PARTICIPANT INFORMATION SHEET

Name of Investigator: Dr Alex Johnstone

Name of Study: STUDY 806 – THE MEAL TIME STUDY

Invitation to participate

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 and calorie distribution throughout the day on appetite control and body weight. We will compare a diet comprised of large breakfast meals (and smaller dinner meals) with one containing large dinner meals (and smaller breakfast meals) to look at energy balance and eating behaviour. This will allow us to investigate the importance of ‘what we eat’ as well as ‘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 20-60, or a female aged over 18 who takes the oral contraceptive pill
– You regularly eat breakfast (at least 5 days per week)
– You have a defined, habitual sleep-awake cycle
– Your BMI is within the range 27-40kg/m²

The exclusion criteria for this study are as follows:

• Anyone with a BMI (in kg/m²) under 27 or over 40
• Females who do not take the oral contraceptive pill
• 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?**

No, 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 giving a reason and your data will be destroyed if you desire.

**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 and complete questionnaires about eating behaviour.

We will provide all food and drinks during the following 66 days (details below).

You will be asked to attend the HNU on eight occasions for Test Days, which last approximately 3 hours (Type A, four times) or 7 hours (Type B, four 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 four day normal diet, fed to your own energy requirements to keep your weight stable.
2. **4 week, BB Weight Loss Diet** – fed to your resting energy requirements to generate weight loss. The BB diet comprises big Breakfasts and smaller evening meals.
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, BD Weight Loss Diet** – fed to your resting energy requirements to generate weight loss. The BD diet comprises big Dinners and smaller morning meals.

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.

Meal times will be standardised for this study and timing must be strictly adhered to.

Study 806 – Form 2, PIS V1, 09/08/17 LRC

IRAS ID: 232521
What measurements will be conducted if I take part?

Baseline Visit (~2hrs):
- **Medical Screening:** you will be asked to complete a health status questionnaire and will be required to provide a small blood sample to confirm eligibility. Bloods tests will include basic haematology (blood cell count) and clinical biochemistry (e.g. sodium/ potassium) which are routine blood tests.
- **Height and Body weight**
- **Blood pressure measurement**
- **RMR (Resting Metabolic Rate):** measures 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 exercise, chronotype (morning/ evening tendencies) and sleep patterns**
- **Questionnaires about eating:** Before the study starts you will be asked to complete a 4day weighed intake diary to analyse your habitual food consumption and appetite questionnaires to assess how hungry & full you feel.

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

**Type A, Days 6, 34, 41 and 69 (~3 hrs)**
- **Body Weight**
- **Blood Pressure**
- **Blood samples – Samples will be collected at 0 and 2hours (before and after the breakfast meal). Analysis of glucose, insulin, lipid profile and gut hormone profile will be conducted from the samples.**

**Type B, Days 8, 36, 43 and 71 (~7 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 (image on the right) whilst your body composition is measured based on your weight and the amount of air you displace when you sit inside the chamber. You will be required to change into a swimming costume for this measurement.**
- **DEXA (Dual energy X-ray absorptiometry) scan - a type of very-low dose x-ray, which measures body composition (fat mass and fat free mass) and bone density. You lie still on a platform type bed, while an**
overhead x-ray scanner scans the body. The scan takes 15 minutes. The radiation dose is less than one tenth of a normal chest x-ray.

• 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 and natural 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 as it leaves your body by a very sensitive machine. The drink may have a slight “off” taste.

• Urine samples will be collected pre-dose and at 3 and 6 hours after the above drink for measuring TBW.

• Resting Metabolic rate (RMR) measurement (30 minutes fasting and for 10 minutes every 30 minutes after breakfast for 6 hours).

• Breath samples - for gastric (stomach) emptying analysis. The breakfast on the test days will contain a stable compound ($^{13}$C 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.

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

A diagram of the Study Schedule and Test Days can be found at the end of this information sheet

Other measurements: (not during test days)

• Faecal samples for assessment of gut microbiota. We will ask you to collect 1 sample per week. Sample pots and instructions on how to collect these samples will be provided.

• Total daily energy expenditure will be measured across each 4 week weight loss periods by the use of doubly labelled water (DLW) and the collection of urine samples. This technique is similar to the TBW technique. A small dose of the naturally occurring stable compound (DLW) will be provided to you mixed with water. As per the TBW method, there are trace amounts of the provided compound already in your body and the dose provided will increase the quantity just enough to measure its excretion from your body over time. The measurement of your energy expenditure can be determined through the rate of loss of the compound from your body as water in urine.

On test days 8 and 43, the drink for the measurement of DLW will be provided as part of the TBW drink. You will also be asked to consume an additional dose on days 22 and 57 when you attend the institute for breakfast and weight measurements.

Urine samples will be collected prior to the dose, at 3 and 6 hours after the dose, and 2, 7, 8, 13 and 14 days after the dose. Collection cups and instructions will be provided.

At the end of each dietary period we will ask you to record the following for 3 days:

• Food Intake (all foods & drinks consumed are recorded)

• Activity - A monitor is used to measure physical activity on three axis (directions) and also records number of steps taken.

• Continuous Glucose Monitoring System (CGMS) - a pager size unit is worn for the test period of 3 days. The monitor records data from the sensor every 10 seconds and stores a glucose reading every 5 minutes.
• Appetite & Motivation to eat – recorded every hour using a paper questionnaire
• Gastrointestinal Questionnaire: once a day you will record gut feelings using a questionnaire (i.e., rumbles, flatulence, bowel movement)
• Details of your sleep and activity to support the above measurements.

What are the possible disadvantages and risks of taking part?

The risks associated with participation in this project are minimal. However, the researchers would like to draw your attention to the following:

• **Dual-energy X-ray absorptiometry (DXA):** By taking part in this study you will receive four DEXA scans. DEXA scans use very low intensity X-ray to image your body. The radiation dose you will receive from these is about equivalent to the 4 days of the normal background radiation we all receive and should be considered negligible.

• **Blood Collection:** Blood collection will be performed by trained and experienced phlebotomists. Blood collection from a vein in your arm is not associated with risks greater than that associated with a routine blood test. There may be mild discomfort and a small amount of localised bruising as a result of blood collection, but no more than is experienced with a routine blood test. Each member of the research team also has extensive experience in blood collection and handling.

• **Risks associated with finding of medical conditions:** We will be assessing you blood pressure, blood chemistry, lipids and glucose throughout this study. If we find a blood test result that is outside of the normal range, we will inform you and your GP in writing. If any medical conditions are subsequently uncovered, this may affect your future insurance status if you have private health insurance. Please contact your insurance company before agreeing to take part in this study if you have any concerns.

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 energy requirements and blood results, which you may find interesting and useful.

What happens when the research study ends?

After the study is completed, you will receive a detailed report on your results which can provide helpful information for you to continue to maintain your post-study body weight or continue to lose weight on your own if you desire.

Will my taking part in this study be kept confidential?

All the samples you provide will be coded to maintain confidentiality. We will store your samples until the study has been completed and then for up to a further 10 years to allow for potential additional analysis by other ethically approved projects. After this time, all samples will be destroyed.

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. If you agree, your contact details may be kept by the research team to re-contact you for future ethically approved studies. Identifiable contact information will be kept after the end of this study and this information will be held in accordance with the data protection act. All of the data will be de-identified at this time.
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 it will be destroyed.

If any of your blood test, blood pressure or DEXA scan results fall outside of the normal range, we will inform you and your GP in writing for your doctor to maintain as a medical record.

**What will happen to the results of the study?**

A report will be generated from the study, which may result in publications; there will be no information in this which will identify you.

**Expenses and Payments**

On completion of the study you will receive a gratuity payment of £100. We will also provide you with feedback on your own body composition, energy expenditure, habitual food intake and blood results.

**What if there is a problem or something goes wrong?**

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, email 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.

**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 North of Scotland Research Ethics Committee.

**Who is organising and funding the research?**

The study is funded by the Medical Research Council and sponsored by the University of Aberdeen.

**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 keep.
Study Diagrams

Figure 1: Study Timeline

Day No: 1 - 4, 5 - 8
8 days

4 weeks
9 - 36

1 week
37 - 43

4 weeks
44 - 71

Screening  MTD1  Breakfasts  Dinners  MTD2  Dinners  Breakfasts  Feedback

3 day Measurements (at the end of each dietary period):
- Activity and Sleep
- Food Intake
- Continuous Glucose Monitoring System (CGMS)
- Appetite Questionnaires

Baseline:
- Consent Paperwork
- Health Status Form
- Blood health markers
- Questionnaires
  (Physical Activity, Sleep & Chronotype)
- Height & Weight
- Blood Pressure
- Resting Metabolic Rate (RMR)
- 4 day Food Diary

Test Day Measurements
Type A (~3 hrs): Day 6, 34, 41 & 69
- Weight
- Blood Pressure
- Blood Samples
  (at 0 and 2hrs for Glucose, Lipids, gut hormones)

Type B (~7 hrs): Day 8, 36, 43 & 71
- Weight
- Resting Metabolic Rate (RMR)
- Waist & Hip Circumference
- Body Fat (BodPod)
- DEXA Scan
- Breath Samples (for Gastric Emptying)
- Appetite Questionnaires
- D₂O¹⁸

Ongoing Measurements:
- Weight
- Faecal Samples
- Total daily Energy expenditure by D₂O¹⁸
Figure 2: Test Day Timelines

Test Day Type A Schedule:
- 0hrs (fasting) Blood Sample
- 2hrs (post-meal) Blood Sample

Test Day Type B Schedule:
- 0hrs (pre-breakfast)
  - Blood Sample
  - Body Weight
  - Waist + Hip Circumference
  - Body Composition (DEXA Scan)
  - Body Fat (BodPod + Bone Density)
- every 15 - 30 mins (for 6 hours)
  - Resting Metabolic Rate (RMR)
  - Breath Samples
  - Questionnaires
- 6hrs (lunch)
  - Urine collection (pre-dose, 3 and 6 hours post-dose)