Krill Oil for Pain and Physical Function in Older Adults

NCT06580912

07/17/2025

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM to Participate in Research, and AUTHORIZATION to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position:_____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant

_____

2. What is the title of this research study?

Krill Oil for Pain and Physical Function in Older Adults

Short Title: **K**rill **O**il for **P**ain in **E**lders **(KOPE)** Study

3. Whom do you contact if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Javier A. Tamargo, PhD, RDN (Ph. 352-273-5795; j.tamargo@ufl.edu)

Study Physicians: Rene Przkora, MD, PhD, FASA (Ph. 409-771-8232; rprzkora@anest.ufl.edu)
Bhanuprasad Sandesara, MD (Ph. 412-607-3914; bsandesara@ufl.edu)

Other Research Staff: Ph. 352-273-9055; DN-KOPEStudy@ufl.edu

4. Who is paying for this Research Study?

This study is sponsored by the Claude D. Pepper Older Americans Independence Center (OAIC) at the University of Florida, which is supported by the National Institute on Aging (NIA).

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be

penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research participant, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research? How long will you be involved?

The purpose of this study is to examine whether taking krill oil reduces pain intensity and improves physical and cognitive function in older adults with chronic musculoskeletal pain. Krill oil is similar to fish oil, a source of omega-3 fatty acids usually found in fatty fish, such as salmon. Omega-3s are essential nutrients, meaning that they must be obtained in the diet since the human body cannot create them on its own.

We will examine the effects of taking krill oil on pain, physical function, and cognitive function. Participation will consist of an initial Screening Visit followed by 3 Study Visits throughout about a 12-week period (3 months). You will be asked to consume the supplement daily for 12 weeks (3 months).

b) What is involved with your participation, and what are the procedures to be followed in the research?

There will be a Screening Visit to determine eligibility followed by a Baseline Visit (which may be performed on the same day) and two follow-up visits at 6 and 12 weeks. The visits will vary in length and will include blood draws, surveys, and cognitive and physical function tests.

You will be randomly assigned (like flipping a coin) to either the 1) Krill Oil group, or a 2) Placebo group. You will be asked to consume 4 capsules of the study product, a total of 4,000 mg of krill oil or placebo, orally once a day with a meal, every day for 12 weeks. You will be asked to maintain your current dietary habits and physical activity levels, and to not participate in other interventional research studies.

We will also ask your permission to store any remaining blood collected from this study. The remaining blood will be stored in a tissue bank (IRB 202100046) for future studies. Choosing not to participate in the tissue bank will not affect your eligibility to participate in this study.

Please **initial** one of the options below:

____ **Yes**, I would like to know more about taking part in the tissue bank and agree to reviewing the separate consent form for further details.

____ **No**, I do not want to participate in the tissue bank. I know this does not affect my eligibility in this study.

c) What are the likely risks or discomforts to you?

Similar to fish oil, krill oil is considered generally safe for older adults. However, taking omega-3 supplements may increase the risk of bleeding when combined with blood thinners (also known as antiplatelet or anticoagulant medications), full-dose aspirin, high-dose non-steroidal anti-inflammatory drugs (NSAIDs), or certain supplements, such as St. John's Wort. There is also a slight risk of developing abnormal heart rhythms with omega-3 supplements. Other potential side effects of omega-3

supplements are usually mild and include unpleasant taste, bad breath, heartburn, and gastrointestinal discomforts, such as nausea and diarrhea. Some individuals may also experience a loss of appetite. Omega-3 supplements are not considered allergenic, but the U.S. Food & Drug Administration (FDA) recommends caution in people who are allergic to seafood.

The risks associated with the placebo, a mixture of vegetable oils, are similar to those for krill oil, and include upper respiratory tract infections, joint and back pain, gastrointestinal disorders, and headaches. There is also a potential risk of worsening cholesterol with the mixed vegetable oil placebo.

Potential risks associated with the study include the risk of falling and/or injuries during the physical function tests, feeling uncomfortable during the mental and physical testing, and bruising or discomfort during the blood draws.

d) What are the likely benefits to you or to others from the research?

You and others may or may not benefit from the study. Potential benefits of taking krill oil include reduced levels of inflammation, improvements in cardiovascular health, reduced pain, and improvements in mental and physical function. Also, you will gain valuable information about your health through the blood tests and assessments of mental and physical function. We will also offer you a report on your dietary habits, called The Healthy Eating Index. Your participation in this study will help advance our knowledge of the role nutrition can have in affecting pain levels in older adults. This research should ultimately lead to the development of better therapies for pain management and the maintenance of physical function in older adults.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

The only alternative to taking part in this study is not to participate. If you do not wish to be in this study, please tell a study team member and do not sign this form.

A description of this clinical trial is available on ClinicalTrials.gov (https://clinicaltrials.gov/study/NCT06580912), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

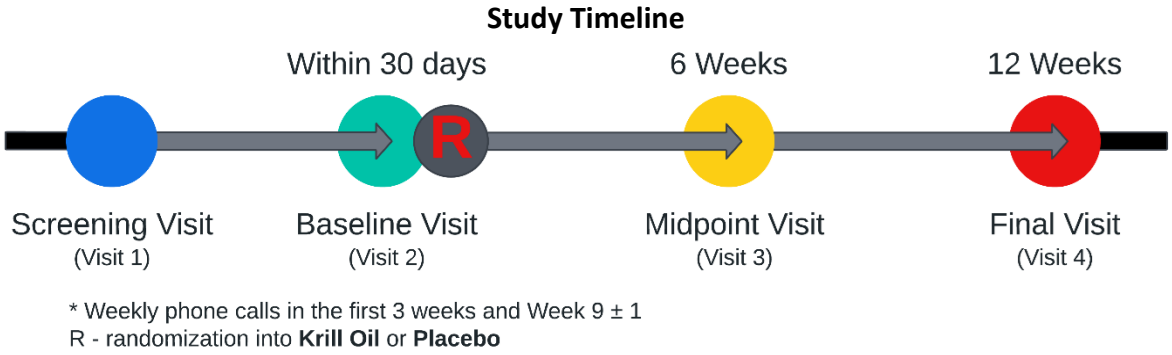
Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

The investigators do not provide clinical care. Your clinical care will not be affected by your participation in the current study.

7. What will be done only because you are in this Research Study?



An initial telephone screening indicated that you may be eligible to participate in the study. Your first in-person visit will determine your eligibility for the study. Details regarding the tests to be conducted during this Screening Visit and other study visits are described below. All study visits will take place at the University of Florida's Clinical and Translational Research Building (CTRB).

Screening Visit (Visit 1)

The screening visit is expected to take approximately 1 hour. Details of study procedures that will be conducted during this visit are listed below. The order of these procedures may vary based on the schedules of study staff.

- Informed Consent review and discussion
- Provide contact and demographic information
- Review of your medical history and medication inventory
- Measurement of your height, weight, and waist circumference
- Measurement of your resting blood pressure and heart rate
- Provide brief information on your pain experience
- Perform a short physical function test (standing balance, walking, standing from a chair)
- Perform a brief mental test

If you qualify to participate and decide to take part in this study, you will be invited to attend a second study visit within 30 days. You may have your Baseline visit on the same day for your convenience. If more than 30 days pass from the screening visit, then you will be re-screened to ensure you still meet the eligibility criteria.

Baseline Visit (Visit 2)

The baseline visit is expected to take approximately 2-3 hours and will include:

- Measurement of your weight and waist circumference
- Measurement of your resting blood pressure and heart rate
- Blood draw/collection (see details below)
- Review of your medical history and medication inventory
- Physical function tests

- Pain and disability surveys
- Dietary assessment
- Mental function tests
- Dispensation of study treatment

Randomization and Study Treatment

If you decide to take part in this study, at the end of the Baseline Visit you will be randomly assigned (much like the flip of a coin) to receive either krill oil or placebo. A placebo is a substance that looks like and is given in the same way as an experimental treatment but contains no medicine, for example a sugar pill. A placebo is used in research studies to show what effect a treatment has compared with taking nothing at all. If you are assigned to receive placebo, you will not receive the benefits of the krill oil, if there are any, nor will you be exposed to its risks, which are described below under "What are the possible discomforts and risks?" Studies have shown, however, that about 1 in 3 persons who take a placebo do improve, if only for a short time. You and the physician and other persons doing the study will not know whether you are receiving placebo or krill oil, but that information is available if it is needed. Also, you will have a 50% chance of receiving krill oil and a 50% chance of receiving placebo. In the remainder of the description of what will be done, both the krill oil and the placebo will be called "study treatment."

In this study, the placebo is a mixture of vegetable oils: a blend of extra-virgin olive oil, corn oil, palm kernel oil, and medium-chain triglycerides in a ratio of 4:4:3:2, which contains approximately 31% SFAs, 46% MUFAs, and 22% PUFAs, with no EPA or DHA. This mixture is similar to the fatty acid composition of the typical Western diet. According to *What We Eat in America*, Americans consume an average of 85 g of fat daily, containing 33% SFAs, 34% MUFAs, and 23% PUFAs, making up about 36% of total energy intake. Within the context of the whole diet, the small amount of mixed fats consumed in the placebo is not expected to have any independent therapeutic effects.

6-Week Follow-Up (Visit 3)

The 6-week visit is expected to take approximately 2 hours and will include:

- Measurement of your weight and waist circumference
- Measurement of your resting blood pressure and heart rate
- Blood draw/collection (see details below)
- Review of your medical history and medication inventory
- Pain and disability surveys
- Physical function tests
- Counting of remaining capsules plus dispensation of study treatment

12-week Follow-Up (Visit 4)

The final visit is expected to take approximately 2-3 hours and will include:

- Measurement of your weight and waist circumference
- Measurement of your resting blood pressure and heart rate
- Blood draw/collection (see details below)

- Review of your medical history and medication inventory
- Physical function tests
- Pain and disability surveys
- Dietary assessment
- Mental function tests
- Counting of remaining capsules

Follow-Up Phone Calls

We will call you between your study visits to inquire about any potential side effects or other health events that you may have experienced. We will call you on a weekly basis for the first 3 weeks after you start taking the study treatment (baseline), and again between the in-person visits at weeks 6 and 12.

Information regarding assessments:

Vital Signs: We will measure your blood pressure and your breathing rate before you do the walking or chair stand tests. If your systolic blood pressure >200 mmHg or diastolic pressure is >110 mmHg, you will not perform those tests to ensure your safety.

Blood Draw: You will be asked to fast for at least 12 hours before Study Visits. We will collect blood from a vein in your arm or hand. After we draw your blood, we will provide a snack for you before you continue with the visit procedures. The purpose of this blood draw is to measure the levels of fatty acids in your blood, as well as other biochemical tests related to your health. If we need to repeat the tests, you may be asked to return for an additional blood draw for which we will compensate $10.

Surveys: You will be asked questions about your medical history, contact information, demographic information, pain, physical ability and limitations, eating habits, and other lifestyle factors. You will also be asked questions about your feelings and emotions, such as depression and stress.

Physical Function: You will complete the *Short Physical Performance Battery*, which includes a balance test, a timed short-distance walk, and repeated chair stands. You will be asked to complete a *6-Minute Walk Test* that measures the amount of distance you can complete on a standard walking course in 6 minutes without running or overexerting yourself. Third, you will be asked to complete a *Hand Grip Strength Test*.

Mental Tests: You will complete a series of exercises that will test your attention, memory, and other aspects of your mental functioning.

If any identifiable information or identifiable biospecimens were collected as part of this research, it is possible that your research information or specimens, with all personally identifiable information removed, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Throughout the study, the research investigators and study team members will contact you by email, text, telephone and/or video conferencing for all study-related communication. Some of the reasons we may contact you may be to schedule your next visit, to ask you questions about your

health, and/or to update you on changes to the study. We will consider your preference in type of communication (shared at the start of your participation in the study) when reaching out to you.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect:

- Name
- Contact information & emergency contact information
- Demographic information
- Address
- Dates
- Medical record identifiers
- Information about your health and medical history
- Information about the medication(s) that you are taking
- Laboratory results
- Any other unique identifying number, characteristic, or code.

This information will be stored in locked filing cabinets or on REDCap (Research Electronic Data Capture) or on computer servers with secure passwords or encrypted electronic storage devices until the completion of the study. All data entered into computers or electronic storage files are assigned participant ID numbers that are de-identified to ensure that all information is protected.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- The study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns, such as the Centers for Disease Control and federal, state and local health departments;
- The IRB that reviewed this Research Study and ensures your rights as a study participant are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

10. How long will you be in this Research Study?

The entire study is approximately 16 weeks (4 months) over the course of 4 separate visits with follow-up calls during the study.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

We plan to screen 120 people to enroll a total of 40 participants who are eligible for the study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

Risks associated with taking omega-3 supplements: Due to its blood thinning properties, taking omega-3 supplements may increase the risk of bleeding at high doses when combined with blood thinning medications (for example, Eliquis, warfarin/Coumadin), full-dose aspirin, high-dose non-steroidal anti-inflammatory drugs (NSAIDs), or certain supplements, such as St. John's Wort. You are not eligible for this study if you are taking or have recently taken these medications or supplements. Also, there is a

slight risk of developing abnormal heart rhythms with omega-3 supplements, which may require medical attention.

Commonly reported side effects of omega-3 supplements are usually mild and include unpleasant taste, bad breath, heartburn, and gastrointestinal discomforts, such as nausea and diarrhea. Some individuals may also experience loss of appetite. Omega-3 supplements are not considered allergenic, but the U.S. Food & Drug Administration (FDA) recommends caution in people who are allergic to seafood.

Risks associated with the placebo: Risks associated with the mixed vegetable oils placebo are similar to those for krill oil, and include upper respiratory tract infections, joint and back pain, gastrointestinal disorders, and headaches. There is also a potential risk for worsening of cholesterol with the mixed vegetable oil placebo.

Risks associated with assessments: Surveys and cognitive function tests pose a minimal risk of mental fatigue, embarrassment, discomfort, and/or frustration. Physical function tests have an inherent risk of physical discomfort, pain, falls, and/or injury.

Risks associated with blood draws: The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure.

This Research Study may also include risks that are unknown at this time.
Please note, taking part in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

There may or may not be benefits to you from your taking part in this research. Potential benefits of taking krill oil include reduced inflammation, improved cardiovascular health, reduced pain, and improvements in cognitive and physical function. Also, you will gain valuable information about your health through blood tests and assessments of cognitive and physical function. We will also offer you a report on your dietary habits, called The Healthy Eating Index.

13b. How could others possibly benefit from this Research Study?

Results from this research have the potential to be widely beneficial to society, with important implications for public health and geriatric medicine. This research will help us understand whether krill oil supplements can be used as a therapeutic approach for pain management and the maintenance of physical function in older adults with chronic pain.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

13d. Will you be allowed to see the research information collected about you for this Research Study?

You may not be allowed to see the research information collected about you for this Research Study, including the research information in your medical record, until after the study is completed. When this Research Study is over, you will be allowed to see any research information collected and placed in your medical record.

14. What other choices do you have if you do not want to be in this study?

If you do not want to be in this study, the alternative choice is simply to not participate. Krill oil is commercially available and may be taken outside of the study. If you do not want to be in this study do not sign this form. If you have already signed this form, please notify the Principal Investigator listed in question 3 above.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop taking part in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. Howevers, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- If participation in the study could be harmful to you
- If you develop a medical condition or need treatment not allowed in the study
- If you do not follow study instructions
- If the study is cancelled
- Unexpected circumstances

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

The Sponsor will pay for all study related clinical services and certain routine clinical services that are required as part of your participation in this study. This may include some clinical services that you could have received if you were not in this study. All other non-study related clinical services will be billed to you or your insurance company as usual. For those services, you will be responsible for paying any deductible, co-insurance, co-payments, and for any non- covered or out-of-network services. Some insurance companies may not cover the cost of routine clinical services if they are associated with research studies. The study coordinator can help you work with UF Health to answer any financial questions you have about your participation in this study.

17. Will you be paid for taking part in this Research Study?

Yes, you will be compensated up to $165 through Visa Reloadable Debit Cards. You will be compensated $50 for completion of the Baseline Visit, $35 for completion of the 6-Week Visit, and $50 for completion of the final 12-Week Visit. If you live outside of Gainesville, you will receive $10 for travel expenses. If an additional blood draw is needed, we will compensate $10.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

18. What if you are injured while in this Research Study?

It is important that you promptly tell any member of the research team if you experience an injury or have questions about any discomforts that you experience while taking part in this study. If you are injured, you will be treated or referred for treatment.

If you are injured while you are taking part in this study, the cost of the diagnosis and/or treatment may be covered by the University of Florida or the study sponsor or billed to you or your insurer just like other medical cost, depending on a number of factors, such as if the injury was the result of the study

intervention, or the way in which the study was conducted. The University of Florida and the study sponsor do not normally provide any other form of compensation for injury. The principal investigator and others involved in the study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while taking part in this Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting and Authorizing Date