

PARTICIPANT INFORMATION SHEET

Study Number:	813
Title of Study:	Focus On Fibre
Principal Investigators:	Professor Alex Johnstone

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 understand the role of dietary fibre in the regulation of appetite control and the adaptation of the microbiome (gut ecosystem) for health.

Why have I been chosen?

You have been chosen because you fulfil our eligibility criteria:

- You have expressed an interest in taking part after seeing the study advertised either on the Rowett Institute website, on social media, in local press, by letter, newsletter or on a public poster
- You are aged over 18 years old
- Your BMI is within the range 28-40kg/m²
- You are a healthy male, or a healthy female who takes the oral contraceptive pill, is on some form of hormonal contraceptive, or is postmenopausal
- Your habitual fibre intake is less than 18g per day

The **exclusion** criteria for this study are as follows

Medication exclusion criteria:

- antibiotic use (within the past 3 months due to impact on gut microbiota)
- statins (current)
- aspirin or other NSAIDs or anti-coagulants (current)
- anti-depressants (current)
- smoking or vaping

Medical exclusion criteria:

- Females who are planning to be pregnant, are pregnant or are breastfeeding
- Anyone with food allergies, self-reported food sensitivity or intolerance
- Anyone with coeliac disease or gluten intolerance
- Anyone taking medication which may affect their appetite
- Anyone with an eating disorder
- Anyone with diabetes
- Anyone with a gastrointestinal disorder, kidney disease, liver disease or gout

- Anyone suffering from a psychiatric disorder or any type of substance abuse
- Anyone suffering from unregulated thyroid disease

Other exclusion criteria:

- Anyone following a vegetarian or vegan diet
- Anyone following a weight loss programme (that may be affecting lifestyle, physical activity & diet)
- Anyone with unsuitable veins for blood sampling
- Anyone who is unable to fluently speak, read and understand English
- Anyone who is unable to comply to an alcohol-free diet for 6 weeks

Do I have to take part?

No. It is up to you to decide whether to take part.

If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.

If you decide to take part, you are still free to withdraw at any time and without giving a reason.

A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What does the study involve?

You will be invited initially to come to the Rowett Human Nutrition Unit (HNU) for a medical screening visit where your eligibility for the study will be confirmed and consent paperwork for participation will be completed.

Before starting the study you will be asked to complete questionnaires about eating behaviour and record a 7day food diary to confirm that your habitual fibre intake is less than 18g per day.

When you start the 6week study period we will provide all food and drinks (details below).

You will be asked to attend the HNU on four occasions for Test Days, each of which lasts approximately 9 hours.

What are the study diets?

You will be provided with three different diets:

1. 2 week Control Diet **CTRL**
2. 2 week High-Fibre Diet – meals provided for *ad libitum* consumption. Fibre content is 10g/day with 20g/day **HF** added pectin. Pectin is a source of dietary fibre found naturally in plants, it is often used to make jam. The pectin we will be using in this study is from apples.
3. 2 week Low-Fibre Diet **LF** – meals provided for *ad libitum* consumption. Fibre content is 10g/day.

As the **HF** and **LF** diet phases are *ad libitum* (you eat until you are comfortably full) snacks will be provided in addition to the study meals. These snacks should only be consumed if you still feel hungry after you have had the main meals.

The only exception to the *ad libitum* feeding are the items in the **HF** diet which contain the added pectin (e.g. yoghurts). The consumption of these foods will be mandatory.

The diets prepared by our Human Nutrition Unit kitchen staff have a fixed composition (30% fat, 15% protein, 55% carbohydrate) and are to be collected on Mondays, Wednesdays & Fridays. We will weigh you on these mornings to follow your progress and provide you with a cooked breakfast.

The menus are developed using common dishes i.e., Cheese & Crumpets, Pasta Bolognese, Chicken Curry, Sandwiches and Puddings.

Only decaffeinated drinks (tea, coffee, juice etc) are to be consumed during the study. We will be able to provide you with a selection of these.

No alcohol will be provided or allowed during the study.

What measurements will be conducted if I take part?

Screening Visit (~2hrs):

- Medical Screening: you will be asked to complete a health status questionnaire
- Height and Body weight
- Blood pressure measurement
- RMR (Resting Metabolic Rate): A Quark Metabolic Monitor will be used to measure the amount of energy used by the body in an inactive state (to simply maintain basic life functions including respiration, circulation, digestion, brain activity etc.). This involves you lying relaxed on a bed for approx 30 mins with your head under a transparent hood. Your RMR results will be used to calculate how much food we need to provide to meet your specific energy requirements.
- All measurements will be conducted after a fast from 10pm the night before. Breakfast will be provided at the end of the screening visit.
- Before the study starts you will be asked to complete a 7day weighed intake diary and questionnaires about eating to analyse your habitual food consumption. These documents will be provided with completion instructions at the screening visit.

Test Days (~9hrs, always on a Friday):

We will measure your body composition, metabolism and health status on four occasions (at baseline and at the end of each diet phase; Study days 0, 14, 28 and 42).

- All measurements will be conducted after a fast from 10pm the night before. Breakfast, Lunch and Dinner will be provided on each test visit, to be consumed in the HNU.
- Body Weight
- Waist and hip circumference (measured with a tape measure)
- Blood Pressure

- Blood samples – Samples will be collected at -20, 0, 40, 60, 90, 120, 180, 200, 220, 240, 270, 300, 330, 360, 390, 420, 450 and 480 mins using a cannula (a total of 18 blood samples per test day ~ 97ml which is equivalent to ~3 tablespoons). The samples will be analysed for glucose, insulin, lipid profile, short chain fatty acid (SCFA) content and gut hormone profile.
- Motivation to eat – recorded eighteen times throughout the visit using a paper questionnaire
- Faecal samples: you will be asked to bring in a sample on each of the four test days. Sample pots and instructions on how to collect these samples will be provided.
- Urine sample - a 5ml spot sample will be collected during the visit to be analysed for urinary metabolites.

Other measurements: (not during test days)

- Continuous glucose monitoring system (CGMS). - On the back of the upper arm a small, water-resistant sensor is applied which includes a thin, flexible and sterile fibre inserted just under the skin. It is held in place with a small adhesive pad and is worn for 14 days. To retrieve data, the sensor can be scanned by any mobile device capable of downloading the FreeStyle Libre app. Each scan over the sensor, using the mobile app, gives a current glucose reading, the last 8-hours of glucose history, and a trend arrow showing if glucose is going up, down, or changing slowly. The scan can be conducted through clothing. A total of 3 sensors will be used throughout the 6week study.
- Appetite and gastrointestinal symptoms: at the end of each day during the study you will be asked to complete a questionnaire with questions which include ‘how hungry have you felt today?’ and ‘have you experienced bloating today?’
- Food consumption: weighback sheets for every day of the study and the food scales from the screening visit will be provided to record food consumption. We will ask you to collect food on a Monday, Wednesday and Friday from the Human Nutrition Unit.

A diagram of the schedule for the study and Test Days can be found at the end of this information sheet.

What will happen to the samples I give?

All the samples will be coded to maintain confidentiality. We will store your samples until the study has been completed and then up to a further 10 years for potential analysis of appetite biomarkers.

Expenses and payments

All study meals will be provided and we are able to offer financial reimbursement for travel expenses related to participation in this study.

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

Although there are no direct benefits to you for taking part, on completion of the study you will receive a report detailing the results from your measurements: weight, height, waist and hip circumference, body fat percentage, RMR measurement and blood results, which you may find interesting and useful.

What are the possible disadvantages or risks of taking part in the study?

To ensure your safety all current guidelines for COVID-19 will be adhered to. Blood sampling and the use of the CGMS sensors may result in minor bruising or irritation at the cannulation or sensor sites. If we find a blood, or other result, that is out with normal ranges we will inform you and your GP.

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 (01224 438607, sylvia.stephen@abdn.ac.uk) you may contact Dr Frank Thies (Chair of the Human Studies Management Committee). You can be assured that he will be a sympathetic listener and that your concerns will be treated seriously. He can be contacted by email: f.thies@abdn.ac.uk. The University carries indemnity insurance for any harm or adverse event and Dr Thies can be contacted for more information about this.

Who has reviewed this study?

This study has been reviewed and approved by the Human Studies Management Committee of the Rowett Institute of Nutrition and Health and the Rowett Institute Ethics Panel.

Who is organising and funding the research?

The study is organised by the university of Aberdeen and funded by the Scottish Government as part of the 'Healthy Diets for a Healthy Weight' research theme.

Will my taking part be kept confidential?

All data collected from you will be coded to ensure your anonymity and you will not be identifiable in any publication of results 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 data will be stored for a maximum of 10 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 10 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 and date**