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Effectiveness of a fortified drink at improving B vitamin biomarkers in older adults

Submission date
27/07/2021

Recruitment status
No longer recruiting

Registration date
28/07/2021

Overall study status
Completed

Last Edited
12/04/2022

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
Many older Irish adults are reported to have low B vitamin levels, while insufficient folate and vitamin B12 is much more common among non-consumers of fortified foods compared to regular consumers. Therefore, new strategies, including new foods targeted at older people, are needed to improve B vitamin levels.
Fortified drinks may improve vitamin status, but most previous studies that investigated the effect of fortified drinks on blood biomarkers were performed in children and included multiple vitamins and minerals to improve nutritional status in areas where deficiencies are common. A limited number of studies investigated the effect of B vitamin fortified drinks in improving B vitamin levels in older adults.
The aim of this study is to investigate the effectiveness of a novel drink product, fortified with folic acid, vitamin B12, vitamin B6 and riboflavin, in optimising B vitamin status in healthy older adults.

Who can participate?
Healthy older adults aged 50 years and over

What does the study involve?
Participants are randomly allocated to receive either a drink supplemented with B vitamins or a placebo (dummy) drink. Measurements include the following: blood samples to measure levels of vitamins B and D, weight, height, waist circumference, hip circumference, and blood pressure. Participants consume the drink once daily for 16 weeks and then measurements are repeated to see if there were any improvements.

What are the possible benefits and risks of participating?
There is no direct benefit to the participants. A small percentage of people feel faint or faint after giving blood. The researchers asked all participants to rest for a few minutes following the blood collection. Trained phlebotomists or health care individuals take the blood samples.

Where is the study run from?
University College Dublin (Ireland) and Ulster University (UK)

When is the study starting and how long is it expected to run for?
January 2017 to January 2020

Who is funding the study?
1. Department of Agriculture, Food and the Marine (Ireland)
2. Department of Agriculture, Environment and Rural Affairs (UK)
3. Smartfish AS (Norway)

Who is the main contact?
Prof. Lorraine Brennan
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
LS-18-60

Study information

Scientific Title
Effectiveness of a fortified drink at improving B vitamin biomarkers in older adults: a controlled intervention trial

Acronym
Opti-Age

Study objectives
A B vitamin-fortified drink is effective at improving B vitamin biomarkers in older Irish adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 28/06/2018, UCD Human Research Ethics Committee (Roebuck Castle, University College Dublin, Belfield, Dublin 4, Ireland; +353 (0)1 716 8767; hrec@ucd.ie), ref: LS-18-60-Brennan
2. Approved 28/06/2018, Ulster University Research Ethics Committee (Cromore Road, Coleraine, BT52 1SA, UK; +44 (0)28 9536 7124; cherp@ulster.ac.uk), ref: UU: REC/18/0033

Study design
Double-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Improving B vitamin biomarkers

Interventions
Participants are randomised by block randomisation to one of two groups:
1. Intervention group receive a 200 ml drink manufactured to contain 200 µg folic acid, 10 µg vitamin B12, 10 mg vitamin B6 and 5 mg riboflavin in the active version.
2. Control group receive a placebo drink in an identical presentation, isocaloric formulation which did not contain B vitamins.

Both the intervention and placebo drinks contain 10 µg vitamin D. Participants consume the drink once daily for 16 weeks.

Intervention Type
Supplement

Primary outcome(s)
1. B vitamin biomarker concentrations measured at baseline and 16 weeks:
1.1. Riboflavin measured by erythrocyte glutathione reductase activation coefficient assay (EGRac)
1.2. Serum folate concentrations measured by a microbiological assay based on a chloramphenicol-resistant strain of Lactobacillus casei
1.3. Serum vitamin B12 determined by microbiological assay using Lactobacillus leichmanni
1.4. Homocysteine measured by fluorescence polarisation assay

Key secondary outcome(s))
Measured at baseline and at 16 weeks:
1. Vitamin D measured as 25-hydroxyvitamin D using liquid chromatography – mass spectrometry (LC–MS)

2. Anthropometric variables: weight measured on a scale, BMI calculated, systolic and diastolic blood pressure measured using an Omron 705IT monitor

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. Free-living adults
2. Aged 50 years and over
3. Consumption of four or less portions of fortified food per week
4. Did not currently or had not in the previous 4 months consumed a supplement containing B vitamins

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
95

Key exclusion criteria
1. Diagnosis of coeliac disease, Crohn’s disease, ulcerative colitis, liver disease (NAFLD and hepatitis) or chronic obstructive pulmonary disease
2. Medication known to interfere with B vitamin metabolism
3. Women taking hormone replacement therapy, pregnant or lactating
4. Taking part in another research
5. Unable to give informed consent to take part

Date of first enrolment
29/06/2018

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Ireland

Study participating centre
University College Dublin
Belfield
Dublin 4
Dublin
Ireland
D04 V1W8

Study participating centre
Ulster University
Cromore Road
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
University College Dublin

ROR
https://ror.org/05m7pjf47

Organisation
University of Ulster

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name
Department of Agriculture, Food and the Marine, Ireland

Alternative Name(s)
An Roinn Talmhaíochta, Bia agus Mara, An Roinn Talmhaiochta Bia agus Mara, Department of Agriculture, Food and the Marine, agriculture_ie, Department of Agriculture, Food and the Marine (Ireland), DAFM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Funder Name
Department of Agriculture, Environment and Rural Affairs, UK Government

Alternative Name(s)
DAERA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Smartfish AS (Norway)

Results and Publications

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 the researchers do not have consent for this.

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	07/12/2021	12/04/2022	Yes	No