

Document Type: Informed Consent Form

Official Title: Impact of Eating Beans on Metabolism

NCT Number: NCT06123208

IRB Approval Date: 09/27/2024

GRAND FORKS HUMAN NUTRITION RESEARCH CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Project Title: **Impact of eating beans on metabolism**
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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 could last up to 3 months.

Why is this research being done?

The purpose of this research is to test how eating a meal containing beans impacts how your body uses food for energy.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, we will test your blood sugar level. This will entail a fingerstick to get a drop of blood. If your sugar levels are normal, we will do a special x-ray scan to find out how much muscle and fat you have. This test will take about 30 minutes.

After this we will schedule you to come to the Center for 3 study visits. Each study visit will last a full day. Before each study visit you will be given a control diet to eat for 3 days. For these 3 days you can only eat the food we give you. You can drink as much water as you want, but only water. There will be at least 7 days between each study visit. Females will be scheduled based on their menstrual cycle.

For each study visit you will come to the Center at 4pm and you will stay in the metabolic room until around 4pm the next day. The metabolic room tells us how your body is using the food you eat for energy. While you are in the metabolic room you may watch TV, read, or work on your computer. You will also collect all your urine while you are in the metabolic room.

We will wake you at 6:30am the next morning. You will collect your urine and go back to bed. You will have to lie quietly in a semi-reclined position without falling asleep until we tell you

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that you may move. This will take about 30 minutes. After this you will rate your feelings of hunger, fullness, and desire to eat.

At 7:30am you will eat the test meal. The test meals are made up of rice, tomatoes, and spices. For each study visit one of the following ingredients will be added to the meal: 1) whole cooked pinto beans, 2) a flour made from the pinto beans, or 3) shrimp. After eating the test meal, you will rate your feelings of hunger, fullness, and desire to eat for the next 5 hours. You will be required to sit quietly during this time, moving as little as possible. You can drink as much water as you want. We will record how much water you drink and when at this study visit. We will give you the same amount of water at the same times to drink at your other study visits.

At 1:00pm you will eat your lunch. For this meal you can eat as much as you want. You do not have to eat everything we give you. After eating the test meal, you will rate your feelings of hunger, fullness, and desire to eat for the next 3 hours.

Could being in this research hurt me?

The most important risk or discomfort that you may expect from taking part in this research include being confined to the metabolic room and collecting your urine. Staff will be there for you at all times in case you experience any difficulties. There are curtains for privacy. Also, during the special x-ray to find out how much muscle and fat you have, you will be exposed to a small amount of radiation. Your total radiation exposure will be very low, like the amount of radiation exposure you would experience from being outside for about $\frac{1}{2}$ a day. A quality assurance check will be completed on the DXA each day prior to its use; the software will not allow the use of the DXA if the quality assurance check fails. Pregnancy tests will be done before the DXA if you are a woman of child-bearing potential.

Will I be compensated for study related injury?

If 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. If you are injured while taking part in this research project because 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.

Will being in this research benefit me?

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It is not expected that you will personally benefit from this research. 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.

How many people will participate in this research?

About 28 people will take part in this study.

Will it cost me money to take part in this research?

You will not have any costs for being in this research study. We do not withhold income, social security, unemployment taxes, or any other taxes. 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.

Will I be paid for taking part in this research?

You will be paid for being in this research study. After you finish the study, you will be given a choice of getting a check for \$580 or getting a membership to Choice Health and Fitness. For the Choice Health and Fitness Membership you have the choice of either a 10-month individual membership or a 7-month family membership. If you are not able to complete all study requirements, you will receive a partial payment of \$100 for each study visit completed.

Who is funding this research?

The United States Department of Agriculture (USDA) is funding this research study. This means that the Grand Forks Human Nutrition Research Center 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 USDA, as specified in the USDA/ARS Privacy Act System of Records
- Study personnel who work at the Grand Forks Human Nutrition Research Center
- The Institutional Review Board (IRB) that reviewed this research

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

What if I agree to be in the research and then change my mind?

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If you decide to leave the study early, we ask that you contact us to let us know. You can contact us by email or by calling the number listed at the top of this form or one of the study staff members.

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.
- 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 contact you about studies you may qualify for in the future. Please indicate below if you consent to be contacted. This information will be kept in a separate file from this signed study consent form.

(Please circle one) YES NO

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

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