You are invited to take part in a research study. Before you decide whether to volunteer, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Please do not hesitate to contact us (see below) if there is anything that is not clear or if you would like more information.

What is the purpose of this study?
To determine whether prebiotic activity is detectable in faecal samples after short term (one week) intake of high-fibre drinks which provide 6g of fibre per day in the diet.

Why have I been chosen?
We are looking for 45 men or women who are generally healthy, aged over 18 years old with a Body Mass Index (BMI) between 18-35kg/m².

Medication Exclusion Criteria:
- antibiotic use within the past 3 months (due to impact on gut microbiota)
- inflammatory bowel disease
- food allergies or self-reported food sensitivity or intolerance
- diagnosis of diabetes
- pregnant or breastfeeding
- unsuitable veins for blood sampling

Other Exclusion Criteria:
- inability to speak, read and understand English
- following a diet for any reason (e.g. religious reasons, vegetarian) that excludes the food prescribed in the study

Do I have to take part?
No, it is up to you to decide if you wish to take part or not. You are free to withdraw at any time, without giving a reason. Unless you specifically withdraw consent to use any data already collected (in which case your data will be destroyed securely), all data to the date of withdrawal will be retained and used for analysis purposes.

What will happen to me if I take part?
If you wish to take part in this study, you can contact the research team directly who will arrange to meet you on dates and times that are convenient for you in the Human Nutrition Unit (HNU) at the Rowett Institute where they will explain the study in more detail and ask you to sign the
consent paperwork. We are based at Foresterhill Health Campus and we have a car park specifically for our volunteers to come for visits.
What do I have to do?

1. Before the study begins we will ask you to attend a screening/orientation visit at the Rowett’s Human Nutrition Unit (HNU), which will involve completing the consent paperwork and a health questionnaire with a member of the study team. We will also measure your height and weight. This visit should last approximately 1 hour.

2. At the screening you will also be given a food diary booklet, food scales and instructions on how to record a 3day weighed food diary. This is to assess your habitual diet before you start the study.

3. After the screening, you will be asked to visit the Human Nutrition Unit on 4 further occasions for measurements (four blood sample collection days) and to collect food on Mondays & Thursdays.

4. The main study comprises 29 continuous days which are broken down into four diet periods (please see study diagram below).

What are the diets?

All meals will be provided by the Human Nutrition Unit kitchen at the Rowett and will be individually prepared to your estimated energy requirements as ready to eat meals.

The study meals will be provided as a 7day rotating menu split into the following four weeks:

- **Week 1**) Baseline week - we will ask you to eat the meals provided by the Rowett as supermarket ready to eat food (no supplementary high fibre drinks).
- **Week 2**) Intervention Period 1, food provided and also supplementary fibre drinks.
- **Week 3**) Washout week - we will ask you to eat the meals provided by the Rowett as supermarket ready to eat food (no supplementary high fibre drinks).
- **Week 4**) Intervention Period 2, food provided and also supplementary fibre drinks.

The drinks you receive in weeks 2) and 4) above will be high fibre flavoured waters.

Collection of the Rowett meals will be required from the HNU on Monday and Thursday mornings during the 4 weeks. Breakfast will be provided at the HNU on these mornings.

**Study Diagram:**

- **4 weeks - all meals provided by HNU kitchen**
- **to be collected on Mondays & Thursdays**

**Day No:**

- 1 - 7
- 8 - 14
- 15 - 21
- 22 - 28
- 29

**Screening:**

- Consent Paperwork
- Health Status Questionnaire
- Height & Body Weight
- 3day Adlib Food Diary

**Baseline**

**Test Day 1**

**Intervention Period 1**

**Test Day 2**

**Wash-out**

**Test Day 3**

**Intervention Period 2**

**Test Day 4**

**Feedback**

**Test Day Measurements:**

- Days 8, 15, 22 & 29
- Body Weight
- Fasted Blood Sample
- Fasted Urine Sample
- Faecal Sample
- GastroIntestinal Questionnaire
- Bristol Stool Chart Questionnaire
- Diet Checklist for Food Intake
**What are the measurements?**

**Baseline visit (day 0, duration ~ 1 hour):**
- Body weight (measured in dressing gown)
- Height
- Collect booklet for 3 day weighed food diary which is to be recorded at home before the study starts.

**Blood sample test days (days 8, 15, 22 and 29 of the study, duration ~ 1½ hours):**
- Body weight (measured in dressing gown)
- Fasted blood sample for lipid profile (Cholesterol, Triglycerides)
- Fasted urine sample (25ml spot sample)
- Faecal samples be required to be brought to the HNU. These will be collected at home (either the evening before or on the morning of the visit) using specific containers which are provided for the collection & transportation of these samples.
- Questionnaires - Gastrointestinal symptoms, Bristol Stool Chart
- Breakfast will be provided at the end of this visit

Total blood collected is no more than 9ml each test day (equivalent to approx. 2 teaspoon) or 36ml over the entire study which is less than one blood donation.

**What will happen to the samples I give?**

All the samples will be coded to maintain confidentiality. We will store your samples anonymously until the study has been completed and then for up to a further 5 years to allow for potential additional analysis in future ethically reviewed and approved studies. After this time, all samples will be destroyed.

**Expenses and payments**

On completion of the study you will receive a gratuity payment of £150.

**What are the possible benefits of taking part in the study?**

Taking part in this research may not benefit you directly. However, as a result of this research we hope to be better able to understand the mechanisms involved to ultimately provide health professionals with invaluable advice in the prevention and treatment of obesity and related conditions. We will provide you with feedback on your own body composition, habitual food intake and blood results.

**What if there is a problem?**

At any time during the study, if you have a complaint or a concern that you have been unable to resolve with the Principal Investigator or Human Nutrition Unit Manager, Mrs Sylvia Stephen (on 01224 438607 or email Sylvia.stephen@abdn.ac.uk), you may contact Professor Baukje DeRoos, Chair of the Human Studies Committee. You can be assured that Baukje will be a sympathetic listener and that your concerns will be treated seriously. He can be contacted on 01224 438636 or by email b.deroos@abdn.ac.uk. The University carries indemnity insurance for any harm or adverse event.

If we find a test result that is out with the normal range, we will inform you and your GP in writing.
Who has reviewed this study?
The Rowett Ethics Panel has approved the study.

Who is organising and funding the research?
This study is being organised by University of Aberdeen and is funded by Tate & Lyle.

Will my taking part be kept confidential?
All data collected from you will be coded to ensure your anonymity in any publication from this study. Only your screening paperwork will have record of your name and will be stored separately to the rest of the documents containing your data. All of the data will be held in locked cabinets, in locked offices and/or on password protected computers/memory sticks. All identifiable data will be stored for a maximum of 5 years, after which they will be destroyed.

The University of Aberdeen is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information http://www.abdn.ac.uk/privacy

CONTACTS FOR STUDY
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Thank you for having taken the time to read this information sheet and for your interest in the study. If you do decide to take part in the study, you will be given a copy of this information sheet and a consent form to sign.