PARTICIPANT INFORMATION SHEET

Study Number:	**814**
Title of Study:	**Scot Sweet**
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 assess the impact of the activity and composition of gut microbiota with inclusion of a non-nutritive sweetener (artificial sweetener) within a high-fibre weight loss diet.

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/m^2
- 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

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)
- anti-depressants (current)
- smoking or vaping
- weight loss medication

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) or who has undergone gastric band/reduction surgery
- 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 Intervention Studies Unit (HISU) 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 record your habitual intake.

When you start the 6week study period we will provide all food and drinks (details below).
You will be asked to attend the HISU on four occasions for Test Days (each of which lasts approximately 1 hour) and on 15 occasions to collect food.

If you normally use artificial sweeteners, you will be asked to stop taking them for the duration of the study.

What are the study diets?

You will be provided with three different diets:

1. 2 week Control Diet (**CTRL**) – moderate fibre, fed to energy balance (1.5 x Resting Metabolic Rate, RMR).
2. 2 week High-Fibre Weight Loss Diet (**HF WL**)– meals are provided at 100% RMR. Fibre content is supplemented with 20g/day fructo-oligosaccharides (FOS). FOS are a source of dietary fibre found naturally in plants.
3. 2 week High-Fibre Weight Loss Diet with added Non-nutritive Sweetener (**HF-NNS WL**) – meals are provided at 100% RMR. Fibre content is supplemented with 20g/day added FOS and the diet will also contain 30mg/day of the non-nutritive sweetener Sucralose.

The consumption of foods containing the added FOS or Sucralose (e.g. drinks/yoghurts) 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 measure your body weight on these mornings to follow your progress and then provide you with a cooked breakfast.

The menus used on the study are developed using common dishes i.e., Cheese & Crumpets, Pasta Bolognaise, Chicken Curry, Sandwiches and Puddings.

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

No alcohol or sugar free drinks (drinks containing artificial sweeteners) will be provided or allowed during the study.

What measurements will be conducted if I take part?

Screening Visit (~90mins):

- Meeting with study team about what the study involves and completion of consent paperwork
- All measurements will be conducted after a fast from 10pm the night before. Breakfast will be provided at the end of the screening visit.
- Medical Screening: you will be asked to complete a health status questionnaire
- Height and Body weight
- 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 approximately 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.
- 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 instructions on how to complete them.

Test Days (~1hr, on either a Monday, Wednesday or 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 1, 15, 29 and 43).

- All measurements will be conducted after a fast from 10pm the night before. Breakfast will be provided on each test visit, to be consumed in the HISU.
- Body Weight
- Blood sample – A sample will be collected using venepuncture (6.7ml at each visit which is equivalent to 1 dessertspoon). The sample will be analysed for glucose, insulin, lipid profile, plasma metabolites (by Metabolomics), short chain fatty acid (SCFA) content and gut hormone profile.
- Faecal sample: you will be asked to bring in a sample on your 1st test visit (day 1). A sample pot and instructions on how to collect this sample will be provided.

- Urine sample - a 5ml spot sample will either be collected during the visit (or brought in from home) to be analysed for urinary metabolites.

Other measurements: (not during test days)

- Body weight measured on food collection days (Monday, Wednesday and Friday weekly)
- Faecal samples: you will be asked to bring in a sample on three further occasions (days 13, 27 and 41).
- 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.

A figure showing the timeline of the study is on Page 7 of this document.

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. If you withdraw from the study for any reason, then we are able to offer financial reimbursement for travel expenses up until withdrawal date.

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

We would hope that by losing weight your metabolic health will improve (e.g. a reduction in blood cholesterol or glucose). On completion of the study you will receive a report detailing the results from your measurements: food records, height, weight, BMI, 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 venepuncture 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, you may contact Prof 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 Prof 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 and the Rowett Institute Ethics Panel.

Who is organising and funding the research?

The study is organised and sponsored 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

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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 keep.

Figure showing the timeline of the study

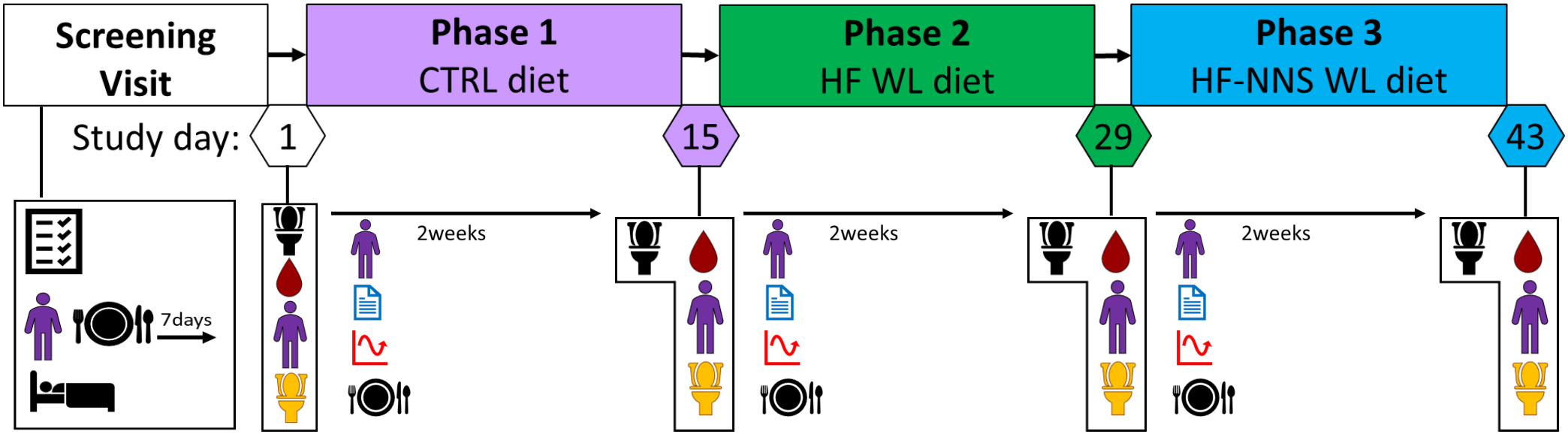

Figure Legend Key:

body weight measurement (at screening, at the test day visits on Days 1, 15, 29 and 43 and each Monday, Wednesday and Friday when study meals are collected);

consent paperwork and appetite questionnaires (DEBQ, TFEI); continuous glucose monitoring system;

end of day gastrointestinal symptoms and appetite questionnaire; faecal sample (on Days 1, 13, 27 and 41); fasted blood sample (on Days 1, 15, 29 and 43);

resting metabolic rate measurement for energy requirements; day test day visit; urine sample (on Days 1, 15, 29 and 43);

weighed food intake records.

Abbreviations:

CTRL, 2week control diet; DEBQ, Dutch eating behaviour questionnaire; FOS, oligofructose; HF WL, 2week high-fibre weight loss diet (including 20g FOS per day); HF-NNS WL, 2week high-fibre + non-nutritive sweetener weight loss diet (including 20g FOS and 30mg NNS per day); NNS, non-nutritive sweetener (sucralose); TFEI, Three Factor Eating Inventory questionnaire.