

Protocol Title: Evaluating the validity of a novel tool to measure children's food intake and improve health

PI Name: Hanim E. Diktas, Ph.D.

Sub-Investigator's Name(s): Chloe P. Lozano, Ph.D.; Stephanie Broyles, Ph.D.; Amanda E. Staiano, Ph.D.; John W. Apolzan, Ph.D.; Corby K. Martin, Ph.D.; Sanjoy Saha Ph.D.

Protocol Version Date: July 01, 2022

Background

Accurate assessment of dietary intake plays a pivotal role in evaluating the nutritional adequacy of children's diet, and; therefore, helps to promote healthy dietary intake and management and prevention of nutrition-related childhood diseases such as obesity.¹⁻⁸ Childhood obesity is a serious public health challenge in the US,⁷ and Louisiana ranks 3rd in the nation for prevalence of obesity in children ages 10-17 years (22.2%).⁹ Increased frequency of large portions of high calorie foods is one cause of childhood obesity.^{1,7,8} Low intake of fruits and vegetables is another cause for the higher prevalence of obesity.^{7,9} Therefore, it is important to track energy intake including intake of USDA MyPlate food group servings.^{1,4-6,10} However, accurately measuring energy intake (total kcal) and food group servings in real time is challenging due to consumers' inability to accurately estimate the portion size of consumed foods.¹⁻⁶ Hence, the development of valid tools that accurately estimate the dietary intake of school-aged children is essential to quantify their dietary patterns and modify intake to improve health.^{1,8} This project aims to adapt an app developed for adults for use in children.

Drs. Martin and Apolzan from PBRC developed the PortionSize app to facilitate personalized dietary intake tracking with just-in-time feedback, and this work builds upon over one decade of research.^{4,5,6,10} To our knowledge, this proposed pilot study will be among the first to assess the validity of a smartphone-based app to quantify children's energy intake and provide immediate feedback on intake of USDA MyPlate recommended food group servings.

The PortionSize app uses emerging technology (e.g., augmented reality) which is unique and has innovative features to estimate food intake and reduce missing data with minimal user burden. Visual comparison procedures and template systems are established in the PortionSize app and will help users to correctly estimate portion size of food and, thus, energy intake. The PortionSize app estimates food selection (before meal) and food waste (after meal) and, thus provides assessment of net food intake. PortionSize is the first known method that provides just-in-time feedback on intake of energy (kcal), saturated fat (g), added sugar (g), and USDA MyPlate food group servings (fruit, vegetable, grain, protein, and dairy). Users will get immediate feedback on the diet quality of the plated meal and left-overs from the meal, and cumulatively throughout the day. Getting immediate feedback on the plated meal will give users the opportunity to modify their plated meal and, thus, their food intake. The PortionSize app

provides an 'all-in-one' platform to both assess dietary patterns and to guide parents and their children to follow a healthier eating pattern.

Many parents are unaware about the importance of their children following a healthy dietary pattern and achieving their recommended intake of food group servings.^{9,11} The PortionSize app will allow parents or caregivers to track energy intake and food group servings for their children thereby improving the health and nutrition literacy of children and parents or caregivers.

Objectives

The objective of this pilot study is to assess the validity of the PortionSize™ app to quantify children's own dietary intake and children's intake by parents or caregivers.

The specific aims are to assess the validity of children's:

1. (a.) energy intake and (b.) intake of USDA MyPlate recommended food group servings (fruit, vegetable, grain, protein, and dairy) *as estimated by children* using the PortionSize app.
2. (a.) energy intake and (b.) intake of USDA MyPlate food group servings *as estimated by parents or caregivers* with the PortionSize app.

The secondary aim is to quantify children's and parents' or caregivers' user satisfaction with the PortionSize app.

Primary Hypotheses:

1. (a). Estimation of energy intake (kcal) with PortionSize by children will be equivalent to known energy estimates (weighted meal) within an equivalence boundary of 25%
1. (b). Estimation of intake of USDA MyPlate recommended food group servings (fruit, vegetable, grain, protein, and dairy) with PortionSize by children will be equivalent to known food group serving estimates (weighted meal) within an equivalence boundary of 25%
2. (a). Estimation of energy intake (kcal) with PortionSize by parents will be equivalent to known energy estimates (weighted meal) within an equivalence boundary of 25%
2. (b). Estimation of intake of USDA MyPlate recommended food group servings (fruit, vegetable, grain, protein, and dairy) with PortionSize by parents will be equivalent to known food group serving estimates (weighted meal) within an equivalence boundary of 25%

Methods

We will recruit 40 **dyads (40 children aged 7-12 years old and 40 parents or caregivers)** using a convenience sample for this pilot study. Children and their parents or caregivers will be trained to use the PortionSize app at Pennington Biomedical

Research Center (PBRC). For specific aims 1a. and 1b., children will use the PortionSize app and estimate food intake from pre-weighed meals at PBRC. For specific aims 2.a. and 2.b., their parents or caregivers will use the PortionSize app and estimate the food intake of their children (at least one meal and a snack each day) for two consecutive days at home.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria of participants (children and parents or caregivers) are presented in Table 1.

Table 1. Inclusion and exclusion criteria (children and parents or caregivers)

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> Children (7-12 years) and their parents or caregivers (18-62 years) 	<ul style="list-style-type: none"> Any condition or circumstance that could impede study completion
<ul style="list-style-type: none"> Parents who have Willingness to use the PortionSize app to estimate the intake of their child food intake (normal/regular diet) from at least a snack and a meal of child for two consecutive days 	<ul style="list-style-type: none"> Child who is a very choosy eater or has a very limited food choice
<ul style="list-style-type: none"> Have iPhone (version 6 or above) and an operable Apple ID, password, and email address, and able to use iPhone 	
<ul style="list-style-type: none"> Willing to use their own smartphone to collect data during the study 	

Procedures

Screening at PBRC Clinic

Parents or caregivers will need to read and sign an informed consent prior to participating in the study. Children will provide an informed assent (verbal assent will be accepted for the child aged less than nine years and written with nine years or above unless parent or child prefers oral) prior to participating in the study. The eligibility of the participants (for both parent or caregiver, and child) to take part in this study will be assessed at the PBRC clinic. Afterward, weight and height of children and parents or caregivers will be measured by trained staff at PBRC clinic. Parents or caregivers will also complete a demographic (parents' or caregiver's age, children's age and date of birth, household income, education, etc.), learning disability survey, and lifestyle behavior questionnaire of children. Children will complete screen time survey. Prior to participants' visit to clinic, IBL staff will conduct a lifestyle behavior interview via phone with parents or caregivers to assess participants' willingness and ability to complete the study procedures.

Table 2. Schedule of study procedures

	Week 1 Screening Visit (~Day 1)	Week 1 (~Day 2)	Week 1 (~Day 3)
Informed consent from parents or caregivers and assent from children	×		
Weight and height of children and parents or caregivers	×		
Completion of screen-time survey by children and children's learning disability survey by parents or caregivers	×		
Training on the PortionSize App for children and parents or caregivers	×		
Assessment of laboratory-based simulated meal by children	×		
Completion of User Satisfaction Survey by children	×		
Parents or caregivers will be instructed to use app over a 2-day period to measure children's food intake (at least one meal and one snack each day) in free-living setting		×	×
Completion of User Satisfaction Survey by parents or caregivers (in person or over the phone, email, videocall, etc.)			×
Review of images to ensure data quality (in person or over the phone or video conference)			×

Screen Time Survey

It has been anticipated that children's screen exposure time may have influence on the using of the PortionSize app; those who have more exposure, will have accurate dietary intake estimation using the PortionSize.¹² Therefore, we will ask the children three questions that were adapted from the National Health and Nutrition Examination Survey¹³ to identify children's screen time. Questions are: 1) Over the past 30 days, on average how many hours per day you sit and watch TV or videos?, 2) Over the past 30 days, on average how many hours per day you use a computer or tab or play computer games or play games using tab or smart phone outside of work or school?, 3)) Over the past 30 days, on average how many hours per day your screen time using apps?.¹³

Learning Disability Survey

It has also been suggested that participants who do not have any learning disabilities, may perform better using the PortionSize compared to those who have learning disability.¹⁴ We will include participants who have learning disability when parents or caregivers would like their children's participation in this study. We will administer a

questionnaire consisting of four questions (binary responses, yes or no) to identify children who have any learning disabilities. Questions are: 1) Does your child have a history of developmental delay?, 2) Does your child have an individualized educational plan at school for learning difficulties?, 3) Does your child have a diagnosed physical disability that might affect their ability to use a smart phone app to take pictures of food?, and 4) Does your child have a diagnosed developmental or intellectual disability?. The questionnaire will be adapted from other studies conducted in PBRC and in individualized education programs.^{15,16}

Directly Weighed Food Intake to Prepare Simulated Test Meals

Trained staff of PBRC will prepare simulated test meals via direct observation. Such simulated meals served as the criterion measures of energy content, and food group quantity for comparisons with the food intake assessments by children using the PortionSize app. Children' energy requirements will be calculated by using sex-specific formulas.¹⁷ Energy requirements will be multiplied by 1.3, and the food selection for the simulated test meal included 30% of this value, which represents a typical lunch. The meals will consist of at least 3 food items and 1 calorie-containing beverage. Menus of meals will be selected from a list of commonly consumed foods from a previous study.¹⁸ Plate waste will be determined at the individual food item level. This measure will range from 0% and 100% and be right-skewed; as such, the mean plate waste will be around 5% of the foods provided, which is similar to the actual plate waste from our free-living data (around 3%).¹⁸ Simulated food provision and plate waste will be covertly weighed, and food intake estimation will be calculated by difference.

Using of the PortionSize App

Trained IBL (Ingestive Behavior Lab) staff will facilitate a 30-minute training for children and parents or caregivers on how to use the PortionSize app to capture dietary intake during their visit at PBRC clinic. Children and parents or caregivers will practice assessing food intake with a sample meal as part of the study procedures. Children will place a reference card (3.25 x 2 inches) next to the meal and use the PortionSize app on their smartphone to capture images of their food selection ("before" image) and plate waste ("after" image). Parents or caregivers will do the same to assess their dietary intake during the practice session.

Afterward, for the specific aim 1.a and 1.b, children will follow the same procedures to estimate energy and food group servings from a weighed or simulated meal (known energy and food group servings) in the clinic on the same day. Children will not eat the simulated meal. Children can use their own or parents' phone to assess food intake. Children will be asked whether they know all the served food's names (from weighed or simulated meal) prior to taking a "before meal" photo using PortionSize. If they do not know, trained nutritionist will support them to know all the food items' names from the simulated meal so that they can search the food item using the PortionSize app. Parents or caregivers will be allowed to attend the training session for children to enhance children's attentiveness. However, parents or caregivers will be requested not to support when children assess food intake with simulated meal using the PortionSize app.

For the specific aim 2.a and 2.b, parents or caregivers will use the PortionSize app and estimate the food intake of their children (at least one meal and a snack each day) for two consecutive days at home. Parents or caregivers will be requested to take notes when they do not find food items in the PortionSize (a subset of food list from the FNDDS) and submit those notes to IBL staff on day 4 in person or over the phone. Such information will support us to extend and update the food list in the PortionSize. All the data will be automatically transmitted and stored in the Automated Data Management Utility (ADMU) and the RFPM image will be analyzed by the nutritionists to measure the portion size of the foods and food intake. As RFPM is an affordable dietary intake assessment method and the error bounds are known,^{4,5} and therefore, we are using RFPM as a reference method in this study. Parents or caregivers will be informed during screening visit that they will receive reminders from IBL if they stop using the app.

User Satisfaction Survey

After completing food intake measurement using PortionSize, children will be requested to complete a user satisfaction survey at PBRC to evaluate PortionSize on several parameters, including ease of use, stratification, and burden. Parents and or caregivers will be allowed to be around to assist children to complete the survey, be attentive during the training session and help during height and weight assessment.

When the parents or caregivers will visit the PBRC clinic after completing food intake measurement using PortionSize for two days, they will complete the same user satisfaction survey to evaluate the PortionSize app. If parents or caregivers want, they complete this survey over-phone. The user satisfaction survey will be adapted from previous studies^{3,4} conducted at PBRC.

Outcome Measures and Data Analysis

The primary analyses assessing equivalence between the PortionSize app, and the criterion measure will rely on equivalence testing using the Two One-side T-test (TOST) method. The criterion measure is the weighed food to compare children's estimations. On the other hand, the criterion measure is the estimated energy (kcal) of the foods from the RFPM to compare parents' or caregivers' estimations. The equivalence bounds are set at $\pm 25\%$ ¹⁹ and Bland Altman analysis²⁰ will be used to test for differences in error variance over levels of the variable being measured (e.g., energy intake). Error is defined as the values from PortionSize minus the respective values from the known estimations (weighed meals) to compare children's estimations. On the other hand, error is defined as the values from PortionSize minus the respective values from the RFPM to compare parents' or caregivers' estimations. Equivalence tests are used to quantify validity, though the mean error from PortionSize will be reported from the Bland and Altman analyses. Multivariable regression analysis will be performed to determine if error differs by the age, sex of the parents and child, screen time, and learning disability of children. However, this is a pilot study and therefore the obtained results (variance of energy intake) from this study may underpower the regression analysis and Bland Altman analysis. User satisfaction will be presented in frequency and percentage.

Study Timelines

June to December, 2022: IRB submission, development of study materials, recruitment, participant training, and food intake estimation by participants using the PortionSize app. January to April, 2023: Analyze results and submit peer-reviewed scientific manuscripts; and disseminate findings to parents, the healthcare community, and other stakeholders.

Provisions to Monitor the Data to Ensure the Safety of Subjects

Adverse events will be monitored at each intervention visit. The PI and his coinvestigators will review all data after a certain interval to ensure the safety of each subject.

Withdrawal of Subjects

Subjects may be withdrawn from the study at any time. If a subject voluntarily withdraws from the study, no additional data will be collected, and they will be considered dropouts in the study. Data already provided will be retained for analysis.

Risks to Subjects

This study involves no greater than minimal risk. The main risk is a 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 from increased awareness of energy and nutrients in foods served.

Sharing of Results with Subjects

The participants may receive information such as body weight and anthropometrics. Those results will be provided to the participant at the end of the study if requested. Participants will have access to the study results once published.

Compensation

Each child will receive \$50 and parent or caregiver will receive \$75 for the successful completion of the study.

Provisions to Protect the Privacy Interests of Subjects

All attempts will be made to maintain a subject's privacy. Safeguards such as password-protected computers and networks have been put in place in order to limit access to subject data. Subjects will be given ample time to read over the consent and assent, ask questions, and agree to participate in the research study. Subjects may decline to answer questions with which they are not comfortable. Each procedure will be explained to the subject before it is performed.

Compensation for Research-Related Injury

No compensation will be provided for research-related injury.

Economic Burden to Subjects

All study-related tests and procedures will be at no cost to the subject. 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 the cost for this data, and this is clearly disclosed in the consent form.

Consent and Assent Process

After the phone-screening, children and parents or caregivers would like to participate in this study, we will email parents or caregivers a copy of the consent and assent form ahead of time in case they want to read it, but they will not sign until they get in the clinic. A designated and trained staff member will obtain informed consent from parents or caregivers and assent from children during the visit. Ample opportunity will be given for the subject to review the consent and assents forms and ask any questions prior to signing the form/s. If subjects wish, they can take the form/s home and return at a different visit. We are aware that consent is an ongoing process.

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