

## **Study design and methodology of a randomized controlled trial for enhancing neuropsychological facets of resiliency in US Army Officers preparing for Ranger School.**

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### Methodological Issue:

Psychophysiological resiliency is critical for individuals working in stressful environments where the ability to manage emotions, maintain situational awareness, and respond quickly and accurately for extended durations is required. Such occupations include law officers, paramedics, trauma physicians, professional athletes, and pilots. The US Army seeks to enhance resiliency in soldiers, in particular, prior to deployment. We are completing a double-blind RCT of omega-3 supplementation on resiliency in officers preparing for Ranger school. This presentation outlines key design elements, including outcome measures, endogenous stressors, monitoring adherence, and data quality assurance.

### Introduction:

The Ranger Resilience and Improved Performance on Phospholipid-Bound Omega-3s (RRIPP-3) study was crafted to evaluate effect of omega-3 fatty acid (n3) supplementation on aspects of neuropsychological functioning relevant to battlefield performance. Briefly, participants were US Army Officers entering Infantry Basic Officer Leadership Course (IBOLC), an ~18-week intensive program combining classroom instruction, field training, and physical fitness. All expressed intention to complete Ranger school, volunteered, and provided informed consent. Treatment consisted of 2.2 g/d n3 from 8 capsules of krill oil; placebo was an equivalent amount of macadamia nut oil. Participants took supplements from IBOLC entry through Ranger entry (22-40 weeks).

### Methods:

Outcome measure: Success vs. failure in Ranger could not serve as primary outcome due to numerous uncontrollable factors (e.g., season, illness, injury, deployments, military operations, etc.), and lack of data to estimate effect size. Accordingly, cognitive functions identified by Army leadership as essential to battlefield performance, including attention, vigilance, response inhibition, spatial working memory, verbal reasoning, and risky decision-making were measured by a

computerized test battery. Anxiety, mood, sleep, and resiliency were assessed with validated questionnaires.

Power Analysis: The study was powered based on prior research showing specific benefit of n3 on response inhibition in healthy young adults.

Stressor: An intense 3-day competitive field maneuver exercise, Leader Forge, is completed week 14 of IBOLC. Leader Forge simulates combat and involves significant stress, physical exertion, and sleep deprivation.

Assessment schedule: Participants completed neuropsychological testing at baseline, before Leader Forge while rested, and immediately after Leader Forge while stressed.

Monitoring Adherence: Erythrocyte lipid profiles were measured at baseline, 8 weeks, pre and post-Leader Forge, pre-Ranger entry, and post-Ranger. This ensured adherence and monitored response to both treatment and placebo.

Quality Assurance: Cognitive data were systematically screened for insufficient effort.

#### Results:

A sample of 555 participants was enrolled from 12 IBOLC classes beginning in August 2016 through January 2018. The blind will be broken in December 2018 when the final participants complete Ranger school. Examination of central tendency in cognitive and psychological measures at baseline shows adequate variability. Correlation matrices indicated tests measured unique facets of cognition. Data from cognitive tests were screened for validity; rates of insufficient effort varied between 0 and 19 percent.

#### Conclusions:

Evaluating an intervention to enhance resiliency in healthy adults presents unique challenges in RCT design. Baseline data collected in our study are promising, and aspects of our approach may have relevance for RCTs to boost resiliency or enhance neuropsychological functioning with other interventions and populations.

#### Disclosures:

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