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Dietary prebiotic interventions for athlete health

Submission date 11/08/2022	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 16/08/2022	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 16/08/2022	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Elite rugby union players follow physiologically and psychologically demanding training schedules, with frequent competitive matches, limited recovery time, and regular international travel. Collectively, these stressors may impair immunity and increase the risk of acute upper respiratory symptoms (URS) (e.g. cough, sneezing, sore throat, and nasal congestion) and gastrointestinal symptoms (GIS) (e.g. bloating, belching, flatulence, nausea, and diarrhoea). The profile, genetic material, and functional activity of the gut microbial community (the gut microbiome) has a substantial influence on immune function. Manipulation of the gut microbiome is possible through dietary intervention, most commonly through pro- or prebiotic dietary supplements. This may provide a potential strategy to help reduce URS and GIS in team sport athletes.

Therefore, the aim of this study is to assess the effects of a 24-week prebiotic supplementation on the severity, duration and incidence of URS and GIS, and immune parameters in male elite rugby union players.

Who can participate?
Elite rugby union players playing in the English Premiership

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of participants being in either group (like tossing a coin) but with an even distribution based on body mass and playing position between the two groups. For 24 weeks, one group of participants will receive a daily prebiotic powder, in single-dose sachets, and the participants in the other group will receive a daily identical-looking and tasting powder, but with no active medicine. Participants and researchers will not know which treatment the participant has received during the study.

What are the possible benefits and risks of participating?
Participants taking part in the study may benefit from the provision of information pertaining to their gut microbiota. Participants may also benefit from reduced illness rates throughout the season, increasing training and match day availability. Advice will also be provided on nutrition for enhancing the gut microflora and immunity.

Some discomfort may be experienced during venepuncture. Following the removal of the needle, pressure will be applied to the punctured area for approximately 10 minutes to avoid the development of a local haematoma. The venepuncture procedure has been risk assessed, and, in relation to current experience at NTU, it is safe. Staff who perform the procedure are appropriately trained and sterile procedures are used at all times. Safe laboratory working practices are followed and all staff have current Hepatitis B vaccination. Only two attempts at venepuncture will be made.

Although rare, prebiotics may cause dose-dependent gastrointestinal side effects such as bloating. Participants who present with symptoms will be monitored by the Club medic and, where considered necessary, removed from the study. Any adverse events will be reported to the Club medic and feedback directly to prebiotic manufacturer Clasado Biosciences.

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

When is the study starting and how long is it expected to run for?
From April 2019 to February 2020

Who is funding the study?
Nottingham Trent University (UK) with the dietary supplements supplied by Clasado Biosciences Ltd (UK)

Who is the main contact?
Dr Neil Williams, neil.williams@ntu.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Neil Williams

ORCID ID
http://orcid.org/0000-0002-2607-4572

Contact details
Nottingham Trent University
SHAPE Research Centre
School of Science and Technology
Clifton Campus
Nottingham
United Kingdom
NG11 8NS
+44 (0)1158485535
neil.williams@ntu.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effects of 24-week prebiotic intervention on self-reported upper respiratory symptoms, gastrointestinal symptoms, and markers of immunity in elite rugby union players.

Study objectives
The 24-week prebiotic (B-GOS) supplementation will reduce the severity, duration, and incidence of upper respiratory and gastrointestinal illness symptoms, and enhance immune parameters (sIgA, and plasma concentrations of C-reactive protein and TNF-α) in elite rugby union players during a competitive season.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/06/2019, Nottingham Trent University Human Ethics Committee (Nottingham Trent University, School of Science and Technology, Clifton Campus, NG11 8NS; +44 115 84 83461; Dianne.Levey@ntu.ac.uk), ref: 612

Study design
Single centre, interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Prevention of upper respiratory and gastrointestinal illness symptoms in elite rugby union players

Interventions
Players will be randomised to consume either 2.9 g/day of the commercially available B-GOS (Bimuno, Clasado Biosciences Ltd, Reading, UK) or 2.9 g/day placebo (maltodextrin) provided as a powder in single dose sachets (Clasado Biosciences Ltd, Reading, UK). Both supplements were identical in taste and colour and blinded at the site of manufacture (Clasado Biosciences Ltd). Participants were matched based on age, body mass, and playing position. Block randomisation was used to randomise players to either the prebiotic group, or placebo group.

Intervention Type
Supplement

Primary outcome measure
Daily upper respiratory symptoms measured using the Jackson questionnaire daily over the 24-week intervention

Secondary outcome measures
1. Gut symptoms measured using a modified visual analog scale assessment tool (Gaskell et al., 2019) weekly over the 24-week intervention
2. Plasma TNFa concentrations measured using ELISA from samples taken at baseline, 12, and 24 weeks
3. Plasma CRP concentrations measured using ELISA from samples taken at baseline, 12, and 24 weeks
4. Salivary IgA concentrations measured using ELISA from samples taken at baseline, 12, and 24 weeks

Overall study start date
24/04/2019

Completion date
24/02/2020

Eligibility

Key inclusion criteria
1. Elite rugby union players playing in the English Premiership
2. Non-smokers
3. No history of gastrointestinal illness
4. Not regularly consuming foods enriched with probiotics, prebiotics, or vitamins

Participant type(s)
Healthy volunteer

Age group
Adult

Sex

Male

Target number of participants
40

Total final enrolment
33

Key exclusion criteria
1. Routine consumption of prebiotic, and/or probiotic supplements
2. Take a daily dose of aspirin or other NSAIDs
3. Intake of drugs that affect gastrointestinal mobility, laxatives in the 4 weeks before the study
4. Vegetarian or vegan diet
5. Previously diagnosed with COPD, emphysema, chronic bronchitis, or similar respiratory illness
6. Asthma exacerbation within the last 12 months (course of steroids, or hospital visit)
7. History of heart failure, pulmonary hypertension, embolism, or other pulmonary heart diseases
8. History of recurrent chest infections
9. Acute infection within the last four weeks
10. Major operation within the past four months
11. History of gastrointestinal drug reaction
12. Use of antibiotics in the past 3 months
13. History or current evidence of gastrointestinal disease e.g. chronic constipation, diarrhoea, irritable bowel syndrome, Crohn's Disease
14. Milk allergy

Date of first enrolment
01/09/2019

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham Trent University
SHAPE Research Centre
School of Science and Technology
Clifton Campus
Nottingham
United Kingdom
NG11 8NS

Study participating centre
London Irish Rugby Football Club
Hazelwood Centre
Sunbury-on-Thames
United Kingdom
TW16 6QU

Sponsor information

Organisation
Nottingham Trent University

Sponsor details
50 Shakespeare Street
Nottingham
England
United Kingdom
NG1 4FQ
No telephone contact available
neil.williams@ntu.ac.uk

Sponsor type
University/education

Website
http://www.ntu.ac.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/10/2022

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 due to the sensitivity behind the data in a competitive environment, it is felt by the participating rugby union club that the sharing of individual data beyond a manuscript publication would not be appropriate.

IPD sharing plan summary
Not expected to be made available