

Document Type: Informed Consent Form

Official Title: Beverages for Thought: Exploring the Relationship Between Blood Glucose and Cognition

NCT Number: NCT005888779

IRB Approval Date: 04/02/2025

GRAND FORKS HUMAN NUTRITION RESEARCH CENTER

CONSENT TO PARTICIPATE IN RESEARCH

Project Title: Beverages for Thought

Principal Investigator: Julie Hess, PhD

Co-Investigators: Shanon Casperson, PhD; Daniel Palmer, MS

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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 participate is up to you.
- If you do not take part, it will not be held against you.
- You can take part now and later drop out if you wish, and it will not be held against you.
- If you do not understand any part of the research or this document, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

You will be asked to complete one study visit for one hour. The study visit will take approximately 60 minutes.

Why is this research being done?

The objective of this study is to conduct novel research on the relationship between blood sugar and cognition.

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 be asked to drink a beverage and do some tasks on paper. After these tasks, you will fill out some questionnaires about your health and your height and weight will be measured.

Could being in this research hurt me?

You will be asked to drink a beverage, which could cause aspiration.

Will being in this research benefit me?

It is not expected that you will personally benefit from this research. There may be possible benefits to others in the future.

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How many people will participate in this research?

Approximately 160 people will take part in this study at the Grand Forks Human Nutrition Research Center or Choice Health & Fitness.

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 or Choice Health & Fitness. 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 regarding 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. Reimbursement for completing the study is \$25. To get this payment, you must complete all the tasks mentioned in this form.

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 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 will be de-identified and might be used for future research or distributed to another investigator for future research without your consent.

Compensation for Injury

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.) 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.

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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 contact us to let us know. You can contact us by email or by calling any of the numbers listed at the top of this form.

You may choose not to join or you may stop taking part at any time without penalty or loss of benefits to which you are otherwise allowed. Your decision will not affect your current or future relations with the GFHNRC or the University of North Dakota (UND).

Who can answer my questions about this research?

The researcher leading this study is Julie Hess, PhD. You may ask any questions that you have now. If you have questions, concerns, or think this research has hurt you or made you sick, please contact Dr. Hess at 701-746-8146.

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 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

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