**Complete Title:** Encouraging Healthy and Sustainable Dietary Substitutions
**Short Title:** Encouraging Healthy and Sustainable Dietary Substitutions
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| Study Title | Encouraging Healthy and Sustainable Dietary Substitutions |
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| **Funder** | National Heart, Lung, and Blood Institute |
| **Clinical Phase** | NA |
| **Study Rationale** | <ul><li>The foods people eat have major implications for both human health and environmental sustainability. Approximately 20% deaths in the US are attributed to unhealthy diet and more than 30% of all anthropogenic greenhouse gas emissions are caused by food production.</li><li>Recently, researchers have identified four simple dietary substitutions that are healthier (i.e., they would improve diet quality and thus reduce risk of diet-related disease) and more environmentally sustainable (i.e., they would reduce carbon emissions associated with food production): replacing beef or pork entrees with chicken or vegetarian entrees; replacing juice with whole fruit; replacing dairy milk with non-dairy alternatives like soy or almond milk; and replacing sugar-sweetened beverages with water.</li><li>However, it remains unknown how to encourage people to adopt these healthy and sustainable dietary substitutions. Messages about health, the environment, or both health and the environment could encourage these substitutions, but limited research has tested these messages against one another.</li><li>Emerging adults merit special attention in research on healthy and sustainable dietary substitutions because they have worse dietary quality than older adults and because their dietary behaviors track into later adulthood.</li></ul> |
| **Study Objective(s)** | Primary<ul><li>To evaluate whether health, environment, or health + environment messages elicit higher perceived message effectiveness than control messages.</li></ul>Secondary<ul><li>To evaluate whether health, environment, or health + environment messages elicit higher perceived message effectiveness than one another.</li></ul> |
| **Study Design** | Randomized experiment. |
| **Subject Population** | Inclusion Criteria<br>1. Age 18-25 |

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| **key criteria for Inclusion and Exclusion:** | 2. Reside in the United States<br>3. Able to complete a survey in English<br>Exclusion Criteria<br>    1. Under the age of 18 or over the age of 26<br>    2. Reside outside of the United States<br>    3. Unable to complete a survey in English |
| **Number of Subjects** | 1,600 |
| **Study Duration** | Each subject's participation will last approximately 10 minutes. The enrollment period is expected to last ~1-2 weeks. |
| **Study Phases** | There are two phases:<br>(1) Screening: screening for eligibility and obtaining consent and<br>(2) Intervention: study intervention/experimental treatment. |
| **Efficacy Evaluations** | The primary outcome is perceived message effectiveness for encouraging healthy and sustainable dietary substitutions. It will be measured with 4 items adapted from prior studies. |
| **Statistical and Analytic Plan** | Primary outcome<br>• We will use linear mixed models to examine the effect of each intervention topic (health, environment, or health + environment) on perceived message effectiveness compared to the control.<br><br>Secondary outcomes<br>• We will use linear mixed models to examine the effect of each intervention topic on perceived message effectiveness compared to the other intervention topics. |
| **Data and Safety Monitoring Plan** | • The principal investigator is responsible for data quality management and ongoing assessment of safety. |

## Introduction

The goal of the analyses described here is to use data we collected through an online randomized experiment to examine consumer responses to different messages about healthy and sustainable dietary substitutions. This analysis examines the effect of different message topics (control vs. health vs. environment vs. health + environment) on perceived message effectiveness for encouraging the healthy and sustainable dietary substitutions. This analysis plan pre-specifies the analyses before collecting data and therefore serves as our ex-ante planned analysis.

## Study Protocol

Participants will complete an online survey programmed in Qualtrics. After providing informed consent, participants will complete 4 experiments in random order: 1 for each of 4 target dietary substitutions (beef and pork, juice, milk, and sugary drinks). Participants will be randomized to 1 of 4 between-subjects experimental arms representing different message topics: a control arm or 1 of 3 intervention arms: health, environment, or health + environment.

Participants will be in the same experimental arm for all 4 experiments. In each of the 4 experiments, participants will view 2 messages from their assigned arm in random order and rate each message. (There will be 3 possible health, environment, and health + environment messages for each of the 4 target dietary substitutions. Participants in these experimental arms will view 2 of these 3 messages, selected at random. There are only 2 possible control messages; participants in the control arm will view these 2 control messages. In all experimental arms, the 2 messages will be shown in random order). In total, participants will rate 8 messages: 2 messages for each of the 4 experiments.

## Objective

The objective of this study is to examine the effect of message topic on perceived message effectiveness for encouraging healthy and sustainable dietary substitutions. We will compare dietary substitution messages focused on health, the environment, both health + environment, or a control topic. We hypothesize that messages about health, the environment, or both health + environment will receive higher perceived message effectiveness ratings than messages about the control topics.

<u>**Statistical Considerations**</u>

**General Principles**

      We will use a two-sided critical alpha of 0.05 to conduct all statistical tests. All confidence intervals presented will be 95% and two-sided. Analyses will include all randomized participants according to experimental conditions they were randomized to (i.e., intent-to-treat). Participants will be prompted to respond to all survey questions before they can continue, so we expect there will be minimal missing data and therefore plan to use complete case analysis.

**Overview**

      Participant characteristics will be descriptively summarized by experimental arm prior to analysis. Means and standard deviations will be used to characterize continuous variables, and frequencies and percentages will be used to describe categorical variables.

**Primary Outcome**

      The primary outcome is perceived message effectiveness (PME). We will assess PME with 4 items: 3 items adapted from Baig[1] and 1 item adapted from Jongenelis.[2] The items will be tailored to each of the 4 target dietary substitutions (beef/pork, juice, milk, and sugary drinks), as shown below:

1. *How much does this message discourage you from wanting to [eat beef and pork / drink juice / drink cow's milk / drink sugary drinks]?*
2. *How much does this message make [eating beef and pork / drinking juice / drinking cow's milk / drinking sugary drinks] seem unpleasant to you?*
3. *How much does this message make you concerned about the effects of [eating beef and pork / drinking juice / drinking cow's milk / drinking sugary drinks]?*
4. *How much does this message make you want to [eat chicken or vegetarian options instead of beef and pork, eat whole fruit instead of drinking juice / drink non-dairy milk instead of cow's milk / drink water instead of sugary drinks]?*

      Responses options for each item are presented as a Likert-type scale: Not at all (coded as 1); Very little (2); Somewhat (3); Quite a bit (4); A great deal (5). We will average responses to these 4 items to create a PME score for each message, assuming sufficient internal consistency (Cronbach's alpha≥.70).

**Statistical Analyses**

We will run separate analyses for each of the 4 experiments (i.e., for each of the 4 dietary substitutions). For each experiment, we will conduct the following analyses:

1. First, primary analyses will use mixed effects linear regression models to **examine whether the intervention *topics* receive higher PME ratings than the control *topic*.** We will regress PME on indicator variables for the experimental arms (health, environment, or health + environment, treating the control as the referent group). The coefficients on the indicator variables for the intervention topics are average differential effects (ADEs) indicating the difference in mean PME between the intervention topic messages and the control topic messages. Our hypothesis will be supported if the coefficients on the indicator variables for the intervention topics are positive and statistically significant. For these planned primary analyses, we will not correct *p*-values for multiple comparisons.

2. Second, secondary analyses will used mixed effects linear regression models to **examine whether the intervention *topics* receive different PME ratings than one another.** We will use the same model as in (1) to compare the ADEs for each intervention topic to one another using Chi-Squared tests. These analyses will correct *p*-values for multiple comparisons using the Bonferroni-Holm procedure, considering 3 tests to compare each intervention topic to the others.

3. Third, we will **descriptively rank the *messages*.** We will estimate mean PME for each message statement and rank those means. These analyses will be descriptive (i.e., we do not plan to perform hypothesis tests).

**Exclusions**

Participants will be excluded if they are younger than 18 years old or older than 25 years old, do not complete the survey, or complete the survey implausibly quickly, defined as completing in <1/3 median survey completion time in a soft launch of the survey.

**Sample Size and Power**

We used G*Power 4 to estimate sample size needs to detect an effect of the health, environment, or health + environment messages vs. the control messages using a repeated measures ANOVA examining between-subjects factors. We estimated power assuming an alpha=0.05, correlation among repeated measures of 0.5 (a conservative estimate based on prior studies[3,4]), and 2 repeated measures (reflecting that participants will rate 2 messages for their

assigned topic in each of the 4 experiments). Under these assumptions, a sample size of 400 participants per experimental arm (1,600 participants total) will yield 90% power to detect a small standardized effect of Cohen's $f=.10$ (or Cohen's $d=.20$) or larger. To our knowledge, there are not similar studies of dietary substitution messages, so we powered to detect a small standardized effect size.[5] The planned sample size will also yield 90% power to detect effects of Cohen's $f=.11$ (or $d=.22$) or larger for comparing each intervention topic vs. the other intervention topics, assuming an alpha=0.0167 (i.e., 0.05 divided by 3, to correct for multiple comparisons).

# References

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2. Jongenelis MI, Drane C, Hasking P, et al. Development and validation of the Alcohol Message Perceived Effectiveness Scale. *Sci Rep*. 2023;13(1):997. doi:10.1038/s41598-023-28141-x

3. Grummon AH, Ruggles PR, Greenfield TK, Hall MG. Designing effective alcohol warnings: Consumer reactions to icons and health topics. *Am J Prev Med*. Published online 2022. doi:https://doi.org/10.1016/j.amepre.2022.09.006

4. Grummon AH, Hall M, Taillie L, Brewer N. How should sugar-sweetened beverage health warnings be designed? A randomized experiment. *Prev Med*. 2019;121:158-166.

5. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Academic press; 2013.