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Official Title: Acute Effects of Fats on Satiety and Energy Needs

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INFORMED CONSENT

TITLE: Acute Effects of Fats on Satiety & Energy Needs (GFHNRC #508)

PROJECT DIRECTOR: Matthew Picklo, PhD **PHONE:** 701-795-8380

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

STATEMENT OF RESEARCH

A person who is to join in research must give his or her informed consent. This consent must be based on a grasp of the nature and risks of the research. This document provides information that is important for this knowledge. Research projects include only subjects who choose to take part. Please take your time in making your decision to join. If you have questions at any time, please ask. You do not have to take part in the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to assess the acute effect of dietary fat on satiety and energy metabolism. How dietary fat sources affect satiety, appetite and energy use is unclear. We will use a controlled setting for the studies. We want to know if the source of dietary fat is related to satiety, satiety hormones, and energy expenditure in a short term (acute) study.

HOW MANY PEOPLE WILL PARTICIPATE?

We need 23 people to complete this project. You are qualified to join the study if you are a male or female between 18-50 years of age with a body mass index (BMI) of 18-34.9 Kg/M^2. Additionally, women must currently use hormonal contraceptives (birth control pills/injections/patch or hormonal IUD). A medical condition that is uncontrolled by medication or physician oversight may rule you out. Certain medications may make you ineligible for the study. You cannot be pregnant or lactating. You cannot use tobacco in any form, including e-cigarettes. You will be excluded if you have a diagnosed eating disorder.

HOW LONG WILL I BE IN THIS STUDY?

The study will last 6-12 weeks depending on the length of time between each test visit. Each treatment will last for 4 days with at least1 week between each of 5 visits.

WHAT WILL HAPPEN DURING THIS STUDY?

Screening/Baseline Visit: Dr. Matthew Picklo or a designee will review the study and answer your questions at the information visit. If you want to join the study, you will fill out a health history questionnaire. Subjects will need to have low reported omega-3 fatty acid intake as assessed on an Omega-3 Checklist. Initial eligibility will be assured by height, weight, finger-stick glucose and medical history. If you qualify and are still interested, you will be scheduled

Date_____
Subject Initials: _____

for a second screening visit. You will be asked to not exercise for 3 days before entrance to the GFHNRC for the second screening visit. You will be asked to fast for 10 hours before this visit. ***Pre-Testing Visit:*** Total energy needs will be estimated to decide the calorie level required for the controlled meals served before testing. In order to do this, resting energy expenditure will be measured using a metabolic cart. You will be asked to rest for 30 minutes and then a plastic hood will be placed over your head. Your breath will be measured for another 30 minutes. We will ask you to remain still during this time. We will ask you to fill out a questionnaire about your physical activity (Stanford Activity Brief Questionnaire). Your resting energy needs will then be multiplied by a factor for physical activity to give your total energy needs.

At this visit we will measure your body composition (fat and lean tissue) with a total body dual-energy X-ray absorptiometry (DXA) scan. For females, a pregnancy test will be done before completing the DXA scan. You will complete a diet history questionnaire on a computer to find out about the foods you have eaten over the last year. A 3 milliliter (less than 1 teaspoon) blood sample will be drawn for genetic testing of fat metabolism.

Intervention: There are five testing visits. Before each visit, you will be asked to eat a controlled diet for 3 days and to not exercise intensely during that time. We will arrange with you a time to pick up your food. You will be admitted to the GFHNRC the evening before testing (about 4 PM) and given a controlled diet for your evening meal. No other foods will be allowed after the dinner meal. Your room will be in a metabolic chamber (a room sized area where we are able to measure your energy use).

In the morning you will be woken early and allowed to use the toilet and get dressed. The test protocol will last about 6 ½ hours. First you will be asked to recline on the chair while we measure your basal energy metabolism which will start about 75 minutes before testing. Following the basal energy metabolism measurement, a line will be placed in your arm for blood draws during the testing period. We will collect all urine after the morning void until the 240 minute timepoint.

We will be measuring your acute responses to intakes of dietary fats and oils. The fat source (oils or cream) (30 g) will be supplied in a smoothie at time 0. At 0 min you will complete the first visual analog scale (VAS) questionnaire testing your hunger, fullness, satiety and desire to eat. You will be trained to mark a place on the rating scale that best describes your current feelings of hunger, fullness, satiety, or desire to eat. Blood will be drawn for satiety hormone measures. Directly after, the test food will be served with 240 ml of water and you will be asked to consume both within 15 min. No other foods will be offered until the end of the testing period but you may ask for water as desired.

Additional VAS and satiety hormone measures will be made at 30, 60, 120, 180 and 240 minutes. From time 0 to 240 min, nonstop assessment of energy and substrate use will be

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performed to determine the response to each treatment. Throughout the trial, you will need to sit quietly to reduce the effect of physical activity on the outcome measures. Also, you will not be able to sleep during the data collection period.

At 300 min you will be given a meal comprised of a single course mixed dish (chicken and noodle casserole) and 360 ml of water. You will be asked to consume as much of this as you want.

Metabolic Chamber Testing - Minutes Relative to test meal									
Parameter	-40	-15	0	30	60	120	180	240	300
Test Food			x						
Ad Libitum Meal									x
VAS			x	x	x	x	x	x	
CCK			x	x	x	x	x	x	
Ghrelin- active			x	x	x	x	x	x	
Insulin			x	x	x	x	x	x	
Plasma Fatty Acids			x	x	x	x	x	x	
REE	x								
EE			x	x	x	x	x	x	
RQ			x	x	x	x	x	x	
Urine			x					x	

After you complete the treatment, you will have at least a 4 day washout period in which there are no limits on your diet or exercise. Three days before the next test visit you will again eat the controlled diet. We will arrange with you for the time to pick up the meals. This will be continued until all five test treatments are finished.

WHAT ARE THE RISKS OF THE STUDY?

Blood Draws: The needle stick may hurt. There is a small risk of bruising. You may feel lightheaded or faint during or right after a blood draw. This is more likely to happen if you have had problems with fainting during blood draws in the past. Let us know. Trained staff will use sterile techniques when drawing blood. However, there is a chance that the site may become infected. A maximum of 498 milliliters (about 33 tablespoons) will be drawn over the 9-13 weeks of the trial. This is similar to the pint or 475 milliliters that blood banks draw every 8 weeks. We will investigate genes related to fat metabolism. No individual information regarding genotypes will be made available to you or to a third party. Genotyping carries no medical or therapeutic value. There is no medical significance associated with the DNA test results. Additional blood samples will be stored with your permission for future studies of nutrition and metabolism.

Metabolic Chamber: The metabolic chamber is a 10-foot by 12-foot bedroom. Some people may find this uncomfortable or emotionally trying (i.e. claustrophobia or boredom). The room has a TV and DVD player, as well as internet access. There are 2 windows that look outside and a window in the door. The door to the room never locks and may be opened at any time. Staff will be available to you at all times while you are in the chamber in case you experience any problems. In addition, you may feel uncomfortable being monitored by closed-circuit video while in the chamber. The camera will be on but it will not be recording any video.

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***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.

Dual Energy X-ray Absorptiometry (DXA): Body composition measures will take about 15 minutes to complete. The DXA measures your body fat, lean mass, and bone mineral content. You will lay face-up on a table, and you cannot be wearing any metal. If your clothing contains metal, you will be asked to change into scrubs that will be provided to you. You must lie still for the 10-minute scan. If the results are found to be inadequate, we may ask you to repeat the scan. The DXA scan is an x-ray and is considered to be a no greater than minimal risk procedure. The radiation dose of the whole-body scan is no more than 1.0 millirem. This dose is equal to roughly 1/620 of normal annual background radiation, 1/4 of the radiation received in a long flight, or 1/10 of the radiation received in a chest x-ray. The effects of small doses of radiation on a developing fetus are not known; therefore, we will not knowingly allow a pregnant woman to have a DXA. Pregnancy tests will be done before the DXA if you are a woman of child-bearing potential.

Resting Metabolic Rate Test: You will need to refrain from exercise for 72 hours before the test. This test will take about 1 hour to complete. You will need to lay flat on your back and stay still during the test. We can provide pillow and blankets to help keep you comfortable during the test period. A plastic dome will be placed over your head. This allows us to monitor air movement and estimate your caloric needs. You will be asked to lie still for a long period of time, which may be uncomfortable. The metabolic machine does produce noise, which may be annoying. The clear plastic hood could make you feel claustrophobic.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study. Results of the research may yield knowledge of satiety and energy metabolism. This may provide important information for dietary advice to maintain a healthy body weight. Once the study is finished, we will provide your results if you want them. Please tell us if you want your results.

WILL IT COST ME ANYTHING TO BE IN THIS 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 relating to 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.

Date_____
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IS THERE ANY COMPENSATION?
Reimbursement for the total study is $530/subject or a 13-month individual membership, or a 10-month family membership to Choice Health & Fitness. Screened but ineligible subjects will be paid $15. If you complete the entire study, payment will be made at the end of the trial. In the event that you drop out of the project, you will be paid for partial participation according to the procedures that were done.

WHO IS FUNDING THE STUDY?
The United States Department of Agriculture is funding this research study.

CONFIDENTIALITY
The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, the study results will be in a summarized manner and you will not be identified. None of the study results will have any names attached. Privacy will be maintained by assigning an identification number which will be used to anonymously code your research data for computer entry. This consent and the check information will be kept in a locked file at the GFHNRC. Dr. Matthew Picklo and the staff assigned to the research study will have access to the data. Confidential information may be made available to the US Department of Agriculture as specified in the USDA/ARS Privacy Act System of Records, to the University of North Dakota, and as required by law or court order. 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).

COMPENSATION FOR INJURY
In the event that this research activity results in an injury, treatment will be available including first aid and emergency treatment. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (health insurance, Medicare, etc.). If you are injured while participating 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.

IS THIS STUDY VOLUNTARY?
You may choose not to participate or you may stop your involvement at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect your current or future dealings with the GFHNRC or the University of North Dakota. If you decide not to do any more of the research tests, we ask that you notify the study coordinator or principal investigator.

Date_____
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SUPPLEMENTAL INFORMATION ABOUT SAMPLES

Science and technology are advancing very rapidly. There may be additional research possible with this study. Part of this specific study is taking blood samples to be stored for future studies of nutrition and metabolism.

You are being asked for your permission to let us keep some of the samples that are leftover and use them for future studies. You will not be contacted about any potential use of these samples. The samples will be kept indefinitely. The samples will be stored separately from this consent and there will be no link to any of your personally identifiable information. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Confidential information may be made available to the US Department of Agriculture as specified in the USDA/ARS Privacy Act System of Records and to the University of North Dakota and as required by law or court order. 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).

Please indicate below if you consent that your samples may be used in future research. You will not be paid an additional amount for this consent. If you choose not to allow the use of your samples for future research, they will be destroyed at the end of the study.

(Please circle one) YES NO

Initials _____

CONTACTS AND QUESTIONS?

The researcher conducting this study is Matthew Picklo, PhD. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact recruitment staff at 701-795-8488 or Dr. Picklo at 701-795-8380.

If you have questions regarding your rights as a research subject, you may contact the University of North Dakota Institutional Review Board at 701-777-4279. You may also call this number about any problems, complaints, or concerns you have about this research study. Please call this number if you cannot reach research staff or you wish to talk with someone who is independent of the research team. General information about being a research subject can be found by clicking "Information for Research Participants" on the web site: http://und.edu/research/resources/human-subjects/research-participants.cfm.

Date_____
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CONSENT

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

_____

Subject Name (Printed)

_____ _____

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

Approval Date: SEP 6 2019
Expiration Date: SEP 5 2020
University of North Dakota IRB

Date_____
Subject Initials: _____