PARTICIPANT INFORMATION SHEET

Name of Investigator: Dr Alex Johnstone

Name of Study: **STUDY 804 - THE BIG BREAKFAST STUDY**

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?**

This study will assess the impact of time of meals, calorie distribution and diet composition throughout the day on appetite control of body weight. We will use large breakfast meals (and smaller evening meals) to look at energy balance and eating behaviour. In addition to ‘what we eat’ we will also investigate the importance of ‘when we eat’ by regulating the time of day when the study meals are consumed.

**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 a healthy male between the ages 18-75, or a female aged over 18 who takes the oral contraceptive pill or has a contraceptive patch or implant
- You regularly eat breakfast (at least 5 days per week)
- You have a defined, habitual sleep-awake cycle
- Your BMI is within the range 27-42kg/m²

The exclusion criteria for this study are as follows

- Anyone with a BMI (in kg/m²) under 27 or over 42
- Females who do not take the oral contraceptive pill, have a contraceptive implant or patch
- Females who are planning to be pregnant, are pregnant or breastfeeding
- Anyone with food allergies
- Anyone with coeliac disease or gluten intolerance
- Anyone taking medication which may affect their appetite or circadian rhythm
- Anyone with an eating disorder
- Anyone with diabetes
- Anyone with a gastrointestinal disorder, kidney disease, liver disease or gout
- Anyone following a vegetarian or vegan diet
- Anyone following a weight loss programme (that may be affecting lifestyle, physical activity & diet)
- Anyone suffering from a psychiatric disorder or any type of substance abuse
- Anyone suffering from unregulated thyroid disease
Do I have to take part?

Participation in this study is voluntary. As a volunteer, you are under no obligation to participate or continue with the study if you do not wish to do so. Therefore, you can withdraw at any time without having to provide a reason for doing so.

What does the study involve?

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

Before starting the diets you will be asked to record a 4 day food diary.

We will provide all food and drinks during the following 66 days (details below). You will be asked to attend the HNU on six occasions for Test Days, which last approximately 5 hours (Type A, three times) or 7 hours (Type B, three times).

A diagram for the study protocol can be found at the end of this information sheet.

What are the study diets?

You will be provided with four different diets:

1. Weight Maintenance 1 [MTD 1] – a three day normal diet, fed to your own energy requirements to keep your weight stable.

2. 4 week, High-Fibre [HF] or High Protein [HP] Weight Loss Diets – fed to your energy requirements. The HF diet has a lot of fruit and vegetables, wheat bran and wholegrain cereals.

3. Weight Maintenance 2 [MTD 2] – a one week normal diet, fed to your own energy requirements to keep your weight stable.

4. 4 week, High Protein [HP] or High-Fibre [HF] Weight Loss Diet – fed to your energy requirements.

The diets are all fixed intake calorie counted meals prepared by our Human Nutrition Unit kitchen staff 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. There are rooms available for a residential stay, if you wish, at no cost.

The menus are developed using common dishes i.e., Cheese & crumpets, Pasta bolognaise, Chilli con carne, Soup, 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?

Baseline 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.
- Questionnaires about eating: Before the study starts you will be asked to complete a 4day weighed intake diary to analyse your habitual food consumption.

On Test Days
We will measure your body composition, metabolism and health status on three occasions (at baseline and the end of each diet). These measurements are to be conducted over two days (Type A & Type B), six visits in total.

**Type A** - Days 6, 34 and 69 (~5 hrs)
- Body Weight
- Waist & Hip Circumference (by tape measure)
- Body composition (% Body Fat) by BodPod® machine. This 5 minute measurement involves you sitting inside the BodPod whilst your composition is measured using air displacement. You will be required to change into a swimming costume for this measurement.
- Thermic Effect of Food (TEF). RMR will be measured using the Quark Metabolic Monitor for metabolic rate before and after eating (TEF). There will be eight measurements in total; once for 30 minutes before breakfast and then seven times for 10 minutes (every half hour) until lunch is served (4hrs after breakfast).

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

**Type B** - Days 8, 36 and 71 (~7 hrs)
- Body Weight
- Blood Pressure
- Total Body Water Content (TBW) – This is a technique that involves drinking a glass of water, which has been formulated to contain deuterium, a stable isotopic compound, which mixes with the water in your body. Your body already contains this substance and the dose is just enough to increase the amount so that it can be measured in a very sensitive machine. The drink may have a slight “off” taste.
- Blood samples – Samples will be collected at 0, 3 and 6 hours using a cannula (a total of three blood samples per test day ~ 25ml which is equivalent to ~1oz). The samples will be analysed for glucose, insulin, lipid profile, gut hormone profile and TBW.
• Breath samples - for gastric (stomach) emptying analysis. The breakfast on the test days will contain a stable isotope marker (13C Octanoic Acid, in a powdered form) that is excreted in breath. This is a lipid molecule, which is safe for humans to consume (even pregnant women) and we will collect breath samples every 15 mins to detect the marker and assess stomach emptying time.

• Motivation to eat – recorded every 30 minutes using a paper questionnaire

• Breakfast & Lunch will be provided at 8am & 2pm respectively. The time of day when meals are consumed is to be regulated on this study so it is important that these times are adhered to.

A diagram of the schedule for the Type B Test Days can be found at the end of this information sheet

Other measurements: (not during test days)

• Gastrointestinal Questionnaire: once a day during each period you will record gut feelings using a questionnaire (i.e., rumbles, flatulence, bowel movement)

• Food record: at the end of each period for 3 days.

• Faecal samples: to be collected during each dietary period. Sample pots and instructions on how to collect these samples will be provided.

What if you find something in my samples?
If we find a blood, or other result, that is out with normal ranges we will inform you and your GP

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 for a further 5 years for potential analysis of appetite biomarkers.

Expenses and payments
All of the 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?
We would hope that by losing weight your metabolic health will improve (e.g. a reduction in blood pressure, body fat levels, blood cholesterol or glucose). 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 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 Baukje de Roos (Chair of the Human Studies Management Committee). You can be assured that Dr de Roos will be a sympathetic listener and that your concerns will be treated seriously. She 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 and Dr de Roos 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 funded by the Scottish Government as part of the ‘Healthy, Safe Diets’ research theme.

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 data will be stored for a maximum of 5 years, after which they will be destroyed.

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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 signed consent form for you to keep.
**Study Diagram:**

- **Baseline:**
  - Consent Paperwork
  - Health Status Questionnaire
  - Height & Weight
  - Blood Pressure
  - 4day Food Diary

- **Test Day Measurements**
  - **Type A (~5 hrs):** Day 6, 34 & 69
    - Weight
    - Waist & Hip Circumferences
    - Body Fat (BodPod)
    - Resting Metabolic Rate (RMR)

- **Type B (~7 hrs):** Day 8, 36 & 71
  - Blood Pressure
  - Blood Samples (at 0, 3 & 6hrs for Glucose & Lipids)
  - Total Body Water ($D_2O^{18}$)
  - Breath Samples (for Gastric Emptying)
  - Appetite Questionnaires

- **Ongoing Measurements:**
  - Weight
  - Faecal Samples
**Test Day Protocol Diagrams:**

**Test Day Type A Schedule:**

- **0hrs (pre-breakfast):**
  - Body Weight
  - Waist + Hip Circumference
  - Body Fat (BodPod)
  - Resting Metabolic Rate (RMR) - every 30 mins (for 4 hours)

- **4hrs (lunch):**

**Test Day Type B Schedule:**

- **0hrs (pre-breakfast):**
  - Weight
  - Total Body Water
  - Blood Pressure
  - Blood Sample

- **3hrs (11am):**
  - Breath Samples

- **6hrs (pre-lunch):**
  - Blood Samples
  - Questionnaires every 30 mins (for 6 hours)