A Trial of Behavioral Economic Interventions Among Food Pantry Clients

NCT04011384

2022-09-27

IRB Study Protocol and Analysis Plan

Protocol

Objectives

Overall objectives

The objectives of the study are to evaluate the influence of a web-based behavioral economic intervention compared to a control group on the following outcomes among food pantry clients:
-Nutritional quality of food chosen at the pantry using food transaction data
-Fruit and vegetable intake measured by dermal carotenoids (a fruit and vegetable biomarker) and a food frequency questionnaire
-Objectively measured height, weight, and blood pressure

Background

Poor dietary habits and food insecurity are significant public health problems: Unhealthy dietary habits are associated with obesity, cardiovascular disease, type 2 diabetes, and certain cancers (1). To comprehensively address these chronic diseases, interventions need to focus on calorie reduction and changing specific dietary habits. For example, potato chips and sweetened beverages are two foods with the strongest links to long-term weight gain, suggesting a need to focus on decreasing their consumption, while vegetables, fruits, whole grains, nuts, and yogurt are protective against weight gain (22). Low-income individuals are at particularly high risk for poor dietary quality and obesity (2-4). Further, it is estimated that 14% of U.S. households experience food insecurity, or insufficient access to safe and nutritious foods (5), which occurs more commonly among low-income, racial/ethnic minority, and immigrant families in the U.S (5). Food insecurity has been associated with low nutrient intake and poor diet (6-9), and a host of negative health outcomes, including hyperlipidemia, hypertension, diabetes (10, 11), depression and anxiety (12, 13), obesity in women (14, 15), and poor maternal mental health (16). The proposed research is focused on clients of a food pantry in Philadelphia, PA that serves a low-income population. Food insecurity among this group is largely concentrated in four sub-sets of the community we will be studying: a) seniors; b) Russian immigrants; c) Orthodox Jewish families with four or more children; and d) those with mental illness. The majority (60%) of these low-income individuals are enrolled in the supplemental nutrition assistance program (SNAP). The food pantry provides their clients with five to seven days worth of meals each month and internal surveys conducted by the pantry reveal that clients report consuming the vast majority of food provided.

Psychological and behavioral economic insights to inform health interventions: There is growing interest in using behavioral science techniques to nudge consumers to make healthier choices, while preserving freedom of choice. One fundamental psychological insight is that two systems of thought operate simultaneously in the human brain, commonly referred to as System 1 and System 2 (23). System 1 thinking is faster (impulsive, reflexive, emotional, and impatient) whereas System 2 thinking is slower (deliberative, controlled, analytical, and patient). System 1 produces an automatic response whereas System 2 produces a reasoned response. The function of System 2 is to monitor the activities of System 1, which requires attention and effort. However, when one's cognitive resources are stretched (for example, when thirsty, hungry, stressed, or in a distracted state), System 1 dominates. Part of the reason humans rely so heavily on System 1 is because we have a limited ability to attend to, process, and remember information (23). This often leads to difficulty remembering and acting upon information that is overly complex. A number of studies have demonstrated that strategies that boost salience and convenience of healthy food options encourage greater selection of those foods in the short-term. Such strategies include serving healthier options at the beginning of a buffet line (24), placing less healthy food in opaque containers so it is out of sight (25), and making water highly visible and accessible (17). In the proposed research, we leverage the following four insights from psychology and behavioral economics:
Status quo bias and default options: Even when beliefs and preferences align with healthy choices, people often choose unhealthy options simply because the choice context promotes them. Status quo bias is the strong tendency to stick with whatever options happen to be the current default (26). For example, countries that automatically enroll people as organ donors have dramatically higher donor rates versus countries where people must opt-in to be a donor (19) and default settings can dramatically increase generic medication prescriptions (20). In the proposed research, we will leverage the status quo bias by pre-populating the shopping baskets of food pantry clients with several healthy, preferred items targeted towards a clients health needs as the default (clients can opt to remove them).
Healthy placement choice architecture: Choice architecture refers to the context in which people make decisions, including what choices are offered and how they are displayed and communicated. Our research has shown that a simple choice architecture nudge displaying bottles of water so they are more visible and accessible in a cafeteria

setting increased purchases of bottled water (17, 18). In the proposed research, we will implement a choice architecture intervention that will place the healthiest options at the top of the webpage for each food category so they are more visible and prominent.
Simple and salient information: Part of the reason humans rely so heavily on System 1 is because we have a limited ability to attend to, process, and remember information (23). This often leads to difficulty remembering and acting upon information that is overly complex, like our current nutrition labels that present lots of numbers, percentages, and serving sizes requiring math calculations on the fly. The traffic light nutrition messages we are testing in this study are designed to engage System 1 by making messages salient and easy to understand. Traffic light labels draw upon automatic associations people have between red and stop and green and go to facilitate immediate cognitive processing. Our team has demonstrated that a traffic light labeling intervention in a hospital cafeteria was associated with a 4-percentage-point decline in sales of unhealthy items and a 5-percentage-point increase in sales of healthy items in a hospital cafeteria over two years (17, 18). We will also use salient messaging to draw attention to discounts for healthier foods (e.g., save 1.5 points by switching from white to brown rice).
Social norms messaging: Human behavior is often influenced by social norms, and most health behaviors are performed within a social context (27). For instance, most people tend to eat meals in the presence of others and are unconsciously influenced by the eating behaviors of their companions. A person is more likely to eat more when he observes that his companion (especially a thin person) is overeating at a meal.(28) Conversely, when others at the table order just the soup and salad for lunch, an individual might be less likely to order the cheeseburger and fries on the menu.(28) Social norms messaging has also been found to influence people in other domains such as increasing environment-friendly behaviors (21). For these reasons, our fourth intervention will display social norms messaging indicating the healthy products most commonly selected by pantry clients (e.g., over half of all customers order bananas when shopping here).

Very few food pantry interventions have been tested: Food pantries are an important way to address food insecurity in the U.S., with 1 in 7 adults accessing food through pantries and meal service programs (5). Historically, food pantries have focused on providing access to free food for those in need, without considering the nutritional quality of food provided. That is now changing. Food pantries are increasingly offering healthier items, but few studies have rigorously tested ways to promote healthier food selections among low-income clients at food pantries. Very few randomized-controlled trials (RCTs) of nutritional interventions have been conducted in food pantries. One such study enrolled individuals with diabetes in a six-month RCT that provided diabetes-appropriate foods, blood sugar monitoring, primary care referral, and self-management support (29). The intervention led to improvements in glycemic control, fruit and vegetable intake, self-efficacy and medication adherence (29). Another RCT found that a motivational interviewing intervention combined with referrals to community services led to a one serving per day increase in fruit and vegetable intake and decreases in food insecurity (30). However, both of these interventions are costly as they require trained personnel to carry out the interventions. One food pantry study tested low-cost, behavioral nudges designed to increase the salience and convenience of healthy foods. In that study, researchers found that moving the placement of protein bars from the end to the front of a dessert line increased selection of those items over less healthy desserts (odds ratio: 1.69) as did placing the bars in sealed, clear plastic bags instead of their original packaging (odds ratio 1.92) (31). This study provides some of the first evidence that such strategies can encourage healthier choices in a food pantry context serving very low-income individuals, but this was a short-term intervention with data on only one food choice outcome. Our proposed research will make a significant contribution beyond existing research by evaluating the influence of a suite of evidence-based behavioral nudges among food pantry clients over a longer period of time (one-year) and examining more comprehensive outcomes, including the nutritional quality of food selections, dietary intake, and health outcomes.

Significant contributions of the proposed research: The proposed study will be one of the first large, longer-term RCTs testing low-cost behavioral nudges among a very low-income group of consumers. This study will improve upon prior work in several ways. First, we will use a randomized-controlled design to follow a large cohort of clients over one year. Second, we will analyze objective transaction data of all food selections made at the pantry over four months (one month pre-baseline and three months post-baseline) at the individual-level and link that with food intake and health data. Third, we will measure fruit and vegetable intake with an objective biomarker and questionnaire, and we will objectively assess health outcomes including weight and blood pressure. This will also be the first study to evaluate these behavioral techniques in the context of an innovative online ordering platform that has the potential to be the future gold standard for food pantries. Although web-based ordering systems are not yet widespread in food pantry settings, their use is growing rapidly. Two of the largest food pantries in New York City (NY Common Pantry and St. John's Bread and Life) have both implemented an online ordering system and the St

Johns system has been replicated in Nevada. Our food pantry partner has also replicated their online system in a neighboring county and the pantry has hosted site visits and shared best practices with the Metropolitan Council on Jewish Poverty who has 30 distribution sites and is moving toward an online system. This work also makes a significant contribution because very few studies of behavioral nudges have been conducted among populations with very high concentrations of poverty. Finally, our research team represents an interdisciplinary collaboration that includes academic and community partners. This partnership enables us to gain valuable insights from practitioners and ensures the research questions we are asking are relevant to practice as well as scientific discovery. This partnership will also help us disseminate these results through conventional academic channels as well as to practitioners. Given widespread interest in implementing these types of low-cost nudges to improve food choices, such rigorous evaluations are sorely needed.

1. Mozaffarian D. Dietary and policy priorities for cardiovascular disease, diabetes, and obesity: a comprehensive review. Circulation. 2016;133(2):187-225.
2. Finkelstein EA, Ruhm CJ, Kosa KM. Economic causes and consequences of obesity. Annu Rev Public Health. 2005;26:239257.
3. Darmon N, Drewnowski A. Does social class predict diet quality? Am J Clin Nutrition. 2008;87:1107-17.
4. Drewnowski A, Darmon N. The economics of obesity: Dietary energy density and energy cost. Am J Clin Nutrition. 2005; 82 (1 Suppl): 265S-73S
5. Coleman-Jensen, A, Rabbitt MP, Gregory C, Singh A. Household food security in the United States in 2014," Economic Research Report No. (EER-194), U.S. Department of Agriculture, Economic Research Service; 2015 Sep. Report No.: EER-194.
6. Rose D. Economic determinants and dietary consequences of food insecurity in the United States. J Nutr. 1999;129:517S20S.
7. Dharod JM, Croom JE, Sady CG. Food insecurity: its relationship
to dietary intake and body weight among Somali refugee women in the United States. J Nutr Educ Behav. 2013;45:47-53.
8. Dixon LB, Winkleby MA, Radimer KL. Dietary intakes and serum nutrients differ between adults from food-insufficient and food-sufficient families: third National Health and Nutrition Examination Survey, 19881994. J Nutr. 2001;131:123246.
9. Mello JA, Gans KM, Risica PM, Kirtania U, Strolla LO, Fournier L. How is food insecurity associated with dietary behaviors? An analysis with low-income, ethnically diverse participants in a nutrition intervention study. J Am Diet Assoc. 2010;110: 190611.
10. Seligman HK, Bindman AB, Vittinghoff E, Kanaya AM, Kushel MB. Food insecurity is associated with diabetes mellitus: results from the National Health Examination and Nutritional Examination Survey 1999-2002. J Gen Intern Med. 2007;22(7):101823.
11. Seligman HK, Laraia BA, Kushnel MB. Food insecurity is associated with chronic disease among low-income NHANES participants. J Nutr 2010;140(2):30410.
12. Whitaker R, Phillips S, Orzol S. Food insecurity and the risks of depression and anxiety in mothers and behavior problems in their preschool-aged children. Pediatrics. 2006;118(3):e85968.
13. Okechukwu CA, El Ayadi AM, Tamers SL, Sabbath EL, Berkman L. Household food insufficiency, financial strain, work-family spillover, and depressive symptoms in the working class: the work, family, and health network study. Am J Public Health. 2012;102(1):12633.
14. Martin K, Ferris A. Food insecurity and gender are risk factors for obesity. J Nutr Educ Behav. 2007;39:31-6.
15. Larson NI, Story MT. Food insecurity and weight status among U.S. children and families. A review of the literature. Am J Prev Med. 2011;40:166-73.
16. Melchior M, Caspi A, Howard LM et al. Mental health context of food insecurity: a representative cohort of families with young children. Pediatrics. 2009;124:564-72.
17. Thorndike AN, Sonnenberg L, Riis J, Barraclough S, Levy DE. A 2-phase labeling and choice architecture intervention to improve healthy food and beverage choices. Am J Public Health. 2012;102:527-33.
18. Thorndike AN, Riis J, Sonnenberg LM, Levy DE. Traffic-light labels and choice architecture: promoting healthy food choices. Am J Prev Med. 2014;46:143-9.
19. Johnson EJ, Goldstein D. Do Defaults Save Lives? Science. 2003;302(5649):1338-9.
20. Patel MS, Day SC, Halpern SD, et al. Generic Medication Prescription Rates After Health System-Wide Redesign of Default Options Within the Electronic Health Record. JAMA Intern Med. 2016;176(6):847-8.
21. Goldstein NJ, Cialdini RB, Griskevicius V. A room with a viewpoint: Using social norms to motivate

environmental conservation in hotels. J Consum Res. 2008;35(3):472-82.
22. Mozaffarian D, Hao T, Rimm EB, Willett WC, Hu FB. Changes in diet and lifestyle and long-term weight gain in women and men. N Engl J Med. 2011;364(25):2392-404.
23. Kahneman, D. Maps of bounded rationality: Psychology for behavioral economics. Am Econ Rev. 2003;93:1449-1475.
24. Wansink B, Hanks AS. Slim by design: Serving healthy foods first in buffet lines improves overall meal selection. PLOS One. 2013;8:1 5.
25. Wansink B. From mindless eating to mindlessly eating better. Physiol Behav. 2010;100:454-63.
26. Samuelson W, Zeckhauser R. Status quo bias in decision making. J Risk Uncertain. 1998;1:7-59.
27. Cialdini RB, Trost MR. Social influence: Social norm, conformity, and compliance. In: Gilbert DT, Fiske ST, Lindzey G, eds. Handbook of social psychology, vol. 2. New York, New York: McGraw-Hill; 1998.
28. McFerran B. Social norms, beliefs, and health. In: Roberto C, Kawachi I, eds. Behavioral economics and public health. New York, New York: Oxford University Press; 2015.
29. Seligman HK, Lyles C, Marshall MB, Prendergast K, Smith MC, Headings A, Bradshaw G, Rosenmoss S, Waxman. A pilot food bank intervention featuring diabetes-appropriate food improved glycemic control among clients in three states. Health Affairs. 2015;34:1956-63.
30. Martin KS, Wu R, Wolff M, Colantonio AG, Grady J. A novel food pantry program. Food security, self-sufficiency, and diet-quality outcomes. AM J Prev Med. 2013;45:569-75.
31. 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 of Pub Health. 2016 (ahead of print);1-7.

Study Design

Design

We will use a random number generator to assign study participants to one of 2 conditions: 1) usual care (control); or 2) behavioral economic intervention. The research team will create the randomization list and a research assistant will assign the participant to the correct online platform condition, but the investigators and data analysts will remain blind to group assignment. This study will contain two parallel groups. Although participants will not initially be aware of the other study condition, they will not be blinded to study condition because those in the intervention condition will be viewing the altered ordering platform as they shop.

Study duration

This study is estimated to take four years. Year 1 will be spent finalizing the research protocol, updating the food panty web-platform, categorizing pantry food with traffic lights, and hiring and training study staff. We will begin recruiting participants and collecting data in the second half of year 1. Subjects' participation will be for four months (one month pre-baseline, three months post-baseline). Participant recruitment will continue through years 2 and 3 of the study and data collection will continue through years 2, 3 and the first half of year 4. Year 4 will be spent cleaning and analyzing data and preparing manuscripts.

Characteristics of the Study Population

Target population

We will aim to recruit 500 individuals (only one per household) who regularly shop at the Jewish Federation food pantry in Philadelphia, PA. We have complete data for 61 participants at the 3-month post-intervention assessment point as of the end of 2020, and we will aim to recruit 439 more participants. Based on demographic data from the previous year, we expect approximately 55% of pantry customers will be women and the racial breakdown will be as follows: 78.5% White, 12.3% Black, 7.8% Asian, 0.1% Native Hawaiian or Other Pacific Islander, 0.5% more than one race, and 0.8% unknown race. We anticipate 1% of the sample to identify as Hispanic. In general, this is largely a very-low income, older, immigrant population. The majority (60%) of these individuals use SNAP benefits.

Subjects enrolled by Penn Researchers

500

Subjects enrolled by Collaborating Researchers

0

Vulnerable Populations

Children Form
Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
Fetuses and/or Neonates Form
Prisoners Form
Other
x **None of the above populations are included in the research study**
The following documents are currently attached to this item:
There are no documents attached for this item.

Subject recruitment
Participants will be recruited on-site at the pantry and remotely by study staff working closely with food pantry staff. Recruitment posters will be displayed at the pantry and recruitment post cards will be provided to food pantry clients. All study materials will be branded with a name and logo so that it is recognizable to participants. We will have all study documents available in the most common languages spoken by food pantry clients (English and Russian) and food pantry staff and study staff who speak these languages will be available to translate and discuss study procedures with clients. Our pantry partners have strong relationships with their clients, are highly invested in this study, and believe we will have no trouble meeting our target goal of 500 individuals out of the nearly 2600 that regularly visit the pantry.

Ukrainian translation was not done because we learned from the food pantry staff and our conversations with clients that the clients are largely English or Russian speaking and do not need Ukrainian language materials. Furthermore, the online ordering system at the food pantry is only available in English or Russian, so all clients shopping there must be able to communicate in one of those two languages. Finally, no clients to date have requested Ukrainian materials.
Attachments:
fp_PostCards Recruitment_EN_v1.0_2020-12-14.pdf (English post card)
fp_PostCards Recruitment_RU_v1.0_2020-12-14.pdf (Russian post card)
fp_Translation for UPenn_RU_2020-12-14.pdf (Certified Translation of PostCards Recruitment 2020-10-06_EN.pdf)
fp_Poster_EN_v1.0_2020-12-14.pdf (English poster, Certified Russian Translation to be included in subsequent modification)

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:
There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:
There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document
Prior to the COVID-19 pandemic, the study was conducted with three assessment points at baseline, 3-months, and 12-months. Since the pandemic, we have changed study protocols to only conduct assessments at baseline and 3-months. Participants who were enrolled prior to the pandemic who have not reached the 12-month time point have been notified that there will be no data collection at 12 months. For completing the assessments at baseline and 3-months, we will compensate participants $25 for each visit. This incentive will be broken up into the following payments: $10 for surveys, $5 for blood pressure measurement, $5 for weight measurement, and $5 for veggie meter

(diet quality) measurement. We will also remunerate participants $25 for completing a training on how to use the pantry online ordering system. Participants will be paid via ClinCards. These are debit cards that we have successfully used in other longitudinal research studies that enable us to automatically load money onto a participants' card, which they can then use at any store like a debit card. We will also approve Check payments for participants who are unable to receive ClinCards. To strengthen cohort retention, we will incentivize successful online shopping each of the three months that participants are in the study after baseline measurements. For completing their baseline order, participants will receive a $5 payment, for months 1 and 2, participants will receive $3, and for month 3, participants will receive $4, totaling $15 for all orders. The total financial compensation for participation is $90 ($25 + $25 + $25 + $15).
Prior to the COVID-19 pandemic, we planned to strengthen cohort retention during the study by entering each participant into several lotteries where 10 people had the chance of winning $5 prizes and one person would win a $100 prize. Because of the shortened timeline of the study (1 year to 3-months), we will no longer use a lottery to encourage cohort retention. We also planned to provide a $3 incentive twice for participants confirming their contact information at 3-months and 12-months. Because of the shortened study timeline and that we will now incentivize shopping monthly, we will no longer provide a $3 incentive for confirming contact information.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
In response to the COVID-19 pandemic, on March 11, 2020, the Mitzvah Food Program at the KleinLife Community Center (where our research study takes place) changed their food order and pick up protocol. No clients are allowed to enter the facility and instead must either order online remotely (maintaining choice selection) or choose a pre-packaged bag that is picked up outside at the door. Study procedures before the start of the COVID-19 pandemic involved participants placing food orders in-person at the food pantry and study staff conducting physical measurements and surveys with participants in-person at the food pantry. These study procedures are detailed below under "Pre-COVID-19 Procedures." Since the start of the pandemic, we have adapted our study procedures to ensure safety for participants and study staff. These new study procedures are as follows.

Participants will be recruited on-site at the Jewish Federation of Greater Philadelphia Food Pantry or remotely by study staff working closely with food pantry staff, following all current COVID-19 safety guidelines. We anticipate that the eventual availability of a vaccine will allow recruitment either remotely or on-site. We will ask participants several screening questions to determine their eligibility. Eligible participants will meet the following criteria:

1) At least 18 years old;
2) Regularly shops at the food pantry (at least once per month)
3) Primary food shopper for household (Only one member of household can participate)
4) Willing and able to place orders themselves or with assistance (while still viewing the screen) using the online ordering system
5) Willing and able to use a blood pressure cuff and scale provided to them for taking blood pressure and weight.
6) We have added the fourth screening criterion to ensure that participants will place online orders even if the pantry is operating remotely. After determining eligibility, we will administer informed consent electronically using the REDCap electronic-consent (e-consent) framework, detailed in the informed consent section of this protocol. We will offer to read the consent form and talk through the process with participants, and we will provide the option of paper consent forms for any participants not comfortable with the electronic consent process.

As part of the informed consent process, participants will be asked whether they would like to be contacted about future opportunities to participate in other research studies. Their response will be documented on the informed consent form (either on REDCap or a paper form). If they answer affirmatively, their name, e-mail, and phone number will be added to a REDCap database separate from this project and will be used for recruitment for studies within the PEACH Lab at the University of Pennsylvania. This database will not be shared with anyone outside of the Lab.

After consenting to participate, we will collect basic contact and demographic data consisting of the following elements: name, date of birth, address, phone number, email address, language, race, ethnicity, education level, gender, children living in household, and cigarette smoking behavior.
We will conduct study assessments with participants at two time points: baseline and 3-months post intervention. We will conduct baseline measurements of height, weight, blood pressure, and diet quality using the Veggie Meter with participants at their homes or at the food pantry following all current COVID-19 safety guidelines. We will use a script to describe measurements when calling participants to schedule their measurement appointments (fp_Script to describe measurements to participants). To aid with contactless measurements, we will provide participants with printed instructions (fp_Measurement Instructions for Participant, fp_Veggie Meter Instructions for Participant).

These documents have been professionally translated

We will administer diet and health surveys (fp_DietSurvey, fp_HealthSurvey) electronically through REDCap surveys. We will provide the option of doing surveys over the phone on an as-needed basis for participants not comfortable with electronic surveys.

Participants will receive $25 for completing all components of baseline measurements ($10 for surveys, $5 for blood pressure, $5 for weight, and $5 for veggie meter). We will provide participants with their blood pressure and weight results at the time of measurement using printed cards (fp_Results Cards). We will provide weight and blood pressure results only and not BMI or Veggie Meter results as these are not meaningful results for participants. Blood pressure results include a desirable range from low to high blood pressure, and direct participants to consult with their doctor if results are outside this range.(1)

Following baseline measurements, participants will be randomized to one of two conditions: 1) the usual care group (control); or 2) the behavioral economic intervention.

To encourage participants to place orders using the food pantry's SmartChoice online ordering system, we will incentivize shopping by paying participants for successfully placing each order. We will train research participants on how to use the SmartChoice system via a walkthrough with study staff prior to their first order, for which they will be remunerated $25. Participants will be remunerated for each order as follows: $5 for baseline, $3 for the first two months of participation, and $4 for the third month of participation. We will provide printed online order guides to support online ordering (fp_Online Order Guide). We will also offer four months of contactless food delivery. Contactless means that when the Research Assistant brings the food to the study participant's home, they will place the food at the door, knock or ring the doorbell, and wait at a safe distance as the participant picks up the food. We will use phone and text messaging through Mosio, a secure text messaging platform, to communicate with participants using text message templates (fp_Text_Message_Templates).

Deliveries will only be offered to those participating in the study remotely, and for that reason we have removed any information about deliveries in our informed consent forms.

Three months after baseline, we will conduct 3-month measurements of weight, blood pressure, and diet quality using the Veggie Meter with participants at their homes or at the food pantry following all current COVID-19 safety guidelines. We will administer the diet survey again electronically through a REDCap survey. We will not administer the health survey at 3-months. We will provide the option of doing the survey over the phone on an as-needed basis for participants not comfortable with electronic surveys. Participants will receive $25 for completing all components of 3-month measurements ($10 for the survey, $5 for blood pressure, $5 for weight, and $5 for veggie meter). We will provide participants with their blood pressure and weight results at the time of measurement using printed cards.

Food delivery will end after four months. We will use a post flyer to inform participants of their last food delivery (fp_PostCards Last Delivery).

After completing all study components, we will use a questionnaire (fp_Post-Study Questions) to ask participants a series of questions about their perceptions of the intervention, provide a short debriefing about study, and then ask whether or not they prefer to keep or remove the intervention depending on the condition they were assigned to.

If we are unable to reach a participant by phone after three attempts at any point throughout the study, we will mail them a letter asking them to contact us (fp_FoodPantryContactInfoFollowUpLetter).

Clean and track-changes Microsoft Word copies of this protocol are attached here (fp_FoodPantryIRBProtocol).

Staff Training and Protections
All study staff will complete HIPAA, GCP, CITI, and safe driving trainings before implementing this protocol. Study staff will use masks, practice social distancing, and use hand sanitizer and wash hands frequently.

Food pickups and deliveries and physical measurements will be contactless for as long as is required by University and government safety guidelines. Blood pressure cuffs, monitors, and scales are considered noncritical surfaces in health care because they only touch intact skin, and we will follow the recommendation to disinfect between each participant use.(2)

To ensure food safety, we will use cooler bags to store refrigerated and frozen items and make sure food is not in transport for long periods of time.

References
1. National Heart, Lung, and Blood Institute. Low Blood Pressure. National Institutes of Health, United States Department of Health and Human Services. https://www.nhlbi.nih.gov/health-topics/low-blood-pressure. Accessed December 14, 2020.
2. Havill NL. Best practices in disinfection of noncritical surfaces in the health care setting: Creating a bundle for success. Am J Infect Control. 2013;41(5 Suppl):S26-S30.

Pre-COVID-19 Procedures
Participants will be allowed to visit the pantry at their normally scheduled time to allow for convenience for the participant. During each visit, participants will order their grocery items using the web-based touchscreen system. The web-based ordering platform at the food pantry, will enable us to easily capture and evaluate all food selections at the pantry over one year per participant. Once orders are placed, a receipt is printed out and food pantry staff fill the order. Before participants place their order , study staff will measure participant weight, height, and blood pressure in a private room, which is estimated to take approximately 5 minutes. To ensure standardized weights over time, trained research assistants will follow a clear protocol (participants will be instructed to wear light clothing, no shoes for weighing, and each participant will be weighed twice on a digital scale). Height will also be assessed to the nearest 1/8 inch using a stadiometer. Participants will then be given the Block Food Frequency Screener in order to measure their fruit and vegetable intake. The screener includes questions about usual fruit and vegetable intake and takes about 5 minutes to complete. Participants were then given a health questionnaire. Participants will have their dermal carotenoid levels measured with a Veggie Meter, a non-invasive device which uses reflection spectroscopy to measure the pigment in the skin which corresponds to fruit and vegetable intake.

Originally, after attending the food distribution at each time point, participants were instructed to visit a nearby LabCorp to complete a blood draw that measured a fruit and vegetable biomarker (beta carotene serum levels) and HbA1c. Blood measurements will also include a lipid panel (total cholesterol, LDL, HDL, triglycerides, and glucose), c-reactive protein, and serum glucose. However, this proved unreliable and burdensome, so the lab tests were eliminated and replaced by the aforementioned dermal carotenoid measurement in October 2019. This did not change the incentive structure. Those who were previously offered LabCorp appointments were given the opportunity to continue going if they so chose, but were not required to have blood work done for study participation.

The following documents are currently attached to this item:
There are no documents attached for this item.

Deception
Does your project use deception?
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
Data will be descriptively summarized and evaluated for quality prior to the evaluation of primary and secondary endpoints. Means and standard deviations will be used to characterize continuous variables such as weight and blood pressure, and frequencies and percentages will be used to describe categorical variables such as nutritional quality. Medians and interquartile ranges will be reported for continuous variables that exhibit skewness. Data will be descriptively summarized overall and by condition. All outcomes will be analyzed at the customer level except for nutritional quality, which will be analyzed at the item level. Analyses will employ population-averaged marginal models estimated by Generalized Estimating Equations (GEE) to account for correlations among longitudinal monthly measurements and items purchased per food pantry customer. Marginal models estimated by GEE are advantageous for their population-level interpretation and robustness of estimated effects to the assumed correlation structure among repeated measurements (meaning unbiased estimates of the effect of the behavioral economic intervention will be obtained whether or not the correlation among repeated measurements within a food pantry customer is modeled correctly). Clusters will be defined at the level of the customer for all analyses, and independence working correlation will be assumed. Linear models will be used for continuous outcomes and logistic models for ordinal outcomes such as nutritional quality. Models will include 2-level intervention, month, and the interaction of intervention and month as categorical variables. The primary analysis of testing the effectiveness of the behavioral economic arm compared to the control arm will be evaluated by the joint test of the null hypothesis test that intervention-month interaction coefficients are 0, denoting no difference in the change in respective outcomes from baseline to month 3 between intervention groups. Secondary analyses will test for changes in intervention effects over time by testing whether intervention-month interaction coefficients are equivalent at month 3. We will evaluate the sensitivity of estimated intervention effects to imbalances in baseline covariates and missing data. To assess the impact of imbalance in baseline covariates, outcomes will be reanalyzed in models that adjust for baseline covariates that differ significantly at the 0.05 level by intervention arm. We will evaluate sensitivity to missing data by inverse probability of weighted GEE and multiple imputation. The Holm procedure77 at a family-wise error rate of 0.05 will be used to account for multiple comparisons in testing differences in five primary outcomes between the two groups (nutritional quality of food selected, fruit and vegetable intake based on the food frequency questionnaire, weight, and blood pressure). Similar analyses of dermal carotenoids will be performed as secondary endpoint analyses.