Document Type: Informed Consent Form

Official Title: Sensitivity of Skin Carotenoid Status to Detect Changes in Intake of Varying Levels of Vegetables

NCT Number: NCT03202043

IRB Approval Date: 04/05/2019

INFORMED CONSENT

TITLE: Juice Study

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DEPARTMENT: USDA Grand Forks Human Nutrition Research Center

STATEMENT OF RESEARCH

A person who is to join in the 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 details that are important for this knowledge. Research projects include only people who choose to take part. Please take your time in making your decision as to whether to join. If you have questions at any time, please ask. You do not have to take part in this study.

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to join an approximately 8-week research study. It is designed to see if drinking a tomato-based vegetable juice will increase your skin carotenoids. Carotenoids are brightly colored pigments found in fruits and vegetables and are part of your skin's natural coloring. We will study genes and metabolites (small molecules) related to carotenoids. You may be put in a group where we ask you to drink juice (intervention) or a group where we ask you to drink water (control). You will not be able to choose which group.

HOW MANY PEOPLE WILL PARTICIPATE?

About 80 people will take part in this study at the USDA Grand Forks Human Nutrition Research Center (GFHNRC).

WHO CAN JOIN THE STUDY?

You may be able to join if you are between the ages of 18-65 years with a body mass index (BMI) between 18.5-29.9 kg/m^2. During the study, you must avoid tanning or donating blood or plasma; continue with your usual diet, exercise, and vitamin routine; not drink more than 1 alcoholic drink/day if you are a woman or 2 for a man; and be willing to drink vegetable juice every day and come to all study visits.

Date: _____
Subject Initials: _____

You cannot join this study if you:

- Are younger than 18 or over 65 years old
- Have a BMI less than 18.5 kg/m^2 or more than 29.9 kg/m^2
- Weigh less than 110 lbs
- Are currently dieting to lose weight
- Are allergic to tomatoes or vegetables
- Are pregnant, lactating, or planning to become pregnant
- Currently use tobacco products or vape
- Eat more than 2 c vegetables/day
- Have high blood sugar (≥200 mg/dl)
- Have high blood pressure (≥130/80)
- Have a medical condition such as diabetes or high blood pressure
- Are taking medication that lowers your cholesterol or triglycerides

HOW LONG WILL I BE IN THIS STUDY?
The study is about 8-10 weeks long.

WHAT WILL HAPPEN DURING THIS STUDY?

Information Visit: Dr. Lisa Jahns or her designee will tell you about the study at this visit and answer any questions. If interested in joining the study, you will be asked to read and sign this informed consent form, fill out some questionnaires, and schedule a screening visit.

Screening Visit: Initial eligibility will be assured by height, weight, finger-stick glucose reading and blood pressure. We will ask you to taste the juice. If you qualify and are interested in joining the study, you will be scheduled for a morning test visit. You will be asked to fast for for at least two hours before the visit.

Dietary Treatment: If you qualify for the study, you will be placed into one of two treatment groups (intervention or control). You cannot choose which group you will be in. Each treatment will last around 8 weeks.

- Intervention group will consist of drinking a bottle of tomato juice each day (either 5.5, 10, or 13 fl oz).

- Control group will consist of drinking one bottle of water each day.

Date: _____
Subject Initials: _____

Visit 1 (week 1): You will come to the GFHNRC in the morning after fasting for at least 10 hours. Your blood will be drawn and your weight taken. We will give you a fingerstick, take your blood pressure, and ask you to provide a saliva sample. We will measure your body composition using dual energy X-ray absorptiometry (DEXA). You will lay face up on a table while wearing light clothing or scrubs. You will remain still for 10 minutes. We will give you 3 skin scans on the palm of your hand and 3 on your finger. You will complete a diet questionnaire on the computer.

Visits 2 (week 4) and 3 (week 8): You will come to the GFHNRC in the morning after fasting for at least 10 hours. Your blood will be drawn and your weight taken. We will give you a fingerstick and take your blood pressure. We will give you 3 skin scans on the palm of your hand and 3 on your finger. You will complete a diet questionnaire on the computer.

Once-weekly visits: You will come to the GFHNRC once each week for the 8 weeks. You will pick up a cooler of juice. At each visit we will do skin scans. You will complete a diet questionnaire on the computer.

WHAT ARE THE RISKS OF THE STUDY?

Blood Draws: The risks of blood draws are small and as a rule are limited to local bruising or swelling. Problems may include slight pain and dizziness. You may feel faint or may faint during or right after a blood draw. This causes no long-term harm. Relief is achieved by putting your head down between your knees or by lying down. If you have had problems with fainting during blood draws in the past, you may be more likely to have them again. A bruise may result at the draw site. Later problems might include a blood clot or infection. However, these worries are very rare. At each of the 3 blood draws, 21 milliliters of blood will be drawn, with an additional 3 ml on the first visit. A total of 66 milliliters of blood will be drawn over the 8 weeks. This is well within safe levels. For example, the blood bank donation limit is 475 milliliters (1 pint) every 8 weeks.

No individual information about genotypes will be made available to you or to a third party. Genotyping carries no medical or therapeutic value. There is no medical significance linked with the genetic test results or metobolite analysis.

DEXA: The DEXA scan is an x-ray and is believed to be a no greater than slight risk procedure. The radiation dose of one 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. A quality assurance check will be done 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. Each subject will

Date: _____
Subject Initials: _____

receive 1 DXA scan, and an extra scan may be needed. 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. Privacy will be offered and every effort will be made to have you feel comfortable.

Skin scans: The skin carotenoid scans are a minimal risk method. They will be used to measure carotenoids in your skin. Scan time will be about 30 seconds per scan, and 6 scans (three on each of 2 machines) will be done at each visit. In this study, the probe will be placed in a manner in which only the hand will be available for scanning.

WHAT ARE THE BENEFITS OF THIS STUDY?
The data collected in this study may help others in the future but there are no direct benefits to you.

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.

IS THERE ANY COMPENSATION?
You will be paid for being in this study. You may choose to receive a total of $325, or a 8-month individual membership to Choice Health & Fitness Center, or 6-month family membership to Choice Health & Fitness Center for completing the study. If you choose not to continue in the study or are found to no longer qualify, you will receive payment pro-rated for the portions of the study done as shown below.

SCREENING VISIT	$10
BASELINE VISIT	$30
BLOOD DRAW	$15
2 X SKIN SCANS (RS AND RRS)	$5
DEXA	$25
SALIVA COLLECTION	$10

Date: _____
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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, we will describe the study results in a summarized manner so that you cannot be identified. Your study record may be reviewed by Government agencies, the University of North Dakota (UND) Research Development and Compliance office, the UND Institutional Review Board, and the GFHNRC.

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 study participants unique subject identification (ID) numbers that will not contain any personal identifiers. This subject ID number will be used on all data collection instruments, including questionnaires and computer records, so that no data can be connected to an individual subject. A master list linking the participants' names to the ID numbers will be kept in a separate locked file in the principal investigator's office, or in a computer file with a password protected access restricted to study personnel. Confidential information may be made available to the US Department of Agriculture as specified in the USDA/ARS Privacy Act System of Records, to UND, 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 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.

CAN I WITHDRAW FROM THE STUDY?
Yes, 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 UND. If you decide not to do any more of the research tests, we ask that you notify the study coordinator or principal investigator.

Date: _____
Subject Initials: _____

CONTACTS AND QUESTIONS?
The researchers leading this study are Lisa Jahns Ph.D., R.D. and James Roemmich, Ph.D. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Becky Stadstad at 701-795-8385 or Dr. Jahns at 701-795-8331.

If you have questions about 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.

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 research on the effects of vegetable juice consumption on health.

You are being asking 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. Your samples will become the property of the GFHNRC. 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 _____

Approval Date: APR 5 2019
Expiration Date: APR 4 2020
University of North Dakota IRB

Date: _____
Subject Initials: _____

SUPPLEMENTAL INFORMATION ABOUT SAMPLES FOR GENETIC RESEARCH

We would like to use your samples for genetic research. No individual information about genotypes will be made available to you or to a third party. Genotyping carries no medical or therapeutic value. There is no medical significance linked with the DNA test results. Your samples will not be sold in the future. Your samples will become the property of the GFHNRC and you do not have rights to them. 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 genetic research. You will not be paid an additional amount for these samples. 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 _____

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. This information will be kept in a separate file from the signed study consent form.

(Please circle one) YES NO

Initials _____

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.

_____

Your Printed Name

_____ _____

Your Signature Date

I have discussed the above points with the subject or, where appropriate, with the participant's legally authorized representative.

_____ _____

Signature of Person Who Obtained Consent Date

Approval Date: APR 5 2019

Expiration Date: APR 4 2020

University of North Dakota IRB

Date: _____

Subject Initials: _____