Protocol Title: USING THE FOODIMAGE™ APP TO ASSESS SMART INTERVENTIONS DESIGNED TO IMPROVE NUTRITION & REDUCE FOOD WASTE

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IRB Review History

This is a subcontract project with Ohio State University as the lead institution and Pennington Biomedical Research Center (PBRC), part of the Louisiana State University system, as the subcontractor who will conduct the human subjects research. PBRC will pursue the research outlined herein and share the resulting data with Dr. Roe at OSU and Dr. Qi at LSU.

Objectives

Long-term Goals and Specific Objectives

Our *long-term goal* is to simultaneously improve global sustainability, enhance national food security, and improve U.S. productivity through improved nutritional intake while improving the competitiveness of the U.S. food system by reducing U.S. household food waste. To reduce household food waste and improve individual nutrition, we leverage the FoodImage™ smartphone app [1], a novel method for measuring household food acquisition, food intake, and food waste decisions, to assess the efficacy of a smart intervention that targets food waste reduction and diet quality improvement. The intervention is designed to improve nutrition by offsetting intake of less nutritious foods with increased fresh fruit and vegetable (FV) intake while simultaneously reducing household food waste via strategies tailored to participating households.

Specific objectives include using the FoodImage app in a randomized controlled trial (RCT), in which we will use the data collected to:

Enroll and Baseline Data Collection	N=46	
Randomly Assign within Matched Pairs	Control (N=23)	Treatment (N=23)
Info on Benefits of FV Consumption	No	Yes
Provision of Free FV Box	Yes	Yes
Intervention	Stress Management	Food Waste Reduction + Replace Less Healthy Foods with FV

We will use the data collected to:

(1) *Test the effects of free FV provision on:* (a) household food waste levels (mass/grams and energy/kilocalories), (b) total FV acquisition (free FV provision plus purchases post-intervention vs. pre-intervention FV purchases), and (c) the consumption of FV (Food Patterns Equivalents Database, FPED). We hypothesize that free FV provision will increase food waste, total FV acquisition, and diet quality (increase the Healthy Eating Index [HEI]). We will test these hypotheses by comparing baseline and follow-up data from participants randomly assigned to the control condition, which features free FV provision and a placebo (stress management) intervention not focused on food waste. Exploratory analyses will examine the effects on dietary energy intake and if the freely provided FV replace non-FV foods in the baseline diet.

(2) Test if a smart intervention to reduce food waste and replace less healthy foods with FV significantly reduces post-intervention food waste compared to the control group while increasing FV acquisition and consumption compared to pre-intervention baseline. We hypothesize that this smart intervention will increase total FV acquisition and FV consumption compared to baseline, and these increases are not expected to differ significantly from control. It is further hypothesized that those receiving the smart intervention will significantly reduce food waste compared to controls. Exploratory analyses will examine the extent to which the smart intervention had the intended effect of replacing less healthy foods with FV consumption.

Background

The most recent Dietary Guidelines (Dietary Guidelines Advisory Committee 2015; at time of grant submission) [2] recommend a dietary pattern featuring greater consumption of FV to reduce the risk of cardiovascular disease, type-2 diabetes, some cancers, and obesity, whose prevention would yield numerous health and economic benefits [3]. Despite extensive public messaging and well-documented evidence of health and economic benefits, only about 10% of Americans eat the recommended amounts of FV [4] with the high cost of FV identified as one barrier to increasing FV intake [5 6].

Given that FV are the most wasted food category and that FV subsidies have regularly been shown to increase FV expenditures but not consistently been shown to increase FV intake [7 8], additional research is needed to:

- Assess whether FV subsidies are efficiently translating program dollars into improved nutrition rather than into increased FV waste and

- Develop interventions that ensure funds targeted to increase household FV acquisition are efficiently translated into improved diet quality.

The assembled investigative team has undertaken key activities that support our objectives. First, the team has used past USDA funding (2017-6702326268) to create and validate FoodImage, a smartphone application (app, available at the Apple App Store) that assists users in collecting and sending data about food acquisition and intake behaviors, including food waste data [1]. The FoodImage app collects data for eating, shopping, food preparation (prep), and refrigerator/cabinet clean-out (toss) occasions. For each of these occasions, a photo and description is included along with supplemental information, including how or why an item is being thrown away and how

that item is being disposed of (e.g., sink disposal, compost, landfill, fed to a pet, etc.). This data is packaged and sent by the FoodImage app to Pennington Biomedical Research Center's secure server for analysis.

The FoodImage app quantifies and efficiently captures the stream of food through a household, from purchase, through prep and eating occasions, to when food is ultimately tossed/discarded. This streamlined 'all-in-one' platform for data collection allows our team to collect and quantify household level waste while minimizing participant burden and leveraging the advantages of approaches that rely on food photography [9 10]. All data collected by the FoodImage app are securely transferred to PBRC's servers for analysis using existing methodology [9 10], which analyzes food images and estimates the quantity, energy, and nutrient content of food consumed and wasted, including delineation of the edible and inedible food waste proportions.

Finally, the FoodImage app, and its data collection methodology, integrates customizable notifications and reminders to remotely prompt participants to record data, resolve data collection problems, etc. These notifications and reminders utilize Ecological Momentary Assessment (EMA) methodology [11] to maximize data collection protocol adherence by reminding participants to capture and send food information at relevant times. This notification functionality of FoodImage can also be leveraged to communicate information about ongoing interventions and can facilitate adherence to dietary changes and strategies to reduce food waste.

Increasing household FV consumption while reducing food waste requires behavior to change in two overlapping domains, each of which has been the focus of considerable work [7 12]. Current efforts to change household level behavior are often compartmentalized, focusing either on increasing FV consumption or reducing food waste, but not on the behaviors together. In doing so, existing interventions fail to consider the linkages between behaviors that occur in households and may affect positive change in one domain with negative or neutral impacts on the other domain (e.g., increase FV consumption but increase food waste or reducing food waste by limiting fresh FV consumption). Hence, it is essential to articulate any unintended consequences that existing programs present across these two domains and create interventions that simultaneously promote behavior change that advance both goals.

Methods

Study Design

We will conduct a randomized controlled trial (RCT) featuring two groups that both receive free boxes of FV. The box of fresh FV will contain about 40% fruit and 60% vegetables and be sufficient to meet 60 ±5% of the household's FV needs as recommended by USDA's MyPlate. The amount of FV provision will scale in proportion to the size of the household as is done with SNAP benefits (as noted earlier, it is estimated that ~20% of participants will actually be eligible for SNAP). The groups differ in the intervention provided, with the treatment group receiving a smart intervention to reduce food waste and replace consumption of less healthy foods with FV and the control group receiving an intensity-matched intervention focused on an unrelated topic (stress management).

Participants

A sample of up to 46 participants from the Baton Rouge, LA area will be enrolled. Due to the prolonged baseline assessment, enrollment is defined as having successfully completed the baseline assessments and having been randomized. Thus, more than 46 participants may begin the baseline period. We will enroll 46 participants. We anticipate ~10% attrition post-enrollment for about 20-21 completers per group and we are adequately powered with anticipated attrition.

Inclusion and Exclusion Criteria

- Inclusion criteria include:
  - Male or female, age 18-62 years
  - Body mass index (BMI) 18.5 – 50 kg/m^2, based on self-reported height and weight
  - Ownership of an iPhone, which the participant is willing to use for the study
  - Access to Apple ID, password, and email address and willing to use them in the course of the study
  - Performs a majority of household food shopping and preparation
  - If children are present in household, all children are between 6-18 years
  - Able to meet the schedule demands for the study

- Exclusion criteria include:
  - Not able to use an iPhone
  - Refusal or unable to use the smartphone app to collect data in free-living conditions
  - Households that purchase groceries less than 1 time per week
  - More than 2 children living in the household
  - Pennington Biomedical Research Center employee
  - Unwilling to sign consent to use web screener questions for data set and analysis.

Recruitment

Participant recruitment will be completed by Pennington Biomedical's recruitment core. Because most FV subsidy policies and programs target populations receiving SNAP, we will include recruitment at local food pantries to ensure an oversampling of participants who are likely SNAP eligible or recipients (target ~20% of participants). During the recruitment Web Screener, we will ask the participants the following 6 Food Insecurity screening questions:

1. In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money for food?
2. In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?

3. In the last 12 months, did you ever cut the size of your meals or skip meals because there wasn't enough money for food?
4. In the last 12 months have you or other members of your household made a statement like, "The food that I bought just didn't last, and I didn't have money to get more."
5. In the last 12 months have you or other members of your household made a statement like, "I couldn't afford to eat balanced meals."

If our 20% SNAP eligibility benchmark is not on target to be met, these questions will become a screening requirement to increase the likelihood of enrolling SNAP eligible participants. Data from web screener questions will be used for data analysis.

Procedures

Prior to enrollment, participants will respond to recruitment, qualify for the study, and schedule a phone call with study staff. The purpose of the phone call with study staff is to ensure that the study is a good fit for the participant in regard to inclusion/ exclusion criteria, participant schedule, and other factors that may affect participant ability to complete the study and collect necessary data.

At Visit 1, participants will come to PBRC and will provide informed consent. Post consent, the participant's height, weight, and BMI will be measured and recorded. Participants will install and learn how to use the FoodImage app. They will complete a baseline questionnaire including questions about demographics, SNAP eligibility, and socioeconomic variables. They will also complete a Household Needs Survey to obtain the height, age, activity level and weight of household members as well as any allergies, intolerances, and food related restrictions in the household. They will also complete a Fruit and Vegetable Preference Survey (FV Preference Survey) to let researchers know which fruits and vegetables can be included in each household's box. If the participant begins to express fatigue or the PBRC employing preforming the visit deems it necessary, the surveys can be sent to the participant via email through REDCap [13]. Participants should complete the surveys within 24 hours of Visit 1 and a PBRC employee will follow-up with the participant if the surveys are not completed during this time. If a mistake is made or questions are unintentionally omitted, a PBRC employee will call the participant within 24 hours to collect the remaining data and/or participants will fill out surveys at Visit 2. Participants will also receive instruction on how to conduct a fridge and cabinet cleanout and how to conduct a household Fruit Vegetable inventory. Following Visit 1, participants will collect data in a free-living environment over the course of approximately 1 week. To prepare for home data collection, participants will be asked to clean out their fridge, freezer and cabinets of any items that need to be discarded. After the cleanout is conducted, the participant will complete a video home inventory of all fruits and vegetables including fresh, frozen, & those otherwise preserved. This fruit and vegetable inventory will be conducted via a Microsoft Teams video call with a study staff member. This video call will be recorded and stored for data analysis purposes. During the call, the participant will perform the home Fruit and Vegetable Inventory guided by the study staff member; the study staff member will ask probing questions to ensure all fruits and vegetables have been show. Following the

call, the study staff member will complete data entry for the fruits and vegetables inventoried on the call. Participants will also complete baseline data collection using the FoodImage app to record food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss) for approximately 3 (24 hour) days; ideally including 1 weekend date.

At Visit 2, participants will be randomized, as described in the analysis section, to one of two groups: A Food Waste & Substitution Group (Treatment Group) or a Stress Management Group (Control Group). Both Groups will receive their first fruit and vegetable box, will complete a lifestyle interview, and will receive their first group specific intervention visit.

Participants in the **treatment group** will meet individually with a trained coach who presents a set of materials that includes an introduction of food waste, ways that food waste can be reduced over time, and how to increase FV consumption by replacing consumption of less healthy foods with FV. The coach and participant then discuss the participant's lifestyle, including things like typical eating, shopping, prepping, storage, and meal habits. They also may discuss things like the number of people in the household, number of shopping trips, meal planning (or lack thereof), etc. The coach and participant will then tailor actions to most effectively reduce food waste and increase FV intake. In ensuing sessions, steps are made to follow up on plans and to introduce new plans to reduce food waste and increase fruit and vegetable intake. Between these in-person sessions, the interventionist will check in with the participant to follow-up on their progress. These check-ins can occur via phone, video chat, etc. To identify ways in which such interventions can be improved and to facilitate intervention fidelity and internal validity, some sessions with participants will be recorded. These recordings will be reviewed by the study team, namely Drs. Martin, Apolzan, and Roe.

During the first session, the coach and participant review the Survival TIPPS (Thriftiness, Inventory, Plan, Prepare, and Store). The coach and participant use specific goal setting techniques to make a plan that reduces food waste and increase FV intake in the immediate future (i.e., daily in the next week). The coach and participant will collaborate to find a technique that the participant finds logistically and financially feasible and efficacious (high self-efficacy) with coach support. Specific goal setting techniques such as SMART (Specific, Measurable, Attainable, Reward, Timebound) goals will be tailored to ensure that the participant has a concrete idea of what to do to enact the plan in their daily life. The participant then receives regular (e.g., three to four per week) semi-structured tips via text, email or call (based on participant preference); these will be modified based on gathered data and delivered to assist the participant in following through with plans to reduce food waste. A mid-week check-in will also be performed in between study visits.

Similar to the treatment group, the **control group** will receive free FV boxes weekly and will meet with a trained coach who will present materials and coaching pertaining to stress management. To identify ways in which such studies can be improved and to facilitate intervention fidelity and internal validity, some sessions with participants will be recorded. These recordings will be reviewed by the study team, namely Drs. Martin, Apolzan, and Roe.

The control group's intervention will be intensity matched to the treatment group. Intensity matching will be achieved by matching: the number of intervention sessions, the structure of the intervention, amount of amount of content in intervention sessions, intervention use of SMART goal setting, session length, number and type of follow up contacts. These intensity matching outcomes will be tracked by coaches via excel tracking and treatment notes to ensure treatment and control group participants receive a time and intensity matched intervention.

Following randomization, coaches will check in with participants in the above outlined intensity matched fashion and participants in both groups will continue interactions with their coach on their respective interventions and will use the Food Image app to record food acquisition (Shop) and food waste from storage clean outs (Toss).

Participants will return weekly for Visits 3 & 4 where they will receive FV boxes and will continue with intervention.

Fruit and vegetables for visits 2-4 will be procured on Tuesday afternoons. Ideally the participants will come in on Wednesdays to pick up their box and receive intervention. If needed, the participants can come to the center on Thursday to receive their box and intervention. In extenuating circumstances, the box and intervention may be delivered at the participant's home. If none of the previous options work, the participant may receive their box or intervention on Friday, but the fruit and vegetables will need to be checked for deterioration and replaced as needed.

In the week following Visit 4 participants will continue intervention, consume their last box of fruit and veg, and will collect their follow up time point of data collection where they will use the FoodImage app to record food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss) for approximately 3 (24 hour) days; ideally including 1 weekend date.

The day before Visit 5, the participant will again complete a video home inventory of all fruits and vegetables including fresh, frozen, & those otherwise preserved. This fruit and vegetable inventory will be conducted via a Microsoft Teams video call with a study staff member. This video call will be recorded and stored for data analysis purposes. During the call, the participant will perform the home Fruit and Vegetable Inventory guided by the study staff member; the study staff member will ask probing questions to ensure all fruits and vegetables have been show. Following the call, the study staff member will complete data entry for the fruits and vegetables inventoried on the call.
At Visit 5, participants will complete either the Food Waste Exit Survey or the Stress Management Exit Survey, based on their randomized group and a final height, weight and BMI will be measured.

Schedule of Procedures

Figure 1: The schedule of procedures is outlined below:

<table>
<tr><th>Study Day</th><th>Visit & Timing</th><th colspan="2">Participant Activity</th></tr>
<tr><td>Prior to D -15*</td><td></td><td colspan="2">Respond to recruitment, qualify for study and schedule study staff phone call.</td></tr>
<tr><td>-15*</td><td>Study Call
(~0.5 hours)</td><td colspan="2">Call with study staff to determine if study is a good fit.</td></tr>
<tr><td>-8*</td><td>Visit 1
(~3 hours)</td><td colspan="2">Attend training @ PBRC to:
• Provide informed consent.
• Measure height weight and BMI.
• Complete Baseline Survey (demographics, including SNAP eligibility assessment, socioeconomic variables), FV Preferences Survey, and Household Needs Survey (self-reported demographics, allergies, intolerances, and restrictions for household members). If desired or deemed necessary by the participant or the PBRC employee conducting the lab visit, surveys may be done after the appointment via REDCap.
• Learn how to conduct household FV inventory.
• Install and learn how to use the FoodImage app.</td></tr>
<tr><td>-8*</td><td>Day of* V1</td><td colspan="2">Conduct a video home inventory of all Fruits & Vegetables (fresh, frozen, or otherwise preserved) via Microsoft Teams Call with study staff member.</td></tr>
<tr><td>-7 - -1*</td><td>Week* following V1</td><td colspan="2">Baseline Data Collection
Use FoodImage to record food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss).
• For approximately 3 (24 hour) days (ideally including 1 weekend date) use FoodImage to record all food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss).</td></tr>
<tr><td rowspan="2">0</td><td rowspan="2">Visit 2
~ +7* days from V1
(~ 3 hours)</td><td colspan="2">Randomization within matched pairs to one of two groups:</td></tr>
<tr><td>Treatment Group
Food Waste & Substitution
• Receive fruit and vegetable box.
• Lifestyle Interview
• Begin Intervention</td><td>Control Group
Stress Management
• Receive fruit and vegetable box.
• Lifestyle Interview
• Begin Intervention</td></tr>
<tr><td>0-7*</td><td>Week* following V2</td><td colspan="2">Interventionist will check in with ppt goals and will send group specific nudges via participant’s preferred form of communication between V2 and V3.</td></tr>
</table>

0-35*	Ongoing until end of study	Use FoodImage to record food acquisition (Shop) & food waste from storage clean outs (Toss); continue interacting with PBRC staff on respective interventions.
8*	**Visit 3** *~ +7* days from V2* (~ 2 hours)	Visit PBRC to receive free box of FV and receive follow up intervention/reinforcement.
8-15*	Week* following V3	Interventionist will check in with ppt goals and will send group specific nudges via participant's preferred form of communication between V3 and V4.
16*	**Visit 4** *~ +7* days from V3* (~ 2 hours)	Visit PBRC to receive free box of FV and receive follow up intervention/reinforcement.
16-23*	Week* following V4	Interventionist will check in with ppt goals and will send group specific nudges via participant's preferred form of communication between V4 and V5.
16-23*	Week* following V4	**Follow Up Data Collection** Use FoodImage to record food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss). • For approximately 3 (24 hour) days (ideally including 1 weekend date) use FoodImage to record all food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss).
24*	Day before* V5	Conduct a home inventory of all Fruits & Vegetables (fresh, frozen, or otherwise preserved) via Microsoft Teams Call with a study staff member.
25*	**Visit 5** *~ +7* days from V4* (~ 1 hour)	Visit PBRC to: • Complete exit survey and review ending home Fruit & Vegetable inventory. • Measure Height, Weight &BMI.

*All Study Days and Visit Timing are approximate. The exact day of a study procedure or appointment may vary slightly due to changes in subject or research facility schedule.

Analysis

Data from the FoodImage app will be prepared for analysis using methods detailed in Roe et al. (2020) [1]. Briefly, images captured through the app are viewed by PBRC's nutrition staff who identify nutrient matches using Standard Reference (SR) 28 and the Food and Nutrient Database for Dietary Studies (FNDDS) 6.0 [14] (USDA 2020b) [15] and estimate the mass of portions of food acquired, prepared, selected, consumed, returned, and discarded at each stage. Specifically, we will obtain mass (grams), energy (kilocalories), and macronutrients for shop, prep, eat, and toss occasions. The SR database provides inedible percentages. Furthermore, for all foods except raw meats where the SR database is used, we will obtain highly granular data. The FNDDS database translates whole food items into FPED values which converts each consumed food and beverage into the 37 USDA Food Patterns components [16]. The FPED values are used to assist in the quantification of diet quality (HEI) and to guide healthy food intake patterns (e.g., the 'five a day' campaign to promote FV consumption). The Food Patterns are measured as cup equivalents for fruits and vegetables. Thus, we can examine the number of servings of fruits, vegetables, dairy, grains, and proteins (each of the food groups) consumed. Also, we will examine diet quality in relation to the USDA Dietary Guidelines for Americans with the HEI [17]. During the two ≥3-day intensive collection windows, participants record the source, reason and destination of all food waste on the app, which is attached to each data point. Receipts associated with food acquisition, which are collected for all 28 days, are processed via Optical Character Reader (OCR) with resulting price data checked for accuracy by human raters.

The method proposed by Pocock and Simon [18] will be used for intervention assignment to minimize imbalance among factors that might be associated with outcomes of interest. Specifically, randomization will be adaptive according to the values of the Aitchison distance calculated using the following prioritized drivers of FV consumption and food waste: 1) the presence of children in the home vs. no children, 2) SNAP eligibility vs. being ineligible, and 3) the presence of a fruit tree and or garden at the home vs. the absence of these amenities. Greevy et al. [19]the sample size required for achieving the same power is often reduced if factors associated with the outcomes are balanced among the intervention groups.

All named personnel are current in their human subject training and have significant experience with the IRB approval process and field experiment designs. The staff involved in communicating with participants are nutrition professionals who have Registered Dietitian Nutritionist credentials and/or a Bachelor or Masters degrees in nutrition.

Theory Driven Hypotheses

Our hypotheses are driven by results from Hamilton and Richards (2019) [20] analysis of household food waste in a stylized model featuring two categories of food that differ in their perishability (e.g., fresh and processed). They postulate that households choose Q,Y, and z to maximize utility:

$u(\gamma Q, Y) - h(\gamma;\theta) + z$, subject to $I = PQ + RY$

where Q is fresh food purchased, Y is processed food purchased, z is a numeraire good, $0<\gamma< 1$ is the fraction of fresh food that is consumed (let consumed fresh food be $X = \gamma Q$), food waste equals $(1-\gamma)Q$, θ is a food waste reduction knowledge variable, P is the price of fresh food, R is the price of processed food, I is income, and $u(.)$ is a continuously differentiable concave utility function this is increasing in both fresh and processed food. It is assumed that processed food is wasted less than fresh food and, for simplicity, we assume processed food is fully consumed (no waste). $h(.)$ is the disutility experienced reducing food waste, which is increasing in γ (effort expended to reduce food waste increases disutility), decreasing in θ (better knowledge of reducing food waste reduces disutility).

Maximizing utility subject to the income constraint yields optimizing values of Q^*, Y^* and γ^*. Denote the marginal cost of household food utilization as $H = h_{\gamma\gamma}\gamma/h_{\gamma}$ and the marginal utility of fresh food as $F = -u_{xx}\gamma Q/u_x > 0$, where subscripts represent partial derivatives (e.g., $h_{\gamma\gamma} = \partial^2 h(.)/\partial\gamma^2$). Comparative statics conducted by Hamilton and Richards [19] reveal that reducing the price of fresh food will increase the demand for fresh produce and increase the amount wasted if $F > \gamma(1 + H) - H$, i.e., if the demand for fresh food is not too price elastic (Hamilton and Richards' Proposition 2). Hamilton and Richards do not calibrate this model and also note that the literature features a broad array of fresh produce price elasticity estimates. Hence we forward:

H1a: FV acquisition, consumption**,** and diet quality will increase in the control group featuring a reduction in the effective price of fresh FV and

H1b: Food waste will increase in the control group featuring a reduction in the effective price of fresh FV,

where the effective price of fresh FV is reduced via free FV provision (the pick-up site is centrally located with free parking and convenient for most Baton Rouge area residents). According to Hamilton and Richards (Proposition 1) if food waste reduction knowledge (θ) is increased then the amount of fresh food consumed will increase while the amount wasted will decline so long as $F > 1 - \gamma$, i.e., so long as demand for fresh food is not too price elastic. Hence, we forward:

H2a: FV acquisition will increase in the treatment group featuring both a reduction in the effective price of fresh FV and a smart intervention to reduce food waste,

H2b: FV consumption will increase without increasing total energy intake and diet quality will also increase in relation to the control group, and

H2c: Food waste in the treatment group will be less than food waste in the control group.

Expected Outcomes

We expect to assess whether programs that subsidized FV acquisition are efficiently translating program dollars into improved nutrition rather than into increased energy intake and increased FV waste and to develop interventions that ensure funds targeted

to increase household FV acquisition are efficiently translated into improved household nutrition. We will:

1. Assess the impact of free FV provision on FV intake and household food waste production
2. Measure the efficacy of the smart intervention
3. Provide insights to guide future policies and interventions that target increased FV consumption through free or subsidized FV provision.

We also expect to improve upon the efficiency of the FoodImage app through continual assessment of participant feedback and by improving the efficiency of image analysis and data input.

Study Endpoints

Primary analysis objectives follow the hypotheses, which we are sufficiently powered to assess:

1) Quantify baseline distributions:
   a. Mass (g), energy (kcals), and macronutrients (g and kcal) for household food waste levels, food purchasing patterns, food intake, and consumption of FV including beginning FV inventory, total FV acquisition, and total FV intake

   b. FPED values, i.e. serving size, for food intake and consumption of FV including FV inventory, total FV acquisition, and total FV intake

   c. Quantify baseline diet quality (i.e. food intake as assessed by the HEI)

2) Determine how the smart intervention altered:
   a. Mass (grams), energy (kcals), and macronutrients (g and kcal) for household food waste levels, food purchasing patterns, food intake, and consumption of FV including FV inventory, total FV acquisition, and total FV intake

   b. FPED values, i.e. serving size, for food intake and consumption of FV including FV inventory, total FV acquisition, and total FV intake

   c. Quantify diet quality (i.e. food intake as assessed by the HEI)

   d. Acquisition and intake of non-FV foods

   e. The percent of household food waste that was FV

Secondary analysis objectives include assessing the demographic (e.g., age, education), household (SNAP eligibility, household size, beginning food inventories), and attitudinal factors (e.g., frugality, health and environmental consciousness) related to the primary analysis targets.

Power analysis

Power analysis was conducted for change in the primary outcome variable (grams [g] of food waste) from baseline to the end of the intervention to detect significant differences between treatment and control groups. Following the methods of our previous study, waste data will be summarized and analyzed by aggregating across measurement days. Based on weekly data from our previous study, the participants in the group receiving a smart food waste reduction intervention reduced their waste at meals by 331 g while the control group only reduced their waste by 33 g (298 g group difference), while the pooled standard deviation of the change in food waste between the control and treatment groups was 295 g, yielding an effect size of 1.01. The power to detect an effect size of 1.01 is 0.92 if there is no attrition (23 per group) and is 0.88 if attrition exceeds the 10% expectation (20 per group or 13% attrition). Given the power analysis is based upon an RCT that did not involve the provision of free FV, we expect effect sizes to be larger in the proposed study due to the presence of free FV, yielding even higher power than projected above.

Provisions to Monitor the Data to Ensure the Safety of Subjects

Adverse events will be monitored at each intervention visit. The PI and his co-investigators will review all data continuously to ensure the safety of each subject.

Withdrawal of Subjects

Subjects may be withdrawn from the study if he/she misses study visits and will be notified of their withdrawal via telephone or mail. If a subject voluntarily withdraws from the study, no additional data will be collected and they will be considered dropouts in the study.

Risks to Subjects

This study involves no greater than minimal risk. The main risk is breach of confidentiality, and the PBRC team will work to minimize this during data collection, handling, and analysis.

Potential Benefits to Subjects

Participants may benefit by increased awareness of their food waste behaviors.

Setting

All research procedures will be conducted at PBRC and in participants' natural environment.

Resources Available

PBRC has all the necessary equipment needed to undertake and execute the proposed research project successfully. All investigators and staff have offices or cubicles. Investigator offices are each equipped with a desk, chair, filing cabinets and shelves, telephone with voice mail, printer, and access to a photocopier and fax. Computers are equipped with software for statistics, data management, and word processing, and computers are connected to the PBRC mainframe with internet access and email access through Outlook Express. Information Technology (IT) provides full technical support to all members of the faculty and staff. PBRC has all the

technological equipment and staff needed to conduct the present study. These information technologies assure efficient data handling and optimal communication among the investigators and the team.

Compensation

Participants will be compensated $100 for successful completion of week 1 and $165 for successful completion of the remaining 21 days (max compensation = $265). Participants will also receive a free fresh seasonal FV box once per week during the final 21 days.

Confidentiality and Provisions to Protect the Privacy Interests of Subjects

Participants' records will be kept confidential to the extent allowed by law. Only Drs. Corby Martin, John Apolzan, and Brian Roe, Danyi Qi, the Ohio State University research team, the Louisiana State University research team, and the PBRC research team will have access to the information participants provide. Information may also be shared with necessary Institutional Review Boards and Offices for Human Research Protection (OSU Institutional Review Board, Pennington Biomedical Research Center IRB, LSU Institutional Review Board, and the Office for Human Research Protection (OHRP)). We will use an identification number rather than participants' names on study records. The information participants provide will be stored on secured network drives and will not be identified using any personal information.

Participants' names and other facts that might identify them will not appear when we present this study or publish its results. The findings will be summarized and reported in group form. Participants will not be identified personally. All participants will have ample opportunity during consent and throughout the study to ask questions concerning study procedures. These questions will be answered promptly and fully by study staff to ensure participant ease. A participant may choose not to answer questions or participate in study procedures at any time.

Compensation for Research-Related Injury

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research the participant will be referred to a treatment facility. Medical treatment may be provided at their expense or at the expense of their health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. PBRC is a research facility and provides medical treatment only as part of research protocols. Should the participant require ongoing medical treatments, they must be provided by community physicians and hospitals.

Economic Burden to Subjects

There will be no study related costs to the participant with the exception of traveling to the PBRC for the study visits. However, use of the FoodImage app will use data from the participant's cellular data plan. Hence, it is possible that the participant would incur cost for this data, and this is clearly disclosed in the consent form.

Consent Process

All subjects participating in the study will provide written informed consent. The consenting process will take place in private rooms at Pennington Biomedical Research Center and will be conducted according to Pennington Biomedical consenting guidelines and practices. Participants can take the consent form home to review prior to deciding if they wish to enroll. All participants are free to withdraw from the study at any time.

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