CHAMP

Uniformed Services University

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INFORMED CONSENT DOCUMENT

PROTOCOL TITLE: Evaluate the use of omega-3 fortified smoothies to improve omega-3 index and physical performance related outcomes among Soldiers

Principal Investigator: Dr. Melissa Rittenhouse, PhD, RD, CSSD, FAND

You are being asked to take part in a research study. Before you decide to take part in this study, you need to understand the risks and benefits so that you can make an informed decision.

This is known as informed consent. This consent form provides information about the research study. Once you understand the study and the procedures, you will be asked to sign this form if you want to take part in this study. Your decision to take part is voluntary. This means you are free to choose if you want to take part in this study. Refusal to participate will involve no penalty or loss of benefits otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits otherwise entitled.

Please read the information below, and ask questions about anything you do not understand, before deciding whether to take part in the study.

You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your participation in this study. Participation is voluntary. You may also leave the research study at any time without penalization

1. KEY INFORMATION

We are seeking your voluntary participation in this research study to determine if Omega-3 Index (O3I) levels reach the goal of 8% with daily consumption of omega-3 smoothies. Research indicates an ideal O3I is greater than 8%; however, past research shows both civilians and military personnel are only around 4%. This research will also evaluate if participants with higher O3I perform better or recover faster from the Army Combat Fitness Test (ACFT). The benefit of this study is you will learn your personal Omega-3 Index levels; however, you may or may not see a performance or recovery benefit.

This is an 8-week study. You will be asked to complete an O3I, requiring a finger prick, and questionnaires that will take less than 15 minutes total. These include demographics and nutrition questions, The Pittsburgh Sleep Quality Index (PSQI) and the Physical

Activity Questionnaire (PAQ). Additionally, you will participant in two Army Combat Fitness Tests (ACFT) week 1 and week 8. After the ACFT you will record your rate of perceived exertion (RPE) using a scale of 6-20 and pain score, using a pain scale ranging from 0-10, one hour and twenty four hours post ACFT. The risks of the study may be bruising or soreness at the site of the finger prick, and a slight risk of infection.

If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell these researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because we are seeking to evaluate the Omega-3 Index levels of Army soldiers and potential benefits to physical performance and recovery.

Omega-3 and Omega-6 fatty acids are essential fatty acids, meaning we must consume them in our diet. There are many foods that provide Omega-6 fatty acids, including meat, certain oils and many processed foods, but far fewer sources of Omega-3 fatty acids; the most common source is salmon. The purpose of this research study is to determine if providing omega-3 smoothies to supplement dietary intake lead to increased performance or recovery, utilizing the ACFT.

The study will aim to recruit up to 100 participants. The study will last 8 weeks.

Your individual Omega-3 Index scores will be available by your participant ID, approximately 2-3 weeks after completion of the study. If you would like to be informed of the overall results of the study, please send an email to omega-3-index-ggg@usuhs.edu.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

You are determined eligible to participate in this research based on the following inclusion and exclusion criteria.

Inclusion criteria:

- Current soldier at Ft. Drum or Ft. Campbell.
- Willing to obtain two finger pricks for the Omega-3 Index (week 1 and week 8)
- Able and willing to complete two ACFT (week 1 and week 8)

Exclusion criteria:

- Allergic to fish

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

Since you were determined eligible to participant, we are currently reviewing the informed consent document (ICD), once all your questions have been answered, if you chose to participate you digitally or physically sign the ICD. After the signed ICD is obtained, you will be asked to complete the questionnaires and complete the finger prick to obtain your baseline O3I. This will take no longer than fifteen minutes. Once this step and the ACFT data are collected the baseline session is complete.

After the baseline session, you will be assigned to the control group (regular smoothie) or the omega-3 group (omega-3 enhanced smoothie). Neither you nor the researchers will know who is receiving which smoothie type. Over the next 8 weeks you will be asked to drink one smoothie daily (Monday-Friday) immediately following training. After 8 weeks we will ask you to complete another O3I, complete the questionnaires and complete the post-intervention ACFT and provide your score, RPE and pain score.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, the risks include bruising or soreness at the finger prick site. To minimize soreness, you can ice your finger. In addition, there is a slight risk of infection. Signs of infection include redness and swelling. If you notice these symptoms within 24 hours after you prick your finger, go to the medical clinic.

There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

You may enhance your knowledge about your dietary habits and how you can improve your Omega-3 Index.

However, there is no guarantee that you will benefit from being in this research.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

There will be no monetary compensation.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

There are no costs for participating in this research.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Dr. Melissa Rittenhouse, PhD, RD, CSSD, FAND, is an Assistant Professor at the Uniformed Services University and employed by the Henry M. Jackson Foundation.

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

The Uniformed Services University is a sponsor. As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

N/A

13. LOCATION OF THE RESEARCH:

Ft. Campbell and Ft. Drum

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

N/A

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. These records may be looked at by staff from the USUHS Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws, but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include, but are not limited to: Assigning you a unique participant ID that will be used on all data collections. All forms will be kept on a USU-secure web based platform such as REDCap or a restricted access, locked cabinet for five years after the study completion. Following this time period, any documentation will be destroyed or erased. To enhance the privacy of

your information, all data will be entered into a database in which individual responses are not identified and will be password protected. After verification of the database information, paper copies of all materials containing identifiers will be shredded five years after completion of the study. Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data.

All efforts will be made to keep the personal information in your research record private, but complete confidentiality cannot be promised. Your information may be shared with the USUHS Institutional Review Board. Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

16. LONG TERM USE OF DATA

The investigator has requested to save the data (demographics, questionnaires, ACFT scores and O3I results) collected from your participation in this research study for possible use in future research. Identifiers might be removed from the identifiable private information or identifiable biospecimens, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent. This future research may be in the same area as the original study or it may be for a different kind of study. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

17. USE OF INFORMATION AND SPECIMENS

During this research study, you will be asked to provide the following types of samples (biological specimens): Blood. All biospecimens will be coded.

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you.

Although research that uses your samples may lead to the development of new inventions, products or discoveries (some that might be patented and licensed), there are no plans to share any potential profits with you.

18. INCIDENTAL FINDINGS:

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding".

Information collected through data collection for this study consists of coded data. This information is unlikely to expose a medically-sensitive concern. If found, the Principal Investigator will notify our Medical Director and appropriate Office of Human Research contact.

Similarly, data collected is unlikely to expose findings for which a researcher would be mandated to report results to appropriate military or civilian authorities.

Participation in the study should not entail any physical or mental risk beyond those described. In the event of a medical emergency while participating in the study, treatment and care will be provided. Information about procedures for providing medical care to participants is disclosed in the informed consent process with participants.

19. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part, which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled. You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, please inform the research staff at omega-3-index-ggg@usuhs.edu. If you withdraw, any previously collected data will be retained at the Uniformed Services University.

The Principal Investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

21. CONTACT INFORMATION:

Principal Investigator (PI)

This research is being conducted by Dr. Melissa Rittenhouse at Uniformed Services University. The Principal Investigators or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Dr. Melissa Rittenhouse, PhD, RD, CSSD, FAND
Phone: 240-630-0210
Email: melissa.rittenhouse.ctr@usuhs.edu
Mailing Address:
Uniformed Services University
4601 Jones Bridge Rd.
Bethesda, MD 20814

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:
Uniformed Services University
Human Research Protection Program
4301 Jones Bridge Rd.
Bethesda, MD 20814
301-295-9534

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date