Department of Nutritional Sciences

CONSENT FORM

Postprandial Triglycerides for Sensitive Risk Screening in Normal-weight Obesity and Metabolically Healthy Obesity

IMPACT OF COVID-19 ON THIS STUDY

This study has been approved to proceed in the context of COVID-19.
At the present time, there is increased risk of COVID-19 exposure with all activities located outside of your personal residence.
However, the researchers are committed to strong measures to lessen risk of COVID-19 spread during your participation in this study.

Should you choose to participate in this study, the following steps will be taken to decrease risk of COVID-19 spread:

- All participants will be screened via telephone prior to attending the laboratory.
- Temperature checks will be conducted on all researchers and participants upon entering the laboratory.
- All individuals will apply hand sanitizer and wear a mask upon entering the laboratory. Researchers will also wear gloves and a laboratory coat.
- If you participate, you will be the only participant in the laboratory and there will never be more than 2 investigators in the laboratory with you.
- As much as possible, individuals in the laboratory will be at least 6 feet apart.
- Investigators will wash their hands or apply hand sanitizer before and after every procedure during your assessment.
- Prior to your arrival in the laboratory, all surfaces that you will contact will be disinfected. This will be repeated after each participant leaves the laboratory. We will also disinfect equipment after each specific test/procedure.

Background Information

You are invited to participate in a research study assessing the screening effectiveness of postprandial triglycerides (increase in triglycerides following a meal) for those at-risk for cardiovascular disease (CVD), but appear normal based on many conventional measures. The primary study measurements of interest are body composition, fasting metabolic values, and blood pressure. We will use an Abbreviated Fat Tolerance Test (AFTT) to assess postprandial triglycerides and compare these results to more traditional markers such as fasting triglycerides with the hope that postprandial triglycerides may allow for earlier, more sensitive detection of CVD risk.

The overall goal of this study is to determine whether there is a difference in postprandial triglycerides in groups with varying body mass index (BMI), midsection fat, and other risk factors. We ask that you read this form and ask any questions you may have before agreeing to enroll in the study. Your participation is entirely voluntary.

To be eligible to participate in this study you must fall into *at least one* of the categories below:

- **BMI 18-25 kg/m^2 with low midsection fat**
- **BMI 18-25 kg/m^2 with elevated midsection fat**
- **BMI $\geq$ 30 kg/m^2 with elevated midsection fat**
- **BMI 18-25 kg/m^2 with normal metabolic markers and blood pressure**
- **BMI $\geq$ 30 kg/m^2 with normal metabolic markers and blood pressure**
- **BMI $\geq$ 30 kg/m^2 with elevated metabolic markers and blood pressure**

Regardless of category above, to be eligible you must **not**:

- Have a chronic disease
- Have a pace-maker or electrical implant
- Be pregnant or likely to be pregnant
- Use tobacco products or illicit drugs
- Use dietary supplements or medications that may influence triglycerides (birth control is allowed)

This study is being conducted by: Bryant Keirns, Department of Nutritional Sciences, Christina Sciarrillo, Department of Nutritional Sciences, Kara Poindexter, Department of Nutritional Sciences; Sam Nielson, Department of Nutritional Sciences; under the direction of Sam R. Emerson, PhD, Department of Nutritional Sciences.

Procedures

***Overview of Study*:** If you participate, you will report to the laboratory on two occasions: a screening assessment and the study assessment. The screening assessment will consist of paperwork (informed consent, health history questionnaire), height and weight/body composition measurement, blood pressure, and one blood draw for a metabolic panel to determine study eligibility. If you qualify for the study, we will give you a chance to eat a snack (not provided), and then you will perform a maximal exercise test.

Note: If we are near the end of recruitment, there is a possibility we will screen using non-invasive techniques (i.e., BMI, body composition, blood pressure) and omit the blood draw if you do not qualify based on those measures.

If you qualify for the study, you will be brought back for a second appointment that will consist of the AFTT, vascular function assessment, and paperwork (physical activity questionnaires, 3-day food record, and a food frequency questionnaire). These procedures are described in detail below. On the day of the study visit, you will arrive in the lab having followed a 10-hour fast. First, you will undergo a non-invasive vascular function assessment. Next, you will undergo a meal tolerance test. In brief, a fasting blood draw is made via single venipuncture. Next, you will consume a hypo-allergenic milkshake. You will then be asked to complete some paperwork and are then free to leave the laboratory for several hours. You will return~3.5 hours after finishing the meal for a body composition (DEXA) scan and then for a final a follow-up blood draw and vascular function assessment to determine your post-meal metabolic and vascular responses.

Screening Visit Specific Procedures:

After confirming self-reported BMI, informed consent, and medical history we will perform the following:

Blood pressure: After laying down in a dark area for ~10 minutes, we will measure your blood pressure using an automatic cuff on the upper-arm 2-3 times.

Body composition: Body composition will be assessed using a Seca mBCA 514 scale. The Seca uses a non-invasive technique called bio-electrical impedance analysis (BIA), which works by sending a small, insensible electrical current through your body and measuring the flow resistance of the electrical current based on different tissues. The Seca also has a weight scale integrated into the system, so we will measure weight simultaneously. We will conduct this measurement to determine whether you qualify for the study based on your midsection fat.

Phlebotomy (single needle sticks): A 21-gauge needle will be used to draw blood from a forearm vein once at the screening visit in order to perform a basic panel including glucose, triglycerides, total cholesterol, LDL cholesterol, and HDL-cholesterol. We will take this blood sample to determine whether you qualify for the study based on your fasting metabolic values.

Exercise test (VO2 Max): If you qualify based on the above screening methods, we will give you a chance to eat a snack and then you will complete a maximal aerobic capacity test to determine aerobic capacity (i.e., VO2peak). The cycling protocol will be similar to the protocols used by Dr. Emerson previously. First, we will estimate your physical activity habits based on a short questionnaire (IPAQ short form), and based on the results will assign you to one of two protocols. Before the exercise test, everyone will complete a warmup of 3 minutes at 25 watts. Throughout the test, everyone will be asked to maintain revolutions per minute (rpm) between 60 and 80 rpm. Depending on your physical activity habits, the test will begin at either 30 or 50 watts and increase by 15 or 25 watts per minute. The exercise test will end when you reach volitional fatigue and can no longer maintain a pedal cadence greater than 60 rpm for 5 consecutive revolutions. Expired gases will be measured throughout the exercise testing via a metabolic cart (Vmax Encore 29n; CareFusion; Franklin Lakes, NJ) and heart rate will be assessed using a wireless system.

Study Visit Specific Procedures:

Body composition: If you qualify for the study visit, we will again measure your body composition using a more accurate method called dual-energy X-ray absorptiometry (DEXA). DEXA is one of the gold-standard techniques for assessing body composition and fat distribution. We will also measure your bone density, among other parameters. DEXA works by scanning your body with a very low dose x-ray beam. The DEXA scan takes about 5 minutes.

AFTT: We will measure the post-meal rise in triglycerides using an abbreviated fat tolerance test (AFTT). You will come into the lab fasted. First, we will collect a fasting/baseline blood draw using single needle stick (described below). You will then consume a gluten-free, dairy-free, high-fat test meal (milk shake consisting of coconut milk, chocolate syrup and protein powder; 70% fat; ~9 kcal/kg). After completing the test meal, we will ask you to complete some paperwork, and then be instructed to leave the lab for ~3-3.5 hours, abstaining from additional food and non-water beverage intake or planned exercise. You will then return for a DEXA scan, vascular assessment, and follow-up blood draw 4-hours after meal completion.

Phlebotomy (single needle sticks): A 21-gauge needle will be used to draw blood from a forearm vein twice (baseline and 4 hours post-AFTT) for those who qualify for the study visit. We will draw ~15 mL pre- and post-AFFT. Therefore, we will draw a total of ~30 mL over the course of the visit.

Flow-mediated dilation via Doppler ultrasound imaging: We will measure vascular function using a technique called flow-mediated dilation. This test will be conducted when you come into the lab fasted for your meal tolerance test, and again at follow-up just before the last blood draw (so about 3.5 hours after you finish the meal). An ultrasound probe will be used to image your brachial artery. We will collect baseline video imaging for 4 minutes. We will then use a pediatric blood pressure cuff to occlude blood flow at the wrist for 4 minutes. The pressure of the blood pressure cuff will be approximately 50 mmHg above your systolic blood pressure. We will then release of the blood pressure cuff to induce an increase in blood flow. The degree of vascular dilation is indicative of vascular health. We will continue to image the blood vessel to measure this dilation for 4 minutes after the cuff is released. Therefore, the measurement takes 12-15 minutes.

Physical activity assessment: You will be administered and asked to complete a questionnaire pertaining to your current physical activity habits.

Dietary assessment: You will be administered and asked to complete a 3-day food record, related to recent dietary intake, and a food frequency questionnaire on your dietary habits relating to the amounts and frequency of foods you consume.

Body image questionnaire – you will be given a short survey asking for your thoughts/attitudes regarding body size and shape.

Participation in the study involves the following time commitment:
Screening visit: 45 – 60 minutes
Study visit: ~5 hours (although you will not be in the lab for the vast majority of this time)
Total time commitment for study: ~5 hours, 45 minutes
Total time commitment for study in the laboratory: ~2 hours

Biospecimen Sampling for Research:
We will be collecting blood samples to measure metabolic markers.

The type of specimens that will be stored and where they will be stored: De-identified serum samples will be stored at -80 C in room that is locked after hours.

Risks and Benefits of Study Participation

The only foreseeable risks involved in this study are related to the *DEXA scan*, *phlebotomy* (single needle sticks), and *flow-mediated dilation* (measurement of blood vessel function). These risks are described in the dedicated sections below. In order to assist with the offset of these risks, we are utilizing the most participant-friendly procedures possible to address our research aims: we are conducting the minimal amount of needle sticks, drawing a relatively small volume of blood, and inflating the wrist cuff for flow-mediated dilation to the lowest possible pressure to still produce the necessary response. In case of injury or illness resulting from this study, emergency medical treatment will be available through transportation to the nearby student health center or hospital. However, this outcome is highly unlikely. 911 will be called in the event an adverse health event takes place during the study. No funds have been set aside by Oklahoma State University to compensate you in the event of illness or injury.

DEXA Scan:
If you choose to participate in this study, you will be exposed to radiation from a DEXA scan (a type of X-ray). This radiation exposure is necessary to obtain the research information desired related to body composition. You will not be exposed to this radiation if you choose not to participate in the study. The amount of radiation from a DEXA scan is less than 1% of the amount of radiation to which an X-ray technologist is permitted to be exposed in one year. Additionally, a whole-body DEXA scan is equivalent to approximately 3 hours of background radiation (radiation to which we are naturally exposed to during daily living). The risk from radiation exposure increases over your lifetime as you receive additional exposure to radiation. If you are a female participant of childbearing potential, a urinary pregnancy test will be provided prior to the DEXA test to confirm you are not pregnant. You cannot participate if you are pregnant.

Phlebotomy/Single Needle Sticks:
Risks of phlebotomy include slight pain/discomfort upon needle insertion, and potential redness and bruising at the site of the insertion. A blood draw may lead to lightheadedness or fainting in some individuals. In order to minimize these risks, we will wipe the site of the blood draw with alcohol to disinfect the area, use disposable sterile needles and tubes to collect blood, and apply pressure to the site following the blood draw to minimize bruising. To protect against infection, we will also provide instructions on how to care for the puncture site and watch it for signs of infection. It is important to know that these blood tests performed in the study are strictly for research purposes. The researcher using your blood sample is not a physician and therefore not qualified to make clinical recommendations. Furthermore, no physicians will review the results of these blood tests, as the researchers are not using this test to make a diagnosis.

Flow-mediated Dilation:
The process of occlusion (i.e. restricting blood flow) will cause a numb feeling, which may be perceived as discomfort or pain. The feeling is similar to that of your arm or leg "falling asleep". When the cuff is released, the return of blood flow will create a warm sensation. Overall, the occlusion of blood flow does not present more than minimal discomfort to participants.

The benefits to participation are: Your metabolic, vascular function, and body composition results will be shared with you if desired. Some individuals find this personal health information very interesting. However, we cannot guarantee or promise that you will find this study or its associated information beneficial.

Compensation
You will receive no financial compensation for your participation in this study.

Confidentiality
The information that you give in the study will be handled confidentially. Your information will be assigned a code number. Your name will not be used in any report.

We will collect your information through paper surveys and metabolic assessments. Paper surveys and data sheets will be stored in a locked filing cabinet in a locked laboratory. Data will be stored electronically on a password-protected program on a password-protected laptop that does not leave the locked laboratory, and backed up on an encrypted and password-protected external hard drive. This informed consent form will be kept for 3 years after the study is complete, and then it will be destroyed. Your data collected as part of this research project, will not be used or distributed for future research studies.

It is unlikely, but possible, that others responsible for research oversight may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so.

Voluntary Nature of the Study
Your participation in this research is voluntary. There is no penalty for refusal to participate, and you are free to withdraw your consent and participation in this project at any time. The alternative is to not participate. On the questionnaires, you can skip any questions that make you uncomfortable and can stop at any time.

Contacts and Questions
The Institutional Review Board (IRB) for the protection of human research participants at Oklahoma State University has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at 405-744-2303, sam.emerson@okstate.edu. If you have questions about your rights as a research volunteer or would simply like to speak with someone other than the research team about concerns regarding this study, please contact the IRB at (405) 744-3377 or irb@okstate.edu. All reports or correspondence will be kept confidential.

You will be given a copy of this information to keep for your records.

Statement of Consent
I have read the above information. I have had the opportunity to ask questions and have my questions answered. I consent to participate in the study.

Indicate Yes or No:

I give consent to be contacted for follow-up in this study or future similar studies:
___Yes ___No

Signature: _____ Date: _____