Document Type: Informed Consent Form

Official Title: Shake It Up: Lipidomics of Lipoproteins and Diet

NCT Number: NCT04120220

IRB Approval Date: 08/23/2021

GRAND FORKS HUMAN NUTRITION RESEARCH CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Project Title: The Shake It Up Study

Principal Investigator: Matthew Picklo

Phone/Email Address: 701-795-8380/matthew.picklo@ usda.gov

Department: USDA Grand Forks Human Nutrition Research Center (GFHNRC)

What should I know about this research?
- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?
We expect that your taking part in this research will last at least 3 weeks.

The initial information meeting will take about ½ hour. A screening visit will be scheduled if you agree to join the study. Screening for the study (including a blood draw) should not take more than 30 minutes.

The treatment period of the study will last at least 15 days depending on the time between test visits. Each test visit consists of an overnight stay followed by an eight (8) hour test day the next morning. There is a washout period of 2 weeks or more between each of the 2 visits.

Why is this research being done?
The purpose of this research is to understand how dietary fat is related to cardiovascular disease (CVD). This study tests the effect of different dietary fats on the level of fat in the blood and the particles that transport fat in the blood. We want to know if these particles change after eating meals made with different fats.

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, you will sign this consent. You will fill out a form which will be used to describe the group characteristics. A W-9 is required before payment can be made. A health history form will help to see if you qualify. You will complete a short physical activity questionnaire. At this information meeting, you can have your height and weight measured to see if you fit the range we need for this study.

Approved: 08/23/2021
Expires: 08/22/2022
University of North Dakota IRB

Date: _____
Subject Initials: _____

Further eligibility will be determined from a separately scheduled fasting (10 hours) blood draw. You will need to refrain from exercise and alcohol for 72 hours before screening. The purpose of the screening blood draw is to determine if your blood sugar and blood lipids are in the range we need for this study.

Inclusion criteria
- Men
- 18-60 years of age
- Normal to overweight (BMI 18.0-29.9 kg/m^2)
- Willing to comply with the demands of the experimental protocol

Exclusion criteria:
- Have fasting blood glucose <60 or >126 mg/dL
- Have fasting blood cholesterol > 300 mg/dL
- Have fasting blood triglyceride >300 mg/dL)
- Have uncontrolled hypertension (BP >140/90 mm Hg)
- Take prescription medications for blood sugar or lipid management or anti-inflammatory steroids (e.g. cortisone)
- Take over the counter use of supplements (fish oil, flax, plant stanol or sterol esters) and unwilling to discontinue use for 6 weeks prior to study initiation
- Have a history of an eating disorder, inability to provide consent, unusual dietary pattern (extreme nutrient or food group restriction; erratic meals due to shift work, etc.)
- Have established cardiovascular, pulmonary, and/or a metabolic disease such as diabetes
- Have cancer
- Use tobacco products or nicotine in any form including snuff, pills, and patches, or e-cigarettes/vaping in the past 6 weeks
- Have alcohol, anabolic steroids, or other substance abuse issues
- Consume more than 3 alcoholic drinks/week
- Are lactose intolerant or have an allergy to dairy foods

During the testing period:
Since you will be eating two meals as part of this study, please let us know if you have any food allergies.

You must refrain from exercise or alcohol for 72 hours prior to admission to the GFHNRC.

There are two testing visits to complete. A description of the test visit is provided below.

You will report to the GFHNRC the evening before testing (about 4 PM) and given dinner. The purpose of this standard dinner is to control blood composition for the following day's testing. No other foods or drinks (except water) will be allowed after the dinner meal.

The following morning, you will be woken early (about 6:30 am) and allowed to use the toilet and get dressed. A line will be placed in your arm for blood draws during the testing period. A (time = 0 hrs) sample of blood will be taken before the meal. The line will be flushed with saline every thirty (30) minutes during the course of the study to prevent clotting.

A fruit-flavored shake will be provided with either dairy fat (cream) or soybean oil as the test oil. You will be asked to drink the shake in 15 minutes. No other foods will be offered until the end of the testing period, but you may ask for water as desired. Blood samples will then be taken at 1, 2, 4, 6, and 8 hours after drinking the shake.

We will ask you to be minimally active in a sitting/reclined position for the 8-hour testing period. You will be allowed to perform activities that require minimal exertion such as but not limited to watching television and videos, reading, playing games.

Following the 8-hour blood draw, the line will be removed. You will be given a snack.

After you complete the first test day, you will have a washout period that lasts at least two weeks We ask that you do not change your dietary or activity habits during this period. The test visit schedule will then be repeated with the second fat. The order that the test fats are given will be random and neither you nor the investigators will know which fat you are consuming at each visit.

During the second test day, you will complete a Diet History Questionnaire to obtain dietary intake over the past month under the instruction of a Registered Dietitian (RD) or designee.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research are:

Blood Draws: There is a small risk of pain and bruising during insertion of the line. If the line clots during the study, a new line may need to be inserted or separate blood draw may need to be performed to complete the test visit. You may feel lightheaded or faint during or right after a blood draw. Trained staff will use sterile techniques when drawing blood. However, there is a slight chance that the site may become infected. A maximum of 144 milliliters (about 10 tablespoons) will be drawn over the entire trial. This value is much less than the pint or 475 milliliters that blood banks may draw every 8 weeks.

Questionnaires: You may feel uncomfortable answering some of the survey questions. Only questions required to determine eligibility and to assess factors related to the research will be asked. If there is a question(s) you wish to not answer, please inform the staff.

Will being in this research benefit me?

Although you may not benefit personally from being in this study, we hope that, in the future, others might benefit from our findings. Results of the research may yield knowledge of how diet affects lipoproteins in the blood. This may provide important information that may guide dietary advice to reduce the risk for CVD.

How many people will participate in this research?
Approximately 16 people will take part in this study at the Grand Forks Human Nutrition Research Center.

Will it cost me money to take part in this research?
You will not have any costs for being in this research study. You will be expected to provide your transportation to and from the GFHNRC. We do not withhold income, social security, unemployment taxes, or any other taxes because you are not an employee of the GFHNRC. You may have to pay income taxes on the money you receive. All tax questions regarding the taxability of the payment should be directed to your personal tax accountant or to your local Internal Revenue Service Office. If you are not a United States citizen, check your documentation to make sure you can receive money from a non-University source without risking your status in the United States.

Will I be paid for taking part in this research?
You will be paid for being in this research study. Reimbursement for completing the study is $350, OR a 9-month individual membership, OR a 6-month family membership to Choice Health & Fitness. If you have had a blood draw as part of screening but are found ineligible, you will be paid $25. If you decide to drop out of the study, you will be paid a prorated amount for the procedures completed. If you complete the entire study, payment will be made following completion.

Who is funding this research?
The United States Department of Agriculture (USDA) is funding this research study. This means that the GFHNRC is receiving payments from the USDA to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or an increase in salary from the USDA for conducting this study.

What happens to information collected for this research?
Your private information may be shared with individuals and organizations that conduct or watch over this research, including:

- The GFHNRC
- The USDA, as specified in the USDA/ARS Privacy Act System of Records
- The University of North Dakota (UND) Research Compliance & Ethics Office
- The Institutional Review Board (IRB) that reviewed this research
- and as required by law or court order.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. Clinical trial information will be submitted to the National Institutes of Health/National Library of Medicine to be included in the clinical trial registry data bank (www.clinicaltrials.gov).

Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

Could being in this research hurt me?
In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.) No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you. If you are injured while taking part in this research project as a result of the negligence of a United States Government employee who is involved in this research project, you may be able to be compensated for your injury in accordance with the requirements of the Federal Tort Claims Act. Compensation from individuals or organizations other than the United States might also be available to you.

What if I agree to be in the research and then change my mind?
If you decide to leave the study early, we ask that you inform the study coordinator or the principal investigator, Matthew Picklo at 701-795-8380; matthew.picklo@usda.gov.
Your decision will not affect your current or future relations with the GFHNRC or UND.

If you begin taking medications during the treatment period, please let study staff or the investigator know. Some medications may interfere with the outcomes of the study. If your medications interfere with the study outcomes, your participation will be ended, and you will be compensated for the portions of the research completed.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 701.777.4279 or UND.irb@UND.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.

Date: _____
Subject Initials: _____

- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.
- You may also visit the UND IRB website for more information about being a research subject: http://und.edu/research/resources/human-subjects/research-participants.html

Request to contact for future studies:
We would like to alert you about studies you may qualify for in the future. Please indicate below if you consent to be contacted.

(Please circle one) YES NO

Initials

Consent:
Your signature documents your consent to take part in this study. You will receive a copy of this form.

Subject's Name: _____

_____ _____
Signature of Subject Date

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

_____ _____
Signature of Person Who Obtained Consent Date