Multi-level Supermarket Discounts of Fruits and Vegetables' Impact on Intake and Health
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Mount Sinai	Protocol Name:	Multi-level supermarket discounts of fruits and vegetables on intake and health
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HRP-503 PROTOCOL TEMPLATE

- *Note that, depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable. Provide information if and when applicable, and in cases where an entire section is not applicable, indicate this by marking the section "N/A". Do not delete any sections.*
- ***For any items below that are already described in the sponsor's protocol, the investigator's protocol, the grant application, or other source documents, you may simply reference the title and page numbers of these documents in the sections below, rather than cutting and pasting into this document. Do not refer to the Sample Consent document, or information on the application form in this document.***
- *Keep an electronic copy of this version of the document. You will need to modify this copy when making changes.*

Brief Summary of Research (250-400 words):

Our objective is to test the effect of various supermarket discount levels on fruit and vegetable (F&V) and non-caloric beverage purchasing and consumption, as well as health outcomes. We will implement this economic intervention in a local supermarket chain to assess the effects of a 32-week intervention of fruit and vegetable (F&V) and non-caloric beverage discounts of 30%, 15%, and 0% (control group) on purchasing, dietary intake, and health outcomes, including body weight and composition, blood pressure, and biochemical markers of cardiovascular disease risk. The 32-week intervention will be preceded by an 8-week baseline and will have a follow-up period of 16 weeks. There will be no discounts in effect during the baseline and follow-up periods.

1) Objectives

Research Question:

What effect does discounting (0, 15, or 30%) fruits, vegetables and non-caloric beverages in a local supermarket chain have on purchasing, eating patterns, and health outcomes in an overweight and obese population?

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Hypotheses:

We hypothesize that with greater discount levels, there will be progressive increases in purchasing and intake of F&V and non-caloric beverages during the intervention period as well as improvement in health outcomes, which will be partially sustained during the follow-up period.

We predict greater relative increases in purchasing and consumption of F&V and improved health outcomes, among those with lower incomes as compared to those with higher incomes. F&V prices are relatively high compared with other foods, and are less affordable to those of lower income, who would be expected to benefit more from price reductions.

Specific Aims:

For the aims below, the first outcome (underlined) within each aim is primary, and the other outcomes are secondary.

Primary Aim 1: To investigate the effects of multi-level discounts on behavioral and health outcomes during the intervention period and their sustained effect during the follow-up period.

For greater price discounts (30% > 15% > 0% group), we predict:

a. *Purchasing Behaviors*
   i. higher individual gross purchasing (i.e., price before discount) of F&V and non-caloric beverages
   ii. reduced individual gross purchasing of less healthy, high energy dense (ED) highly processed foods (e.g., processed bakery items)

b. *Consumption Behaviors*
   i. higher individual F&V intake (g), the primary outcome measure (used to power the study), as assessed by 24-h dietary recalls and Brief Block Food Frequency Questionnaires (FFQ) (confirmed by biomarkers: plasma carotenoids and Vitamin C), as well as greater intake of non-caloric beverages
   ii. decreased high energy-dense (ED) food intake (g), lower total fat intake (g), and lower daily energy intake (kcal)

c. *Health Outcomes*
   i. lower body weight (kg) and BMI (kg/m^2), lower % body fat
   ii. improved metabolic syndrome risk factors (fasting glucose, blood lipids, blood pressure)

Primary Aim 2: To investigate the effects of income as a moderator of outcome measures.

2) Background

Significance

Although the health benefits of a diet rich in fruits and vegetables (F&V) are widely accepted, most Americans do not incorporate enough F&V into their daily diet. In 2009, only 32.5% of Americans consumed ≥ 2 servings of fruits, and only 26.3% consumed ≥ 3 servings of vegetables a day. Also, knowledge of the health benefits of F&V is quite low among Americans, especially African–American adolescents and women.

Cardiovascular disease (CVD) is the leading cause of death in the US. Risk factors (e.g., high cholesterol, hypertension, obesity, diabetes) for CVD are influenced by diet, including F&V intake. Prospective cohort studies show that F&V intake helps protect against heart disease and ischemic or hemorrhagic stroke and is associated with higher HDL cholesterol. Both observational and interventional studies of F&V intake have found lowering of blood pressure (BP) with increasing F&V. A common strategy for weight loss often involves increasing F&V intake. In one randomized controlled trial (RCT), plasma C-reactive protein (CRP), an inflammatory marker, was significantly reduced after a 4-wk intervention to increase F&V intake. Several studies have linked a diet high in F&V to lower risk of type 2 diabetes. Diets low in F&V can lead to lower plasma levels of vitamins and carotenoids. Epidemiological studies have found a correlation between F&V intake and prevention of atherosclerosis, certain cancers, diabetes, arthritis, Alzheimer's, and aging. Evidence keeps building that higher F&V intake can reduce the incidence of many chronic diseases.

In Western countries, adults tend to gain weight steadily, about 1-2 lbs/year, with slight variations due to sex, age, socioeconomic (SES) status, and ethnicity. In large cohort studies, a diet high in F&V has been associated with lower body weight. Intervention studies to increase F&V consumption have led to weight loss or weight maintenance. Greater F&V intake may also help to prevent weight gain. One explanation for this finding is that F&V are lower in energy-density (ED), kcal/g, due to high water and fiber, and low fat content, which enhances satiety and reduces daily energy intake. Evidence suggests that inclusion of F&V in the diet can reduce ad libitum energy intake by displacing high-ED foods. Increasing dietary F&V can lead to weight loss even in the absence of instructions to reduce total energy intake. Adding three apples/pears to the daily diet for 10 wk reduced both energy intake and body weight. Also, weight loss was greater and hunger ratings were lower in a group of obese subjects encouraged to increase F&V intake and decrease dietary fat as compared to those asked to restrict portion size and decrease dietary fat. A 5% weight reduction is sufficient to significantly reduce CVD risk factors, including cholesterol, glucose, and blood pressure, all part of the metabolic syndrome. Even interventions that improve dietary quality without weight loss can benefit health. Epidemiological studies show associations between high F&V intake and low cardiovascular risk, irrespective of BMI, body weight, or body fat. Inversely, diets

low in F&V are linked to greater energy intake, higher BMI, excess weight gain, and greater risk of chronic diseases. Decreased purchasing of F&V may help explain socioeconomic (SES) variation in the prevalence of chronic diseases.

Food choice depends on various factors, including convenience, cost, preference, age, culture, and knowledge. Cost is a major factor in making choices, disproportionately affecting those of lower income. Consumers often list cost as a key barrier to purchasing F&V, with low-income families purchasing fewer F&V than those of high-income. Relative to other foods, the cost for most F&V is greater than it was three decades ago. At the same time, prices have declined for commercially-packaged processed foods, including snack foods and foods high in calories, refined sugar, or fat. Snack food consumption has markedly increased in the US, with the average energy intake rising from 11% in 1977 to 24% in 2006, and likely contributing to increased daily energy intake. Increased snack intake has occurred concurrently with decreased F&V intake. The relatively high cost of F&V has been a key barrier to meeting daily F&V recommendations.

An approach to increase F&V intake that has received little attention is implementing price subsidies to encourage consumers to buy more F&V and buy less unhealthy foods. A subsidy, unlike a tax on unhealthy foods, does not carry the negative connotations of impinging on freedom of choice. In recent years, various governmental agencies have become involved in regulating prices of consumer foods, via taxation of unhealthy foods, e.g., sugary beverages, which leads to reduced purchasing and intake. (Implementing a tax-like increase in a supermarket study would not be feasible as the company would not voluntarily agree to it, and shoppers would turn to other stores.) Much less has been done on the subsidy side to encourage purchasing and consumption of healthy foods. However, the government has long been involved in providing subsidies at the farm level, especially for corn, to promote cheaper feed for cattle and to encourage conversion of corn to ethanol, which has led to the extensive and economical use of high fructose corn syrup instead of sugar in the processing of packaged snack foods. Thus, the use of governmental subsidies is familiar, but has not been used to promote purchasing and consumption of F&V. As suggested by Kelly Brownell, taxes collected on unhealthy foods could be used to subsidize F&V.

In addition to governmental subsidies, local programs such as the NYC GreenCart represent recent attempts to increase access to fruits at lower than usual prices in low income neighborhoods. Cathy Nonas, R.D., has been involved in this initiative and was also instrumental in implementing restaurant calorie labeling regulation in NYC and is one of our consultants.

Economic models have been developed to estimate the impact of price on food consumption. Recent reviews suggest that F&V intake is responsive to price changes, and that a reduction in F&V prices by 10% would increase consumption by 5%. A nationwide study found that the high price of F&V was sociated with decreased F&V purchases, and that F&V purchases increase when cost is reduced or when e cost of less healthy foods is increased. Furthermore, in targeting low-income women and children,

increased provision of F&V within the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), led to greater F&V purchasing. Lower F&V prices have been associated with lower body weight even among low-income groups. These studies suggest that F&V subsidies lead to increased F&V intake, particularly among low SES individuals.

If F&V discounts lead to positive outcomes, this could motivate the USDA to revisit its current food subsidy policy. Also, it may encourage the Supplemental Nutrition Assistance Program (SNAP) (food stamps) to revise its food restrictions or to add incentives to encourage more F&V purchasing as recently done by the WIC program. In its revised 2014 guidelines, WIC restricted their funds to healthier foods and provided a greater number of healthy food choices. Recently, Walmart implemented a number of price-reducing efforts by accepting lower profit margins for F&V and improving efficiency in the supply chain by boosting locally sourced produce instead of having produce shipped, which has saved customers $1 billion/y. The Walmart initiative has already spurred many smaller food markets to adopt similar strategies. Although large F&V discounts may not be sustainable on a continuous basis by supermarkets alone, periodic discounts (sales) are achievable, particularly since F&V represent only about 11% of total supermarket sales. Periodic sales may lead to behavioral change even when discounts are over, especially if we can show a sustained effect after the discounts have ended as found in our preliminary study. Our main objective, however, is to encourage F&V subsidies at the government level.

Although subsidy studies are still relatively novel, several have shown promising results at increasing purchasing of F&V and modifying behavior. With cash-back rebates of 10% or 25% on healthy foods, the ratio of F&V to total food expenditure increased by 5.7% and 8.5%, respectively, while decreasing the ratio of unhealthy food to total food expenditure by 5.6% and 7.2%. A contrarian study by Epstein et al. found that although subjects purchased more F&V when prices were reduced, they used some of the savings to purchase more unhealthy food. However, that study involved a simulated laboratory supermarket, and the findings may not generalize to the real world. Two studies in school cafeterias reported that fruit purchases tripled or quadrupled following a 50% discount. Studies on vending machines showed that a 50% price reduction of low-fat (≤3g fat) snacks increased sales by 93%. Since US consumers buy most of their food from supermarkets, spending over $551 billion annually, the Robert Wood Johnson Foundation identified the supermarket as a key venue for promoting healthier foods. Of the few supermarket interventions published to date, none have examined the effects of discounting F&V on purchasing as well as food intake, body weight, or other health-related measures. Several of the supermarket studies found that discounting healthy foods led to increased purchasing, and one showed sustained purchasing effects after a 12.5% discount ended. Thus, the time seems right to study the main and sustained effects of F&V discounts on purchasing, intake, and other health outcomes.

Economic Analysis: A cornerstone of economics is that as price decreases, demand increases. Empirical studies of demand curves, however, are largely based on correlational observations of price variation and demand. In this proposal, we will experimentally manipulate price via a community-based intervention, with shoppers randomly assigned to receive varied discount levels. Dr. Eric Finkelstein, a world-

renowned health economist specializing in obesity is a consultant to the application. We will estimate demand for F&V by regressing the level of purchasing and consumption against discount price levels. We will also assess the impact of each discount level on changes in individual health-related measures (weight, BMI, % body fat, systolic and diastolic blood pressure, fasting HDL cholesterol, triglyceride, CRP, HbA1c, and fasting blood glucose) and on the composite metabolic syndrome. We will also examine the supermarket's net profit (difference between real cost and selling price of each food item or the profit margin) at each discount level. Although larger discounts might be expected to result in reduced profit margins, the losses may be offset by more frequent shopping, leading to purchases of other non-subsidized products with higher profit margins. Effects of the discount level on net profits will be useful in encouraging store owners to adopt discounts.

Innovation

Greater F&V intake can help reduce the risk of certain chronic diseases, such as coronary heart disease, hypertension, cancer, and obesity. Yet, F&V intake continues to be well below daily recommended intake. Food choices are often influenced by one's food budget, with an undue impact on low-income shoppers. An intervention that makes F&V more affordable could lead to increased purchasing and intake, which may gradually alter dietary preference, eating habits, and overall health outcomes. The proposed study builds upon a successful preliminary study, utilizing an ongoing collaboration with a popular NYC supermarket chain. The study would be the first randomized controlled trial (RCT) to systematically investigate the effects of multilevel discounts of F&V and non-caloric beverages on purchasing as well as intake and measured health outcomes, including body weight/composition, blood lipids, and blood pressure in a real world urban setting. Besides 24-h recalls of dietary intake, we will use quantitative biomarkers (carotenoids) for confirming F&V intake as well as a brief food frequency questionnaire (FFQ), to better contextualize our participants' dietary choices. Although this is a community project, the individual will be the unit of study, with sampling of biomedical measures conducted in a hospital setting. The intervention will employ novel methods of recruiting within the supermarket, using free F&V samples on food carts, and study ads printed on store receipts. We also will use novel methodology, store loyalty scan cards, both for tracking purchases and for automatically implementing discounts. To sustain motivation, the control group will receive 30% discounts for a 16 wk period after the 56-wk study is over (weeks 57-73). This way we will be able to inform subjects initially that everyone will receive a discount after either 8 or 56 weeks, and subjects will only learn their individual discount level after the 8-wk baseline period, which should reduce possible disappointment with the assigned group during the study and help sustain motivation.

Preliminary Study

The preliminary study findings were published electronically in July 2013, and then in print in the December 2013 issue of the journal Obesity. The preliminary study was funded by a seed grant from Columbia University's Institute for Social and Economic Research and Policy and the Robert Wood Johnson Foundation. The CEO of D'Agostino Supermarkets, Nicholas D'Agostino III, granted access to office resources in two Manhattan supermarkets, and graciously declined reimbursement for the cost

incurred by the discounts.

Methods and Participants: The study comprised a 4-wk baseline, an 8-wk discount intervention, and a 4-wk follow-up with no discounts. Following the baseline period, Ss were randomized into two groups: a 50% discount on select F&V and non-caloric beverages, or no discount. All subjects received new D'Agostino Rewards scan cards to track purchasing and to implement discounts. Type, quantity, and cost of purchased items were based on data from scans of the bar codes. Overweight and obese (BMI≥25-40) shoppers were recruited from two D'Agostino Supermarkets, and n=47 (33 f, 14 m) was used for analysis. Age, BMI, income, and % gender did not differ between intervention groups, and the sex ratio was about 3:1; f:m. Household incomes had a good spread between $10,000 and $150,000.

Results: Purchasing of F&V. During the intervention period, gross weekly purchasing of F&V by the discount group was nearly 3 times that of the control group. Purchasing of F&V increased from baseline to intervention, P<0.0001, and then decreased from intervention to follow-up, P=0.002, but remained higher than at baseline, *P* =0.01. Gross purchasing of F&V did not change significantly for the control group. Income (mean by income bracket) was inversely related to F&V purchasing in the discount group during the intervention, r = -0.75.

The discount group increased F&V% of total purchasing nearly threefold from baseline (7%) to intervention (20%), P=0.001, and then declined from intervention to follow-up (14%), P=0.05, but remained higher than baseline. In contrast, % F&V purchasing by the control group did not change.

F&V intake from 24-h recalls. F&V intake increased for the discount group between baseline and intervention, P=0.037, which was correlated with gross weekly F&V purchases, P=0.0004, and partially sustained during follow-up, P<0.05. In contrast, F&V intake by the control group did not correlate with gross weekly F&V purchases, P=0.56.

Body Weight and Composition. Although body weight decreased significantly within the discount group during the intervention (-1.1 kg±1.8 SD), but not within the control group, the difference between the groups was not significant, and there were no body composition changes during the intervention.

Discussion

The results showed that the discount intervention had a marked impact on purchasing, which translated into increased F&V intake. The F&V discount led to nearly 3X purchasing and 1.5X F&V intake by the discount group relative to the control group during the intervention. (The tripling of F&V spending by the discount group following a 50% discount shows that all the net savings from the discount were spent on buying more F&V. The net savings alone would cover 2X discounted F&V, but in addition the subjects purchased 1X more out of their pocket due to the discount.) The modest but significant weight loss within e discount group implies that the increased purchasing and F&V intake translated into weight change, t because it did not differ significantly between groups, the study failed to demonstrate a differential

weight effect, which may require a longer intervention time and/or a larger sample size. Given the positive findings with a 50% discount, we will test lower discount levels of 30% and 15% which are more realistic as potential subsidies by the government. Although the discounted non-caloric beverages did not appear to contribute to changes in purchasing and intake in the preliminary study, we will continue to include them in the discounted products. It is possible that we did not include enough non-caloric beverages to make an impact on purchasing, and the subjects may not have been trained adequately to distinguish purchased bottled water from tap water in their dietary recalls. We plan to improve upon this in this study.

3) Setting of the Human Research

All subjects will be recruited from active shoppers at one of several predetermined Allegiance affiliate supermarkets in the Greater New York City community. The Screening Visit and all subsequent Study Visits will take place at Mt. Sinai Morningside/St. Luke's Hospital or at Quest Diagnostics.

4) Resources Available to Conduct the Human Research

Enrollees will be 360 men and women ranging from 18 to 65 y.o., and estimating a dropout rate of 37.5%, this should lead to 225 completers. We are excluding those under 18 y.o. for two reasons: 1) There are relatively few customers under the age of 18 who are the primary shoppers for the household; and 2) we wish to recruit participants who are no longer growing in stature. The upper limit of 70 y.o. was used because older participants may experience non-volitional weight loss that is sometimes associated with aging. To reduce potential COVID exposure for high risk populations, we are reducing the age limit to 65. Similarly, the upper limit of BMI 50 kg/m^2 was initially chosen because the degree of obesity >50 kg/m^2 is often associated with morbidity. However, to reduce risk to high-risk populations, the upper limit is reduced to 40 kg/m^2 We are limiting our sample to primary shoppers of the household who do ≥30% of total grocery shopping at their selected Allegiance affiliated supermarket, and regularly use their loyalty cards, to ensure that each participant generates sufficient purchasing data for analysis and that the intake data collected reflects the discount intervention's effects on purchasing. The exclusion criteria are designed to eliminate potential confounding factors that may affect purchasing or consumption behavior or body weight.

Participants will be carefully monitored using resources at Mt. Sinai Morningside/St. Luke's Clinical Research Unit (CRU). The unit director, Jeanine Albu, MD has agreed to provide both the space and resources necessary to conduct all of the minimally invasive medical procedures written into the protocol, Dr. Jeanine Albu, MD will also serve as the safety officer for this trial. Dr. Albu has experience conducting clinical research studies and a good understanding of obesity research. She will review the reports sent by the research coordinator, Aniema Nzesi, MS, and will use the checklist attached to this document to determine whether there is any corrective action, trigger of an ad hoc review or stopping rule that should be communicated to the PI, the hospital IRB, and the NIH. In

addition, the safety officer may indicate whether the study investigator should report any specific out-of-range laboratory data to the participants and their physician.

Dr. Geliebter is a licensed psychologist and will deal with any psychological issues that may arise. Dr. Geliebter, as PI, will be in charge of the overall project. Allegiance will facilitate obtaining purchasing data. Allegiance will send participant shopping data to us on a monthly basis. The lab manager (Shaunte Baboumian, MS) and research coordinator (Aniema Nzesi, MS) will supervise the study team and other staff members and will report any adverse effects reported by subjects in the study to the PI. The PI will have ultimate responsibility for ensuring participant well-being and for the integrity of data collection in the lab (where data are scored, entered, and analyzed).

All experimental procedures will be explained and questions answered. The risks and benefits of participation will be described before obtaining a signed IRB-approved informed consent form. No pressure will be exerted on the subjects to participate, and they have the right to withdraw from the study at any time. Research personnel will be told to report any untoward participant reactions directly to the research coordinator. Minor concerns raised by subjects (e.g., embarrassment about reporting body weight) will be addressed by research staff.

5) Study Design

a) Recruitment Methods

We will recruit 360 overweight and obese (BMI 24.5-40) subjects, and assuming a 20% dropout rate, this should lead to 240 completers. All subjects will be recruited among active shoppers at a predetermined Allegiance affiliated supermarket. Using strategies developed during the preliminary study, we will recruit shoppers by a cart display of weekly F&V samples and by listing study ads on store receipts, placing laminated posters by the cash register, and periodic email messages to shoppers Subjects will be screened by a structured phone interview or by an in-person interview at the Allegiance affiliate supermarket.

b) Inclusion and Exclusion Criteria

Inclusion Criteria:

- Between 18 and 65 years of age
- BMI of 24.5 to 40 kg/m²
- Accessible by telephone and email
- Self-identify as primary shopper for household
- Shops for > 30% of total grocery foods at a single Allegiance affiliated supermarket
- Consumes > 50% of food purchased at the Allegiance affiliated supermarket
- Weight stable (+/-5% in past 3 months)
- Agrees to the following study conditions:

- Be assigned to either one of the three study groups
- Use their newly issued reward cards each time they shop for 56 weeks
- Maintain 100% of their total grocery shopping at their designated supermarket for 56 weeks
- Not initiate a weight loss diet during the course of study
- Eat out or order take-out no more than five times per week
- Maintain non-smoking status throughout study (if non-smoker)
- Stop using their old loyalty card and use a new one we provide
- Not share new loyalty card with anyone else

Exclusion Criteria:

- Participating in other related research studies
- Plans to leave the area or take a vacation >4 weeks consecutively or more than 6 weeks total within the 56 -week period
- Currently enrolled in a weight loss program
- Engaging in more than 10 hrs of exercise and/or 8 hrs of weight training per week; participating in athletic competitions, marathons, or 'bodybuilding'
- Restrictive eating habits (e.g., vegan, paleo, ketogenic, exclusively organic, gluten free, weight loss diet)
- Having surgery for obesity or taking weight-loss drugs
- Drinks excessively (3 or more drinks per day for men or 2 or more drinks per day for women)
- Change in smoking pattern in the previous 3 months (e.g., quit or began smoking in previous 3 months)
- Currently pregnant or plans to become pregnant within the next year
- Has given birth in the previous 12 months
- Currently breastfeeding or has breastfed in the previous 12 months
- Has a serious medical or psychiatric illness
  - Medical Diagnoses: uncontrolled diabetes, chronic organ failure (heart, lung, kidney, pancreas, etc.), inflammatory conditions (irritable bowel syndrome/disease, chronic malabsorptive diseases), hypertension >140/90 at the Screening Visit, HIV/AIDS, current serious STD, cancer (or < 5 years cancer free), major surgery within the previous 3 years, or other chronic disease which may impact weight status.
  - Psychiatric Diagnoses: severe depression, bipolar disorder, schizophrenia, dementia, eating disorder, or any other psychiatric condition which may impact typical intake of foods/fluids.
- Dependent on or abusing alcohol or other drugs, or not drug-free/sober for at least 6 months
- Currently receiving governmental discounts on fruits/vegetables (i.e., SNAP, WIC)
- Physical disability impacting safety of study procedures/tasks
- Has a chronic disease or takes medications that can put the individual at increased risk for a severe COVID-19 infection

Several exclusions, such as serious disease, change in medications, or use of illicit drugs will help limit confounding influences on body weight and health outcomes. We will recruit weight-stable overweight and obese subjects, a group that generally reports low consumption of F&V. Increasing F&V intake in this overweight group is likely to lead to relatively greater health benefits and possible weight reduction than in those of normal weight, who are more likely to be consuming adequate F&V. The participant should be the main shopper who is already purchasing at least 30% of food at a given Allegiance affiliate supermarkets and is consuming at least 50% of the food purchased. We will include subjects who dine out (or order take-out) for lunch or dinner up to 5 times/wk. The primary food shopper and consumer will be the unit of analysis.

Review of the rate of subject accrual and adherence to inclusion/exclusion criteria will occur bimonthly during the recruitment period. This will assure that participants will meet eligibility criteria and ethnic diversity goals outlined in the grant application.

c) Number of Subjects

We will recruit 360 overweight and obese (BMI 24.5-40) subjects, and estimating a 37.5% dropout rate, this should lead to 225 completers.

d) Study Timelines

The total study period for each subject is 56 weeks. The study will commence with an 8-week baseline followed by a 32-week intervention and a 16-week follow-up period. Participants in the control group will receive a 16-week discount of 30% after they complete the follow up period (weeks 57 through 73).

e) Endpoints

The primary endpoints will be at 40 and 56 weeks of participation. Once participants have started the intervention, data on compliance to the protocol will be collected at each visit by research staff and reviewed quarterly by the PI, the study statistician, and the safety officer. Compliance by participants will be evaluated by reviewing records. Data from subjects who show little or no purchasing during the first 8 weeks will be withdrawn from the study and from the analyses. If any serious issue arises, the study team will contact the individual to try to resolve any problems that exist. If the safety officer has concerns about whether compliance has reached a level that might inhibit the ability of the study to test its primary hypotheses, suggestions will be made for improving compliance.

An annual report will include a list and summary of adverse events. In addition, the annual report will address: (1) whether adverse event rates are consistent with pre-study assumptions, (2) reason for dropouts from the study, (3) whether all participants met entry criteria, (4) whether continuation of the

study is justified in order to collect additional data to accomplish the aims of the study, and (5) whether conditions are such that the study should be terminated prematurely. The annual report will be signed by the Safety Officer and will be forwarded to the IRB and to the NIH. A statement reflecting the results of the review will be sent to the NIH in the annual report (non-competing continuation). The adverse event form will be used by the study staff to report adverse events as they happen. The study statistician, the principal investigator, and the safety officer will review adverse event rates quarterly. Serious adverse events will be reported to the IRB, and if appropriate to NIH.

Significant adverse events (SAEs) that are unanticipated or possibly related to the study intervention will be reported to the Safety Officer and PI as they happen, and to the IRB, and NIH within two weeks. Anticipated SAEs or those unrelated to the study intervention will be reported to the Safety Officer and PI as they happen, and to the IRB and NIH on a monthly basis.

We will monitor adverse effects in all participants; the safety officer, together with the PI, will alert the IRB and the NIH if a larger than reasonably expected adverse rate should occur. Other issues relating to stopping rules for this trial include:

New information

It is unlikely that new information will become available during this study that would necessitate stopping it.

Limits of assumptions

It is possible that excessive study dropouts and/or missing data by interim measurement time points will limit the value of data analysis of measurements. We have allowed for a 20% dropout rate, and a rate higher than 30% would be of concern. The dropout rate will be monitored semiannually.

Limits of rules

We acknowledge that there are other situations that could occur that might warrant stopping the study, which would be included in "Other situations that have occurred since the last safety report that warrant discussion," to allow for communication of concerns to the study PI, statistician, and the safety officer.

f) Procedures Involved in the Human Research

Baseline Period: The 8 week baseline period and preceding pre-baseline period, will give subjects time to adjust to food shopping in one Allegiance affiliated supermarket. We will also monitor protocol compliance and spending level. The average amount spent on food shopping for the home per year per household (average 2.5 persons) for the NYC area is $4066 ±112 SEM [144]. Those not meeting a minimum of $29/wk (~3 SD from the mean), or not reachable by phone for 24-h recalls, will be withdrawn from the study. 24-hour recalls will be obtained by phone calls in between visits. Under-

reporting of energy intake is common, and will be checked by comparing dietary recalls with estimated basal metabolic rates, via prediction equations. Deviations of reported energy intake from expected will be used as a covariate (compliance scale, 1-5) in the analyses.

Intervention Period: After the 8-wk baseline period, we will continue to monitor subjects' purchasing on a bimonthly basis to ensure that the card is being used. Subjects will be encouraged to contact us with any questions or concerns.

Follow-up Period: There will be a confidential exit interview with subjects at the end of the study (wk 56). The interview will follow after the final study payment, if possible, to decrease social desirability bias in responses. The interview will review compliance with the protocol, help detect any previous reporting bias, and obtain feedback about the subjects' experience. (**Appendix H**) (Duration: 10 min)

PROCEDURE

Phone Screening

Potential participants will be recruited at participating Allegiance affiliated supermarkets using flyers and study ads printed on store receipts, or email messages. These materials will include contact information for the study. If a subject calls to express interest in participating in the study, a phone screening (**Appendix A**) will be conducted by the research coordinator or the study team. Alternatively, subjects may be screened by the research team in-person in the supermarket where the potential subject is shopping. This screening will be used to assess preliminary eligibility for the study. During screening, subjects will be asked to self-report their estimated height and weight. Subjects will also be asked to respond to questions relevant to the basic inclusion and exclusion criteria for the study as outlined in section 5b. We are requesting a waiver of signed consent for this phone and in-store screening. If participants report a BMI between 23.5 and 24.5, they will be invited for the screening visit as the likelihood of subjects underestimating their weight and/or overestimating their height is high.

Screening Visit **(Duration: ~20 min)**

An in-person screening will be scheduled for qualified subjects (as evidenced by phone/in-store screening) at Mount Sinai Morningside/St. Luke's Hospital or Quest Diagnostics. Prior to this visit, subjects will fast overnight for a minimum of 12 hours. The written consent may be obtained in-person or virtually using REDCap and a secure hospital Zoom interface. In this instance, participants will be provided a copy of the consent form to download from REDCap and the study will be explained using a HIPAA-compliant Zoom account from the hospital. The participant will be asked to sign the consent form through REDCap. Consent forms may also be signed in person. Study details will be explained to participants followed by a short morning questionnaire. Subjects will then have their height and weight obtained in duplicate and their body temperature measured. Body weight will be assessed on a beam scale and body composition assessed using a Tanita scale based on bioelectrical impedance (BIA). Waist rcumference over light clothing will be obtained in duplicate. Participants will be asked to provide, ther in-person or virtually using REDCap and a secure Zoom interface, information on their past

medical history (Appendix M), and will fill out a Behavioral checklist questionnaire (Appendix D). Next, blood pressure readings will be made in duplicate. Blood will be drawn to screen for unknown diabetes (fasting glucose, HbA1C) and elevated lipid profile (total cholesterol, LDL, HDL, triglycerides). Electrolytes and liver function will also be measured as indicators of general health status. A urine sample will be collected and analyzed using the T-Cup TDOA-1144 14 Panel Urine Drug Screen for drug testing, as well as sent to Quest Diagnostics for female subjects < 55 y.o to confirm their non-pregnant status. The pregnancy test will only be repeated at subsequent study visits if there is unexplained weight gain or upon participant request.

Suicidality Inquiry and Follow-up Procedure

In the event that a subject responds affirmatively ("yes") to screening questions related to suicidality and/or depression, they will be advised by study staff to seek counsel from a licensed psychologist from the Mount Sinai faculty practice trained to address depression and suicidality. In addition, study staff will be required to follow up with the subject twice thereafter – once to confirm an appointment was made and/or try to address any barriers to making an appointment and then again to confirm the subject attended their scheduled appointment with a licensed psychologist.

If subjects qualify based on the Screening Visit, an account will be created for the participant through Allegiance. Subjects will be asked to stop using their current Allegiance affiliated supermarket reward card after they will be provided with a new scan card at the next study visit time (Study Visit 1).

Study Visit 1; wk 0 **(Duration: ~20 min)**

After the results of the blood tests are reviewed, eligible subjects will be asked to come in for study visit 1. Prior to this visit, subjects will fast overnight for a minimum of 12 hours. Body temperature will be taken and a short Morning Questionnaire completed. Participants will also complete a Behavioral checklist (Appendix D), a F&V Liking assessment (Appendix F) as well as an Income questionnaire (Appendix B), either in-person or virtually using REDCap and a secure Zoom interface,. A small blood sample will be drawn and a general blood chemistry panel will be ordered (fasting glucose, protein bound glucose (fructosamine), lipid profile (total cholesterol, LDL, HDL, triglycerides) and CRP). Next, blood pressure readings will be made in duplicate.

Body weight will be assessed on a beam scale and body composition assessed using a Tanita scale based on bioelectrical impedance (BIA).

Subjects will then be instructed on how to complete 24-hour dietary recalls and estimate portion sizes and will complete a Brief Block FFQ on-site as well as a 7 day physical activity recall. At the close of visit 1, subjects will receive an individualized timetable for future study visits, and will agree to receive phone calls for 24-h dietary recalls (3 unannounced phone calls during 1 week in between study visits) and one physical activity recall without being given an exact date.

Subjects will be informed that there will be different discount levels (30, 15, 0%), and that those in the 0% discount group will receive a discount of 30% for 16 weeks after the study, beginning Week 57. The Allegiance-affiliated supermarket reward scan cards provided at visit 1 with be used to track purchases and to activate the discounts during the intervention period.

Study Visit 2-5; wk 8, 24, 40, 56 **(Duration: ~30 min))**
These visits will take place at the hospital or Quest Diagnostics during the final week of each period end-point (wk 8, 24, 40 and 56).

Each one of these visits will be preceded by a 12-hour overnight fast. After completing the morning questionnaire, the nurse will take body temperature, blood pressure readings and draw a blood sample. The same chemistry panel described for visit 1 will be ordered. Body weight and body composition will be assessed as described for visit 1 and a Brief Block FFQ will be completed either in-person or virtually using REDCap and a secure Zoom interface,

Subjects will receive, in paper if they wish, and e-mail format, a summary of foods and beverages available for discount during the study as well as a list of conditions to remain in the study. At each visit, subjects will be asked to present the Allegiance affiliate supermarket tag provided to them for use in the study. Staff will confirm that the number on the tag presented matches the tag number provided at Visit 1.

Finally, subjects will be reminded that in the weeks following these visits they will receive phone calls for 24-h dietary and physical activity recalls, without being given exact dates.

Study visit 2; wk 8 (Duration ~20 min)

In addition to the general chemistry panel, the blood draw will be used to assess carotenoids to reflect F&V intake (only if the participant is not currently taking vitamin A supplements).

At this study visit, they will be informed of their randomization into 1 of 3 discount level groups, stratified by gender within each grocery store. Subjects will receive, in paper, if they wish, and e-mail format, a summary of foods and beverages available for discount during the study as well as a list of conditions to remain in the study. Subjects will be asked to save their receipts if they believe they did not receive the expected discount, to bring to our attention (rather than to store staff or managers) at their next visit for possible reimbursement.

Study Visit 4; wk 40 **(Duration: ~20 min)**

addition to the general chemistry panel described for visit 2-5, the blood draw will be used to assess rotenoids to reflect F&V intake (only if the participant is not currently taking vitamin A supplements).

Study Visit 5; wk 56 **(Duration: ~ 30 min)**

This visit will also include a confidential exit interview, either in-person or virtually using REDCap and a secure Zoom interface, with subjects (**Appendix G**) at the end of the study. The interview will follow after the final study payment, if possible, to decrease social desirability bias in responses. The interview will review compliance with the protocol, help detect any previous reporting bias, and obtain feedback about the subjects' experience (**Appendix H**). Although no deception is used in this protocol, a debriefing session will be used to review the purpose of the study and answer any questions subjects may have. General nutritional information will also be provided.

Measures

Food Purchasing Data: Data will be recorded via the scan cards and transmitted by Allegiance electronically on a secured server. Purchases will be categorized by type, quantity, and price, and separated by study period (baseline, intervention, or follow-up). Gross dollars of discounted F&V will be obtained and further categorized, first by whether fruit or vegetable. Then, fruits will be further categorized as citrus, berries, melons, and lycopene/red (tomatoes, watermelon). Vegetables will be categorized as dark green leafy (kale), red/orange, legumes, starchy (green peas, corn), allicin/bulb (garlic, scallion). These additional subcategories will be considered as secondary outcomes. We will examine non-caloric beverages and categorize by diet sodas and bottled water. We also assess categories of food of high energy density (ED). ED is defined as kilocalories per unit weight (kcal/g). High ED foods tend to have more fat and sugar, e.g., packaged snack foods, whereas low ED foods consist mainly of F&V. There is no definitive consensus on what demarcates low or high ED [137], but a useful benchmark for low ED would be < 1 kcal/g and for high ED would be > 4 kcal/g. We will examine purchasing of food items > 4 kcal/g, including bakery, candies, ice cream, and salty snacks and categorize this data. We will examine purchases of specified high energy foods (including bakery goods) and processed snack foods (incl., confectionaries, salty snacks, ice cream).

24-h Dietary Recalls (NDSR): The 24-hour dietary recalls will be collected using Nutrition Data System for Research (NDSR), a computer-based software application developed at the University of Minnesota Nutrition Coordinating Center (NCC) that facilitates the collection of recalls in a standardized fashion. After all foods are coded and assigned weights, they will be reviewed, edited, and analyzed using the NDSR, which encompasses the USDA Food and Nutrient Database for Dietary Studies (FNDDS). The NDSR contains more than 11,100 food images and can handle the great majority of supermarket processed foods. It is adequate for characterizing intake for between-group comparisons, 3-day recalls will minimize intra-individual day-to-day variability and provide a better estimate of dietary intake. Energy and macronutrient content will be obtained from three NDSR dietary recalls by phone on randomly selected 2 weekdays and 1 weekend day, during the middle of each study period. 24-h recalls are less burdensome than food diaries and less likely to influence eating behavior, as it is without forewarning [151]. The NDSR is a fully computerized, interview-administered, validated, five-

step process. Subjects are guided through the previous 24-h to obtain food and beverage intake in five passes: pass 1 includes a quick list of foods and beverages consumed the previous day; pass 2 includes probe questions for foods forgotten during the quick list; pass 3 sorts foods chronologically and into eating occasions; pass 4 collects more details about the amount, preparation, and additions to the foods consumed; and pass 5 is a final review and probe for anything missed. The five-pass method provides multiple opportunities for subjects to remember and report additional foods and beverages. Special instructions and follow-up questions are incorporated. Subjects will be provided with food and beverage images via NDSR booklet materials to reduce error in estimating amounts. After all foods are coded and assigned weights, they will be reviewed, edited, and analyzed using NDSR which encompasses the USDA Food and Nutrient Database for Dietary Studies (FNDDS) and will provide weighted means for ED, calories, and macro- and micro-nutrient composition. (Duration: 15 min per phone recall)

Dietary Measures: The NDSR contains the great majority of supermarket food items and will provide an estimate of 24-h daily energy intake. For solid foods, we will calculate (g and serving sizes) high ED foods (> 4 kcal/g) and low ED foods (<1 kcal/g), mean energy density, as well as the daily fat content (g), a proxy for high calorie content. We will analyze F&V intake (g), which is the primary outcome measure (used to power the study). From the consumption of high ED foods, we will assess whether increased F&V intake displaces intake of high ED foods. Plasma carotenoids and Vitamin C will be used to corroborate the more subjective measure of 24-h dietary recall. In addition, the Brief Block Food Frequency Questionnaire (FFQ) will be administered to corroborate the dietary assessments.

Physical Activity Measures: Physical activity measures will be collected using the International Physical Activity Questionnaire (IPAQ) Short Last 7 Day Telephone Format. It is an open access questionnaire designed primarily for population surveillance of physical activity among adults. It has been developed and tested for use in adults (age range of 15-69 years). IPAQ assesses physical activity undertaken across a comprehensive set of domains including: leisure time physical activity, domestic and gardening activities, work related physical activity and transport related physical activity. The IPAQ short form asks about three specific types of activity undertaken in the four domains introduced above. The specific types of activity that are assessed are walking, moderate-intensity activities and vigorous-intensity activities. An additional indicator variable of time spent in sedentary activity is also included. Guidelines for Data Processing and Analysis of the IPAQ are available and will be followed. (5 min per phone call)

Phone (or In-Store) Screener: A baseline screener **(Appendix A)** will be used to obtain estimated height and weight and determine if subjects meet the basic eligibility criteria for the study as outlined in section 5b.

Questionnaires and Interview: A brief interview (Morning Questionnaire (**Appendix L**)) and four questionnaires will be completed virtually using REDCap and a secure Zoom interface during or close in time to visit 1- 5 including the Behavioral Checklist **(Appendix D),** Appetite Ratings (**Appendix E**),

Fruit, Vegetable, and Snack Food Liking **(Appendix F)**, and Brief Block Food Frequency Questionnaire (**Appendix J**). The screening visit will include the Morning Questionnaire, Behavioral Checklist (**Appendix D**) and a Medical History Questionnaire (**Appendix M**).

Morning Questionnaire: Consists of two questions to ensure that the participant has fasted for 12h (Duration: < 1 min)

Medical History Questionnaire: will be used at Screening Visit to obtain additional medical history information. (Duration: 10 min)

Income questionnaire (Appendix B) will be used to obtain additional income information. This questionnaire will be emailed only prior to visit 1. (Duration: 5 min)

Behavioral Checklist: A brief structured interview will help ensure adherence, e.g., no change in smoking, diet, medications, etc. Deviations will be controlled for if imbalanced by group. This questionnaire will be completed at or close to the screening visit and during subsequent study visits. (Duration: 10 min)

Appetite Ratings: Visual Analogue Scales (VAS) will be used to rate hunger and satiety (**Appendix E**) on the 5 morning visits. Questions include "How hungry do you feel?", "How full do you feel?", and "How much is your desire to eat?" with anchors for "Extremely" and "Not at all" to help assess whether increases in F&V intake alters appetite. (Duration: 1 min)

Fruit, Vegetable, and Snack Food Liking (**Appendix F**): This measure contains ratings of 5 frequently eaten items from the categories of fruits, vegetables, and snack foods. Food preferences may change after exposure and eating behavior of F&V [160], with increases in F&V liking, which may help sustain the intervention effects. It has been shown that preference increases for previously disliked vegetables after 9-10 taste exposures [161]. Although the majority of this research has been in children, it may also occur in adults [162]. (Duration: 4 min)

Brief Block Food Frequency Questionnaire (FFQ): will be administered to corroborate the 24h-dietary recalls and purchasing data. (Duration: 15 minutes)

Physical Assessments: All anthropometric measures will be made in duplicate at wk 0, 8, 24, 40, 56 on S&R 11 in the patient examining room by trained research technicians blind to the subjects' group assignment. Subjects will be asked to use the bathroom to void and to remove footwear and empty pockets prior to measurement.

1. Height will be measured with a stadiometer (at Screening Visit only)

2. Weight by beam scale digital scale

Body Composition: Lean (fat-free mass) and fat mass will be assessed by:

Bioelectrical Impedance Analysis (BIA) by Tanita scale will be used as a measure of body composition. It provides a measure of % body fat as well as a measure of lean mass.

Blood Pressure (BP): BP will be assessed in a seated position after 20 min of rest, using the BPM-200 automated sphygmomanometer (BpTRU Medical Devices, Coquitlam BC, Canada), which meets or exceeds the Advancement of Medical Instrumentation standards for overall accuracy vs. auscultation. BP with this instrument is accurate within 3 mm Hg or 2%, whichever is greater. (Duration: 5 min)

Fasting Blood Plasma Samples: Biomarkers will be used to confirm 24-hr dietary recalls of F&V intake. F&V intake has been shown to consistently correlate with carotenoids. Blood samples will be collected from a forearm vein in the Clinical Research Unit (CRU). Plasma carotenoid concentrations are sensitive to small changes and to both high and low F&V intake. Additional plasma samples will be assayed for total cholesterol, LDL, HDL, triglycerides, glucose, HbA1C, protein bound glucose, CRP, electrolytes and liver function by Quest Diagnostics. (Duration of blood draw: 5 min)

Specimen Collection

Blood Plasma Samples: Biomarkers will be used to confirm 24-hr dietary recalls of F&V intake. F&V intake has been shown to consistently correlate with carotenoids. Blood samples will be collected from a forearm vein and kept in EDTA-coated tubes in aluminum foil to protect from light. The samples will be centrifuged at 4°C to obtain plasma and kept in labeled cryomicrotubes at -80°C until assayed. Otherwise they will not be stored further. Carotenoids (lutein, zeaxanthin, alpha-carotene, beta-carotene, beta-cryptoxanthin, trans-lycopene, cis-lycopenes) will be assayed at the Carotenoids and Health Laboratory, USDA-Human Nutrition Research Center on Aging, Tufts Univ. Carotenoids will be measured by high-performance liquid chromatography (HPLC) with a C30 column from plasma that has been extracted with CHCl3:CH3OH (2:1, v/v) and hexane. Age, gender, dietary fat intake, vitamin supplement intake, and BMI will be used as covariates for the analyses.

Data Management and Confidentiality

Purchasing data will be collected via supermarket scan-card technology by Allegiance and sent to the research team over a secured server. Other data will be collected at assessment visits. Blood samples will be collected and analyzed by the Tufts Carotenoids and Health Laboratory for plasma carotenoids levels. Other blood samples will be analyzed by a commercial laboratory (Quest Lab) for cholesterol (LDL and HDL), glucose, CRP, HbA1C, and triglycerides. Personal information and data will be obtained from questionnaires and clinical interviews, dietary intake records, and psychological scales. These data will be used to evaluate the effectiveness of the interventions. The information will be used for research purposes only, and will be stored in a secure place at the hospital. It will be kept strictly

confidential, and a person's identity will not be revealed when the data are published. Upon participant request, samples for measurement in the lab will be de-identified using a pseudonym prior to submission to Quest Diagnostics.

All data collected will be kept in strict confidence. No information will be given to anyone without permission from the participant. With participant permission in the informed consent, the participant's PCP may be contacted if the participant lab results are concerning. The PCP will receive a copy of the participant's lab results for further follow-up. We will also send a copy of the signed consent form to Allegiance.

Confidentiality will be assured by use of coded data, whether generated in the supermarket or in the hospital, with a randomly generated code number unique to the participant. The database will be secured with password protection. The data manager will receive only coded information to be entered into the database under those codes. Electronic communication with outside collaborators will involve only coded, unidentifiable information. AE reports and annual summaries will not include subject-identifiable material and will use only coded identification numbers.

Locked file cabinets will be used to store subjects' folders. The study team will review new data for completeness and accuracy, enter the data into a password-protected network database, and double-check the data. Subjects with missing data will be contacted as soon as possible. The data analyst will supervise data management, implement protocols for missing data, and conduct preliminary data analyses.

Provisions to Monitor the Data to Ensure the Safety of Subjects

Part I: Elements of a Data and Safety Monitoring Plan
MSSM Principal Monitor: Jeanine Albu, MD
Indicate whether this person is the PI, a Team Member, or is Independent: Independent
Last Name: Albu
First Name: Jeanine
Academic Title: Professor, Division of Endocrinology MSSL Department: Medicine
Mailing Address: MSSL Clark 4th flr
Phone: **212) 523-4120**
Fax: ***N/A***
E-mail: Jeanine Albu @mountsinai,org

MSSM Additional Monitor: **N/A**

The safety officer for this trial, Jeanine Albu, is Professor of Medicine in the Division of Endocrinology at MSSL. Dr. Albu has experience conducting clinical research studies and has a good understanding of obesity research. She will review the reports sent by the research coordinator at the frequency outlined above and will use the checklist attached to this document to determine whether there is any corrective action, trigger of an ad hoc review or stopping rule that should be communicated to the PI, the hospital IRB, and the NIH. In addition, the safety officer may indicate whether the study investigator should report any specific out-of-range laboratory data to the participants and their physician.

3. List the specific items that will be monitored for safety (e.g., adverse events, subject compliance with the protocol, drop outs, etc.).

- Subject accrual, adherence to inclusion/exclusion criteria
- Adverse events
- Participant compliance to treatment protocol

*4. Indicate the frequency at which **ACCUMULATED** safety and data information (items listed in number 3 above and interim analysis of efficacy outcomes) will be reviewed by the monitor(s) or the Data Monitoring Committee (DMC). Although this information must be reviewed at least annually, the higher the study risks, the more frequently reviews must be scheduled.*

Measurement and reporting of subject accrual, adherence to inclusion/exclusion criteria

Review of the rate of subject accrual and adherence to inclusion/exclusion criteria will occur bimonthly during the recruitment period. This will assure that participants will meet eligibility criteria and ethnic diversity goals outlined in the grant application.

Reporting of adverse events

SAEs that are unanticipated or possibly related to the study intervention will be reported to the Safety Officer and PI as they happen, and to the IRB and NIH within two weeks. Anticipated SAEs or those unrelated to the study intervention will be reported to the Safety Officer and PI as they happen, and to the IRB and NIH on a monthly basis.

An annual report will include a list and summary of adverse events. In addition, the annual report will address:
(1) whether adverse event rates are consistent with pre-study assumptions, (2) reason for dropouts from the study, (3) whether all participants met entry criteria, (4) whether continuation of the study is justified in order to collect additional data to accomplish the aims of the study, and (5) whether conditions are such that the study should be terminated prematurely. The annual report will be signed by the Safety Officer and will be forwarded to the IRB and the NIH. A statement reflecting the results of the review will be sent to the NIH in the annual report (non-

competing continuation). The adverse event form will be used by the study staff to report adverse events as they happen. The study statistician, the principal investigator, and the safety officer will review adverse event rates bimonthly. Serious adverse events will be reported to the IRB, and the NIH.

5. Where applicable, describe rules which will guide interruption or alteration of the study design.

We will monitor adverse effects in all participants; and the safety officer, together with the PI, will alert the IRB and the NIH if a larger than reasonably expected adverse rate should occur. Other issues relating to stopping rules for this trial include:

- **New information**
  It is unlikely that new information will become available during this study that would necessitate stopping it
- **Limits of assumptions**
  It is possible that excessive study dropouts and/or missing data by interim measurement time points will limit the value of data analysis of measurements. We have allowed for a 37.5% drop out rate, and a rate higher than 47.5% would be of concern. The dropout rate will be monitored semiannually.
- **Limits of rules**
  We acknowledge that there are other situations that could occur that might warrant stopping the study, which would be included in "Other situations that have occurred since the last safety report that warrant discussion," to allow for communication of concerns to the study PI, statistician, and the safety officer.

6. Where applicable, indicate dose selection procedures that will be used to minimize toxicity.
N/A

7. List any specialized grading system that will be used to evaluate adverse events (e.g., National Cancer Institute Common Toxicity Criteria).

The following definitions will be used to grade adverse events:
An adverse event (AE) is defined here as any untoward medical occurrence that is temporally associated with participation in the clinical study. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.) or any combination of these. A serious adverse event (SAE) is any adverse event that results in one or more of the following outcomes: death, life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity, congenital anomaly or birth defect, significant medical event based on clinical judgment. AE

severity will be graded by severity (mild, moderate, or severe) depending on the intensity of the event for the participant. An AE will be termed 'mild' if it does not have a major impact on the participant, 'moderate' if it causes the participant some minor inconvenience and 'severe' if it causes a substantial disruption to the participant's well-being. A participant can have a severe event that is not a SAE and a moderate event that meets the SAE definition. AE's will also be categorized according to the likelihood that they are related to the study intervention as: definitely, probably, possibly, or unrelated to the study intervention.

8. Describe procedures that will be used to assure data accuracy and completeness.
Purchasing data is automatically saved via scan-card technology: therefore very few, if any, errors should occur. All data collected will be imported to SPSS for analyses and double-checked to minimize data entry errors. Range checks will be applied to all data entered, and out-of-range values will be compared with original data forms.

9. Should a temporary or permanent suspension of your study occur, in addition to the PPHS, indicate to whom (NIH, FDA, sponsor, IRB) will you report the occurrence.

NIH

Part II. Data Monitoring Committee/Data Safety Monitoring Board (DMC/DSMB)

N/A

6) Withdrawal of Subjects

Data from subjects who show little or no purchasing for 8 weeks will be dropped from the study. Otherwise, no pressure will be exerted on the subjects to participate, and they have the right to withdraw from the study at any time. Once an issue is identified, subjects will be contacted by the research team. If there is not resolution of the issue within the following week, the subject will be removed (dropped) from the study, and their discounted card (when applicable) will be deactivated. Data will be analyzed for participants with complete data sets up through Study Visit 3 (week 24). Participants with fewer data points due to drop-out will not be included in analyses.

7) Risks to Subjects

The risks involved in this study are minor. Minimal risks in this study include bruising, more rarely inflammation or infection, and fainting during the blood draws. One might expect one such episode of bruising or fainting once per ten blood draws. An adverse event rate exceeding once per five blood draws will be reported to the IRB and the NIH.

All subjects will be made aware that their food purchasing in the supermarket will be tracked.

In light of the global pandemic, participants are at risk of contracting COVID-19 infections when visiting the clinical research unit facility. According to the CDC website, there is an additional risk of severe COVID-19 infections for individuals who:

- Are 65 years and older
- Live in a nursing home or long-term care facility
- Have underlying medical conditions, particularly if not well controlled, including:
  - Chronic lung disease or moderate to severe asthma
  - Serious heart conditions
  - The immunocompromised (cancer treatment, smoking, bone marrow transplant or whole organ transplantation, immune deficiencies, poorly controlled HIV/AIDS and prolonged use of corticosteroids and other immune-weakening medications)
- People with severe obesity (BMI ≥ 40.0 kg/m2)
- People with diabetes
- People with chronic kidney disease undergoing dialysis
- People with liver disease

In line with these guidelines, we have created a COVID-19 High Risk Screening Tool to track each potential participant's risk for severe illness from COVID-19 infection. Those with 2 or more risk factors will not be recruited for participation at this time.

8) Provisions for Research Related Harm/Injury

We do not anticipate participants needing any medical or psychological resources as a result of an adverse event associated with this study. But, participants will receive a referral for treatment at the end of the study (if indicated) as well as any requested health information.

9) Potential Benefits to Subjects

Increasing F&V intake in this overweight group is likely to lead to relatively greater health benefits and possible weight reduction than in those of normal weight, who are more likely to be

consuming adequate F&V. All subjects will also receive a brief nutritional counseling session at end with recommendations and education regarding the benefit of increasing F&V intake in their daily diet. Participants will receive discounts on fruits, vegetables and non-caloric sodas.

A direct benefit would be the nutritional session at end of the study and referral for treatment (if appropriate) as well as the health information provided to the subjects. Participants will be monetarily compensated for their participation. Those subjects may lose weight. Participants may benefit from increased awareness of health factors related to foods that might improve their ability to control their weight in the future. Thus, it is possible that the proposed study will enhance the well-being of the subjects. The potential benefit to the field of obesity intervention and prevention outweighs the risks posed to subjects in this study.

10) Provisions to Protect the Privacy Interests of Subjects

All experimental procedures will be explained and questions answered. The risks and benefits of participation will be described before obtaining a signed IRB-approved informed consent form. No pressure will be exerted on the subjects to participate. Minor concerns raised by subjects (e.g., embarrassment about reporting body weight) will be addressed by research staff. Efforts will be made to ensure that visits to the Clinical Research Unit (CRU) at the Endocrinology Division or at Quest Diagnostics are as comfortable as possible for participants. Research staff members will be HIPAA-sensitive when communicating with participants in person, over the phone, and over email, ensuring that protected health information (PHI) is only communicated with the participant themselves or other parties whom the subject has granted consent to share information with. Research staff will approach all shoppers at grocery stores to participate, as all shoppers would benefit from increased fruit and vegetable consumption. Subjects will also have the opportunity to express interest to research staff.

11) Economic Impact on Subjects

4

12) Payments to Subjects

Subjects will be compensated by check: $50 for the screening visit, $85 for each of the following five study visits, with a $100 bonus for study completion, for a possible total of $575. The check will also include compensation for mass transit travel (projected value: $5.50) to and from the hospital. Subjects whose travel by public transportation might exceed 30 min will be given check reimbursement for taxis. These moderate incentives remunerate subjects for time and travel for assessment visits (and not for the initial supermarket visit), and are the same across groups. Thus, the remuneration is unlikely to influence the study outcome and should not reduce the

generalizability of the findings to everyday shopping behavior, food intake, body weight, and metabolic risk factors.

13) Consent Process

- *If you will be following "SOP HRP-090 Informed Consent Process for Research", after addressing the points above, indicate this. Otherwise, also describe:*
    - *The role of the individuals listed in the application as being involved in the consent process.*
    - *The time that will be devoted to the consent discussion.*
    - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
    - *Steps that will be taken to ensure the subjects' understanding.*
    - *Describe any tools that will be utilized during the consent process*

Waiver or Alteration of the Consent Process

If the Human Research involves a request for a waiver or alteration of the consent process, review the "CHECKLIST HRP-415 Criteria for Waiver or Alteration of the Consent Process" and make sure your submission provides adequate information for the IRB to assess the criteria for approval. It is highly recommended that you provide additional information here to address each of the criteria for approval (e.g. impracticability).

Informed consent will be obtained by the study team after the study is explained and all questions answered. Approximately 25 minutes will be devoted to the consent discussion. The informed consent form will have first been approved by the IRB at the Icahn School of Medicine at Mount Sinai. No vulnerable populations will be included in this study.

The risks and benefits of participation will be described before obtaining a signed IRB-approved informed-consent form. No pressure will be exerted on the subjects to participate.

14) Process to Document Consent in Writing

This section always applies. Describe whether and how consent of the subject will be documented in writing. If using the standard PPHS consent template, simply indicate this.

If you are requesting a waiver of documentation of consent (consent will be obtained but the subject or representative will not sign a consent document) review the "CHECKLIST HRP-416

Criteria for Waiver of Written Documentation of Consent" and address each of the criteria for approval. Describe whether you will be using a consent document without a signature page, some other kind of script, etc.

Note: If HIPAA applies, the HIPAA regulations regarding documentation are stricter and may require that a signature be obtained. In most cases, the use of the combined consent/HIPAA authorization is most appropriate and so the waiver request may not be granted for consent if it will be required for HIPAA.

The standard IRB consent template will be used to document subject consent in writing either in-person or virtually on REDCap using a secure Zoom interface.

15) Vulnerable Populations

Indicate specifically whether you will include (target) or exclude each of the following populations:

Include	*Exclude*	*Vulnerable Population Type*
	x	*Adults unable to consent*
	x	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	x	*Wards of the State (e.g. foster children)*
	x	*Pregnant women*
	x	*Prisoners*

N/A

16) Multi-Site Human Research (Coordinating Center)

N/A

17) Community-Based Participatory Research

N/A

18) Sharing of Results with Subjects

One of the ways we will disseminate study results will be through the Columbia Community

Partnership for Health (CCPH) site. Allegiance affiliated supermarket' owners and staff as well as merchants from the Greater Harlem community and subjects will be invited to hear presentations of the findings. The site is funded by the Community Engagement Core Resource (CECR) at the Irving Institute for Clinical and Translational Research.

If during the Screening Visit or any of the subsequent Study Visits one of the subjects' questionnaire responses, biochemical data points, or physical assessments indicates an increased risk for disease from baseline (or previously absent disease with higher risk at baseline), then the subject will be encouraged to speak with their primary care physician. The research team will make these data available to the PCP.

19) External IRB Review History

N/A

20) Control of Drugs, Biologics, or Devices

N/A