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Investigating the effects of an eight-week intervention with beetroot on cognitive function and gut health

Submission date
18/03/2019

Recruitment status
No longer recruiting

Registration date
03/04/2019

Overall study status
Completed

Last Edited
20/01/2020

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
A reduction in blood flow to the brain is implicated in cognitive decline into older age, therefore the ability to improve blood perfusion to the brain in older adults is likely to impact on cognitive health in this population. Studies have demonstrated heightened regional blood perfusion in the brain following dietary nitrate consumption, which is present in beetroot and other vegetables. Dietary nitrate is converted to nitric oxide in the body, which helps to widen blood vessels in the body. Researchers have demonstrated acute improvements in cognitive performance after a dose of dietary nitrate, however the longer-term effects are currently poorly understood. Furthermore, supplementing with vegetables such as beetroot may increase dietary fibre intake over a prolonged period, leading to changes in gut microbiota. This can have a positive effect on gut health. This research proposal aims to investigate the link between dietary nitrate and cognitive performance and functional capacity in older adults, and assess the effect of dietary supplementation with beetroot on gut microbiota in this population. The main aim of this randomised, two-arm parallel trial is to assess cognitive test scores before and after intervention with beetroot in healthy older adults.

Who can participate?
Males and females between the ages of 60 and 80 years who are free of chronic illness.

What does the study involve?
Participants are randomly allocated to one of two interventions for a duration of eight weeks (150g beetroot plus one banana every second day or one banana every second day). Changes in cognitive test scores before, during and after the intervention period will be assessed. Participants will also be assessed for changes in gut microbiota and gut functioning, blood pressure, and functional capacity.

What are the possible benefits and risks of participating?
Participants may benefit from monetary reimbursement and from undergoing a body

composition analysis. There are minor risks. Beetroot consumption can cause beeturia, discolouration of the urine, which is harmless and perfectly normal. Blood sampling can cause some minor bruising.

Where is the study run from?
NU-Food Research Centre, Newcastle University.

When is the study starting and how long is it expected to run?
22/01/2018 to 23/07/2018.

Who is funding the study?
1. G's Fresh Ltd (UK)
2. Newcastle University (UK)

Who is the main contact?
Miss Tess Capper, t.capper2@newcastle.ac.uk
Professor Emma Stevenson, emma.stevenson@newcastle.ac.uk

Contact information

Type(s)
Public

Contact name
Miss Tess Capper

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Investigating the effects of an eight-week intervention with whole beetroot on cognitive function, functional capacity and gut health in older adults

Study objectives
1. Following beetroot consumption, cognitive test scores will improve
2. Following beetroot consumption, gut microbiota will show increased diversity and thus overall gut functioning will be improved

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/12/2017, Faculty of Medical Sciences Research Ethics Committee (Newcastle University Medical School, Framlington Place, Newcastle upon Tyne, NE2 4HH; 0191 208 6000; fmsethics@ncl.ac.uk)

Study design
Randomised two-armed open-label parallel intervention trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Digestive health

Interventions
Eight weeks of supplementation with 150g whole cooked beetroot every second day plus one banana OR one banana every second day as a control.

Participants were randomised online at randomization.com. Participants were allocated in a random order to receive one of two interventions above. Participants were asked to consume the intervention foods every second day for eight weeks and data was collected at baseline, at 5 weeks (midway) and at 9 weeks (end of study).

Intervention Type
Supplement

Primary outcome measure
Changes in cognitive test scores assessed by CogTrack online cognition programme at baseline, 5 and 9 weeks.

Secondary outcome measures
1. Functional capacity measured by timed-up-and-go, grip strength and spirometry at baseline, 5 and 9 weeks
2. Gut microbiome measured by bacterial composition and short-chain fatty acid production at baseline, 5 and 9 weeks
3. Blood pressure measured at baseline, 5 and 9 weeks

Overall study start date
05/02/2018

Completion date
24/05/2018

Eligibility

Key inclusion criteria
1. Male or female between the ages of 60 and 80 years
2. In good health i.e. free of chronic illness
3. BMI greater than 20.0kg/m2

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Vegetarianism
2. Vitamin or other dietary supplements – will be stopped for 4 weeks previous
3. Active cancer and any diagnosis of malignant cancer in the last 5 years
4. Excessive alcohol intake
5. Allergy or intolerance to the intervention food
6. Smoking
8. Epilepsy
9. Psychoactive medication
10. Mental health issues
11. Repetitive gastric reflux
12. Use of antibiotics in the last month
13. Drugs: corticosteroids, sildenafil, aspirin, anti-hypertensives (Ca2+ channel blockers, ACE inhibitors), diuretics, beta-blockers, antacids, anticoagulants, nitrate-derived agents, and anti-

cholinergics. Those on statins and hormone replacement therapy must have had a stable dose over the past 3 months and no changes to dose are to occur during the study

Date of first enrolment
03/01/2018

Date of final enrolment
05/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NU-Food Research Centre
School of Natural and Environmental Sciences
Agriculture Building
King's Road
Newcastle University
Newcastle upon Tyne
United Kingdom
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Sponsor information

Organisation
Newcastle University

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Industry

Funder Name
G's Fresh Ltd.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		16/01/2020	20/01/2020	No	No