

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

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

Dr Lorraine Brennan

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Home

**Study type(s)**

Other

**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**

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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/01/2017

## **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

## **Age group**

Senior

## **Sex**

Both

## **Target number of participants**

95

## **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**

Ireland

Northern Ireland

United Kingdom

**Study participating centre**

**University College Dublin**

Belfield

Dublin 4

Dublin

Ireland

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**Study participating centre**

**Ulster University**

Cromore Road

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**Sponsor information****Organisation**

University College Dublin

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**Sponsor type**

University/education

**Website**

<http://www.ucd.ie/>

**ROR**

<https://ror.org/05m7pjf47>

**Organisation**

University of Ulster

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**Sponsor type**

University/education

**Website**

<http://www.ulster.ac.uk/>

**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

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal. No additional documents are available.

**Intention to publish date**

01/10/2021

**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?
<a href="#">Results article</a>		07/12/2021	12/04/2022	Yes	No