Determining Dietary Pattern Accompanying Egg Intake Using Remote Food Photography Method

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Summary

Eggs are nutrient dense, convenient, affordable, and provide key macro and micronutrients in one's diet. Despite having a lot of benefits of consuming eggs in relation to health recent epidemiological studies raise health concerns about egg intake for subgroups of people. For instance, under free-living conditions, higher egg intake is associated with increased cardiovascular disease (CVD) risk in diabetic individuals as well as increased risk of developing type 2 diabetes. However, these studies do not establish that egg consumption "causes" health issues.

It is also possible that the association of egg intake with increased CVD risk in diabetics, or with a greater risk of developing diabetes, is simply due to the other foods that people usually eat with eggs, such as saturated fats, and not due to eggs *per se*.

For part I, the investigators propose to test this hypothesis by determining the food intake of 48 non-diabetic individuals under free-living conditions using the remote food photography method (RFPM), which uses smartphone technology. The frequency of egg consumption will be obtained using a food frequency questionnaire (FFQ). In addition, participants will record their food intake using food record diary and a 24-hour food recall method. Energy intake information gathered from RFPM will be compared with the 7-day food record and the 24-hour recall.

Next, for part II, the same study participants will be offered four separate test breakfasts of similar calories, containing 1) Eggs; 2) Eggs with a high amount of saturated fat; 3) Cereal breakfast (neither eggs nor saturated fat); or 4) Cereal breakfast with a high amount of saturated fat. Alteration of blood glucose, insulin, hunger, and satiety hormones (ghrelin, PYY, GLP-1), and metabolic rate will be measured before and after each breakfast in part II.

The investigators expect to determine if the purported association of eggs to alterations in glucose control and related metabolic alterations are independent of eggs, but mainly due to saturated fat is eaten along with eggs rather than the egg consumption itself.

A. Specific Aims/ Objectives:

1. To use the RFPM to accurately determine the dietary pattern associated with egg intake in 48 free living non-diabetic individuals who eat eggs often.

2. To assess and compare the hormonal levels related to hunger and satiety following; A-Egg breakfast, B-Eggs breakfast with high amount of saturated fat, C- Cereal breakfast, D-Cereal breakfast with high amount of saturated fat.
3. To assess and compare insulin levels and blood glucose levels following A-Egg breakfast, B-Eggs breakfast with high amount of saturated fat, C- Cereal breakfast, D-Cereal breakfast with high amount of saturated fat.
4. To examine whether total energy intake and consumption of saturated fat will be associated with the baseline insulin levels, blood glucose levels, Homeostatic Model Assessment (HOMA) index of insulin resistance calculated using glucose and insulin levels, and HbA1C levels.
5. To compare diet induced thermogenesis in A-Egg breakfast, B-Eggs breakfast with high amount of saturated fat, C- Cereal breakfast, D-Cereal breakfast with high amount of saturated fat.
6. To compare RFPM method with 7-day food record and 24-hour recall in dietary assessment

B. Hypotheses:

These aims will test the following hypotheses:

1. Meals that include eggs will have higher energy and saturated fat contents as determined by RFPM, compared to corresponding meals (i.e. breakfast, lunch, or dinner) without eggs.
2. As determined by RFPM, individuals of the study sample who will be in the highest quartile in terms of egg consumption in the free-living condition (defined as high egg consumers) will have a higher intake of saturated fat and total energy as compared to individuals who will be in the lowest quartile in terms of egg consumption (defined as low egg consumers).
3. Baseline insulin level, blood glucose level, the Homeostatic Model Assessment (HOMA) index of insulin resistance using fasting glucose and insulin levels, and HbA1C will be positively associated with total EI and saturated fat intake determined by RFPM, even when adjusted for age, sex, BMI and waist circumference
4. Above outcome variables will not be associated with egg intake determined by RFPM.

5. In the randomized partial crossover study, presence of eggs in the breakfast will be associated with a) a greater increase (i.e. both area under the curve and pre-post change) in satiety hormones (i.e. PYY and GLP-1), b) a less profound increase in blood glucose and insulin levels, c) a greater decrease in the hunger hormone (ghrelin) and d) an increase in the area under the curve of metabolic rate when controlled for the content of saturated fat in the test diets.
6. In the randomized partial crossover study, presence of a high amount of saturated fat in the breakfast will be associated with a) a greater increase (i.e. both area under the curve and pre-post change) in satiety hormones (i.e. PYY and GLP-1), b) a less profound increase in blood glucose and insulin levels, c) a greater decrease in the hunger hormone (ghrelin) and d) an increase in the area under the curve of metabolic rate when controlled for the presence of eggs in the test diets.
7. In the randomized partial crossover study, the associations mentioned in hypothesis 5 will be moderated by the presence of a high amount of saturated fat in the diet.
8. Estimates of total EI by RFPM will be significantly greater than EI estimates by 7-day food record and the 24-hour recall in dietary assessment.

C. Significance:

An association between egg consumption and diabetes should not be ignored. However, it is important to identify if such an association does indeed exist and, if so, whether or not there is evidence that suggests that it is not the eggs themselves that drive the association, but rather a concurrent undesirable profile of macronutrient intake. Food intake data assessed by subjective recall methods are highly questionable due to potential inaccuracies [23]. Capturing food intake data in real time by RFPM is the greatest strength of this project. The RFPM has been validated for accuracy against the doubly labeled water method [24, 25]. With high accuracy, we will identify the nutrients associated with egg consumption. Intake at every meal will be captured for 7 days in a free-living population, which eliminates the reporting bias around subjective measures of food intake and provides greater fidelity of reporting usual diet. This will help in better understanding the health effects that are currently ascribed to eggs by epidemiological studies using dietary recall methods. We expect that this study will demonstrate that intake of eggs is associated with an undesirable profile of macronutrient intake. By doing measuring blood

glucose, insulin levels following four tests breakfast that include eggs and saturated fats we will be able to measure the acute effects of egg based diet and influence of saturated fats to glycemic status. In addition, by doing huger and satiety hormones will enable to explain the changes that coexist with insulin and glucose alterations. RMR will give indirect measurement of fed state. Overall, the studies will provide stronger evidence to accept or refute some of the adverse effects reportedly associated with egg consumption, so that appropriate dietary recommendations could be designed. It will form the basis for future research to determine if the dietary pattern accompanying eggs and not eggs per se is linked to diabetes and other adverse metabolic consequences.

Study Design and Methods

I. Subjects:

A. Overview:

The proposed study will comprise of two parts: Part I: an observational study based on ecological momentary assessment, and Part II: a randomized partial crossover clinical trial. Same subjects will participate in both parts of the study.

In the observational study, the dietary intake of the subjects will be evaluated using an ecological momentary assessment approach for 7 days. In the randomized partial crossover clinical trial, four test breakfasts will be administered so that each subject will get exposed to only two out of the four diets (thus, partial crossover). Therefore, there will be six possible combinations of diets (i.e. 4! / 2! [4-2]!) and 12 possible ordered combinations (i.e. permutations; 4! / [4-2]!) of diets. Four subjects will be randomly assigned to each of these 12 possible ordered combinations of diets. Thus, the total sample size will be 48 (i.e. n = 4x12).

B. Recruitment:

Advertisements for the recruitment of participants will be posted on social media and notice boards within the Texas Tech University (TTU) including the web-based notice boards (Tech Announce), radio and television. Appendix A-1 and Appendix A-2 provide written material and Flyer Ad that would be used for these announcements. No students of any investigators will be recruited or enrolled for this study and flyer ads or person-to-person solicitation scripts will not

be administered in any of the investigator's classrooms. The flyer ad described in Appendix A-2 will be posted and displayed on and around Texas Tech University campus on all appropriately designated signage areas when permission to do so has been granted by the proper authority. The flyer will be designed to have tear-off contact information tabs for all participants interested in the study.

Inclusion criteria:

- 48 non-diabetic individuals (fasting glucose < 126 mg/dL)
- male or female
- BMI $\geq$ 20 and $\leq$ 60 kg/m^2
- Age: 18 – 65 years

Exclusion criteria:

- Diabetes
- On antidiabetic medication
- Pregnant or lactating females
- Having a history of gestational diabetes
- Having an unstable cardiac condition
- Having a major systemic illness
- Having a history of drug abuse
- Having a history of eating disorders
- Having uncontrolled hypothyroidism
- Having familial hyperlipidemias
- Having allergies sensitivity to or dislike of eggs
- Consumption of < 1 egg per week
- Attempting to lose weight
- On medications that may influence or inhibit appetite, sensory functioning, or hormone signaling- e.g. antibiotics, anti-depressants, obesity medications. Weight loss > 5% in the past 3 months.

II. Procedures:

A. Initial work

Individuals who express an interest in participating will be contacted by a graduate research assistant who will administer a structured telephone interview (Appendix B) to 1) provide information related to the requirements of the study, along with potential risks and benefits 2) Screen for eligibility based on specific inclusion and exclusion criteria. All potential subjects will be informed that their responses will remain confidential and that taking part in the screening interview in no way obligates them to participate.

Potential participants who meet participation criteria as assessed via the telephone prescreening process will be contacted by the study team via email/phone within 48 hours following the interview to inform of eligibility (or ineligibility) and to schedule an initial visit if deemed eligible.

B. Anthropometric Measurements and Blood Pressure

Height and weight will be measured using a wall-mounted stadiometer and standardized scale, respectively. BMI (body mass index) will be calculated from the measured height and weight using the formula weight (kg)/height^2 (m^2). Waist and hip circumference will be measured according to the World Health Organization's methods for measuring waist and hip circumference [26]. Blood pressure will be measured using a standardized electronic sphygmomanometer.

C. Remote Food Photography Method (RFPM)

RFPM was developed and validated by our co-investigator (CM). RFPM employs smartphone technology as a means of estimating energy intake remotely from participants' home environments. Collection of RFPM data will be done using the SmartIntake© smartphone "app". Subjects will be trained to take photos of foods before eating and of the leftovers, if any. Subjects can use their own phone or a smartphone will be provided with the app. The photographs will be sent to co-investigator (CM), where they will analyze the RFPM data (food images) in coordination with the collaborators on the project and quantify energy and macronutrient intake. These data will be sent back.

D. Test Meals

Four test breakfasts will be matched for energy density, and macronutrient composition (Table 1). Breakfasts will be prepared and assembled onsite at Texas Tech University. Preparing and serving meals will be done in accordance with standardized measures and in compliance with food safety regulations.

Table 1. Macronutrient Composition of Test Breakfasts

	Test Breakfast A-Egg Breakfast	Test Breakfast B- Egg Breakfast with High Saturated Fat	Test breakfast C-Cereal Breakfast	Test Breakfast D-Cereal Breakfast with High Saturated Fat
Energy (kcal)	438	450	447.48	449.6
Protein (g)	22.6	23.4	21.41	22.56
Fat (g)	22.61	24.91	19.55	22
Saturated Fat (g)	5.193	10.893	2.916	10.616
Carbohydrates (g)	44.37	40.45	48.741	41.8
Fiber (g)	10	11.5	7.427	5.667
Glycemic Index	37.48	35.98	55.54	51.52
Glycemic Load	16.63	14.55	27.07	21.53
Weight (g)	328	310	387	352
Energy density (kcal/g)	1.34	1.45	1.17	1.28

Table 2. Contents of Test Breakfasts

A-Egg Breakfast	B- Egg Breakfast with High Saturated Fat	C- Cereal Breakfast	D-Cereal Breakfast with High Saturated Fat
2 Scrambled Eggs	2 Scrambled Eggs	1c Special K RTE High Pro Cereal	1c Special K RTE High Pro Cereal
120 mL Skim Milk	120 mL 2% milk	200 mL Silk Original Soymilk	200 mL Silk Original Soymilk
2 Slices Nature's Own Double Fiber Wheat Bread	2 Slices Nature's Own Double Fiber Wheat Bread	1 Slice Mrs. Bairds Extra Thin Bread	1/2 Slice Arnold Double Protein Whole Grain Bread
30g Margarine	15 g Butter	35g Margarine	15 g Butter
18g Smucker's Strawberry Jam	15g Smucker's Strawberry Jam	10 g Smucker's Sugar Free Strawberry Jam	

Table 3. Flow of Procedures

Group (n=4)	**Visit 1**	**1-7 Days**	**Visit 2**

Height, weight, waist and hip circumference and blood pressure	x		
Test Breakfast 1 (Part II)	x		
Blood for HbA1c (Part II)	x		
Blood (glucose, insulin, GLP-1, PYY3-36, ghrelin) at 30 min before and 30, 60, 90, 120, 180, min. after breakfast (Part II)	x		x
Food frequency questionnaire (Part I)	x		
Satiety questionnaire at 30 min before and 30, 60, 90, 120, 180 min after breakfast (Part II)	x		x
RMR measurement at 30 min before and 60 and 120 min after breakfast (Part II)	x		
24-hour Recall (Part I)		D1	
Sending images of the pre-and leftovers of all meals including snacks (Part I)		x	
Test Breakfast 2 (Part II)			x

E. Blood work

To collect blood samples, an IV catheter will be placed in the subject's upper limb by a registered nurse. Hence, there will be one needle stick per visit. If an adequate blood sample cannot be accessed using the IV catheter, which happens rarely, with the subject's approval, a singlestick needle blood withdrawal will be performed. However, there will be total of 4 needle sticks including the initial needle stick done to insert the IV catheter applied in a single visit. The recruited registered nurse is an experienced person who is currently working in the ER. She is properly trained in placing IV catheters and drawing blood. A total of 20 mL (4 teaspoons/ 1.3 tablespoons) of blood will be taken at all pre-and postprandial blood draws, which will be used to assess the levels of hormones via radioimmunoassay kit, blood glucose levels and HbA1c. Blood will be drawn into chilled EDTA tubes (Greiner Vacuette, Monroe, NC) and immediately spun at 1600 x g for 15 minutes at 4°C. Aprotinin (0.6TIU/ml, Phoenix Pharmaceuticals Inc, Burlingame, CA) will be immediately added to the plasma which then will be aliquoted and stored at -80 degrees until assayed for HbA1C, ghrelin, PYY3-36, GLP-1 and insulin. For blood glucose levels, samples will be collected for sodium fluoride containing EDTA tubes (Greiner Vacuette, Monroe, NC). Blood draws will be continuously done at 30 minutes before and 30, 60, 90, 120 and 180 minutes after breakfast consumption. The room has been designed to conduct blood draws.

F. Food Frequency Questionnaire

Food frequency questionnaire (FFQ) adapted from diet history questionnaire (DHQ) by national cancer institute, to identify subjects belonging to quartiles for egg consumption. Number of eggs eaten per week will be determine based on FFQ. This will be given on the first visit.

G. Resting Metabolic Rate

RMR will be determined using a MedGem® indirect calorimeter as follows: The subject will sit comfortably in a chair wearing a nose clip, and will breathe normally into a mouthpiece. The RMR measurement will take approximately 10 minutes. RMR will be measured 30 minutes pre- and 60 and 120 min post breakfast.

H. Hunger and Satiety Questionnaire

Hunger and fullness will be assessed using a Visual Analog Scale (VAS) (Appendix E). This will be provided 30 min before and 30, 60, 90, 120, 180 min after breakfast during all the visits.

I. Food Record and 24-hour Recall

Food record will be maintained by each subject for 7-day period (Appendix G). A 24-hour recall will be collected on the day 1 of the 7 days using Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool.

Visit 1- The eligible subjects will come to TTU clinic (Tech Plaza rooms 302 and 305) at about 8 AM after 10 hours fast. Here subjects are allowed to take water. After obtaining informed written consent (Appendix C), anthropometric measurements like weight, height, waist and hip circumferences and blood pressure measurements will be taken (Table 4).

Next, pre-prandial blood sampling will be down 30 minutes prior to test breakfast 1. To retrieve blood samples, an IV catheter will be placed by the registered nurse. Blood draws will be continuously done at 30 before and 30, 60, 90, 120, and 180 minutes after breakfast consumption. Pre-prandial blood draw will be done to assess fasting blood glucose, HbA1c, and hormone levels (i.e. serum insulin PYY, GLP1, ghrelin). Post-prandial blood draws will be done to assess blood glucose and hormone levels. Following pre-prandial blood draw, subjects will be asked to assess their hunger and fullness using the visual analog scale (VAS) (Appendix E).

The RMR will be tested for each subject, followed by a standardized test breakfast 1, provided a smartphone and trained to photograph their food intake, using the smartphone provided. The subjects will be asked to consume the entire breakfast in 10 minutes. A food frequency

questionnaire (FFQ) (Appendix F) will be given to assess the egg consumption. RMR will be determined 60 and 120 min post breakfast. Blood draws and VAS administration will be continuously done at 30, 60, 90, 120 and 180 minutes after breakfast consumption. After testing is complete at the 180-minute post-breakfast mark, the subject's IV catheter will be removed.

Subjects will take photos of foods before eating and of the leftovers if any with the help of a smartphone using SmartIntake© app for 7-days. Participants will record all meals for the next 7 days in a food record (Appendix G) as well. On the following day (day 1 of 7 days) a 24-hour recall will be done using Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool.

Visit 2- On day 8, participants will be asked to return with 10 hours fast. As in Visit 1, an IV catheter will be placed by the registered nurse in the subject's upper limb to collect blood for blood glucose, and hormones. Blood will be collected for fasting blood glucose levels and insulin levels PYY, GLP1, ghrelin (as described above) 30 minutes prior to the breakfast. They will be randomized to receive test breakfast 2. Blood draws will be continuously done at 30, 60, 90, 120 and 180 minutes after breakfast consumption. Following each blood draw, subjects will be asked to assess their hunger and fullness using the visual analog scale (VAS) (Appendix E). RMR will be determined 30 mins prior and 60 and 120 min post breakfast.

Outcome Measures:

A. Primary Outcome Measures:

1. Difference of energy intake (kcal) in meals containing eggs as compared to meals that do not contain eggs

Energy intake will be determined using Remote Food Photography Method (RFPM) and the meals of all test subjects will be categorized based on the presence or the absence of eggs in the meals.

[Time Frame: Day 1-7 of the ecological momentary assessment part (Part I) of the study]

2. Difference of energy intake (kcal) in high egg consumers as compared to low egg consumers

Comparison of mean daily energy intake as measured by Remote Food Photography Method (RFPM) between high egg consumers and low egg consumers identified by providing a food frequency questionnaire (FFQ).

[Time Frame: Day 1-7 of the ecological momentary assessment part (Part I) of the study]

3. Difference of saturated fat (g) intake in meals containing eggs as compared to meals that do not contain eggs

Saturated fat intake will be determined using Remote Food Photography Method (RFPM) and the meals of all test subjects will be categorized based on the presence or the absence of eggs in the meals.

[Time Frame: Day 1-7 of the ecological momentary assessment part (Part I) of the study]

4. Difference of saturated fat (g) intake in high egg consumers as compared to low egg consumers

Comparison of saturated fat intake as measured by Remote Food Photography Method (RFPM) between high egg consumers and low egg consumers identified by providing a food frequency questionnaire (FFQ).

[Time Frame: Day 1-7 of the ecological momentary assessment part (Part I) of the study]

5. Difference of blood glucose levels compared between different test breakfasts

This will be measured on visit 1 and 2 after providing test breakfasts.

[Time Frame: Changes in concentration (area under the curve; AUC) from 30 minutes prior to breakfast to 180 minutes after consumption of test breakfasts (Part II of the study)]

6. Difference of insulin levels compared between different test breakfasts

This will be measured on visit 1 and 2 after providing test breakfasts.

[Time Frame: Changes in concentration (area under the curve; AUC) from 30 minutes prior to breakfast to 180 minutes after consumption of test breakfasts (Part II of the study)]

B. Secondary Outcome Measures:

1. Difference of subjective hunger level compared between different test breakfasts

This will be measured on visit 1 and 2 after providing test breakfasts.

[Time Frame: Changes in scores (arbitrary units AU) from 30 minutes prior to breakfast to 180 minutes after consumption of test breakfasts (Part II of the study)]

2. Difference of subjective satiety level compared between different test breakfasts

This will be measured on visit 1 and 2 after providing test breakfasts.

[Time Frame: Changes in scores (arbitrary units AU) from 30 minutes prior to breakfast to 180 minutes after consumption of test breakfasts (Part II of the study)]

3. Difference of objective hunger compared between different test breakfasts

This will be measured on visit 1 and 2 after providing test breakfasts by measuring serum ghrelin levels.
[Time Frame: Changes in concentration (area under the curve AUC) from 30 minutes prior to breakfast to 180 minutes after consumption of test breakfasts (Part II of the study)]
4. Difference of objective satiety compared between different test breakfasts using serum Glucagon-like peptide-1 (GLP-1) levels.
This will be measured on visit 1 and 2 after providing test breakfasts by measuring serum GLP-1 levels.
[Time Frame: Changes in concentration (area under the curve AUC) from 30 minutes prior to breakfast to 180 minutes after consumption of test breakfasts (Part II of the study)]
5. Difference of objective satiety compared between different test breakfasts using serum Peptide YY (PYY 3-36) levels
This will be measured on visit 1 and 2 after providing test breakfasts by measuring serum PYY 3-36 levels.
[Time Frame: Changes in concentration (area under the curve AUC) from 30 minutes prior to breakfast to 180 minutes after consumption of test breakfasts (Part II of the study)]
6. Difference of HbA1c levels in high egg consumers as compared to low egg consumers
This will be measured by taking blood on the visit 1.
[Time Frame: Changes in blood concentration (arbitrary units AU) on visit 1 (Part II of the study)]
7. Difference in Homeostasis Model Assessment-Insulin resistance (HOMA-IR) compared between different test breakfasts
This will be calculated using blood glucose and insulin levels.
[Time Frame: Changes in HOMA-IR values (arbitrary units AU) on visit 1 and 2 after providing test breakfasts (Part II of the study)]
8. Difference in Resting Metabolic Rate (RMR) compared between different test breakfasts
RMR will be assessed following different test breakfasts on visit 1 and 2.
[Time Frame: Changes in RMR (kcal/24hrs) on visit 1 and 2 following each test breakfast (Part II of the study)]
9. Difference in total energy intake (kcal) compared between Remote Food Photography Method (RFPM), 7-day food record and 24-hour recall

Comparison of mean energy intake as determined by RFPM with mean energy intake determined by 7-day food record and a single 24-hour recall.
[Time Frame: Day 1-7 of the ecological momentary assessment part (Part I) of the study]

Statistical Analyses Plan (SAP):

Data will be imported to R statistical software and the distributions will be examined visually to make a decision about the appropriate statistical tests (i.e. parametric / non-parametric) to be used for all comparisons. All statistical analyses will be conducted using R statistical software. Family-wise error rate will be maintained at 0.05.

Free living EI and saturated fat intake during main three meals (i.e. breakfast, lunch and dinner) of each subject will be determined using RFPM and the meals of all test subjects will be categorized based on the presence or the absence of eggs in the meals. Means of EI and saturated fat intake during each main meal will be compared between the two categories (i.e. eggs present vs. eggs absent) using multi-level mixed-effects regression models constructed using the lmerTest package in R statistical software. Age, sex, baseline BMI and / or waist circumference will be included in the models as subject-level covariates.

Based on RFPM data, mean EI and saturated fat intake of the high egg consumers (i.e. individuals in the top quartile based on egg consumption) will be compared with the mean EI and saturated fat intake of the low egg consumers (i.e. individuals in the bottom quartile based on egg consumption) via Welch t-tests or the Wilcoxon test, depending on the distributions of the data.

Linear regression models will be constructed to examined the associations between a) total EI, b) saturated fat intake and c) egg intake and each of i) baseline insulin level, ii) blood glucose level, iii) HOMA-IR, and iv) HbA1C level. The usual regression assumptions will be assessed and any concerns will be ameliorated as appropriate (e.g. apply a transformation as guided by Box-Cox)

Using the data obtained in the randomized partial crossover trial, multi-level mixed effects regression models will be constructed using the lmerTest package in R statistical software to predict each of a) PYY (AUC and pre-post change); b) GLP-1 (AUC and pre-post change); c) ghrelin (AUC and pre-post change); d) blood glucose (AUC and pre-post change); e) insulin (AUC and pre-post change); f) metabolic rate using i) the presence of eggs in the diet; ii) the

presence of a high content of saturated fat in the diet; iii) their interaction. Age, sex, baseline BMI and / or waist circumference will be included in the models as subject-level covariates.

Mean EI estimates of food records and 24-hour recall methods will be compared with the EI estimates of RFPM both with and without controlling for age, sex, baseline BMI and / or waist circumference by constructing a mixed-effects regression model to predict EI using the lmerTest package in R statistical software. The methods of estimation will be included in the model as a categorical independent variable and RFPM will be specified as the reference category. Age, sex, baseline BMI and / or waist circumference will be included in the models as subject-level covariates.

Potential Risks:

There will be little or no long-term risk expected from participation in this research project. Since there are multiple blood draws, they will be done by an experienced registered nurse who is working in the ER so that the pain and discomfort will be minimal. And blood draws will be done using aseptic techniques. No risk is anticipated for eating breakfast containing eggs or from RFPM or questionnaires for food intake.

As with any research study, there are risks for breach of confidentiality. To mitigate this risk the master list of participant names and corresponding participant codes will be stored separately and securely from the electronic research database in the locked office in a secure locked filing cabin (i.e. behind 2 locks per HIPPA standards for patient records). There will be no personal identifying information in the research database; therefore, participants cannot be identified from that source. All electronic files containing participant identifying data will be password protected and stored on digital recording media in separate locations (in locked filing cabinets behind locked doors) at TTU. The participant signed Informed Consent will be similarly stored.

The participants will be informed of the right to withdraw from the study at any point. The participants who withdraw will be provided with compensation and other benefits for the time spent up to the point of withdrawal. The participants will be provided with access to the study personnel and the PI throughout the period of intervention via telephone, text messaging or email. If an unexpected non-emergent adverse event is to occur, the participants will be referred to a health care facility. For any urgent health concerns, participants will be instructed to dial 911

for immediate help. If an unexpected medical event occurs during the study visits, the subjects will be immediately referred to the nearest medical facility. All study staff have current Basic Life Support CPR training. The IRB will be notified regarding any adverse events that occur during the study.

Potential Benefits:

Participants will learn about their blood sugar, insulin and satiety hormone values. They will also learn about their resting metabolic rate.

Subject Compensation

Participants in the study will be compensated $100 for participation. Subjects will receive $25 for the 1st visit. Once subjects send all the photos of what they have consumed for all 7 days they will receive another $50 ($7 for each day). Finally, subjects will receive $25 for 2nd visit. If a subject begins any visit and is unable to complete it, $10 will be rewarded. Ten dollars will be awarded if a subject cannot complete all the VAS or stay for all the blood draws or consume test breakfasts.

On each of these designated days, subjects' will be required to fill out the required paperwork to receive compensation. Our research team will follow the guidelines stated in OP 62.25 *Payments to Research Participants,* and all subject information gathered to receive compensation will be kept confidential. The grant received from the Egg Nutrition Center will cover subject compensation

Adverse Events and Liability

The proposed research study only contains minimum risk beyond ordinary life circumstances. Some unexpected adverse effects that are possible in this study are related to IV catheter insertion and removal. A trained certified registered nurse will take all precautions to minimize any adverse events regarding the blood-sampling component of this study. The participants will be provided with the phone number and email of the study PI and also email contact information for non-urgent concerns and or adverse events reporting. For urgent medical concerns, participants will be directed to contact their healthcare provider or visit local urgent care facilities (contact information will be provided during the enrollment process). For medical

emergencies, the participants will be instructed to dial 911. The TTU IRB will be notified per TTU reporting guidelines regarding any adverse events that occur during the study.

Informed Consent Form (ICF)

Please see attached consent form in Appendix C on pages 27 to 32.

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Appendix A-1: Recruitment Announcement

TechAnnounce Advertisement

Non-Diabetic Individuals Needed for a Study on Dietary Patterns Using Remote Food Photography Method (RFPM).

Texas Tech University Department of Nutritional Sciences

What will I be asked to do?

You will be required to visit our facility in the morning for two days. There will be several blood draws using a iv catheter and filling in some questionnaires. You will be given a test breakfast and trained to use food photography. For seven days, you will have to take photographs of what you have eaten throughout the day using smart phones.

You can be considered to participate in this study if:

1. You are a male or female within the ages of 18-65 years of age.

2. You are within the BMI range of 20-60 kg/m^2.
3. You have not lost weight ≥5% in the past 3 months.
4. You are not a patient with diabetes.

Compensation of $100 for your time (two visits) is included.

Transportation to our clinic will not be provided and all participation is completely confidential. Your participation in this study is greatly appreciated and you can stop participating at any time during the study if you so desire.

For more information or if you are interested in participating, please contact Samudani Dhanasekara Graduate Teaching Assistant, at rfpmstudyttu@gmail.com or by phone at 281-235-2280.

This study has been approved by the TTU Institutional Review Board.

Appendix A-2 Recruiting Announcement- Flyer

Non-Diabetic Individuals Needed for a Study on Dietary Patterns Using Remote Food Photography Method (RFPM).

Texas Tech University Department of Nutritional Sciences

What will I be asked to do?

You will be required to visit our facility in the morning for the first visit and there will be several blood draws using an iv catheter and filling in some questionnaires. You will be given a test breakfast and trained to use food photography. For seven days, you will have to take photographs of what you have eaten throughout the day using smart phones. After seven days, you will be required to visit the facility again and have the second test meal, several blood draws and filling in some questionnaires.

You can be considered to participate in this study if:

1. You are a male or female within the ages of 18-65 years of age.
2. You are within the BMI range of 20-60 kg/m^2.
3. You have not lost weight ≥5% in the past 3 months.
4. You are not a patient with diabetes.

Compensation of $100 for your time (two visits) is included.
Transportation to our clinic will not be provided and all participation is completely confidential. Your participation in this study is greatly appreciated and you can stop participating at any time during the study if you so desire.

For more information or if you are interested in participating, please contact Samudani Dhanasekara, Graduate Research Assistant, at rfpmstudyttu@gmail.com or by phone at 281-235-2280.

Thank You!

This study has been approved by the TTU Institutional Review Board.

RFPM Research Study **(281) 235-2280** rfpmstudyttu@gmail.com

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Appendix B: Telephone Screening Interview Protocol

Hello, during this conversation, we are going to give you information about the study and also ask you some questions. Please respond carefully. Once the telephone interview is complete, we will review your information with the study team to determine if you are eligible. You will be informed of the outcome within **48 hours** of this call and if you are eligible, scheduled for your first appointment. Your responses here are confidential within the study team and you are in no way obligated to participate by completing this prescreening.

Name: _____

Phone: _____

Email: _____

Age: _____ **Gender: M ☐ F ☐**

Height: _____ **Weight:** _____

BMI: _____

(Research personnel will use given height and weight to calculate BMI)

How did you hear about this study? _____

This call will last approximately 30 minutes. If at any point, you have any questions or do not wish to continue, please tell me so. The purpose of this study is to study on usual dietary patterns using remote food photography method (RFPM). You will be required to visit our facility in the morning for the first visit and there will be several blood draws and questionnaires. You will be given a test breakfast and trained to use SmartIntake© smartphone "app" used in food photography. For seven days, you will have to take photographs of food including snacks before eating and of the leftovers, using smart phones. After seven days, you will be required to visit the facility again and have the second test meal. There will be several blood draws on the second visit.

Would you like to learn more about the study and see whether you would be eligible to participate? Y N.

If No: Thank you very much for your time, may we keep your contact information on file to inform you of future studies?

If Yes: Ok good. Let's continue.

a) For your participation in this study you will be compensated for your time. After this phone interview, if you are eligible, you will be scheduled for the first visit. Upon completion of the first and second visits and sending photographs of what you have eaten on all 7 days and maintaining a food record you will be eligible to receive $100.
b) If you are determined to be eligible, the first visit will be scheduled for a date within the next couple of weeks. The first visit will last approximately 4 hours. First, we will have you sign some papers (Informed Consent). At this visit you will have body weight, height, waist and hip circumference measured along with blood pressure. You will be offered a test breakfast and train to take photographs of food using smart phones.
c) There will be several blood draws via IV catheter and filling up of questionnaires. For blood draws a trained registered nurse will insert an IV catheter, which is small needle and a tube. After insertion of IV catheter, the needle will be removed leaving the plastic tube for 3 hours. We will take one blood sample before and five blood samples after breakfast. Since we leave the IV catheter inserted till the blood withdrawal is over you will have one needle stick per visit. If iv-catheterization fails at some point, which happens very rarely we will take blood from separate needle sticks every half an hour. However, there will be total of 4 needle sticks including the initial needle stick done to insert the IV catheter applied in a single visit if the IV catheterization fails.
d) You will be asked to take photographs of all the meal including the snacks for 7 days. You have to take photographs before and after (the left overs) you have taken each meal.
e) On day 1 of the seven days we will contact you through phone to assess get a 24-hour recall of your energy intake.
f) After 7 days, you will have to visit the facility for the 2nd visit.
g) The second visit will last up to 4 hours and you will be given the second test meal. There will be several blood draws via an IV catheter as mentioned above.

Do you have any questions up to this point?

Are you still interested in this study? If yes, I have some more questions. *Y N*

Eligibility for the study

1. Have you lost or gained more than 5% of your body weight in past 3 months?
   Y N Current weight:_____x.05=_____5% of CBW
2. Have you been involved in a formal weight loss program in the past 3 months?
   Y N
3. Tell me what medications you are taking now (list)_____
   _____
4. Are you currently on or have been on within the past 4 weeks any anti-depressant, anti-epileptic, or anti-anxiety medicines? Y N
   Which ones: _____
5. Have you experienced persistent loss of appetite, nausea or vomiting (last 4 weeks)?
   Y N
6. Have you taken any weight loss medications in the past 4 weeks? Y N
   List them: _____
7. Do you smoke? Y N
   If No, when did you last smoke? Date: _____
8. Do you drink alcohol? Y N
   If Yes, how much and how often? _____
9. Do you have a history of substance or alcohol abuse? Y N
10. Do you currently have any of the following conditions?

Diabetes Mellitus	Y	N
Ischemic Heart disease	Y	N
Cerebrovascular accidents (strokes)	Y	N
Congenital heart disease	Y	N
Hypertension	Y	N
Polycystic ovary syndrome	Y	N
Prader-Willi syndrome	Y	N
Major systemic illness	Y	N

Familial hyperlipidemia Y N

Endocrine diseases (Cushing's syndrome,
Grave's disease, Hashimoto's thyroiditis) Y N

If Yes, please specify _____

_____

11. Are you currently diagnosed with diabetes mellitus? Y N
12. Did you have any abnormal blood glucose report? Y N

If Yes, please explain:_____

_____

13. Do you have any family history of diabetes mellitus? Y N

If Yes, please explain: _____

_____

14. Do you have a history of eating disorders such as bulimia nervosa, anorexia nervosa, or binge eating disorder? Y N

If Yes, please describe: _____

_____

15. If female, are you pregnant or lactating, or suspect you might be pregnant or currently trying to conceive? Y N
16. Do you have any allergies sensitivity to or dislike of eggs? Y N
17. How many eggs do you consume for a week? _____
18. Do you currently take vitamins or other over the counter 'remedies'? Y N

List: _____

_____

19. Do you like and will you eat eggs? Y N
20. Do you like and will you eat Special K® Cereal? Y N
21. Do you like and will you consume skim milk? Y N
22. Do you like and will you consume 2% milk? Y N
23. Do you like and will you consume Silk® Original Soy Milk? Y N
24. Do you like and will you eat Mrs. Bairds® Extra Thin White Bread? Y N
25. Do you like and will you eat Nature's Own® Double Fiber Wheat Bread? Y N
26. Do you like and will you eat Arnold® Double Protein Whole Grain Bread? Y N

27. Do you like and will you eat butter? Y N

28. Do you like and will you eat margarine? Y N

29. Do you like and will you eat Smuckers® Strawberry Jam? Y N

30. Do you like and will you eat Smuckers® Sugar Free Strawberry Jam? Y N

31. Will you drink water or diet coke? Y N

32. Do you have an iPhone? Y N

If yes, are you willing to use your phone or do you want a separate phone to use in the study? _____

Are you still interested in participating in this study? Y N

If Yes, we will let you know whether you are eligible within 48 hours of this call and if you are eligible, scheduled for your first appointment. Thank you for your cooperation.

Appendix C

Informed Consent Form (ICF)

WRITTEN CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Study of Dietary Patterns Using Remote Food Photography Method (RFPM).

Protocol Number: IRB 2017-215

Introduction:

You are invited to participate in a research study by Dr. Nikhil Dhurandhar, Department Chair of the Nutritional Sciences Department at Texas Tech University (phone number: [806]-742-5270). There are two main parts of this study. In the first part, you will be sending photographs of which you have eaten including snacks for seven days using RFPM. As the second part of the study, you will be participating in 1 of 2 potential experiments for this study. Participation in either experiment will require a total of 2 visits to our facility at Texas Tech University. On the 1st visit you will have to come fasting for 10 hours. However, you are allowed to take water. Height, weight, waist and hip circumference and blood pressure will be determined as described below. Small amount of blood will be collected before and after you have taken the breakfast and you will have to fill out some questionnaires. Similar procedures will be taken place on the 2nd visit as well. You will be asked to eat two different breakfasts in each visit.

Purpose of the Study:

The purpose of this study is to use the Remote Food Photography Method (RFPM) to understand the usual dietary patterns of a person.

Explanation of the Procedures:

There will be two visits to our facility during this study. On the 1st visit, you will report after not eating or drinking anything that morning between 7:00 am and 9:00 am. You need to be fasting for 10 hours i.e. not eating or drinking overnight, however, you are allowed to drink water.

Visit 1

Measurements including height, weight, waist and hip circumference, and blood pressure will be done before breakfast is served in a fasted state. We will also be taking a small amount of blood (4 teaspoons) and asking you to answer a hunger questionnaire before breakfast is served.

To take blood, a trained registered nurse, will place an IV catheter into your upper limb. We will take one blood sample before and five blood samples after breakfast. Since we leave the IV catheter inserted till the blood withdrawal is over you will have one needle stick per visit. If IV-catheterization fails at some point, which happens very rarely we will take blood from separate needle sticks every half an hour. However, there will be total of 4 needle sticks including the initial needle stick will be done to insert the IV catheter applied in a single visit.

This blood will be used to test blood glucose levels, glycosylated hemoglobin HbA1c (glucose bound hemoglobin) and for amounts of the substances that can control your feelings of hunger and fullness. Your signature on this document also allows us to store the leftover sample for tests that will be done at a later time. After the completion of the study and all publications have been accepted, all blood specimens will be destroyed.

You will then fill out a standardized questionnaire about your feelings of hunger. Breakfast will be brought to you at this point and you will be trained how to use RFPM by using SmartIntake© smartphone app. For this you can use your own phone or we will provide you with a phone. You will be served breakfast called Test Breakfast 1. This will be either one of the four breakfasts that we will be testing in this study. The type of breakfast you will get will be randomly assigned. Composition of each breakfast is stated below (Table 1).

Table 1. Composition of Breakfasts

A-Egg Breakfast	B- Egg Breakfast with High Saturated Fat	C- Cereal Breakfast	D-Cereal Breakfast with High Saturated Fat
2 Scrambled Eggs	2 Scrambled Eggs	1c Special K RTE High Pro Cereal	1c Special K RTE High Pro Cereal
120 mL Skim Milk	120 mL 2% milk	200 mL Silk Original Soymilk	200 mL Silk Original Soymilk
2 Slices Nature's Own Double Fiber Wheat Bread	2 Slices Nature's Own Double Fiber Wheat Bread	1 Slice Mrs. Bairds Extra Thin Bread	1/2 Slice Arnold Double Protein Whole Grain Bread

30g Margarine	15 g Butter	35g Margarine	15 g Butter
18g Smucker's Strawberry Jam	15g Smucker's Strawberry Jam	10 g Smucker's Sugar Free Strawberry Jam	

You will not be able to use any electronics at any mealtime during this study. You will have 10 minutes to eat all food before you. You then relax and fill out the same questionnaire at the same time blood (4 teaspoons) is taken at 30, 60, 90, 120 and 180 minutes after breakfast. In addition, your resting metabolic rate (RMR) will be measured using indirect calorimetry 30 min before and 60 and 120 min after the breakfast.

Days 1-7:

You will take photos of foods before eating and of the leftovers, if any with the help of a smartphone using SmartIntake© app for 7-days. You will record all meals for the next 7 days in a food record as well. On the following day (day 1 of 7 days) a 24-hour recall will be done using Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool. For that, we will send you a link to login and enter your dietary intake.

Visit 2

After 7 days, you will come to our facility between 7:00 am and 9:00 am and eat Test Breakfast 2. First, registered nurse will place an IV catheter into your upper limb. Blood will be collected before the breakfast is served and you will then fill out a standardized questionnaire about your feelings of hunger. In addition, your RMR will be measured. Next either Test Breakfast 2. Again, Test Breakfast 2 will be one of the four breakfasts that we will be tested. You will not be able to use any electronics at any mealtime during this study. You will have 10 minutes to eat all food before you. You then relax and fill out the same questionnaire at the same time blood is taken at 30, 60, 90, 120 and 180 minutes after breakfast. In addition, your resting metabolic rate (RMR) will be measured using indirect calorimetry 30 min before and 60 and 120 min after the breakfast.

You will receive $25 for the 1st visit. Once you send all the photos of what you have consumed for all 7 days you will receive another $50 ($7 for each day). Finally, you will receive $25 for 2nd visit. A total of $100 will be paid to you. If on any day, you begin testing and are unable to complete it for any reason, you will be given $10 as payment for your time. Ten dollars will be awarded if you cannot complete all the VAS or stay for all the blood draws or consume test breakfasts.

In order to receive payment for your participation, you will have to provide the researchers with some personal information. This information is needed to distribute cash and verify receipt of payment. All given information will be kept private and confidential. Any questions about this matter should be brought to the attention of the researchers. If you are not a US citizen 30% will be deducted from your payment.

Potential Risks and Discomforts:

All blood drawing procedures will be done by a trained expert (registered nurse). This expert will take all precautions to minimize any adverse occurrences. However, there is a small risk for localized bruising, pain, and infection at the site of blood drawing.

Potential Benefits:

If you decide to participate in this research study, you will learn your height, weight, body mass index (BMI), waist and hip circumference and blood pressure. You will also learn about their blood sugar, insulin and satiety hormone values. They will also learn about their resting metabolic rate.

Privacy and Confidentiality:

Only Dr. Dhurandhar and his research team will be able to see the data and information on this project. All files, information, and recorded data will be kept in a locked file cabinet within a locked laboratory or office. Only those working on this project will have access to the cabinet. Your participation in this study will generate a subject ID code, and that is what will be used to record and analyze data. Anything with your name on it, besides a copy of this consent form, will be destroyed. If this study becomes published, your name will not be used and record of your participation will not be mentioned.

Financial Obligation:

By taking part in this study, you will not be responsible for any costs. You and your insurance company will not be billed for any services related to your participation in this research.

Participation:

Your participation in this study is completely voluntary and refusal to participate in this study will not result in any penalty or loss of benefits to which you are otherwise entitled to. You can stop your participation in this study at any time, even in the middle of a test, with no penalty or loss of benefits. If you decide to withdraw from this study, please contact Dr. Dhurandhar.

Your Rights and Information about Your Consent:

Dr. Dhurandhar will answer any questions you have about this study. Please reach him by calling the following phone number: [806]-742-5270 or by emailing him at the following email address: nikhil.dhurandhar@ttu.edu. Questions can also be directed to the Human Research Protection Program (HRPP), Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409, [806]-742-2064.

If this research project causes injury (physical, psychological, financial, etc.), Texas Tech University or the Student Health Services, may not be able to treat your injury. You will have to pay for treatment from your own insurance. The University does not have insurance to cover such injuries. More information about these matters may be obtained from Dr. Alice Young, Faculty Fellow for Research Integrity, Office for Vice President for Research, (806) 742-3905, Room 103 Holden Hall, Texas Tech University, Lubbock, Texas, 79409.

Signature of Research Subject:

_____

Name of Subject (please print)

Signature of Subject | Date (M/D/Y)

Signature of Investigator (person doing the consenting):

I have explained the research to the person and answered all of his/her questions. I believe that he/she understands the information and freely decides to participate.

Name of Investigator

Signature of Investigator | Date (M/D/Y)

This consent form is no longer valid after_____

Appendix D

Data Collection Sheet

Subject ID: _____ **Date:** _____

Age: _____ **Male:** ☐ **Female:** ☐

Visit No: _____

Anthropometrics:

Height:_____ Weight:_____

Calculated BMI:_____ Use BMI formula: wt (kg)/ ht (m^2)

Waist Circumference:_____ Hip Circumference:_____

_____ _____

_____ _____

Avg:_____ Avg:_____

Blood Pressure:_____ mm Hg

Blood Draw, VAS, and Meal

Time IV Catheter is placed:_____

Time Fasting Blood Sample Taken:_____ Time of Fasting VAS:_____

Time of RMR:_____

RMR: _____

Time Breakfast Given (10 min. to eat):_____

Type of Breakfast:

Test Breakfast A ☐ Test Breakfast B ☐

Test Breakfast C ☐ Test Breakfast D ☐

Training for RFPM: _____

Postprandial Blood Draws, VAS and RMR (times of each) and values of RMR:

30 minutes:_____ VAS:_____ RMR: _____

60 minutes:_____ VAS:_____ RMR: _____

90 minutes:_____ VAS:_____ RMR: _____

120 minutes:_____ VAS:_____ RMR:_____

180 minutes:_____ VAS:_____ RMR: _____

Time of Food Frequency Questionnaire: _____

Time of IV Catheter Removal:_____

Appendix E

Visual Analog Scale (VAS) Questionnaire

Subject ID: _____ **Date:** _____

Age: _____ **Male:** ☐ **Female:** ☐

Visit No: _____

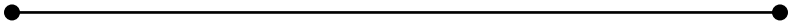
Instructions:
For each question, please make an up-and-down line at the point on the line that best describes

1. **How hungry do you feel at this moment?**

Not at all hungry — Extremely hungry

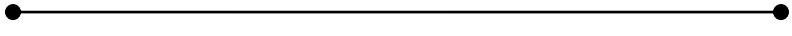
2. **How thirsty do you feel at this moment?**

Not at all thirsty — Extremely thirsty



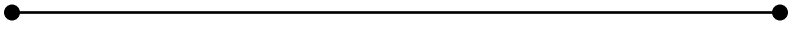
3. **How full does your stomach feel at this moment?**

Not at all full — Extremely full



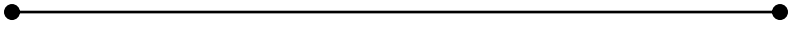
4. **How empty does your stomach feel at this moment?**

Not at all empty — Extremely empty



5. **How much do you think you could eat right now?**

Nothing at all — A large amount



Appendix F

Food Frequency Questionnaire

Subject ID: _____ **Date:** _____

Age: _____ **Male:** ☐ **Female:** ☐

GENERAL INSTRUCTIONS

- **Answer each question as best you can. Estimate if you are not sure. A guess is better than leaving a blank.**
- **Put an X in the box next to your answer.**
- **If you make any changes, cross out the incorrect answer and put an X in the box next to the correct answer. Also, draw a circle around the correct answer.**

1. How often do you eat **eggs, egg whites,** or **egg substitutes** (NOT counting eggs in baked goods and desserts)?

   ☐ 2 times per week
   ☐3–4 times per week
   ☐5–6 times per week
   ☐1 time per day
   ☐2 or more times per day

2. Each time you ate **eggs**, how many did you usually eat?

   ☐1 egg
   ☐2 eggs
   ☐3 or more eggs

3. How often were the eggs you ate **egg substitutes** or **egg whites only**?

   ☐Almost never or never
   ☐About ¼ of the time
   ☐About ½ of the time
   ☐About ¾ of the time
   ☐Almost always or always

4. How often were the eggs you ate **regular whole eggs**?

☐Almost never or never
☐About ¼ of the time
☐About ½ of the time
☐About ¾ of the time
☐Almost always or always

5. How often were the eggs you ate **cooked in oil, butter,** or **margarine**?

☐Almost never or never
☐About ¼ of the time
☐About ½ of the time
☐About ¾ of the time
☐Almost always or always

6. How often were the eggs you ate part of **egg salad**?

☐Almost never or never
☐About ¼ of the time
☐About ½ of the time
☐About ¾ of the time
☐Almost always or always

7. How often do eat eggs for your breakfast?

☐Almost never or never
☐About ¼ of the time
☐About ½ of the time
☐About ¾ of the time
☐Almost always or always

8. How often do you eat eggs with bacon?

☐Almost never or never
☐About ¼ of the time
☐About ½ of the time
☐About ¾ of the time
☐Almost always or always

9. How often do you eat eggs with hash browns?
   - ☐Almost never or never
   - ☐About ¼ of the time
   - ☐About ½ of the time
   - ☐About ¾ of the time
   - ☐Almost always or always

Appendix G

Food Record

Subject ID: _____ **Date:** _____

Age: _____ **Male:** ☐ **Female:** ☐

GENERAL INSTRUCTIONS

- **Complete this form as accurately as possible.**
- **Use separate forms for each day.**
- **Record all foods, beverages, and supplements that you consume each day.**

Time	Food/Drink	Type	Preparation	Amount

Appendix H

The proposal submitted to the Egg Nutrition Center
Determining dietary pattern accompanying egg intake

Principal Investigator: [1]Nikhil V. Dhurandhar, PhD

Co-investigators: [2]Corby Martin, PhD

[1]John A. Dawson, PhD

[1]Department of Nutritional Sciences
Texas Tech University
Lubbock, TX 79409

[2]Pennington Biomedical Research Center
Louisiana State University System
Baton Rouge, LA 70808

A. Abstract

Eggs are nutrient dense, convenient, affordable, and provide key macro and micronutrients in one's diet. However, recent epidemiological studies raise health concerns about egg intake for subgroups of people, indicating These studies indicated that under free living conditions, higher egg intake is associated with increased cardiovascular disease (CVD) risk in diabetic individuals. Also, greater egg consumption is reportedly associated with greater risk of type 2 diabetes. If indeed diabetes is a concern associated with egg consumption, unequivocal data are urgently required to express appropriate caution. Likewise, eggs should be cleared of the concerns, if ill-founded. Therefore, our *Central hypothesis* is that the association of egg intake with increased CVD risk in diabetics, or with greater risk of developing diabetes, is due to the accompanying dietary pattern, and not due to eggs per se. We propose to test this hypothesis by determining the food intake of 40 non-diabetic individuals. Food intake will be determined using the remote food photography method which employs smartphone technology as a means of estimating energy intake remotely from participants' home environments. We expect to observe that the purported association of eggs to dysregulated glycemic control is independent of eggs, but mainly due to the dietary pattern around egg intake. If true, an informational campaign will be needed to clear eggs from the "guilt by association". Alternatively, if eggs intake is indeed associated with impaired glycemic control, then appropriate steps should be taken to inform people accordingly.

B. Background

Eggs are nutrient dense, convenient, affordable, and are valuable in providing key macro and micronutrients in one's diet. Particularly, eggs are known for their superior quality of proteins and essential amino acids such as leucine, which can augment insulin action to improve glycemic control. Overall, meta-analyses and epidemiological studies strongly indicate that daily egg consumption does not adversely affect plasma lipoproteins with regards to the risk for CVD (cardiovascular disease) or stroke among healthy individuals [1-8]. In fact, egg consumption improves weight loss [9, 10] or blood lipid and glucose profiles of diabetic individuals[11]. However, recent epidemiological studies raise health concerns about egg intake for subgroups of people. These studies indicated that under free living conditions, higher egg intake is associated with increased CVD risk in diabetic individuals [3, 12, 13]. Also, greater egg consumption is reportedly associated with greater risk of type 2 diabetes [14-16]. ***If indeed diabetes is a concern associated with egg consumption, unequivocal data are urgently required to express appropriate caution***. Likewise, eggs should be cleared of the concerns, if ill-founded.

Several issues question the applicability of the epidemiological observations about egg consumption and diabetes. While eggs improve glycemic control of diabetic individuals under the controlled environment of experimental intervention [11], epidemiological studies indicate that under free living conditions, higher egg intake predicts risk of diabetes or CVD risk for diabetic individuals. Possibly, higher egg intake is simply a marker for other dietary indiscretions. For instance, from lowest to highest egg consumers, men reported greater daily energy intake from 1,870 kcal to 2,372 kcal, greater saturated fat intake and a 5-fold increase in bacon consumption, although their BMIs were nearly identical [3] - this strongly suggests that greater egg intake is associated with greater intake of other nutrients. Predictably, the association of CVD with egg consumption disappeared when bacon intake was also considered [3]. *Individuals predisposed to impaired glycemic control* may be particularly susceptible to undesirable health effects of higher saturated fat and energy intake. In such individuals, saturated fat may overwhelm the beneficial effects of eggs on lipid and glycemic profile. A possibility that beneficial effects of eggs on lipids can get counterbalanced is also expressed by Hu et al. [3]. For a clearer understanding in those with impaired glycemic control, the effect of eggs should be separated from that of accompanying saturated fat consumed.

Therefore, our ***Central hypothesis*** is that the association of egg intake with increased CVD risk in diabetics, or with greater risk of developing diabetes, is due to the accompanying dietary pattern, and not due to eggs per se. Specifically, we postulate that rather than eggs, the greater energy intake and saturated fat intake (e.g. bacon, butter, hash browns, etc.) associated with *greater* egg consumption contribute to the stated health risks. We propose to test this hypothesis as follows, by using the remote food photography method (RFPM), which was developed and validated by our co-investigator (CM). RFPM employs smartphone technology as a means of estimating energy intake remotely from participants' home environments.

Aim: Use the RFPM to accurately determine the dietary pattern associated with egg intake in 40 free living non-diabetic individuals who eat eggs often.
This aim will test the following hypotheses:

1. Meals that include eggs have higher energy and saturated fat content vs similar meals without eggs.
2. The daily total energy and saturated fat intakes are different between low and high egg consumers.
3. The HbA1C levels are positively associated with total energy intake or saturated fat intake.
4. When adjusted for age, body mass index (BMI), waist circumference, energy and saturated fat intake, HbA1c is not significantly associated with egg intake.

C. Significance

An association between egg consumption and diabetes should not be ignored. However, it is important to identify if such an association does indeed exist and, if so, whether or not there is evidence that suggests that it is not the eggs themselves that drive the association, but rather a concurrent undesirable profile of macronutrient intake. Food intake data assessed by subjective recall methods are highly questionable due to potential inaccuracies [17]. Capturing food intake data in real time by RFPM is the greatest strength of this project. The RFPM has been validated for accuracy against the doubly labeled water method [18, 19]. With high accuracy, we will identify the nutrients associated with egg consumption. Intake at every meal will be captured for 7 days in a free living population, which eliminates the reporting bias around subjective measures of food intake and provides greater fidelity of reporting usual diet. This will help in better understanding the health effects that are currently ascribed to eggs by epidemiological studies using dietary recall methods. We expect that this study will demonstrate that intake of eggs is associated with an undesirable profile of macronutrient intake. Overall, the studies will provide stronger evidence to accept or refute some of the adverse effects reportedly associated with egg consumption, so that appropriate dietary recommendations could be designed. It will form the basis for future research to determine if the dietary pattern accompanying eggs and not eggs per se is linked to diabetes and other adverse metabolic consequences.

D. Research plan

Overview: Subjects who routinely eat eggs will be recruited. Their food consumption pattern will be assessed by food frequency questionnaire (FFQ), to identify subjects belonging to quartiles for egg consumption. Number of eggs eaten per week will be determine based on FFQ. This will allow us to identify low and high consumers of eggs (bottom vs top quartile for egg consumption per week). Next, the RFPM, - a highly validated and innovative approach that uses camera-enabled Smart phones with data transfer capability [19] will be used to accurately assess food intake during all meals and snacks for 7 days. The RFPM will quantitate and compare the daily intake of saturated fat and energy, and saturated fat intake accompanying eggs between low and high egg consuming individuals.

Subjects: Inclusion criteria: 40 non-diabetic individuals (fasting glucose < 126 mg/dL), male or female, BMI $\geq$ 20 and $\leq$ 60 kg/m^2, Age: 18 – 65 y, Weight loss < 5% in the past 3 months. Exclusion: Diabetes, on diabetes medication, pregnant or lactating females, those with a history of gestational diabetes, have an unstable cardiac condition, a major systemic illness, a history of drug abuse or eating disorders, have uncontrolled hypothyroidism, have familial hyperlipidemias, allergies sensitivity to or dislike of eggs, consumption of < 1 egg per week, or attempting to lose weight.

Approach: After determining eligibility and obtaining informed consent, the eligible subjects will come to TTU clinic on at about 8 AM after an overnight fast. Blood test for HbA1c and fasting glucose be determined by the finger stick method. Next, each subject will be offered a standardized breakfast (e.g. bagel, 4 tsp cream cheese, 6 oz non-fat yogurt, 1 fruit (apple), 8 oz fruit juice), provided a smartphone and trained to photograph their food intake, using the smartphone provided. They will record all meals for the next 7 days (consumed under free living conditions) and the RFPM technology will be used to quantitate and analyze energy intake and macronutrients.

Outcome measures: Age, baseline BMI, HbA1c, waist circumference, baseline fasting glucose, per meal, daily and 7-d intake of energy, saturated fat, cholesterol, and eggs.

Statistical procedures:

a. Power calculations: With 40 subjects, we will be at least 80% powered to detect effect sizes that are equal to or greater than 0.45, which is a fairly modest effect size, using a nominal value of 0.05 for the level of each test. We will similarly be powered to detect a correlation with magnitude of at least 0.43; see Figure 1. With conservative adjustment for multiple comparisons, these thresholds rise to 0.61 and 0.53, respectively; see Figure 2.

Figure 1:

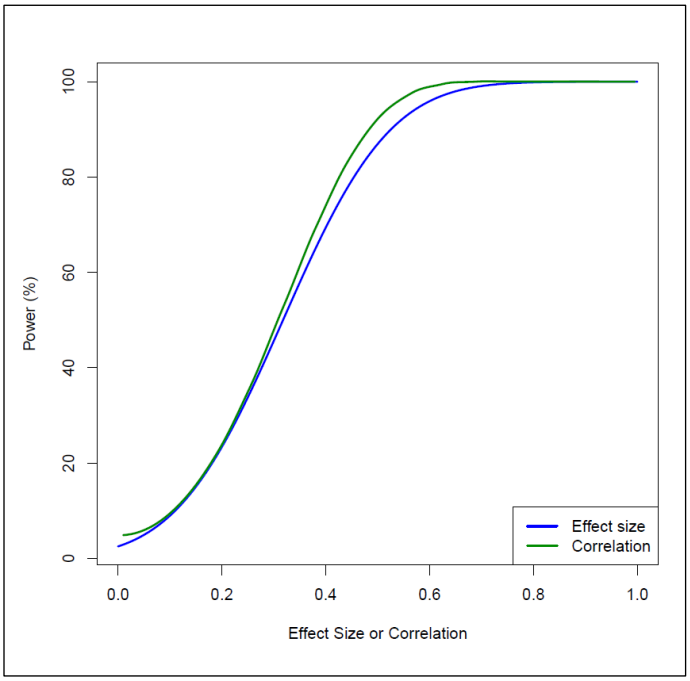
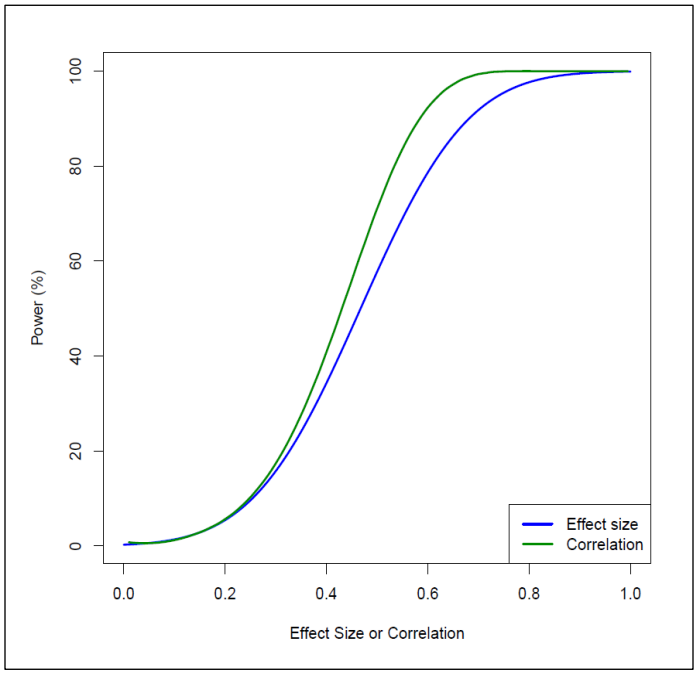


Figure 2:



b. Analyses:

i. Within-subject comparison of meals that include eggs vs similar meals (e.g. breakfast vs breakfasts) without eggs for energy and saturated fat content.

ii. Comparison of daily energy and saturated fat intakes between low and high egg consumers (top quartile vs bottom quartile as determined by FFQ). Because this measure of egg consumption is

based on self-reported FFQ recall, as a sensitivity analysis we will also consider the correlations between these outcomes and observed egg consumption over the period of observation.

iii. Correlation between HbA1C or fasting glucose levels and total energy intake or saturated fat intake (for 7 days), with and without adjustment for age, BMI, energy and saturated fat intake.

Expected results: We expect that meals, particularly breakfasts, that include eggs have higher energy and saturated fat content due to accompanying foods (such as hash browns, fries, sausages, or bacon). This may further contribute to greater overall energy and saturated fat intake for high egg consumers vs those who consume eggs less frequently. Finally, we anticipate that when adjusted for age, BMI, energy and saturated fat intake, fasting blood glucose or HbA1c will not be significantly associated with egg intake.

Implications: we expect that the purported association of eggs to dysregulated glycemic control is independent of eggs, but mainly due to the dietary pattern around egg intake. If true, an informational campaign will be needed to clear eggs from the "guilt by association". However, if egg intake is indeed associated with impaired glycemic control, then appropriate steps should be taken to inform people accordingly.

Investigators**: We have assembled a strong team of researchers that covers various aspects of this study. As a physician, the PI was an obesity practitioner for 8 years in India and treated over 10,000 cases of obesity, has conducted several clinical trials, including studies to investigate the effect of eggs [9, 10, 20, 21]. Dr. Dawson is a well-trained biostatistician with specific expertise in obesity and metabolic conditions. He designed the power analyses and statistical analyses for this project, and he will be responsible for all statistical analyses. Dr. Martin has pioneered and validated the remote food photography method (RFPM) described below, which photographically records food intake and adds a very unique strength to our study. In addition, we have excellent clinical research facilities and equipment, currently used for several funded clinical protocols. With the help these outstanding facilities and well experienced team, we expect to successfully complete the proposed study.**

PROJECTED TIME PERIOD:
Months: 0 – 3: IRB approval, training of researchers at Texas Tech University for RFPM by PBRC team
Months 4 – 8: Recruiting subjects and conduct of the research plan
Months 9 – 12: Data analysis, study report, data presentation and manuscript preparation begins.

E. REFERENCES

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F. Budget:

a) TTU Costs

Dr. John A. Dawson	$ 5,382.00
Recruitment / advertisement	$3,500.00
Subject compensation	$4,000.00
Blood tests	$ 2,000.00
RFPM training	$ 2,000.00
Publication costs	$1,500.00
Conference presentation	$2,000.00
b) PBRC subcontract	
RFPM	$22,771.00
Direct cost	**$ 43,153.00**
Indirect cost (10%)	**$4,315.00**
Total cost	**$47,468.00**

G. Budget Justification

a. TTU costs

Personnel: Dr. Dawson's help will be invaluable for statistical analyses of this study. A very modest salary support is requested. To keep costs down, salary support for principle investigator or research associates is not requested.

Recruitment costs: We need 40 subjects for participating in this 7 day study. Considering the broad age and BMI range, we expect to recruit college students as well as others. This will require substantial recruitment efforts. The recruitment will be helped by newspaper and other media announcements, for which these funds are requested.

Subject compensation: Each subject is required to report to clinic at the beginning and end of the study and photograph each meal before and after consumption for 7 days. Funds are requested to provide to subjects as compensation for their time.

Blood tests: To reduce costs, we will use the finger stick approach. This will not need a phlebotomist, blood draw, storage, shipment of samples or payment to commercial clinical laboratories for blood tests. Instead, we will use commonly available strips for HbA1c and blood glucose determinations.

RFPM training: This is the most critical part of the study. Therefore, we will send a researcher to PBRC to receive training in RFPM from Dr. Corby Martin. Funds are requested for this training.

Publication costs and conference presentations: A modest amount is requested towards travel and registration for conferences such as Obesity Week, American Diabetes Association, or Experimental Biology, to present data and towards journal charges as publication costs.

b. PBRC Subcontract (PI: Corby K. Martin, Ph.D.)

Personnel

Corby K. Martin, PhD, Principal Investigator on the PBRC Subcontract (0.3 calendar months, Y1). Dr. Martin is an Associate Professor, and Director of the Ingestive Behavior Laboratory at the Pennington Biomedical Research Center (PBRC). Dr. Martin developed and validated the Remote Food Photography Method (RFPM) during an R21 grant and subsequently developed the SmartIntake© smartphone "app", which is used to collect RFPM data with little participant burden. During the proposed project, Dr. Martin and his team will train Dr. Dhurandhar's team on the collection of RFPM data utilizing the SmartIntake© app. Further, Dr. Martin's team will analyze the RFPM data (food images) in coordination with the collaborators on the project and these data will be sent to Dr. Dhurandhar.

Karissa Elsass, Research Specialist (2.22 calendar months, Y1). Karissa Elsass has extensive experience with the Remote Food Photography Method (RFPM) and SmartIntake© app. She is a key team member and is responsible for management and analysis of all RFPM data. During the proposed project, Ms. Elsass and will be responsible for preparing and managing the Food Photography Application©, which will be used to manage the remote collection of RFPM data at TTU. Ms. Elsass and will also be responsible for analysis of the RFPM data (food images) to quantify meal level energy and nutrient intake data for the participants enrolled in the study.

H. Raymond Allen, PhD, Director of the Nutrition Research Group (0.24 calendar months, Y1). Dr. Allen is the Director of the Nutrition Research Group and the Manager of the Population Health Intervention Information System at the PBRC. Dr. Allen has been a key team member for more than a decade in developing digital photography methods, including the RFPM and the SmartIntake© app. Further, he developed the Food Photography Application©, the software program used by PBRC to analyze food images, and manages its archive of standard portion images. Dr. Allen has an extensive history of working with Dr. Martin and the research team. Dr. Allen will be responsible for the technical management of the SmartIntake© app and the resulting RFPM data, and he will be responsible for extraction of food intake data and transmission of these data to the TTU team.

Non-Personnel Costs

iPhones:
$1,200 (Yr 1) is requested to purchase 3 iPhones for use by participants during the study. In order to collect the RFPM data, participants must utilize a smartphone to capture images before and after they eat using the SmartIntake© application. If they do not have a personal iPhone or would prefer not to use their personal iPhone, study staff can provide them with a phone to use throughout the duration of their RFPM data collection period.

Voice and Data Service for iPhones:
$1,440 total (Y1) is requested to provide voice and data service for 6 months for the 4 iPhones we are requesting to purchase. In order to use the SmartIntake© application, the phone that the participant is utilizing must have a voice and data plan.

Shipping for iPhones & materials:
$70 total ($35 Y1) is requested to ship phones and RFPM materials to and from TTU.