Document Type: Informed Consent Form

Official Title: Disease Risk Reduction and n-3 Rich Rainbow Trout (Fish for Health)

NCT Number: NCT02204709

IRB Approval Date: 02/07/2020

INFORMED CONSENT

TITLE: Fish for Health (HNRC Study #029)

PROJECT DIRECTOR: Matthew Picklo, Ph.D. **PHONE #** 701-795-8380

DEPARTMENT: USDA Grand Forks Human Nutrition Research Center (GFHNRC)

STATEMENT OF RESEARCH

A person who is to participate in the research must give his or her informed consent to such participation. 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. Research projects include only subjects who choose to take part. Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask. You do not have to take part in the study.

WHAT IS THE PURPOSE OF THIS STUDY?

Dietary guidelines recommend eating fish, particularly those enriched with omega 3 fatty acids, for reducing cardiovascular disease (CVD) risk. This study is being done to determine how eating fish raised to have different levels of omega 3 (n3) fatty acids will reduce CVD risk markers in people with elevated CVD risk.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 43 people will take part in this study at the USDA Grand Forks Human Nutrition Research Center.

ELIGIBILITY: You may participate if you are 20-70 years old with a body mass index (BMI) ≥ 25.0 and < 40 kg/m^2.

You cannot participate in the study if you:

- are allergic to fish
- use tobacco products or nicotine in any form including snuff, pills, and patches, or e-cigarettes in the past 6 months
- have established cardiovascular, pulmonary, and/or a metabolic disease such as diabetes
- have uncontrolled high blood pressure
- have alcohol, anabolic steroids, or other substance abuse issues
- consume more than 3 alcoholic drinks/week
- have cancer
- are pregnant or nursing

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- take non-steroidal anti-inflammatory drugs such as aspirin, ibuprofen or Aleve, lipid modifying drugs such as statins, or medications for blood glucose such as insulin or metformin

You are eligible if you are taking medication for high blood pressure. You must let us know of all the drugs you are taking in order to determine your eligibility and for your safety.

HOW LONG WILL I BE IN THIS STUDY?
Your total participation in the study will last about 34 weeks and will take a total of approximately 21½ hours of your time. This study consists of three (3) separate 6-week (42 day) treatments and two (2) separate 8-week (56 day) minimum washout periods. An orientation meeting will take about ½ hour. Screening for the study should not take more than 1½ hours and may include a separately scheduled blood draw.

At the beginning (Day 0) and end (Day 42) of each treatment period, blood draws, urine collection, and body composition determination will be performed. These should take about 35 minutes each visit for a total of 3½ hours over the duration of the study.

A total of six, 24 hour urine collections (to be turned in Day 0 and Day 42 of each study arm) are required. Pickup of the urine collection container will take no longer than 10 minutes for a total of 1 hour for the study.

Weekly pickup of food, dietary records, and counseling will take about 16 hours for the entire study. Weekly pickup of food will take 15 minutes for each of 18 treatment weeks. Initially, you will meet with a registered dietitian to be taught diet record keeping (online or on paper) and the importance of dietary compliance in a ½ hour session. You will complete a 3-day diet record 15 times throughout the trial (days 14, 28, 42 during each of 3 treatment periods and during each of the two the washout periods). After completing the diet record, you will meet with a registered dietitian to review your diet record entries and to monitor treatment compliance. Each session should take about 45 minutes for a total of about 11 hours.

WHAT WILL HAPPEN DURING THIS STUDY?
Application: You may apply to join the study by completing the on-line application on Survey Monkey or by paper application. Eligible applicants will be invited to an information/screening appointment.

Information/Screening Visit: Dr. Matthew Picklo or his designee will tell you about the study at the information visit and answer any questions. If interested in joining the study, you will fill out a demographic form which will be used to describe the group

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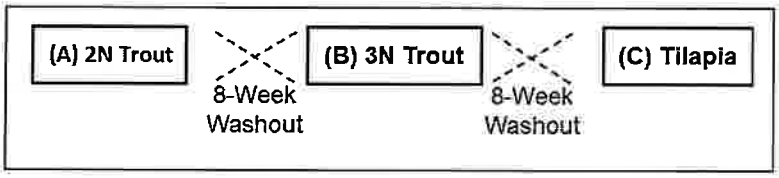
characteristics, a W-9 which is required before a check can be issued for payment, an Omega-3 checklist will determine the intake of n3 foods, and a health history form to determine if you are medically able to participate. At this visit, you have the option of having abdominal circumference, height, and weight determined.

A separate visit may be scheduled to draw blood following a 10 hour fast. After receiving the results of your blood work, a physician may meet with you to determine your suitability for the study, if required.

Dietary Treatment:



If you are found eligible for the study, you will be randomized into one of three treatment groups (A, B,C). Each treatment will last 6 weeks followed by a washout period of ≥ 8 weeks, followed by crossing over to the alternate treatment group for 6 weeks. Treatment A will consist of a twice weekly 200 gram (about 7 ounces) portion of 2N farmed, rainbow trout for 6 weeks. Treatment B will be a 200 gram portion of 3N farmed, rainbow trout twice weekly. Treatment C will be a 200 gram portion of farmed tilapia, a low omega-3 fatty acid containing fish, twice weekly.

Fish will be served on a bed of rice as pre-prepared entrees that just need re-heating. Details of re-heating and entrée consumption will be clearly described by the GFHNRC dietitian.

Measures: Functional and biomarker measures will be taken before (day 0) and after (day 42) of fish consumption. Blood and urine will be taken to study markers of inflammation, cardiovascular health, and omega 3 fatty acid status. We will also measure blood pressure, body weight and composition (by DXA scan), and plasma lipids (cholesterol, LDL, HDL, triglycerides).

You will keep a 3 day diet record a total of 15 times (3x each treatment for A, B, C and for each of two washout periods) to assess basal nutrient intake. Your diet records will be reported on days 14, 28, and 42 of each of the treatment periods and washouts.

WHAT ARE THE RISKS OF THE STUDY?

Blood Draws: The needle stick may hurt. There is a small risk of bruising. There is a rare risk of infection. You may feel lightheaded or faint during or right after a blood draw.

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This is more likely to happen if you have had problems with fainting during blood draws in the past. Let us know. Trained staff will use sterile techniques when drawing blood. However, there is a chance that the site may become infected.

260 mL of blood will be drawn during the entire study, 8 mL for screening and 42 mL for each of the other six visits. This is well within the limit for volume and frequency of blood donation of 475 mL or 32 tablespoons every 8 weeks.

DXA: The Dual Energy X-ray Absorptiometry (DXA) is considered to be no greater than minimal risk. The radiation dose of the whole-body DXA scan is 0.6 mrem. This dose is equal to about 1/451 of normal annual background radiation, 1/15 of the radiation received in a transatlantic flight, or 1/50 of the radiation received in a chest X-ray. You will receive six DXA scans. The effects of small doses of radiation on a developing fetus are not known; therefore, we will not allow pregnant women to have a DXA. Pregnancy tests will be done before the DXA if you are a woman of child-bearing potential.

WHAT ARE THE BENEFITS OF THIS STUDY?
You will not benefit personally from being in this study, except the satisfaction that the results of the research may yield knowledge about whether eating fish high in omega 3 fatty acids reduces CVD risk markers.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will be expected to provide your transportation to and from the Grand Forks Human Nutrition Research Center. We do not withhold income, social security, unemployment taxes, or any other taxes because you are not an employee of the Grand Forks Human Nutrition Research Center. 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 jeopardizing your status in the United States.

IS THERE ANY COMPENSATION?
You will receive an honorarium of ***$500 for completion of the study***. If a you choose not to continue in the study or are found to no longer qualify for the study, you will receive payment pro-rated for the portions of the study completed.

Blood Draw (Screening): $15.00 x 1 = $15.00
24 Hour Urine Collection: $10.00 x 6 = $60.00
Blood Draw: $15.00 x 6 = $90.00
Food Pick Up/Consumption: $4.00 x 18 = $72.00

Diet Records: $15.00 x 15 = $225.00

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, the study results will be in a summarized manner and you will not be identified. None of the study results will have any names attached. Confidentiality will be maintained by assigning an identification number which will be used to anonymously code your research data for computer entry. This consent and the check information will be kept in a locked file at the Grand Forks Human Nutrition Research Center. Dr. Matthew Picklo and the staff assigned to the research study will have access to the data. 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).

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 participating 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.

IS THIS STUDY VOLUNTARY?
Yes, you may choose not to participate or you may discontinue your participation 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. If you decide not to do any more of the research tests, we ask that you notify the study coordinator or principal investigator.

CONTACTS AND QUESTIONS?
The researcher conducting this study is Matthew Picklo, Ph.D. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research

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please contact recruitment staff at 701-795-8396 or Dr. Picklo at 701-795-8380. If you have questions regarding your rights as a research subject, or if you have any concerns or complaints about the research, you may contact the University of North Dakota Institutional Review Board at (701) 777-4279. Please call this number if you cannot reach research staff, or you wish to talk with someone else.

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.

Subjects 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

Approval Date: FEB 7 2020

Expiration Date: FEB 6 2021

University of North Dakota IRB

Date_____

Subject Initials: _____