Official Title: The UnProcessed Pantry Project (UP3): A Novel Approach to Improving Dietary Quality for Low-Income Adults Served by Rural Food Pantries
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Study Protocol with Statistical Analysis Plan and Informed Consent Form

STUDY PROTOCOL

Title: The UnProcessed Pantry Project

Principal Investigator (PI): Carmen Byker Shanks PhD RDN

A. RATIONALE AND PURPOSE OF RESEARCH.

The UnProcessed Pantry Project (UP3) a research study that aims to improve the health of food pantry participants by taking strategic steps within the food pantry environment and with clients to increase access to and consumption of unprocessed foods. The overall goal of UP3 is to develop a framework to apply in food pantries towards improving food pantry participant health through an improved diet with less ultra-processed foods. The specific research question being asked is: does minimizing ultra-processed food consumption improve dietary intake among rural food pantry clients?

B. RESEARCH PROCEDURES

The *UP3* pilot study will be conducted by 2 rural food pantries in Montana for 12 weeks. There will be 1 control group that are eligible to be served by a different food pantry in Montana. Participants will undergo the following research methods upon consent.

The pilot study will investigate potential short-term effects of UP3 on dietary quality (primary outcome) among participants. It is hypothesized that UP3 will improve access to less processed foods and decrease access to ultra-processed foods at the food pantry, which will improve overall dietary quality of individuals as measured by the Healthy Eating Index-2015 compared to baseline. Biomarkers of health data (i.e., weight, systolic blood pressure, HbA1c, fasting lipid panel) will be collected to determine the feasibility of measuring potential short-term health effects alongside UP3. Demographic and food security data will be collected by survey characterize the population. Psychosocial factors will be collected by survey to understand changes in knowledge, attitudes, and perceptions about processed foods.

Beginning in December 2019 and January 2020, participants ages 18 and above who access 1 of the 2 food pantry sites will be asked to participate in *UP3* through flyers and on-site recruitment. 1 control group that are eligible to be served by a rural food pantry will be recruited. Stratified recruitment will occur to recruit for demographic diversity and risk for chronic disease as measured by baseline screening. Participants must be able to attend UP3 meetings. Exclusion criteria will include pregnancy, unstable vital signs, or food allergy as measured by baseline screening. All participants will give written informed consent.

UP3 will begin at the same time for participants at each food pantry. *UP3* will proceed by providing informed consent to the experimental and control groups. The control group will not receive an intervention.

Experimental group participants will meet with a registered dietitian and research staff at the beginning of the intervention to learn the intervention protocol, including instruction to keep exercise constant. The experimental group of participants will pick up food every week, enough to make up at least 50% of their diet based off of calculations from USDA's Dietary Guidelines for Americans 2015. Every other week, they will be provided with experiential nutrition education

targeted toward knowledge, attitudes, and perceptions about increasing un-processed food intake and decreasing ultra-processed food intake. Every other week, the participants will check in with a research staff member about goals, successes, and challenges of the intervention.

For the experimental group, dietary quality, survey data, and biomarkers of health measures (BMI, waist circumference, HbA1C, fasting lipid panel, systolic blood pressure) will be collected at pre (1 week) and post (12 weeks). Height, weight, survey data, and dietary quality will be collected at 6 weeks. These measures will be collected at the food pantry when participants pick up food. Measures taken at the food pantry will be collected in a closed off and private space and at a mobile draw station (compliant with Biosafety Committee Standards) by a certified phlebotomist and research staff.

For the control group, dietary quality, survey data, and height and weight will be collected at pre (0 weeks) and post (12 weeks). These measures will be collected at a food pantry in a closed off and private space by a certified phlebotomist and research staff, compliant with Biosafety Committee Standards.

C. RECRUITMENT PROCEDURES

During December 2019 and January 2020, experimental group participants will be recruited among clients that are (1) currently served or (2) are eligible to be served by participating sites

The sites will be provided with recruitment flyers. The 1-page recruitment flyers hung at sites. Staff that are not on the research team at each location will be trained to direct clients with questions to further inquire with a research team member. The staff at sites that are not on the research team will not participate in the informed consent process or data collection. When a client indicates interest in the study, the staff will refer the client to a research team member on location. If no research team member is available to talk to the client on location, staff will collect the client's e-mail and phone number and provide to the research team member to make contact at a later time. Contact information will include name, phone number, and e-mail entered into a table. The client will also be provided with the study coordinator's phone number and e-mail address through the recruitment flyer and can self-initiate contact to indicate interest. Upon contact, the research team member will provide a brief verbal overview of UP3 using a script. If the client still indicates interest, the client will be provided with a screening survey to collect information about exclusion factors and basic demographic information. The client will be provided with the opportunity for informed consent upon determining eligibility, explained below.

Local health care providers will additionally identify patients at risk for chronic disease that qualify for a sliding fee scale. The provider will randomize a list of 100 individuals meeting the identification criteria. The first 20 individuals on the randomized list will be called and provided study details directly from a script (attached). If the patient indicates interest in participation in the study, the staff member will document contact information. Contact information will include name, phone number, and e-mail entered into a table and will notify a member of the research team who will follow up with the interested patient. If a patient is not interested in participating, the staff will tally the interaction but will not collect contact information. Staff that are not on the research team will be trained to direct patients with questions to further inquire with a member of the research team. The staff that are not on the research team will not participate in the informed consent process or data collection. When a patient indicates interest in the study, a research team member will call the participant and provide a brief verbal overview of UP3 using a script. If the client still indicates interest, the client will be provided with multiple days and times to complete a screening survey) to collect information about exclusion factors and basic

demographic information. The client will be provided with the opportunity for informed consent upon determining eligibility, explained below.

For control group participants, 1-page recruitment flyers will be hung in the food pantry at the control site. The staff at the control site that are not on the research team will not participate in the informed consent process or data collection. When a client indicates interest in the study, the staff will refer the client to a research team member on location. If no research team member is available to talk to the client on location, staff will collect the client's e-mail and phone number and provide to the research team member to make contact at a later time. Contact information will include name, phone number, and e-mail entered into a table. The client will also be provided with the study coordinator's phone number and e-mail address through the recruitment flyer and can self-initiate contact to indicate interest. Upon contact, the research team member will provide a brief verbal overview of the control group using a script. If the client still indicates interest, the client will be provided with a screening survey to collect information about exclusion factors and basic demographic information. The client will be provided with the opportunity for informed consent upon determining eligibility, explained below.

Participants will take the screening survey in a private location at study sites. The screening survey will include a participant code to keep survey data anonymous. The participant code will be connected with the participant's name and contact information on a separate Excel spreadsheet that is saved and stored securely on the research team's computer. Contact information will include phone number and e-mail. The screening survey will be collected and stored in a locked cabinet.

The top of the screening survey includes a statement about retention of the screening data: *Data collected in the screening survey will be retained to track retention and characteristics of prospective participants that ultimately participate or decline participation in UP3. Prospective participants can stop taking the survey at any time. Participants can decline to answer screening survey questions. Your answers will be kept completely confidential and your name will not be associated with any of the screening results.*

After completing the screening survey, the client will be told that eligibility will be determined and will be contacted about their participation in UP3 as experimental or control group within a month of initial contact. The research staff will determine UP3 eligibility by reviewing the screening survey for inclusion and exclusion criteria.

D. INFORMED CONSENT

If eligible, the prospective participant will be contacted by a research team member using a script to discuss their eligibility in the study and schedule a time to provide informed consent and, if consenting, participate in baseline screening.

During the informed consent, the prospective participant will be provided an informed consent document. The prospective participant will be provided an opportunity to discuss any questions about the study with the research team. The prospective participant will read the informed consent form and decide about participation. The prospective participant will provide a signature on the informed consent form upon agreeing to participate in UP3. Informed consent will be conducted at the study sites simultaneous with baseline screening.

E. COMPENSATION

Experimental group participants will receive incentives in the form of gift cards ($150 each, or

$50 at 3 times during the study – baseline, 6 weeks, 12 weeks). Control group participants will receive incentives in the form of gift cards ($50 each, or $25 at 2 times during the study – baseline and 12 weeks).

F. STUDY LOCATION

Screening, consenting, study measures, and intervention activities will be carried out at the food pantry locations. Measures taken at the food pantry will be collected in a closed off and private space and at a mobile draw station (compliant with Biosafety Committee Standards) by a certified phlebotomist and research staff.

G. RISKS AND BENEFITS (ADVERSE EFFECTS)

The risk for the experimental group is considered minimal and no greater than obtaining blood for a medical procedure or food allergies. The participant will have drops of blood taken on two occasions. The blood will be taken from a finger by finger stick. The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting. The risk of consuming food includes an allergic reaction to foods provided. For the control group, there are no known risks to participation in this study beyond what is encountered in daily life.

H. DATA CONFIDENTIALITY

All data will be coded, kept in a locked file cabinet in the PI's lab or on the PI's computer.

STATISTICAL ANALYSIS PLAN

Descriptive statistics were performed for all study data. Participants provide 24 hour dietary recalls at 3 time point throughout the study period using the Automated Self-Administered 24 hour (ASA24) assessment tool. The HEI-2015 uses a scoring system with a scale 0-100, where a score of 100 represents a diet in complete agreement with the Dietary Guidelines for Americans. The score is totaled from 13 component scores. High consumption of the following food groups corresponds to a higher component score: total fruits, whole fruits, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids. Alternatively, high consumption of refined grains, sodium, added sugars, and saturated fats corresponds to *lower* component scores, as these items should only be consumed in limited quantities. SAS macros provided by the National Cancer Institute were used to compute HEI-2015 scores for each dietary recall at pre- and post-intervention using the Simple HEI Scoring Algorithm. HEI scores were presented as means and standard deviations (SD). A paired-sample t-test was conducted to test for differences between means at pre- and post- intervention.

INFORMED CONSENT FORM

Experimental Group

UP3 RESEARCH PARTICIPANT CONSENT FORM – UP3 Intervention Group
FOR PARTICIPATION IN HUMAN RESEARCH AT MONTANA STATE UNIVERSITY

Title The UnProcessed Pantry Project (UP3)

Rationale You are being asked to participate in a research study about how the degree of food processing affects your health. The intervention lasts for 12 weeks. This may help us obtain a better understanding of how food processing influences your food choices and your health.

Participants You will be recruited through local food pantry to participate in a 12 week intervention. You will be asked to learn about a healthy diet. You will be asked to decrease intake of ultra-processed foods. You must acquire food from the Gallatin Valley Food Bank or Livingston Food Resource Center and be at risk for a chronic disease. You may not be pregnant, have unstable vital signs, or a food allergy with adverse health reactions to participate in this study. You must be able to attend scheduled intervention activities.

Procedures
During week 0 of the trial, baseline health measures assessment will be gathered in at a mobile draw station at your local food pantry. Health measures will include height and weight to assess Body Mass Index, waist circumference, blood pressure, and blood collection to assess cholesterol and A1c. Additionally, you will complete a dietary intake assessment and survey.

During weeks 1 through 12 you will follow an unprocessed diet. This means you will eat fresh foods and healthfully prepared foods. During the study period, you will attend nutrition education classes every other week and pick up 50% of your food supply every week. You will be asked questions about how the project is going for you at weeks 4, 6, 8, 10, and 11. At week 6 and week 12 of the intervention, health measures, dietary intake, and a survey will be collected.

Risks
Drops of blood will be collected from your finger on 2 occasions. One finger will be selected and cleansed with rubbing alcohol. Your finger will be stuck using a sterile lancet. The first drop of blood will be wiped away. The next 2 to 4 drops of blood will be put on a collection tool and used for tests. You will be provided with a band aid. Occasionally it is necessary to stick the finger a second time in order to get enough blood. This is the standard medical method used to obtain blood for tests. There is momentary pain at the time the needle is inserted into finger, but other discomfort should be minimal. In about 10% of the cases there is a small amount of bleeding under the skin which will produce a bruise. The risk of infection is less than 1 in 1,000. The risk of consuming food include an allergic reaction to foods provided. We will ask you your known food allergies and exclude you from the study if you have a food allergy. If participants lose too much weight at 6 weeks (as defined by more than 2.5 pounds per week), then they will be asked to modify their diet and asked to follow the Dietary Guidelines for Americans.

Benefits
This study is of no benefit to you.

Alternatives Participation is voluntary, and you can choose to not answer any question that you do not want to answer, and you can stop at anytime.

Cost to Subject None

Funding This study is being funded by National Institutes of Health.

Compensation You will receive a total of $150 in gift cards. Gift cards will be distributed in $50 increments at baseline (0 weeks), 6 weeks, and 12 weeks.

Questions You should feel free to ask questions at any time to the research team.

Confidentiality Your records will be coded with a number to maintain your anonymity. Any identifying information will be kept in a lock file which only the principal investigators have access to.

Injury or Compensation This study is classified as minimal risk to you. In the event your participation in this research supported by National Institutes of Health results in a research injury to you, medical treatment will be available. Call 911 in a medical emergency. Further information about your research injury specific treatment may be obtained by calling Carmen Byker Shanks at 406-994-1952.

Questions If you have questions about the research, contact Carmen Byker Shanks at 406-994-1952 [cbykershanks@montana.edu]. If you have additional questions about the rights of human subjects they can contact the Chair of the Institutional Review Board, Mark Quinn, (406) 994-4707 [mquinn@montana.edu].

AUTHORIZATION

I have read the above and understand the discomforts, inconvenience and risk of this study. I, _____ *(name of subject),* agree to participate in this research. I understand that I may later refuse to participate and that I may withdraw from the study at any time. I have received a copy of this consent form for my own records.

Signed: _____

Investigator: _____

Date: _____

Control Group

UP3 RESEARCH PARTICIPANT CONSENT FORM – UP3 Control Group
FOR PARTICIPATION IN HUMAN RESEARCH AT MONTANA STATE UNIVERSITY

Title The UnProcessed Pantry Project (UP3)

Rationale You are being asked to participate in a research study about how the degree of food processing affects your health. This may help us obtain a better understanding of how food processing influences your food choices and your health.

Participants You will be recruited through your local food pantry to participate in a research study. You will be asked to report your diet, take a survey, and have your height and weight measured on 2 occasions, once in February and once in April. You should be a client at a local food pantry and be at risk for a chronic disease as indicated in a screening survey. You may not be pregnant, have unstable vital signs, or a food allergy with adverse health reactions to participate in this study. You must be able to attend 2 measurement meetings.

Procedures
During February, baseline measures will be gathered in at a mobile research station at your local food pantry. Measures will include height and weight to assess Body Mass Index, waist circumference, a dietary intake assessment, and survey. You will be asked to maintain your current diet and exercise. During April, follow up measures will be gathered in at a mobile research station at your local food pantry. Measures will include height and weight to assess Body Mass Index, waist circumference, a dietary intake assessment, and survey.

Risks
There are no known risks to participation in this study beyond what is encountered in daily life.

Benefits
This study is of no benefit to you.

Alternatives Participation is voluntary, and you can choose to not answer any question that you do not want to answer, and you can stop at anytime.

Cost to Subject None

Funding This study is being funded by National Institutes of Health.

Compensation You will receive a total of $50 in gift cards. Gift cards will be distributed in $25 increments at each measurement day, once in February and once in April.

Questions You should feel free to ask questions at any time to the research team.

Confidentiality Your records will be coded with a number to maintain your anonymity. Any identifying information will be kept in a lock file which only the principal investigators have access to.

Injury or Compensation This study is classified as minimal risk to you. In the event your participation in this research supported by National Institutes of Health results in a research injury to you, medical treatment will be available. Call 911 in a medical emergency. Further

information about your research injury specific treatment may be obtained by calling Carmen Byker Shanks at 406-994-1952.

Questions If you have questions about the research, contact Carmen Byker Shanks at 406-994-1952 [cbykershanks@montana.edu]. If you have additional questions about the rights of human subjects they can contact the Chair of the Institutional Review Board, Mark Quinn, (406) 994-4707 [mquinn@montana.edu].

AUTHORIZATION

I have read the above and understand the discomforts, inconvenience and risk of this study. I, _____ *(name of subject),* agree to participate in this research. I understand that I may later refuse to participate and that I may withdraw from the study at any time. I have received a copy of this consent form for my own records.

Signed: _____

Investigator: _____

Date: _____

APPROVED
MSU IRB
12-09-2019
Date approved