Validation Study of a Passive Image-Assisted Dietary Assessment With Automated Image Analysis Process

NCT03267004

5/21/24

INFORMED CONSENT STATEMENT

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Committee # Name of Study Volunteer

Dietary Assessment via Digital Images

You are being asked to take part in a research study. All research studies carried out at the University of Tennessee are covered by the rules of the federal government as well as rules of the state of Tennessee and the university. Under these rules, the researcher will first explain the study, and then he or she will ask you to participate. You will be asked to sign this agreement, which states that the study has been explained, that your questions have been answered, and that you agree to participate.

The researcher will explain the purpose of the study. She/he will explain how the study will be carried out and what you will be expected to do. The researcher will also explain the possible risks and possible benefits of being in the study. You should ask the researcher any questions you have about any of these things before you decide whether you wish to take part in the study. This process is called informed consent.

This form also explains the research study. Please read the form and talk to the researcher about any questions you may have. Then, if you decide to be in the study, please sign and date this form in front of the person who explained the study to you. You will be given a copy of this form to keep.

INTRODUCTION

Nature and Purpose of the Study

Tsz-Kiu Chui and Dr. Hollie Raynor are conducting a study to investigate the accuracy of a new dietary assessment method using images taken by Sony Smarteyeglass. A total of 30 men and women will participate in this study.

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You have been asked to participate in the study because you are of a healthy weight according to medical standards, an adult between the ages of 18 and 65, and do not have any dietary restrictions to prevent you from taking part in this study. Also, you do not wear any electronic medical devices (such as cardiac pacemakers, implantable defibrillators, etc.) that would make you ineligible for the study.

Please inform researchers any food allergies before enrolling in the research.

INFORMATION ABOUT PARTICIPANTS' INVOLVEMENT IN THE STUDY

Explanation of Procedures

You will be asked to come to the Healthy Eating and Activity Laboratory (HEAL) for 1, 30-minute screening session, and then for 2, 40-minute meal sessions, with approximately one week occurring between each session. During the screening session, after consenting, you will be asked questions about your demographic information (age, race, education, etc.) and your height and weight will be measured. Then you will be scheduled for two meal sessions. You will be asked to stop eating a minimum of two hours prior to the scheduled meal sessions and only consume water during that period.

During both meal sessions, instructions on how to wear and use Sony Smarteyeglass will be provided to you. The instructions will include how to wear and use the Sony Smarteyeglass. You will be asked to put on the Sony Smarteyeglass and to initiate the recording via the controller of the Sony Smarteyeglass. Next, you will look at each provided food at the table prior to starting to eat. Then, you will turn your head toward your left shoulder and look at each food from the left side, and you will turn your head toward your right shoulder and repeat the same steps. After you looked at each provided food, you will take one bite of each provided food. For the first bite of each food, you will hold the food, either in your hand or on a fork or spoon (depending on the food), approximately 12 inches in front of the eyeglasses and to look at the food. Following taking the first bite of each provided food, you will eat normally until satisfied and be given 30 minutes to eat. At the end of 30 minutes, you will be instructed to again look at each provided food at the table following the exact same procedure at the beginning of the meal.

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For each meal session you will be provided with one of two meals. Meal 1 consists of a turkey and provolone cheese sandwich, chicken and wild rice, chocolate chips cookie, and potato chip. Meal 2 consists of a ham and cheddar cheese wrap, pasta with broccoli and Alfredo sauce, chocolate ice-cream, and red seedless grapes.

On the day following the meal session, you will be called to complete a dietary recall of all foods and beverages consumed within the past 24 hours. The phone call will take approximately 20 minutes to complete.

The second meal session will follow the same procedure as the first meal session, but you will be provided with the meal, either Meal 1 or 2, that you did not receive in the first meal session. At the end of second meal session, you will be asked to complete a questionnaire to provide feedback on your experience using Sony Smarteyeglass. You will need to complete all meal sessions within 4 weeks of the initial screening session. Please call Tsz-Kiu Chui at (865) 974-0752 if you have any questions about these procedures for the study.

All information collected during the study including telephone screening, screening session, and meal sessions will be used for research purpose.

RISKS

Risks of this investigation are considered minimal. Participants may be allergic to foods used in this investigation, but participants will be phone-screened on this criterion. However, you may be at risk for unknown food allergies. Videos/images taken by Sony Smarteyeglass may capture things other than served foods during the meal sessions; however, all meal sessions will be conducted in HEAL (JHB 102) with only one participant at each scheduled time period. In addition, no personal identification information will be digitally recorded during sessions. Other possible risks related to the research may include loss of confidentiality, discomfort (such as eye strain, fatigue, nausea, or motion sickness) while using the Sony Smarteyeglass, and the use of Sony Smarteyeglass may affect the performance of electronic medical device such as cardiac pacemakers and implantable defibrillators. Most studies involve some risk to confidentiality and it is possible that someone could find out you were in this study or see your study information,

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but the investigators believe this risk is unlikely because of the procedures we will use to protect your information.

BENEFITS

There are no direct benefits to participating in this study. However, the results of this study may provide important information to the development of new dietary assessment methodology.

CONFIDENTIALITY

All your records from this study will be kept confidential. Data will be stored securely and will be made available only to persons conducting the study unless participants specifically give permission in writing to do otherwise. No reference will be made in oral or written reports, which could link participants to the study. Participants will be given a unique identification number that will be used on all documents and electronic data files with no references to individual names, addresses, or phone numbers. Hard copies of data will be stored securely and accessible only to research personnel. No personal identification information including participants' names, addresses, or phone numbers will be digitally recorded by Sony Smarteyeglass during sessions. Videos/images will be downloaded directly to the university server weekly and saved as electronic data files with a unique identification number assigned to each documents and files. Only project staffs will have access to the electronic copies of videos/images. Videos/images will only be analyzed by the project staffs using the DietCam software.

COMPENSATION

Participants who complete all study sessions will receive a $20 gift card from Walmart. After the completion of the all 24-hour dietary recalls, the gift card will be mailed to participants. Participants will fill out (name and address) an incentive form and sign the form at the end of second meal session. All information collected to facilitate payment will only be used by the project staff.

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EMERGENCY MEDICAL TREATMENT

The University of Tennessee does not "automatically" reimburse subjects for medical claims or other compensation. If physical injury is suffered in the course of research, or for more information, please notify the investigator in charge, Dr. Hollie Raynor, at (865) 974-6259 or Tsz-Kiu Chui, at (865) 974-0752.

CONTACT INFORMATION

If you have questions at any time about the study or the procedures, or you experience adverse effects as a result of participating in this study, you may contact the researcher, Tsz-Kiu Chui 102 Jessie Harris Building, The University of Tennessee, Knoxville, TN 37996-1920, (865) 974-0752. If you have questions about your rights as a participant, contact the Office of Research Compliance Officer at (865) 974-7697.

PARTICIPATION

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at any time without penalty and without loss of benefits to which you are otherwise entitled. However, under any circumstances, the researchers may end your participation in the research. It is possible participants could excluded after enrollment (due to the screening procedures performed at the lab, etc.). Participants may also be excluded after enrollment if they no longer meet eligibility criteria (such as discovery of unknown food allergy). If participants were excluded from the study before data collection is completed, your ineligibility data will be kept indefinitely for publication purposes.

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CONSENT

I HAVE READ THE ABOVE INFORMATION. I HAVE RECEIVED A COPY OF THIS FORM. I AGREE TO PARTICIPATE IN THIS STUDY.

_____ _____

Signature of study volunteer Date

I ASSURE THAT I HAVE FULLY EXPLAINED TO THE ABOVE STUDY VOLUNTEER/AUTHORIZED REPRESENTATIVE, THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

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Signature of investigator Date

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