Human Subjects Research Protocol

The Common Human Subjects Protocol Cover Form **must** be completed and accompany this form. This Protocol form should be completed for any human subjects research proposal that does not have a specific "protocol," such as a grant application. This form must be submitted along with a copy of the complete grant proposal and all the information in this form **must** be consistent with that proposal. This protocol form, once IRB approved, will be the working protocol for that research. **When completing this document, do not refer to page numbers within your grant**. If revisions are necessary during the course of the research, amendments should refer to this protocol form, not the grant proposal. Enter responses for all sections. Check N/A if the section does not apply. All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the InfoEd Resource Materials page for more information.

PROTOCOL SUMMARY

Project Title:	Protocol Version Date:
Examining Cooking as a Health Behavior	6-14-19

Principal Investigator: Jean Harvey PhD, RD

Grant Sponsor: USDA Hatch Act Funds Grant Number: VT-H02510

(For grants routed through UVM, indicate the OSP Proposal ID # located at the top of the OSP Routing Form)

Lay Language Summary: *(Please use non-technical language that would be understood by nonscientific IRB members to summarize the proposed research project. The information must include: (1) a brief statement of the problem and related theory supporting the intent of the study, and (2) a brief but specific description of the procedure(s) involving the human subjects. Please do not exceed one single-spaced 8 ½ X 11" page.)*

With the rise in obesity in America correlating strongly with the decline in the frequency that Americans cook at home, cooking may be an important behavior to encourage to promote health. Increasing the prevalence of Americans who cook meals at home may be an important health behavior to target, because cooking at home is widely regarded as being healthier than consuming food away from home. While interventions are limited in number and scope, the positive benefits of cooking at home on dietary quality seem to cut across age groups and populations from college students to older adults.[6, 7]Cooking classes may be an important intervention target because they may increase one's food agency. Thinking of cooking as a health behavior, cooking classes may be equivalent to exercise classes for someone trying to increase their physical activity. The exercise classes give one the skills, social structure, and self-efficacy to begin exercising on one's own. This study is designed to test whether cooking classes could do the same for someone's food agency and cooking frequency.

The proposed pilot study will examine cooking as an intervention target for weight control in overweight adults. The study will also examine whether interventions designed to promote cooking at home can increase participants' sense of food agency, and overcome common barriers to cooking at home such as time scarcity and budget constrictions. The study will utilize a cooking pedagogy designed to not just teach participants the basics of cooking different foods, but how to be efficient, mindful cooks. If we find that cooking class participation positively impacts diet and health outcomes, we will bolster the case for promoting cooking at home as a health behavior for multiple populations.

The study aims to recruit 64 overweight or obese adults to participate in a 24-week 2 part weight loss intervention. The intervention will include a weekly in-person behavioral weight control program and a bi-weekly cooking class. Each participant will be assigned to either the treatment group which will receive active cooking lessons or the control group which will receive demonstration only cooking lessons. Assessments including anthropometric measures and questionnaire data will be collected at baseline and week 24.

Aim 1: To determine if the addition of cooking classes to a behavioral weight control intervention improves weight loss and diet quality in overweight and obese adults.

Aim 2: To evaluate changes in food agency, cooking perceptions, and cooking frequency for individuals participating in the COOKING versus DEMONSTRATION conditions.

Weight Control Program: We have developed and implemented a theory-based group-delivered behavioral weight control program in two previous studies that incorporates the elements of current thinking and empirical data on successful weight loss programs,[37-39] including restricted calorie intake and increased physical activity. Key behavioral strategies to facilitate making sustained changes in dietary habits and activity patterns are introduced, promoted and reinforced throughout the program. In-

person sessions facilitated by an interventionist provide the group meetings. The program provides 24 weekly facilitated group sessions over 6 months. Target weight losses of 10% of baseline weight are promoted. Behavioral strategies are drawn from social cognitive theory[40] and self-regulation theory[41] and mirror the core components incorporated into such successful programs as Look AHEAD.[42]

Cooking Classes: The demonstration condition will serve as an "attention only" control. Previous research suggests that demonstrations of cooking have little to no impact on cooking behavior, therefore, cooking demonstrations can be used to "even out" the time and attention devoted to the active cooking participants without introducing bias into the study design. Subjects in the demonstration condition will also begin with a brief lecture on the day's lesson followed by a cooking demonstration that covers the same topics as the active intervention group. All participants will receive the same printed information and also have an opportunity to sample the prepared food at the end of class. The demonstrations will be led by the same chef as the active intervention group.

PURPOSE AND OBJECTIVES

Purpose: *The importance of the research and the potential knowledge to be gained should be explained in detail. Give background information.*

Frequency and Importance of Cooking at Home

Over the last twenty years Americans' eating habits have shifted, with fewer meals cooked at home and more meals eaten outside the home from restaurants, convenience stores, fast food locations, and cafeterias.[1-3] The latest analysis by the United States Department of Agriculture (USDA) Economic Research Service (ERS) indicated that household expenditures on food away from home have been steadily increasing over time and reached 43.7% of food expenditures in 2014.[4] As a percent of total household income, food away from home accounted for 5.4% of disposable income in 2014. Because food away from home is typically far less healthy[5-9] than food eaten at home, it is no surprise that many public health interventions have focused on attempting to make meals away from home healthier. However, Americans still report spending more of their disposable income on food eaten at home (6%), and at least 90% report at least sometimes cooking at home[10]. Regardless, it is clear that with innumerable options available to outsource cooking, this once necessary domestic behavior has declined in recent years in step with the rise of convenience food consumption.[11] In fact, the decline in cooking has been cited as being responsible for the increase in the prevalence of obesity and other chronic disease risk factors.[12] Despite this, few interventions have focused on overcoming the barriers people face to cooking more frequently at home and helping people cook healthy meals at home.[3]

Increasing the prevalence of Americans who cook meals at home may be an important health behavior to target, because cooking at home is widely regarded as being healthier than consuming food away from home. While interventions are limited in number and scope, the positive benefits of cooking at home on dietary quality seem to cut across age groups and populations from college students to older adults.[6,7] A study by Wolfson et al., looking at data from the National Health and Nutrition Examination Survey found that adults who cook dinner frequently at home had diets lower in total energy, fat, and sugar than those who cooked less frequently at home.[13] This association between cooking dinner more frequently at home and a healthier diet was present regardless of whether someone was actively attempting to lose weight or not.[13] Additional research from the USDA ERS has also found that food prepared at home is of higher dietary quality than food prepared away from home, with food prepared away from home associated with diets higher in calories, saturated fat, added sugars, and lower in fruits, vegetables, and whole grains.[8, 9] In addition to research associating cooking at home with better diet quality, there is also evidence that increasing one's cooking knowledge and/or skill is associated with increased healthy food intake.[14, 15] Finally, some research has associated cooking at home with lower Body Mass Index (BMI).[16] Despite all of the evidence indicating that cooking at home should be considered a health behavior, several studies have found that cooking at home is not associated with diet quality or BMI benefits,[17,18] indicating that learning how to cook healthfully at home may be essential for positive health benefits.

In addition to any potential benefits on dietary quality and weight status, it may be the case that cooking positively impacts social and emotional health.[6] In a survey of young adults, Larson et al., found that eating dinner with others versus eating on the run was associated with higher intakes of fruits and vegetables, and that the majority of young adults surveyed wanted to eat with others, but reported not having enough time.[19] Cooking ability has also been linked to lower depressive symptoms, and higher mental well-being in adolescents, while participation in a culinary intervention was associated with greater quality of life in adults.[20,21] In a review of the literature surrounding cooking and health, Mills et al. even found some evidence that[2] cooking could have positive benefits on cultural identity and personal relationships.[22] All of these findings build the case that cooking at home may impart benefits beyond improving one's diet or weight.

Barriers to Cooking at Home

There are a variety of societal and technological shifts since the 1960's that are often cited as reasons for why Americans cook less frequently at home, such as a notable increase in women joining the workforce, advances in food technology, and mass food preparation.[5] However, on an individual basis, issues such as lack of cooking knowledge, restricted access to healthy foods, economic constraints, and time scarcity have all been cited as potential factors for the decline in home cooking frequency.[5,23,24] Time scarcity is a fascinating concept to consider as a barrier for cooking at home, as there have always been and will always be 24 hours in a day. Therefore, it's not that Americans today have less total time than Americans in the 1960's, but that they choose to, or need to, spend that time differently, and feel that tasks like cooking can be shortened

or offloaded to preserve time for other activities.[23] Time scarcity seems to be a cooking barrier for many populations. Many parents report that time scarcity is a barrier to providing healthy meals, and that they often resort to using convenience foods and picking up take out to feed their families.[25] A longitudinal analysis of Australian adults indicated that time scarcity was associated with eating out more, less fruit and vegetable consumption, and higher intakes of discretionary calories.[22] Economic analyses have also indicated that time scarcity is associated with increased intake of fast food.[26] Although much work has illustrated that many people feel that they cannot engage in health behaviors such as cooking because of perceived or actual time scarcity,[22,23] very few intervention studies have examined potential strategies that might decrease people's perceptions of time scarcity and increase the number of days they are willing to cook meals at home.

Encouraging Cooking at Home

While cooking has been associated with a number of positive nutrition and health outcomes, current cooking interventions suffer from a number of methodological limitations.[27] In many, cooking skills or cooking "classes" are rarely presented as a sole component in interventions but are combined with nutrition, exercise, mindfulness, parenting, etc. topics.[28] It's not clear then if cooking has value alone or just in concert with other treatment components. Current cooking interventions are also quite variable in length; 6-10 weeks of weekly sessions with 90-120 minutes devoted to class. Interventions also differ substantially in the level of engagement participants have with hands on cooking; some simply observe skills while others practice skills and create full meals. Finally, most evaluations of cooking interventions have relied on self-report measures that are rarely validated, thus calling into question the many positive outcomes cited above.[29] A more robust approach to evaluation is desperately needed.

Overweight women may be especially motivated to learn about and engage in cooking behaviors. Women are often the "gatekeeper" of a family's meal and food life, so improving their cooking knowledge and skill may have a ripple effect for the entire family.[30] Ready-to-eat, convenience and restaurant foods are often significantly higher in calories, fat, salt and sugar than whole, home-prepared foods,[8] yet current state-of-the-art obesity treatment programs do not address cooking or home food preparation skills at all. To our knowledge, there has never been a weight management intervention that includes and isolates a cooking intervention. Adding cooking as a health behavior to a well-proven behavioral obesity treatment may improve weight loss, weight maintenance and diet quality. Obesity remains the greatest public health crisis of[3] our time. Developing skills to facilitate and enhance weight management could have significant public health impact.

Cooking classes may be an advantageous way to address many barriers to cooking. Cooking classes can impact time poverty by helping participants learn how to plan meals and easily prepare ingredients.[5] They may also teach budgeting skills to address economic barriers. However, very few rigorous studies have been conducted that design and evaluate cooking interventions in any adult population.[7] A 2018 review by Hollywood and colleagues[31] evaluated the behavior change techniques used in cooking interventions that were most likely to result in long-term behavior change. Fifty-nine cooking and food skills interventions were identified by two systematic reviews. Only 24 interventions included practical cooking sessions to develop cooking skills while all others were based on wider food skills like nutrition knowledge and budgeting. Of the 24 cooking interventions, only 12 were randomized controlled trials. Of those reporting a long-term behavior change (greater than 3 months; n=14), the majority included a "practical skills element" and information on "how to carry out the task" versus just a demonstration of the task. This suggests that food demonstrations are not sufficient to encourage behavior change. The authors also concluded that the vast majority of outcome measures relied on self-report thus, results are to be interpreted with caution.

Fostering Food Agency

Cooking classes may be an important intervention target because they may increase one's food agency. Thinking of cooking as a health behavior, cooking classes may be equivalent to exercise classes for someone trying to increase their physical activity. The exercise classes give one the skills, social structure, and self-efficacy to begin exercising on one's own. This study is designed to test whether cooking classes could do the same for someone's food agency and cooking frequency. Food agency looks at cooking as more than just a manual skill, it takes into account the sensory, socio-cultural (e.g. time, money) and physical environments involved in cooking, and it incorporates the ability to adapt. Those with high food agency feel empowered in their cooking practice, as they have the planning and preparatory skills, as well as the cooking skills to be successful.[32] Trubek et al., have developed a pedagogy for cooking classes designed to increase food agency by addressing the cognitive, technical, and mechanical skills necessary to make a meal.[27, 32] By using pedagogy designed to increase one's food agency, the participant is better prepared to overcome potential daily challenges that could prevent them from meeting their cooking, nutrition, and social goals. The pedagogy emphasizes not just skill building like how to read and use a recipe, but adaptability and the development of decision-making and organizational skills that will be helpful no matter the food environment, time, or resource limitations.[28] The concept of food agency views cooking behavior in a more holistic way. It is not enough to just teach someone the mechanics of cooking, in order for cooking to become an ingrained practice, you must teach someone how to overcome barriers and adapt to the conditions they face in daily life. Like many other health behaviors, encouraging someone to cook will only be successful if that person feels empowered to take the practice and apply it in their own life to form a habit.

Increasing Motivation to Adopt Cooking as a Health Behavior

Along with teaching cooking competency through a pedagogy that emphasizes food agency, it may be helpful to provide a material incentive to help overcome remaining barriers to healthy cooking. Incentives have been deployed successfully for a variety of health behaviors and health outcomes such as exercise and weight loss.[33,34] Incentives can be offered in many forms, on a variety of schedules, and in various amounts. As provisioning food, deciding what to buy, and having the resources to buy it, are often cited as barriers to cooking at home, it may be the case that providing people with meals and/or recipes each week could serve as incentives to overcome the provisioning barrier and encourage people to implement the skills learned during

their cooking classes. Recently, meal kit delivery services such as Hello Fresh, Blue Apron, and Purple Carrot have risen in popularity.[35] These services provide subscribers with the raw ingredients in the correct amounts necessary to make particular recipes and then also provide the recipes. Previous research has shown that providing participants with food increases their weight loss,[36] but there is very little research indicating if providing food has a positive impact on cooking behavior or diet quality.

Summary

The current study will expand on previous research surrounding the efficacy of employing cooking classes to build cooking skills, foster food agency, and improve dietary behaviors by employing a rigorous randomized controlled trial design and validated outcome measures in overweight or obese adults. The overall goal is to determine if encouraging cooking as a health behavior actually improves health outcomes.

***References**. Include references to prior human or animal research and references that are relevant to the design and conduct of the study.*

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Objectives: *Clearly state the primary and secondary objective(s) of the study.*

Objective: The overall goal of the study is to determine if the addition of cooking classes to a standard behavioral weight loss program (COOKING) will improve weight loss and diet quality when compared to a weight loss program with an attention only control (DEMONSTRATION).

Aim 1: To determine if the addition of cooking classes to a behavioral weight control intervention improves weight loss and diet quality in overweight and obese adults.

Aim 2: To evaluate changes in food agency, cooking perceptions and cooking frequency for individuals participating in the COOKING versus DEMONSTRATION conditions.

Aim 3: To explore the feasibility and acceptability of adding cooking classes to a standard behavioral weight loss intervention.

METHODS AND PROCEDURES

Study Design: *Describe the research design, including a description of any new methodology and its advantage over existing methodologies.*

We propose a two arm randomized control trial to examine whether the addition of an active cooking lesson versus a passive observed lesson to a behavioral weight loss intervention results in significantly greater weight loss. Additionally, the study will examine whether interventions designed to promote cooking at home can increase participants' sense of food agency, and overcome common barriers to cooking at home such as time scarcity and budget constrictions.

Overweight and obese but otherwise healthy participants (n=64) will be recruited using online postings on local Front Porch Forum sites, the University of Vermont's weekly announcement newsletter (research studies), and the University of Vermont Medical Center's wellness calendar. Additionally, physical posters will be posted around UVM's campus, UVMMC's campus, and local physician's offices who agree to display posters. We will also draw from a running waitlist of interested weight loss participants held by the Nutrition and Food Sciences Department. Recruitment and study initiation will occur in two waves. Wave 1 aims to recruit 32 individuals who will then be randomized to 1) a 24 week, 24 session group behavioral weight loss intervention with 12 bi-weekly cooking lessons; or, 2) the same 24 week, 24 session group behavioral weight loss intervention with 12 bi-weekly cooking demonstrations. Both groups get the same intervention and the same counselor delivered intervention elements; the presence of active cooking lessons vs. passive observed cooking demonstrations is the only difference between conditions. Assessments will be conducted at 0, 3 and 6 months. Wave 2 (n=32) will follow the same process as Wave 1 approximately two months after Wave 1 is initiated.

To be eligible to participate, individuals must be at least 18 years old and overweight or obese (have a Body Mass Index (BMI) 25-50 kg/m2). Individuals must also be free of medical problems that might contraindicate participation in a behavioral weight loss program containing an exercise component, not currently on medication that might affect weight loss, not pregnant or lactating, not enrolled in another weight reduction program and not currently cooking more than 3 meals at home per week. All participants must have a computer with Internet access (at home or work) in order to track their diet and exercise behaviors. Participants must also agree to be randomized to either of the study arms.

Group assignments will be determined by a random assignment table created by the UVM Medical Biostatistics department using PROC PLAN in SAS. The program will stratify (arrange) groups so that they are statistically similar in distribution of both gender and weight classification (BMI<30 and BMI≥30 This program will allow study personnel to access a series of envelopes that will tell them which group the participant is assigned to. A participant ID number will be permanently associated with the participant to identify which group they have been assigned to. To avoid differential impact of and to assure equal representation in each group, eligible subjects will be stratified by BMI and gender. To minimize loss to follow up, standardized training of staff will be provided focusing on rapport building, motivational interviewing and problem solving. Participants will be educated on the importance of follow up and detailed contact information is obtained at study initiation.

The Behavioral Weight Loss Program: We have developed and implemented a theory-based group-delivered behavioral weight control program in two previous studies that incorporates the elements of current thinking and empirical data on successful weight loss programs,[37-39] including restricted calorie intake and increased physical activity. Key behavioral strategies to facilitate making sustained changes in dietary habits and activity patterns are introduced, promoted and reinforced throughout the program. In-person sessions facilitated by an interventionist provide the group meetings. The program provides 24 weekly facilitated group sessions over 6 months. Target weight losses of 10% of baseline weight are promoted. Behavioral strategies are drawn from social cognitive theory[40] and self-regulation theory[41] and mirror the core components incorporated into such successful programs as Look AHEAD.[42] In addition to attending weekly classes, participants will track their food intake, exercise, and weight. They will share their online tracking diaries with the group facilitator who will offer individualized feedback on their progress.

The Cooking Program

Active Intervention. Twelve cooking classes will be run every other week after the in-person weight loss meetings. These lessons will be patterned after Dr. Amy Trubek's cooking pedagogy and will be tailored for individuals specifically interested in weight loss. Classes will begin with a brief lecture on the day's topic, followed by a laboratory session. Participants work in teams of two in the NFS foods lab to actively practice skills and cook a meal. Subjects will receive recipes and information sheets that cover pantry supplies, grocery lists, knife skills and cooking equipment. Classes will be taught by a chef trained in the pedagogy by Dr. Trubek and participants will have the opportunity to sample the food they prepared at the end of class.

Demonstrations. The demonstration condition will serve as an "attention only" control. Previous research suggests that demonstrations of cooking have little to no impact on cooking behavior, therefore, cooking demonstrations can be used to "even out" the time and attention devoted to the active cooking participants without introducing bias into the study design. Subjects in the demonstration condition will also begin with a brief lecture on the day's lesson followed by a cooking demonstration that covers the same topics as the active intervention group. All participants will receive the same printed information and also have an opportunity to sample the prepared food at the end of class. The demonstrations will be led by the same chef as the active intervention group.

Procedures: *Describe all procedures (sequentially) to which human participants will be subjected. Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes. Describe the types, frequency and duration of tests, study visits, interviews, questionnaires, etc. Include required screening procedures performed before enrollment and while on study. Please provide in table, list or outline format for ease of review. (describe and attach all instruments)*

Note: A clinical research protocol may involve interventions that are strictly experimental or it may involve some aspect of research (e.g., randomization among standard treatments for collection and analysis of routine clinical data for research purposes). It is important for this section to distinguish between interventions that are experimental and/or carried out for research purposes versus those procedures that are considered standard therapy. In addition, routine procedures performed solely for research purposes (e.g., additional diagnostic/follow-up tests) should be identified.

Recruitment and Screening

Advertisements will be posted to local Front Porch Forums, in a local newspaper, on the UVM employee newsletter, the University of Vermont Medical Center employee wellness newsletter (see attached for drafts of each advertisement). Individuals interested in participating will be directed to a secure online recruitment survey which queries for basic contact information and eligibly criteria (self-reported height and weight, age, cooking habits, etc.) and provides additional information regarding the study. Individuals who appear likely to be eligible based on this online registration will receive a brief phone screen conducted by research staff to confirm initial eligibility for the study and will be scheduled for an in-person orientation session where the study will be reviewed in detail, questions will be addressed. Participants will be provided with an orientation packet that includes directions for using MyFitnessPal, a handout outlining MyFitnessPal privacy information, directions for photo elicitations, and an informed consent document will be provided to take home. Participants interested in enrolling in the study will be asked to sign a consent form approved by the UVM Research Protections Office and baseline data collection will begin, including collection of height and body weight data. Participants will be asked to record dietary intake for three days using My Fitness Pal as a behavioral run in and to complete questionnaires online. Directions for how to access both of these elements will be provided to participants and a helpline contact will be provided. Only after all these eligibility criteria have been satisfied will participants be randomized.

The College of Medicine Bioinformatics will create a randomization scheme that allows the research coordinator to blindly assign participants to one of the two study groups.

Questionnaires will be administered through the study website at baseline and study end. Participants will receive links to the questionnaires and reminders to complete questionnaires via email. These measures are outlined in greater detail below. In addition to baseline and study end questionnaires, weekly data collection will be administered through the study website. Participants will receive reminders to complete weekly data submissions, and will be given information regarding a helpline for using the study website and data entry.

Table 1 outlines when each measure will occur during the study.

Measures	Baseline	Weekly	Week 12	Week 24
ASA24	■			■
HEI (calculated)	■			■
CAFPAS	■			■
Cooking Perceptions and Behaviors	■			■
Height, Weight, BMI	■		■	■
Cooking Frequency	■	■		
Photo Elicitation	■	■		
Class Evaluation				■

Quantitative Measures

Automated Self-Administered 24-Hour Dietary Assessment Tool (ASA24) – The ASA24 is a web-based dietary assessment tool developed by the National Cancer Institute that allows collection of multiple, automatically coded, self-administered 24-hour recalls. The ASA24 has been validated and used in many different populations and nutrition studies.[43] When completing the ASA24, the participant is first prompted to report the time of all food and drinks consumed. Next, they search a list of foods and select which foods they ate at each meal. If there is a gap of more than three hours between reported eating occasions participants are then asked if they ate anything during that gap. There is then a detail pass where participants are asked about preparation methods, portion sizes and anything they added to a food. Finally, participants are asked about foods that people commonly forget to include and can add any of these foods to their recall. Detailed instructions with pictures for completing the recall are available on the ASA24 website and participants will be made aware of this resource.
Foods included in the ASA24 all code to the USDA's Food and Nutrient Database for Dietary Studies, and so all entries can be automatically coded.[43] Healthy Eating Index (HEI) – The HEI is a measure of overall diet quality, and can assess compliance with the U.S. Dietary Guidelines, as well as measure changes in dietary patterns. The HEI is updated with each set of Dietary Guidelines, and has been validated for the 2005 and 2010 Dietary Guidelines.[44] The HEI is a valid and reliable tool for assessing dietary quality in a variety of population subgroups and nutrition interventions.[44] The validation for the 2015 Dietary Guidelines is expected soon. The HEI takes into account one's intake of the following foods when calculating a total score, total fruit, whole fruit, total vegetables, dark green vegetables, legumes, whole grains, dairy, total protein foods, seafood, eggs, soy

products, nuts and seeds, refined grains, saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, sodium, calories from added sugars, and total calories.[44] The HEI calculates final scores from 24-hour recalls like the ASA24.

Cooking and Food Provisioning Action Scale (CAFPAS): The CAFPAS scale measures cooking and food preparation practices or the degree to which individuals can set and achieve cooking and food provisioning goals. The CAFPAS includes 28 items with three subscales: Food Self-Efficacy, Food Attitude, and Structure. The CAFPAS scale has been shown to predict reported meals cooked per week and has adequate internal validity and test-retest reliability.[45]

The Cooking Perceptions and Behaviors Questionnaire: The Cooking Perceptions and Behaviors questionnaire is a 53-item survey designed to assess three factors: Perceptions of Cooking, Cooking Confidence and Attitudes, and Cooking Behaviors. This survey has been used in previous research to measure cooking perceptions and behavior.[46]

Weekly Assessment of Cooking Frequency: Each week, participants will use the study website to record how many times that week they cooked at home. The weekly surveys should take 5 minutes to fill out.

Height, Weight, and BMI: Measurements will be taken at the time of weekly classes. Height will be measured with a standardized stadiometer. Weight will be measured on a calibrated research scale (Tanita), and BMI will be calculated using height (m) and weight (kg) measurements.

Demographics Questionnaire: A five question paper questionnaire will be given to each participant at the first class meeting. Participants will be asked to fill out the questionnaire in private during the time they are having their weight and height measured. This questionnaire will gather information regarding participants marital status, education, and employment. Participants may leave any questions they do not wish to answer unanswered. Data from these questionnaires will be recorded in to the REDCap study website by study staff. Once data has been recorded, paper questionnaires will be destroyed.

Qualitative Measures

Photo Elicitation – With photo elicitation, participants take photos of a particular topic, and then these photos are used as the starting point for an interview between the participant and researcher. Photo elicitation has been used in public health research previously with a variety of projects and populations.[47] For this study, participants will be asked to take photos with their smartphones or cameras and then upload two photos each week to the study website. Instructions will ask participants to capture the meal that week they feel most represents their interpretation of a "healthy meal," and the meal they ate that week that least represents their interpretation of a "healthy meal." Both the intervention and control group will be instructed to take these weekly photos and label them as a meal they cooked at home or a meal they did not cook at home. Participants will be informed verbally and in writing that they should not include themselves or others in the pictures they submit, and that in order to protect their privacy, any pictures that contain individuals will be deleted and they will be asked to submit a replacement picture. At orientation, participants will be provided with an instruction sheet which outlines how they are expected to submit their meal photos and reiterates that they should not include themselves or others in the photos. At the conclusion of the study, investigators will randomly select ten participants from the control group and ten participants from the intervention group to interview about their photos. The interviews will ask questions about why the photos represented healthy or unhealthy meals to the participants, where the meals were prepared, how the photos may have changed over time, and how the various interventions may have impacted the photos.

Cooking Class/Demonstration Evaluation – At the conclusion of the cooking classes for the intervention group and the cooking demonstrations for the control group there will be a class evaluation given to assess participants' impressions of the classes or demonstrations. This evaluation will be available on the study website, and participants will have time in class to complete the evaluation and can do so on their smart phone or tablet. Participants will also have the option to complete this evaluation at a later time on their home computer.

Intervention

Participants in both treatment and control groups will attend weekly sessions of the behavioral weight loss program. Sessions will be 1 hour long and will include a weekly lesson as well as a group discussion. These sessions will be standalone meetings (1 hour) every other week for 24 weeks and paired with the cooking class biweekly (2 hours). Weight loss meetings and cooking classes will occur in the same space.

Every week participants will be asked to track their food, exercise, and weight every day. The tracking will be done through My Fitness Pal and reviewed by the group facilitator on a weekly basis in order to offer individualized feedback to participants. Participants will be asked to complete short weekly homework assignments that relate to the week's lesson. Homework will also be reviewed by the group facilitator.

Facilities and Equipment Needed

Cooking Labs – The cooking classes and demonstrations will take place in the Nutrition and Food Sciences teaching kitchen located in the Marsh Life Science building. The teaching kitchen has room for 16 students to complete hands on cooking labs, and an additional space where students can get directions, eat, and watch cooking demos. The kitchens are fully stocked with the necessary kitchen equipment.

Follow-up Data Collection

Participants will be alerted prior to their follow-up assessment appointment to complete the online questionnaires which are anticipated to take approximately 30 minutes to complete and 3 days of the ASA24 (less than 30 minutes per day). They will also be scheduled to come into the research office to get weighed, at which time the weight loss achieved will be recorded.

All participants (in both treatment conditions) will be offered small incentives such as tote bags, cookbooks, exercise equipment, gift cards, etc. (valued at approximately $ 5-25) after completion of the follow-up data collection visits as a token of appreciate for their participation.

For research involving survey, questionnaires, etc.: *Describe the setting and the mode of administering the instrument and the provisions for maintaining privacy and confidentiality. Include the duration, intervals of administration, and overall length of participation. (describe and attach all instruments)*

☐ ***Not applicable***

Surveys and questionnaires will be administered online through the study website (REDCap). Participants will be sent links to questionnaires through their email. Participants will be able to save and return to questionnaires with a unique 8 digit ID provided by REDCap, however participants will not have access to review the questionnaires after completion or to make changes after submitting the forms. They will be provided with a helpline contact should they encounter difficulty in completing the forms. If participants prefer, they can complete the forms using a paper copy rather than online. It is expected that the online baseline and follow-up assessment questionnaires will take less than 30 minutes to complete and the in-person follow up assessment (weighing in) will take less than 30 minutes. The baseline and follow-up ASA24 3 day tracking is estimated to take less than 30 minutes for each entry.

Statistical Considerations: *Delineate the precise outcomes to be measured and analyzed. Describe how these results will be measured and statistically analyzed. Delineate methods used to estimate the required number of subjects. Describe power calculations if the study involves comparisons. Perform this analysis on each of the primary and secondary objectives, if possible.*

Aim 1: To determine if the addition of cooking classes to a behavioral weight control intervention improves weight loss and diet quality in overweight and obese adults.
Hypothesis 1: Weight loss and diet quality (as measured by the Healthy Eating Index) will be significantly greater in the Cooking vs. Demonstration condition at 12 and 24 weeks.

Aim 2: To evaluate changes in food agency, cooking perceptions and cooking frequency for individuals participating in the COOKING versus DEMONSTRATION conditions.
Hypothesis 2: Food agency, cooking perceptions and cooking frequency will be significantly greater in the COOKING versus DEMONSTRATION conditions at 12 and 24 weeks.

Analysis Aims 1 and 2: The first and second hypotheses will be addressed using a repeated measures analysis of variance with treatment condition as the between group factors and assessment time as the within subject factor recalling that the baseline value will be subtracted from all subsequent values. An intent-to-treat approach will be used as the definitive analysis perspective for both the primary hypothesis testing and the secondary analysis of data. The use of a multiple imputation process will be conducted if the missing data can be assumed to be missing at random or completely at random. The intent-to-treat approach will require the use of a mixed model approach that can deal with repeated measures data and which can also deal with missing data (e.g. SAS ProcMixed or BMDP5V)

Aim 3: To explore the feasibility and acceptability of adding cooking classes to a standard behavioral weight loss intervention.
Analysis Aim 3: Feasibility and acceptability will be monitored by evaluating attendance and self-monitoring as well as qualitative data related to the perceived usefulness of the cooking classes or demonstrations.

Risks/Benefits: *Describe any potential or known risks. This includes physical, psychological, social, legal or other risks. Estimate the probability that given risk may occur, its severity and potential reversibility. If the study involves a placebo or washout period, the risks related to these must be addressed in both the protocol and consent. Describe the planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits to subjects and others. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research and why the risks are reasonable in relation to the knowledge that reasonably may result. If there are no benefits state so.*

Potential Risks.
No social, legal or other risks are anticipated as part of this project. All assessment procedures and intervention recommendations have been used in previous studies without adverse outcomes. Assessment methods reflect procedures that individuals might encounter in a routine health care visit (i.e., weight assessment) or questionnaire measures that have been implemented in numerous studies without difficulties (e.g., dietary intake and physical activity questionnaires).

Intervention methods are similarly very low risk. Behavioral weight control interventions recommend that individuals make changes to dietary intake and physical activity, all of which are comparable to the recommendations made by national advisory panels and recognized leaders in health recommendations. Specifically, the intervention goals outlined are consistent with NHLBI recommendations, the American Heart Association, the American Diabetes Association, etc. These intervention

recommendations for diet and activity habit change have minimal risk. The most common risk associated with participation in the interventions is soreness or musculoskeletal injury, although this occurs infrequently. Precautions will be taken to further minimize risk by making recommendations for graded increases that slowly increase activity duration and frequency and appropriate stretching. Moderate exercise prescriptions rather than vigorous levels of physical activity should also minimize these risks.

A potential risk in the present study is that participants may fail to lose weight in the program, but this risk occurs in all approaches to weight control. Alternative approaches to weight loss, including stricter diets, pharmacological interventions, and surgical procedures, are considered to have greater risk than the dietary and physical activity program described in this protocol. Participants may utilize unhealthy dietary practices to lose weight and/or may experience minor musculoskeletal injuries during exercise; however, this is considered unlikely and precautions will be taken to further minimize this risk.

Protection Against Risk. Every effort will be made to keep participants' information private and confidential. Confidentiality will be ensured by coding data with a unique ID number, and all data collected will be stored in locked files with access restricted to study personnel, and password protected computer data files. Participants will not be personally identified in any scientific reports generated by the study or any other dissemination efforts. All results will be presented in aggregate form. All project staff will undergo training and ongoing continuing education about methods to protect confidentiality.

Participants will be taught warm-up and stretching techniques to precede all exercise sessions to minimize the chance of muscle injury. In addition, weekly self-monitoring diaries will be submitted and reviewed at regular intervals throughout the study allowing for assessment of nutritional adequacy. No calorie goals will be set below 1200 kcal/day to provide participants with sufficient calories for a nutritionally adequate diet. Participants who become pregnant during the course of the 18-month study will be dropped from the treatment protocol, and participants who experience other medical problems during the course of the study will be referred to their personal physician for care as appropriate.

Potential Benefits
The potential benefit to the participants will be the skills and knowledge in lifestyle behaviors to successfully lose weight and prevent/deter weight re-gain. Further, participants may benefit from the improved health and psychological well-being that commonly accompanies weight loss. These benefits to the individual participant are considered substantial.

This study will expand our understanding of cooking's potential as a health behavior, by testing several novel interventions, including a cooking pedagogy designed to increase food agency, and provision of material support for cooking at home. Very little previous research has addressed cooking at home as a potential health behavior. Even less previous work has attempted to motivate people to cook at home. Furthermore, the pedagogy to be used for the cooking class intervention in this study has been explicitly designed to increase one's food agency, a new theoretical concept, that aims to empower one's cooking practice. The relationship between food agency and health has not been explored thoroughly, and this study will examine associations between food agency, cooking at home, diet quality, and weight outcomes. In addition to using a new methodological scale associated with food agency, the proposal will use the qualitative technique of photo elicitation to gather qualitative evidence of participants' cooking experiences, perceptions, and barriers. Therefore, the results of this study will be of interest to those designing behavioral weight loss programs for adults.

Therapeutic Alternatives: *List the therapeutic alternatives that are reasonably available that may be of benefit to the potential subject and include in the consent form as well.*

☐ ***Not Applicable***

There are a variety of weight loss programs available as a therapeutic alternative. Individuals can join commercial programs or speak with their physician to get assistance with their weight loss efforts. In addition, pharmacological interventions, and surgical procedures that produce weight loss are available, if deemed appropriate by the individual's physician.

Data Safety and Monitoring: *The specific design of a Data and Safety Monitoring Plan (DSMP) for a protocol may vary extensively depending on the potential risks, size, and complexity of the research study. For a minimal risk study, a DSMP could be as simple as a description of the Principal Investigator's plan for monitoring the data and performance of safety reviews or it could be as complex as the initiation of an external, independent Data Safety and Monitoring Board (DSMB). The UVM/UVM Medical Center process for review of adverse events should be included in the DSMP.*

Safety of the subjects. The proposed study poses no serious physical, psychological, or legal risks to participants. Therefore, the trial will be monitored by the PI's (Jean Harvey, PhD, RD and Lizzy Pope, PhD, RD), the Research Project Coordinator (Mattie Alpaugh, MSD) and group facilitators. Weekly meetings or conference calls will be held to evaluate the status of study participants. Any serious adverse events will be recorded on a standard form and reported to the Research Coordinator, to the PI's and the UVM IRB.

Data. Research participants will complete some questionnaires online as dictated by the study protocol. Only their subject identification number will appear on the questionnaires; no names or other personal identifiers will be included on data collection forms. All data collected by the research coordinator is considered part of the participant's confidential record. Data collected from research participants will be stored as password protected electronic data files. All data will remain confidential. A file will be maintained that associates the participant name with that participant's study identification. This file will remain in a locked file cabinet at UVM and will not be stored with the actual study data. This file will be destroyed at the end of the study.

Storage of Collected Data. All electronic data will be stored in password-protected files. Data will only be accessed when coded or audited. The study's project manager will work closely with the UVM Medical Biostatics facility to ensure the secure storage of all project data, using appropriate data safety procedures. Site specific data, or data not initially entered into REDCap will be sent to the study statistician using secure FTP transfers. All original transferred data files will be stored on a dedicated PC with limited and secured password protected access in a private locked office. Data management and editing of these files will take place prior to archiving any data files into a SAS based project specific database with specific documentation of any editing and data review adjudications while the original data files will be retained intact. Only archived data files will be used to derive analysis data files to address specific hypotheses or project monitoring reports

The data entry system will require a login identification and password in order to gain access to the data. Where appropriate, validation and range rules will be applied to the actual entry field. Only the Biostatistics staff will be able to view the data in its raw state. All other authorized personnel (Principal Investigators, Research Coordinator) will view data via forms and reports created by the Biostatistics staff.

Data collected using paper questionnaires will be entered by study staff into the REDCap system. Prior to being entered into REDCap all hardcopies of questionnaires will be stored in a locked filing cabinet in a locked office. Once data has been entered, hardcopies will be destroyed using a locked Secure Shred bin located in the Nutrition and Food Sciences Department.

Direct Data Entry by Participants. Questionnaires will be completed by participants directly online. These questionnaires will utilize formats that include range and validity checks, as appropriate, as well as queries to assure that all items have been answered before completing the form, to assure the most accurate data collection and will be identified only by unique participant IDs. Participants will not have access to review the questionnaires after completed or to make changes after submitting the forms. Participants will be provided with a "helpline" contact should they encounter difficulty in completing the forms.

Access to Cleaned Computer Data. Once the study is complete, and all data have been collected, entered, and passed the verification process, the director of the Bioinformatics facility, will make the data available to the Principal Investigators and their designates. Only the Principal Investigators can give permission for the release of aggregated study data. No confidential information may be released without the express written consent of the study participants. Only copies of the aggregated, de-identified finalized data will be released.

Adverse Event and Unanticipated Problem (UAP) Reporting: *Describe how events and UAPs will be evaluated and reported to the IRB. All protocols should specify that, in the absence of more stringent reporting requirements, the guidelines established in the Committees on Human Research "Adverse Event and Unanticipated Problems Reporting Policy" will be followed. The UVM/UVM Medical Center process for review of adverse events and UAPs to subjects or others should be included in the DSMP.*

Weekly meetings or conference calls will be held to evaluate the status of study participants. Any serious adverse events will be recorded on a standard form and reported to the Research Coordinator, to the PI's and the UVM IRB.

Withdrawal Procedures: *Define the precise criteria for withdrawing subjects from the study. Include a description of study requirements for when a subject withdraws him or herself from the study (if applicable).*

Participants may withdraw from the study at any time by notifying the PI or Study Coordinator in writing (or by email) of their intention.

If necessary, subjects may be terminated or withdrawn by the Principal Investigator without the consent of the participant if continued participation would be contraindicated, including because the participant (1) becomes pregnant (and therefore it would not be appropriate to follow a weight loss program); (2) develops a life threatening disease for which weight loss is contraindicated; (3) joins another weight control program (such as Weight Watchers, Jenny Craig, NutriSystems, etc.); or (4) the participant moves more than 120 miles from the clinical center with no plans to return during study assessment windows.

Sources of Materials: *Identify sources of research material obtained from individually identifiable human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.*

The anthropometric, behavioral, and self-report questionnaire data collected in this study will be obtained for research purposes only.

DRUG AND DEVICE INFORMATION

Investigators are encouraged to consult the UVM Medical Center Investigational Pharmacy Drug Service (847-4863) prior to finalizing study drug/substance procedures.

Drug (s) [X] ***Not applicable***

Drug name – generic followed by brand name and common abbreviations. Availability – Source and pharmacology, vial or product sizes and supplier. If a placebo will be used, identify its contents and source. (attach investigational drug brochure)

Preparation: Reconstitution instructions; preparation of a sterile product, compounded dosage form; mixing guidelines, including fluid and volume required. Identify who will prepare.

Storage and stability – for both intact and mixed products.

Administration – Describe acceptable routes and methods of administration and any associated risks of administration.

Toxicity – Accurate but concise listings of major toxicities. Rare toxicities, which may be severe, should be included by indicated incidence. Also adverse interactions with other drugs used in the protocol regimen as well as specific foods should be noted. Address significant drug or drug/food interactions in the consent form as well. List all with above details.

Is it FDA approved: (include FDA IND Number)

1. *in the dosage form specified? If no, provide justification for proposed use and source of the study drug in that form.*
2. *for the route of administration specified? If no, provide justification for route and describe the method to accomplish.*
3. *for the intended action?*

Device (s) [X] ***Not applicable***

Device name and indications (attach investigational device brochure)

Is it FDA approved: (include FDA IDE Number)

1. *for indication specified? If no, provide justification for proposed use and source of the device.*

Risk assessment (non-significant/significant risk) - PI or sponsor needs to assess risk of a device based upon the use of the device with human subjects in a research environment.

SUBJECT CHARACTERISTICS, IDENTIFICATION AND RECRUITMENT

Subject Selection: *Provide rationale for subject selection in terms of the scientific objectives and proposed study design.*

This study aims to evaluate changes in food agency including cooking frequency between the two interventions. Therefore, subjects are selected to provide a sample of individuals positioned to increase their food agency and cooking frequency. Towards this end, only individuals who are cooking (from scratch) no more than 3 meals at home per week will be eligible. All participants must have a computer or smart device with internet access (at home or work) in order to track their diet and exercise behaviors, as this is central to the behavioral weight loss intervention. The study does not seek to introduce use of this technology to naïve users who have no daily access. Furthermore, potential participants will be required to demonstrate some ability to comply with study intervention procedures to be eligible (specifically, they must complete an online dietary self-monitoring diary for 3 days so that only adequately motivated individuals who are likely to stay engaged for the full 24 week study period are enrolled and randomized.

Vulnerable Populations: *Explain the rationale for involvement of special classes of subjects, if any. Discuss what procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risk (physical, psychological, etc.).*

[X] ***Not applicable***

Number of Subjects: *What is the anticipated number of subjects to be enrolled at UVM/UVM Medical Center and in the case of a multi-center study, with UVM/UVM Medical Center as the lead, the total number of subjects for the entire study.*

This is a pilot study with no previous data available to calculate expected statistical power. The sample size chosen was practical as our foods lab can only accommodate 16 people at a time. Two waves of each intervention arm would give us data on approximately 64 subjects. This preliminary data will be used to determine the sample size power needed for a larger study with sufficient statistical power.

Inclusion/Exclusion Criteria: *Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined and by whom. Changes to the eligibility criteria at a later phase of the research have the potential to invalidate the research.*

To be eligible to participate, participants must be at least 18 years old and have a Body Mass Index (BMI) between 25-50 kg/m2. Review of previous research studies conducted by this research groups has found that individuals with a BMI greater than 50 do not have success with the planned intervention. These individuals require a more intensive approach to see a

reduction in weight than what they study intervention offers. Individuals must also be free of medical problems that might contraindicate participation in a behavioral weight loss program containing an exercise component, not currently on medication that might affect weight loss, and not enrolled in another weight reduction program (all of which would be problematic confounds for the primary outcome of body weight). Participants will also be excluded if they are pregnant, plan to become pregnant in the next six month, or are lactating as these would be problematic confounds for the primary outcome of body weight. Additionally, weight loss is not generally recommended for pregnant women and when it is must be closely monitored by a physician. Participants will not be eligible if they are currently cooking (from scratch) more than 3 meals at home per week. All participants must have a computer with Internet access (at home or work) in order to track their diet and exercise behaviors. Participants must also agree to be randomized to either of the study arms and be available for both scheduled meeting times.

Inclusion of Minorities and Women: *Describe efforts to include minorities and women. If either minorities or women are excluded, include a justification for the exclusion.*

Women and minorities will be included. Women are more likely to participate in weight loss interventions than men.

Inclusion of Children: *Describe efforts to include children. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children. When included, the plan must also describe the expertise of the investigative team in working with children, the appropriateness of the available facilities to accommodate children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.* ***If children are excluded*** *then provide appropriate justification. Provide target accrual for this population.*

We propose to exclude children under 18 years of age because the proposed behavioral weight loss intervention has not been studied in children. Effective behavioral obesity treatment for children requires appropriate adaptation for their developmental needs. Thus, the current intervention approach may not be appropriate for younger children. However, children aged 18-21 will be eligible to participate.

For protocols including the use of an investigational drug, indicate whether women of childbearing potential have been included and, if not, include appropriate justification.

Not applicable

If HIV testing is included specifically for research purposes explain how the test results will be protected against unauthorized disclosure. Include if the subjects are to be informed of the test results. If yes, include the process and provision for counseling. If no, a rationale for not informing the subjects should be included.

X ***Not applicable***

Recruitment: *Describe plans for identifying and recruitment of subjects. All recruitment materials (flyers, ads, letters, etc) need to be IRB approved prior to use.*

Subjects will be recruited to participate from the greater Burlington area using social media, newspaper ads or by drawing on our existing waiting list.
Interested persons will be directed to a secure online recruitment survey which queries for basic contact information and eligibly criteria (self-reported height and weight, age, etc.) and provides additional information regarding the study. Individuals who appear likely to be eligible based on this online registration will receive a brief phone screen conducted by research staff to confirm initial eligibility for the study and will be scheduled for an in-person orientation session where the study will be reviewed in detail, questions will be addressed and an informed consent document will be provided to take home. After considering the study for a minimum of 1 week, interested participants will be asked to sign a consent form at the first baseline data collection visit. Consent forms will have been approved by the University of Vermont Institutional Review Board.

FINANCIAL CONSIDERATIONS

Expense to Subject: *If the investigation involves the possibility of added expense to the subject (longer hospitalization, extra studies, etc.) indicate in detail how this will be handled. In cases where the FDA has authorized the drug or device company to charge the patient for the experimental drug or device,* ***a copy of the authorization letter from the FDA or sponsor must accompany the application. Final approval will not be granted until the IRB receives this documentation.***
There are very limited circumstances under which study participants may be responsible (either directly or via their insurance) for covering some study-related expenses. If the study participant or their insurer(s) will be billed for any portion of the research study, provide a justification as to why this is appropriate and acceptable. For example, if the study involves treatment that is documented standard of care and not investigational, state so. In these cases, the protocol and the consent should clearly define what is standard of care and what is research.

No additional expense to participants is anticipated, other than parking costs for onsite visits of $1/hour if arriving before 3:30, or childcare costs, if needed, and no proposed research procedures will be billed to participants.

Payment for participation: *Describe all plans to pay subjects, either in cash, a gift or gift certificate. Please note that all payments must be prorated throughout the life of the study. The IRB will not approve a study where there is only a lump sum payment at the end of the study because this can be considered coercive. The amount of payment must be justified. Clarify if subjects will be reimbursed for travel or other expenses.*

☐ ***Not applicable***

Participants will be offered small tokens for attending data collection visits. Items such as tote bags, cookbooks, exercise equipment, gift cards, etc. (value of $ 5-25) will be provided to those who provide follow-up data.

Collaborating Sites. *When research involving human subjects will take place at collaborating sites or other performance sites when UVM/UVM Medical Center is the lead site, the principal investigator must provide in this section a list of the collaborating sites and their Federalwide Assurance numbers when applicable. (agreements may be necessary)*

X ***Not applicable***

INFORMED CONSENT

Consent Procedures: *Describe the consent procedures to be followed, including the circumstances under which consent will be obtained, who will seek it, and the methods of documenting consent. Specify the form(s) that will be used e.g. consent (if multiple forms explain and place identifier on each form), assent form and/or HIPAA authorization (if PHI is included). These form(s) must accompany the protocol as an appendix or attachment.*

Note: Only those individuals authorized to solicit consent may sign the consent form confirming that the prospective subject was provided the necessary information and that any questions asked were answered.

Interested persons will be directed to a secure online recruitment survey which queries for basic contact information and eligibly criteria (self-reported height and weight, age, etc.) and provides additional information regarding the study. Individuals who appear likely to be eligible based on this online registration will receive a brief phone screen conducted by research staff to confirm initial eligibility for the study and will be scheduled for an in-person orientation session. During the orientation designated staff who have been certified to obtain consent will discuss the informed consent form with the subject volunteer, reviewing each aspect of the consent form and allowing individuals to ask questions. This orientation may be delivered in a group setting, although if scheduling does not permit engaging in the group orientation, the subject volunteer may be orientated individually. Subject volunteers often benefit from the group process in that they hear questions that others ask which may not have occurred to them but are of interest to them in their decision making about participation. Subject volunteers will be provided with a copy of the consent form at the group orientation but will not be asked to sign the form until they return for an individual visit. Individuals who remain interested in the study after the orientation session and have reviewed the consent form will be invited to return for an individual screening session at which the remainder of the consent process will occur. This consent process will take place in a quiet and private room. The person obtaining consent at this visit will be an individual who has been certified to obtain consent for the study and this person will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and follow-up requirements of the study. Participant privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. No research related procedures will be performed prior to obtaining informed consent. All signatures and dates will be obtained. A copy of the signed consent will be given to the participant. The informed consent process will be documented in each subject's research record.

Following informed consent, the remainder of screening will be conducted (e.g., self monitoring diary completed, discussion of randomization acceptance) and baseline data will be collected. Only those individuals with complete baseline data will be randomized.

The contact information and screening information of participants who decline consent will be destroyed.

Information Withheld From Subjects: *Will any information about the research purpose and design be withheld from potential or participating subjects? If so, explain and justify the non-disclosure and describe plans for post-study debriefing.*

X ***Not applicable***

Attach full grant application, including budget information and/or any contract or draft contract associated with this application.

All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the InfoEd Resource Materials page for more information.