Baylor University
Department of Health, Human Performance, and Recreation

Consent Form for Research

PROTOCOL TITLE: To Chew or Not to Chew?: Assessing the Differences Between Chewing and Swallowing Arugula Extract Capsules on Plasma Nitrate Levels, Blood Pressure, and Heart Rate

PRINCIPAL INVESTIGATOR: **Tomas Chapman-Lopez, MS**

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- If you partake in this study, you will be required to consume arugula extract in a capsulated form.
- In order to participate, you must meet the following inclusion criteria:
  - Males between the ages of 18 and 50
  - Non-smoker
  - No previously diagnosed or known chronic or cardiometabolic diseases
  - Considered apparently healthy according to guidelines established by the American College of Sports Medicine
  - Not currently taking any prescription medications that may affect blood pressure, heart rate, or mental state
  - Not currently taking any prescription stimulants or anti-depressants
- Risks or discomforts from this research include minimal skin discomfort from blood draw and inflation of blood pressure cuff. Also, there is an unlikely, but possible flatulence, abdominal cramping, and discomfort from consuming arugula extract due to the fiber content.
- You will undergo a single body composition assessment using dual x-ray absorptiometry (DXA).
- The possible benefits of this study include learning more about your health and how arugula extract can influence general health. You will receive a comprehensive health profile (body composition assessment, health risk information based on your personal information).

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- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form. Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

Why is this study being done?

The purpose of the study is to determine the efficacy of chewing an arugula extract capsule compared to swallowing in healthy individuals. We will examine nitrate, nitrite, and downstream biomarkers of nitric oxide breakdown when swallowing or chewing arugula extract capsules. A biomarker is a measurable substance in your body whose presence may indicate health or disease processes.

What will happen if I take part in this research study?

If you agree to take part in this study, you will be asked to come to the Baylor Laboratories for Exercise Science and Technology (BLEST) in Marrs-McLean Gym (MMG) on the Baylor University campus for the following:

Visit 1 (about 1 hour)

- Report to BLEST after a 4-hour fast that is limited to water ingestion only. You will be asked to wear standard clothing attire that is comfortable.
- Complete a health history review with a study investigator. This process will be used to identify any characteristic or condition that may preclude participation in the study.
- Undergo body stature and composition assessments. We will measure your height by stadiometer and weight by digital scale. We will measure your waist girth using a cloth tape. You will undergo a body composition assessment using dual x-ray absorptiometry (DXA).
- Provide a baseline blood sample to quantify your cardiometabolic health.
- You will be provided instructions on how to record your diet and physical activity.

For two (2) days before each subsequent Visit and the day of the Visit, you will be asked to maintain complete records of your diet and physical activity. You must follow all diet and physical record-keeping instructions (explained and reviewed during Visit 1) and deliver these daily records to the lab by e-mail attachment, fax, or in-person in the morning following each day. You should follow the same daily diet and physical activities before and during each experimental condition so that differences in diet, nutrient intake, and physical activity do not affect our measurements.

- Visit 2 - 3 (about 1.5 hours)

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- Report to BLEST after a 6- to 8-hour fast that is limited to water ingestion only. You will be asked to wear standard clothing attire.
- Provide blood samples. a venous catheter inserted into the most prominent vein site in the antecubital space of the lower arm. A blood sample, equal to about 16 mL, will be taken after insertion of venous catheter and then sampled every hour for a total of 3 hours (e.g., baseline, 1-hour, 2-hours, 3-hours post-ingestion) using 10mL red top serum collection tubes and 6mL plasma EDTA tubes, through a standardized vacutainer apparatus. One (1) 10mL red top tube and one (1) 6mL plasma tube will be taken at each sampling time point. Each condition (visits 2-4) will have a total blood draw volume of 64mL, while the initial visit will be a total blood draw volume of 16mL.

Visit 1	**Visit 2**	**Visit 3**	**Visit 4**
Conditions Will be randomized	A	B	C
Assessment Informed Consent Protocols	Swallow Arugula Extract Capsule 1000mg	Chew Arugula Extract Capsule 1000mg	Nothing
(1) Blood Draw	(4) Blood Draws (e.g., baseline, 1-HR, 2-HR, 3-HR post-consumption)	(4) Blood Draws (e.g., baseline, 1-HR, 2-HR, 3-HR post-consumption)	(4) Blood Draws (e.g., baseline, 1-HR, 2-HR, 3-HR post-consumption)
Blood Pressure DEXA	(4) Blood Pressure Heart Rate Monitor	(4) Blood Pressure Heart Rate Monitor	(4) Blood Pressure Heart Rate Monitor
A minimum of 72-hours is required between all conditions that will serve as a wash out period. The expected amount of time to complete the study is 3 weeks.			

Table 1. Study Protocol

How long will I be in this study and how many people will be in the study?

Participation in this study will last a total of 14 days over 2 weeks. You will partake in a screening session, and two arugula extract sessions, one pre- and one post-control assessment

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without any arugula extract. Each visit will be composed of four (4) blood sample collections using a venous catheter. Twelve (12) subjects will take part in this research study.

What are the risks of taking part in this research study?

There are some risks you might experience from being in this study. Risk includes:

- The primary risk associated with dual-energy x-ray absorptiometry (DXA) is with radiation exposure. The radiation dose for one DXA scan to measure body composition is 1.5 millirem. This is similar to the amount of natural background radiation you would receive in one month while living in Waco, TX, or less than what you would be exposed to during an airplane flight from New York City to Los Angeles (2 to 5 millirem). The maximal permissible x-ray dose for non-occupational exposure is 500 millirem per year.
- Blood sampling may impose minor bruising, swelling, and itching of the affected area. As with any similar procedure that disrupts the skin barrier, there is an increased risk of infection.
- Ultrasound assessment may be uncomfortable due to the blood pressure cuff being inflated.
- Side effects of arugula could include flatulence and stomach cramping and discomfort. Arugula contains Vitamin K which can interfere with medications known as blood thinners. Arugula extract contains oxalates and can contribute to the formation of oxalate-based kidney stones.

Are there any benefits from being in this research study?

The possible benefits of this study include learning more about your health and how arugula extract can influence general health. You will receive a comprehensive health profile (body composition assessment, copy of blood work, and health risk information based on your personal information).

What if you learn something about my health that I did not know?

Although the assessments you will have in this study are being undertaken for research purposes only, it is possible that researchers may notice something that could be important to your health. If so, we will contact you to explain what was noticed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

Compensation

Individuals who choose to participate in this research study will not be compensated for participation in this study.

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How Will You Protect my Information?

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The researcher plans to protect your confidentiality.

We will keep the records of this study confidential by keeping paper copies of your data in a locked filing cabinet in the researcher's office. Your data will also be scanned and stored in electronic format on a jump drive stored in the researcher's office. Your name will be assigned a code and the key list to this code will be stored separately from your study data. We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records.

The following people or groups may review your study records for purposes such as quality control or safety:

- Representatives of Baylor University and the BU Institutional Review Board
- Federal and state agencies that oversee or review research (such as the HHS Office of Human Research Protection or the Food and Drug Administration)

The results of this study may also be used for teaching, publications, or presentations at professional meetings. If your individual results are discussed, your identity will be protected by using a code number or pseudonym rather than your name or other identifying information.

Will information and/or biospecimens you collect about me be used for future research studies?

Information and/or biospecimens collected from you as part of this research may be used or distributed for future research studies, even if the identifiers are removed.

What happens if I am hurt by participating in this research study?

If you become ill or injured as a result of your participation in the study, you should seek medical treatment from your doctor or treatment center of choice. You should promptly tell the researcher about any illness or injury.

There are no plans for Baylor University to pay you or give you other compensation for your injury or illness. You do not give up any of your legal rights to seek compensation by signing this form.

Is it possible that I will be asked to leave the study?

The researcher may take you out of this study without your permission. This may happen because:



- The researcher thinks it is in your best interest
- You can't make the required study visits
- Other administrative reasons

Your Participation in this Study is Voluntary

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will be kept confidential. You cannot withdraw information collected prior to your withdrawal.

If you are a Baylor student or faculty/staff member, you may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your grades or job status at Baylor University. You will not be offered or receive any special consideration if you take part in this research study.

Contact Information for the Study Team and Questions about the Research

If you have any questions about this research, you may contact:

Jeffrey S. Forsse, Ph.D.,
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Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

Baylor University Institutional Review Board
Office of the Vice Provost for Research

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Project: 2015974
Date: 02/17/2023

Phone: 254-710-3708
Email: irb@baylor.edu

Your Consent

SIGNATURE OF SUBJECT:

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____ _____

Signature of Subject Date

Signature of Person Obtaining Consent:

I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.

_____ _____

Signature of Person Obtaining Consent Date

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