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Influence of amino acids on muscle preservation and functional improvements in obese, elderly adults

Submission date
11/02/2021

Recruitment status
No longer recruiting

Registration date
12/02/2021

Overall study status
Completed

Last Edited
03/10/2022

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
Muscle atrophy (when muscles waste away) and obesity increase the risk of disability and death in the elderly. Recent studies have demonstrated that certain essential amino acids that make up protein may help prevent muscle loss and even improve overall metabolism. The aim of this study is to compare the influence of two different types of meal replacements (ie., one with individual amino acids and one with protein alone) consumed once a day on the preservation of muscle and reduction of excess adipose (fat) tissue in older, obese individuals.

Who can participate?
Individuals from all racial, ethnic and/or cultural backgrounds between the ages of 60-85 with a body mass index of 26-40 kg/m²

What does the study involve?
Participants are randomly assigned to consume an Experimental Meal Replacement or Optifast once a day for 4 weeks. They are asked to visit the clinic for measurement of muscle and fat, physical function, and metabolic risk factors like cholesterol before and immediately following supplementation.

What are the possible benefits and risks of participating?
If proven to be effective, the Experimental Meal Replacement may help older individuals maintain or even improve their functional independence while reducing the risk of metabolic diseases. There were no anticipated risks to participants.

Where is the study run from?
University of Alaska Fairbanks (USA)

When is the study starting and how long is it expected to run for?
August 2017 to December 2018

Who is funding the study?
Essential Blends, LLC (USA)

Who is the main contact?
Robert H. Coker, PhD
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1427567-13

Study information

Scientific Title
Once/day provision of essential amino acid enriched meal replacement improves body composition and physical function in obese elderly: a randomized controlled trial

Acronym
EAAIMF

Study objectives

It is hypothesized that an essential amino acid-enriched meal replacement (EMR) would promote improvements in body composition, skeletal muscle, intrahepatic lipid and physical function compared to an isocaloric commercially available meal replacement (ie., Optifast®) in obese elderly individuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/09/2017, UAF Institutional Review Board (UAF Institutional Review Board, 909 Koyukuk Drive, Suite 212, PO Box 757270, Fairbanks, AK 99775-7270, USA; +1 (0)907 474 7800; uaf-irb@alaska.edu), ref: 986801-17

Study design
Double-blind parallel 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 available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Body composition, skeletal muscle, intrahepatic lipid and physical function in obese elderly individuals

Interventions
A computerized random number generator is used for group assignment. An individual not affiliated with this study or the academic program is responsible for blinding of the meal replacements. Individuals are randomly assigned to consume an Experimental Meal Replacement or Optifast once a day for 4 weeks.

Intervention Type
Supplement

Primary outcome measure
Measured during pre-supplementation and post-supplementation visits 4 weeks apart:
1. Body weight and height measured using an electronic scale/stadiometer (Health-O-Meter, St. McCook, IL, USA)
2. Body composition measured using a dual-energy x-ray absorptiometry scanner (General Electric Lunar iDXA, Madison, WI)

3. Thigh skeletal muscle cross-sectional area and intrahepatic lipid measured using a molecular resonance imaging/spectroscopy (Toshiba Excelart/Vantage 1.5 T MRI/MRS imaging system, Canon, Ōtawara, Tochigi, Japan), muscle cross-sectional area further quantified using Osirix (Geneva, Switzerland)
4. Physical function parameters including measurements of grip strength, floor transfer time and walking distance/speed

Secondary outcome measures
Measured during pre-supplementation and post-supplementation visits 4 weeks apart:
1. Blood samples collected and analyzed for metabolic, lipid and hepatic blood panels by LabCorp (1626 30th Avenue, Fairbanks, AK)
2. Bone mineral density measured using a dual-energy x-ray absorptiometry scanner (General Electric Lunar iDXA, Madison, WI)

Overall study start date
28/08/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Individuals from all racial, ethnic and/or cultural backgrounds
2. Between the ages of 60-85 years old
3. Body mass index of 26-40 kg/m²

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
30

Total final enrolment
37

Key exclusion criteria
1. Individuals with a pacemaker or other implanted metal device or object
2. Previously diagnosed with insulin-dependent diabetes, active cancer or malignancy, or a chronic inflammatory condition
3. Individuals taking medications, supplements or corticosteroids that might influence metabolism or corticosteroids
4. Any individual with a disease or condition that places them at risk or harm to themselves or others

Date of first enrolment
07/09/2017

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
United States of America

Study participating centre
University of Alaska Fairbanks
PO Box 757000
2140 Koyukuk Drive
Fairbanks
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Sponsor information

Organisation
Essential Blends, LLC

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Essential Blends, LLC

Results and Publications

Publication and dissemination plan
Submission of data to the Journal, Nutrients. Data were presented previously to the annual meeting of The Obesity Society

Intention to publish date
01/03/2021

Individual participant data (IPD) sharing plan
The de-identified datasets generated during and/or analysed during the current study are/will be available upon request from Robert H. Coker, PhD (rcoker@alaska.edu).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		22/01/2021	12/05/2022	No	No
Results article		01/10/2022	03/10/2022	Yes	No