Official title: Validity of an AI-based Program to Identify Foods and Estimate Food Portion Size
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Title: Testing the validity of an artificial intelligence-based program to identify foods and estimate food portion size among adults, a pilot study.

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Background:

Accurately quantifying food intake is vital to promoting health and reducing chronic disease risk. Food intake encompasses energy intake, nutrient intake (macronutrients, micronutrients, vitamins, minerals), and intake of various food groups (e.g., fruits, vegetables); thus, it reflects the nutritional status of individuals. Nutrition affects disease risk, including risk of developing obesity,[1] diabetes,[2] and cancer,[3] all of which negatively affect the United States (US). Nonetheless, accurate assessment of food and nutrient intake has remained challenging, despite methodological improvements. Self-report methods, namely food records, are a mainstay of nutritional research,[4] with food recall being another popular method.[5] These methods rely on the participant to accurately estimate portion size and, for food recall, remember what was consumed. The accuracy of these methods has been questioned[6-9] and the problems with human recall have been comprehensively outlined.[10] As a result, there remains a significant need for methods that are sufficiently accurate to provide users, clinicians, and researchers with data to guide health promotion efforts.

The PortionSize™ app was designed by our laboratory to overcome the limitations outlined above and to guide users to follow specific diets. PortionSize relies on users capturing images of their food selection and waste. Food intake data are immediately provided since the user relies on built-in tools, including templates, to estimate portion size within the app. Although the PortionSize app provides users (and clinicians and researchers) with real-time information about food intake, it comes at the cost of increased user burden since the user must identify foods in their images and estimate portion size. This differs from other food photography-based methods that our laboratory and other groups have developed, including the Remote Food Photography Method© (RFPM) and SmartIntake® app. For example, when using the RFPM and SmartIntake app, users only need to capture images of their foods with the app; identify any foods that are not identifiable from a wrapper, container, or logo; and the app sends the images to the researchers for analysis. Indeed, based on our research, participants view SmartIntake as less burdensome and more preferred compared to PortionSize [11], and we expect that this could negatively affect peoples' use of PortionSize over time.

To reduce PortionSize's user burden, we aim to utilize machine learning, image recognition, and artificial intelligence for nutrition tracking. However, before we can incorporate these technologies into PortionSize, they first need to be validated. Therefore, we aim to test the validity of Nutrition AI technology, currently embedded in the Openfit® app, to identify foods and to estimate portion size (food volume) using automated methods. When using the Nutrition AI in Openfit, if the user believes the automated identification of the food and/or portion estimate needs correcting, adjustments can be made manually. However, this user burden is likely to be low and will also be explored in the current study. Therefore, the <u>primary aims</u> of the current pilot study are to: 1a) test the validity of Nutrition AI at identifying foods, 1b) test the validity of Nutrition AI at quantifying the amount of food provided, and 1c) assess user satisfaction and usability of Nutrition AI in Openfit among adults in Baton Rouge, Louisiana. Openfit is not currently designed to assess plate waste, though Nutrition AI has the potential to assess plate waste and ultimately food intake. Therefore, the secondary aims of this pilot study are to: 2a) test the validity of Nutrition AI to identify plate waste and, 2b) test the validity of Nutrition AI to quantify the amount plate waste, and 2c) to assess user satisfaction and usability of the Nutrition AI in Openfit to assess plate waste, among adults in Baton Rouge, Louisiana. From this data we can calculate food intake (food plated – plate waste).

Primary Hypotheses:

1a) Nutrition AI will correctly identify ≥70% of foods plated with automated methods, and ≥80% after user correction.

1b) Compared to weighed values, energy estimates (kcal) of foods plated, from Nutrition AI, will be:

i. Within error margins of 20% without user correction (automated)

ii. Within error margins of 15% with user correction (semi-automated)

Secondary Hypotheses:

2a) Nutrition AI will correctly identify ≥60% of plate waste with automated methods, and ≥80% after user correction.

2b) Compared to weighed values, energy estimates (kcal) of plate waste, from Nutrition AI, will be:

i. Within error margins of 20% without user correction (automated)

ii. Within error margins of 15% with user correction (semi-automated)

Methods

Study Design

For this pilot study, using a convenience sample, we will recruit up to 25 adults to use the Nutrition AI technology in Openfit to identify and estimate portion size of foods provided and simulated plate waste, and food intake in a laboratory setting at Pennington Biomedical Research Center (PBRC) and/or Louisiana State University (LSU). Laboratory members within the Ingestive Behavioral Laboratory will also test the ability of Nutrition AI to identify foods and to quantify foods provided, plate waste and food intake, in the laboratory. Meals will be simulated, and participants will not consume the foods provided.

Participants and Recruitment

We will recruit up to 25 adults

- Inclusion criteria include:
    - Male or female, age 18-62 years
    - Self-reported body mass index (BMI) 18.5-50 kg/m^2

- Exclusion criteria include:
  - Any condition or circumstance that could impede study completion
  - Unfamiliar with or not able to use an iPhone

NOTE: PBRC and LSU employees (vulnerable populations) will be targeted and invited to participate. The consent form will explicitly specify that if a PBRC or LSU employee chooses not to participate, there will be no impact on their employment.

Procedures

Written informed consent will initially be obtained. We will then obtain:

- Demographics (self-reported): DOB, race, ethnicity, sex, employment, income, marital status, education level (Lifestyle, Demographics, and Health Questionnaire)
- Anthropometrics (self-reported): height, weight, BMI

On being deemed eligible, participants will receive training on how to use the Openfit app housing the Nutrition AI technology. Subsequently, participants will be randomly assigned to one of five study menus (5 participants per menu) of differing calorie levels (see Table 1). Participants will use a provided smartphone to identify foods and quantify the amount of food plated (e.g., an apple) and simulated plate waste (e.g., half an apple) with Nutrition AI. Within each study menu, participants will be served two meals of a similar calorie level. These two meals will be served during the same study visit. To ensure we are testing the validity of the Nutrition AI across differing portion sizes, each meal (e.g., the chicken meal), will be tested across two different study menus where the amount of food provided and plate waste differs. The amount of plate waste will be assigned randomly using an exponential distribution, with the minimal being 0% remaining (i.e., no waste) and the maximum being 74%[12]. On average we will aim for ~5% plate waste across tests to reflect average plate waste in free-living conditions[13].

These tests will be conducted via Openfit in a laboratory-based setting at PBRC or LSU. Simulated food provision and plate waste will be covertly identified and weighed, and participants will not eat the food provided. During the study visit, tasks completed by each participant on the iPhone will be recorded using the record function on the iPhone and the recording will be saved to the iPhone camera roll. Data will be accessed from the iPhone at study completion. Consent, training, and testing will span up to ~2 hours.

Near the end of the visit, participants will complete the Computer System Usability Questionnaire (CSUQ) [14]. The CSUQ is a standardized, reliable, and valid questionnaire originally designed to evaluate computer programs that has been used to quantify the usability of mobile phone apps. Participants will also complete a user satisfaction survey to quantify satisfaction and ease of use of Openfit for tracking dietary intake.

Outcome measures

Primary outcomes:

1a) Agreement surrounding identification of food and beverages provided compared with known identification, at the item level (e.g., for burger n=10), and across all items where identification is determined by:

I. Nutrition AI without user correction (automated)

II. Nutrition AI with user correction (semi-automated)

1b) Error between mean estimates of portion weights (g), energy (kcal) and macronutrients (fat, carbohydrates, protein) and known portion weights, energy, and macronutrients of provided food and beverages, where estimates are determined by:

I. Nutrition AI without user correction (automated)
II. Nutrition AI with user correction (semi-automated)

1c) User satisfaction and usability of Nutrition AI for identification of food and beverages and for estimating portion size.

Secondary outcomes*:*

2a) Agreement surrounding identification of plate waste compared with known identification, at the item level (e.g., for burger n=10), and across all items, where identification is determined by:

I. Nutrition AI without user correction (automated)
II. Nutrition AI with user correction (semi-automated)

2b) Error between mean estimates of portion weights (g), energy (kcal) and macronutrients (fat, carbohydrates, protein) and known portion weights, energy, and macronutrients of plate waste, where estimates are determined by:

I. Nutrition AI without user correction (automated)
II. Nutrition AI with user correction (semi-automated)

2c) User satisfaction and usability of Nutrition AI for identification of food and beverages and for estimating portion size of plate waste.

2d) Error between mean estimates of portion weights (g), energy (kcal) and macronutrients (fat, carbohydrates, protein) and known portion weights, energy, and macronutrients of food intake (food plated – plate waste), where estimates are determined by:

I. Nutrition AI without user correction (automated)
II. Nutrition AI with user correction (semi-automated)

Statistical analyses

For a food identified through the Nutrition AI to be considered an exact food match, the name of the food identified must match or be a close match to the food served. For example, a fruit cocktail identified as a fruit salad is an acceptable match[15]. Proportions will be used to assess whether the percentage of food items plated that were correctly identified by Nutrition AI is different to the percentage of foods correctly identified by a criterion method (human rater). Descriptive data will also be used to describe the frequency at which food plated and plate waste were correctly identified.

Mean error and Bland-Altman analysis[16] will be performed to determine errors in estimation of energy intake and food group servings from the Nutrition AI compared to estimations from the criterion measure[17].

Responses to the user satisfaction and usability questionnaires will be assessed using frequencies and percentages for Likert scale data. Open responses will be evaluated using qualitative methods to identify common themes.

Provisions to Monitor the Data to Ensure the Safety of Subjects

Adverse events will be monitored.

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.

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 energy and nutrients in food served.

Sharing of Results with Subjects

Participants will have access to the study results once published.

Setting

The Ingestive Behavior, Weight Management, and Health Promotion Laboratory at PBRC, and 162 Knapp Hall or 252 Knapp Hall at LSU.

Compensation

Participants will receive $50 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 to limit access to subject data. Subjects will be given ample time to read over the consent, 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. We will always ensure the privacy of the subjects.

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.

Consent Process

A designated and trained staff member will obtain informed consent during the visit. Ample opportunity will be given for the subject to review the consent form and ask any questions prior to signing the form. If subjects wish, they can take the form home and return at a different visit. We are aware that consent is an ongoing process.

Table 1. PortionSize AI Groups

Menu 1- 400 kcal each meal	
Burger	**Chicken**
Tomato	Ready Rice
Onion	Oranges
Burger bun	Carrots
Cheese slice	Butter
Ketchup	Sweet Tea
Cookies	
Coke	
Menu 2- 800 kcal each meal	
Chicken	**Pizza**
Ready Rice	Lettuce
Oranges	Tomato
Carrots	Dressing
Butter	Cookies
Sweet Tea	Coke
Menu 3- 500 kcal each meal	
Pizza	**Pork Chop**
Lettuce	Broccoli
Tomato	Butter
Dressing	Apple Slices
Cookies	Sweet Tea
Coke	
Menu 4- 700 kcal each meal	
Pork Chop	**Lettuce**
Broccoli	Carrot
Butter	Tomato
Apple Slices	Pre-cooked frozen chicken
Sweet Tea	Dressing
	Milk
Menu 5- 600 kcal each meal	
Lettuce	**Burger**
Carrot	Tomato
Tomato	Onion
Pre-cooked frozen chicken	Burger bun
Dressing	Cheese slice
Milk	Ketchup
	Cookies
	Coke

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