Trial record **1 of 1** for: Krill Oil army

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Ranger Resilience and Improved Performance on Phospholipid Bound Omega-3's (RRIPP-3)

ClinicalTrials.gov Identifier: NCT02908932

Recruitment Status : Enrolling by invitation
First Posted : September 21, 2016
Last Update Posted : September 21, 2016

Sponsor:
Medical University of South Carolina

Collaborators:
National Institutes of Health (NIH)
Aker Biomarine Antarctic AS

Information provided by (Responsible Party):
Bernadette Marriott, Medical University of South Carolina

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:
The goal of this study is to determine if supplementation with **krill oil** concentrate containing the phospholipid-bound omega-3 fatty acids improves performance on specific cognitive tests that underlie key elements in U.S. **Army** Infantry Basic Officer Leaders Course (IBOLC) and in Ranger School (Training) at Fort Benning, GA.

Condition or disease	Intervention/treatment
Nutrition Fatty Acids, Omega-3 Cognition Resilience, Psychological Psychology, Military	Dietary Supplement: Phospholipid-bound omega-3 supplement Dietary Supplement: Placebo supplement

Hide Detailed Description

Detailed Description:

The U.S. Army invests significant time and money in training its leaders. Individuals who choose the Army Infantry as their career expend significant time, energy, and commitment to self-development to achieve their career goals. While Infantry Basic Officer Leaders Course (IBOLC) graduates have demonstrated their ability to perform skills required for Ranger School success, personal stress during Ranger School appears to be a continual barrier to successful Ranger School graduation, with only 45.25% of IBOLC graduates having passed Ranger training in 2013. Omega-3 highly unsaturated fatty acids (HUFAs), specifically EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid), are concentrated in neural tissues, are essential for neural function (McNamara & Carlson, 2006), and must be obtained from dietary sources. United States (U.S.) food production practices over the last century have resulted in a dramatic change in the fatty acid profile of the U.S. diet. At the same time, evidence continues to build regarding the potential importance of omega-3 HUFAs on emotional state, cognitive function, and mental health. The purpose of this study is to investigate whether supplementation with omega-3 HUFAs from a krill oil concentrate will improve emotional status and related cognitive performance under stress among Infantry Officer Trainees during IBOLC, (Part I) and subsequent Ranger School (Part II). More broadly, Americans continue to report living under a high level of stress, with 20% reporting states of severe stress. The potential impact of this study would be information that would support the role for dietary supplementation of omega-3 HUFAs from krill oil concentrate in contributing to improving mood, emotional status, and cognitive performance among the U.S. population.

Overview: The Ranger Resilience and Improved Performance on Phospholipid Bound Omega-3's (RRIPP-3 Study) is a double-blinded, randomized, placebo-controlled trial conducted by the Medical University of South Carolina (MUSC) in partnership with the National Institutes of Health (NIH) working with the permission of the leadership of IBOLC and the U.S. Army Ranger Training School at Fort Benning, GA. Participants (450 individuals) will be randomized to one of two experimental groups for 2 Parts: Part I: IBOLC and Part II Ranger School.

Intervention Schedule: Participants will be provided with capsules of krill oil concentrate (2.3g/day HUFAs with EPA and DHA ratio of approximately 2:1) or placebo (macadamia nut oil and appropriate matching colorant for krill oil) delivered in 8 capsules per day during Part I (IBOLC training) only.

Compliance Monitoring: Finger prick blood samples will be collected for assessment of fatty acids at baseline and at specific time points during IBOLC and pre- and post-Ranger training and analyzed at a collaborating laboratory at the National Institutes of Health.

Study Participants: Sample Size: The sample size calculation is based on differences in one of the specific cognitive tests between the placebo and treatment groups based on prior omega-3 supplementation studies. The total sample size needed to detect the between groups difference is 352 (176 per group). Accounting for a potential attrition rate of 25%, the total number of enrolled subjects=450. Calculations were made using PASS 2008 software, (Version 08.0.13, Kaysvile, Utah).

Location, Population, and Recruitment Strategy: This study will be conducted at Fort Benning, GA with laboratory analytic support at NIH and MUSC. All healthy individuals who have arrived at Fort Benning to participate in IBOLC with the intention of continuing directly into Ranger Training after completion of IBOLC will be eligible for the study. Information about the RRIPP-3 Study will be available to IBOLC students upon arrival at Fort Benning prior to IBOLC. Those interested in potentially participating in the study can review the information about the study at the beginning of IBOLC and sign up for a screening/enrollment session. After seeing videos about the study and the informed consent process, and answering eligibility questions, if students remain interested, they will be asked to sign an informed consent and Health Insurance Portability and Accountability Act (HIPAA) for the baseline assessments. Once consent is obtained, the volunteer will participate in study baseline and enrollment, randomized, and provided with their omega-3 HUFA or placebo capsules.

Study Sessions: Overview: All participants will be expected to participate in 5 sessions held at Fort Benning. During the enrollment session a 24-hour dietary recall and 30-day food frequency questionnaire will be administered. Subsequent sessions will be scheduled at the 8 week check-in and two mid-points of IBOLC, and after leaving Ranger School (whether training is completed or not). Trained study coordinators will collect the data for the RRIPP-3 study. With the exception of the dietary assessment interview, the assessments for the RRIPP-3 study will be participant self-responses. Whether by self-response or coordinator interview, the responses will be collected directly into an automated, assessment order-sequenced computer test battery. With the exception of the informed consent documents, all participant information will be directly entered into the MUSC secure server as part of the RRIPP-3 study file. Participants will be assigned a study ID number at enrollment that will be used for the study duration. All data will be collected and filed in conjunction with the participant study ID number.

USDA Automated Multiple-Pass Method (AMPM) 24-Hour Dietary Assessment: AMPM (USDA, http://www.ars.usda.gov/Services/) is a computerized method for collecting interviewer-administered 24-hour dietary recalls in person. Food Frequency Questionnaire: The Diet History Questionnaire (DHQ) is a freely available food frequency questionnaire (FFQ). The DHQ II consists of 134 food items and 8 dietary supplement questions. RRIPP-3 will use the DHQ II electronic version which includes usual intake over the previous 30 days with portion size (NCI, 2010).

Data Coding and Analysis: Data will be collected and managed using REDCap electronic data capture tools hosted at MUSC (redcap.musc.edu) (Harris et al., 2009). All coded RRIPP-3 study data

will be collected and separately transferred to the MUSC secure server. This coded data will be labeled only with the participant study id and participant randomization number. Adverse events will be reported using eIRB, South Carolina's federated online IRB system.

Randomization Scheme: The 2 treatment groups will be balanced with respect to commissioning source and post-graduation destination using a stratified blocked design.

Statistical Analysis Intent to treat and verified compliance assessments: All hypotheses will be tested using both "intent to treat" and "as-per-protocol" criteria.

Data Analysis: Improvement on critical facets of cognitive function during IBOLC (Part I) and Ranger School (Part II): Descriptive statistics (e.g. means, standard deviations, medians, percentages) will be used to characterize the 2 treatment groups. T-tests, chi-square tests, or non-parametric tests (Wilcoxon rank sum, Fisher's exact) will be used to compare baseline characteristics between groups. As IBOLC class unit may represent an intraclass correlation, a variable will be created to represent class representation in the combined model. In addition, time on intervention and time to Part II end-point may vary between subjects and thus may be adjusted for in analysis as appropriate.

The primary analyses will involve generalized linear mixed models (GLMMs) (with random subject effects) performed to determine whether group assignment to active or placebo treatment improves scores on cognitive function and psychological assessments. The primary outcomes measure for cognitive function from the cognitive and psychological measures are outlined above. Other intermediary variables will be included in the model as indicated. Hypothesis tests will be 2-tailed, and p-values will be compared to an overall alpha level of 0.05. Secondary analyses will be conducted to examine treatment efficacy in subject subgroups, although the statistical power may be lower for any such analyses given the reduced sample size. GLMMs and non-linear mixed models with random subject and intraclass cluster effects will be used as appropriate.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	450 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
Official Title:	Ranger Resilience and Improved Performance on Phospholipid Bound Omega-3's
Study Start Date :	August 2016
Estimated Primary Completion Date :	March 2018
Estimated Study Completion Date :	March 2018

Resource links provided by the National Library of Medicine NIH NLM

MedlinePlus related topics: Dietary Supplements

Drug Information available for: Omega-3 Fatty Acids

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Phospholipid-bound omega-3 supplement 2.3g/d omega-3 HUFAs (with the EPA to DHA ratio of approximately 2:1), delivered in 8 capsules/day in **Krill oil** concentrates (Aker BioMarine Antarctic AS, Norway). Participants will receive supplements for the duration of IBOLC (19 weeks) and up until entry in Ranger. Time between completion of IBOLC and entry in Ranger is variable, ranging from 1 weeks to 10 weeks (4 weeks typical). Total duration on supplement thus ranges from 20 to 30 weeks.	Dietary Supplement: Phospholipid-bound omega-3 supplement The dietary supplement is produced by Aker BioMarine. These **krill oil** capsules received a GRAS status approval from the U.S. Food and Drug Administration (FDA) in 2010. Aker BioMarine has a new pending application (2015) with the U.S. FDA for GRAS status for its new product on which this study capsule is based. Aker BioMarine markets a number of different **krill**-based omega-3 supplement products in the U.S. The US Food and Drug Administration (FDA) has determined that an Investigator New Drug (IND) Application is not required for this study. This phospholipid-bound omega-3 dietary supplement is provided in capsule form.
Placebo Comparator: Placebo supplement Matching placebo capsules, substituting macadamia nut **oil** and appropriate colorant for **krill oil**. Macadamia nut **oil** has not been associated with psychological, cognitive, or health benefits. Furthermore, it is not typically consumed in large quantities and is therefore useful in tracking blood serum levels to assess compliance within the placebo arm. Placebo capsules have been produced by Aker Biomarine. As with the experimental arm, participants will take 8 capsules daily for the duration of the study (20-30 weeks).	Dietary Supplement: Placebo supplement Placebo capsules that are identical in size and color to the experimental but contain an equal amount of macadamia nut **oil**.

Outcome Measures

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Primary Outcome Measures :

1. Change (vs. baseline) in Inhibition and Rule-Making [Time Frame: baseline, week 14, week 16, within 72 hours of ending Ranger training]

   Stroop

2. Change (vs. baseline) in psychological resiliency [Time Frame: baseline, week 14, week 16, within 72 hours of ending Ranger training]

   Connor-Davidson Resilience Scale (CD-RISC)

3. Group differences on Land Navigation scores (from IBOLC gradebook) [Time Frame: data collected by Army throughout 5 months of IBOLC training and scores summed at the end of 5 months and provided to study pi]

   Land navigation tests the ability of candidates to navigate from one point to another using a map and compass while equipped with their individual combat gear.

4. Group differences on Marksmanship scores (from IBOLC gradebook) [Time Frame: data collected by Army throughout 5 months of IBOLC training and scores summed at the end of 5 months and provided to study pi]

   The underlying construct, visual psychomotor control, is assessed by evaluating whether "Marksman" or higher ranking was achieved on first attempt.

5. Change (vs. baseline) in Focused Attention and Information processing speed [Time Frame: baseline, week 14, week 16, within 72 hours of ending Ranger training]

   Digit-Symbol Coding

6. Change (vs. baseline) in physiological resiliency [Time Frame: baseline, week 14, week 16, within 72 hours of ending Ranger training]

   Composite score from Patient Reported Outcomes Measurement Information System (PROMIS), v. 1.0 for Applied Cognition, Fatigue, & Sleep-related impairment

Secondary Outcome Measures :

1. Change (vs. baseline) in Working Memory [Time Frame: baseline, week 14, week 16,within 72 hours of ending Ranger training]

   Figural Continuous Paired Associates Test (FCPAT; Turner, Drummond, Salamat, & Brown 2007)

2. Anxiety as a Measure of Psychological Functioning [Time Frame: baseline, week 14, week 16, within 72 hours of ending Ranger training]

   Anxiety: Spielberger State / Trait Anxiety Inventory (STAI; Speilberger 1983)

3. Stress Response [Time Frame: within 72 hours of ending Ranger training]

   Peritraumatic Distress Inventory (PDI; Brunet et al. 2001)

4. Mood State as a measure of Psychological Functioning [Time Frame: baseline, week 14, week 16, within 72 hours of ending Ranger training]

   Mood State:Profile of Mood States - Bipolar (POMS-Bipolar;Lohr and McNair 1988)

5. Change (vs. baseline) in Reasoning [Time Frame: baseline, week 14, week 16, within 72 hours of ending Ranger training]

   Grammatical Reasoning (Lieberman, Caruso, Niro, & Bathalon 2006)

6. Change (vs. baseline) in Visual Attention [Time Frame: baseline, week 14, week 16, within 72 hours of ending Ranger training]

   Four-Choice Visual Reaction Time Test (Lieberman, Caruso, Niro, & Bathalon 2006)

7. Change (vs. baseline) in Decision-Making [Time Frame: baseline, week 14, week 16, within 72 hours of ending Ranger training]

   Balloon Analogue Risk Task (BART: Lejuez et al., 2002)

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: Child, Adult, Senior
Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

1. Entry into IBOLC
2. No self-reported previous injuries that would impede potential physical performance success in IBOLC or Ranger training

Exclusion Criteria:

1. Infection, autoimmune disease, or fever of unknown origin
2. Coronary Heart Disease
3. History of seizures, except for febrile seizures during childhood
4. Known allergy to crustaceans (shellfish) or nuts
5. Vegetarian food preference.
6. Regular use of omega-3 containing supplements within the last 3 months.
7. Reported consumption of seafood three or more times per week within the last three months.
8. Carry diagnosis of Type I or Type II diabetes
9. Take hypoglycemic agents
10. Refusal to stop taking specific dietary supplements pertinent to the study with the exception of standard multivitamins during study participation
11. For women, pregnancy or intention to become pregnant during the potential study duration

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02908932***

Locations

United States, Georgia

US **Army**, Fort Benning
Fort Benning, Georgia, United States, 31905

United States, Maryland

National Institutes of Health
Bethesda, Maryland, United States, 20892

United States, South Carolina

Medical University of South Carolina
Charleston, South Carolina, United States, 29425

Sponsors and Collaborators

Medical University of South Carolina

National Institutes of Health (NIH)

Aker Biomarine Antarctic AS

Investigators

Principal Investigator: Bernadette P Marriott, PhD Medical University of South Carolina

More Information

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Publications:

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Responsible Party:	Bernadette Marriott, Professor, Medical University of South Carolina
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Other Study ID Numbers:	Pro00051532
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Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No