PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Plain Language Statement	
Reference Number:	2023-317
Full Project Title:	Can 8 weeks of supplementation with 4g/day of Krill Oil reduce pain and enhance recovery from muscle damaging exercise in young, untrained, healthy men and women? Krill oil supplementation as an exercise recovery aid.
Principal Researcher:	Dr D. Lee Hamilton
Associate Researcher(s):	Dr Aaron Fox, Dr Giselle Allsopp, Dr Rhiannon Snipe, Dr Nicholas Charalambous, Mr Matthew Retallack and Miss Elham Yaghoobi

This Plain Language Statement and Consent Form is 12 pages long. Please make sure you have all the pages.

1. Your Consent

You are invited to take part in this research project which will investigate the effects of daily, oral Krill Oil supplementation for 8 weeks on recovery from muscle damage. As part of this we will also address the impact of supplementation on sleep quality, and lean mass in young, apparently healthy, and untrained adults. For female participants, we will also be investigating the effects of Krill oil supplementation on menstrual pain.

This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it. Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker or doctor (GP). Feel free to do this. Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form in the presence of a research staff member at your familiarisation session at Deakin University. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project. You will be given a copy of the Plain Language Statement and Consent Form to keep as a record.

Participation in this study is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether or not to participate will not affect your relationship with Deakin University or the project researchers.

2. Background

Exercise-induced muscle damage (EIMD) occurs primarily from the performance of new exercise, and its severity is impacted by the type, intensity, and duration of training. EIMD can lead to pain, swelling, loss of muscle strength and power, reduced range of motion (ROM), delayed onset muscle soreness (DOMS) and impaired recovery. To avoid further injuring the area experiencing DOMS, it is recommended that training intensity be reduced, or to avoid training body parts suffering from DOMS for several days. Both scenarios can result in significant lost training time and for new trainees can result in exercise drop out. Anti-inflammatory compounds can improve the pain symptoms, but long-term use of anti-inflammatory compounds can come with side-effects in addition to potentially reducing training adaptations. Other strategies such as exercise and massage can relieve pain but no treatment methods to date have been found to restore original function or prevent muscle damage.

Some evidence suggests that diet supplementation with antioxidants or omega-3 fatty acids (omega-3s) can either reduce the damage associated with EIMD or aid in recovery. Krill oil is a natural and sustainable source of both omega-3s and antioxidants and so it is possible that supplementing the diet with krill oil, prior to EIMD, may augment the recovery response.

Sleep disturbance is common among adults, yet sleep is crucial to improve your daytime performance. There is some preliminary evidence that Omega-3 supplementation in certain contexts can improve sleep quality.

There is also evidence to suggest that omega-3 supplementation may assist with pain associated with menstrual cramps.

Finally, some evidence suggests that long term supplementation with omega-3s can lead to improvements in lean mass i.e., omega-3s may be leading to muscle gains.

These data collectively suggest that an omega-3 and antioxidant combined supplement such as krill oil may improve muscle pain/function, muscle damage, sleep quality, menstrual pain, and total body lean mass.

Krill oil is generally accepted as safe with no adverse outcomes reported in the dose range that we propose to use. To our knowledge no study has addressed if long term krill oil supplementation can prevent or enhance the recovery from EIMD.

** 3. Purpose

Within this study, we will be using a supplement produced by Aker Biomarine called Superba Boost. They are supporting this project by providing the supplement and placebo capsules for free. The 4 capsules you'll be asked to consume per day will contain either 4g of krill oil, the active component that we are investigating in this study or 4 g of mixed vegetable oil (placebo). All the capsules are made of black gelatine which will prevent you from seeing the colour of the oil inside thus preventing you from knowing what group you are in. All participants will be randomly allocated to either the krill oil group or the placebo group. Neither you nor the researchers will know what group you'll be in.

Primary Aim: This study aims to investigate if 4g of Kill oil supplementation for 8 weeks can reduce muscle pain and muscle damage and improve functional recovery in young, untrained, and healthy adults.

Secondary Aims: This study will also be investigating the effects of 4g of Krill oil supplementation for 8 weeks on sleep quality, and total body lean mass in young, untrained, and healthy adults. For female participants the influence of 4g of Krill oil supplementation on menstrual pain will also be assessed.

A total of 60 healthy and untrained individuals aged 18 to 35 years will be required to complete this project.

You have been invited to participate in this research project because you are:

- Healthy
- 18-35 years of age
- BMI between 18.5 and 30
- No regular resistance training in the past 6 months
- Weight stable for last 2 months
- Do not regularly consume oily fish (salmon, tuna, ...) or shellfish (mussels, shrimp, …)

This study is supported by Aker Biomarine in collaboration with Deakin University. This trial has been initiated by Dr D. Lee Hamilton, the Principal investigator of the study.

4. Procedures – what you will be asked to do

To participate in this study, you must have passed the initial telephone screening which has a series of questions to determine your eligibility. It also includes a pre-exercise health screen to make sure that participation in this study is safe for you . You have received this form because you have passed that screen and are eligible to participate. After reading this, you will have the opportunity to ask us any questions about the study. After this, if you consent to participate in this study, you will be asked to attend the laboratory for visit 1 in week 1 of the study period that you will be assigned to. For this first visit we ask that you arrive rested (no strenuous activity in the past 24hrs) and fasted for the body composition assessment in the first visit. You will be sent a food frequency questionnaire to fill out in the mail or we could forward on an electronic copy to your email. You will need to bring this form to the first visit that will be held at Deakin University, Waurn Ponds.

To confirm that you are giving informed consent to participate in this study, you will be asked to sign this Participant Information and Consent Form.

Upon entry into the study, you will be randomly allocated (like the flip of a coin) to one of two supplement groups. You will have a one in two chance of being in either group. This is called randomisation. This is a standard research method used to ensure that the results of a study are true and correct.

Study Duration

The study will take 10 weeks to complete. Week 1 involves onboarding and familiarisation. In week 2 you would start the 8 week supplementation period. In week 10 we will perform the muscle damage protocol and other testing described below.

Krill oil Supplement Pills

Each participant in this study will be asked to consume either: A) 4 x supplement pills which contain the recommended amount of Krill oil, or B) 4 x similar pills that contain placebo (mixed vegetable oil). You will not be told which group you have been assigned to until the conclusion of the study. You will be asked to consume 2 pills with two separate meals. Your consumption will be recorded by carrying out a pill count at the end of the study. Compliance will also be monitored via finger blood testing to confirm changes in your omega-3 status.

Exercise-induced muscle damage protocol

All participants in this study will take part in EIMD protocol in week 10 (at no cost to you). The program will take place at Deakin University, Waurn Ponds. You will be given a standardised breakfast prior to your EIMD. Immediately after the EIMD protocol you will be given a standarised recovery meal. There is an initial assessment directly after the muscle damage protocol. This assessment will be repeated 48hr later.

Study Measures

We will collect information from you and conduct a number of tests throughout the study. These tests will be conducted at pre-testing and post testing unless otherwise indicated below.

- Total body and regional (arms and legs) body composition (amount of muscle and fat) will be measured using a non-invasive method referred to as dual energy X-ray absorptiometry (DXA). The assessment of body composition by DXA involves you lying on a bed for approximately 8 minutes whilst a scanning arm moves along the length of your body above you. You will be exposed to a small dose of X-ray radiation with each scan. The dose of X-ray radiation is similar to what would be achieved by consuming a large portion of Brazil nuts. You will need to fill out two forms (DXA-Mandatory Athletes Screening and Deakin Consent – DEXA) as part of our internal record keeping associated with the DEXA scanner. Both forms must be completed before the scanning process.You will be scanned 3 times via ultrasound to measure muscle swelling in week 10 (before and immediately after muscle damage and 48hr after damage).
- A machine called an isokinetic dynamometer will be used to assess your muscle function and to administer the EIMD protocol. You will perform maximal strength testing followed by 30 sets of 10 repetitions. You will rest for 1 minute between sets. This protocol has been shown to induce a moderate amount of pain for ~48hrsin the quadriceps and it will also cause a reduction in basic muscle function. This test will be conducted at Deakin University at the same day as your 2nd DXA scan.
- We will use Visual Analogue Scales (VAS) to monitor your muscle pain by the

descriptors “no pain” as 0 and “worst pain imaginable” as 10. This scale is standard practice in pain research. The VAS for assessing pain is valid, reliable and sensitive. We will ask you to rate your pain during a body weight squat, the muscle function test and in response to a pressure device pressing on your affected muscles. We will also apply pressure to your muscle and ask you at what point the pressure become painful.

- We will also ask you to donate a 20ml venous blood sample to allow us to measure circulating markers of muscle damage before and after the EIMD protocol, and again at 48hr after muscle damage.
- We will be pricking your finger to provide us with a droplet of blood for the omega-3 index testing to help us to confirm that you have been regularly supplementing throughout the study in weeks 1 and 10.
- Your food intake will be assessed using a 3-day diet dairy at the beginning and the end of this study. At baseline, you will also be asked to record your food intake on food frequency questionnaire before your first visit. You will be asked to eat the same food again before the final testing of this study.
- Your sleep will be monitored using Pittsburgh Sleep Quality Index (PSQI), as a self-report questionnaire prior to beginning supplementation in week 1, after that in week 9.
- For females participating in this project, you will also be required to fill out a menstrual diary to track your menstrual cycle. Additionally, you will also be asked to record your contraception strategies in the same diary. Females can start supplementation for anytime of their cycle, but we will time the EIMD protocol to occur between days 3 and 10 of your cycle – thus it is important that you accurately track your cycle so that we can predict when this will be.

**Below is our study timeline and measures mapped out for you.

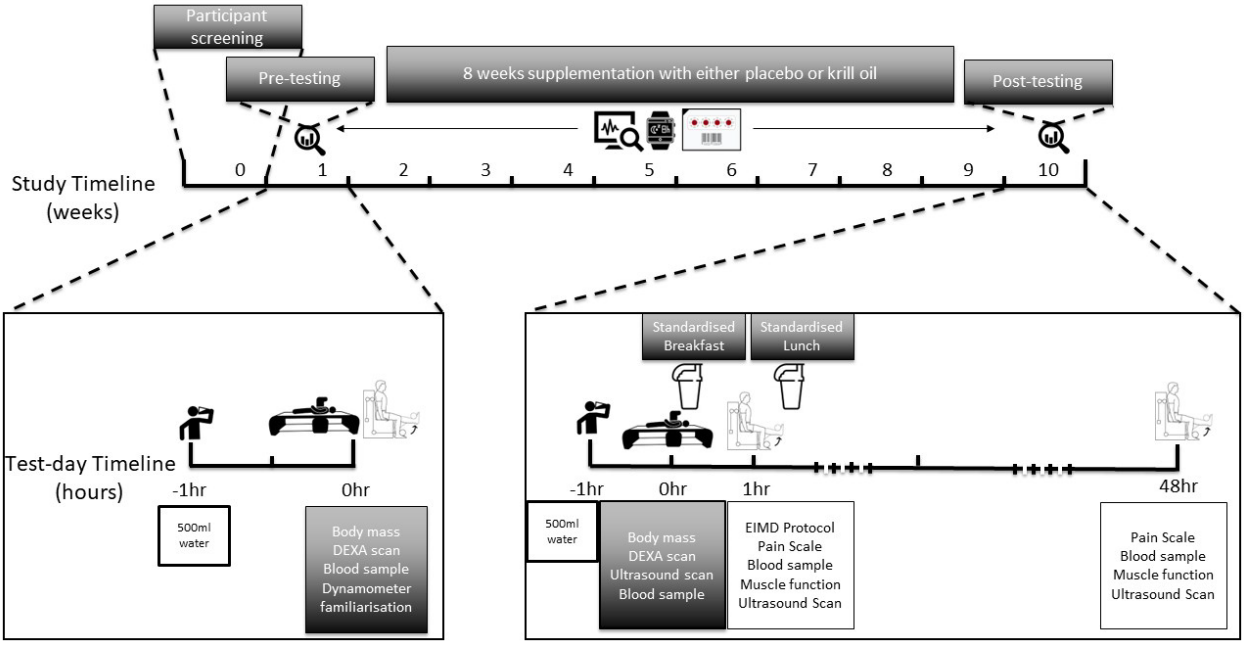

Figure 1. Proposed study and test-day timelines.

Visit to Deakin University
This study will involve **3 visits** to Deakin University over a 10-week period:

Visit 1 (Pre-supplementation Testing; Week 1)
Total time will be 2 hours and will involve monitoring body composition, familiarisation with the strength testing equipment and Omega-3 index testing. We will give you either krill oil supplement tablets or a placebo, a reminder will also be provided to start your supplementation in Week 2. Sleep and dietary monitoring will also be initiated at this visit.

Visit 2 (Post-supplementation Testing; Week 10)
Total time will be approximately 2-2.5 hours. Prior to the EIMD protocol, body composition, omega-3 index, venous blood sample and muscle thickness will be measured. 1hr prior to the muscle damage protocol you will be given a standardised breakfast consisting mainly of carbohydrate (breakfast cereal with skimmed milk) including half of your supplement for that day. A standardised warm-up will be applied. Immediately after this, muscle pain and function will be measured, venous blood sample and muscle swelling will be measured again. Immediately after the muscle damage protocol you will be given a standardised lunch consisting mainly of carbohydrate (low fat cheese sandwich, with orange juice) and the other half of your supplement.

Visit 3 (Post-EIMD Testing Week 10)
Total time will be 1 hour and will involve the assessment of your recovery from the damage protocol. Firstly, a venous blood sample will be collected and muscle swelling will be assessed by ultrasound scanning. Following this you will repeat the stardardised warm-up, followed by muscle function and pain measurements 48hrs after visit 2.

5. Possible benefits

We cannot guarantee or promise that you will receive any benefits from this project, but we expect that the following benefits will occur:

a. You will receive detailed information on your body composition and omega-3 index.

b. If you are in the supplementation group, you will very likely improve your omega-3 index which may reduce your cardiovascular risk.

6. Possible risks

Possible risks, side effects and discomforts include the following:

a. EIMD protocol – The EIMD will cause you to experience some moderate and transient muscle soreness initially following the sessions, it may last up to 72 hours but will subside then after. However, this protocol has been shown to be safe and acceptable. Precautions have been taken to minimise the risk of physical injury to you, but as with all types of exercise there are some risks involved, such as muscle strain. You will be given advice on how to recognise if there might be a problem that may require further medical attention.

b. This study involves exposure to a very small amount of X-ray radiation from the DXA scan of your body. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose you will receive from the DXA scans of your body will be approximately **0.02** mSv. At these dose levels, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. The risk is believed to be minimal and is similar to eating a large portion of Brazil nuts.

** If you have been involved in any other research studies that involve radiation, please inform us. Please keep this Patient Information and Consent Form that includes information about your exposure to radiation in this study for at least five years. You will be required to provide this information to researchers of any future research studies involving exposure to radiation.

c. Participants will be asked to consume Krill oil supplementation, but the amount prescribed is within the recommended range for a healthy diet. Possible side effects, such as upset stomach, are possible but very rare.

** You will be continuously monitored during the duration of the study to enable and ensure early detection of any problems that you may experience in regard to the risks mentioned above. You are advised to report any adverse events that you are facing during the duration of this trial. In most cases, a period of ice and rest would improve the symptoms. However, depending on the severity and duration, it may be advised to seek medical attention.

d. In addition to the risks outlined in this document, we recognise the challenging circumstances the COVID-19 pandemic has caused for many community members. As such, we would like to highlight that if you, or those close to you are experiencing distress, or are in need of additional support, you are encouraged to contact the Beyond Blue Support Service. They provide advice and support via telephone 24/7 (just call 1300 22 4636).

7. Other Treatments Whilst on Study

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including non-prescription medications, vitamins or herbal remedies and any changes to these during your participation in the study. We request that, where possible, you abstain from consuming other nutritional supplements and if you need to take any pain medications throughout the duration of the study we ask that you take note of the dose and timing and let us know.

8. Privacy, Confidentiality and Disclosure of Information

Any personal information provided by you to the researchers involved with this project will remain confidential. It will only be disclosed with your permission, subject to legal requirements.

All collected information will be labelled with a unique study code, and not with your name or any other identifying information, which will be kept separate from the information collected. All paper copies of this information will be kept in a locked filing cabinet in the researcher's office at Deakin University or in a password protected computer. The information collected from this study will be kept until the end of the project and then placed in archives for 5 years from the publication of findings. All data will also be kept in a database stored on a computer which will be password-protected and only accessible to the research staff involved in this study and may be used in future research which is closely related to this project. In the future, we may also wish to share some non-identifiable data with other groups that obtain relevant ethics approval that are not immediately involved in this project, but your information will be non-identifiable.

It is the intention of the researchers to publish the results of this project. In such circumstances your identity will not be disclosed. In all cases, information will be provided in such a way that you cannot be identified. In addition, any information collected will be coded and de-identified, and stored securely in electronic format where only researchers will have access to the data.

The results of this project will be discussed at national and/or international conferences. In all cases your identity and personal information will not be disclosed. ***It is possible that your data may be used for other research projects; all confidentiality will be upheld and your data will remain coded and non-identifiable. If you do not wish your data to be used for other research purposes please notify the principal researcher.*** Information will be provided in such a way that you cannot be identified. In accordance with the *Freedom of Information Act* 1982 (Vic), you have the right to access and to request correction of information held about you by Deakin University.

9. New Information Arising During the Project

Although unlikely, during the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research.

Similarly, as you will be monitored during each visit, if it appears for any reason that you or the research staff are at risk by your continuing participation in the visits, the person(s) supervising the research will stop your participation. In all cases you will be offered all available care to suit your needs and medical condition.

10. Results of Project

Upon completion of the project, it is anticipated that the results will be submitted for potential peer-review and journal publication in the field of musculoskeletal and dietary science. The results may also be presented orally to a scientific meeting in Australia or internationally. Upon completion of the study, all participants will be invited to a group presentation conducted by the researchers who will outline the main findings from the study. In addition, all participants will receive a copy (booklet) of their key results upon request.

11. Further Information or Any Problems

If you require further information or if you have any problems concerning this project (for example, any side effects), you can contact the principal researcher or associate researcher.

Contact Person	Telephone Number
Dr D. Lee Hamilton Miss Elham Yaghoobi	+61 3 924 45207 +61 48 46 42 679

12. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with Deakin University. You will also have the option to withdraw your data and tissues from the research project if you wish to do so.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team or complete and return the Revocation of Consent Form attached. This notice will allow the research team to inform you if there are any health risks or special requirements linked to Withdrawing.

13. Benefits

We cannot guarantee that you will experience any benefits from taking part in this research. However, at the completion of the study, you will receive information about your body composition (muscle and fat mass), omega-3 index (an important marker of cardiovascular health), sleep and diet which may be helpful to you. Furthermore, after completing all visits (1, 2, 3) of the project, you will receive a free work-out plan with nutrition advice from professional trainers as compensation for your participation and contribution to the research. Whilst you are visiting Deakin for our study, parking will be free for you. Additionally, you will be provided with a $75 voucher at the end of visit 3 to thank you for your time and contribution to the study. You will also receive personalized health information and advice on exercise and nutrition, with a referral to an accredited personal trainer upon completion of the project.

14. Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project are being reviewed by the Deakin University Human Research Ethics Committee for approval. (2023-317).

15. Termination of the Study

This research project may be stopped for a variety of reasons. These may include reasons such as unacceptable side effects.

16. Complaints contact details.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Manager, Research Integrity, Deakin University, 75 Pigdons Rd, Waurn Ponds, Victoria 3216, Telephone: 5227 2333, research-ethics@deakin.edu.au

Please quote project number [2023-371].

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Consent Form	
Date:	XXX
Full Project Title:	Can 8 weeks of supplementation with 4g/day of Krill Oil reduce pain and enhance recovery from muscle damaging exercise in young, untrained, healthy men and women? Krill oil supplementation as an exercise recovery aid.
Reference Number:	**[2023-317]**

I have read and I understand the attached Plain Language Statement.

I freely agree to participate in this project according to the conditions in the Plain Language Statement.

I have been given a copy of the Plain Language Statement and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details, including where information about this project is published, or presented in any public form.

Participant's Name (printed) .....

Signature ..... Date .....

Witness's Name (printed) .....

Signature ..... Date .....

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Withdrawal of Consent Form	
Date:	XXX
Full Project Title:	Can 8 weeks of supplementation with 4g/day of Krill Oil reduce pain and enhance recovery from muscle damaging exercise in young, untrained, healthy men and women? Krill oil supplementation as an exercise recovery aid.
Reference Number:	**[2023-317]**

I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardise my relationship with Deakin University.

Participant's Name (printed) .....

Signature ..... Date .....

Please post or email this form to:
Dr D. Lee Hamilton
School of Exercise and Nutrition Sciences
Deakin University
75 Pigdons Rd
Waurn Ponds, Victoria 3216