PROTOCOL AND STATISTICAL ANALYSIS PLAN

Study Title: Tanglewood to Table: A walking farmer's market group and control

Institution/Site:	University of Kentucky
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RESEARCH DESCRIPTION

****!!!PLEASE READ!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.**

Workaround(s):

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

The Tanglewood Trail walking group is a community-initiated walking group, spontaneously established in summer 2016 and continued with UK IRB-approved structure and support in 2017. Community members meet at the Housing Authority in Whitesburg, KY and walk the approximately 1 kilometer Tanglewood Trail connecting the Housing Authority to the Farmer's Market. In 2017, participants that walked to the Farmer's Market received a $10 voucher on Saturdays during the season (June-October). Adults 18 years and older received one voucher each time they walk. While this program was initiated by community members and UK researchers were not involved with its creation or tracking any component of the program, UK researchers became involved in the summer of 2017. This partnership was strengthened and, following IRB-approval, will continue into the 2018 season with another Walking Group and an extension of the Walking Group beyond the Farmer's Market season as a feasibility study and new name: Fresh Steps. The current proposed study will target non-pregnant healthy, 18+ years old, community members who are willing and able to walk the Tanglewood Trail on Saturday mornings, June-September 2018 and willing and able to walk 1 mile at the Cowan Community Center, October 2018 – February 2019. All participants will receive $10 to spend on fruits and vegetables at the Farmer's Market, June-September, and a $20 healthy prepared meal from CANES kitchen October-February. An additional control group (in nearby Harlan county) will be added. The control group will only receive monthly nutrition education via home mail or e-mail. We hypothesize that adults who regularly attend the walking group and subsequently purchase fruits and vegetables at the Farmer's Market (June-September) and consume a healthy prepared meal (October-February) will experience an increase in physical activity, fruit and vegetable intake, and community engagement, and an improvement in anthropometrics and biomarkers associated with adulthood chronic disease (including cholesterol, hemoglobin A1c, blood pressure, carotenoid status, weight, and waist circumference).

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section.

Specific Aim 1: Compare the short-term and long-term impact of the active intervention and control condition on healthy lifestyle behaviors (PA and nutritional patterns) associated with chronic disease risk reduction. Hypothesis 1: Participants in the active intervention whose levels of PA and F/V consumption are meeting national recommendations at baseline (BL) will be more likely to maintain these at 4 and 8 months than participants in the control group whose levels fall within national recommendations at baseline. Hypothesis 2: Participants in the active intervention whose levels of PA and F/V consumption not meeting national recommendations at BL will have greater improvement in PA and F/V consumption at 4 and 8 months compared to participants in the control group whose levels are not meeting national recommendations at BL. Specific Aim 2 Compare the short-term and long-term impact of the active intervention and control condition on anthropometric (weight and waist circumference) and biological (blood pressure (BP), HbgA1c, and lipids) chronic disease risk factors. Hypothesis 1: Participants in the active intervention whose anthropometric and biological measures are within normal ranges at BL will be more likely to maintain these ranges throughout the period of the study than participants in the control group whose levels are within normal ranges at BL. Hypothesis 2: Participants in the active intervention whose anthropometric and biological measures outside of normal ranges at BL will have greater improvement in these measures at 4 and 8 months than participants in the control group whose levels are outside of normal ranges at BL.

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a research repository describe the repository design and operating procedures. For relevant information to include, see question 22 of the UK IRB "Frequently Asked Questions (FAQs) on the

Return of Research Results or Incidental Research Findings" [PDF].

The sample population consists of a convenience sample that is participating in a pilot study. This study will focus on nonpregnant healthy adult (ages 18+) community members who walk the Tanglewood Trail on Saturdays, June-September 2018 and at Letcher County Recreation Center October 2018 – February 2019. Any interested community members who are 18 years or older, nonpregnant and able to voluntarily give their consent are welcome to join the study. Seventy-five participants will be recruited to participate in this project in Whitesburg ("walking group"), and seventy-five control participants will be recruited in Harlan ("control group"), who will only receive monthly nutrition education via e-mail or home mail. An information session for any potentially interested individuals will be held by the UK program manager with the help of the community leader following IRB approval. The 75 walking group participants will meet at the Housing Authority at a designated time each Saturday. When they arrive, they will be signed in by a community leader and receive a farmer's market voucher (see attached) for $10. They will walk as a group to the farmer's market and hand their voucher to the market manager, who will give them $10 in tokens to purchase fruits and vegetables at the market. The voucher will have two sides: one side will ask participants to check off what fruits and vegetables they ate over the past week, the second side will ask how participants used what they purchased at the market last week (ie. How much was eaten fresh vs. preserved) and how many steps they took over the past week, tracked using a pedometer provided at the baseline measurements in May 2018. They will turn the filled-out voucher in as they leave the market. During the meal preparation portion of the study, participants will complete weekly meal evaluation sheets. The walking group will receive 1) Education - nutrition education weekly via a combination of nutrition posts on Facebook (2/mo June –Sept), recipe and phytonutrient cards that includes a video recipe demonstration (1/mo), and recipe samples with cards (1/mo). Post-farmer's market: 1 weekly recipe demonstration (YouTube and offered live), recipes with nutrition/phytonutrient information to accompany meals (Oct – Jan); 2) Vouchers- weekly $10 farmer's market vouchers (June – Sept), weekly $20 healthy meal vouchers (Oct – Jan); 3) PA - 1 day/week community walk along Tanglewood Trail (June-Sept) and admission to Recreation Center (Oct – Jan), and 4) Activity trackers - a 3DTriSport pedometer. The 75 control group participants will receive monthly nutrition education via their choice of e-mail or home mail. Nutrition education will focus on phytonutrients, the importance of fruit and vegetable intake, how these factors might protect them from environmental pollutants, and healthy cooking. This nutrition education will also be provided to walking group participants via Facebook. Walking group participants will also have access to monthly Farmer's Market samples of Plate it Up Kentucky Proud recipes and recipe cards. No participants will receive medications – neither real nor placebo. Data for both the walking group and control group will be a time series collection of blood pressure, finger-stick total cholesterol, LDL, HDL, triglycerides, hemoglobin A1c (cardiocheck meter), height, weight, waist circumference, carotenoid status (carotenoid RS, which is a non-invasive instrument that is a reliable indicator of fruit and vegetable intake (see attached), Newest Vital Sign (NVS) rapid screening test for health literacy, and a survey (see attached). Measurements will be taken and surveys collected three times – baseline data will be collected in May 2018, mid-point data collected late September/early October 2018, and follow-up data collected in February 2019. Only walking group participants will receive pedometers and report weekly steps to the community leader at the Farmer's Market (June through September) or CANES Kitchen (October through February). Finger stick tests will be conducted by University of Kentucky employees who have completed all necessary biohazard training (see attached IBC approval and certificates of completion). Lysol wipes will be available to wipe down equipment as needed. Hand sanitizer will be provided to each researcher to use between glove changes. Gloves will be changed between each participant. Heat packets will be available for participants with cold hands to make the finger stick go faster and easier. Band-Aids will be provided after each stick. Lancets will be used to take the finger stick and all materials will be disposed of in sharps containers. All sharps containers will remain sealed until the research team returns to the University of Kentucky that same day to dispose of the sharps containers. Additionally, focus groups with walking group participants will be conducted in October 2018 and February 2019. Questions for the focus groups will be formulated out of 5-10 informant interviews conducted in July (with each interview lasting approximately 30 minutes – 1 hour). Participants for both interviews and focus groups will be recruited with the help of the market manager and community leader, and all participants will be informed that they are participating in the interviews and/or focus groups for research purposes and sign a consent form. Questions asked will assess program use, attitude/behavior change over the course of the program, social capital, and social cohesion.

Attachments

Back to Top

Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners or others who are likely to be vulnerable. If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of these groups requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

• A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
• A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
• The proposed dates of enrollment (beginning and end);
• The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button.

Based on walking group numbers from summer 2017 we anticipate a maximum enrollment of 75 walking group participants (18+ years old, nonpregnant) and 75 control participants. Previous research in Letcher County suggests the majority of participants will be white, ages 18-65, both male and female, of moderate health status. A prerequisite for participating in this study is the ability to walk 1 mile (assessed using the Exercise and Sports Science Adult Pre-Exercise Screening Tool, Stage 1 – see attached), nonpregnant, pre-supposing a baseline health status. Any interested community members over the age of 18 and in moderate or good health will be included. Since our focus is on changes in rates of chronic disease in adulthood, children will be excluded from study participation (but may walk with their parents). Institutionalized adults, pregnant adults, adults with impaired consent capacity, and prisoners will be excluded. No one will be excluded based on sex/gender or racial/ethnic identity. Seventy-five participants in Harlan County will be enrolled in the control group with the same inclusion/exclusion criteria as the walking group. Interview and focus group participants will include volunteers from the walking group. All participants will be informed that the interviews and focus groups are for research purposes, and sign a consent form.

Attachments

Subject Recruitment Methods & Privacy: Describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information. Describe the setting in which an individual will be interacting with an investigator. If applicable, describe proposed outreach programs for recruiting women and minorities as participants in clinical research.

Please note: Based upon both legal and ethical concerns, the UK Medical Institutional Review Board (IRB) will not approve finder's fees for research studies.

A community leader will build a Facebook group (following IRB approval) in April 2018 to help recruit walking group participants. Following IRB approval an information session will be held by the program manager and community leader to introduce the study and answer any questions. Interested participants will be invited to a baseline data collection event in May 2018, following IRB approval. Interested participants will be told about the study and that their involvement is completely voluntary. We will obtain consent from those that are interested in participating in the study. We will then invite consented participants to fill out a survey and have the above measurements (see section 3) taken in return for a farmer's market t-shirt. A community leader at Pine Mountain Settlement School in Harlan County (see attached LOS) will help recruit 75 participants for the control sample. A similar procedure of recruitment and consent will be followed. Privacy will be maintained through de-identification of all survey and measurement data. The surveys and measurement data sheets will contain a cover sheet that has a place to record the participant's name. The next page will be where the first question is listed and a space for the survey code to be recorded. Once the survey has been coded the cover sheet will be removed from the post-surveys and shredded. Participants will be asked to indicate which fruits and vegetables they purchased at the market on shopping card (see attached). The card will have a place for their name and they will give them to the community leader before leaving the market. The community leader will collect these weekly and give them to UK researcher bi-weekly. The shopping card data will be matched to participants' measurement data on an electronic datasheet. Once all of the data has been collected in September the electronic list of names will be replaced with a code to de-identify participants, the cover sheets of the surveys that contain participant names will be shredded and the surveys and shopping cards will be stored securely in a locked drawer in the PI's locked office. The electronic data that is generated will be stored on a password protected computer. Throughout the study, any study materials that contain participant names will be stored in a locked filing cabinet in the PI's locked office. In the event this data is published it will be done so by aggregating the data without identifying individuals.

Back to Top

Advertising: Specify if any advertising will be performed. If yes, please see "Advertisements - Application Instructions" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment" or "Advertising" on ORI's IRB Survival Handbook web page for the PI Guide to Identification and Recruitment of Human Subjects for Research [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

A community leader will build a Facebook group (following IRB approval) in April 2018 to help recruit walking group participants. The attached flyer will be used to recruit participants (date and location of the information session will be added following IRB-approval, when a date and location is scheduled).

Attachments

Attach Type	File Name
Advertising	Harlan Ad APPROVED.pdf
Advertising	Harlan Ad with EO language .pdf
Advertising	Fresh StepsWalking GroupAPPROVED.pdf

Informed Consent Process: Describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent (Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application), steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent (i.e., research involving adult subjects with impaired consent capacity) and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page. For additional information, see the "Informed Consent Standard Operating Procedures (SOPs)" [PDF].

Informed Consent for Research Involving Emancipated Individuals
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [PDF].

Informed Consent for Research Involving Non-English Speaking Subjects
If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.

Research Repositories
If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the "University of Kentucky Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use" [PDF].

All study personnel that will obtain consent are listed in Form A. Participants will be told they can decide to stop their participation at any time. The consent form will be read to any study participants with visual issues. UK study personnel will speak to study participants at an appropriate volume to be heard by study participants. Study personnel will ask if they are speaking loud enough, they will tell study participants to let them know when they need to speak up or slow down or repeat a question, and study personnel will be in tune to signs of study participants straining to hear. Consent will be obtained before physical measurements or survey data is collected. To obtain consent the UK study personnel will ask potential participants if they would like to participate in a research study that involves asking them questions about their health and diet and will also involve education material on phytonutrients, the importance of fruits and vegetables, how these factors might protect them from environmental pollution, and healthy cooking. They will be told their participation is completely voluntary, and extend beyond the farmer's market season. All consenting participants will be given the opportunity to sign a photo release. Whether they sign or not does not impact their participation in the study. All consenting participants will complete the Adult Pre-Exercise Screening Tool to assess their ability to take part in the walking group. They will also be told their survey answers will not be reported individually or with their name, but as anonymous aggregated data. Additionally, they will be told their participation is voluntary and they can withdraw from the study at any time and they do not have to answer any questions that they are not comfortable answering. If the participant agrees the consent form will be given to them and their signature obtained. The participant will be given a copy of an investigator-signed consent form. The UK study personnel will ask if the participant would like to move elsewhere to complete the survey and anthropometric/biological data collection. Study personnel will also explain that the consent forms and surveys will be stored separately in a locked drawer in the PI's locked office and that an electronic file will be created that lists their name and survey code. This list will be destroyed following the collection and entry of post-survey data. Any electronic files generated from this study will be stored on a password protected computer. Obtaining consent and completing the survey will take approximately 15 minutes. An additional 30 minutes will be needed to complete the anthropometric and biological measurements. The midpoint and post data will be collected in the same manner as the pre data. The UK study personnel will offer the same explanation of the survey and anthropometric/biological measurements and the same procedures will be followed, consent however will not be obtained again. The midline and post-surveys will contain a cover sheet that has a place to record the participant's name. The next page will be where the first question is listed and a space for the survey code to be recorded. Once the survey has been coded the cover sheet will be removed from the midline and post-surveys and shredded once all data has been entered electronically. At time of recruitment, interview and focus group participants will be told they are participating in an interview or focus group for research purposes. At the time of each interview and at the time of the focus group, the researcher will explain again that the interview and focus groups are being conducted for research purposes, and no one will be forced to participate or answer any questions they do not wish to answer. All participants who agree to participate will sign a consent form.

Back to Top

Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

Following IRB approval, beginning in May 2018 community members will show up to a designated location approximately 1 kilometer

from the Farmer's Market. Participants will fill out a survey and have anthropometric and biological measurements taken. Carotenoid status will be measured via carotenoid RS scanner (this is strictly an objective measure of diet derived pigments in the skin, and not used for diagnosing any medical condition). Anthropometric data will be collected by UK researchers and include weight (digital scale), height (portable stadiometer), waist circumference (tape) and blood pressure (digital blood pressure machine) Finger stick tests will be conducted by University of Kentucky employees who have completed all necessary biohazard training. All labs will be done on site, with the use of finger stick meters. Lysol wipes will be available to wipe down equipment as needed. Hand sanitizer will be provided to each researcher to use between glove changes. Gloves will be changed between each participant. Heat packets will be available for participants with cold hands to make the finger stick go faster and easier. Band-Aids will be provided after each stick. Lancets will be used to take the finger stick and all materials will be disposed of in sharps containers. All sharps containers will remain sealed until the research team returns to the University of Kentucky that same day to dispose of the sharps containers. In June through September 2018, participants in the walking group will meet at the Housing Authority to be signed in by a community member, and walk approximately 1 kilometer to the Farmer's Market, in exchange for $10 they can spend at the market. Once per month walking group participants will be exposed to Plate it Up Kentucky Proud recipe samples and recipe cards. In October 2018 through February 2019, participants in the walking group will be asked to walk 1 mile at Cowan Community Center and track their activity using a provided pedometer. Participants will report weekly steps to the community leader at CANES Kitchen, where participants will also receive one prepared, healthy meal per week for 16 weeks. Participants will be provided with the opportunity to watch the meal being made, as well as the recipe for the meal, including all ingredients and directions. Participants will complete weekly meal evaluation sheets. Post-data will be collected in September 2017; the same survey will be administered and participants will again have their anthropometric and biological measurements taken. A second post-survey will be distributed in November 2017. This survey will be a shorter version of the post-survey administered in September 2017. No clinical care will be given as a part of this research study. All interviews and focus groups will be conducted by a Registered Dietitian with previous training in the social sciences. Five to ten informant interviews will be conducted in July 2018. At least one focus group of 5-10 people will be scheduled, with the hope of scheduling 2 focus groups of 5-10 people each. The focus group(s) will be held at the Letcher County Extension Office. No questions will be asked for identifying markers or information and participants do not have to answer any question they do not feel comfortable or do not wish to answer.

Attachments

Attach Type	File Name
ResearchProcedures	Pre Survey 5.11.18 v5.docx
ResearchProcedures	Post Survey 5.11.18 v6.docx
ResearchProcedures	NVS for Health Literacy.pdf

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

Data for both the walking group and control group will be a time series collection of blood pressure, finger-stick total cholesterol, LDL, HDL, triglycerides, hemoglobin A1c (cardiocheck meter), height, weight, waist circumference, carotenoid status (carotenoid RS, which is a non-invasive instrument that is a reliable indicator of fruit and vegetable intake (see attached), and a survey (see attached). Measurements will be taken and surveys collected three times – baseline data will be collected in May 2018, mid-point data collected late September/early October 2018, and follow-up data collected in February 2019. Only walking group participants will receive pedometers and report weekly steps to the community leader at the Farmer's Market (June through September) or CANES Kitchen (October through February). During the meal preparation portion of the study, participants will complete weekly meal evaluation sheets. Finger stick tests will be conducted by University of Kentucky employees who have completed all necessary biohazard training (see attached IBC approval and certificates of completion). Lysol wipes will be available to wipe down equipment as needed. Hand sanitizer will be provided to each researcher to use between glove changes. Gloves will be changed between each participant. Heat packets will be available for participants with cold hands to make the finger stick go faster and easier. Band-Aids will be provided after each stick. Lancets will be used to take the finger stick and all materials will be disposed of in sharps containers. All sharps containers will remain sealed until the research team returns to the University of Kentucky that same day to dispose of the sharps containers. Additionally, focus groups with walking group participants will be conducted in October 2018 and February 2019. Questions for the focus groups will be formulated out of 5-10 informant interviews conducted in July (with each interview lasting approximately 30 minutes – 1 hour). Participants for both interviews and focus groups will be recruited with the help of the market manager and community leader, and all participants will be informed that they are participating in the interviews and/or focus groups for research purposes and sign a consent form. Questions asked will assess program use, attitude/behavior change over the course of the program, social capital, and social cohesion.

Attachments

Attach Type	File Name
DataCollection	Meal Evaluation.docx
DataCollection	Interview Script.docx

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources

may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see FDA Guidance). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see ORI's Off-Site Research web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

PI – Dawn Brewer, PhD, RDN, LD Program Manager – Annie Koempel, RDN, LD Graduate research assistants – Kelci McHugh, Abbey Moellering Undergraduate research assistants – Shelley Stiltner, Kelly Blackburn, Robert Powers Community Leader – Valerie Horn The PI, program manager, and research assistants will be responsible for all data collection and analysis. All education materials will be developed by the program manager and research assistants with oversite by the PI. The program manager and undergraduate research assistants will be USDA Good Agricultural Practices (GAP) trained to serve Plate it Up Kentucky Proud samples at one Farmer's Market per month. Undergraduate research assistants will also assist in data entry as needed (they will complete CITI certification and be added to research personnel list before having access to data). The community leader will manage the Facebook group and sign the walking group in every Saturday. The community leader has completed NIH Protecting Human Research Participants training. The PI will provide guidance through the process. The PI has space to store all of the consent forms, paper surveys, shopping cards and measurement data sheets in a locked drawer in the PI's locked office. All UK study personnel have UK computers (Dawn Brewer and Annie Koempel have department desktops; all research assistants will use department laptops that do not leave Funkhouser 212) and statistical analysis software (SAS) to carry out research procedures, which are all password protected to secure any electronic files that are generated from this study. The PI has funds to purchase paper and food supplies and transportation to conduct the study. Additional equipment and tools include: Omron HBF-5168 scale, stadiometer, Cardiochek lipid panel meters, A1c now meters, 3DTriSport pedometers, carotenoid scanner, and Omron 5 series blood pressure monitors. In the event that unanticipated problems or noncompliance issues occur or the situation arises that requires submission of protocol modifications or interim results, the PI will first consult the Office of Research Integrity's website to determine action steps appropriate to the issue. If the PI still has questions, she will contact the Office of Research Integrity to obtain the appropriate protocol to resolve a situation.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

No physical, psychological, social, legal, cultural, or financial risks can be perceived from participating in this research, including participation in the focus groups. No psychological risk can be perceived from answering survey questions, focus group questions, or obtaining measures. In the rare case that a dangerous blood pressure or hemoglobin A1c is recorded, the participant will be referred immediately to the local emergency department for care. All foods prepared for the farmer's market will be accompanied by a recipe card with ingredients. Potential allergens will be identified and communicated to all participants. Participants will not be forced to taste any food. Undergraduate research assistants will be GAP trained and knowledgeable about food safety issues. Finger stick tests will be conducted by University of Kentucky employees who have completed all necessary biohazard training. Lysol wipes will be available to wipe down equipment as needed. Hand sanitizer will be provided to each researcher to use between glove changes. Gloves will be changed between each participant. Heat packets will be available for participants with cold hands to make the finger stick go faster and easier. Lancets will be used to take the finger stick and all materials will be disposed of in sharps containers. Band-Aids will be provided to participants after each stick. All sharps containers will remain sealed until the research team returns to the University of Kentucky that same day to dispose of the sharps containers. There are minimal and short term risks associated with finger sticks, such as initial pain and tenderness for at least a day or two. There are no known risks of using a carotenoid scanner. A potential risk is a breach of confidentiality, which is minimal due to the study being voluntary, identifiable data remaining with the program manager until it is placed in a safe, locked drawer in a locked office on UK's campus, removing the signed consent form from the coded survey, shredding the cover sheet that contains names on the post-surveys, storing shopping cards in a locked drawer in the PI's locked office, deleting the document containing participant names and codes once the post-survey data has been coded, using a password protected computer, and storing any hard copies of study-related material in a locked drawer that is in a locked office.

Back to Top

Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the

provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

Participation in every aspect of the intervention is voluntary. Participants do not have to respond to any survey or focus group questions that they are uncomfortable answering or participate in any anthropometric or biological measurements they are uncomfortable with. All identifiable data will be transported directly to the program manager's locked office on UK's campus. The program manager will keep any identifiable data with her at all times until it is locked in a drawer in her locked office. The program manager and primary investigator will be the only two with access. When identifiable data (names) is being collected it will be on the cover sheet or consent form of a survey and will be detached from survey data that will include a code that is linked to the participant. At the end of the study, the cover sheets will be deleted and consent forms will be stored separately from the surveys in a locked drawer in the PI's locked office. The electronic list containing the names and survey codes will be deleted once all post-survey data is entered, which will be entered within a month following collection. However, the assigning of codes, and generating the electronic document that lists codes and names from surveys will occur the day of data collection at UK. The study population consists of adults ages 18 years or older who are in good enough health to walk 1 kilometer to the farmer's market. Finger stick tests will be conducted by University of Kentucky employees who have completed all necessary biohazard training and have received training by a Registered Dietitian in how to use the meters. Lysol wipes will be available to wipe down equipment as needed. Hand sanitizer will be provided to each researcher to use between glove changes. Gloves will be changed between each participant. Heat packets will be available for participants with cold hands to make the finger stick go faster and easier. Lancets will be used to take the finger stick and all materials will be disposed of in sharps containers. All sharps containers will remain sealed until the research team returns to the University of Kentucky that same day to dispose of the sharps containers. All labs will be conducted on site and materials disposed of as indicated above. There are minimal and short term risks associated with finger sticks, such as initial pain and tenderness for at least a day or two. There are no known risks of using a carotenoid scanner.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc…), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [PDF].

Potential benefits include (but are not limited to) a decreased risk for high blood pressure, high blood glucose, and cardiovascular disease; a decrease in oxidative stress; a decrease in generalized inflammation; an increase in community engagement; an increase in physical activity, and an increase in overall fruit and vegetable consumption. There is no more than minimal risk to participants in this intervention with the benefits outweighing any risk. There is a risk for initial pain and tenderness for at least one day or two from participating in the finger stick tests, however this side effects are minimal and short term. There is however, a potential risk of a breach in confidentiality, which is minimal due to the study being voluntary, identifiable data remaining with the program manager until it is placed in a safe, locked drawer in a locked office on UK's campus, removing the signed consent form/cover sheet from the coded pre/post surveys, deleting the document containing participant names and codes once the post-survey data has been coded, shredding the cover sheets attached to post-surveys with participants names, using a password protected computer, and storing any hard copies of study-related material in a locked drawer that is in a locked office.

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

N/A

Back to Top

Research Materials, Records and Privacy: Identify the sources of research material obtained from individually identifiable living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):
If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

Participants will be asked to fill out three surveys following IRB approval (May 2018, October 2018, February 2019). The surveys contain questions about demographics, self-reported health, physical activity, fruit and vegetable consumption, and community engagement. During the Farmer's Market season, walking group participants will be asked to complete weekly shopping cards that will require them to mark which fruits and vegetables they purchased at the farmer's market and how they used the fruits and vegetables they purchased at the previous market. After the Farmer's Market season, walking group participants will be asked to complete meal evaluations assessing the acceptability of the meal they received the previous week. Participants will be asked for finger-stick total cholesterol, LDL, HDL, triglycerides, hemoglobin A1c (cardio check meter), height, weight, waist circumference, blood pressure, and carotenoid status (carotenoid RS, which is a non-invasive instrument that is a reliable indicator of fruit and vegetable intake) three times (May 2018, October 2018, February 2019). The collected data will be collated and summarized without identification or attribution to the individual participants. All reports will only reveal aggregated summaries across participants. The surveys with attached consent forms will be collected and stored separately in a locked drawer in the PI's locked office at 209C

Funkhouser Building, University of Kentucky. An electronic document containing participant name and code will be generated and stored on a password protected computer. Following the collection of post-survey data and coding of the post-survey data the electronic document containing the names and codes will be deleted. To minimize risk of identification the consent forms will be removed from the survey and the survey will have a code written on it. The consent forms, shopping cards and surveys will not be stored together, but both will be in a locked drawer. The information collected will be used to assess whether walking 1 mile to the farmer's market and spending approximately $10 at the market (June through September) and receiving a healthy prepared meal once per week (October through February) improves physical activity, fruit and vegetable intake, community engagement, group cohesion, and chronic disease-related biomarkers (i.e. cholesterol, A1c, etc).

Confidentiality: Specify where the data/specimens will be stored and how the researcher will protect both the data and/or specimens with respect to privacy and confidentiality. Address physical security measures (e.g., locked facility, limited access); data security (e.g., password-protection, data encryption); safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality); and procedures employed when sharing material or data, (e.g., honest broker (if applicable), written agreement with recipient not to re-identify). If you plan to procure, store, and/or share material (tissue/specimens/data) expressly for use in current or future research, describe measures that you will take to secure and safeguard confidentiality and privacy.

Provide a time table for destroying the data/specimens and identify how they will be destroyed, or provide rationale for perpetual maintenance [Note: The investigator is responsible for retaining the signed consent and assent documents and IRB research records for at least six years after study closure as outlined in the Study Closure SOP [PDF]. If the research falls under the authority of FDA or other regulatory agency, the investigator is responsible for retaining the signed documents and IRB records for the period specified if longer than six years after completion of the study]. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK.

> *NIH-funded genomic research*: The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Please note: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [PDF].

Also please note that storage of data on cloud services may not be appropriate and is subject to applicable university policies regarding the use of cloud services. If deemed too sensitive or inappropriate to be stored or collected using cloud services, the IRB may require an alternate method of data storage in accordance with applicable university policies and the electronic data security guidance document referenced above.

If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriate protected.

Back to Top

The collated data will only reveal summarized data without identifiable information. The de-identified data will be available electronically and stored on a password protected computer. The electronic document containing names with respective survey codes will be deleted after post-survey data has been collected and therefore will not be stored. The list will be deleted by January 2020. Any study materials and raw data will be retained for 6 years after study closure in a locked drawer within a locked office or on a password protected computer (PI's UK DHN desktop in her locked office at 209C Funkhouser Building). The PI and program manager assigned to the project and involved in data collection will have access to these items. Digital data will be deleted per UK Policy A13-050.

Back to Top

Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

Walking group participants will be offered a farmer's market t-shirt at the baseline data collection time (May 2018) and all participants will be offered a $10 gift card at midpoint (late September/early October 2018) and post-data collection (February 2019). Walking group participants will receive weekly $10 vouchers to spend on fruits and vegetables at the Farmer's Market (June through September) and a weekly healthy meal valued at $20 (October through February). Catered meals will be provided for focus group participants to encourage participation.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

N/A

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, clinical research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, clinical research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, clinical research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

N/A the study does not have greater than minimal risk.

Back to Top

Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

Participants can voice their concerns to the PI, Co-PIs, program manager, or the Office of Research Integrity, which is listed on the consent form.

Does your research involve **Non-English Speaking Subjects or Subjects from a Foreign Culture**?

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.

Include contact information for someone who can act as a cultural consultant for your study. The person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted. The consultant should not have any direct involvement with the study. If you do not know someone who would be willing to act as your cultural consultant, the Office of Research Integrity will try to find someone to fill this role (this may delay the approval process for your protocol). Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study. For more details, see ORI's help page on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

For recruitment of Non-English speaking subjects, the consent document needs to be in the subject's native language. Download the informed consent template available in the E-IRB "Informed Consent/Assent Process" section and use it as a guide for developing the consent document. (Note: Your translated consent document can be attached to your application in the "Informed Consent" section; **be sure to save your responses in this section first.**)

If research is to be conducted at an international location, identify local regulations, laws, or ethics review requirements for human subject protection. If the project has been or will be reviewed by a local Ethics Committee, attach a copy of the review to the UK IRB using the attachment button below. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?

○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing, and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

Back to Top

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the PI assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials, IDE regulatory requirements for SR device trials, and abbreviated regulatory requirements for NSR device trials. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe your (the PI's) experience/knowledge/training (if any) in serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if you have transferred any sponsor obligations to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the PI completed the mandatory PI-sponsor training prior to this submission?

○ Yes ○ No

If you (the PI) have completed equivalent sponsor-investigator training, you may submit documentation of the content for the IRB's consideration.

Attachments

HIPAA

Is HIPAA applicable? ○ Yes ◉ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s):

- ☐ HIPAA De-identification Certification Form
- ☐ HIPAA Waiver of Authorization

Attachments

STATISTICAL ANALYSIS PLAN

This study will recruit approximately 150 participants, who will be divided into walking or non-walking groups to assess dietary behavior. Outcomes will compare the change in fruit and vegetable intake, health and exercise at baseline, 4 months and 8 months using survey metrics. Significance will be determined using a two-way ANOVA with a post-hoc Tukey's t-test; $p<0.05$.