The reliability and validity of the PortionSize™ and MyFitnessPal© apps (Study 1: Laboratory-based evaluation).

NCT 04700904

Approved: December 3, 2020

Title: The reliability and validity of the PortionSize and MyFitnessPal apps (Study 1: Laboratory-based evaluation).

Principal Investigators: Corby K. Martin, Ph.D.; John W. Apolzan, Ph.D.

Co-Investigator: Stephanie T. Broyles, Ph.D, James L. Dorling, Ph.D.

Protocol Version Date: December 1, 2020

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), and thus 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 (U.S). Nonetheless, accurate assessment of food and nutrient intake has remained challenging, despite an improvement in methods. Self-report methods, namely food records, are a mainstay of nutritional epidemiology 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 have 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 researchers with good outcome data and 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. However, despite promising early indications, the PortionSize app has yet to be fully validated. Determining the accuracy of PortionSize is vital before users can utilize the app to obtain immediate feedback about their food intake. We accordingly aim to test the validity of PortionSize during two buffet meals in a controlled laboratory setting and compare this to another app that has been adopted widely - MyFitnessPal©, which is an electronic food record.

Methods

Study Design

We will recruit adults to use the PortionSize app or the MyFitnessPal during laboratory-based simulated meals.

Participants and Recruitment

We will recruit 43 adults (approximately equal proportion of men and women) who will be randomly assigned in approximately a 1:1 ratio to use PortionSize at the first visit (and MyFitnessPal at the second visit), or MyFitnessPal at the first visit (and PortionSize

at the second visit). We expect to enroll an approximately equal number of participants with body mass indexes (BMI; kg/m^2) between 18.5 to 25; 25 to 30; and 30 – 50kg/m^2. Recruitment will be stratified based on sex and body mass index.

- Inclusion criteria include:
    - Male or female, age 18-70 years
    - Body mass index (BMI) 18.5-50 kg/m^2
    - Ownership of an iPhone model 6s or later, which the participant is willing to use for the study
    - Access to Apple ID, password, and email address and willing to use them in the course of the study
    - Willing to use data and any accompanying charges as part of study participation
    - Willing to be re-contacted for future research and/or follow-up

- Exclusion criteria include
    - Center employee, as previous reviewers argued that they are not representative of the community
    - Any condition or circumstance that could impede study completion

Procedures

Screening visit/Study Visit 1

In the screening visit, written informed consent will initially be obtained. We will then obtain:

- Demographics: age, race, ethnicity, sex, employment, income, marital status, education level (Appendix A: Lifestyle, Demographics, and Health Questionnaire)
- Anthropometrics: height, weight, and BMI

On being deemed eligible, in this within subjects design, participants will be randomized to use either PortionSize or my MyFitnessPal at this first visit, with the other app being used at the second visit. They will receive training on the app that they will use that day to subsequently rate a meal. Training will span up to ~45 minutes.

Participants will then estimate food intake from a simulated lunch meal; i.e., they will not eat food during the meals. The meal will consist of at least three foods, one calorie containing beverage, and may contain a vitamin and/or supplement. Participants' energy requirements will be calculated using sex-specific formulas. Energy requirements will be multiplied by 1.3 and the food selection for the simulated test meal will include 30% of this value, which represents a typical lunch. Plate waste will be determined at the individual food item level and will range between 0% and 100%, but the distribution will be skewed to the lower end such that mean plate waste is ~5% of foods provided, which is slightly higher than actual plate waste from our free-living data

(~3%). [11] Simulated food provision and plate waste will be covertly weighed, and simulated food intake calculated by difference.

When participants use PortionSize, they will be instructed to use PortionSize to estimate food provision and plate waste. PortionSize will then calculate food intake, with energy intake being the primary outcome variable. PortionSize will also transfer the food images to the Food Photography Application for expert rater analysis, and these are secondary outcome data. When participants use MyFitnessPal, they will enter estimated food intake into the app.

Near the end of the visit where participants used the MyFitnessPal app, they will complete the MyFitnessPal User Satisfaction Survey (Appendix B) and the MyFitnessPal Computer System Usability Questionnaire (MyFitnessPal CSUQ) (Appendix C) to quantify satisfaction and ease of use of the MyFitnessPal app. The CSUQ is a standardized, reliable, and valid questionnaire originally designed to evaluate computer programs[12,13] that has been used to quantify the usability of mobile phone apps.[14,15] Similarly, at the end of the visit where they used the PortionSize app, they will complete the PortionSize User Satisfaction Survey (Appendix D), as well as the PortionSize CSUQ (Appendix E). Additionally, only after the visit that includes the PortionSize app, participants will complete a modified version of a self-administered food frequency questionnaire (Appendix F, Diet History Questionnaire, Version 3.0 or the DHQ-III).[16] Specifically, the DHQ-III was modified such that participants will report the presence of vitamins and supplements during the test meal. Thus, only those items (vitamins and supplements) of the DHQ-III will be administered, and the instructions will ask participants to note if those items were present in the test meal.

Study Visit 2

Participants will return within approximately three to 14 days to be trained on the app not used at the first visit. They will then estimate food intake from another simulated lunch meal. This will be conducted exactly as Study Visit 1. Participants will then complete either the PortionSize User Satisfaction Survey or the MyFitnessPal User Satisfaction Survey, depending on which app they used during Study Visit 2. They will also complete either the PortionSize CSUQ or the MyFitnessPal CSUQ.

Participants then will complete an the User Preference Survey (Appendix G) to determine which app (PortionSize or MyFitnessPal) they prefer, think is most accurate, etc.

Outcome measures

The **primary analyses** assessing equivalence between PortionSize and the criterion measures (and MyFitnessPal and the criterion measures), will rely on equivalence testing using the Two One-side T-test (TOST)[17,18] method. The criterion measure is directly weighed foods from the simulated lunch meal. Differences in the observed error from PortionSize and MyFitnessPal will be compared with dependent t-tests, with error calculated as the difference between each experimental method and the criterion variable (e.g., energy intake values from PortionSize minus energy intake values from

weighed foods). These procedures will also produce results indicating if the error from each method differs from zero. Subsequent regression-based **exploratory analyses** will determine if error from the apps varies by body mass (kg, BMI), age, or sex; and will evaluate differences in user satisfaction and preference between the apps. Bland-Altman analysis[19] will be used to test for differences in error variance over levels of the variable being measured (e.g., food intake).

Thus, primary endpoints will be:

- Energy intake (kcal)
- User satisfaction and usability of the app

Secondary endpoints will be:

- Nutrients (e.g., fat, carbohydrate, and protein) and food groups (PortionSize only) intake
    - Only PortionSize has the ability to provide output in food groups due to the link with the FNDDS database.

Exploratory endpoints include the modified Dietary History Questionnaire (DHQ) as a comparator for the possible dietary supplement. This specific addition was not an outcome included in the grant and was added post award.

Schedule of procedures

The schedule of procedures is outlined below:

Procedure	Screening and Study Visit 1	Study Visit 2
Informed Consent	X	
Demographics, Anthropometrics, Eligibility Evaluation	X	
Randomization (to use PortionSize or MyFitnessPal first)	X	
Training on PortionSize or MyFitnessPal app	X	X
Use of app during simulated laboratory-based meals	X	X
User Satisfaction Survey, CSUQ	X	X
Modified Dietary Questionnaire (DHQIII[16])	PortionSize visit only	PortionSize visit only
User Preference Survey		X

The screening portion of the first visit will last approximately 60 minutes. The remainder of Study Visit 1 and Study Visit 2 will last approximately 120 minutes.

Power calculation

We will recruit 43 participants and we are powered even if we experience attrition of up to 10%, resulting in 39 participants finishing both visits. Estimated food intake values form the PortionSize (and MyFitnessPal) will be compared to directly weighed values. Equivalence tests that follow the Two One-sided T-test (TOST)[17,18] method will be used with alpha = 0.05 and specified acceptable lower and upper bounds of equivalence (error reflects the difference between weighed intake and estimates from either PortionSize or MyFitnessPal). Equivalence is set as within ± 6% of the directly weighed value. With as few as 39 participants completing the PortionSize and MyFitnessPal condition, we have at least 0.80 power to detect equivalence with ±6% error bounds (±35.2 kcal). Additionally, with 39 participants completing the PortionSize and MyFitnessPal condition, we have power of 0.80 to detect a 46 kcal difference in error (effect size = 0.6) between the conditions. Finally, with 39 participants completing the PortionSize and MyFitnessPal condition, we have 0.80 power to detect an R^2 of 0.17, which is acceptable as studies with Bland-Altman analysis find that poor methods of measurement frequently have $R^2 \geq 0.16$.[22]

Provisions to Monitor the Data to Ensure the Safety of Subjects

Adverse events will be monitored at each intervention visit. The PI and his co-investigators will review all data continuously to ensure the safety of each subject.

Withdrawal of Subjects

Subjects may be withdrawn from the study if he/she misses study visits and will be notified of their withdrawal via telephone or mail. 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 their portion sizes with various food groups.

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.

Setting

The Ingestive Behavior, Weight Management, and Health Promotion Laboratory at Pennington Biomedical Research Center.

Compensation

Participants 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, 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.

Participants will be advised to read the current version of the Privacy Statement for MyFitnessPal provided as a link within the consent form to understand how the company will use their information. The current version can be found here:

https://account.underarmour.com/en-us/privacy_and_terms

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. The subject will incur transportation costs in getting to Pennington Biomedical Research Center. It is also possible that the subject twill incur data charges by using their own smartphone during the study. The chances of this occurring can be mitigated by connecting their smartphone to WiFi while at the Center.

Consent Process

A designated and trained staff member will obtain informed consent during the first visit. Ample opportunity will be given for the subject to review the consent and ask any questions prior to signing the consent 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.

References

1. Swinburn BA, Caterson I, Seidell JC, James WP. Diet, nutrition and the prevention of excess weight gain and obesity. *Public Health Nutr.* 2004;7(1A):123-146.
2. Ley SH, Hamdy O, Mohan V, Hu FB. Prevention and management of type 2 diabetes: dietary components and nutritional strategies. *Lancet.* 2014;383(9933):1999-2007.
3. Huang T, Yang B, Zheng J, Li G, Wahlqvist ML, Li D. Cardiovascular disease mortality and cancer incidence in vegetarians: a meta-analysis and systematic review. *Ann Nutr Metab.* 2012;60(4):233-240.
4. Willett WC. *Nutritional epidemiology.* New York: Oxford University Press; 1998.
5. Lytle LA, Nicastro HL, Roberts SB, et al. Accumulating Data to Optimally Predict Obesity Treatment (ADOPT) Core Measures: Behavioral Domain. *Obesity (Silver Spring).* 2018;26 Suppl 2:S16-S24.
6. Beaton GH, Burema J, Ritenbaugh C. Errors in the interpretation of dietary assessments. *Am J Clin Nutr.* 1997;65(4 Suppl):1100S-1107S.
7. Tran KM, Johnson RK, Soultanakis RP, Matthews DE. In-person vs telephone-administered multiple-pass 24-hour recalls in women: validation with doubly labeled water. *J Am Diet Assoc.* 2000;100(7):777-783.
8. Schoeller DA, Bandini LG, Dietz WH. Inaccuracies in self-reported intake identified by comparison with the doubly labelled water method. *Can J Physiol Pharmacol.* 1990;68(7):941-949.
9. Bandini LG, Schoeller DA, Cyr HN, Dietz WH. Validity of reported energy intake in obese and nonobese adolescents. *Am J Clin Nutr.* 1990;52(3):421-425.
10. Archer E, Pavela G, Lavie CJ. The Inadmissibility of What We Eat in America and NHANES Dietary Data in Nutrition and Obesity Research and the Scientific Formulation of National Dietary Guidelines. *Mayo Clin Proc.* 2015.
11. Roe BE, Apolzan JW, Qi D, Allen HR, Martin CK. Plate waste of adults in the United States measured in free-living conditions. *PLoS One.* 2018;13(2):e0191813.
12. Lewis JR. IBM computer usability satisfaction questionnaires: Psychometric evaluation and instructions for use. *International Journal of Human-Computer Interaction.* 1995;7(1):57-78.
13. Lewis JR. Usability: Lessons Learned ... and Yet to Be Learned. *International Journal of Human-Computer Interaction.* 2014;30(9):663-684.
14. Al Ayubi SU, Parmanto B, Branch R, Ding D. A Persuasive and Social mHealth Application for Physical Activity: A Usability and Feasibility Study. *JMIR mHealth and uHealth.* 2014;2(2):e25.
15. English LL, Dunsmuir D, Kumbakumba E, et al. The PAediatric Risk Assessment (PARA) Mobile App to Reduce Postdischarge Child Mortality: Design, Usability, and Feasibility for Health Care Workers in Uganda. *JMIR mHealth and uHealth.* 2016;4(1):e16.
16. Diet History Questionnaire, Version 3.0. National Institutes of Health, Applied Research Program. National Cancer Institute. 2018.
17. Limentani GB, Ringo MC, Ye F, Bergquist ML, McSorely EO. Beyong the t-test: statistical equivalence testing *Analyitical Chemistry.* 2005:221-226.

18. Walker E, Nowaki AS. Understanding Equivalence and Noninferiority Testing. *J Gen Intern Med.* 2010;26(2):192-196.
19. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet.* 1986;1(8476):307-310.
20. *Calculation of Sample Size and Power for ICC* [computer program]. 2015.
21. Zou GY. Sample size formulas for estimating intraclass correlation coefficients with precision and assurance. *Stat Med.* 2012;31(29):3972-3981.
22. Bray GA, DeLany JP, Volaufova J, Harsha DW, Champagne C. Prediction of body fat in 12-y-old African American and white children: evaluation of methods. *Am J Clin Nutr.* 2002;76(5):980-990.