Impact of Astaxanthin on Cognition in Recreationally Active Females
Informed Consent
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University of North Alabama

Human Subject Committee (HSC)

Informed Consent Form

Title: The Impact of Astaxanthin on Muscle Soreness and Cognition in Recreationally Active Females
Principal Investigator: Gaven Barker, Department of Kinesiology
Date: Click here to enter a date.

PURPOSE OF RESEARCH STUDY:

- This research study aims to determine if astaxanthin supplementation (12 mg/day) affects the perceived sensation of muscle soreness and cognitive performance following mental fatigue.
- We anticipate that approximately 24 people will participate in this study.

Inclusion Criteria:

- You must be 18-39 years of age.
- You must meet the American College of Sports Medicine low risk guidelines
    - This includes but is not limited to being free of pain during exercise, shortness of breath, dizziness, tachycardia (ie., heart skipping beats), heart murmurs, currently taking a cardiovascular prescription medication (eg., statins), or having Type 1 or 2 Diabetes.
- You must be actively training in some form of resistance training at least 2x per week.
- You must not have any known medical condition that would contradict your participation in this study.
- You must have a regular menstrual cycle.

- Do you meet all of the criteria listed above? (Circle one) YES NO

- If circled NO above, please do not continue. Initials _____ Date _____

PROCEDURES:

- Your anthropometric measurements (height, weight, and body fat percentage) will be assessed during the first session.
- You will either receive astaxanthin (12 mg/kg per day) and a placebo supplement, once a day for a total of 7 days.
- You will participate in a total of 4 sessions. Sessions 1 & 2 will be completed 48-hours a

part, followed by 4-weeks of supplementation, and then sessions 3 & 4 which will be 48-hours a part.

- Sessions 1 & 3 will consist of estimating a 3-6RM, followed by 5 sets of 10 reps of leg press at 60% of 1RM with a 3-second count lower using metronome. There will be 3-mintues of recovery in-between sets.
- Sessions 2 & 4 will consist of 3 sets (65%, 70%, 75%) of leg press to failure. There will be 3-mintues of recovery in-between sets.
- You will complete a food and training log on the free MyFitnessPal app.
- You will fill out a soreness and recovery questionnaire before and after sessions 1 & 3 as well as 24, 36, & 48 hours after sessions 1 & 3.
- You will complete a series of familiarizations with the cognitive assessment software on an iPad. You'll complete 3 different series of cognitive assessments, with each battery of tests lasting ~11 minutes.
- For experimental trials, you will complete two rounds of the cognitive battery with either a 15-minute mental fatigue task or a video control in between the two rounds.
- A lipid panel will be collected using a small finger prick before and after supplementation.
- You are to arrive well-hydrated and fasted for at least four hours to each trial. Each trial is separated by 24 hours.
- When you finish the trials 4 and 8, you'll provide a 24-hour food log to the researcher, who will then ask you to replicate this same diet for the remainder trials each day before you come in for testing.
- You must refrain from all physical activity the 24 hours before testing, and you must refrain from alcohol for 48 hours before testing and caffeine on the day of testing. A list of dietary supplements will be provided for you to avoid during the duration of the study.
- It is important for you to get a normal night of sleep since sleep can affect cognition. If you had a poor night of sleep, please inform us so we can reschedule you for another day.

RISKS/DISCOMFORTS:

- The risks associated with participation in this study are no greater than those encountered in a normal exercise.
- The foreseeable physiological risks for participation in the current study will be muscle soreness and all other potential risks and discomfort associated with intense physical exertion (heavy breathing, elevated heart rate, extreme fatigue, etc.) While it is extremely unlikely, it is possible that you could experience a heart attack, stroke or other cardiovascular event as a result of participating in this project.
- The American College of Sports Medicine (ACSM) outlines the likelihood of risk for adverse events during exercise participation:
- "Although the relative risk of sudden cardiac death and a heart attack are higher during vigorous physical activity vs. rest the risk of these events is very low. This translates to 1 death to approximately 2,897,057 exercise hours."

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW:

- It is your right to withdraw from the study at any point for any reason. Withdrawing from the study will not adversely affect you in any manner. You should also understand that the investigator might require you to withdraw from the study. If you wish to withdraw at any

point during the study please contact the Principle Investigator, Gaven Barker gbarker@una.edu.

CIRCUMSTANCES THAT COULD LEAD US TO END YOUR PARTICIPATION:

- Under certain circumstances we may decide to end your participation before you have completed the study. Specifically, we may stop your participation under the following circumstances: an injury resulting in no longer being able to complete the study, and other health concerns developed by you.

ALTERNATIVES TO PARTICIPATION:

There are no alternatives to participation**.**

CONFIDENTIALITY:

- Information collected through this study may be published in a professional journal and/or presented at a professional meeting. However, your name or your specific information will in no way be identifiable.
- Each set of data will have a random numerical identifier in the top right corner. Upon completion of the project, all identifying information linking individuals with any data will be removed. The data will be kept in the Kinesiology department in the GA office. Data will be retained in the case that future analyses and/or presentations are possible. A master list will be kept and available only to the PI. Data will be kept by the PI with no identifiers on the actual data sheets. It will be kept indefinitely for any further analysis. Any data stored on a flash drive will be password protected and only accessible to investigators. Data will be **stored** in the locked office of Gaven Barker. Data will only be available to **members of this research team**.

COSTS

- There are no costs to participate

COMPENSATION:

- This project is part of a larger dissertation. By successfully completing all parts of the dissertation, participants will be compensated $50.

IF YOU HAVE QUESTIONS OR CONCERNS:

You can ask questions about this research study now or at any time during the study, by talking to the researcher(s) working with you or by emailing Gaven Barker (gbarker@una.edu).

If you have questions about your rights as a research participant or feel that you have not been treated fairly, please call the Office of Sponsored Programs (256) 765-4523.

IF YOU ARE HARMED BY PARTICIPATING IN THE STUDY:

- If you feel that you have been harmed in any way by participating in this study, please call Dr. Lauren Killen, Associate Professor in Kinesiology and Human Performance Lab director at 256-765-4774. Please also notify the Office of Sponsored Programs (256) 765-4523.
- This study does not have any program for compensating or treating you for harm you may suffer as a result of your participation.

SIGNATURES

WHAT YOUR SIGNATURE MEANS:

Your signature below means that you understand the information in this consent form. Your signature also means that you agree to participate in the study.
By signing this consent form, you have not waived any legal rights you otherwise would have as a participant in a research study.

Participant's Signature Click here to enter text.
Date Click here to enter a date.

Signature of Person Obtaining Consent
(Investigator or HSC Approved Designee)

Date Click here to enter a date.