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STUDY PROTOCOL

Impact of Behavioral Economic Strategies on Low-Income Older Adults' Food Choices in Online Retail Settings

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Study Personnel

Principal Investigator

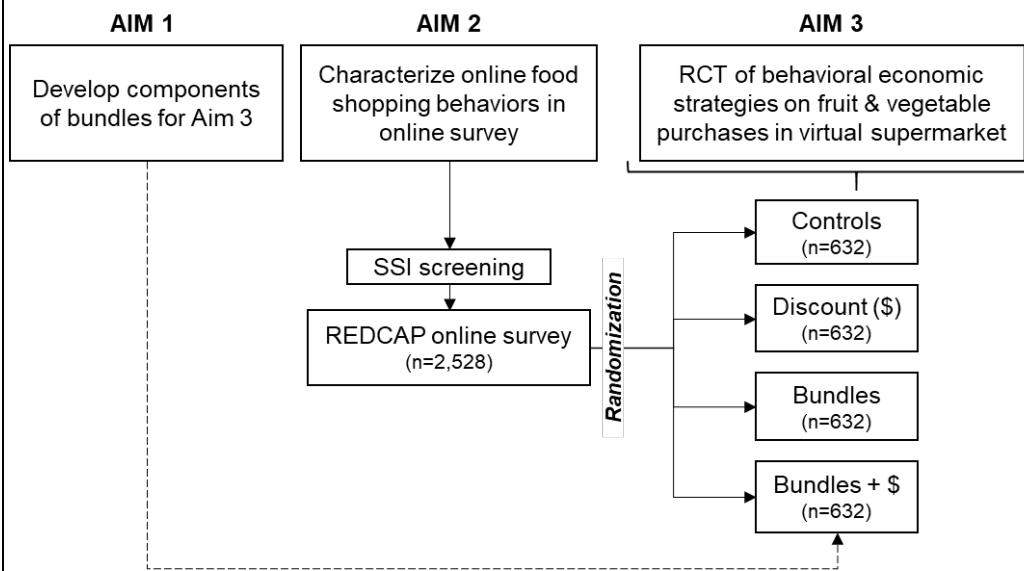
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Synopsis

Study Description

The specific aims of this proposal are to 1) develop the components of a behavioral economics strategy (i.e., healthy bundle defaults) to influence diet behaviors; 2) characterize the online grocery shopping behaviors and attitudes of low-income adults nationally; and 3) examine the extent to which "healthy bundles defaults" and other behavioral economic strategies increase fruit and vegetable purchases among low-income adults in an online randomized controlled experiment.

The figure below shows the flow of our aims. To accomplish Aim 1, we will develop the components for the bundles in our online experiment, using publically-available data from the National Household Food Acquisition and Purchase Survey (FoodAPS). To accomplish Aim 2, we will use an online survey that we have already developed (and uploaded to Research Navigator). The survey will be administered to 2,692 participants, whom we will recruit through CloudResearch. After completing the online survey, the same participants will be randomized into one of four conditions and then participate in our experimental study (Aim 3) by clicking a link and simulating a shopping task in a web-based supermarket platform developed by Cauldron Science Ltd.



Overall, the research study will occur over 5 years (see timeline below). The development of the bundles and the web-based supermarket will occur in Year 1; data collection will occur in Years 2-4; data analysis will occur in Year 4; and Year 5 will involve development of manuscripts and dissemination activities. There will be no interaction with participants in Years 1 and 5.

Project timeline	Year 1		Year 2		Year 3		Year 4		Year 5	
Task Description	Q1/2	Q3/4								
Design of bundles & website	X	X								
Data collection			X		X		X			
Data analysis							X	X		
Manuscript/dissemination		X		X		X			X	X

Objectives

Our primary objectives are to capture behaviors and attitudes related to online grocery shopping among low-income American adults; and examine the extent to which different behavioral economic strategies influence fruit and vegetable purchases of low-income adults in a web-based supermarket. Our secondary objective is to examine whether the impact of our different behavioral economic strategies differs by age group, gender, and race/ethnicity.

Endpoints

The endpoints for the online survey will be 1) whether participants report shopping for groceries online, and 2) whether participants report consuming at least 5 daily servings of fruits and vegetables. Among those who shop online for groceries, we will estimate the frequency of online grocery shopping, types of groceries purchased online, types of online retailers, and methods of delivery; and amount (\$ and %) spent on online grocery shopping relative to the amount spent on in-store grocery shopping per week. We will also calculate the frequency (%) of reasons that participants choose as motivating or preventing them from purchasing groceries online (e.g., price, quality).

The endpoint for the intervention is the proportion of real dollars spent on total fruit and vegetables per basket (i.e., shopping cart items) across conditions.

Study Population

The study population is a sample of low-income adults aged >18 years who have ever received SNAP benefits, read and speak English, live with fewer than 5 people, and have access to a personal computer, laptop, tablet, or mobile phone. Low-income adults are the target subject population because disparities in healthy food purchases and dietary intake are linked to the growing prevalence of obesity among low-income adults. In addition, low-income consumers participating in SNAP are able to use their SNAP benefits in online transactions with participating retailers in select geographies.

Accrual Ceiling

We require 158 participants in each of the four arms (total n=632) to adequately power our analysis. This sample size provides power to detect a 9% difference between any experimental condition and controls. To allow examination of potential interaction effects

by demographic characteristics, we plan a total sample size of 2,692 participants (the rule of thumb that four times the sample size is needed to assess interactions compared to main effects requires us to enroll at least 2,528 participants). The number of persons found to be ineligible during screening is unknown.

Phase

Not applicable.

Description of Sites/Facilities Enrolling Participants

We propose to recruit our sample through CloudResearch, an online research company that recruits volunteer research participants from dozens of online panel providers. This means that people navigated to the panel website, created an account, and verified their desire to participate in studies by confirming their email address. Participants who join a panel have the option to unsubscribe at any time. When a study starts in the field, CloudResearch uses an assignment process to match participants with surveys they are likely to be eligible for and complete, with proprietary quality control procedures to ensure participants do not take the same survey twice. To reduce selection bias associated with the topic of the survey, invitations do not include specific details of the survey. Participants who complete CloudResearch's online surveys receive points that can be redeemed for various incentives, including cash, lotteries, or donations to charity. We have approval from NYU Medical Center Information Technology (MCIT) to use CloudResearch for recruitment.

We will use Qualtrics to create and distribute the survey.

We will also use Cauldron Science Ltd., which provides subscribers with access to their web-based tool "Gorilla". "Gorilla" allows researchers to plan, design, and carry out online psychology experiments for research purposes, including a supermarket platform. The platform is already built and we have a license to use it for our experiment, with approval from the NIH, approval from NYU Medical Center Information Technology (MCIT), and a fully executed contract via the NYU legal office.

Description of Study Intervention

The people participating in the study will complete an online survey about what factors motivate or prevent them from shopping for groceries online. After completing the survey, all participants will participate in an online randomized controlled experiment. At the end of the survey, participants will be directed to click the link to our web-based supermarket and to emulate a typical online grocery shopping experience. Participants will be asked to simulate one grocery shopping trip in a web-based supermarket and to select a typical week's worth of food for their household, including fruits and vegetables. Participants will be randomized to one of four conditions. To mimic existing double-dollar incentive

programs, participants randomized to receive discounts will receive half-off qualifying fruits and vegetables. The discount will be applied directly to participants' online shopping cart items at point of selection. Participants randomized to healthy bundle defaults with no discount will be offered a bundle of food and beverage items pre-loaded in their online shopping cart (i.e., a healthy default). This bundle will be determined by participants' answers to two questions in the online survey asking which fruits and beverages they purchase most often. Participants randomized to healthy bundle defaults plus a discount will receive a half-off discount on an identical tailored bundle. Participants will be allowed to remove the bundle from their shopping cart. Prior to shopping, participants will be given instructions regarding the discount and/or bundles.

Study Duration

The study will last 5 years, but data collection will specifically occur in 3 time periods, including quarters 1 and 2 of years 2, 3, and 4 of the study.

Participant Duration

The online survey will take approximately 10-15 minutes to complete and the simulated grocery shopping trip will take an additional 10-15 minutes, so the study will take a total of 20-30 minutes to complete. Participants randomized to receive discounts will receive half-off qualifying fruits and vegetables. Participants may participate in the study at any time of day.

Schema

Schedule of Activities (SoA)

The people participating in the study will complete an online survey about what factors motivate or prevent them from shopping for groceries online. After completing the survey, all participants will participate in an online randomized controlled experiment. At the end of the survey, participants will be directed to click the link to our web-based supermarket and to emulate a typical online grocery shopping experience. Participants will be asked to simulate one grocery shopping trip in a web-based supermarket and to select a typical week's worth of food for their household, including fruits and vegetables.

To incentivize participation and truthful responses, we will also notify participants prior to the experiment that they are automatically entered into a lottery to have the items in their shopping cart delivered to their household if they complete both the survey and shopping trip task. Every one in ten participants will be selected randomly and CloudResearch will distribute gift cards to winners. The PI will randomly select lottery winners using participant ID's, which are not linked to personally identifiable information at any point in the study. CloudResearch will also debrief lottery winners about the purpose of the task, including

the justification for providing lottery winners gift cards with money loaded on to it equivalent to the amount of money that they spent in the study (rather than having the groceries delivered). The participants who do not win the lottery will also be debriefed.

The online survey will take approximately 10-15 minutes to complete and the simulated grocery shopping trip will take an additional 10-15 minutes, so the study will take a total of 20-30 minutes to complete.

End of Study Definition

The end of study is when we have collected data from 2,692 participants who have completed our online survey on Qualtrics and completed our online grocery shopping task on the “Gorilla” web-based supermarket platform.

1 – Statement of Compliance

1.1 Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the study participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

2 - Introduction

2.1 Study Rationale

The successful completion of the proposed research may highlight which issues related to online shopping could be addressed by changes to federal and local nutrition assistance programs; and for whom these changes would have the greatest impact.

2.2 Background

Dietary behaviors play a critical role in shaping multiple cardiovascular risk factors, including obesity, weight gain, and blood glucose levels. (1) Diets rich in energy, added sugars, and saturated fat, and low in whole grains, nuts, fruits, and vegetables, are positively associated with risk of excess adiposity, higher BMI, and increased risk of poor cardiovascular health. (2) (3) (4) In conjunction with decreased consumption of energy-dense foods, increased fruit and vegetable consumption has been shown to prevent obesity and weight gain. (5) However, low-income adults consume fewer fruits and vegetables and have poorer diet quality scores than higher income adults. (6) (7)

Previous research has shown that food affordability and access to fast food restaurants and supermarkets are linked to obesity, high blood pressure, diabetes, and metabolic syndrome, (8) (9) likely via poor dietary behaviors and excess energy intake. (1) In particular, disparities in food affordability and healthy food access contributes to inadequate intake of healthy foods among low-income adults. (10) Low-income adults often live on fixed budgets and spend a greater proportion of their income on food than those in higher-income households. (11) Further, access to supermarkets and healthy food is lower — and availability of energy-dense foods and fast food restaurants is higher — in low-income neighborhoods. (12) Therefore, interventions to increase the affordability and accessibility of healthy foods may help improve diet behaviors in low-income adults.

To address disparities in the cost of healthy foods and increase the purchasing power of low-income adults, the United States Department of Agriculture (USDA) also offers financial assistance through food assistance programs, such as the Supplemental Nutrition Assistance Program (SNAP) program. In 2016, SNAP served a monthly average of about 44.2 million people in 21.8 low-income households. (13) Recent studies have found that SNAP participation is associated with a decrease in food insecurity as well as reduced health care spending among low-income adults. (14) (15) However, household participation in SNAP is associated with lower HDL cholesterol, elevated fasting glucose, and metabolic syndrome. (16) Research also suggests that adult SNAP participants purchase fewer vegetables, fruits, and whole grains than lower income nonparticipants; (17) and purchase

more total calories, sodium, and sugars. (18) Therefore, it is critical to evaluate potential policy proposals that promote healthy diet behaviors in SNAP households.

In select geographies, low-income consumers participating in SNAP are able to use their SNAP benefits in online transactions with participating retailers. (19) According to the Pew Research Center, internet use has increased by 74% and 89% in the past decade among U.S. adults, with higher overall use among younger age groups. (20) Though absolute levels of internet use are lower for low-income consumers relative to higher income consumers, internet use increased by 27% between 2008 (54%) and 2018 (81%) among those with an annual income below \$30,000. (20) Though most adults in the U.S. still visit a brick-and-mortar store to buy groceries at least once a week, (21) online grocery shopping is rapidly expanding in popularity. For example, a recent survey indicated that approximately 20% of consumers who are responsible for grocery shopping for their household shopped online for groceries "at least occasionally" in 2018. (22) However, little is known about online grocery shopping behaviors and attitudes of low-income adults nationally.

The growth in online grocery shopping offers a promising opportunity to tailor healthy eating interventions to online food retail environments. Unlike most brick-and-mortar food stores, online groceries can be ordered at any time of the day and can be delivered to consumers' homes. Home delivery is a key benefit to low-income adults living in areas with limited access to healthy foods (i.e., food deserts). Online grocery shopping also has the potential to address other barriers to healthy eating, including few opportunities to plan and susceptibility to in-store marketing cues, which may lead to impulse purchases. (23) (24) (25) Relative to brick-and-mortar stores, it is easier to modify the design of online environments to influence consumer decision-making (e.g., default shopping cart items). On the other hand, online grocery shopping has many potential drawbacks. Exposure to unhealthy foods and beverages may be higher due to online retailers targeting products to consumers using personal information or previous purchase data. In addition, some grocery retailers may not deliver to low-income neighborhoods, and low-income consumers may not have regular internet access. This study will make a significant contribution by being the first to characterize online food shopping behaviors in a national sample of low-income adults.

Interventions informed by behavioral economics can promote healthier food choices by nudging consumers in subtle, low-cost ways that honor individual preferences. (26) According to Thaler and Sunstein, nudges are "any aspect of the choice architecture that alters behavior in a predictable way without forbidding any options or significantly changing their economic incentives". Nudges leverage behavioral heuristics and biases based on the psychology of decision-making to change shopping environments. For example, people are highly susceptible to the status quo bias, (27) or the preference for inaction and for things to stay the same. One way to leverage this bias to promote health is to change default options in the environment so that people are defaulted into healthy choices, but can opt out of them if they desire. Default options have been shown to increase participation in organ donation in opt-out countries, (28) and increase orders of healthy foods in restaurants with healthy

default side items on menus (e.g., salad instead of fries). (29) Providing subsidies for qualifying healthy food purchases is also a popular and effective strategy for promoting healthy food purchases. (30) (31) Though an economic strategy, subsidies may help to mitigate "present biased preferences," or consumers' tendency to ignore future health effects by focusing on immediate rewards, (27) and cues in the environment that elicit temptation (e.g., promotions). A recent review of food pricing interventions found that subsidies improve dietary behaviors foods, especially multicomponent interventions (e.g., subsidies combined with education). (30) With the option to use SNAP benefits online, there are a host of opportunities to create unique behavioral nudges to increase healthy food consumption. (32) Recently, a laboratory-based study found that displaying discounted 'bundles' in a brick-and-mortar grocery store led to a 15% increase in fruit and vegetable purchases. (33) However, no research has focused on bundling healthy food items in online food environments, or studying the effect of adding default food items to a shopping cart.

To date, only a few studies have tested interventions aimed at encouraging consumers to purchase healthier food items in online supermarkets and results are mixed. Previous research has found that front-of-pack nutrition labels, product placement, and product promotions increased diet quality and promoted healthier food choices in online supermarkets, (34) (35) (36) (37) whereas healthy swaps (i.e., offering healthy alternatives) did not appear to affect purchases. (38) Similarly, previous work has found that subsidies on healthy foods improved the nutrient quality of foods purchased in an online supermarket, (39) though they may result in higher calories purchased overall. (35) (38) Both discounts and bundling may be effective strategies to promote healthy food choices among individuals with a fixed budget, especially in online settings where individuals are able to preorder and deliver groceries to their home. To our knowledge, no research has evaluated interventions designed to promote healthier online food purchases among low-income adults.

2.3 Risk/Benefit Assessment

2.3.1 Known Potential Risks

There is low risk of a breach of confidentiality. Participants may be frustrated when completing survey and when we debrief them about the lottery and how CloudResearch is emailing them a gift card instead of delivering their shopping cart items to their residential address. As described above, the lottery is used to incentivize participation and truthful responses and this approach will mitigate potential issues related to delivery and avoid complications associated with changing grocery stock items. It is important that the participant thinks they are actually getting the groceries because it will encourage participants to provide truthful answers; whereas, knowledge of getting a gift card might result in participants making choices that do not reflect their actual preferences. We also anticipate that participants would prefer money they can spend on anything, rather than being restricted to grocery items.

2.3.2 Known Potential Benefits

There are no direct benefits to subjects.

2.3.3 Assessment of Potential Risks and Benefits

We will not collect personally identifiable information, so the potential risks are minimal. Thus, we assess that the benefits outweigh the risks.

3 - Objectives and Endpoints

3.1 Objectives and Endpoints

Our primary objectives are to capture behaviors and attitudes related to online grocery shopping among low-income American adults; and examine the extent to which different behavioral economic strategies influence fruit and vegetable purchases of low-income adults in a web-based supermarket. Our secondary objective is to examine whether the impact of our different behavioral economic strategies differs by age group, gender, and race/ethnicity.

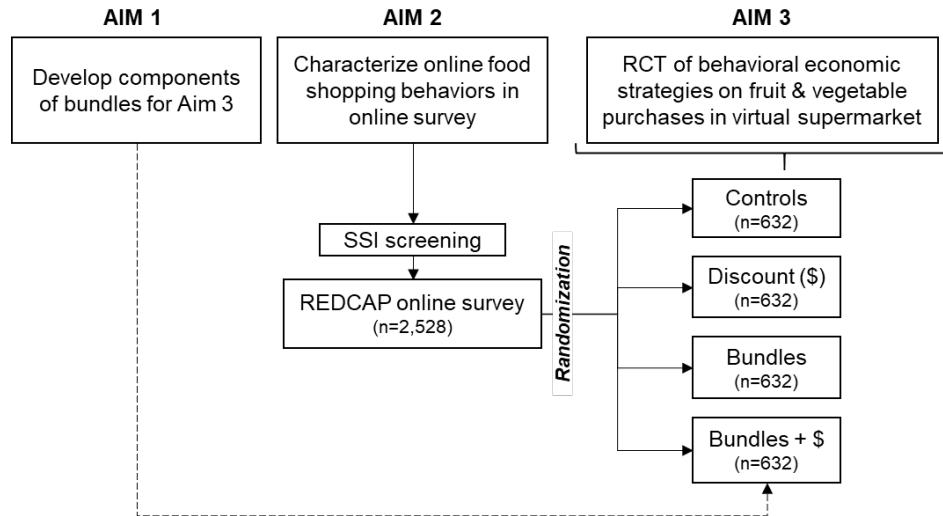
The endpoints for the online survey will be 1) whether participants report shopping for groceries online, and 2) whether participants report consuming at least 5 daily servings of fruits and vegetables. Among those who shop online for groceries, we will estimate the frequency of online grocery shopping, types of groceries purchased online, types of online retailers, and methods of delivery; and amount (\$ and %) spent on online grocery shopping relative to the amount spent on in-store grocery shopping per week. We will also calculate the frequency (%) of reasons that participants choose as motivating or preventing them from purchasing groceries online (e.g., price, quality).

The endpoint for the intervention is the proportion of real dollars spent on total fruit and vegetables per basket (i.e., shopping cart items) across conditions.

4 - Study Design

4.1 Overall Design

This research study includes three aims (see figure below), though only Aim 2 and Aim 3 involve human subjects. The duration of the study is 5 years.



In Aim 1, we will develop the components of healthy bundle defaults (i.e., preloaded cart items) using publically available data from the National Household Food Acquisition and Purchase Survey (FoodAPS), the literature, and expert advice. Specifically, we will measure the frequency of food and beverage purchases in FoodAPS, to enable us to determine the most frequent healthy food purchases by category (e.g., fruits, vegetables) among low-income households by household size, gender, and race/ethnicity. These healthy bundle defaults will be used in Aim 3, specifically the arms with healthy bundle defaults. The development of the bundles will occur in Year 1. Aim 1 does not involve human subjects research.

In Aim 2, we will recruit 2,692 low-income adults aged >18 years from a nationwide nonprobability panel via CloudResearch and administer an online survey to characterize participants' online grocery shopping behaviors and attitudes. After completing the online survey, we will randomize all participants from Aim 2 to one of four conditions, including 1) no intervention, 2) discount on eligible fruits and vegetables, 3) healthy bundle defaults with no discount, and 4) healthy bundle defaults plus a discount.

In Aim 3, participants will click a link and simulate a shopping experience by selecting a week's worth of SNAP-eligible groceries for their household in a web-based supermarket platform. We will also use Cauldron Science Ltd., which provides subscribers with access to their web-based tool "Gorilla". "Gorilla" allows researchers to plan, design, and carry out online psychology experiments for research purposes, including a supermarket platform. The platform is already built and we have a license to use it for our experiment, with approval

from the NIH, approval from NYU Medical Center Information Technology (MCIT), and a fully executed contract via the NYU legal office.

We will examine the impact of our behavioral economic strategies on the proportion of real dollars spent on total fruits and vegetables per online shopping basket. We will also explore whether the impact of our intervention on food purchases differs by sociodemographics. Data collection for Aims 2-3 will occur in Years 2-4.

4.2 Scientific Rationale for Study Design

The study design proposed will achieve robust and unbiased results because a randomized controlled experiment is a gold standard approach. To mimic existing double-dollar incentive programs, participants randomized to receive discounts will receive half-off qualifying fruits and vegetables.

4.3 End of Study Definition

The end of study is when we have collected data from 2,692 participants who have completed our online survey on Qualtrics and completed our online grocery shopping task on the “Gorilla” web-based supermarket platform.

5 - Study Population

5.1 Inclusion Criteria

The inclusion criteria include: 1) aged 18-99 years; 2) ability to read and speak English; 3) have ever received SNAP benefits, 4) live with fewer than 5 people; and 5) access to a personal computer, laptop, tablet, or mobile phone.

5.2 Exclusion Criteria

The exclusion criteria include: 1) aged <18 years or >99 years; 2) lack the ability to read and speak English; 3) have never received SNAP benefits, 4) live with 5 or more people; and/or 5) do not have access to a personal computer, laptop, tablet, or mobile phone.

5.3 Lifestyle Considerations

There will be no restrictions during any parts of the study pertaining to lifestyle and/or diet.

5.4 Screen Failures

Screen failures include those who do not meet all of our inclusion criteria. Potential participants will answer four pre-screening questions to determine their eligibility. The pre-screening questions include those related to 1) age; 2) the ability to read and speak English; 3) receipt of SNAP benefits (ever), and 4) the number of household members (we do not explicitly ask about access to a personal computer, laptop, tablet, or mobile phone, since they are using Qualtrics to access our survey, which requires access to such devices). If they do not meet our inclusion criteria, these subjects will see the text "Thank you for your time, but unfortunately, you are not eligible for this study."

Re-screening is not applicable.

5.5 Strategies for Recruitment and Retention

We propose to recruit our sample through CloudResearch, an online research company that recruits volunteer research participants from dozens of online providers. This means that people navigated to the panel website, created an account, and verified their desire to participate in studies by confirming their email address. CloudResearch uses an assignment process to match participants with surveys they are likely to be eligible for and complete, with proprietary quality control procedures to ensure participants do not take the same survey twice. To reduce selection bias associated with the topic of the survey, invitations do not include specific details of the survey. Participants who complete CloudResearch's online surveys receive points that can be redeemed for various incentives, including cash, lotteries, or donations to charity. We have approval from NYU Medical Center Information Technology

(MCIT) to use CloudResearch for recruitment. The online survey is already developed (and uploaded to Research Navigator).

To incentivize participation and truthful responses, we will also notify participants prior to the experiment that they are automatically entered into a lottery to have the items in their shopping cart delivered to their household if they complete both the survey and the shopping trip task.

6 - Study Procedures

The people participating in the study will complete an online survey about what factors motivate or prevent them from shopping for groceries online. After completing the survey, all participants will participate in an online randomized controlled experiment. At the end of the survey, participants will be directed to click the link to our web-based supermarket.

Participants will be asked to select a typical week's worth of food for their household and assume they need to buy the most important things, including the fruits and vegetables they typically buy. Participants will be randomized to one of four conditions. To mimic existing double-dollar incentive programs, participants randomized to receive discounts will receive half-off qualifying fruits and vegetables. The discount will be applied directly to participants' online shopping cart items at point of selection. Participants randomized to healthy bundle defaults with no discount will be offered a bundle of food and beverage items pre-loaded in their online shopping cart (i.e., a healthy default). This bundle will be determined by participants' answers to two questions in the online survey asking which fruits and beverages they purchase most often. Participants randomized to healthy bundle defaults plus a discount will receive a half-off discount on an identical tailored bundle. Participants will be allowed to remove the bundle from their shopping cart. Prior to shopping, participants will be given instructions regarding the discount and/or bundles.

We will recruit a nationwide non probability panel of 2,692 low-income adults >18 years through CloudResearch, an online surveying company that recruits volunteer research participants through their online panels and other online communities. Participants who complete CloudResearch's online surveys receive points that can be redeemed for various incentives, including cash, lotteries, or donations to charity. Potential participants will click the link for our online study and complete an online consent. After providing consent, potential participants will complete four pre-screening questions to determine their eligibility. The pre-screening questions include those related to 1) age; 2) the ability to read and speak English; 3) receipt of SNAP benefits (ever), and 4) the number of household members (we do not explicitly ask about access to a personal computer, laptop, tablet, or mobile phone, since they are using Qualtrics to access our survey, which requires access to such devices). All questions in the survey, including the pre-screening questions, will be completed on a personal computer, laptop, tablet, or mobile phone and will take approximately 10-15

minutes to complete. We will use Qualtrics to create and distribute the survey. At the end of the survey, participants will be asked to simulate one grocery shopping trip in a web-based supermarket and to select a typical week's worth of food for their household, including fruits and vegetables, which will take an additional 10-15 minutes.

We will assess hypothetical purchases, so no payment will be taken and participants will be informed that they will not normally receive the shopping cart items. To incentivize participation and truthful responses, however, participants will be notified prior to the experiment that they are automatically entered into a lottery to have the items in their shopping cart delivered to their household if they complete both the survey and the shopping trip task. Our budget allows us to offer delivery of shopping cart items to one in ten participants. At the end of the study, CloudResearch will reveal to participants who win the lottery that they will be provided with a gift card with the equivalent amount of money loaded onto it that they spent in the study (rather than having the groceries delivered). This approach will mitigate potential issues related to delivery and avoid complications associated with changing grocery stock items. We also anticipate that participants would prefer money they can spend on anything, rather than being restricted to grocery items. CloudResearch will also debrief participants about the purpose of the study, including the justification for providing lottery winners a gift card instead of groceries. The participants who do not win the lottery will also be debriefed.

After completing the online survey, we will randomize all participants from Aim 2 to one of four conditions, including 1) no intervention, 2) discount on eligible fruits and vegetables, 3) healthy bundle defaults with no discount, and 4) healthy bundle defaults plus a discount. All participants will answer the same set of questions in the online survey on Qualtrics. After clicking the link to access the web-based supermarket platform on the "Gorilla" platform, participants will be randomized to one of the four experimental conditions outlined in Aim 3. The "Gorilla" platform has a randomization function built into its design. No blinding will be done.

Adherence to the protocol will be assessed by completion of the online survey data and the "checking out" of our online grocery store with a minimum of two items in the cart (no payment will be taken).

7 - Study Intervention Discontinuation and Participant Discontinuation/Withdrawal

7.1 Discontinuation of Study Intervention

Study modification will occur in the event of an unexpected problem or any necessary change to the protocol. Study team members put in charge of IRB communications will work with the Principal Investigator to prepare, submit, and address comments on modifications.

This study may be discontinued in the event that participants find the gift card instead of delivering grocery items from their shopping cart is too upsetting, although we do not think this is likely since participants would likely prefer money they can spend on anything rather than being restricted to grocery items.

7.2 Participant Discontinuation/Withdrawal from the Study

The participants are allowed to withdraw from the online survey and online grocery shopping experience at any point, with no penalty.

7.3 Lost to Follow-Up

Not applicable.

9 - Statistical Considerations

9.1 Statistical Hypotheses

We will test the working hypothesis that the likelihood of shopping online for groceries is higher among adults who are male, White, and younger; and that adults who shop online will have higher adjusted odds of consuming at least 5 daily servings of fruits and vegetables than those who do not shop online. We also hypothesize that participants exposed to healthy bundle defaults plus a discount will spend more on fruits and vegetables than controls; and that the effect size will be larger relative to arms with only discounts or only bundles.

9.2 Sample Size Considerations

Based on previous work (40), we require 158 participants in each of the four arms (total n=632) to adequately power our analysis. This sample size provides power to detect a 9% difference between any experimental condition and controls. To allow examination of potential interaction effects by demographic characteristics, we plan a total sample size of 2,692 participants (the rule of thumb that four times the sample size is needed to assess interactions compared to main effects requires us to enroll at least 2,528 participants).

9.3 Populations for Analyses

The study population is a sample of low-income adults aged >18 years who have ever received SNAP benefits, read and speak English, live with fewer than 5 people, and have access to a personal computer, laptop, tablet, or mobile phone. Low-income adults are the target subject population because disparities in healthy food purchases and dietary intake are linked to the growing prevalence of obesity among low-income adults. In addition, low-income consumers participating in SNAP are able to use their SNAP benefits in online transactions with participating retailers in select geographies (19).

9.4 Statistical Analyses

For Aim 1, we will measure the frequency of food and beverage purchases in FoodAPS, to enable us to determine the most frequent healthy food purchases by category (e.g., fruits, vegetables) among low-income households by household size, gender, and race/ethnicity.

For Aim 2, we will report our results using averages and standard deviations, or median and interquartile range. In exploratory analyses, we will use logistic regression to compare differences between groups, adjusting for relevant covariates. To determine whether the distribution of demographics is equivalent between our groups of comparison, we will use independent samples T-tests and Chi-square tests. We will do the same for comparing the distribution of demographics and grocery shopping behaviors between our sample and the

FoodAPS sample. We will use a two-sided alpha of 0.05 as the threshold for statistical significance.

For Aim 3, we will perform a linear regression to assess balance of demographic characteristics across the four study conditions; because of randomization, these characteristics should be balanced. To assess differences in the proportion of real dollars spent on total fruits and vegetables across experimental conditions, we will regress the outcome variable on indicator variables for the experimental conditions, with the control condition as the reference group; if necessary, we will also adjust for any respondent characteristics that may be unbalanced by condition. We will test for potential interaction effects by age group, gender, and race/ethnicity. We will also conduct a sensitivity analysis excluding participants who report that they would never consider shopping online for groceries. The design and methods proposed will achieve robust and unbiased results because a randomized controlled experiment is a gold standard approach.

9.4.1 General Approach

For Aim 1, we will measure the frequency of food and beverage purchases in FoodAPS, to enable us to determine the most frequent healthy food purchases by category (e.g., fruits, vegetables) among low-income households by household size, gender, and race/ethnicity.

For Aim 2, we will report our results using averages and standard deviations, or median and interquartile range. In exploratory analyses, we will use logistic regression to compare differences between groups, adjusting for relevant covariates. To determine whether the distribution of demographics is equivalent between our groups of comparison, we will use independent samples T-tests and Chi-square tests. We will do the same for comparing the distribution of demographics and grocery shopping behaviors between our sample and the FoodAPS sample. We will use a two-sided alpha of 0.05 as the threshold for statistical significance.

For Aim 3, we will perform a linear regression to assess balance of demographic characteristics across the four study conditions; because of randomization, these characteristics should be balanced. To assess differences in the proportion of real dollars spent on total fruits and vegetables across experimental conditions, we will regress the outcome variable on indicator variables for the experimental conditions, with the control condition as the reference group; if necessary, we will also adjust for any respondent characteristics that may be unbalanced by condition. We will test for potential interaction effects by age group, gender, and race/ethnicity. We will also conduct a sensitivity analysis excluding participants who report that they would never consider shopping online for groceries. The design and methods proposed will achieve robust and unbiased results because a randomized controlled experiment is a gold standard approach.

9.4.2 Analysis of the Primary Efficacy Endpoint(s)

The primary outcome for Aim 1 is the healthy food item per category (fruits and vegetables) purchased most often per subgroup by household size (1-4 persons), gender (female, male), and race/ethnicity (Black, Hispanic/Latino, White). We will measure the frequency of food and beverage purchases in FoodAPS, to enable us to determine the most frequent healthy food purchases by category (e.g., fruits, vegetables) among low-income households by household size, gender, and race/ethnicity.

The primary outcomes for Aim 2 will be 1) whether participants report shopping for groceries online, and 2) whether participants report consuming at least 5 daily servings of fruits and vegetables. Among those who shop online for groceries, we will estimate the frequency of online grocery shopping, types of groceries purchased online, types of online retailers, and methods of delivery; and amount (\$ and %) spent on online grocery shopping relative to the amount spent on in-store grocery shopping per week. We will also calculate the frequency (%) of reasons that participants choose as motivating or preventing them from purchasing groceries online (e.g., price, quality). We will report our results using averages and standard deviations, or median and interquartile range. In exploratory analyses, we will use logistic regression to compare differences between groups, adjusting for relevant covariates. To determine whether the distribution of demographics is equivalent between our groups of comparison, we will use independent samples T-tests and Chi-square tests. We will do the same for comparing the distribution of demographics and grocery shopping behaviors between our sample and the FoodAPS sample. We will use a two-sided alpha of 0.05 as the threshold for statistical significance.

The primary outcome for Aim 3 is the proportion of real dollars spent on total fruit and vegetables per basket (i.e., shopping cart items) across conditions. We will perform a linear regression to assess balance of demographic characteristics across the four study conditions; because of randomization, these characteristics should be balanced. To assess differences in the proportion of real dollars spent on total fruits and vegetables across experimental conditions, we will regress the outcome variable on indicator variables for the experimental conditions, with the control condition as the reference group; if necessary, we will also adjust for any respondent characteristics that may be unbalanced by condition. The design and methods proposed will achieve robust and unbiased results because a randomized controlled experiment is a gold standard approach.

9.4.3 Analysis of the Secondary Endpoint(s)

We will test for potential interaction effects by age group, gender, and race/ethnicity. We will also conduct a sensitivity analysis excluding participants who report that they would never consider shopping online for groceries.

9.4.4 Safety Analyses

Not applicable.

9.4.5 Baseline Descriptive Analyses (if applicable)

Not applicable.

9.4.6 Planned Interim Analyses (if applicable)

Not applicable.

9.4.7 Tabulation of Individual Participant Data

Individual participant data will not be listed by measure and time point. Only aggregated data will be presented.

9.4.8 Exploratory Analyses

We will explore whether online shopping behaviors differ by sociodemographic factors and diet in Aim 2.

10 – Ethical Considerations

10.1 Regulatory, Ethical, and Study Oversight Considerations

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46. The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

10.1.1.1 Consent/Accent and Other Informational Documents Provided to Participants

The consent based on the IRB template has been uploaded to the CONSENT FORMS section of submission in Research Navigator.

10.1.1.2 Consent Procedures and Documentation

Potential participants consent to participate in CloudResearch studies when they first respond to a CloudResearch advertisement. Potential participants also provide consent at the start of each survey using a computer-based consent form. Participants will be asked to read a consent form on the first page of the online survey, and click "yes" to consent and begin the survey or "no" to end the survey. Before obtaining consent, we will inform potential participants of the potential risks, which are minimal because we are not collecting personally identifiable information. To mitigate the risk of coercion, participants will receive compensation whether or not they complete the survey questions, and will be informed of this at the beginning of the survey.

10.1.2 Study Discontinuation and Closure

The study will be terminated or temporarily suspended based on PI decision, IRB decision in the event of an Unanticipated Problem. If an unanticipated problem is recognized, data collection will stop and any corrective action or explanation that can be given to participants experiencing this issue will be administered. Then, a modification to rectify the issue will be submitted to the IRB (and details sent to the sponsor if applicable) and new methods to avoid the problem will be used going forward. The study team will work with the IRB to ensure that any problems participants experienced prior to the change are ethically addressed. The consent process also includes text that informs the participants they can call or email the Principal Investigator with any questions. We will also inform participants that any questions, concerns, suggestions, or complaints that have not been or cannot be

addressed by the researcher, or if they wish to report research-related harm, they can contact the IRB.

10.1.3 Data Confidentiality and Participant Policy

We are not collecting personally identifiable information at any point, including participants' names and home addresses. CloudResearch will send the debriefing document to all people who participate in the online grocery shopping task about the purpose of the task, including the justification for providing lottery winners a gift card.

The "Gorilla" web-based supermarket platform is fully compliant with data protection and security policies. All traffic to and from the "Gorilla" platform is encrypted and the database is encrypted using industry-standard cryptography. The PI will also own the research data that has been collected using the "Gorilla" platform, and he will be able to delete all data for an experiment or data pertaining to an individual participant.

10.1.4 Future Use of Stored Data

Study data will be retained for the longer of 3 years after close out or 5 years after final reporting/publication. We are not storing data beyond the current studies for future research and publications. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

10.1.5 Study Oversight

The research team will only ever have access to unique ID numbers for all participants, which will allow for linkage between participants' responses in Qualtrics and participants' selections from the "Gorilla" web-based supermarket platform.

10.1.6 Key Roles and Study Governance

The Principal Investigator is Pasquale Rummo, PhD, MPH, NYU School of Medicine, 180 Madison Ave, Room 3-54, 646-501-3371, pasquale.rummo@nyulangone.org. The PI also has a Mentoring Committee. A K01 award from the NIH is a training grant, which requires training and mentorship from a team of mentors and co-mentors. My mentors and co-mentors include Brian Elbel, PhD, MPH; Joshua Chodosh, MD, MSHS; Christina Roberto, PhD; Lorna Thorpe, PhD, MPH; and Andrea Troxel, ScD. My mentors and co-mentors are not a part of the study team and will not interact with data at any point.

10.1.8 Quality Assurance and Quality Control

We will do a soft launch of both the online survey and the web-based supermarket shopping experience, to ensure quality of collected data. To prevent subjects from entering multiple survey responses, the Qualtrics survey will prevent multiple submissions. The research team will also monitor the data collected from participants from the online survey, including identifying short duration time. CloudResearch will identify repeat IP addresses.

10.1.9 Data Handling and Record Keeping

10.1.9.1 Data Collection and Management Responsibilities

Data will be collected from a national sample of 2,692 low-income adults aged >18 years who read and speak English and have ever received SNAP benefits. We will collect online survey responses using Qualtrics, and grocery shopping selections using the “Gorilla” web-based supermarket platform. Participants will be able to access our online survey and the web-based supermarket platform via personal computer, laptop, tablet, or mobile phone.

10.1.9.2 Study Records Retention

Study documents will be retained for the longer of 3 years after close out or 5 years after final reporting/publication. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

10.1.10 Protocol Deviations

If a protocol deviation occurs, data collection will stop and any corrective action or explanation that can be given to participants experiencing this issue will be administered. Then, a modification to rectify the issue will be submitted to the IRB (and details sent to the sponsor if applicable) and new methods to avoid the problem will be used going forward. The study team will work with the IRB to ensure that any problems participants experienced prior to the change are ethically addressed.

10.1.11 Publication and Data Sharing Policy

The Principal Investigator, Pasquale Rummo, holds primary responsibility for publishing the study results. The plan is to generate at least 5 manuscripts with work from this award by June 2025.

10.1.12 Conflict of Interest Policy

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the NYU Langone Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULH investigators will follow the applicable conflict of interest policies.

10.2 Additional Considerations

The Research Assistant will go through a variety of training to ensure understanding of the study protocol and their responsibilities. First, the Principal Investigator will set up an individual training session with the Research Assistant to discuss in detail the study aims, recruitment methods, confidentiality, and study procedures. Secondly, the study team member will shadow the Principal Investigator while they do a test run of the online survey and the grocery shopping task and data collection procedures. Thirdly, the Research Assistant will do a test run of the online survey and the grocery shopping task and data collection procedures with the Principal Investigator shadowing them.

11 – Study Finances

11.1 Funding Source

NIH/NIA

11.2 Costs to Subjects

There are no costs to subjects for being in this study.

11.3 Subject Payment

Every one in ten participants will be selected randomly and CloudResearch will distribute gift cards to winners with money loaded on to it equivalent to the amount of money they spent in the study. The PI will randomly select lottery winners using participant ID's, which are not linked to personally identifiable information at any point in the study.

We will adhere to NYULH Human Subjects Payment Policy.

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