditions, tobacco use history and dependence, and tobacco use environment. Static images of mock e-cigarette ads will be created based on publicized ads in brand company websites and emails.

A. Research Procedures

Young adult subjects will be recruited from online study panels administered by Qualtrics. Qualtrics will send out a brief description of the study for young adult recruitment (see Attachment A). Those who are interested in participating will first receive a screening survey (see Attachment B) to ensure eligibility. Those who are eligible will move on to the informed consent page (see Attachment C) and those who agree with the consent will proceed to complete the study survey (see Attachment D). In the survey, subjects will first answer a series of questions about demographics, health conditions, tobacco use history and dependence, and tobacco use environment. Afterward, for experiment 1, subjects will be randomly assigned to one of six conditions where they will be exposed to an e-cigarette ad either featuring an e-cigarette product that may or may not include high-impact flavor features. Condition 1 (control condition) will not include any high-impact flavor features and conditions 2-6 will include at least one high-impact flavor feature (flavor name, product color that coincides with flavor name, flavor sensation descriptor, and flavor choice claim). Attachment E includes stimuli for each experimental condition. Each ad will also include other ad features (e.g., nicotine warning label, generic marketing claim) to help increase ad authenticity. The conditions are:

- Condition 1: Black product with tobacco flavor name
- Condition 2: Black product with strawberry flavor name
- Condition 3: Colorful (strawberry color) product with strawberry flavor name
- Condition 4: Colorful (strawberry color) product with strawberry flavor name + strawberry image
- Condition 5: Colorful (strawberry color) product with strawberry flavor name + strawberry image + strawberry flavor sensation descriptor
- Condition 6: Colorful (strawberry color) product with strawberry flavor name + strawberry image + strawberry flavor sensation descriptor + flavor choice claim

We chose to assess strawberry as the product flavor in these ads because it is a commonly marketed and available e-cigarette flavor^{14,15} in the retail environment, and one of the most frequently mentioned e-cigarette flavors among users on social media sites.¹⁶⁻¹⁸ Strawberry has also been cited as one of the most appealing,^{14,19} and highly rated²⁰ e-cigarette flavors among users. It is therefore a flavor commonly used in e-cigarette research, including laboratory experiments, to assess user perceptions, use intentions, and use behaviors.^{14,15,20}

During the experiment, subjects will be required to view each ad for a minimum of 10 seconds and will then answer questions about their intentions and perceptions of using the e-cigarette products shown in each ad.

For experiment 2, subjects will be randomly assigned to one of six conditions where they will be exposed to an e-cigarette ad with or without reduced exposure claims, FDA-authorized claims, and scientific facts about FDA-authorized claims. Attachment E includes stimuli for each experimental condition.

- Condition 1: E-cigarette ad without any claims
- Condition 2: E-cigarette ad with reduced exposure claim
- Condition 3: E-cigarette ad with reduced exposure claim and FDA-authorized claim
- Condition 4: E-cigarette ad with reduced exposure claim, FDA-authorized claim, and scientific facts about FDA-authorization
- Condition 5: E-cigarette ad with FDA-authorized claim
- Condition 6: E-cigarette ad with FDA-authorized claim and scientific facts about FDA-authorization

During the experiment, subjects will be required to view each ad for a minimum of 10 seconds and will then answer questions about their intentions and perceptions of using the e-cigarette products shown in each ad.

After completing the survey questions, subjects will view debriefing messages about the harm of tobacco and e-cigarette use. The debriefing messages will also include information about how the tobacco industry targets young people with appealing advertisements and a list of e-cigarette and cigarette cessation resources for those who need quitting support.

B. Duration for Study and Each Subject

It will take subjects approximately 20 minutes to complete the entire survey.

1.4 Preliminary Data

This study is informed by preliminary data from several of our previous projects. For instance, our previous online heatmap experiment study,⁸ eye tracking studies,^{9,10} and in-depth interviews¹¹ all provide information about the most impactful e-cigarette marketing features in changing perceptions and use interests among young adults of various tobacco use behaviors. In our online heatmap experiment, we found that noticing fruit flavors and fruit images in e-cigarette ads was associated with e-cigarette product appeal and switching interest among young adult dual-users of e-cigarettes and cigarettes.⁸ Noticing price promotions was also associated with e-cigarette product appeal, but no other features were influential in increasing participants' interest in completely switching to e-cigarettes.⁸ In our eye-tracking study assessing cartridge-based e-cigarette product features in print ads, we found that overall, longer dwell time for multiple flavor choice descriptions (choice of fruit, menthol, tobacco flavors) was positively associated with e-cigarette appeal, and a shorter entry time for fruit flavor descriptions was associated with positive e-cigarette use expectancies.⁹ Similarly, in our eye-tracking study assessing disposable e-cigarette product features in social media marketing, attention to fruit/candy descriptors (names and promotional claims for fruit and candy flavors) generated product use interest among young adults who smoke.¹⁰ Our interviews that followed the eye-tracking study for cartridge-based e-cigarette products revealed that young adults who do not use tobacco and those who smoke cigarettes generally noticed fruit and multiple flavors in the ads, which were seen as appealing and were reported to generate product use interest because of bright colors, sensory appeal, and a variety of flavor options.¹¹ Based on the findings from these studies, it is important to further assess the influence of flavor features in e-cigarette ads to understand which flavor features, or which combination of flavor features together, are most impactful in changing perceptions and use interests.

1.5 Sample Size Justification

There will be 3,000 subjects enrolled in the study. Our previous studies using a similar study design examining the influence of e-cigarette marketing features used sample sizes of approximately 3,000 to obtain sufficient power for detecting differences in product perceptions and use interest with small to moderate effect sizes. Other studies have shown that 500 subjects per group (6 randomizing conditions) will provide sufficient power to detect differences in perceptions and use intentions after viewing varying ad features as well as the moderating effect of tobacco-use status on those associations.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The predictor variable will be subjects' conditions they are assigned to for the two experiments.

B. Dependent Variables or Outcome Measures

For both experiments, four groups of outcome measures will be used. See the Survey attachment for detailed measures

1. Ad appeal
2. E-cigarette use intentions
3. E-cigarette risk perceptions
4. E-cigarette outcome expectancies

1.7 Specimen Collection

A. Primary Specimen Collection

- **Types of Specimens:** N/A
- **Annotation:** N/A
- **Transport:** N/A
- **Processing:** N/A
- **Storage:** N/A
- **Disposition:** N/A

B. Secondary Specimen Collection

- **Types of Specimens:** N/A
- **Annotation:** N/A
- **Transport:** N/A
- **Storage:** N/A
- **Disposition:** N/A

1.8 Data Collection

A. Primary Data Collection

- **Location:** The survey will be programmed online, via Qualtrics, an online survey platform.
- **Process of Data Collection:** Data collection will be managed by Qualtrics, and young adult subjects will be recruited from Qualtrics' existing study panels.
- **Timing and Frequency:** The survey will be a one-time occurrence estimated to take approximately 20 minutes.
- **Procedures for Audio/Visual Recording:** N/A
- **Study Instruments:** The survey is included with this application (see Attachment D). The study survey will assess tobacco-using history, perceptions about tobacco products and tobacco use, perceptions of e-cigarette ads with various features and claims, intentions perceptions of using the products in these ads, and subject demographics.
- **Ethnographic Studies, Interviews, Or Observation:** N/A
- **Subject Identifiers:** Data will be collected from young adult subjects online who are registered users of Qualtrics survey panels. Qualtrics takes extensive measures to ensure that all registered members' privacy and personal information are treated confidentially and kept secure. For this study, all data will be de-identified and anonymous to the PI and no personal information will be released to the PI. We will set up the Qualtrics survey in a way to not collect subjects' PI addresses using the Anonymous Response features, in order to collect completely anonymous survey responses. At the beginning of the survey, Qualtrics will generate a random Subject ID.

B. Secondary Data Collection

- **Type of Records:** N/A
- **Location:** N/A
- **Inclusion/Exclusion:** N/A
- **Data Abstraction Form(s):** N/A

1.9 Interviews, Focus Groups, Surveys, and/or Observations

A. Administration

- **Timing and Frequency**
See Section 1.8A.
- **Location**
See Section 1.8A.
- **Procedures For Audio And Visual Recording**
N/A
- **Person Identifiers**

N/A

B. Study Instruments

- **Evaluation Instrument Details**
See Section 1.8A.
- **Study Instruments For Ethnographic Studies**
N/A
- **Oral Histories Or Interviews General Framework**
N/A
- **Referral Information**
N/A

2.0 Project Management

2.1 Research Staff and Qualifications

Dr. Julia Chen-Sankey, PhD, MPP, Assistant Professor, Institute for Nicotine & Tobacco Studies and Rutgers School of Public Health, PI of this project, is an experienced researcher with expertise in tobacco product marketing influence among young adults. Specifically, Dr. Chen-Sankey has led several projects examining attention to specific marketing features of tobacco vape product ads and associations with product perceptions and use intentions among young adults. Dr. Chen-Sankey has also conducted online survey studies using subjects recruited through research companies such as Qualtrics. The PI will be involved in the study design, implementation, and data analysis and has completed relevant IRB/CITI trainings.

Kathryn La Capria, MPH, Research Associate, Institute for Nicotine & Tobacco Studies, research assistant and project manager of this project, will assist in data collection and research support throughout the life of the project.

Siyam Meng, MA, Research Assistant, Institute for Nicotine & Tobacco Studies, will assist in data analysis and manuscript writing.

Research Staff Training

All study members who are involved in this study have completed relevant IRB/CITI trainings and will receive specific trainings on this study protocol. All study team members will be provided with a copy of the protocol. There will be weekly project meetings where specific procedures and individual tasks will be discussed in full detail to ensure that the study team is following the protocol.

2.2 Resources Available

We will use Qualtrics, offered through Rutgers, to program, host, and administer the online survey. Qualtrics will also use their study panels for subject recruitment. This is a resource available to Rutgers faculty (<https://oit.rutgers.edu/qualtrics>).

The PI has access to various statistical analysis programs (SPSS, SAS, STATA) through their work at the Rutgers Institute for Nicotine & Tobacco Studies.

2.4 Research Sites

The Rutgers Institute for Nicotine & Tobacco Studies will serve as the administrative base for this project. Research activities (i.e., data storage and data analysis) will be conducted using computers/servers located in the study team's Rutgers office space at the Rutgers Institute for Nicotine & Tobacco Studies (303 George Street, Suite 500, New Brunswick, NJ.)

3.0 Multi Center Research

N/A

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Subjects will be registered Qualtrics study panel members. Potential subjects will initially review a brief description of the study (see Attachment A), and those who are interested in participating will proceed to the eligibility screening questions assessing their age and tobacco use history (see Attachment B). If eligible, they will then be directed to the online consent form (see Attachment C).

B. Recruitment Details

In Spring 2025, subjects will be recruited via Qualtrics' online study panels. Potential subjects who see and choose to complete our task (i.e., study) will complete it using Qualtrics' survey platform. Recruitment is anticipated to take approximately three weeks.

C. Subject Screening

▪ Inclusion Criteria

Three groups of young adult subjects (ages 18-30) will be included in the study. The first group is those who are exclusive cigarette smokers (n=1000), defined as those who have smoked at least 100 cigarettes in their lifetime and have smoked at least one cigarette in the past 30 days but have not used e-cigarettes in the past 30 days. The second group is those who are dual users of cigarettes and e-cigarettes (n=1000). Those in this group have smoked more than 100 cigarettes in their lifetime and have smoked a cigarette and also used an e-cigarette in the past 30 days. The third group is those who are non-tobacco users (n=1000), defined as those who have never used any tobacco product before or have never "regularly" used tobacco products before and are currently not using any tobacco products (in the past 30 days).

▪ Exclusion Criteria

Any subjects not meeting the inclusion criteria described in 4.1.C will be excluded from the study. Individuals will be further excluded if they do not provide consent to participate in the study.

D. Privacy Protections

Our survey will be publicized via Qualtrics (see Attachment D) to their registered study panel members. The screening questions (see Attachment B) pertain solely to demographics and tobacco use history and do not request any personally identifiable information. The PI will not receive the responses to the screening questions from Qualtrics if the subjects do not agree with the consent form or do not complete the survey.

4.2 Obtaining Identifiable Information About Non-Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects

3,000

B. Total Number of Subjects If Multicenter Study

N/A

C. Feasibility

Based on prior studies conducted by the research team using a research company with study panels and other similar online sample providers, we anticipate that the recruitment of eligible subjects will take approximately three weeks.

4.4 Consent Procedures

A. Consent Process

▪ Location of Consent Process

- The consent process will take place online, via the Qualtrics platform.
- **Ongoing Consent**
N/A
 - **Individual Roles for Researchers Involved in Consent**
The researchers will program the consent form into the start of the online study.
 - **Consent Discussion Duration**
Consent will be obtained through an online form, so there will be no set duration for the discussion.
 - **Coercion or Undue Influence**
The online consent document will specify that the prospective subjects are not required to participate and may exit the study at any time.
 - **Subject Understanding**
The online consent process will explain the nature of the study experience before requesting consent for participation. The consent form (see Attachment C) will thoroughly convey the nature of the study and communicate potential risks involved with participation and the voluntary nature of participation. The form will also provide contact information for the PI and the Rutgers IRB so that subjects may ask further questions about the study, their participation, and their rights as subjects.
 - **Protecting Privacy**
The study will not request any personally identifiable information during the consent process; if Qualtrics collects such information, the researchers of the study will not be able to accept it.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
N/A
- **Destruction of Identifiers**
N/A
- **Use of Deception/Concealment**
N/A
 - a. **Minimal Risk Justification**
N/A
 - b. **Alternatives**
N/A
 - c. **Subject Debriefing**
N/A

C. Documentation of Consent

- **Documenting Consent**
N/A
- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**
All aspects of the study procedures will be done online. We request a waiver of documented consent. All potential subjects will be shown an online consent form describing the study and its voluntary nature, the confidentiality and privacy of their responses, and providing contact information for the study PI. The consent form will state that by clicking the "I agree" button at the bottom of the page, they will have provided their consent. Only after clicking "I agree" will they advance to the study survey. These are typical consent methods used for online survey studies and will allow us to make sure all data are de-identified and anonymous.

4.5 Special Consent/Populations

A. Enrolling Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
N/A
- **Non-Parental Permission**
N/A

- **Assent Process**
N/A
- **Documentation of Assent**
N/A
- **Reaching Age of Majority During Study**
N/A

B. Enrolling Wards of the State

N/A

- **Research Outside of NJ Involving Minors**
N/A

C. Enrolling Non-English-Speaking Subjects

N/A

- **Process for Non-English-Speaking Subjects**
N/A
- **Short Form Consent for Non-English Speakers**
N/A

D. Enrolling Adults Unable to Consent / Decisionally Impaired Adults

N/A

- **Assessing Adult Capacity to Consent**
N/A
- **Selecting a Surrogate & Consent Process**
N/A
- **Subject Assent**
N/A
- **Selecting a Witness to the Surrogate Consent Process**
N/A
- **Removing a Subject**
N/A

E. Special Consent Considerations

N/A

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses

Other than participation time, which is expected to be brief, there is no cost associated with participation in this survey.

B. Compensation/Incentives

Subjects will be compensated with points that could be redeemed for cash.

C. Compensation Documentation

Subjects who receive the compensation will receive points that could be redeemed for cash per Qualtrics' policy and therefore, compensation documentation will be documented by Qualtrics.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Subject Risks of Harm

The risk of harm to all study subjects is minimal. This study involves standard survey procedures, and the information obtained is recorded in such a manner that human subjects cannot be identified directly. Although the survey collects some information about behaviors that might be considered sensitive, including sexual orientation, the dataset contains no personal identifiers. In the unlikely event of a data breach, reported behaviors could not be

linked to individual subjects. Participation in this study poses no serious physical, psychological, or social risks to subjects. Given that all data collected will be anonymous, participation in the study does not put the subject at legal risk or civil liability. Subjects will be exposed to images of e-cigarette ads, but these ads are ones that could be encountered in daily life in stores and/or via marketing. Therefore, young adult subjects could have already encountered e-cigarette ads through various channels of ad exposure. During the study, if subjects feel uncomfortable with a question, they can quit the survey at any time. There is some risk in showing ads to non-users because the ads could stimulate or increase their interest in these products (as they might in real life). However, these exposures are very brief, and young adults are already exposed to those ads in their everyday lives. Precautions will also be taken to minimize these risks by showing subjects health education messages at the end of the survey about the harms of tobacco and e-cigarette use. The debriefing messages will also include information about how the tobacco industry targets young people with appealing advertisements and a list of e-cigarette and cigarette cessation resources for those who need quitting support.

- **Existing Condition/Disorder**

N/A

- **Additional Considerations**

- a. N/A

- b. N/A

- **Minimizing Risks**

As described above, the study will expose young adult subjects to e-cigarette ads, which might increase their interest in using the products. Precautions will also be taken to minimize these risks by showing subjects messages at the end of the survey about the harm of e-cigarette use. The debriefing messages will also include information about tobacco industry targeting through appealing advertisements and a list of e-cigarette and cigarette cessation resources for those who need quitting support.

- **Certificate of Confidentiality**

This is an NIH-funded study and will automatically be issued a Certificate of Confidentiality (CoC) from NIH.

- **Risks of Harm to Non-Subjects**

N/A

B. Potential Direct Benefits to Subjects

There are no known direct benefits to subjects, however, subjects may experience other benefits, such as the personal satisfaction of knowing they have contributed to a research project.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

N/A

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

N/A

A. Special Populations

N/A

5.4 General Data Protection Regulation (GDPR)

N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)

N/A

6.0 Data Management Plan

6.1 Data Analysis

We will use linear regressions to assess the associations between experimental conditions and various outcomes described above. We will add the interaction terms to the regression models to test the interactive effects of tobacco-use status and the experimental effect. We will also provide estimates of participant characteristics and assess their even distributions across conditions.

6.2 Data Security

By design, the identity of the subjects recruited via the research company's study panels is anonymous to the PI. Survey response data collected through Qualtrics is absent of all identifying data (e.g., name, birth date, e-mail address). All data collected from this study will be deleted by the PI within 90 days of study closure.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan

N/A (research does not pose greater than minimal risk of harm to subjects.)

B. Data/Safety Monitoring Board Details

N/A (research does not pose greater than minimal risk of harm to subjects.)

6.4 Reporting Results

A. Subject Results Reporting

N/A

B. Aggregate Results

N/A

C. Professional Reporting

Upon data collection and analysis, we plan to share results with the scientific community through conference presentations and publication in scholarly journals.

D. Clinical Trials Registration, Results Reporting and Consent Posting

N/A

6.5 Secondary Use of the Data

There are no plans for secondary use of data.

7.0 Research Repositories – Specimens and/or Data

All data collected will be retained by the PI and available within the electronic databases of the Rutgers Institute for Nicotine & Tobacco Studies.

8.0 Approvals/Authorizations

N/A

9.0 Bibliography

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