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Can a nutritional omega-3 fatty acid formulation improve brain health in NCAA football athletes over the course of a season?

Submission date
04/10/2019

Recruitment status
No longer recruiting

Registration date
15/10/2019

Overall study status
Completed

Last Edited
29/09/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Recognizing the potential neuroprotective effect of omega-3 fatty acids administration was the foundation of the current study. The typical American diet is scarce in omega-3 fatty acids with an estimated combined intake of about 100 mg/day. As such, we sought to examine the effect of supplemental omega-3 fatty acids on changes in a surrogate biological marker of neurological injury, serum Nf-L, over the course of a competitive season in American football athletes. We hypothesized that those American football athletes supplemented with omega-3 fatty acids throughout the duration of their competitive season would exhibit lower levels of serum Nf-L throughout the course of the season compared to their counterparts not supplementing with omega-3 fatty acids.

Who can participate?
NCAA players from the selected teams

What does the study involve?
American football exposes athletes to subconcussive repetitive head impacts (RHI). Subconcussive RHI elevate serum neurofilament light (Nf-L), a biomarker of axonal injury. This study involves if Omega-3 fatty acid supplementation in American football athletes blunt the symptoms of RHI through decreasing Nf-L biomarker

What are the possible benefits and risks of participating?
Since this study does not impact the nature of American Football, there is no additional risk to be expected. Potential benefits could be that Omega-3 fatty acids improve RHI symptoms

Where is the study run from?
1. Texas Christian University, USA
2. Wisconsin La Crosse University, USA

When is the study starting and how long is it expected to run for?
May 2016 to December 2017

Who is funding the study?
Struct Nutrition, LLC, USA

Who is the main contact?
Dr Jonathan Oliver
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Contact information

Type(s)
Scientific

Contact name
Dr Jonathan Oliver

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Mindset2016-001-298

Study information

Scientific Title
Effect of a nutritional, proprietary omega-3 fatty acid formulation on serum Nf-L levels in NCAA football athletes over the course of a season

Study objectives
NCAA college football athletes supplemented with omega-3 fatty acids throughout the duration of their competitive season would exhibit lower levels of serum Nf-L throughout the course of the season compared to their counterparts not supplementing with omega-3 fatty acids.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 19/05/2016, TCU Institutional Review Board (Office of Research, Sadler Hall, Suite 3101
Fort Worth, Texas 76129; research@tcu.edu; +1 817 257 7104), ref: 1605-053-1605

Study design
Multicenter non-randomized interventional study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Nutritional invervention study in a healthy, athletic, male population

Interventions
Multicenter, non-randomized, interventional study design examining the effect of daily supplementation with highly bioavailable omega-3 fatty acids on plasma fatty acids levels, and peripheral levels of Nf-L over the course of an NCAA American football season. This study recruited participants from two geographically distinct NCAA American football teams. The team that received supplementation was a NCAA Division I team, while the control team competed at the NCAA Division III level.

One team received treatment of omega-3 FA and the other team was control and received placebo. Blood was sampled at specific times before, during and after the during pre-season and regular season that coincided with changes in sport intensity, physical contact, and likely changes in incidence and severity of head impacts.

Intervention Type
Supplement

Primary outcome(s)
Serum Nf-L levels.
Blood was obtained from participants at various time points chosen to coincide with changes in practice intensity, the amount of physical contact, and the number and magnitude of head impacts

Key secondary outcome(s))
Plasma fatty acids levels sampled as above

Completion date
15/12/2017

Eligibility

Key inclusion criteria
Players of NCAA Division I and III teams

Participant type(s)

Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
66

Key exclusion criteria
1.Younger than 18 years of age
2. The use of long-term anti-inflammatory therapy (≥ 20 days)
3. The use of anti-hypertensive medications
4. The use of medications known to affect blood lipids
5. The consumption of fish oil or omega-3 FA supplementation
6. Self-reported consumption of more than two servings of fish per week
7. Athletes who were injured (including concussive injuries), became ill, were unable to participate in regularly scheduled conditioning, practice, or competitions, or those who did not meet the threshold compliance standards for daily supplementation (≥ 80%) were excluded.

Date of first enrolment
31/05/2016

Date of final enrolment
15/09/2016

Locations

Countries of recruitment
United States of America

Study participating centre
Texas Christian University (TCU)
2800 S University Dr
Fort Worth, TX
United States of America
76129

Study participating centre
University of Wisconsin - La Crosse
1725 State St
La Crosse, WI

United States of America
54601

Sponsor information

Organisation
Struct Nutrition, LLC

Funder(s)

Funder type
Industry

Funder Name
Struct Nutrition, LLC

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	control group results	29/05/2018	07/10/2019	Yes	No
Results article	results	27/09/2021	29/09/2021	Yes	No
Abstract results	conference abstract	01/05/2018	07/10/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes