

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

Submission date 27/07/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/07/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/04/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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 Talmhaíochta 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

[Results article](#)

Details

Date created

07/12/2021

Date added

12/04/2022

Peer reviewed?

Yes

Patient-facing?

No