NCT03421106

A Multilevel Intervention in the Hunger Relief Network to Improve Diet Among Adults Experiencing Food Insecurity (SuperShelf)

Date: November 10, 2020

Instructions for Completing the IRB-1 Study Protocol Form

IRB-1 Study Protocol

Protocol Version # and/or Date: Version 2, 11/10/20

Study Protocol Title: A multicomponent intervention in the hunger relief network to improve diet among adults experiencing food insecurity

Clinical Trial/GCP Training

Is this a research study in which one or more human subjects are prospectively assigned[1] to one or more biomedical or behavioral interventions[2] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes[3] (i.e a clinical trial)? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes

Is the study fully or partially funded by the NIH? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes

Have the required key personnel completed Good Clinical Practice (GCP) Training? Indicate "yes," "no," or "N/A" in the space immediately below. (Note that IRB approval will not be given for NIH funded clinical trials until all required key personnel complete the GCP training.)

Yes

[1]The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[2]An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive/behavioral therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

[3] 3.Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention, behavioral intervention for psychiatric symptoms); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Research Plan

Purpose/Introduction: [State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s). Provide a clear and succinct summary description of the background information that led to the plan for this project. Provide references as appropriate and, when applicable, previous work in animal and/or human studies. Provide previous UConn protocol number, if applicable.]

The proposed study is an evaluation of a 1-year, group-randomized intervention in 8 intervention and 8 control food pantries (called *food shelves* in Minnesota). The study aims to improve the health of low-income adults experiencing food insecurity. The study will enroll a cohort of clients at baseline and follow them for 1 year to assess changes in overall diet quality. The intervention targets the supply of nutritious foods through food pantry sourcing changes and capacity-building. It also targets healthy food demand using behavioral economics. This 5 year study is NIH funded. NIH study aims are as follows:

Aim 1 (primary outcome): To evaluate the impact of the intervention on clients' overall diet quality. We will follow a cohort of clients for 1 year to assess change in diet quality (measured by Healthy Eating Index, or HEI). H1: Pre/post changes in HEI will show a greater positive change among intervention clients compared with controls.

Aim 2: To evaluate the impact of the intervention on the following additional client outcomes:
2a: Self-reported cardiovascular (CV) health. In the cohort described in Aim 1, CV health will be assessed by the American Heart Association's Life's Simple 7 (LS7) scores. H2a: Pre/post changes in LS7 scores will show a greater positive change among intervention clients compared with controls.
2b: Nutritional quality of food selected. We will perform pre/post client cart assessments to measure the nutritional quality of foods selected by clients at their food pantry visit, as measured by HEI scores, in a repeated cross-sectional study H2b: On average, HEI scores among clients at intervention food pantries will be higher after the intervention compared with controls.

Aim 3: To evaluate the impact of the intervention on the nutritional quality of food offered at food pantries, measured by a pre/post Food Assortment Scoring Tool (FAST). H3: Pre/post FAST scores will show a greater positive change among intervention food pantries (n = 8) compared with controls (n = 8).

Aim 4: To measure implementation of policies and practices that promote a nutrition-focused hunger relief network, as assessed by pre/post surveys and key informant interviews with hunger relief agency staff.

Exploratory aim: To evaluate the cultural appropriateness of food shelf foods and services as measured by: (1) the availability of culturally-specific food, and (2) client satisfaction assessed by pre/post surveys.

Outcomes:

Primary Endpoint/Event/Outcome: The primary outcome is change in overall diet quality scores among clients, as measured by the USDA's Healthy Eating Index (HEI). A cohort of clients will take two 24 hour recalls at each time point to measure overall dietary quality.

Secondary Endpoint(s)/Event(s)/Outcome(s): Secondary outcomes include: change in cardiovascular (CV) health as measured by the American Heart Association's Life's Simple 7 (LS7) scores collected vis participant survey; change in the nutritional quality of food selected by clients at their food shelf visit as measured by HEI; change in the nutritional quality of food offered at food pantries as measured by HEI during environmental assessments; implementation of policies and practices that promote a nutrition-focused hunger relief network, qualitatively assessed through key informant interviews; and cultural appropriateness of food shelf foods and services as measured by the availability of culturally-specific food, and client satisfaction assessed by pre/post surveys.

Significance of Research Question/Purpose:

In 2014, an estimated 14% of U.S. households experienced food insecurity (i.e., they lacked access to enough food for an active, healthy life for all household members).[1] Food insecurity disproportionately affects low-income, African-American and Hispanic households,[1] and immigrant and refugee families.[2] Those who are food insecure are more likely to demonstrate poor dietary outcomes,[3] resulting in a disproportionate burden of chronic conditions affecting low-income and minority groups.[3] Food insecurity has been linked to cardiovascular disease and its risk factors.[4–7] Food pantry clients have demonstrated poor nutritional outcomes,[8–11] and dissatisfaction with the quality of food offered.[12,13] Unlike most food assistance programs (e.g., the National School Lunch Program), there are currently no standards for the nutritional quality of food shelf food offerings.[14] The hunger relief network has both supply-side issues that constrain what is offered to clients, and demand-side issues moving healthy food through the system in a timely way.[14–17] Few interventions have been equipped to address both challenges, but small-scale efforts have shown promise. Meanwhile, local and national hunger relief agencies have suggested promising practices to promote a healthy and culturally appropriate food shelf, and to "nudge" clients towards healthier food selection,[18–20] but most of these efforts have not been systematically adopted or rigorously evaluated. Coordinated efforts are needed to address both food shelf environment and client behaviors.

Preliminary Data:

We completed a pilot study testing the effect of the intervention in two food pantries. This study examined he nutritional quality of foods available at the pantries and the foods selected by adults visiting food pantries using the HEI. The intervention (SuperShelf) was implemented in two food pantries (Sites A and B), with two other pantries (Sites C and D) serving as a control for pantry outcomes. The intervention aimed to increase the amount and variety of healthy foods (supply), as well as the appeal of healthy foods (demand) using behavioral economics strategies. Assessments included baseline and 4-month follow-up client surveys, client cart inventories, pantry inventories and environmental assessments. A fidelity score (range 0-100) was assigned to each intervention pantry to measure the degree of implementation. HEI was generated for each client cart and pantry. The study was conducted among clients visiting the two intervention pantries before (n= 71) and after (n =70) the intervention. Results demonstrated that fidelity scores differed by intervention site (Site A=82, Site B=51). At Site A, in adjusted models, client cart HEI scores increased on average by 11·8 points ($P<0·0001$), whereas there was no change at Site B. HEI pantry environment scores increased in intervention pantries (Site A=8 points, Site B=19 points) and decreased slightly in control pantries (Site C=-4 points, Site D=-3 points). Data suggest that when implemented as intended, SuperShelf has the potential to improve the nutritional quality of foods available to and selected by pantry clients. The current study will expand the evaluation to include additional outcomes, including client dietary intake.

For EACH Participant Population State the Number of Participants to be Enrolled and Screened and/or the number of participant records reviewed (including, HIPAA covered health records and FERPA covered school records), if applicable: [State the total number of participants/records to be enrolled and, if enrolling more than one participant population, describe the total enrollment for each. Tip: consider attrition and the number of participants who may fail screening. Use of a range may provide flexibility. Note that the range must be justified in the **Justification of Sample Size section below**.]

We have enrolled 504 adult clients at food pantries.All participants draw from the same population but they were enrolled in two groups with different study activities.

The original target sample size was 544, but UMN IRB approval was granted in May 22, 2018 to increase the sample size to 589 in case attrition was higher than expected. However, due to COVID-19, we completed enrollment in March 2020 with 504 participants and will not be enrolling more participants.

1. The first group (Sample A), consists of a cohort followed over one year. Recruitment of Sample A is complete. A total of 317 were enrolled; at this time, 214 have completed pre/post measures including the primary outcome, and a small number of participants continue to be followed. The remainder are lost-to follow up or did not complete primary outcomes measures. We will be adequately powered with 176 participants completing pre/post primary outcome measures.

2. The second group (Sample B), consists of a cross-sectional sample with no identifiable data collected for the study, to collect a secondary outcome measure. Recruitment of Sample B stopped early due to COVID-19. We collected data 272 clients at 16 sites at pre-assessment (17 per site) 187 clients at 11 sites at post-assessment. However, post-assessment data could not be completed at the final 5 sites after March 2020 for two reasons: 1) Food pantries in Minnesota stopped offering client choice shopping for food at the start of the COVID-19 pandemic, thus we could not assess what foods clients selected at their visit (the primary purpose of the measure), and 2) UMN's "sunrise plan" for human subjects research studies has so far not included community-based studies without a clear clinical treatment benefit for participants, due to the unpredictability of community environments. As it is unclear when these conditions necessary for data collection will change during the study period, we are proceeding with the study analysis without these data. As participants are not followed over time, there is no consideration of attrition.

Justification of Sample Size: [For qualitative and pilot studies, describe how the proposed sample size is appropriate for achieving the anticipated results. For quantitative studies, provide a power analysis that includes effect size, power and level of significance with references for how the sample size was determined. Explain the rate of attrition and possible number who fail the screening, with references as appropriate.]

Power Analysis:

Healthy Eating Index (HEI). For the outcome of change in overall diet HEI scores (the primary outcome), power is computed based on the t-test at the individual client level, but sample size is inflated for the group randomization design by a factor of 1+(m-1)*ICC where m is the average cluster size and ICC is the intracluster correlation. A SD of 14.4 is based on change in individual total diet HEI scores from the PI's pilot study of 43 food shelf clients[21] assuming that individual total diet variability is a better reflection of the variability in client selection than the variability across food

pantries. We anticipate an ICC for HEI scores of 0.05 based on the same data.[21] Under these assumptions and using a two-sided type I error rate of 5%, this study would have 80% power to detect a mean difference in 7.5 HEI points between intervention and control. With a originally planned average cluster size *m* of 11 and number of clusters *k* of 16, we require at least 176 participants with pre/post measures, or at least 272 enrolled to account for 30% attrition. We have surpassed this number for our primary outcome. This calculation also yields more than adequate power to detect the same mean difference in the HEI of food selected at the visit based on actual the standard deviation in our baseline sample (secondary outcome), for which we collected two repeated-sectional samples (with the second sample of 187 collected at post-assessment),.

Enrollment of UConn Students and/or Employees: [Will UConn students be enrolled? If so, describe if these students include those who any key research personnel teaches, or for whom any key research personnel has responsibility. Will UConn employees be enrolled? If so, describe if these employees report to any key personnel. For each group, explain why this population is *necessary* to the study. Tip: convenience is not sufficient justification.]

N/A

Enrollment of Key Personnel, Spouses or Dependents/Relatives: Will study key personnel, spouses of key personnel, or dependents/relatives of any key personnel be enrolled in the study? If so, describe and provide justification.

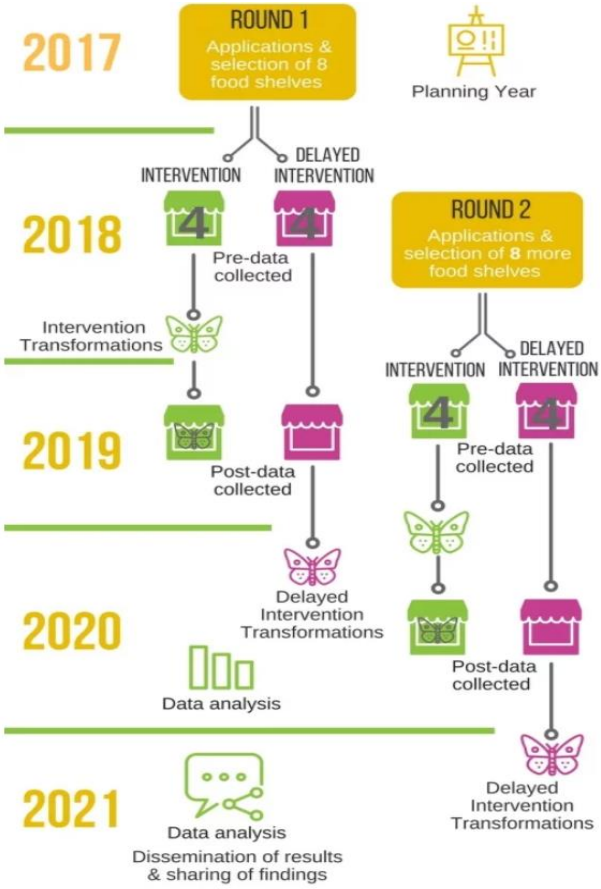
N/A

For EACH Participant Population Describe Screening Procedures, if applicable: [Describe when participants will be screened and how this will occur. Include copies of all screening forms and related documents. Describe procedures to notify participants of the screening result, if applicable. Provide a copy of the screening instrument.]

. No screening of additional participants will take place.

Anticipated Study Time Frame: [Describe the estimated time frame of the study from anticipated start to anticipated finish. If the study will occur in more than phase include these in the time frame. Use of a table is often helpful.]

The total study period is five years (April 2017 to March 2022). Participants in Sample A, which assesses the primary outcome, are followed up with after 1 year. Study participants were enrolled from Jan 2018 to March 2020. Below is a visual representation of the originally planned study and its timeline. The intervention and evaluation occur in two waves (4 intervention and 4 control food pantries in year 2, 4 intervention and 4 control food pantries in year 3).



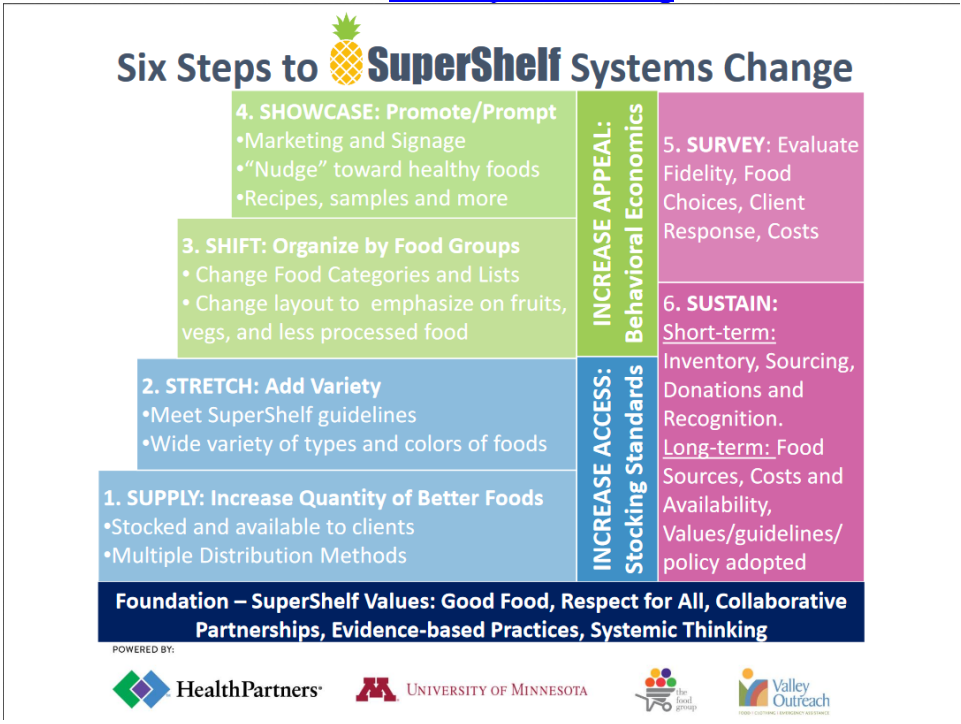
Design, Procedures, Materials and Methods: [Describe the study design, including the sequence ll study procedures. Experimental procedures should be clearly described and labeled as such. If the study uses control or experimental groups, or different treatment arms, clearly describe what participation will be like for each of the groups or study arms. Tip: describe procedures in the order conducted, where they will be conducted and how long they will take to complete. The IRB strongly suggests that investigators incorporate *flexibility* into the study design to accommodate anticipated events (i.e. explain how missed study appointments can be made up by participants). If this study offers treatment for the participants' condition, complete the Treatment Study Supplemental Form (IRB-1C) and attach it to this application for review. Use of a table is often helpful here.

Design Overview: The intervention is an environmental-level intervention at 16 food pantries. Participants are exposed to the intervention through their normal pattern of visits to the food pantry (determined by the participant). It is a group-randomized study in which 8 pantries are randomly assigned to the intervention ("transformation") and 8 are randomly assigned to the control ("delayed transformation") arm. The intervention will be implemented over one year and will occur in two waves (4 intervention and 4 control food pantries in year 2, 4 intervention and 4 control food pantries in year 3). Clients will be recruited from intervention and control food pantries, and measures will be conducted before and after the intervention. The final period of the study focuses on dissemination of our findings.

Food pantry intervention ("transformation") activities: At the food pantry level, activities support the goal of increasing the nutritional quality of foods available to clients to make the healthy choice

the easy choice. Food pantries will receive ongoing visits from trained UMN Extension educators, supervised by the study's Community Outreach Coordinator, who work with food pantry managers to increase the supply of healthy food through sourcing and the appeal and the appeal of healthy food through behavioral economics. This occurs over a period of months. Food pantries "transform into a SuperShelf" according to the 6 steps outlined below.

Pantries were selected via a request for applications to food pantries in the state of Minnesota. Food pantries will applied either via paper or online by responding to a brief list of questions to evaluated capacity to complete intervention and evaluation activities.
More information is available at www.SuperShelfmn.org



Control sites**.** Control food pantries ("delayed transformation sites") do not receive any intervention until completion of the evaluation. After evaluation measures are complete, they receive support from UMN Extension and the study Community Outreach Coordinator in transforming to be a SuperShelf.

Quality Improvement Survey: A needs assessment was conducted in 2017 in the form of a statewide survey of clients at food pantries throughout the state of Minnesota. This survey was created by community partners and resulted in an aggregated report of client preferences in Minnesota. Food pantries were asked to give an anonymous 16-question survey to a convenience sample of 25 clients, with questions about frequency food pantry use and most requested types of food. No participant identifiers were collected. In 2019 the survey was repeated at the request of community partners for the purposes of surveillance.

Data collected at the Food Pantry

Inventory. Food pantry inventory is assessed by research data collectors in a single "snapshot" measure during the client data collection period. The measures include only food available for clients to choose at their visit, and thus excludes back-stock. Inventory is conducted when the pantry was closed to clients, but stocked as it typically would be for clients. Data collectors record the item details for each product, including the item name, brand, net product weight, the exact count of the

product, and special nutritional notes on the label (e.g., reduced sodium, reduced fat). For pre-packaged items, data were obtained from package labels. Non-packaged items like produce were weighed with the container weight (e.g., bin, cart) subtracted. From the inventory, a Healthy Eating Score is created.

Food Assortment Scoring Tool (FAST). Over 5 consecutive days, pantry staff and volunteers food pantries sort and weigh the food that moved onto the shelves from storage areas into 13 categories of food. The resulting data is used to calculate a FAST score of the nutritional quality of food available to clients, to be compared with the inventory HEI score (gold standard), since FAST has not yet been validated to assess change over a long period time.

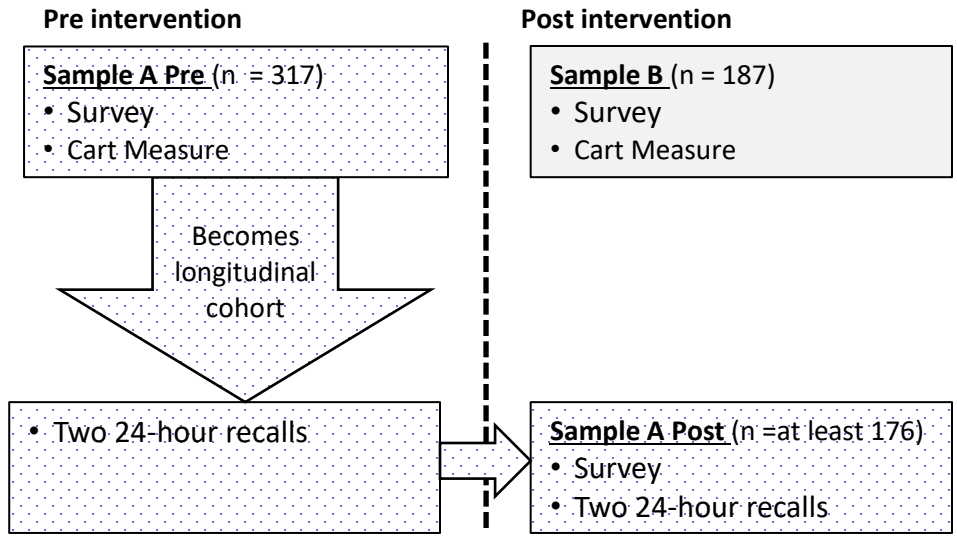
Manager survey. At the time of pre and post data collection, managers complete a survey with questions about food pantry operations and the organization, not about the manager. This includes food distribution practices, food pantry policies, staffing patterns, and food sourcing.

Note that data collection at the food pantry level may still be conducted if it can be done safely during the study period.

Previously completed participant activities

The schema for Sample A and Sample B, including the activities, is presented below.

Client Activities Schema



We recruited a group of participants (n=317) to participate as a longitudinal cohort. This is referred to as Sample A. Participants were approached at their food pantry visit at one of the 16 food pantries in the study after selecting their food. After obtaining informed consent, participants completed the study activities below. Participants earned up to $45 for completing all measures. Activities included:

1. Completing a Pre survey (similar to the Post survey described in detail below) asking about demographic information, Life's Simple 7, food pantry usage and pantry satisfaction questions

2. Completing a contact information and availability to enable us to follow up with them
3. Allowing research staff to record (by photograph) the food they had selected at their visit
4. Completing up to two 24-hour dietary recalls over the phone in approximately the subsequent month following the food pantry visit

Key informant interviews. For Wave 1 sites, we also completed 32 interviews at pre and post with food pantry managers (n=16) and volunteers (n=16) to assess food pantry intervention implementation processes, challenges, and successes.

Sample B activities**.** We could not collect client food selection data during the post-assessment in Sample A. Doing so would not be practical because researchers will not be with them during a food pantry visit; indeed, Sample A clients may not even be using the food pantry at the post-assessment time. Instead, to assess change in client food selection at the pantry, we needed a Sample B for a repeated cross-sectional design (two samples). Thus, we recruited a second set of non-cohort participants for whom no identifying data is collected and no follow-up is needed. The subjects in Sample B were be given an incentive in the form of a prepaid debit card for $15. Activities included the following:

1. Taing a shortened version of the survey that includes demographics, and food pantry usage and satisfaction
2. Allowing research staff to record (by photograph) the food they selected at their visit

Recruitment process for Sample B: Recruitment took place at the food pantry during clients' visits. After they selected their food (to avoid influencing choice), all clients over age 18 were approached by data collectors to gauge interest in the study.

Subjects were told that they are being invited to participate in a research study to evaluate the impact of food pantry changes on the food that is selected and consumed by clients. They were told all of what will be asked of them to do, including allowing us to record their selections from the food pantry for that day and taking a survey. They were told that for their participation they will receive an incentive based on their completion of the activities. Potential participants will be notified that participation is completely voluntary and confidential.

If they are interested and eligible, research staff had a consent conversation with the participant. Study staff walked through the consent document, including discussing the background information of the study, study tasks that participants will be asked to complete, risks and benefits of the study, compensation for completing study tasks, confidentiality, and the voluntary nature of the study. We obtained documented written consent.

Assessments and recruitment documents were offered in English, Spanish, and Somali by bilingual data collectors who are deployed to pantries based on the expected population of clients. Because the study recruits from all parts of Minnesota include many rural sites, many food pantries have few non-English speakers; the vast majority of participants have been English speakers.

Sample B survey procedures. The survey took approximately 15 minutes. Participants took the survey through an online REDCap form at the food shelf with the data collector available to answer questions. Participants could also choose to have the data collector administer the survey verbally, or take the survey on a paper copy if they prefer.

Client cart procedures. After clients select food from their pantry visit, and while they completed the survey, staff took photographs food selected at the visit. Pre-packaged items are photographed to capture the product name, brand, size, quantity, special nutritional notes on the label (e.g., reduced sodium, reduced fat) and, for grain items, whether the first ingredient was a whole grain. Non-packaged items like produce are photographed on a scale with its weight displayed. Following the pantry visit, photograph data are entered into a nutrient database.

Ongoing participant activities

Sample A activities. At post-assessment, we ask participants in Sample A to conduct the following activities, for which they receive up to $45 for completing all measures.

1. Take the Post survey online, over the phone, or by mail ($15)
2. Complete two 24 hour diet recalls. ($15 per recall)

Follow-up with Sample A: Participants can take the survey online via a REDCap link, over the phone with a data collector, or by mail. At follow up, participants are mailed a notification that we will be contacting them soon. Data collectors follow up by calling participants. When participants cannot be reached by phone, participants are emailed the survey by REDCap and mailed a hard copy of the survey. We also send a text reminder. Due to the transient nature of the study population, we will use a broad range of strategies to re-engage with participants at the time of follow-up. In particular, if it is determined that the phone number originally provided by the participant are not valid (e.g. incorrect number, disconnected service, etc.) we will employ the other methods for reconnecting with the participant, not exceeding 3 points of contact with these methods. Potential methods include: social media (e.g. SuperShelf's FaceBook page), WhitePages, and web-based phone/messaging services (e.g. WhatsApp, Viber) and LexisNexis. In our work with food pantry clients to date, we have found that many participants are interested in continuing to participate at follow-up, but delay completing activities due to the many competing priorities in their daily lives. For the final month of retention data collection in each Wave, participants will be given a "last chance" to participate, with an extra $10 offered for completing the follow-up survey. This was successful in increasing follow-up during Wave 1.

Sample A survey procedures: Once participants have been contacted, they complete a survey that takes approximately 20 minutes. This can be completed on the phone with data collectors, though an online link, or by mail. No participants in Sample A completed the survey in Somali; therefore, follow-up will be done using English and Spanish surveys only. Upon completion of the survey, they are contacted by the Nutrition Coordinating Center at the University of Minnesota to complete two dietary recalls.

24 hour dietary recall procedures: Once the survey is complete, clients are contacted by phone to obtain two unannounced dietary recalls though the Nutrition Coordinating Center (NCC) at the University of Minnesota (http://www.ncc.umn.edu/). Each dietary recall takes approximately 20-30 minutes to complete. The 24-hour dietary recalls are collected using Nutrition Data System for Research (NDSR), a computer-based software application developed at NCC that facilitates the collection of recalls in a standardized fashion.[22,23] Dietary intake data gathered by interview is governed by a multiple-pass interview approach. Participants are assisted by a Food Amounts Booklet that helps in estimating quantities consumed. Five distinct passes provide multiple opportunities for the participant to recall food intake. The first pass involves obtaining from the participant a listing of all foods and beverages consumed in the previous 24 hours. This listing is reviewed with the participant for completeness and correctness (second pass). The interviewer then collects detailed information about each reported food and beverage, including the amount

consumed and method of preparation (third pass). In the optional fourth pass, the interviewer then probes for commonly forgotten foods. Finally, the detailed information is reviewed for completeness and correctness (fifth pass). The complete protocol for dietary recalls is attached.

[Describe study procedures for use of interviews or focus groups if applicable. Include details such as how long each procedure will take to complete, who will be asked to participate in these procedures and where these procedures will be conducted. Provide copies of interview and focus group questions/topic areas.]

NA . No additional interviews or focus groups will take place.

[If the study includes *measures, survey instruments and questionnaires (including the collection of demographic data)*, identify each and, if available, provide references for the measures. Describe what they intend to measure (relate to purpose/hypothesis) and their psychometric properties (e.g., reliability and validity). Identify any that were specifically created for the study and attach a copy for IRB review.]

Measures

Healthy Eating Index. Data from pantry inventory, client carts, and 24-hour dietary recalls are used create three sets of Healthy Eating Index-2015 (HEI) scores. The HEI is a validated tool developed by the National Cancer Institute and the USDA in which a higher HEI score indicates better alignment with the Dietary Guidelines for Americans.[24,25] The HEI is calculated using nutrient density, so it can measure the diet quality of any amount or assortment of foods.[26]

Survey Measures. Complete surveys are found in the attached documentation. Note that in measures, food pantries are referred to using the more common term *food shelf* in Minnesota.

The Sample A post-survey assesses the following: food pantry use, frequency and duration, food pantry satisfaction with food and service, amount of food received at food pantry, household size and age composition, employment, SNAP and WIC participation, Hunger Vital Sign (food insecurity), Life's Simple 7, and global self-rated health, and cancer screening behaviors. The survey takes approximately 20 minutes to complete.

Sample B survey assesses the following: food pantry use, frequency and duration, food pantry satisfaction with food and service, amount of food received at food pantry, household size and age composition, employment, SNAP and WIC participation, Hunger Vital Sign (food insecurity), global self-rated health, and demographics (age category, race, language, and education status). It also asks two open ended questions: What else is important for us to ask about in our research? And "Help us understand your story. Why is the food shelf important to you?" The survey takes approximately 15 minutes to complete.

Most questions were created for the survey and are not scales (i.e., do not have psychometric properties). Well-establish measures include the following:
-Hunger Vital Sign: This 2-item food insecurity screener has demonstrated sensitivity of 97% and specificity of 83% for identifying food insecurity.[27]
-Global self-rated health has demonstrated strong predictive validity for a range of health outcomes. [28–30]

-Life's Simple 7: . This score represents a summary of 7 components associated with health, including total cholesterol, blood pressure, fasting glucose, physical activity, healthy diet, smoking, and body mass index, all captured through self-report. For health data that is not always known, LS7 prompts for other information – for example, if blood glucose is not known, LS7 asks whether participants have Type I or II diabetes or currently take medications to manage glucose. LS7 was developed by the American Heart Association in 2010 to set national 2020 goals for CV health promotion. Higher LS7 scores have been associated with lower lifetime occurrence of chronic diseases including diabetes. Scores are based a scale of 0-14, with each of the 7 items scored as 0 (poor), 1 (intermediate), or 2 (ideal). [31–33]

[If applicable, describe the use of audiotape and/or videotape, provide justification for use and indicate if this is a requirement of participation.]

NA

[If the study involves use of *deception* or *incomplete disclosure*, explain the reason why this is necessary to answer the research question(s). Complete the alteration of consent section below]

NA

[Describe opportunities provided to participants to ask questions in order for them to make an informed decision regarding participation.]

No additional participants will be recruited. Participants had the opportunity to ask questions about the study before being consented by study staff. Study staff walked through the consent document, including discussing the background information of the study, study tasks that participants were asked to complete, risks and benefits of the study, compensation for completing study tasks, confidentiality, the voluntary nature of the study, and study staff as well as IRB contact information. Subjects will consent for themselves.

Questions such as the following were be asked to assess the subject's understanding of participation in the study.

• What questions do you have regarding what we are asking you to do?

• What concerns about this process do you have?

Data Analysis: [For all studies, specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.]

Data Analysis Plan:

Primary outcome (HEI). To examine change in overall diet, we will use mixed-model linear regression models with fixed effects for treatment group, baseline client- and food pantry-level covariates, and a random effect for food pantry (to account for correlation within food pantries) to assess intervention effect on mean change. Change will be calculated as post-intervention score minus pre-intervention score in client-level overall diet HEI score. We will specify a correlation structure for the random effect appropriate for longitudinal data (e.g. autoregressive, Toeplitz or compound

symmetry). Pre and post-intervention component scores and change scores will be calculated for the HEI subcomponents for descriptive purposes. We will also proceed with a sensitivity analysis of the 11 sites where data was collected pre-COVID, as dietary habits may be different during COVID-19, for which we are powered to detect an effect size of 8.15 points.

Secondary and exploratory outcomes. For food selected at the visit, we will compare post intervention HEI scores between intervention and control groups, adjusted for clustering within the food pantry (random effects) and adjusted for food pantry-level baseline HEI bag check scores and relevant covariates (client and food pantry level). HEI subcomponent scores will be calculated for descriptive purposes. We will proceed with analysis of HEI bag check scores for the 11 sites in which we have complete pre/post data, for which we are powered to detect and effect size of 7.27 points. Change in CV health scores (Life's Simple 7) and satisfaction scores will be analyzed using models described above.

Inclusion/Exclusion Criteria: [List ALL inclusion and exclusion criteria. Any proposed exclusion criterion based on gender (women of childbearing potential), age, or race must include justification for the exclusion.]

Inclusion Criteria: Any adult who comes to a participating food pantry on a day in which data collection is taking place will be able to participate in the study, as long as they do not fit our exclusion criteria. This group, based on the demographic of adults who participate in food pantries' services will include groups with socioeconomic disadvantage. Only one adult per household may participate. We will enroll clients who speak English, Spanish or Somali. Participants must have access to a phone.

Exclusion Criteria:

- Under the age of 18
- Mentally incapable of providing informed consent
- Food pantry clients that do not speak English, Spanish or Somali.

[Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, study termination, etc.]

Withdrawal Circumstances: Participants will be withdrawn if it is determined that they were ineligible at the time of enrollment; for example, if two participants from the same household mistakenly enroll, the second to enroll will be withdrawn.

Withdrawal Procedures: When participants withdraw we will not continue to collect data.

Termination Procedures: NA

Potential Harms/Risks and Inconveniences: [Describe the potential risks to participants (and secondary participants, if applicable) and ***steps taken to minimize risks*** for each participant population. Assess the likelihood of the risk occurring and, if it were to occur, the seriousness to the participant. Types of risks to consider include, but are not limited to: physical, psychological, social, legal, employment, and financial.

[Describe any anticipated inconveniences the participants may experience (such as: their time, abstention from food, etc.).]

This study presents minimal risk. There is slight risk that participants may feel uncomfortable responding to some of the survey questions, including the food insecurity

questions, and questions related to food pantry usage, or questions related to their dietary intake during the 24 hour diet recall. To minimize the risk of discomfort, all questions have a "prefer not to answer" options. Staff administering dietary recalls are trained to prompt in a way that minimizes participant discomfort, for example, asking "when is the first time you ate or drank in the morning?" instead of "what did you eat for breakfast?"

Benefits: [Describe anticipated benefits to the individual participants. If test results will be provided, describe and explain procedures to help participants understand the results. If individual participants may not benefit directly, state so here. Do not include compensation or earned course credits in this section.]

There is no direct benefit to individual participants.

[Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals (i.e., athletes or autistic children).]

This study will contribute an understanding of interventions that address diet-related outcomes among food insecure populations. This is a population at a high risk of poor diet and chronic disease. Until recently, food pantries were an uncommon and overlooked setting for research. This study is one of few large-scale rigorously evaluated interventions in food pantries.

Risk/Benefit Analysis: [Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.]

The risk to individual participants is minimal, whereas the potential benefit is the identification of an evidence-based intervention to address a food insecure population. Food insecurity has been identified as growing problem, particularly in the post-pandemic (COVID-19) era, and very little research has identified effective strategies to improve the nutritional quality of food clients can receive. The research transforms the food pantries that participants are likely to visit to make them more client-centered; thus the broader study could be beneficial to participants, though this benefit would be experienced whether or not the individual completes our study measures.

Economic Considerations: [Describe any costs to the participants or amount and method of compensation provided. Describe how you arrived at the amount and the plan for compensation; if it will be prorated, please provide the breakdown. Experimental or extra course credit should be considered an economic consideration and included in this section. Indicate when participants will receive compensation.]

Payment: Incentives will be given in prepaid debit cards, ClinCards, which are a secure and safe way to administer research participant incentives. As we will be providing incentives to participants in increments based on their completion of study activities that we will not be present for (over the phone 24 hour recalls), using prepaid, reloadable debit cards makes the most sense, so participants can receive their incentive in more timely manner, and gift cards do not have to be sent in the mail.

Subjects in Sample A received the ClinCard at their first visit, and then additional incentives are added as participants complete study activities. New ClinCards can be mailed if participants misplace empty cards. Compensation levels is determined based on study activity completion. When participants are given the ClinCards, they will be walked through the features of ClinCards:

- Worldwide acceptance of card.

- Protection against fraud with MasterCard Zero Liability.
- No bank account required for recipients of cards.
- 24/7 customer service.
- Card can be used as a PIN based transaction, with signature point of sale, or for cash withdrawal at a bank or ATM.
- There will be a fee charged to the cardholder if an ATM is used to withdraw cash, if the card has no activity for three months, or if transactions are made in foreign currencies.
- Participants should track the amount on the card and tell a cashier how much is left on the card if they plan to use it for an amount over the amount left on the card
- Balance of card can be checked at myclincard.com

1. For Sample A, they may receive up to $45 for completing all post-assesment activities, after having received up to $45 during the pre-assessment. This includes the survey ($15) and up to two 24-hour dietary recalls ($15 each)
2. The compensation for Sample B is $15, also paid by ClinCard.

Data Safety Monitoring: [This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated, and communicated to the IRB in a timely manner. Although the investigators initially propose a Data Safety Monitoring Plan (DSMP), the IRB must approve the plan and may require revision of the plan. A DSMP is required for all human studies at the University of Connecticut except for studies reviewed under the Exempt Criteria. For studies that present more than minimal risk to participants, the IRB will review and determine on a case-by-case basis whether a data safety monitoring board is most appropriate. Please refer to the IRB's policy regarding data safety monitoring *before* completing this section - http://research.uconn.edu/policies-procedures.

Issues that should be addressed in the DSMP include the following:

1. Frequency of the monitoring.
2. Who will conduct the monitoring (Under UConn policy a student cannot be the sole person responsible for monitoring the data and safety of the protocol procedures?)
3. What data will be monitored (include compliance with approved IRB protocol?
4. How the data will be evaluated for problems?
5. What actions will be taken upon the occurrence of specific events or end points?
6. Who will communicate to the IRB and how will communication will occur?
7. Describe procedures to inform the sponsor.

Sample response to issues listed above for minimal risk/slight increase over minimal risk – "Survey results will be monitored by the PI in conjunction with the student investigator once every two weeks (items 1, 2 and 3). Survey responses will be reviewed to monitor for clarity (i.e., the same question is skipped by 5 or more participants). In that case, the question will be revised and an amendment will be submitted to the IRB (items 4, 5 and 6)."

A copy of our DSMP is included in this application. Because the intervention and evaluation activities are low risk, the data safety monitoring plan for this trial focuses on close monitoring of recruitment, retention, and safety by the principal investigator (PI) in conjunction with a Safety Officer. A Safety Officer was considered to be appropriate for this study (rather than a full Data Safety and Monitoring Board) as the study was not high-risk and did not involve a highly vulnerable patient population. The Safety Officer will fulfill many of the roles of a DSMP. Participant safety problems identified by the PI or Safety Officer will be promptly reported to NHLBI and to the IRB at the University of Minnesota. The ongoing safety officer for this trial is Jerica Berge, PhD, Professor

in the Department of Family Medicine and Community Health at the University of Minnesota. Dr. Berge has substantial experience leading NIH-funded behavioral intervention studies and has a strong understanding of the types of risks associated with behavioral interventions involving environmental changes and dietary measurements. She has served on other DSMBs for randomized studies.

As Safety Officer, Dr. Berge will:

- Review recruitment reports (quarterly) from the start of recruitment at the end of Year 1 to the end of recruitment in year 4. This includes assuring that participants meet gender, racial/ethnic and SES diversity. While we do not expect large deviations from our quarterly recruitment goal, Dr. Berge will help the research team to consider alternate recruitment strategies to ensure that diversity recruitment goals are met.
- Review retention reports (quarterly) beginning six months after the start of recruitment, until data collection is completed in year 4. This includes assuring that there is no unexpected loss-to-follow-up, and that the rate of loss-to-follow-up is not differential across the intervention and control groups. While some loss-to-follow up is expected, Dr. Berge will help the research ream to consider retention strategies to endure that retention goals are met, and that retention is adequate across interventions and controls.
- Monitor Unexpected Problems/Adverse Events and the adequacy of reporting of such events (quarterly)
- After each report review or at any other time, suggest other corrective action, trigger of an ad hoc review, or trigger of a stopping rule, that should be communicated to the study investigator, the University of Minnesota IRB, and the NHLBI.

The project manager is responsible for assembling the data and producing the recruitment and retention reports outlined in this plan, as well as, assuring that copies of these reports are sent to the principal investigator and Safety Officer, which are reviewed by the PI. Reports contain, at a minimum, the following:

1. Study summary and issues or problems
2. Changes to protocols or consent procedures
3. Recruitment and Retention
    a. Total recruitment status
    b. Recruitment by gender, ethnicity, and race
    c. Completion of study components for enrolled participants
    d. Participant retention by intervention vs. control (6 months post, 1 year post for both waves)
4. Safety assessment
    a. Unanticipated problems/Adverse Events/Serious Adverse Events and reporting of events

Beyond the review of the Safety Officer, issues of recruitment will be discussed at weekly research team meetings as the need emerges. The research team will also discuss issues relating to the study protocol, consent procedures, in-home visits and observations, intervention visits, overall data quality, and data analysis as needed during their weekly meetings.

<u>Data Management:</u>

Data management systems in this project include the design of online interface, data entry forms, supervising the collection and processing of all data, training and certification of data collection and entry personnel, and designing and implementing all quality control procedures. All of these activities will be accomplished under the supervision of Data Manager with consultation from the study's analyst. REDCap is the primary means of collecting data for the study. The Data Manager for the study is the University of Minnesota's REDCap Administrator, who has developed a data entry

interface using the web-based data capture software, which is hosted on the secure network maintained by the University of Minnesota Academic Health Center. The Data Manager will manage the assembly of all the client data into one complete dataset: merge 24-hour recall data from the NDSR and match client survey data. The Data Manager will produce the study codebooks.

Data Security:
Digital data for this project will be stored on REDcap. REDcap is a secure database housed on secure servers operated by the University of Minnesota Academic Health Center's Information Systems group (AHC-IS). Access to the database by username and password will require specific permission from the principal investigator and the data manager.

REDCap uses a MySQL database via a secure web interface with data checks used during data entry to ensure data quality. REDCap includes a complete suite of features to support HIPAA compliance, including a full audit trail, user-based privileges, and integration with the institutional LDAP server. The MySQL database and the web server will both be housed on secure servers operated by the University of Minnesota Academic Health Centers Information Systems group (AHC-IS). The servers are in a physically secure location on campus and are backed up nightly, with the backups stored in accordance with the AHC-IS retention schedule of daily, weekly, and monthly tapes retained for 1month, 3 months, and 6 months, respectively. Weekly backup tapes are stored offsite. The AHC-IS servers provide a stable, secure, well-maintained, and high-capacity data storage environment, and both REDCap and MySQL are widely-used, powerful, reliable, well-supported systems. Access to the study's data in REDCap will be restricted to the members of the study team by username and password. Additional protection of identifying information will be maintained by restricting identifiers only to those who need to see them. Any paper surveys, the 24-hour recall database, and the client cart data will have a participant number ID only, but will not itself contain any identifiable information for the client

Beyond REDCap survey data, all other electronic data will be stored on Box Secure Storage. These data are de-identified and include 24-hour dietary recall data, client cart data, and key informant interview transcripts. It also includes all other data that is not human subjects data on the food pantries (inventory, FAST data, pantry photos, statewide client survey data).

Data that is collected on paper will be stored in a locked carrying case while onsite at the food pantry. The paper copies will be brought back to the office entered into REDcap and stored in locked cabinets of the Project Manager's locked office.

Privacy/Confidentiality Part 1: [Explain how the privacy interests of participants will be maintained during the study (note that **privacy pertains to the individual not to the data**). Describe how data will be coded. Do not use the any potentially identifiable information such as initials of participants as part of the code. Explain how long data will be kept in an identifiable format and how long de-identified data will be retained. Explain how long the master key or audio or video recordings obtained, will be kept. Consider whether keeping de-identified data will be retained indefinitely and whether participants may be contacted for a follow-up study (explain procedures to retain identifiable contact data is kept.]

Provisions to Protect the Privacy Interests of Participants:
In this minimal risk study, study activities will take place in a private space at the food pantry. No data on participation or individual client responses will be disclosed to the food pantry, and the food pantry will not be involved in any way in attempts to follow up with participants. Any data reported to the food pantry will be reported in aggregate.

Unique Study IDs are assigned to participants with numerical codes based on the food pantry they were recruited from. The codes do not contain any information about the individual themselves such as initials. Those Study IDs are used in place of identifiers outside of a single form in REDCap. Participant identifiers are not saved to any devices. The link between identifiers and codes will be maintained for 5 years, at which point identifiable data will be deleted. De-identified data will be maintained indefinitely for future data analysis.

For Sample B, we do not collect any identifiers because we do not need to follow up with these participants. It is necessary to maintain identifiers for Sample A because we will be collecting data at two time points. We will need the phone numbers of participants to call to administer post data collection (two 24 hour recalls, and a survey) and to send text messages as reminders. We need their email addresses to send reminders and to maintain updated telephone numbers. Postal address are needed to send the post survey as option for participants to complete it on a hard copy if requested (vs online). Participant contact information will not be used for any other purposes.

Although photographs are taken in the food shelf, the photos are only of the food clients select, never the clients themselves.

If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained.

N/A

Be sure to state whether any limits to confidentiality exist (e.g. mandated reporting) and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data.

NA

If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.]

NA

Privacy/Confidentiality Part 2: Complete the Data Security Assessment Form: [**This form IS REQUIRED for ALL studies**. The form is available here - https://ovpr.uconn.edu/services/rics/irb/irb-forms-infoed/. This form will be used to assess procedures for protecting confidentiality of data collected during the study and stored after closure. It will also be used to assess plans for storage and security of electronic data in accordance with University Best Practices. Review the document proving tips to complete the form located at http://content.research.uconn.edu/pdf/storrs/rcs/irb/TipsDataSecurityAssessmentForm.docx.

Informed Consent

As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about and understand the study. Even if you are not targeting participants from "Special Populations" as listed on page 4, such populations may be included in recruitment efforts. Please keep this in mind as you design the Consent Process and provide the information requested in this section.

Consent/permission Setting: [Describe the consent/permission process including *who* will obtain it, *where* and *when* will it be obtained, and *how* much time participants will have to make a decision. Describe how the privacy of the participants will be maintained throughout the consent process.

State whether an assessment of consent/permission materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).]

Consent Process:

No additional participants will be consented. The consent version to be used (attached) is formatted according to the University of Minnesota standards for obtaining consent.

Trained research staff conducted the consent and recruitment process. Data collectors were hired and all had a minimum of one year of experience in obtaining informed consent in research studies. Data collectors obtaining informed consent were added to the IRB application. They have completed all relevant trainings.

Recruitment took place at the food pantry during clients' visits. After they selected their food (to avoid influencing choice), all clients were approached by data collectors to gauge interest in the study. Participants were eligible if they are ≥18 years old and were mentally capable of consent and participation, have access to a phone (Sample A only), and speak English, Spanish or Somali.

Subjects were told that they are being invited to participate in a research study to evaluate the impact of food pantry changes on the food that is selected and consumed by clients. They were told all of what will be asked of them to do, including allowing us to record their selections from the food pantry for that day and taking a survey. They were told that for their participation they will receive an incentive of $15. Potential participants will be notified that participation is completely voluntary and confidential.

If they were interested after hearing about the study activates, research staff will have a consent conversation with the participant in a private section of the food pantry. This area might be a spare room, office, or an area separate from where clients are selecting their food. Study staff will walk through the consent document, including discussing the background information of the study, study tasks that participants will be asked to complete, risks and benefits of the study, compensation for completing study tasks, confidentiality, the voluntary nature of the study, and study staff as well as IRB contact information. Subjects will consent for themselves.

Questions such as the following were be asked to assess the subject's understanding of participation in the study.

• What questions do you have regarding what we are asking you to do?

• What concerns about this process do you have?

We obtained documented written consent. Participants could take as much time at the food pantry to decide whether to consent to participate, but because the measures are based on food selected that day, they could not decide to participate at another time.

Capacity to Consent: [Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers or hearing difficulty. If a participant is incapable of

providing consent, you will need to obtain consent from the participant's legal guardian (please see the IRB website for additional information).]

Non-English Speaking Participants:

A protocol specific to non-English speakers will be followed. A bilingual Spanish-speaking or Somali-speaking data collector will be present at food pantries where they are most likely to be needed. They are responsible for recruiting, obtaining informed consent, administering assessments with clients, and follow up over the phone.

Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A

Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: N/A

Adults Unable to Consent: N/A

Parent/Guardian Permission and Assent: [If enrolling children, state how many parents/guardians will provide permission, when the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained. For longitudinal studies, assent may happen at several points during the study.]

N/A

Documentation of Consent: [Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, parental permission sheet. child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants (templates and instructions are available on the IRB website).]

We obtained documented written consent. A copy of the consent for Sample B is included in this protocol.

Waiver or Alteration of Consent: [The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either a **waiver of consent** (i.e., participants will not be asked to give consent), an **alteration of consent** (e.g., deception) or a **waiver of signed consent** (i.e., participants will give consent after reading an information sheet), please answer the following questions using specific information from the study:]

N/A

Waiver (i.e. participants will not be asked to give consent) or alteration of consent (e.g. use of deception/incomplete disclosure in research):

- Why is the study considered to be minimal risk? N/A

- How will the waiver affect the participants' rights and welfare? The IRB must find that participants' rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.

N/A

- Explain why the research could not be practicably carried out without the waiver. For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.

  N/A

- Explain why the research could not be practicably carried out without using identifiable private information and/or identifiable biospecimens.

  N/A

- How will important information be returned to the participants, if appropriate? For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.

  N/A

- Indicate if the waiver/alteration as noted above is applicable to the entire study or to a portion of the study.

  N/A

Waiver of ***signed*** consent (i.e. , no signature, participants give consent only after reading an information sheet). Tip: if the investigator will obtain information through oral or written communication with the prospective participant or if the investigator will obtain private identifiable information or identifiable biospecimens by accessing records, then a waiver of signed consent is NOT required.,:

N/A

- Why is the study considered to be minimal risk?

  N/A

- Does a breach of confidentiality constitute the principal risk to participants? Relate this to the .risks associated with a breach of confidentiality and indicate how risks will be minimized because of the waiver of signed consent.

  N/A

- Would the signed consent form be the only record linking the participant to the research? Relate this to the procedures to protect privacy/confidentiality.

  N/A

- Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.

  N/A

- Describe if the participants or their legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained. Not applicable to FDA Regulated Studies.

  N/A

References / Literature Review:

References

1. Coleman-Jensen A, Rabbitt M, Singh A. Household Food Security in the United States in 2014. Unites States Department of Agriculture; 2015 Sep. Report No.: 194.

2. Chilton M, Black MM, Berkowitz C, Casey PH, Cook J, Cutts D, et al. Food insecurity and risk of poor health among US-born children of immigrants. Am J Public Health. 2009 Mar;99(3):556–62.

3. Drewnowski A, Eichelsdoerfer P. Can Low-Income Americans Afford a Healthy Diet? Nutr Today. 2010 Nov;44(6):246–9.

4. Shin J-I, Bautista LE, Walsh MC, Malecki KC, Nieto FJ. Food insecurity and dyslipidemia in a representative population-based sample in the US. Prev Med. 2015 Aug;77:186–90.

5. Tayie FA, Zizza CA. Food insecurity and dyslipidemia among adults in the United States. Prev Med. 2009 May;48(5):480–5.

6. Irving SM, Njai RS, Siegel PZ. Food insecurity and self-reported hypertension among Hispanic, black, and white adults in 12 states, Behavioral Risk Factor Surveillance System, 2009. Prev Chronic Dis. 2014;11:E161.

7. Ford ES. Food security and cardiovascular disease risk among adults in the United States: findings from the National Health and Nutrition Examination Survey, 2003-2008. Prev Chronic Dis. 2013;10:E202.

8. Rush TJ, Ng V, Irwin JD, Stitt LW, He M. Food insecurity and dietary intake of immigrant food bank users. Can J Diet Pract Res. 2007;68(2):73–8.

9. Duffy P, Zizza C, Jacoby J, Tayie FA. Diet quality is low among female food pantry clients in Eastern Alabama. J Nutr Educ Behav. 2009 Dec;41(6):414–9.

10. Starkey LJ, Kuhnlein HV, Gray-Donald K. Food bank users: sociodemographic and nutritional characteristics. CMAJ. 1998 May 5;158(9):1143–9.

11. Robaina KA, Martin KS. Food insecurity, poor diet quality, and obesity among food pantry participants in Hartford, CT. J Nutr Educ Behav. 2013 Mar;45(2):159–64.

12. Weinfeld N, Mills G, Borger C, Gearing M, Macaluso T, Montaquila J, et al. Hunger in America 2014 [Internet]. Chicago, IL: Feeding America; 2014 [cited 2015 Nov 6]. Available from: http://help.feedingamerica.org/HungerInAmerica/hunger-in-america-2014-full-report.pdf

13. Verpy H, Smith C, Reicks M. Attitudes and behaviors of food donors and perceived needs and wants of food shelf clients. J Nutr Educ Behav. 2003 Feb;35(1):6–15.

14. Shimada T, Ross M, Campbell EC, Webb KL. A model to drive research-based policy change: Improving the nutritional quality of emergency food. Journal of Hunger & Environmental Nutrition. 2013;8(3):281–93.

15. Ross CE, Hill TD. Reconceptualizing the Association between Food Insufficiency and Body Weight: Distinguishing Hunger from Economic Hardship. Sociological Perspectives. 2013 Dec;56(4):547–67.

16. Campbell EC, Ross M, Webb KL. Improving the nutritional quality of emergency food: A study of food bank organizational culture, capacity, and practices. Journal of Hunger & Environmental Nutrition. 2013;8(3):261–80.

17. Rochester JS, Nanney MS, Story M. Assessing foodshelves' ability to distribute healthy foods to foodshelf clients. Journal of Hunger & Environmental Nutrition. 2011;6(1):10–26.

18. Wilson NLW. When the Cupboards Are Bare: Nudging Food Pantry Clients to Healthier Foods. Jounral of the Association for Consumer Research. 2016 Jan;1(1).

19. Wilson NLW, Just DR, Swigert J, Wansink B. Food pantry selection solutions: a randomized controlled trial in client-choice food pantries to nudge clients to targeted foods. J Public Health (Oxf). 2016 May 12;

20. Caspi CE, Canterbury M, Carlson S, Bain J, Bohen L, Grannon K, et al. A behavioural economics approach to improving healthy food selection among food pantry clients. Public Health Nutr. 2019 Aug;22(12):2303–13.

21. Caspi C, Friebur R, Davey C, Nanney MS. Results of a pilot intervention to improve dietary outcomes among adults experiencing food insecurity. Journal of Hunger & Environmental Nutrition. 2016 Apr;

22. Feskanich D, Sielaff BH, Chong K, Buzzard IM. Computerized collection and analysis of dietary intake information. Comput Methods Programs Biomed. 1989 Sep;30(1):47–57.

23. Johnson RK, Driscoll P, Goran MI. Comparison of multiple-pass 24-hour recall estimates of energy intake with total energy expenditure determined by the doubly labeled water method in young children. J Am Diet Assoc. 1996 Nov;96(11):1140–4.

24. Guenther PM, Reedy J, Krebs-Smith SM, Reeve BB. Evaluation of the Healthy Eating Index-2005. Journal of the American Dietetic Association. 2008;108(11):1854–64.

25. Guenther PM, Reedy J, Krebs-Smith SM. Development of the Healthy Eating Index-2005. Journal of the American Dietetic Association. 2008;108(11):1896–901.

26. Jahns L, Scheett AJ, Johnson LAK, Krebs-Smith SM, Payne CR, Whigham LD, et al. Diet Quality of Items Advertised in Supermarket Sales Circulars Compared to Diets of the US Population, as Assessed by the Healthy Eating Index-2010. Journal of the Academy of Nutrition and Dietetics. 2016;116(1):115-122.e1.

27. Hager ER, Quigg AM, Black MM, Coleman SM, Heeren T, Rose-Jacobs R, et al. Development and validity of a 2-item screen to identify families at risk for food insecurity. Pediatrics. 2010 Jul;126(1):e26-32.

28. Schnittker J, Bacak V. The Increasing Predictive Validity of Self-Rated Health. PLoS One [Internet]. 2014 Jan 22 [cited 2020 May 21];9(1). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3899056/

29. Idler EL, Benyamini Y. Self-rated health and mortality: a review of twenty-seven community studies. J Health Soc Behav. 1997 Mar;38(1):21–37.

30. Bombak AE. Self-Rated Health and Public Health: A Critical Perspective. Front Public Health [Internet]. 2013 May 20 [cited 2020 May 21];1. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3855002/

31. Lloyd-Jones DM, Hong Y, Labarthe D, Mozaffarian D, Appel LJ, Horn LV, et al. Defining and setting national goals for cardiovascular health promotion and disease reduction: The American Heart Association's strategic impact goal through 2020 and beyond. Circulation. 2010 Feb 2;121(4):586–613.

32. Fretts AM, Howard BV, McKnight B, Duncan GE, Beresford SAA, Mete M, et al. Life's Simple 7 and incidence of diabetes among American Indians: the Strong Heart Family Study. Diabetes Care. 2014 Aug;37(8):2240–5.

33. Kulshreshtha A, Vaccarino V, Goyal A, McClellan W, Nahab F, Howard VJ, et al. Family history of stroke and cardiovascular health in a national cohort. J Stroke Cerebrovasc Dis. 2015 Feb;24(2):447–54.