Protocol

Cannabis Edibles Packaging Imagery Experiment

IRB00111438

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Background, Rationale, and Context

The rate of cannabis legalization in the U.S. has increased rapidly in recent years. This has led to the proliferation of non-combustible cannabis products, like edibles (cannabis-infused food products), that do not involve inhaling toxic smoke, can be used with discretion, and have no smell. While popular in recreational states, these products pose unique public health challenges. Although edibles are packaged as appealing food products and are perceived to be less harmful than other cannabis products, their marketing has led to overconsumption of tetrahydrocannabinol (THC), the psychoactive component in cannabis. While smoking cannabis results in an immediate high, intoxication from consuming edibles can be delayed up to two hours or more. This can lead to consuming more than the recommended serving, which can result in unexpected, stronger, and longer-lasting highs as well as severe anxiety, vomiting, and psychotic episodes. Since cannabis is regulated on a state-by-state basis, there is substantial variation in the regulation of product packaging and warnings that inform consumers. Furthermore, little research has been conducted on edibles, resulting in significant gaps in understanding how packaging and warnings impact product appeal, knowledge, harm perceptions and willingness to try edibles. This proposal will address these gaps by testing the impact of cannabis edibles product packaging and delayed-effects warnings using controlled, experimental designs. In Aim 1, we will identify a sample of recreational edible products and content analyze text and visual elements on the packaging. We will conduct two experiments to evaluate the impact of these elements on product appeal, harm perceptions and willingness to try cannabis edibles. This protocol is for the second experiment, testing various images on product packaging. Separate IRB applications will also be submitted for Aims 2 and 3.

Objective(s)

The overarching goal of this project is to understand elements of cannabis edible packaging that impact appeal, knowledge, harm perceptions and willingness to try cannabis edibles. This information is critically needed and can help guide policymakers as they establish best practices for packaging of cannabis edibles. The goal of Aim 1 is to document cannabis industry practices, identifying product descriptors and imagery on packaging that increase appeal and reduce harm perceptions, which in turn may increase willingness to try edibles.

Roles

University of North Carolina at Chapel Hill

Dr. Lazard and her team will be responsible for developing product imagery stimuli and will assist with interpretation and dissemination of data.

Boston University

Dr. Ross will assist with protocol development, survey design, and interpretation and dissemination of data.

Methods and Measures

Design

We will conduct a cross-sectional, between-subjects experiment with a national convenience sample (n=1250) of US adults, aged 18-65, from CloudResearch's Prime Panels. Prime Panels aggregates market research panels where panel participants opt into surveys for a small incentive. The participants will see pictures of four different cannabis edibles products and answer questions about each. Each participant will be randomized to one of five conditions, four intervention conditions where the package is altered to contain an image of interest and one control condition, without any of the images. The product descriptors utilized in this experiment were derived from previous non-human subjects research from the overall grant that analyzed currently available cannabis edibles products.

After completing screening questions assessing age, residence, race, ethnicity, and history of cannabis use (any form, past year), participants will be randomized to a condition. For each product shown, they will answer questions related to appeal, harm perceptions, and willingness to try the product if it were available to them. After completing the product-specific items, participants will be asked about their use of cannabis edibles specifically (ever cannabis users only), other substance use, dietary restrictions, and demographic items such as educational attainment, employment, and sexual orientation.

Setting
Participants will complete the online survey on a device and at a location of their choosing.

Subject Selection Criteria

Study participants can be users or nonusers of cannabis.

Inclusion Criteria
- US resident
- Aged 18-65, inclusive
- Approximately 13% of participants will be those who identify as Black/African American
- Approximately 16% of participants will be those who identify as Hispanic
- Approximately 50% of participants will be past year cannabis users
- Was not a participant in Experiment 1 (IRB00104038)

Exclusion Criteria
- Does not currently reside in the United States
- Younger than 18 or older than 65
- Otherwise eligible but demographic and/or user group quotas have been met
- Was a participant in Experiment 1 (IRB00104038)

Sample Size
The study will include five conditions with approximately 250 participants per condition, totaling 1,250 participants. The protocol includes a maximum of 1,375 participants to account for incidental over-enrollment due to simultaneous completions of the online survey and potential replacement of poor-quality respondents.

Interventions and Interactions

Participants will complete a 15-minute online survey, where they will be randomized to one of five conditions: four intervention conditions with a different image on the package and one without any imagery. Participants in each condition will be shown four different cannabis product packages, created from real product packages but with a product descriptor of interest (for the four intervention conditions). They will answer a series of questions for each package that includes perceptions of product and package appeal, harm, and willingness to try the product.

Outcome Measure(s)

Primary Outcomes

(1) Product Appeal: One item to assess the appeal of the product. Results will be reported as mean for all products within condition.
Question: How appealing is this product to you?
Response options: (0) Not at all appealing to (10) Very appealing
Time Frame: After exposure to product packaging; 1 min

(2) Package Appeal: One item to assess appeal of the packaging of the product. Results will be reported as mean for all products within condition.
Question: How appealing is this packaging to you?
Response options: (0) Not at all appealing to (10) Very appealing
Time Frame: After exposure to product packaging; 1 min

(3) Product Harm Perceptions (Absolute): One item to assess participants' opinions of safety of the product. Results will be reported as the number of each type of response.
Question: How safe do you think it would be to eat the edible in this package?
Response options: (1) Completely unsafe, (2) Somewhat unsafe, (3) Somewhat safe, (4) Completely safe
Time Frame: After exposure to product packaging; 1 min

(4) Package Harm Perceptions (Absolute): One item to assess participants' opinions of product safety based on the packaging. Results will be reported as the number of each type of response.
Question: How much does this packaging make you think this edible is safe to consume?
Response options: (1) Not at all; (2) A little; (3) Somewhat; (4) A lot
Time Frame: After exposure to product packaging; 1 min

(5) Willingness to Try Free Sample: One question will assess the participant's willingness to try the product shown. Results will be reported as the number of each type of response.
Question: How interested would you be in a free sample of this product?
Response options: (1) Not at all; (2) Slightly; (3) Somewhat; (4) Moderately; (5) Very
Time Frame: After exposure to product packaging; 1 min

(6) Willingness to Try Product: One item to assess the participants' willingness to try the product based on the packaging. Results will be reported as the number of each type of response.
Question: How much does seeing this packaging make you want to try this edible?
Response options: (1) Not at all; (2) A little; (3) Somewhat; (4) A lot
Time Frame: After exposure to product packaging; 1 min

Secondary Outcomes

(7) Appeal to Children: One item to assess the participants' assessment of the product packaging's potential appeal to children. Results will be reported as mean for all products within condition.
Question: How appealing do you think this packaging would be to children?
Response options: (0) Not at all appealing to (10) Very appealing
Time Frame: After exposure to product packaging; 1 min

(8) Product Harm Perceptions (Relative): One question assessing participants' opinions of safety of the product compared to other, similar, products. Results will be reported as the number of each type of response.
Question: Compared to other edible products on the market, how safe do you think the edible in this package is?
Response options: (1) Much less safe; (2) Somewhat less safe; (3) As safe; (4) Somewhat safer; (5) Much safer
Time Frame: After exposure to product packaging; 1 min

Other Outcomes

9) Perception of Quality: One item to assess the participants' perceptions of the quality of the product. Results will be reported as the number of each type of response.
Question: To what extent do you agree or disagree that this looks like a good quality product?
Response options: (1) Strongly disagree to (5) Strongly agree
Time Frame: After exposure to product packaging; 1 min

(10) Perception of Good Taste: One item to assess the participants' perceptions of the taste of the product. Results will be reported as the number of each type of response.
Question: To what extent do you agree or disagree that this edible might taste good?
Response options: (1) Strongly disagree to (5) Strongly agree
Time Frame: After exposure to product packaging; 1 min

(11) Perception of Healthfulness of Product: One item to asses the participants' perceptions of the healthfulness of the product based on the packaging. Results will be reported as the number of each type of response.
Question: How much does this packaging make you think this edible is healthy?
Response options: (1) Not at all; (2) A little; (3) Somewhat; (4) A lot
Time Frame: After exposure to product packaging; 1 min

Analytical Plan

Analysis. Participants will rate four packages of varying product type. To account for the within-subject repeated measures, we fit linear mixed-effects models for continuous outcomes and mixed-effects logistic and ordinal regression models for categorical outcomes. Participants will be included as random-effects to account for the repeated measures and experimental conditions will be included as fixed-effects to reflect the between-subjects design. For this experiment, we will test differences in product appeal, harm perceptions and willingness to try between each of the four imagery conditions and the no image condition. Adjusted models will include age, sex, race, ethnicity, education, and residence in a state with legalized cannabis, history of cannabis and edible use, and use of other products like tobacco. For cannabis use, we consider both recentness (current/former/never) and frequency (daily/non-daily) of use. Secondary analyses will explore whether effects vary by race, ethnicity, sex, and history of cannabis and edible use. Analyses will be performed with a two-tailed significance level ($p < 0.05$).

THC content and serving size. Unlike other cannabis products, there is little variation in potency and serving size of edible packaging. However, all packages displayed in the experiments will contain 100mg THC and 10mg serving sizes, the maximum allowable in most states, to control for the potential impact of varying levels of THC and serving sizes on consumer perceptions. Packages in experiments will not contain CBD.

Sex as a biological variable. Men are more likely to use cannabis than females, however, limited data, including our pilot, show that among cannabis users, males and females consume edibles at the same rate. However, there are sex differences in rates of edible metabolism which may impact perceptions of harm. For this reason, in this and subsequent aims, we will explore whether sex moderates our findings.

Human Subjects Protection

Overview

The experiment utilizes an aggregation of opt-in panels to recruit participants to an online survey. Participants will receive a generic notification of potential eligibility from their chosen panel (i.e. “New online survey for you!”) and will click on the link if they are interested. They will read and agree to a brief screening consent form (study information form), complete screening questions, and if eligible, will be permitted to continue to the main consent and survey.

Potential Risks

Any expected risks of this study are minimal. The survey will not collect any personally identifiable information. The survey panels from which participants are recruited will not have access to any study data, and the study team will not have any access to identifying information, such as email address. Study participants will be assigned a random ID by CloudResearch when they accept the invitation to being the screening section of the survey. This ID is not connected to personally identifiable information.

Expected Benefits

Participants are not expected to benefit directly from the research, but results will yield generalizable knowledge regarding marketing practices for cannabis edibles, which may inform future public health policy.

Subject Recruitment Methods

Participants will be recruited through CloudResearch’s Prime Panels, which is a proprietary aggregation of market research panels. Participants of these panels self-select into a system where they receive notifications of surveys for which they may be eligible. If interested, they click on the link that brings them to the survey. The participants will be directed to the PHS Surveys site link, which will begin with a brief consent form. Interested participants will agree to the survey by checking a box, and will then be directed to a brief screener to assess eligibility. Eligible participants will then be directed to the main survey. Participants will be assigned a random ID that is not linked to their personally identifiable information.

Consent

A waiver of the requirements for signed informed consent is requested. The only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. Participants will read a study information sheet at the beginning of the survey and

be asked to select a checkbox to indicate their desire to participate or to decline participation. The study information sheet will disclose the standard elements of consent, including the study purpose, risks, benefits, compensation, rights as a participant, and contact information for the study's PI and Wake Forest IRB and Research Participant Advocate.

Compensation
Participants will be compensated with an amount and format they have agreed to with their panel. Participants may receive their compensation in the form of gift cards, airline miles, points, or other rewards. As with all market research, the amount is typically nominal (<$5), although there is no way to know what the exact compensation for each participant will be.

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. To help ensure subject privacy and confidentiality, only a unique study identifier will be appear on the data collection form. No personally identifiable information will be collected. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring
The Principal Investigator will be responsible for the overall monitoring of the data and safety of study participants. The Principal Investigator will be assisted by other members of the study staff, as appropriate.

Reporting of Unanticipated Problems, Adverse Events, or Deviations
Any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes will be reported promptly by the Principal Investigator or designated member of the research team to the IRB and sponsor or appropriate government agency, if appropriate.

Adverse Event Definitions
Adverse Event (AE)
An adverse event (AE) is defined as any unexpected, unfavorable or unintended condition that occurs immediately during sample or data collection.

Serious Adverse Event (SAE)
A serious adverse event (SAE) is any untoward medical occurrence that occurs during sample or data collection that satisfies any of these criteria: results in death; is life-threatening; requires inpatient hospitalization or prolongs existing hospitalization; results in persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions; or if the event results in a congenital anomaly or birth defect.

Recording Adverse Events.
When an AE occurs, it is the responsibility of the Investigator to review all documentation (e.g., medical progress notes, laboratory, and diagnostics reports) relative to the event. The study staff will then record all relevant information regarding an AE on the AE Form.

'Expectedness': AEs can be 'Unexpected' or 'Expected' for expedited reporting purposes only.

Attribution of the AE:

Definite–The AE is clearly related to the study participation.
Probable–The AE is likely related to the study participation.
Possible–The AE may be related to the study participation.
Unlikely–The AE is doubtfully related to the study participation.
Unrelated–The AE is clearly NOT related to the study participation.

STRC SAE Reporting Requirements.
The Safety and Toxicity Reporting Committee (STRC) is responsible for reviewing SAEs for WFBCCC Institutional studies. STRC currently requires that all unexpected 4 and all grade 5 SAEs on these trials be reported to them for review. All WFBCCC Clinical Protocol and Data Management (CPDM) staff members assisting a Principal Investigator in investigating, documenting and reporting an SAE qualifying for STRC reporting are responsible for informing a clinical member of the STRC as well as the entire committee via the email notification procedure of the occurrence of an SAE

WFUHS IRB AE Reporting Requirements.
Any unanticipated problems involving risks to subjects or others and adverse events shall be promptly reported to the IRB, according to institutional policy. Reporting to the IRB is required regardless of the funding source, study sponsor, or whether the event involves an investigational or marketed drug, biologic or device. Reportable events are not limited to physical injury, but include psychological, economic and social harm. Reportable events may arise as a result of drugs, biological agents, devices, procedures or other interventions, or as a result of questionnaires, surveys, observations or other interactions with research subjects.

All members of the research team are responsible for the appropriate reporting to the IRB and other applicable parties of unanticipated problems involving risk to subjects or others. The Principal Investigator, however, is ultimately responsible for ensuring the prompt reporting of unanticipated problems involving risk to subjects or others to the IRB. The Principal Investigator is also responsible for ensuring that all reported unanticipated risks to subjects and others which they receive are reviewed to determine whether the report represents a change in the risks and/or benefits to study participants, and whether any changes in the informed consent, protocol or other study-related documents are required.

Any unanticipated problems involving risks to subjects or others occurring at a site where the study has been approved by the WFUHS IRB (internal events) must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.
Any unanticipated problems involving risks to subjects or others occurring at another site conducting the same study that has been approved by the WFUHS IRB (external events) must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.
Any event, incident, experience, or outcome that alters the risk versus potential benefit of the research and as a result warrants a substantive change in the research protocol or informed consent process/document in order to ensure the safety, rights or welfare of research subjects.

References

Appendix

1. Consent Form
2. Questionnaire
3. Survey Image
4. Package Stimuli