

# The effect of prebiotic supplementation on asthma

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<b>Registration date</b> 19/05/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/05/2021	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Many prevalent health disorders (including asthma) cause patients to have increased levels of inflammation. A potential cause for the increased inflammation could be due to the types and activity of the bacteria that reside in the gut (gut microbiota). Evidence suggests that in asthma, the gut becomes more permeable which could contribute to increased levels of inflammation. However, the human gut is also home to many strains of beneficial bacteria, such as Bifidobacterium and Lactobacilli, which when in sufficient amounts can exert a health benefit and reduce systemic inflammation.

Dietary prebiotics, a form of non-digestible carbohydrate, are shown to encourage the growth and activity of beneficial bacteria and can confer a health benefit. Recent nutritional research into prebiotics has highlighted their potential to improve digestive health, and to have an effect on the immune system and inflammatory responses. Prebiotics may help modulate systemic inflammation in asthma, improving disease management. This study aims to assess the effects of a 3-week prebiotic supplementation period on asthma control and markers of systemic inflammation.

### Who can participate?

Patients aged 18-50 with a GP diagnosis of asthma and a current asthma medication prescription,

### What does the study involve?

Participants are recruited into a 9-week study involving five visits to the laboratory. Visit one is a familiarisation session, with visits 2, 3, 4 and 5 occurring before and after each 21-day intervention period. At each visit participants will perform lung function tests, have a blood sample taken, provide a saliva sample and have their body composition assessed with a scan, and complete asthma control, asthma quality of life, and asthma medication questionnaires. Participants will complete two 3-week dietary intervention periods (taking a daily prebiotic powder or placebo (dummy) powder) with a two-week washout period between each intervention.

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

Participants will undergo an in-depth personalised assessment of asthma. This will collect information regarding lung function, and the assessment of forced expiratory volume, which

means the amount of air a person can forcefully exhale in one second. Other lung measurements will also be recorded. In terms of the nutritional supplements, no specific benefits are anticipated. However, it is possible that asthma symptoms may be reduced. Slight discomfort may occur during blood sampling, but all investigators taking blood samples will be fully trained and will take the utmost care. Although very rare some individuals may feel symptoms of digestive discomfort such as bloating and abdominal cramps during the prebiotic supplementation period.

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

When is the study starting and how long is it expected to run for?  
October 2019 to September 2023

Who is funding the study?  
Nottingham Trent University (UK)

Who is the main contact?  
Dr Neil Williams  
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## Contact information

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## Additional identifiers

### Protocol serial number

NTU Ethics Committee Approved Protocol #675

## Study information

### Scientific Title

The effects of a prebiotic supplement on quality of life, control of asthma, and markers of systemic inflammation in adults with asthma: a double-blind, placebo-controlled, crossover trial

### Study objectives

It is hypothesised that a prebiotic galacto-oligosaccharide mixture (B-GOS) will reduce markers of systemic inflammation whilst improving quality of life, and asthma control in adults with asthma.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 24/03/2021, Nottingham Trent University College of Science and Technology Ethical Committee (Humans) (New Hall Block Room 178, Clifton Lane, Nottingham, NG11 8NS, UK; +44 (0)115 84 83461; dianne.levey@ntu.ac.uk), ref: #675

### Primary study design

Interventional

### Study design

Single-centre randomized double-blind placebo-controlled cross-over controlled study

### Study type(s)

Treatment

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

Asthma

### Interventions

Participants are randomized by block randomisation for two 21-day treatment periods with a 2-week washout between treatments:

1. Prebiotic Bimuno galactooligosaccharide powder – 5.8 g of galactooligosaccharide provided daily in two 2.9 g dose. One sachet taken in the morning and one in the evening.
2. Placebo maltodextrin powder (Clasado Ltd, Milton Keynes, UK) – 5.8 g of maltodextrin, provided in two 2.9 g doses. One sachet taken in the morning and one in the evening for 3 weeks.

### Intervention Type

Supplement

### **Primary outcome(s)**

Pro-inflammatory markers including c-reactive protein, Th2 cytokines, Th1/17 cytokines, NFkB and TNFa measured using enzyme-linked immunosorbent assay and multiplex bead array assays at day 0 and day 21

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

1. Asthma control measured using the asthma control questionnaire (ACQ) at day 0 and day 21 of each intervention period
2. Asthma individual quality of life measured using the asthma quality of life questionnaire (AQLQ) at day 0 and day 21 of each intervention period
3. Use of asthma medication during the study measured using medication adherence report scale - for asthma (MARS-A) at day 0 and day 21 of each intervention period
4. Body composition measured using dual X-ray absorptometry (iDXA) at day 0 and day 21 of each intervention period

### **Completion date**

01/09/2023

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18-50 years of age
2. Body mass index (BMI) of 18.5-35 kg·m<sup>2</sup>
3. Non-smoker
4. Asthma severity defined as Steps 1 to 5 based on British Thoracic Society guidelines
5. Current asthma diagnosis and medication prescription from GP (e.g. maintenance and reliever inhalers)
6. In the researcher's opinion, able and willing to follow all the trial requirements
7. Potential participants must disclose any nutritional supplements they take to the researcher, to determine whether these may be considered as exclusion criteria

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

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

50 Years

### **Sex**

All

### **Key exclusion criteria**

1. Suffer from asthma but do not have a current medication prescription from GP (e.g. maintenance and reliever inhalers)
2. Regularly consume Omega-3 supplements, and/or eat high levels of Omega-3 (e.g. more than 1-2 portions of oily fish such as salmon or mackerel a week).
3. Take aspirin or other non-steroidal anti-inflammatory drugs such as ibuprofen once a day on 5 of the 7 days of the week
4. Females only: pregnant or planning a pregnancy during the time of the study (on each visit participants will be asked to complete a pregnancy test if within childbearing age)
5. Consumed prebiotics and/or probiotics (supplements), drugs that affect gastrointestinal mobility or laxatives in the 4 weeks before signing the consent form
6. Vegetarian or vegan diet
7. Previously diagnosed with chronic obstructive pulmonary disease (COPD), emphysema, chronic bronchitis, or similar respiratory (breathing-related) illness
8. Admitted to hospital during the past 12 months for asthma
9. History of heart failure, pulmonary hypertension, embolism, or other pulmonary heart disease
10. History of recurrent chest infections
11. Acute infection in the last 4 weeks and/or major operation in the past 4 months
12. History of gastrointestinal drug reaction
13. Taken antibiotics in the past 3 months
14. History or current evidence of gastrointestinal disease (e.g. chronic constipation, diarrhoea, irritable bowel syndrome, Crohn's disease)
15. Recently taken part in other research projects. Please notify the chief investigator
16. Are or believe they may be lactose intolerant
17. Regularly take antioxidant supplements, such as beta-carotene, vitamin A, vitamin C, vitamin E, lutein and selenium
18. Standard multivitamin and mineral supplements are acceptable; however, If a single antioxidant supplement (e.g. Vitamin C) is more than the recommended daily Dietary Reference Values (DRVs) this must be checked with the chief investigator

**Date of first enrolment**

01/11/2021

**Date of final enrolment**

12/12/2022

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Nottingham Trent University**

School of Science and Technology

Clifton Campus

Nottingham

United Kingdom

NG11 8NS

# Sponsor information

## Organisation

Nottingham Trent University

## ROR

<https://ror.org/04xyxjd90>

# Funder(s)

## Funder type

University/education

## Funder Name

Nottingham Trent University

## Alternative Name(s)

NTU

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

United Kingdom

# 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