IRB-Approved Study Protocol for

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

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Institutional Review Board
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IRB Review Plan

Objectives

Long-term Goals and Specific Objectives

Our *long-term goal* is to create simple and accessible interventions that assist individuals with weight control. In particular, we aim to provide easy-to-use phone apps that allow participants to monitor the portion sizes of the foods they consume. These apps guide participants on appropriate portion sizes and provide recommendations of food groups that should be consumed. To that end, we have developed the PortionSize app. This app measures portion sizes and enables users to quantify energy composition of foods consumed, further to the amount of food groups consumed, including food supplements. Moreover, the app provides personalized, real-time rudimentary feedback on portions consumed based on an individual's current weight and weight goals. For instance, individuals with a given weight looking to gain or lose weight will be encouraged by the app to increase and decrease the amount of portions they consume, respectively. We foresee the app being utilized in the obesity field to help people understand how large their portions are and to help them manage (reduce) portion size and better adhere to a weight loss diet. We also think that the app has other potential uses, including treatment of patients with anorexia nervosa, and to help improve nutrition intake. However, we must first validate the app to ascertain if it provides a valid and reliable measure of portion size, and if it is convenient and usable.

Specific objectives:

(1) Examine the validity, reliability and perceived participant satisfaction of the PortionSize app.

Background

We propose to improve the accuracy of portion size measurement, as it is poorly determined by self-report measures [1]. This will occur via the development of the **PortionSize smartphone app**. This app will provide templates superimposed on individuals food images to provide real-time visual feedback of food consumed. We will validate the ability of PortionSize to measure portion size, energy/macronutrient intake and food groups. Specifically, we will first compare measures calculated from the app against weighed portions of food groups and rater analysis of food photos in a controlled setting and then deploy the app in free-living conditions to examine the validity against rater analysis of food photos. We will also assess satisfaction and general convenience of the app with users.

The study will yield a convenient, easy-to-use app ready to calculate portion size and food intake measurement. It will also pave the way for further validation work, and ultimately provide an app that assists individuals in managing their portion sizes, nutrition, and body weight.

Rationale and Significance

Overweight and obesity are a burgeoning public health concern, yet only a small minority of smartphone apps that claim to facilitate healthy eating and weight loss incorporate evidence-based principles [2]. Such innovations are important as humans fundamentally cannot accurately estimate portion size. Indeed, portion size estimation errors account for ~50% of the error in self-reported food intake [1], and data from our laboratory has demonstrated that extensive training results in only modest improvements in portion size estimation accuracy and that portion size estimates remain inaccurate [3]. Another study found that professionals with extensive nutrition training (i.e. Licensed Registered Dietician Nutritionists) cannot accurately estimate portion size [4]. These data clearly indicate that there is a significant need for an app that allows users to obtain real-time feedback about the portion size of their food selections, and our research indicates that no existing app fulfills this need. Obtaining apps that accurately quantify portion sizes would be incorporated into existing or future weight loss interventions, as well as treatments that foster adherence to diabetic diets or other special diets (e.g., diets to reduce hypertension, triglyceride or enhance intake with).

Inclusion and Exclusion Criteria
Inclusion Criteria are:

1. Aged 18-65
2. Male or female age 18-65 years
3. BMI 18.5-45 kg/m^2 based upon self-reported height and weight
4. Have an iPhone and an operable Apple ID, password, and email address and is willing to use these to collect data during the study, acknowledging that data usage, and associated charges, are a result of study participation

Exclusion Criteria are:

1. For females, pregnancy or breast feeding
2. Currently diagnosed with an eating disorder
3. Disease that severely affects metabolism, including diabetes, hypercholesterolemia, or dyslipidemia.
4. Has gained or lost more than 10 lbs in last 3 months
5. PBRC Faculty/Staff Member
6. Has suffered serious mental illness that has resulted in serious functional impairment and has substantially interfered with one's life activities within the last 5 years.
7. Any other medical, psychiatric, or behavioral factors in the judgement of the Principle Investigator or Medical Investigator that may interfere with study participation or the ability to follow the protocol

Number of Subjects
We expect up to 15 participants to complete both Phase 1 and Phase 2. Pennington Biomedical Research Center employees are not eligible to participate.

Recruitment Methods
A sample of up to 15 adults will be recruited from the Baton Rouge, Louisiana area to participate in both Phase 1 and Phase 2.

Study Timelines
Participants will complete the procedures as noted in the Procedures section. The study involves one visit to Louisiana State University (LSU) campus or the Pennington Biomedical (PBRC) campus for Phase 1. Phase 2 will be completed in-person or remotely after Phase 1 before participants make a return visit to either LSU or PBRC afterwards.

It will take up to six months to recruit participants and have them complete Phase 1 and Phase 2. All data analyses and study cessation will occur shortly after.

Study Endpoints
The primary endpoint of this study is validity and reliability of portion size and energy intake measurement, measured with the PortionSize app in controlled and free-living conditions.

Secondary endpoints include satisfaction with the PortionSize app and the ease of using the app.

Procedures Involved
Phase 1: Testing the PortionSize Smartphone App. The validity, reliability and satisfaction of the PortionSize app under controlled conditions will be quantified in the Phase 1. Participants will partake in an in-person lab visit at either LSU or PBRC. All assessments will be conducted in a controlled room. Initially, participants will complete an informed consent. Then participants will have their height and weight recorded and will complete a set of questionnaires on demographics and lifestyle factors. A food frequency questionnaire (Diet History Questionnaire, Version 3.0 [5]) will also be administered. Afterwards, participants will be trained on using the PortionSize app.

Next, participants will use the app to measure the portions, energy composition and the food groups of pre-weighed foods that differ in size and composition. These food items will be provided by the researchers and will serve as the criterion measures of portion size, energy content and food group quantity, further to rater analysis of food photos [6]. Food portions administered will be carefully selected to reflect a plethora of food items and portion sizes. Some selected food items will be re-assessed within and between users to obtain intra- and inter-rater reliability, respectively. The participant will not consume the food items they are administered to assess.

Participants will complete a user preference survey (Appendix 1: PortionSize User Preference Survey (Phase 1)) to report their satisfaction with the PortionSize app. This survey evaluates how much participants liked the app and includes questions about ease of use and satisfaction. The survey was modeled from surveys developed to assess satisfaction with the Remote Food Photography Method app [6]. Afterwards, the participants will complete the Computer System Usability Survey (CSUQ) [7].

Phase 2: Testing the PortionSize Smartphone App in free-living conditions

Phase 2 will occur in participants' natural environment and will involve the 15 participants from Phase 1. In free-living conditions, participants will capture before and after pictures of the foods and food supplements they consume and use the app to quantify the portion sizes of the items within the pictures. Participants will use the app for 3 days (two weekdays and one weekend day) in free-living conditions.

At the end of Phase 2, we will compare the portion size, energy/macronutrient composition and food group data collected from PortionSize and compare these to rater analysis of food photos. Participants will also return to complete the same CSUQ survey on app usability. Lastly, the PortionSize User Satisfaction Survey (Phase 2) (Appendix 2) will be administered to assess participant satisfaction and the ease of using PortionSize app for capturing information about portion sizes.

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

Description	Phase 1	Phase 2
Consent and eligibility	**X**	
Remote training on the use of app to capture food images and quantify portion sizes	**X**	
Lifestyle and Demographics Questionnaire, RFPM Lifestyle Interview, Food Frequency Questionnaire, body weight, height, BMI	**X**	
Use of app to measure pre-weighed lab meal portions	**X**	
Pen and paper User Satisfaction Surveys	**X**	
Instructed to use app over 3-day period in free-living setting		**X**
Return for pen and paper User Surveys		**X**

All named personnel have experience with the IRB approval process and field experiment designs.

Data and Specimen Management

Analysis

Phase 1 analysis objectives include:

1) Determining if portion size estimation measured with the PortionSize app is significantly different from criterion values (directly weighed food portions).
2) Determining if energy, macronutrient, saturated fat, added sugar and food group estimation measured with the PortionSize app is significantly different from criterion values (directly weighed food portions and rater analysis of food photos).
3) Determining how reliable the PortionSize app is in examining energy, macronutrient, saturated fat, added sugar and food group values.
4) Determining the differences in energy, macronutrient, saturated fat, added sugar and food group values between rater analysis of the food photos and directly weighed foods.
5) Determining the differences in estimated energy, macronutrient, saturated fat, added sugar and food group error between the PortionSize app and the rater analysis of food photos.
6) Determining if the PortionSize app provides a reliable measure of portion size, energy intake, macronutrient intake, saturated fat, added sugar and food groups.
7) Determining if participants are satisfied with the PortionSize app as measured in Appendix 1 (PortionSize User Preference Survey (Phase 1)).
8) Determining if the PortionSize app is easy to use and provides adequate instructions for use.
9) Qualitative assessments by respondents of the desirable and undesirable features of the app.

Phase 2 analysis objectives include:

1) Determining if portion size estimation measured with the PortionSize app in free-living conditions is significantly different from the criterion value (rater analysis of food photos).
2) Determining energy, macronutrient, saturated fat, added sugar and food group estimation measured with the PortionSize app in free-living conditions is significantly different from the criterion value (rater analysis of individual food photos).
3) Determining if energy intake estimation measured with the PortionSize app in free-living conditions is significantly different from estimated energy requirements [8-10].
4) Determining if energy intake estimation measured from the rater analysis of food photos is significantly different from estimated energy requirements [8-10].
5) Quantifying satisfaction levels with the PortionSize app as measured in Appendix 2 (PortionSize User Preference Survey (Phase 2)).
6) Qualitative assessments by respondents of the desirable and undesirable features of the app.

Withdrawal of Subjects

Subjects may be withdrawn from the study if they are non-compliant with study procedures and they will be notified of their withdrawal via telephone or mail.
Subjects may voluntarily withdraw from the study at any time. No additional data will be collected and they will be considered drop outs in the study.

Risks to Subjects
This study involves no greater than minimal risk. The main risk is breach of confidentiality, and the PBRC team will work to minimize this during data collection, handling, and analysis.

Potential Benefits to Subjects
Participants may benefit by increased awareness of their portion sizes with various food groups.

Setting
All research procedures will be conducted at LSU main campus, PBRC's campus, or remotely through videoconference calling, and in participants' natural environment.

Resources Available
PBRC and LSU main campus has all the necessary equipment needed to undertake and execute the proposed research project successfully. All investigators and staff have offices or cubicles. Investigator offices are each equipped with a desk, chair, filing cabinets and shelves, telephone with voice mail, and access to a printer, photocopier and fax. Computers are equipped with software for statistics, data management, and word processing, and computers are connected to the PBRC mainframe with internet access and email access through Outlook Express. Information Technology (IT) provides full technical support to all members of the faculty and staff. PBRC has all the technological equipment and staff needed to conduct the present study. These information technologies assure efficient data handling and optimal communication among the investigators and the team.

Compensation
Participants will be compensated $75 for successful completion of both Phase 1 and Phase 2. All compensation and recruitment success figures are based on historical averages from previous PBRC studies with similar respondent burden.

Confidentiality and Provisions to Protect the Privacy Interests of Subjects
Participants' records will be kept confidential to the extent allowed by law. Only Drs. Corby Martin, John Apolzan, and James Dorling, and the PBRC research team will have access to the information participants provide. We will use an identification number rather than participants' names on study records. The information participants provide will be stored on secured network drives and will not be identified using any personal information.

Participants' names and other facts that might identify them will not appear when we present this study or publish its results. The findings will be summarized and reported in group form. Participants will not be identified personally. All participants will have ample opportunity during consent and throughout the study to ask questions concerning study procedures. These questions will be answered promptly and fully by study staff to ensure participant ease. A participant may choose not to answer questions or participate in study procedures at any time.

Data Safety Monitoring Plan
Study recruitment, study progress, participant complaints, data collection, data management, data integrity, data security, and eventually data analysis will be staffed at weekly meetings at PBRC.

Compensation for Research-Related Injury
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 or LSU. In the unlikely event of injury or medical illness resulting from the research, the participant will be referred to a treatment facility. Medical treatment may be provided at their expense or at the expense of their health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. PBRC is a research facility and provides medical treatment only as part of research protocols. Should the participant require ongoing medical treatments, they must be provided by community physicians and hospitals.

Economic Burden to Subjects
There will be no study related costs to the participant. However, use of the PortionSize app will use data from the participant's cellular data plan. Hence, it is possible that the participant would incur cost for this data and this is clearly disclosed in the consent form.

Consent Process
All subjects participating in the study will provide written informed consent. The consenting process will take place in private rooms at Pennington Biomedical Research Center or LSU main campus and will be conducted according to Pennington Biomedical consenting guidelines and practices. Participants can take the consent form home to review prior to deciding if they wish to enroll. All participants are free to withdraw from the study at any time.

References

1 Beasley J, Riley WT, Jean-Mary J. Accuracy of a PDA-based dietary assessment program. *Nutrition* 2005;**21**:672–7.
2 Breton ER, Fuemmeler BF, Abroms LC. Weight loss-there is an app for that! But does it adhere to evidence-informed practices? *Transl Behav Med* 2011;**1**:523–9.
3 Martin CK, Anton SD, York-Crowe E, *et al.* Empirical evaluation of the ability to learn a calorie counting system and estimate portion size and food intake. *Br J Nutr* 2007;**98**:439–44.
4 Champagne CM, Bray GA, Kurtz AA, *et al.* Energy intake and energy expenditure: A controlled study comparing dietitians and non-dietitians. *J Am Diet Assoc* 2002;**102**:1428–32.
5 Diet History Questionnaire, Version 3.0. National Institutes of Health, Applied Research Program, National Cancer Institute. 2018.
6 Martin CK, Correa JB, Han H, *et al.* Validity of the remote food photography method (RFPM) for estimating energy and nutrient intake in near real-time. *Obesity* 2012;**20**:891–9.
7 Lewis JR. Usability: Lessons Learned ... and Yet to Be Learned. *International Journal of Human-Computer Interaction.* 2014;30(9):663-684
8 Thomas DM, Martin CK, Redman LM, *et al.* Effect of dietary adherence on the body weight plateau: A mathematical model incorporating intermittent compliance with energy intake prescription. *Am J Clin Nutr* 2014;**100**:787–95. doi:10.3945/ajcn.113.079822
9 Thomas DM, Schoeller DA, Redman LA, *et al.* A computational model to determine energy intake during weight loss. *Am J Clin Nutr* 2010;**92**:1326–31.
10 Hall KD, Chow CC. Estimating changes in free-living energy intake and its confidence interval. *Am J Clin Nutr* 2011;**94**:66–74.