IRB-Approved Consent Form for

Pilot validation of an app to estimate and manage portion size: The PortionSize Smartphone App

ClinicalTrials.gov ID Number: NCT04494971

Institutional Review Board
Pennington Biomedical IRB FWA 00006218

Approval Date: 24 August 2020

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#PBRC 2019-013

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR AN ADULT
INFORMED CONSENT - PART I

Title of Study: Pilot validation of an app to estimate and manage portion size: The PortionSize Smartphone App

Key Information:

- **Why am I being asked to review this form?**
  - You are being asked to take part in a research study. This form is provided so that you may read and understand the reasons why you might or might not want to participate in the research. Your participation is voluntary.

- **What is the purpose, duration, and procedures of this study?**
  - The purpose of this research study is to test the use of an iPhone app as a way to measure portion size and food intake
  - Your expected time in this study will be 3 days consisting of 2 study visits.
  - The procedures involved in this study include:
    - Training on the app and using the app to rate particular portions given to you in a lab setting
    - Using the app over 3 days in a free-living setting
    - Complete surveys on user preference, app usability, lifestyle, demographic, and food intake

- **What are the possible risks and discomforts?**
  - This study involves no greater than minimal risk. The main risk is breach of confidentiality, and the PBRC team will work to minimize this risk by following existing best practices for data collection, handling, and analysis.
  - A more comprehensive and detailed description of reasonably foreseeable risks to subjects are included later in Section 6 of the informed consent.

- **What are the possible benefits?**
  - We cannot promise any benefits from your being in the study. Your participation may help us gain knowledge that may help people in the future.

- **If you choose not to participate in the study, are there other choices?**
  - You have the choice at any time not to participate in this research study.
  - *If you decide not to participate in this study,* any health benefits to which you are entitled will not be affected in any way.

Detailed Information:

1- Who is doing the study?

Investigator Information:

Principal Investigator: Corby K. Martin, Ph.D.
Phone: 225-763-2585
Fax: 225-763-3022
Email Address: Corby.Martin@pbrc.edu

Sub Investigators: John W. Apolzan, Ph.D. (Grant Co-PI)
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Drs. Martin and Apolzan direct this study. We expect about 15 people from the Baton Rouge area will be enrolled in this study. The study will take place over a period of ~6 months. Your expected time in this study will be approximately 3-7 days. Phase 1 will involve 1 visit to a facility at either LSU main campus or PBRC. Phase 2 will occur over approximately 7 days and will include an additional visit either in person or remotely through video calling. If the additional visit is conducted remotely, then the researcher will audio record your survey responses to minimize visit time.

This project will help validate the PortionSize app. Drs. Martin and Apolzan are inventors of the PortionSize app, which will be tested during this project. They do not currently have any financial gain from the PortionSize app, however it could be available for licensing through LSU-Pennington in the future. If a license is acquired, Drs. Martin and Apolzan may possibly receive a royalty payment.

2- Where is the study being conducted?

This study takes place at the LSU main campus and PBRC. Visits can also be conducted virtually through video calls.

3- What is the purpose of this study?

The purpose of this study is to test the use of an iPhone app as a way to measure portion size and food intake.

4- Who is eligible to participate in the study?

- Be able to consent
- Be 18 to 65 years of age
- Have a body mass index ranging from 18.5-45 kg/m^2
- Have an iPhone model 6S or later and an operable email address.
- Have an apple ID and password that is used regularly (so the app can be downloaded)
- Be willing to use these to collect data during the study, acknowledging that data usage, and associated charges, are a result of study participation
- Be willing to use an iPhone app and a pen-and-paper food dairy during the study at LSU main campus or PBRC and at home. Keep in mind that using your iPhone will use a small amount of your cellular data.

You may not qualify for this study based on other eligibility criteria not listed. The study coordinator will go over this information in detail.

5- What will happen to you if you take part in the study?

Phase 1 (LSU/PBRC). You will be trained to use the smartphone app and then use the app to determine portions of foods at LSU main campus and/or PBRC. You will also tell us your satisfaction with the smartphone app.

Phase 2 (free-living). You will then be asked to use the app for 3 days in free-living conditions to measure the portion size of the foods that you eat. Of the 3 days, 2 will occur on weekdays and 1 will occur on a weekend day. On completion of phase 2, you will tell us how satisfied you are with the app.

The following table shows what will happen at each study visit:

Table 1. Schedule of visits and protocol (N =15)

Description	Phase 1	Phase 2
Consent and Eligibility	**X**	
Lifestyle and Demographics Questionnaire, RFPM Lifestyle Interview, Food Frequency Questionnaire, body weight, height, BMI	**X**	
Training on and use of app to capture food images and quantify portion sizes	**X**	
Use of app to measure pre-weighed lab meal portion	**X**	

Pen and paper User Satisfaction and Usability Surveys	X	
Instructed to use app over ~3-day period in free-living setting		X
User Surveys and interviews		X

6- What are the possible risks and discomforts?

This study involves no greater than minimal risk. The main risk is breach of confidentiality, and the PBRC team will work to minimize this risk by following existing best practices for data collection, handling, and analysis. Although unlikely, you may feel uncomfortable answering certain questionnaire questions. You do not have to answer any questions you do not want to answer. If you opt to have your Phase 2 survey done remotely, you may feel uncomfortable having the audio of your survey responses recorded. In this case, the researcher can fill out your survey responses in real time. You may also feel uncomfortable capturing images of foods in certain environments, such as at a dinner for work. In these rare cases, you will be instructed to record your food selection and waste via a food record.

Unforeseeable Risks Involving Pregnant Women

If you are pregnant or become pregnant, you are excluded from partaking in the study.

Interviews/Questionnaires

You do not have to answer any questions you do not want to answer.

Will I be notified if my data or images result in an incidental finding?

During a research study, a researcher may notice something that he or she was not looking for. This is called an “incidental” or “unexpected” finding. These incidental findings are not directly related to the research. However, they may show important information about the health of a research volunteer.

Researchers may share some or all of their findings with you. However, you may not learn about any findings for a very long time. If such findings occur, you will be notified by trained study personnel and referred to a treatment facility for further testing and/or treatment.

Risks: It can be very upsetting to learn unexpected information about your health. This is especially true if you learn that you have or will develop a condition that has no treatment or cure. There is a chance that unexpected findings could affect your family or social relationships, change your family planning decisions, or affect you financially. You might need more tests and procedures to find out what the information really means. It’s also possible that the information might be incorrect, so you would worry without cause.

7- What are the possible benefits?

We cannot promise any benefits from your being in the study. If you take part in this study, you may help others in the future. You may also benefit by increased awareness of their portion sizes with various food groups.

8- If you do not want to take part in the study, are there other choices?

You have the choice at any time not to participate in this research study. If you choose not to participate, any health benefits to which you are entitled will not be affected in any way. You have the right to take part now and change your mind later on.

9- If you have any questions or problems, whom can you call?

If you have any questions about your rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of Pennington Biomedical at 225-763-2513. If you have any questions about the research study, contact Corby K. Martin at 225-763-2585.

10- What information will be kept private?

Every effort will be made to maintain the confidentiality of your study records. However, someone from the Pennington Biomedical Research Center, may inspect and/or copy the medical records related to the study. Results of the study may be published; however, we will keep your name and other identifying information private. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.

De-identified Information for Future Research

Any personal information that could identify you will be removed from your data. Your data may be used for future research studies or given to another investigator for future research without asking for your additional permission.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

11- Can your taking part in the study end early?

Dr. Martin, or the study sponsor can withdraw you from the study for any reason or for no reason. Possible reasons for withdrawal include non-compliance with study procedures and not taking pictures of your meals. The sponsor of the study may also end the study early.

You may withdraw from the study at any time without penalty; however, all data Pennington Biomedical has previously collected cannot be removed from the study.

12- What if information becomes available that might affect your decision to stay in the study?

During the course of this study there may be new findings from this or other research which may affect your willingness to continue participation. Information concerning any such new findings will be provided to you.

Significant New Findings

During the course of this study there may be new findings from this or other research. which may affect your willingness to continue participation. Information concerning any such new findings will be provided to you.

Clinically Relevant Research Results

In this study, you will not be informed of any clinically relevant research results, including your individual results, that may be discovered.

13- What charges will you have to pay?

There will be no study related costs to you other than the cost of traveling to the Pennington Biomedical Research Center. However, use of the PortionSize app will use cellular data from your plan. So, it is possible that you could incur cost for this data.

14- What payment will you receive?

If you complete phase 1 and phase 2 of this study, we will compensate you $75.00 for completion of the study. If you do not complete the entire study, you will not be compensated. Compensation is not pro-rated and failure to complete all aspects of the study will result in now payment. Your check will be requested from the LSU payroll department when you complete the study or at the appropriate milestone if you are compensated during the course of the study. It usually takes about 3-4 weeks for it to arrive at Pennington Biomedical Research Center.

U.S. citizens, legal resident aliens, and those who have a work eligible visa will need to provide their social security number to receive payment.

You are subject to a 1099 for receiving compensation. Payments in excess of $600 per calendar year are considered taxable income. If you will be paid more than $600, Pennington Biomedical/LSU will report this income to the IRS.

Non-US citizens are subject to having taxes withheld from payment and will need a passport, visa and 1-94 for payment to be processed.

I authorize that all information provided on this Informed Consent form and HIPAA Authorization form, including any and all personal and financial data may be shared with the Internal Revenue Service (IRS) for tax reporting. This data will be securely retained indefinitely.

15- Will you be compensated for a study-related injury or medical illness?

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research procedures in which you participate, you will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should you require ongoing medical treatments, they must be provided by community physicians and hospitals.

16- Signatures

By signing this consent form, I agree to participate in the study as it is described. The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study investigators. I agree with the terms above and acknowledge that I will be given a copy of this signed consent form.

With my signature, I also acknowledge that I have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information.

_____
Printed Name of Volunteer

_____ _____
Signature of Volunteer Date

_____
Printed Name of Person Administering Informed Consent

_____ _____
Signature of Person Administering Informed Consent Date

Corby K. Martin, Ph.D
Principal Investigator