

# Perspective of different forms of essential amino acid supplements and effects on appetite in older men and women

<b>Submission date</b> 23/06/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 01/07/2016	<b>Overall study status</b> Completed	
<b>Last Edited</b> 17/12/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

### Background and study aims

The purpose of the study is to understand the preferences of elderly people when taking nutritional supplements rich in essential amino acids in different forms, and to see how these supplements affect their appetite. Through finding this out the researchers hope to ensure beneficial supplements can be designed in a form people will like. The study involves two experiments to investigate the effects of these supplements on appetite measures in the form of a nutritional Bar and Gel.

### Who can participate?

Healthy volunteers aged between 60-80 years old.

### What does the study involve?

There are two arms to the study. Each participant can choose whether to take part in both arms or just one. If they choose to take part in one arm, they can also decide which arm they wish to take part in. For arm 1, each participant attends the trial participating centre on three separate days. On each day, they take one of three tests. They do all three tests, on separate days, in a random order. The first test involves eating a nutritional bar rich in essential amino acids and then resting an hour before eating a breakfast of porridge. The second test involves eating a nutritional gel rich in essential amino acids and testing an hour before eating a breakfast of porridge. The third test involves not taking any nutritional supplements and just eating the porridge. All participants give blood samples throughout the tests and are asked to fill in questionnaires in the hour between eating the supplements and having breakfast. For arm 2, the participants again attend three sessions in a random order and eat nutritional supplements and /or breakfast as before. However, this time, those participants taking the supplements eat the breakfast at the same time, rather than waiting an hour and no blood samples are taken.

### What are the possible benefits and risks of participating?

It is unlikely that participants will experience any long-term physiological benefits from taking part in this study. Blood samples will be taken by trained researchers using aseptic techniques and in accordance with local and national guidelines to minimise any risks.. Blood sample

preparation will be separated from the testing area and participants to prevent cross-contamination and reduce the potential of any accidents. Deterioration of kidney function as result of eating a lot of protein can happen over a number of years, however only if the person already has kidney problems.. Due to the acute nature of the supplementation in this study even if a person is suffering from kidney problems the risk of making it worse by taking part in this study is very small.

Where is the study run from?

Leeds Beckett University (Carnegie Research Institute) and Higher Education Innovation Funding (HEIF) has been secured for this study.

When is study starting and how long is it expected to run for?

January 2015 to March 2016

Who is funding the study?

1. Leeds Beckett University
2. Higher Education Innovation Funding (HEIF)

Who is the main contact?

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## Contact information

**Type(s)**

Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

1

# Study information

## Scientific Title

The impact of essential amino acid supplements enriched with L-leucine on appetite and energy intake in elderly: a randomised, crossover trial

## Study objectives

It is expected that essential amino acid based nutritional supplements enriched with L-leucine will not compromise appetite and energy intake in healthy elderly people.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Leeds Beckett Local Research Ethics Committee, 18/02/2015

## Study design

Randomised, crossover trial design

## Primary study design

Interventional

## Secondary study design

Randomised cross over trial

## Study setting(s)

Home

## Study type(s)

Treatment

## Participant information sheet

See additional files

## Health condition(s) or problem(s) studied

Nutritional supplements

## Interventions

There are two arms to the study. Each participant can choose whether to take part in both arms or just one. If they choose to take part in one arm, they can also decide which arm they wish to take part in.

### Arm 1:

Each participant attends the trial participating centre on three separate days. on each day, they take one of three tests. They do all three tests, on separate days, in a random order. These tests are:

1. Consuming an essential amino acids based nutritional bar enriched with L-leucine: oral administration of a 37.5 g nutrition bar (134.5 kcal) containing 7.5 g of essential amino acids (40% L-Leucine)
2. Consuming an essential amino acids based nutritional gel enriched with L-leucine: oral

administration of a 50 ml nutrition gel (113.9 kcal) containing 7.5 g of essential amino acids (40% L-Leucine)

3. No consumption of an essential amino acids based supplement

All participants then wait for an hour before consuming an ad-lib breakfast (standardised breakfast of porridge). During this hour, they are asked to complete questionnaires on hunger and opinion of the supplement consumed (if any).

At the start of each of the three sessions, a phlebotomist inserts a cannula into a vein of each participant. Blood samples are taken at a number of occasions throughout the testing session for later hormonal response analysis.

Arm 2:

This arm of the study is very similar to arm 1. There are again three tests that all participants take part in over three days in a random order. These tests are almost identical to those of arm 1. However, this time the ad lib breakfast is eaten at the same time as the amino acid supplements are consumed (if any). Participants are also not required to give any blood samples.

## **Intervention Type**

Supplement

## **Primary outcome measure**

Arm 1:

1. Composite appetite ratings using visual analogue scales, taken at baseline immediately post-consumption and every 15 min until post consumption of the ad lib breakfast
2. Energy intake, measured via the quantity of breakfast consumed

Arm 2:

Composite appetite ratings using visual analogue scales before and after the ad lib breakfast

## **Secondary outcome measures**

Arm 1:

1. Gut hormone concentrations from blood samples, via plate reader and ELISA. Measurements to be taken at baseline immediately post-consumption and every 30 min until the ad lib breakfast
2. Plasma concentration of essential amino acids from blood samples, via gas chromatography mass spectrometry. Measurements to be taken at baseline immediately post-consumption and every 30 min until the ad lib breakfast
3. Palatability, measured using visual analogue scales. Measurements to be taken at baseline immediately post-consumption and every 15 min until post consumption of the ad lib breakfast

Arm 2:

Palatability, measured using visual analogue scales before and after the ad lib breakfast

## **Overall study start date**

01/01/2015

## **Completion date**

01/03/2016

## **Eligibility**

**Key inclusion criteria**

1. Male and female adults aged between 60 and 80
2. Free from vascular and metabolic disease

**Participant type(s)**

Healthy volunteer

**Age group**

Senior

**Sex**

Both

**Target number of participants**

10

**Total final enrolment**

11

**Key exclusion criteria**

1. Smoking
2. Use of oestrogens within the previous three months
3. Lactose intolerant

**Date of first enrolment**

01/07/2015

**Date of final enrolment**

01/10/2015

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Carnegie Faculty, Leeds Beckett University**

Room 211 Fairfax Hall

Headingley Campus

Leeds

United Kingdom

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**Sponsor information**

**Organisation**

Leeds Beckett University

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**Sponsor type**

University/education

**ROR**

<https://ror.org/02xsh5r57>

**Funder(s)****Funder type**

Research council

**Funder Name**

Higher Education Innovation Funding (HEIF)

**Funder Name**

Leeds Beckett University

**Alternative Name(s)**

Leeds Beckett

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

# Results and Publications

## Publication and dissemination plan

1. Preliminary results ESPEN September 2016
2. Publication November 2016 (One article on females, and a case study article on men)

## Intention to publish date

30/11/2016

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		30/06/2016	13/07/2016	No	Yes
<a href="#">Results article</a>	results	28/11/2017	17/12/2019	Yes	No