ISRCTN96342002 https://doi.org/10.1186/ISRCTN96342002

Improving physical fitness and cognition with a nutritional intervention

Submission date
22/07/2020

Recruitment status
No longer recruiting

Registration date
28/07/2020

Overall study status
Completed

Last Edited
18/08/2023

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
This study aims to enhance and optimize human fitness and cognitive performance in Air Force airmen through a multimodal physical fitness and nutritional supplement intervention.

Who can participate?
Active Air Force airmen, healthy men and women aged 18-45

What does the study involve?
Participants will receive either a nutritional supplement plus physical fitness training or a placebo (dummy supplement) plus physical fitness training. Fitness measures, cognitive outcomes and blood samples will be collected before and after the intervention (after 12 weeks).

What are the possible benefits and risks of participating?
Benefits include enhanced physical fitness and improved cognitive functioning. Risks are minimal and, for the fitness intervention include normal risks due to strength and resistance training and the supplement is not believed to entail risks as it only includes over the counter supplements that do not exceed recommended daily allowances and that have science-backed evidence for their safety and improving health and/or cognition.

Where is the study run from?
The Air Force Research Lab, the 711th Human Performance Wing, in Dayton, OH (USA)

When is the study starting and how long is it expected to run for?
March 2015 to August 2018

Who is funding the study?
Abbott Nutrition, through the Center for Nutrition, Learning and Memory at the University of Illinois who sponsored the project

Who is the main contact?
Aron Barbey
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ANGC1402

Study information

Scientific Title
Enhanced physical and cognitive performance in active duty airmen: evidence from a randomized multimodal physical fitness and nutritional intervention

Study objectives
A multi-modal nutritional beverage plus physical fitness training will improve cognitive and fitness more than a placebo beverage paired with physical fitness training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2015, Department of the Air Force, Air Force Research Laboratory, Wright-Patterson Air Force Base Institutional Review Board (1864 4th St, Wright-Patterson AFB, OH 45433, USA; +1 (0)937 656 5437; alex.trigo.2@us.af.mil); ref: FWR20150132H

Study design
Single-center interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not applicable (study is already completed)

Health condition(s) or problem(s) studied
Optimization of human performance in United States Air Force airmen

Interventions
The intervention is a two-arm trial, with one group receiving a nutritional beverage and physical fitness intervention and the other group receiving a placebo beverage and the same physical fitness intervention. Participants are block randomized across seven blocks of the study (each block has about 25 participants), with blocks alternating between the nutritional and placebo beverages. The intervention lasts 12 weeks. Beverages are liquid, 8-ounce bottles manufactured by Abbott Nutrition (Columbus, OH) and participants consume two beverages each day for 12 weeks. The exercise intervention occurs in the lab 5 days a week and includes strength, endurance, aerobic and interval training and all participants are guided in proper form and observed by athletic trainers.

Intervention Type
Supplement

Primary outcome measure
Primary fitness measures, all measured at both pre- and post-intervention (12 weeks):
R/L means an average of both the Right and Left side of the body
1. Abdominal circumference (inches), measured using a tape measure
2. Sled Push & Pull R/L (seconds) measured by pushing (15 yds) and pulling (15 yds) a 140 lb sled twice
3. Rotation Smash Ball R/L (inches), measured distance thrown of a heavy medicine ball
4. Weight (pounds), measured with a scale
5. Wingate Upper Body (Watts/kg) measured using an arm crank with fixed resistance for 30 seconds
6. Body fat (% body weight) measured using DEXA overall and segmented body composition
7. Modified Illinois Agility (seconds) measured by quickly completing a weaving running course
8. Pull-ups (1 minute to complete as many as possible)
9. Push-ups (1 minute to complete as many as possible)
10. Sit-ups (1 minute to complete as many as possible)
11. Standing long jump (inches), best of three jumps from a 2-foot static position
12. VO2 Max (mL/kg/min), oxygen consumption measured on treadmill
13. Wingate Lower Body (Watts/kg), bicycle pedal with fixed resistance for 30 seconds
14. Lateral Bridge R/L (seconds), isometric hold for 30 seconds
15. Lower Y Balance Test R/L (seconds), multi-planar movement to test lower body balance
16. Supine Bridge R/L (seconds), isometric hold until exhaustion
17. Upper Y Balance Test R/L (seconds), multi-planar movement to test upper body balance
18. Diastolic blood pressure (mmHg), average of three readings taken at rest
19. Systolic blood pressure (mmHg), average of three readings taken at rest
20. Maximum heart rate (beats/minute), measured with electronic monitor
21. Resting heart rate (beats/minute, measured with electronic monitor
22. Lean muscle mass (pounds), measured with DEXA overall and segmented body composition

Primary cognitive measures, all measured at both pre- and post-intervention (12 weeks):
1. Immediate Free Recall Words (from previously seen words, recall as many as possible)
2. Immediate Free Recall Pictures (from previously seen pictures, recall as many as possible)
3. Keep Track (of the last instance of a given category)
4. Paired Associates Immediate Recall (given one word from a pair already seen, recall the other word in the pair immediately)
5. Paired Associates Delayed Recall (given one word from a pair already seen, recall the other word in the pair after a delay)
6. Number Series (identify the pattern in a sequence of numbers)
7. Letter Series (identify the pattern in a sequence of letters)
8. Symmetry Span (hold items in memory while checking symmetry in a matrix)
9. Rotation Span (hold items in memory while rotating letters)
10. Stroop Task (determine if the font color and word match)
11. Symbol Digit Modalities (use a lookup table to translate symbols into numbers quick as possible)

Secondary outcome measures
All measured at both pre- and post-intervention (12 weeks):
1. Cortisol (ug/dL) measured using blood test
2. Ferritin (ng/mL) measured using blood test

3. Folate (ng/mL) measured using blood test
4. High-Density Lipoprotein (mg/dL) measured using blood test
5. Low-Density Lipoprotein (mg/dL) measured using blood test
6. Triglycerides (mg/dL) measured using blood test
7. Vitamin B12 (pg/mL) measured using blood test
8 Saturated Fatty Acids (mol %) measured using blood test
9. Monounsaturated Fatty Acids (mol %) measured using blood test
10. Omega-3 PUFAs (mol %) measured using blood test
11. Omega-6 PUFAs (mol %) measured using blood test
12. Trans Fatty Acids (mol %) measured using blood test
13. Lutein density, measured in fovea and parafovea of eye using MPOD device

Overall study start date
15/03/2015

Completion date
15/08/2018

Eligibility

Key inclusion criteria
1. Active-duty Air Force status
2. Commit to study participation for 14 consecutive weeks
3. At least 18 but no older than 45 to minimize the risk of physical injury or cardiovascular occurrence due to the study's required fitness activity

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
203

Key exclusion criteria
Study participants shall not:
1. Have a Department of Defense medical profile for mental and/or physical function limitation nor have a pregnancy profile
2. Be currently be taking prescription blood pressure medication
3. Take herbal dietary supplements, performance supplements or any other substance that

contained ingredients that might affect cardiovascular response with exercise one week before study participation begins
4. Have a musculoskeletal injury that would limit their ability to engage in heavy resistance training and aerobic exercise
5. Have cardiovascular or respiratory disease that would limit their ability to engage in heavy resistance training and aerobic exercise

Date of first enrolment
15/01/2016

Date of final enrolment
15/05/2018

Locations

Countries of recruitment
United States of America

Study participating centre
711th Human Performance Wing
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Wright-Patterson AFB, OH
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Sponsor information

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ROR
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Funder(s)

Funder type
Industry

Funder Name
Abbott Nutrition

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
The study has been provisionally accepted at Scientific Reports, pending the registration of this trial in this database.

Intention to publish date
25/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as this data was collected through the United States Air Force, so is considered CUI (controlled unclassified information).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/10/2020	18/08/2023	Yes	No