

Study Title: Examining Cooking as Health Behavior

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Consent to Participate in Research

Title of Research Project: Examining Cooking as a Health Behavior

Principal Investigator: Jean Harvey PhD, RD

Sponsor: University of Vermont, College of Agriculture and Life Sciences; USDA Hatch Act Funds

Introduction

You are being invited to take part in this research study because you are interested in losing weight and improving your cooking skills and also have a BMI over 25. This study is designed to investigate the role active cooking lessons may play in weight loss interventions. This study is being conducted by the University of Vermont.

The study uses a behavioral weight loss program that guides individuals to make changes to their diets and exercise through gradual, lasting changes. It will also include cooking classes to see if increasing someone's comfort level with cooking and cooking frequency can positively impact weight-loss. If you think of cooking as a health behavior, cooking classes can be used like exercise classes. For someone trying to be more physically active, exercise classes give people the skills, social structure, and confidence to begin exercising on their own. This study is designed to test whether cooking classes could do the same for someone's comfort with cooking and how often they cook.

If you choose to participate in this study, you will be randomly assigned to one of two groups. You will not be able to decide which group you are assigned to, and must be willing to be assigned to either group. Both groups will take part in a 24-week in-person behavioral weight loss program and 12 chef-led cooking classes every other week. The only difference between the two groups is that one group will participate in active, hands-on cooking lessons, while the other will observe a cooking demonstration. All participants will receive expert advice on diet and exercise, and may benefit by losing weight. All programs will take place over a 6-month period. There is minimal risk to participating in the study, however potential risks include muscle soreness or injury from exercise.

At the beginning and end of the study participants will also be asked to complete a series of questionnaires as well as complete 3 days of food tracking using the Automated Self-Administered 24-Hour Dietary Assessment tool. On a weekly basis, participants will also be asked to track their food, exercise, weight, and cooking frequency. Participants will have their weight measured (privately) at every class meeting.

Your participation is completely voluntary. The information above is only a brief summary of the study. If you are interested in learning more, it is important to read the following pages for additional detailed information about the study. If you decide to take part in the research, you will be asked to provide written consent at the end of this document.

We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

Why is This Research Study Being Conducted?

The purpose of this study is to determine if encouraging cooking as a health behavior actually improves health outcomes. Specifically, this study aims to understand if the addition of active cooking classes to a standard behavioral weight loss program will improve weight loss and diet quality when compared to a weight loss program with demonstration only cooking classes.

How Many People Will Take Part In The Study?

Approximately 64 people will take part in this study.

What Is Involved In The Study?

Participation requires a time commitment of 6 months. Assessments in the form of questionnaires will be completed at both the beginning of the study and the study end. The questionnaires will ask about your cooking behaviors, your cooking frequency, and an evaluation of the cooking class at the end of the study. The questionnaires should take approximately 30 minutes to complete. Additionally, you will be asked to complete 3 days of tracking their diet using the Automated Self- Administered 24- Hour Dietary Assessment Tool (ASA-24). Each day of tracking using the tool should take less than 30 minutes. The data collected from the ASA-24 will be used by the study personnel to calculate a Healthy Eating Index score, which assess diet quality. You will also be asked to take photos of a few meals you eat each week and submit these photos to the study staff. 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.

After initial assessments and tracking are complete, you will be assigned **at random** to participate in one of two groups (Active and Demonstration). Group assignments will be determined using a random assignment table designed using a randomization algorithm by the UVM medical biostatistics department. 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. Study personnel will not choose which group a participant is assigned to and cannot change which group a participant is in.

Both groups will participate in the same behavioral weight loss program. This program will take place in-person at the University of Vermont's campus for 24 weeks. Classes will be held once a week for 1-2 hours and will include a behavioral weight management lesson provided by a trained facilitator as well as a group discussion. You will also be asked to complete weekly homework assignments that build on skills discussed in that week's lesson. Part of your treatment program is exercise. You will be asked to exercise (what we recommend is walking but modifications can be made when necessary) on your own and track the number of minutes spent exercising. Throughout the 24-week program you will be asked to track your food,

exercise, and weight daily and share this tracking with your class facilitator so that they can monitor your progress.

Both groups will also attend 12 in-person cooking classes. These classes will take place every other week at the same time and place as the weight-management classes. During weeks that a cooking lesson takes place the total class time will be 2 hours. The only difference between the two groups is that one will receive active, hands-on cooking lessons (Active Group) while the other group will receive a demonstration only cooking lesson (Demonstration Group). Participants in the active group will be given a brief lecture at the beginning of the class which reviews the concepts of the week's recipe. Participants will then work in teams of two in a food lab at the University of Vermont to actively practice skills and cook a meal. Participants will receive recipes and information sheets that cover pantry supplies, grocery lists, knife skills and cooking equipment. Participants will have the opportunity to sample the food they prepared at the end of class. Participants in the demonstration classes 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 cooking 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 lessons will be led by the same chef for both the Active and Demonstration groups, will cover the same topics, and use the same recipes.

What Are The Benefits of Participating In The Study?

We hope that individuals who participate will learn the skills and behaviors necessary to help them lose weight and maintain that loss. However, you may or may not benefit from participating in this study as responses to weight loss programs vary from person to person. Everyone, however, will get expert feedback on their eating and exercise behaviors.

What Are The Risks and Discomforts Of The Study?

There are minimal risks for participating in behavioral weight control programs. You may feel uneasy about answering the personal questions included in the interview. However, you do not have to answer any questions that make you feel uncomfortable. The information you provide will be kept confidential and not shared with non-research staff. No identifiable information about you will ever be published or shared without your consent.

Additionally:

- Some individuals may experience initial muscle soreness from the exercise program.
 - You will be taught warm-up and stretching techniques to use before all exercise sessions to minimize the chance of muscle soreness.
- It is also possible that some participants may not lose weight.

What Other Options Are There?

Any number of commercial weight loss programs are available as alternatives to participation in this study. It is also possible to seek the guidance of a physician or registered dietitian who may help facilitate your weight loss efforts. Finally, weight loss medications or surgery are available for those who are considered by their physicians to be appropriate for these approaches.

Are There Any Costs?

There is **no cost** for participation other than your time. It will take you approximately **5-6 hours a week** to complete the exercise prescribed, attend your class meeting and complete your food

and exercise diary. It will take approximately 30 minutes to complete the online assessment questionnaires at the beginning and end of the study and approximately 90 total minutes to track food using the ASA-24 tool at both the beginning and end of the study.

What Is the Compensation?

In return for your time, you will be offered small tokens for attending data collection visits. These tokens may include items ranging in value from \$5-\$25 such as tote bags, water bottles, cookbooks, exercise equipment or gift cards. . Due to the value of these tokens, we may need to collect your name and address in order to procure and distribute these items.

Can You Withdraw or Be Withdrawn From This Study?

You may choose to end your participation in the study at **any** time.

You will be asked to withdraw from the study if:

- You do not complete study questionnaires or ASA-24 food logs. We ask that you complete weekly My Fitness Pal food logs throughout the study, however failure to complete these logs will **not** result in your withdrawal from the study.
- You, at any time during the study, join another weight control program (such as Weight Watchers, Jenny Craig, NutriSystems, etc),
- Begin to take weight loss medications,
- You become pregnant over the course of the 6-month study, or
- Experience other medical problems during the course of the study and continued participation presents health risks.

Finally, the investigators reserve the right to end your participation in the research at any time.

What About Confidentiality?

All the information you give us will be kept strictly confidential. You will be assigned identification numbers for the purposes of data collection and your name will not be connected to your ID numbers. A record of your progress will be kept in confidential form in the Marsh Life Sciences Building at the University of Vermont. Our study computers will require a password to use and they will be encrypted, which is a special protection against people who do not have the password from gaining access to the information on the computer.

Additionally, the results of this study may eventually be published and information may be exchanged between investigators; however, your confidentiality will be maintained during this process. Individual names and other personally identifiable information will not be used. The University of Vermont Institutional Review Board and regulatory authorities can be granted direct access to your original research records for verification of research procedures and/or data.

Please note that email communication is neither private nor secure. Though we are taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

Contact Information

You may contact Mattie Alpaugh, the research coordinator, at 802-656-9526 if you have any questions or concerns at any time before deciding to enroll in the study or during the course of the study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been harmed as a result of your participation in this study you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

STATEMENT OF CONSENT

You have been given and have read or have had read to you a summary of this research study. It has been explained to your full satisfaction. Should you have any further questions about the research, you realize you are free to contact the person conducting the study at the address and telephone number given below.

You understand the exact procedures you will undergo, including any potential benefits, risks, or discomforts.

You acknowledge that your participation is voluntary and are aware that you may refuse to participate or withdraw at any time without penalty or prejudice.

You understand that a record of your progress will be kept in confidential form in Marsh Life Sciences at the University of Vermont. You understand that the results of this study may eventually be published and that information may be exchanged between investigators, but that your confidentiality will be maintained.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

Signature of Subject Date

Name of Subject Printed Date

Signature of Principal Investigator or Designee Date

Name of Principal Investigator or Designee Printed Date

Principal Investigator: Jean Harvey, PhD, RD
Address: Department of Nutrition and Food Sciences, 250 Carrigan Wing, UVM
Phone: 802.656.0668

Committee on Human Research
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