

# Can drinking beetroot juice prevent and reduce the severity of winter viral infections in residential and nursing homes?

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<b>Registration date</b> 13/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/11/2022	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Residents in care homes are at increased risk of developing viral infections, particularly during the winter months. This study aims will look at whether daily consumption of a beetroot juice supplement (which is naturally high in nitrates) will help prevent or lessen the impact of winter viruses such as flu, the common cold, as well as new viruses such as COVID-19.

### Who can participate?

Care home residents aged 65 years old, taking a normal diet, and willing to participate following a taste-test of the beetroot juice are eligible to take part in the study. Those who are on a soft diet or using thickener, using antiseptic mouthwash, are in short term respite care, or are identified as being in the last few days of life, are not eligible to take part in the study.

### What does the study involve?

Participants in this study will take nitric oxide that comes in the form of concentrated beetroot juice. The juice comes in a small container and is drunk once-a-day for two months (60 days). The only ingredients in the juice are crushed beetroot with 2% lemon juice from concentrate. There are no other additives, preservatives or other allergens, and there is no risk of cross-contamination during manufacturing.

Half of the care homes in the study will have active juice, and the other half an inactive juice that does not contain nitrates. Neither the participants nor their care home will know which sort of juice they receive. The active and inactive juice look and taste the same. Participants will be able to have a taste test of the juice before the study to make sure they can take it.

The study team will also ask to collect a specimen of spit and urine from participants at the beginning and end of the study. This will be used to test the levels of nitrate/nitrite in the body. The results will be recorded, and the samples will be disposed of immediately.

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

Concentrated beetroot juice is widely used by athletes to help their performance. It has been

tested in many studies and lowers blood pressure a little. In lab studies, nitric oxide is shown to be anti-microbial– a feature that might help in fighting infections. Beetroot juice (both active and inactive) will also contribute to one of the participant's 'five-a-day'.

Due to its wide use, we do not think participants will be at risk by taking part in the study. The most common side-effect of drinking beetroot juice is that urine may go red or pink coloured. Less commonly, faeces may also go red or pink coloured, but this colour is noticeably different from blood. On rare occasions, beetroot may cause a rash or stomach cramps (usually because the individual has a food allergy or intolerance). The care home staff will look out for side effects, and participants are encouraged to speak to the care home staff if they have any concerns.

Where is the study run from?  
The University of Nottingham (UK)

When is the study starting and how long is it expected to run for?  
From September 2020 to September 2021

Who is funding the study?  
The Biomedical Research Centre and Senior Investigators, University of Nottingham (UK)

Who is the main contact?  
Mrs Di Havard (Trial Manager) and Prof Philip Bath (CI)  
beet-winter@nottingham.ac.uk

## Contact information

**Type(s)**  
Public

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**Type(s)**  
Scientific

**Contact name**  
Prof Philip Bath

**Contact details**

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

288542

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

IRAS 288542, Version 2.0 19/10/20

**Study information****Scientific Title**

Nitric oxide for preventing and reducing the severity of winter viral infections in care (residential and nursing) homes (BEET-Winter)

**Acronym**

BEET-Winter

**Study objectives**

1. To determine if it is feasible to recruit residents in care homes into a trial aiming to reduce winter infections
2. To determine if nitric oxide given as dietary nitrate reduces winter-timed infections and their severity in care home residents.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 25/11/2010, West Midlands - Coventry & Warwickshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8009; coventryandwarwick.rec@hra.nhs.uk), ref: 20/WM/0278

**Study design**

Prospective phase II cluster-randomized double-blind placebo-controlled trial assessing feasibility and proof of principle

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

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

Winter respiratory viral infections in care home residents

## **Interventions**

Homes, and not participants, will be randomised. Randomisation will be stratified by care home type (residential vs nursing/mixed), prior COVID-19 in phase 1 of pandemic (yes vs no), and size of care home (number of residents <32 vs >32). Residents and care home staff are blinded, with a double-blind design.

Participants will be randomly allocated to receive either:

1. Nitric Oxide in the form of 70 ml of beetroot juice containing 400 mg nitrate given once daily for 60 days
2. Placebo in the form of 70 ml of beetroot juice containing 0 mg nitrate given once daily for 60 days

The intervention and placebo are foods and not investigational products. Active beetroot juice is available from supermarkets and on-line.

Participants will be invited for three follow-up visits. The first follow up visit will occur on day 14, where saliva/urine nitrate/nitrite test, dietary nitrate intake from menu, and beetroot juice adherence will be assessed. The second follow up visit will be on day 60, where the clinical tests Clinical Frailty Index (CFI), Barthel index (BI), 6 item cognitive impairment test (6CIT), quality of life visual analogue scale (EQ-VAS), and EuroQol 5-dimension 5-level (EQ-5D-5L) quality of life questionnaire, as well as dietary nitrate intake from menu and saliva/urine nitrate/nitrite test will be assessed. The final follow up visit will be on day 90 where saliva/urine nitrate/nitrite test and dietary nitrate intake from menu will be assessed.

## **Intervention Type**

Supplement

## **Primary outcome(s)**

1. Feasibility of conducting a larger scale trial assessed using data on the recruitment of care homes, recruitment of residents, assessment of background infection rate, assessment of background dietary nitrate intake, adherence to the intervention, ability to measure the ordinal outcome, an estimation of the intra-cluster correlation (ICC), and incidence of death between baseline and 60 days
2. Severity of the first infection measured using a 5 level ordinal outcome (using the worst level if >1 event, where a score of: 0 represents no symptoms of infection; 1 represents symptoms of infection; 2 represents symptoms of infection needing healthcare advice such as a call to 111, or

GP appointment; 3 represents hospitalisation for any reason, or intention to hospitalise but advance directive precluded this; or 4 represents death from any cause) between baseline and 60 days

### **Key secondary outcome(s)**

1. Severity of worst infection stratified by subgroups of age (median), sex, size of home (median), type of care home (residential, nursing), home's location (median deprivation index), and infection location (respiratory tract, gastrointestinal tract, urinary tract, cutaneous) measured using a 5 level ordinal outcome (where a score of: 0 represents no symptoms of infection; 1 represents symptoms of infection; 2 represents symptoms of infection needing healthcare advice such as a call to 111, or GP appointment; 3 represents hospitalisation for any reason, or intention to hospitalise but advance directive precluded this; or 4 represents death from any cause) between baseline and 60 days
2. Number of infections measured using patient records between baseline and 60 days
3. Time to first infection measured using patient records between baseline and first identification of infection
4. Time to first hospitalisation or death in home measured using patient records between baseline and first record of hospitalisation or death in home
5. Disposition at day 60 measured using patient records (options such as care home, with relative /friend, another home, hospital, or died) at 60 days
6. Frailty measured using the Clinical Frailty Index (CFI) at baseline and 60 days
7. Activities of daily living measured using the Barthel index (BI) at baseline and 60 days
8. Cognitive impairment measured using the 6 item cognitive impairment test (6CIT) at baseline and 60 days
9. Quality of life measured using the visual analogue scale (EQ-VAS) and the EuroQol 5-dimension 5-level (EQ-5D-5L) quality of life questionnaire at baseline and 60 days
10. Global outcome measured as a combination of the severity of first infection, frailty, activities of daily living, cognitive impairment, and quality of life at baseline and 60 days
11. Incidence of death from all causes measured using patient records between baseline and 60 days
12. Incidence of fatal serious adverse events (SAE) measured using patient records between baseline and 60 days
13. Salivary nitrite/nitrate and urinary nitrate measured using salivary and urine samples collected at baseline, 14, 60, and 90 days
14. Care home dietary nitrate intake measured from care home menus at baseline, 14, 60, and 90 days

### **Completion date**

30/09/2021

## **Eligibility**

### **Key inclusion criteria**

1. Residents from 26 participating care homes (residential and nursing) with 16 participants from each
2. Aged  $\geq 65$  years
3. Currently consuming a normal diet
4. Willing to take treatment having taste-tested a beetroot shot

### **Participant type(s)**

Other

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Total final enrolment**

49

**Key exclusion criteria**

1. Unwilling to participate or opted-out of the trial (resident, or family, if resident lacks capacity)
2. Currently consuming a soft diet or using a thickener
3. Using antiseptic mouthwash
4. Identified by care home staff to be in the last few days of life
5. Short-term respite care
6. Care home staff

**Date of first enrolment**

01/05/2021

**Date of final enrolment**

31/05/2021

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

United Kingdom

England

**Study participating centre****Sutton Manor Care Home**

Priestsic Road  
Sutton in Ashfield  
United Kingdom  
NG17 2AH

**Study participating centre****Sutton Lodge**

Priestsic Road  
Sutton in Ashfield  
United Kingdom  
NG17 2AH

**Study participating centre**  
**Wren Hall Nursing Home**  
234 Nottingham Road  
Selston  
United Kingdom  
NG16 6AB

**Study participating centre**  
**Sutton Court**  
Priestsic Road  
Sutton in Ashfield  
United Kingdom  
NG17 2AH

**Study participating centre**  
**Church Farm at Skylarks**  
Adbolton Lane  
West Bridgford  
Nottingham  
United Kingdom  
NG2 5AS

**Study participating centre**  
**Lynwood Court Care Centre**  
Rise Road  
Ascot  
United Kingdom  
SL5 0FG

**Study participating centre**  
**Landermeads**  
265 High Rd  
Chilwell  
Beeston  
Nottingham  
United Kingdom  
NG9 5DD

**Study participating centre**

**Aria Court**

Coronation Close  
March  
United Kingdom  
PE15 9PP

**Study participating centre**

**Springbank Care Home**

17 Ashgate Road  
Chesterfield  
United Kingdom  
S40 4AA

**Study participating centre**

**Ashbourne Lodge care home**

Derby Road  
Ashbourne  
United Kingdom  
DE6 1BH

**Study participating centre**

**Appletrees**

Arlington Gardens  
Grantham  
United Kingdom  
NG31 7GQ

**Study participating centre**

**Cedar Falls**

Little London Road  
Spalding  
United Kingdom  
PE11 2UA

**Study participating centre**

**Ashdene Care Home**

89 Eastgate  
Sleaford  
United Kingdom  
NG34 7EE



**Study participating centre****Acer Court Care Home**

Coronation Close

March

United Kingdom

PE15 9PP

**Study participating centre****Barnfield Manor**

Barnfield Close

Heath Road

Holmewood

Chesterfield

United Kingdom

S42 5RH

**Study participating centre****Burton Closes Care Home**

Haddon Road

Bakewell

United Kingdom

DE45 1BG

## **Sponsor information**

**Organisation**

University of Nottingham

**ROR**

<https://ror.org/01ee9ar58>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Funder Name

Philip Bath NIHR Senior Investigator Award

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Participant information sheet	16/11/2022	18/11/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Preprint results</a>	Protocol and Statistical Analysis Plan version 1.0	26/04/2022	17/11/2022	No	No
<a href="#">Protocol file</a>		09/08/2021	29/09/2021	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes