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STUDY PROTOCOL

Impact of Online Ordering on Low-Income Adults' Food Security in Online Food Pantry Settings

NYULH Study Number

s22-01523

Principal Investigator

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Protocol Version

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Synopsis

Study Description

The specific aims of this proposal are to 1) ascertain whether the transition to online ordering at a choice-based food pantry network in New York City influences food security status among 386 food pantry clients and 2) determine whether there are differences in outcome by age group (18-61 vs. ≥62 years).

To accomplish Aim 1, study team members will conduct a natural experiment with two conditions in food pantry sites within the Met Council Kosher Food Pantry Network. To accomplish Aim 2, we will test for potential interaction effects at the individual-level by adding an interaction term for age group.

Overall, the research study will occur over 18 months (see timeline below). Year 1 will involve survey design and data collection. Year 2 will involve data analysis and development of dissemination materials.

Table 1. Timeline																		
	Year 1 of grant												Year 2 of grant					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Design of survey, training RA, and IRB approval	X	X	X															
Data collection				X	X	X	pause	**Online ordering transition**	pause	X	X	X						
Data analysis													X	X	X	X		
Write and disseminate results																	X	X

Objectives

Our primary objectives are to determine whether the transition to online ordering at a choice-based food pantry network influences food security status among low-income adults and determining whether there are differences in impact by age group.
Endpoints The endpoint for Aim 1 for the intervention arm is the successful completion of the follow-up period, including food and nutrition security status, total fruits and vegetables selected per visit, total energy intake, intake of key food groups, and time to obtain food from food pantry per visit. The endpoint for Aim 2 is the completion of data analysis.
Study Population The study population for Aim 1 is a sample of low-income adults aged ≥18 years..
Accrual Ceiling We require a total sample size of 193 participants per condition for Aim 1 (total n=386). Aim 2 will not involve participant enrollment.
Phase Not applicable.
Description of Sites/Facilities Enrolling Participants We propose to recruit participants from food pantry clients at food pantry sites within the Met Council Kosher Food Pantry Network, a network that contains 65 pantry partners and over 200 community partners in NYC. Met Council procures and distributes kosher food to their network of kosher food pantries and provides ongoing support with reporting, pantry set up and maintenance, advocacy, and programming. The Network primarily serves immigrants, seniors living on fixed incomes, the un- and underemployed and anyone else in need in immigrant-dense neighborhoods.
Study Duration The study will last 18 months, but data collection will specifically occur in 2 time periods, including months 4-6 and 10-12 in Year 1 of the study.
Participant Duration The total participant duration will be approximately 30-50 minutes to complete the survey and record food selections for both data collection periods.

Schedule of Activities (SoA)

During the baseline data collection period, all participants will complete a survey about their food and nutrition security, diet behaviors, and frequency of food pantry visits. To finish, the Research Assistant will record their food selections from the current food pantry visit.

During the follow-up data collection period, all participants will complete a survey about their food and nutrition security, diet behaviors, and frequency of food pantry visits. Participants in the control arm will record their food selections from their most recent food pantry visit and send them to the study team.

End of Study Definition

The end of the study is when we have disseminated our results.

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 Background

Compared to food secure adults, adults experiencing food insecurity have lower energy intake, lower intake of key nutrients, and poorer diet quality.[1-5] Food insecurity is also associated with poor or fair health, underweight status, and chronic health issues, such as diabetes and hypertension.[2-12] Malnutrition among low-income adults who use food pantries is also linked to a lack of housing, barriers to accessing health care and other social resources, unemployment, substance abuse, and domestic conflict.[13]

In NYC, 1.5 million residents are food insecure, a 36% increase from before the COVID-19 pandemic.[14] Evidence from survey research suggests that food insecurity and hunger are also higher among immigrants (vs. non-immigrants) and older (vs. younger) adults in NYC, potentially due to higher rates of income inadequacy and fixed incomes, respectively.[15-17] These disparities are likely to grow in the future given how population growth in NYC is driven by older adults, and how population growth of older adults is driven by growth in immigrant older adults.[18]

In the Parent Grant, we established how nutrition assistance programs, such as meal delivery programs and the Supplemental Nutrition Assistance Program (SNAP), address key barriers to healthy eating in low-income adults. Food pantries are also a key source of nutrition and healthy foods for low-income adults, especially for low-income older adults, who use food pantries as their primary source of food assistance.[19,20] In NYC, approximately 1.4 million residents rely on food pantries for emergency food assistance each year, including one out of every five older adults.[17] Previous studies show that visiting a food pantry mitigates food insecurity among food pantry clients,[21-23] and may improve diet quality among food insecure clients.[24,25] The use of food pantries may also mitigate chronic disease risk among food pantry clients, including diabetes and heart disease.[21,26]

However, mistrust of emergency food resources may be disproportionately higher in immigrant (vs. non-immigrant) communities,[27] potentially due to stigma, fear of interaction with government representatives (e.g. NYPD, ICE), and other factors.[28] Evidence from qualitative research, for example, suggests that the stigma of waiting in public to be served reduces utilization and satisfaction of food pantries.[29] This was corroborated by a recent review study noting how food pantry clients describe reasonable wait times and an “easy process” as a cornerstones of good customer service in food pantry settings.[30] Thus, strategies to increase food pantry use may support food security and healthy eating behaviors among low-income adults, especially those designed to mitigating the high opportunity costs of waiting in line and stigma, such as digital ordering.

In the Parent Grant, we are leveraging the rapid growth in online grocery shopping and expansion of retailers accepting SNAP benefits in online transactions. The recent shift to online ordering in some food pantries affords a similar opportunity to support food security and a healthy diet among low-income adults, which we aim to leverage in this Administrative Supplement. Online ordering is available in a small number of food pantries across the U.S., such as the Portland Open Bible Community Pantry in Portland, OR and The Open Door in Essex County, MA, largely due to increases in food insecurity and social distancing measures during the COVID-19 pandemic.[31,32] Anecdotal evidence suggests online ordering has contributed to increased food pantry use, potentially due to reductions in wait times, reduced stigmatization, and increases in self-efficacy and self-sufficiency.[33-37] Increases in food pantry, in

turn, may improve food pantry clients' food security status and increase fruit and vegetable intake relative to a traditional distribution model,[38,39] especially in combination with changes to food "pricing" (e.g., assigning foods with high nutritional value fewer points than less healthy food). To our knowledge, however, there have been no evaluations of the transition to online ordering in food pantries.

2.2 Study Rationale

The successful completion of the proposed research may highlight and support the development of a novel approach to improving food security and healthy food choices in a high-need population.

2.3 Potential Risks and Benefits

2.3.1 Known Potential Risks

There is a risk of breach of confidentiality. To reduce the likelihood of a breach of confidentiality, we will store the survey responses on Qualtrics, which is password protected and encrypted. We will collect names, phone numbers, email addresses, and mailing addresses in a secure REDCap form to facilitate data collection in the follow-up period, which will be conducted virtually, and to distribute gift cards. The REDCap data will not be linked to Qualtrics survey responses. The content of the participants' responses to survey questions will pertain only to their food and nutrition security status, intake of key foods, and frequency of food pantry visits. We will not be asking for information that could place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing or employability.

Participants may receive texting over mobile/cell phones and this method of communication may also result in a breach of their confidential information because text messages to mobile/cell phones are not encrypted. This method of communication will only be used with participants' agreement/consent.

Participants may become frustrated when completing the survey It will be made clear to participants that they are free to skip any questions they do not wish to answer or stop at any time.

2.3.2 Known Potential Benefits

There are no direct benefits to subjects. This study will provide evidence to be used in evaluating the effect of food pantries' transitioning to online ordering on clients' food selection. Met Council and other food pantries will be able to reference this information when deciding whether to transition their pantries to online ordering.

3 - Objectives and Endpoints

3.1 Primary Objective

Our primary objectives are to determine whether the transition to online ordering at a choice-based food pantry network influences food security status among low-income adults and determining whether there are differences in impact by age group.

3.2 Endpoints

The endpoint for Aim 1, the intervention, is the successful completion of the follow-up period data collection, including food and nutrition security status, total fruits and vegetables selected per visit, diet behaviors, and time to obtain food from food pantry per visit.
The endpoint for Aim 2 is the completion of data analysis.

4 - Study Design

4.1 Overall Design

This research study includes two aims, though only Aim 1 involves human subjects. The duration of the study is 18 months.

In Aim 1, study team members will recruit low-income adults aged ≥18 years. Participants will be recruited from a food pantry that is not scheduled to transition to online ordering (control) and a food pantry that is scheduled to transition to online ordering after the baseline data collection period (intervention). Participants in both arms will complete an in-person survey. Potential participants who are not able to take the survey in-person, will be offered the option to take the survey online. To assess potential changes in fruit and vegetable intake, we will administer the Behavioral Risk Factor Surveillance System (BRFSS) 6-item brief dietary assessment tool (questions 9-14 in the survey attached in Research Navigator). A Research Assistant will record the food items they received in the relevant visit to the pantry. After the transition to online ordering at the intervention food pantry, participants will again complete the survey over the phone. The survey will be administered by a member of the study team using the Follow-Up Survey Guide. Participants in the control arm will record their food selections and send them to the study team during the phone call. Food selections for participants in the intervention arm will be accessible through the online ordering platform. The study team will then analyze the baseline and follow-up data for differences in outcomes between study conditions.

In Aim 2, we will test for potential interaction effects at the individual-level by adding an interaction term for age group (18-61 vs. ≥62 years).

4.2 Scientific Rationale for Study Design

The design and methods proposed will achieve robust and unbiased results because random assignment to an intervention group or control group in the context of a natural experiment minimizes bias.

4.3 End of Study Definition

The end of the study is when we have disseminated our results.

5 - Study Population

5.1 Inclusion Criteria

In order to be eligible for participation in **Aim 1 Control Arm** of this study, an individual must meet all of the following criteria:

1) aged 18 years or older
2) have capacity and willingness to provide consent

In order to be eligible for participation in **Aim 1 Intervention Arm** of this study, an individual must meet all of the following criteria:

1) aged 18 years or older
2) have capacity and willingness to provide consent

5.2 Exclusion Criteria

The exclusion criteria for both arms of Aim 1 include: 1) aged <18 years..

5.3 Vulnerable Populations

Adults who have used the food pantry are the target subject population because strategies to increase food pantry use may support food security and healthy eating behaviors among low-income adults, especially those designed to mitigate the high opportunity costs of waiting in line and stigma, such as digital ordering.

5.4 Lifestyle Considerations

Participants in the intervention arm will have to transition with their food pantry to online ordering after the baseline data collection period regardless of their participation in this research study. The change will be brought on “naturally” by the food pantry (not the NYULH researchers or specifically as part of this research study). There will be no other restrictions during any other parts of the study pertaining to lifestyle and/or diet.

5.5 Strategies for Recruitment and Retention

For Aim 1, we will choose the food pantry recruiting sites with help from Met Council Kosher Food Pantry Network. We will aim to select a control site that is similar to the intervention site based on food pantry characteristics (e.g., number of food pantry clients per week, primary language(s) spoken) and community-level characteristics (e.g., neighborhood poverty level).

IRB-approved NYULH study personnel will recruit participants in person at two Met Council food pantries and will obtain permission from the food pantries prior to in-person recruitment at their

facilities. We will have support from food pantry staff members in introducing the NYULH study to potential participants. The study personnel will be on-site at the food pantry to introduce the study to food pantry clients and answer questions. Food pantry staff will also be available to direct food pantry clients to the study personnel. The study team will provide the food pantry with a recruitment flyer to post and/or pass out informing clients of the study and directing them to scan a QR code for the consent form with more information about the study and access to the study team's contact information. After scanning the QR code, clients will first see a short paragraph ("Pre-Consent QR Code Copy") listing the eligibility requirements and explaining what the consent is, in addition to a note that they do not need to sign the form at that moment. After the short paragraph, they will be able to scroll down to view the consent.

We will collect names, phone numbers, email addresses, and mailing addresses from participants in a secure REDCap form to facilitate the follow-up data collection, which will be conducted virtually, and to distribute gift cards.

Screen failures include those who do not meet all of our inclusion criteria. Potential participants will be asked to answer one pre-screening question about their age to determine their eligibility. If they do not meet our inclusion criteria, these participants will be told by the Research Assistant, "Thank you for your time, but unfortunately, you are not eligible for this study." We will immediately discard information from screen failures and from individuals that do not provide consent to take part in this study. Re-screening is not applicable.

Prior to the follow-up period, the study team will provide the food pantry with a flyer and post-card-sized handouts to remind participants of the upcoming follow-up surveys.

Aim 2 will not involve any participant recruitment.

6 - Study Procedures

6.1 Aim 1

Data collection in the baseline period will occur during the two to four month period prior to the intervention month (months t-2 to t-4), and data collection in the follow-up period will occur during the two-to-four-month period after the transition to digital ordering (months t+2 to t+4). The months immediately preceding (t-1) and following (t+1) the intervention month will be omitted to account for potential uncertainty in the implementation of online ordering and to allow for sufficient time for food pantry clients to return to their food pantry, respectively.

For the baseline period/visit (in person), consent will take place in person at the food pantry and data collection will take place in person at the food pantry, with the option to take the survey online offered on a case-by-case basis. The following will occur for both arms:

- Participants will be asked to complete a survey about their food and nutrition security, diet behaviors, and frequency of food pantry visits. The survey will take about 10 minutes to complete. Survey responses will be collected using Qualtrics.

- We will administer the Behavioral Risk Factor Surveillance System (BRFSS) 6-item brief dietary assessment tool to participants in both arms to assess potential changes in fruit and vegetable intake (questions 9-14 in the survey attached in Research Navigator).

- Participants will be given a card with an appointment time of their choosing that falls within the follow-up period, which will also include the phone number for an IRB-approved NYULH study personnel that they can reach if they need to re-schedule.

- The food pantry items selected by participants will be documented in-person by the Research Assistant. It will take approximately 5 minutes for the Research Assistant to record the participants' food selections.

For the follow-up period/visit (virtual/phone):

- **Intervention Arm**

    - We will send follow-up reminders to participants via email and/or text, based on their preference.

    - Participants will be asked to complete a survey by phone about their food and nutrition security, diet behaviors, and frequency of food pantry visits. The survey will take approximately 20-25 minutes to complete. The survey will be administered by a member of the study team using the Follow-Up Survey Guide.

    - Data on participants' food selections will be gathered from the online ordering system. This data will be provided to the study team by Met Council. Participants will not need to wait for the Research Assistant to record their selections.

- **Control Arm**
    - We will send follow-up reminders to participants via email and/or text, based on their preference.
    - Participants will be asked to complete a survey by phone about their food and nutrition security, diet behaviors, and frequency of food pantry visits. The survey will take approximately 20-25 minutes to complete. The survey will be administered by a member of the study team using the Follow-Up Survey Guide.
    - Since the follow-up data collection occurs virtually and the study team will not be on site at the food pantry to record food selections, we will instruct participants to take a photo of their selections at their next food pantry visit and email or text the photo to the research team, using the information on the appointment card. It will take approximately 5 minutes for participants to record their food selections and send them to the study team. If participants do not remember to take the photo, we will assess their recall of their selections during the follow-up conversation.

6.2 Aim 2

We will test for potential interaction effects at the individual-level by adding an interaction term for age group (18-61 vs. ≥62 years). We will use the data collected for Aim 1 to complete these analyses. No additional data will be collected for Aim 2.

7 - Participant Discontinuation/Withdrawal

7.1 Participant Discontinuation/Withdrawal from the Study

The participants are allowed to withdraw from the study at any point with no penalty.

7.2 Lost to Follow-Up

Not applicable.

8 - Statistical Considerations

8.1 Statistical Hypotheses

In Aim 1, we will test the working hypotheses that 1) food security will improve (i.e. food security score will decrease) among participants visiting a food pantry that transition to online ordering in the follow-up period, but not among those in the control arm, and 2) participants visiting a food pantry that transitions to online ordering will also select more fruits and vegetables per visit, have higher fruit and vegetable intake, and spend less time accessing food pantries in the follow-up (vs. baseline) period compared to those in the control arm.

For Aim 2, we hypothesize that improvements in food security due to online ordering will be larger for younger adults.

8.2 Sample Size Considerations

To calculate our sample size, we used estimates from a similar study that found that a food bank-delivered intervention (diabetes-appropriate food packages, text-based health education, and referrals to health care) resulted in a decrease in the mean food security score from 2.8 to 2.3, or a 6.3% decrease in the percentage of participants with low or very low food security status.[40] Based on this study, we assume the standard deviation of the food security score is 1.5 and estimate that 155 participants in each condition (total n=310) will provide 90% power to detect a 0.5 difference in food security score between experimental and control conditions. To account for a potential attrition rate of 20% in the follow-up period, we plan to recruit a total sample size of 193 participants per condition (total n=386).

8.3 Populations for Analyses

The study population is a sample of adults aged ≥18 years.

8.4 Statistical Analyses

We will perform a linear regression to assess balance of demographic characteristics between conditions; because of the natural experiment design, these characteristics should be balanced. To assess differences in outcomes between study 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 random assignment to an intervention group or control group in the context of a natural experiment minimizes bias.

We will also test for potential interaction effects at the individual-level by adding an interaction term for age group (18-61 vs. ≥62 years). In the food pantry network, an average of 25% of clients served are above 61 years of age, so we will have adequate variation to assess potential interactions by age group. For assessing differences in the frequency of food pantry visits per month at the food pantry-level, we will also add an interaction term for age group, which the

food pantry network measures as child (<18 years), adult (18-61 years), and older adult (≥62 years).

8.4.1 General Approach

For Aim 1, we will examine differences in outcomes between study conditions, including food and nutrition security, intake of key foods, and frequency of food pantry visits.

For Aim 2, we will examine differences in outcomes between adult (18-61 years) and older adult (≥62 years) participants.

8.4.2 Analysis of the Primary Efficacy Endpoint(s)

The primary outcome for Aim 1 is food security status. We will use the United States Department of Agriculture (USDA) six-item food security survey module to assess food security status, where the range of points is zero to six points, and higher points corresponds to lower food security.[41] Food security status will be categorized according to USDA guidelines, including very low (5-6); low (2–4); and high or marginal (0-1) food security. We will perform a linear regression to assess balance of demographic characteristics between conditions; because of the natural experiment design, these characteristics should be balanced. To assess differences in outcomes between study 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 primary outcome for Aim 2 is the same as Aim 1 and measured using the same specifications. We will test for potential interaction effects at the individual-level by adding an interaction term for age group (18-61 vs. ≥62 years). In the food pantry network, an average of 25% of clients served are above 61 years of age, so we will have adequate variation to assess potential interactions by age group.

8.4.3 Analysis of the Secondary Endpoint(s)

The secondary outcomes for Aim 1 include changes in: 1) total cup-equivalents of fruits and vegetables selected per visit; 2) intake of fruits and vegetables; 3) time to obtain food from food pantry per visit (minutes); and 4) individual-level frequency of food pantry visits per month (n). To capture a potential increase in *new* clients visiting the food pantry due to the transition to online ordering, we will also measure changes in the frequency of food pantry visits per month at the food pantry-level (n).

The primary outcome for Aim 2 is the same as Aim 1 and measured using the same specifications, including number of fruits and vegetables selected per visit; total energy intake; intake of key food groups; time to obtain food from food pantry per visit; and individual-level and food pantry-level frequency of food pantry visits per month. For assessing differences in the frequency of food pantry visits per month at the food pantry-level, we will add an interaction term for age group, which the food pantry network measures as child (<18 years), adult (18-61 years), and older adult (≥62 years).

8.4.4 Safety Analyses

Not applicable.

8.4.5 Baseline Descriptive Analyses

Not applicable.

8.4.6 Planned Interim Analyses

Not applicable.

8.4.7 Tabulation of Individual Participant Data

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

8.4.8 Exploratory Analyses

For Aim 1, we will examine differences in outcomes between study conditions, including food and nutrition security, intake of fruits and vegetables, and frequency of food pantry visits. We will perform a linear regression to assess balance of demographic characteristics between conditions; because of the natural experiment design, these characteristics should be balanced. To assess differences in outcomes between study 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 random assignment to an intervention group or control group in the context of a natural experiment minimizes bias.

For Aim 2, we will examine differences in outcomes between adult (18-61 years) and older adult (≥62 years) participants. We will test for potential interaction effects at the individual-level by adding an interaction term for age group (18-61 vs. ≥62 years). In the food pantry network, an average of 25% of clients served are above 61 years of age, so we will have adequate variation to assess potential interactions by age group. For assessing differences in the frequency of food pantry visits per month at the food pantry-level, we will also add an interaction term for age group, which the food pantry network measures as child (<18 years), adult (18-61 years), and older adult (≥62 years).

9 – Ethical Considerations

9.1 Regulatory, Ethical, and Study Oversight Considerations

The Principal 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, study information sheet (with key information), application for waiver of documentation of consent, recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent materials 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.

9.2 Informed Consent Process

9.2.1 Consent and Other Informational Documents Provided to Participants

Consent materials describing in detail the study, study procedures, and risks will be given to the participant and documentation of informed consent is required prior to starting study.

9.2.2 Consent Procedures and Documentation

Aim 1: IRB-approved NYULH study personnel will obtain verbal informed consent from participants in a private space at the food pantry. Extensive discussion of risks and possible benefits of participation will be provided to potential participants. Potential participants will be given an IRB-approved study information sheet (with key information) and asked to review the document. The NYULH study personnel will explain the research study to potential participants and answer any questions that may arise. All participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Potential participants will have the opportunity to carefully review the consent document and ask questions prior to consenting. Potential participants will also have the opportunity to discuss the study with their family or friends or think about it prior to agreeing to participate. Participants will give their verbal consent prior to any study procedures being done specifically for the study. Participants may withdraw consent at any time throughout the course of the study. The rights and welfare of the participants will be protected by emphasizing to them their use and access to the food pantry will not be adversely affected if they decline to participate in this study.

The consent process, including the name of the individual obtaining consent, will be thoroughly documented in the subject's research record. Any alteration to the standard consent process

(e.g. use of a translator, consent from a legally authorized representative, consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

Aim 2: NA

9.3 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 document 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.

9.4 Participant and Data Confidentiality

Participant confidentiality will be strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

We will only collect names, phone numbers, email addresses, and mailing addresses from participants in a secure REDCap form during the baseline data collection period to facilitate follow-up data collection, which will be conducted virtually, and to distribute gift cards. Only the study team will have access to the data. PII will not be connected to Qualtrics survey responses. Extreme care will be taken to guarantee confidentiality of participants' responses.

To further protect the privacy of study participants, a Certificate of Confidentiality will be obtained from the NIH. This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

9.5 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 be storing data beyond the current research study 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.

9.6 Study Oversight

The research team will only ever have access to unique ID numbers for all participants, which will allow for linkage between participants' survey responses, dietary assessment responses, and food selection data.

9.7 Key Roles and Study Governance

The Principal Investigator is Pasquale Rummo, PhD, MPH, NYU Grossman School of Medicine, Department of Population Health, 180 Madison Ave, Room 3-54, 646-501-3371, pasquale.rummo@nyulangone.org. The Research Coordinator is Carla Seet, MPH, NYU Grossman School of Medicine, Department of Population Health, 180 Madison Ave, carla.seet@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. The mentors and co-mentors include Brian Elbel, PhD, MPH; Joshua Chodosh, MD, MSHS; Christina Roberto, PhD; Lorna Thorpe, PhD, MPH; and Andrea Troxel, ScD. The mentors and co-mentors are not a part of the study team and will not be engaged in human subjects research activities at any point including accessing research data.

9.8 Quality Assurance and Quality Control

Prior to enrolling participants, we will test the survey tool and the dietary assessment methods. The research team will also monitor the data collected from participants from the survey.

9..9 Data Handling and Record Keeping

9..9.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the study staff at the site under the supervision of the PI. The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

9.9.2 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.

9.10 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.

9.11 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 one manuscript with work from this award and to submit at least one abstracts to conferences for oral or poster presentations.

9.12 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 – Study Finances

10.1 Funding Source

NIH/NIA.

10.2 Costs to Subjects

The NYULH study team may communicate with participants by text during the follow-up data collection period if participants agree to communication by text. Participants will be responsible for all fees charged by their carrier's service plan for text messaging. This research study and NYU Langone Health will not cover the cost related to any increased charges, data usage against plan limits or changes to data fees from the research texts.

10.3 Subject Payment

Aim 1: Participants will receive $30 for the baseline data collection period and $50 for the follow-up data collection period. Participants will receive a total of $80 if they complete both time periods. Incentives will be provided in gift card format and will be distributed in person after the baseline data collection and by email or mailing address, depending on the participant's preference, after the follow-up data collection.

We will adhere to NYULH Human Subjects Payment Policy.

Aim 2: NA

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