

Document Type: Informed Consent Form

Official Title: Daily Protein Intake Patterns on Energy Metabolism and the Motivation to Snack

NCT Number: NCT02795442

IRB Approval Date: 01/19/2024

CONSENT TO PARTICIPATE IN RESEARCH

TITLE: *Daily protein intake patterns on energy metabolism and the motivation to snack*

PROJECT DIRECTOR: *Shanon Casperson, PhD*

PHONE # *701-795-8497*

DEPARTMENT: *USDA Grand Forks Human Nutrition Research Center (GFHNR)*

STATEMENT OF RESEARCH

A person who is to participate in research must give his or her informed consent. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Only people who want to take part in a research study may do so. Please take your time in making your decision about joining this study. If you have questions at any time, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to determine if when you eat your protein can change how your body uses food for energy. We will also test if eating a high protein breakfast can change your craving for snack foods.

HOW MANY PEOPLE WILL PARTICIPATE?

We need 40 people to complete this research study at the USDA Grand Forks Human Nutrition Research Center.

HOW LONG WILL I BE IN THIS STUDY?

Your total time commitment will depend on your schedule, the availability of the metabolic room, and nursing support at the center. This study involves this information and consenting meeting and a screening visit to determine your eligibility. If you qualify you will then follow a 3-day diet that will require you to come to the center each day to pick up your food and then stay in our metabolic room for about 3 days. This will happen two times. There will be at least 14 days between each study visit. Females will be scheduled based on their menstrual cycle.

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WHAT WILL HAPPEN DURING THIS STUDY?

A. Screening Visit

If you decide to join the study after reading and signing this Informed Consent, we will schedule you to come back for your first screening visit to find out if you are eligible. It will take about an hour to finish all screening tests.

You must arrive for this visit without eating or drinking anything but water for 12 hours.

During this visit, a nurse and/or trained staff will obtain your medical history, height, weight and blood pressure. About a tablespoon of blood will be taken to evaluate your overall health. You will also fill out a food frequency survey so we can understand your usual food intake.

If your screening results are abnormal, you may not be permitted to take part in this study. If the results are normal you will be scheduled for your pre-study and study visits.

B. Pre-Study Visit

The pre-study visit will take about one hour. All women of child-bearing age will do a urine pregnancy test.

We will calculate your total calorie needs by having you lie in a quiet room and put a clear domed hood over your head to collect your breath. You will be asked to breathe normally while you lay awake in bed for about 30 minutes. You will also fill out an activity questionnaire to find out how active you are. These results will be used to calculate your calorie needs.

A special x-ray scan will be done to evaluate how much muscle and fat you have. This test will take about 30 minutes and does not involve any injections or blood draws. Results of this scan will be made available to you upon request.

You will then do a taste test to pick your most liked snack foods. You will taste a brownie, a blondie, a Hershey Kiss® and a Nutter Butter® Cookie Bite and rate them on a scale of 1 (don't like) to 10 (like very much). You will then taste raw cucumber, a sugar snap pea, a baby carrot, and a red pepper slice and rate them on a scale of 1 (don't like) to 10 (like very much). Your favorite from each group will be used during the snack game at the end of each study visit.

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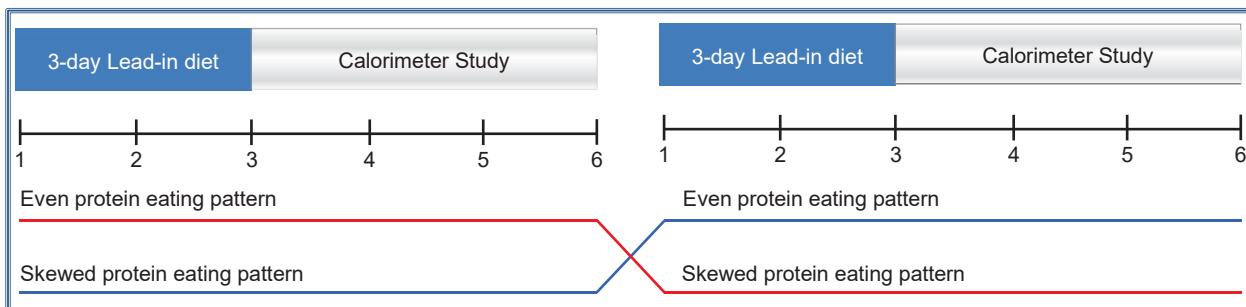
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C. Experimental Overview

Each study visit will last for 6 days and will be separated by at least 14 days. This will happen 2 different times. We will give you all your food and you **will not** be able to eat or drink anything else except for water. There will be no limit on water; you may drink as much water as you want at any time. If you usually drink caffeine, you will need to wean yourself off because no caffeine will be allowed during your studies. You will not be able to exercise or participate in sports for the 6 days you are eating the study foods. You will wear an activity monitor to record your activity during your study visits.

For the 1st 3 days you will need to pick up your food daily (M-F). Instructions will be provided about proper handling of your food and when to eat each meal. The afternoon/evening of day 3 you will enter the metabolic room and stay until mid-morning of day 6. You may watch TV, read, play on your computer, or bring your game system from home. While you are in the metabolic room you will be asked to collect all your urine and answer questions about how hungry you are and how much you would like to eat. On day 6 we will take blood 3 times, you will answer a series of true/false questions about how you are feeling, and you will play a game to earn the snack foods you picked during your pre-testing visit. Everything we will ask you to do is explained below.

This figure will give you an idea of how the study will go. We will not know which diet pattern you will start with. The diet for each study will be the same except for how much protein you eat at each meal.



For the even protein eating pattern you will have the same amount of protein at each meal; about 3 to 4 ounces of meat. For the skewed protein eating pattern you will have a small amount of protein for breakfast, a medium amount for lunch, and a large amount for supper. This pattern mimics how we normally eat our protein.

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D. Experimental Tests

The following describes all testing procedures for each stay:

- 1) *Metabolic Room:* The metabolic room will provide us with an estimate about how your body is using food for energy. You will be able to choose how you spend your time (watching TV, reading, etc.). You will not be allowed to sleep during the day. You will be monitored by a closed-circuit video system at all times. The temperature is kept at about 72°, extra blankets can be provided if needed. You will stay in the metabolic room for about 3 days.
- 2) *Resting Energy Expenditure:* As soon as we wake you up each morning, we will ask you to void your bladder and then return to bed. You will then be asked to lie quietly in a semi-reclined position without falling asleep until we tell you that you may move. This will take about 30 to 45 minutes each morning.
- 3) *Urine Samples:* You will be asked to collect your urine while you are in the metabolic room. You will be asked to void your bladder when you wake up, before lunch and supper, and before going to bed. In addition to these times, you will need to collect all other urine you produce during the day.
- 4) *Satiety Measurements:* You will be asked to rate your hunger, fullness, and desire to eat different types of foods before each meal, and at 30, 60, 90, 120, 180, and 240 minutes.
- 5) *Blood Draws:* On day 6 we will take about 2½ tablespoons of blood 3 different times. The 1st time will be before you eat breakfast, the 2nd time will be right before you start the snack game, and the 3rd time will be when you finish the game and are eating your snacks.
- 6) *Questionnaires:* You will be asked questions about how you are feeling at that moment. You will answer with a simple true or false. You will fill out the questionnaire before the snack game and after you finish eating the snacks.
- 7) *Snack Game:* This is a computer task that will be done in the morning on day 6. It is like playing a slot machine game. There are 2 computers. At one computer you will play to get a small serving of your favorite sweet snack food. At the other computer you will play to get a small serving of your favorite veggie snack food. You will press the mouse button until the color and shape of the objects match. You win points each time all the objects match. For every 5 points you win you will get a serving of the snack food you are playing for. You can go back and forth between the 2 computers as often as you like. You can play as fast or slow as you like. When you finish playing you will be able to eat the snacks you earned.

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E. Experimental Tests Not Related To This Research

Some of your urine and blood taken during this study will be stored indefinitely in the scientist's laboratory and may be used in future research. These samples are left over after the research study tests are done and do not involve extra samples being taken. These leftover samples will be labeled only with the code number that will be assigned to you for this study. There will be no human genetic tests performed on these leftover samples.

Please indicate whether you will allow your samples to be used in future research by initialing one of the following statements:

I agree to allow my samples to be preserved for future research.

I do not agree to allow my samples to be preserved for future use.

Your decision will not affect any benefits to which you are otherwise entitled or your current or future relations with the Grand Forks Human Nutrition Research Center or the University of North Dakota. If in the future you decide that you do not want your samples used for research, please notify Dr. Casperson at 701-795-8497 and your samples will be destroyed.

WHAT ARE THE RISKS OF THE STUDY?

The risk involved with doing the tests that were just explained are thought to be limited, yet, you need to know what those risk might be. Most of them are listed below and may vary from person to person. There may be other side effects that cannot be predicted.

1) *Risks from determining your body composition*

The test to determine how much muscle and fat you have involves minor x-ray exposure. The effective dose exposure is equal to spending about 3 uninterrupted hours outside. Normal daily background exposure is 0.5 mrem. The risks associated with this test are very small.

2) *Risks from taking your blood*

The risks of taking blood include possible pain, bruising, or infection. The use of sterile methods will minimize these risks but will not remove them completely. We will take about 8 tablespoons of blood during the entire study. Some individuals experience lightheadedness and/or nausea and vomiting during or right after their blood is taken. Some people have fainted. There are no long-term problems related to these responses. In our experience, this occurs in about 3.3% of people.

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3) *Risks from filling out questionnaires*

Some of the forms we are asking you to fill out may cause you to feel stress, anxious, or upset. You may feel uncomfortable answering some of the questions. We will only ask questions that are important to the study. If there is a question(s) you do not want to answer, please inform the staff to see if you can still take part in the study.

4) *Risks from the test to estimate your caloric needs*

We will be placing a clear plastic dome over your head and you may experience claustrophobia. Claustrophobia is a fear of enclosed spaces. Most people know if they experience this type of fear. The dome is completely see-through to help avoid any fears. Should you not be able to do this test you may still be able to take part in the study.

5) *Risks from staying in the metabolic room*

The metabolic room is 10 feet wide and 12 feet deep and some people may find this uncomfortable or emotionally difficult (e.g. claustrophobia and/or boredom). You will be shown the room prior to your participation so that you can be familiar with it. There are 2 windows and the glass door does not lock. If you find that you feel overwhelmed you can open the door, but this will stop your study. Staff will be here for you at all times in case you experience any difficulties. In addition, you may feel uncomfortable being monitored by closed-circuit video. No video recording will take place. There are curtains for privacy.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit personally from being in this study. However, the knowledge we will gain from your participation will help us better understand how our body uses the energy we get from eating different combinations of foods and how those combinations contribute to the wanting of different types of snack foods.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY

This study involves the investigation of complex physiological processes. There is no alternative procedure that could be used to gain the knowledge that we will learn during this study. The only alternative is to not take part in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

There will be no charge to you for any tests done during the study. You will be expected to provide your transportation to and from the center. In addition, we do not withhold taxes from any monies you will receive. Any questions you have related to taxes will need to be directed to your personal accountant or the Internal Revenue Service.

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WILL I BE PAID FOR PARTICIPATING?

You will be compensated for being in this research study. A total of \$1,340.00 will be paid upon completion of all study visits. You also have the option to receive a 32-month individual membership or a 23-month family membership to Choice Health and Fitness. 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 receive payment for a pro-rated amount for the portions of the study completed. Membership to Choice Health and Fitness will not be offered to those who do not complete the study. If you are not a United States citizen, you will need to check your documentation to make sure that you can receive monetary compensation from us without risking your visa status.

- a. Meal pick-up - \$5.00/day
- b. Screening visit - \$35.00 (if disqualified due to results of the screening)
- c. Overnight visits - \$150.00

COMPENSATION FOR STUDY RELATED INJURY

In the event that any research test 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.

WHO IS FUNDING THE STUDY?

The USDA Grand Forks Human Nutrition Research Center is funding this research study. No one on the research team will receive a direct payment or an increase in salary for conducting this study.

CONFIDENTIALITY

Study records that identify you will be kept confidential as required by law. Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the US Department of Agriculture, as specified in the USDA/ARS Privacy Act System of Records, the UND Research Development and Compliance office, and the University of North Dakota Institutional Review Board.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of assigning you a unique identification (ID) number that will not

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contain any personal identifiers. This ID number will be used on all data collection instruments, including questionnaires and computer records, so that no data can be connected to you. A master list linking your name to your ID number will be kept in a separate locked file or in a computer file with password protected access that is restricted to study personnel.

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).

USE AND DISCLOSURE OF YOUR RESEARCH STUDY INFORMATION

All tests will be done only because you are in this study. The results of this study may be published in scientific journals. Any reports or articles about this study will only describe the study results in a summarized manner so that you cannot be identified. You may see or receive a copy of some, but not all, research information that is collected about you. If you would like a copy of your study results, please contact the scientist listed below.

THIS STUDY IS VOLUNTARY

Your involvement in this study is completely voluntary. You may choose not to join 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 relations with the Grand Forks Human Nutrition Research Center or the University of North Dakota. We will let you know about any new info that might cause you to change your mind about being in this study. We ask that you tell us if at any time you no longer wish to be in the study.

REASONS FOR THE SCIENTIST TO STOP YOUR PARTICIPATION

The scientist reserves the right to stop your involvement in the study if they feel you are not complying with the study protocol or if an event occurs that affects your safety or well-being, or the safety and well-being of other study participants.

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CONTACTS AND QUESTIONS

The scientist conducting this study is Shanon Casperson, PhD. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Dr. Casperson at shanon.casperson@ars.usda.gov or by phone at 701-795-8497.

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 call this number about any problems, complaints, or concerns you have about this research study.
- You may 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>

Informed consent is required of all persons who participate in research studies. Your signature indicates that the study you have volunteered for has been explained to you, that your questions have been answered, and that you agree to take part in this study. By signing this consent form you are authorizing the use and disclosure of your health information for the purpose of completing the research study. You will receive a copy of this form.

Subject 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

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