**PARTICIPANT INFORMATION SHEET**

**STUDY NO: 810**

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<th>Name of Investigator:</th>
<th>Professor Alex Johnstone</th>
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**Name of Study:** FADiets: Food additives – do processed foods impact on gut and metabolic health?

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.

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**What is the purpose of this study?**

To assess the effect in healthy human volunteers of an E number which is a food additive and commonly used and consumed emulsifier, on gut function, gut inflammation and glucose metabolism. We will be using a powdered soy lecithin product in the food to compare a diet with and without this ingredient. This is a collaborative project with the University of Liverpool.

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**Why have I been chosen?**

We are looking for 20 men or women who are generally healthy, aged between 18 and 65 years old who are overweight or obese (BMI range 27-40kg/m²).

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**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 a reason, and your data will be destroyed.

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**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.

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**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 record your height and weight. This visit should last approximately 1 hour.

2. After the screening, you will be asked to visit the Human Nutrition Unit on 5 further occasions for measurements (a baseline visit, four blood sample days)
3. The main study comprises 45 continuous days which involve an initial 7-day period in free-living conditions, followed by a 14-day low calorie diet with supplementary emulsifier, a 7-day washout period and a 14-day low calorie diet with no emulsifiers.

**What are the diets?**

1) an initial 7-day period when we will ask you to record a weighed intake food diary, to note your normal eating habits. These 7-days are free-living so no meals will be provided by the Rowett.
2) a 14-day low calorie diet, either with or without supplementary emulsifiers (all meals will be provided),
3) a 7-day washout period when you return to free-living conditions (no meals provided) and record a second weighed intake food diary,
4) a second 14-day low calorie diet, either with or without supplementary emulsifiers (all meals will be provided).

The two diets you receive in periods 2) and 4) will be randomised and will either be:
- a controlled diet containing a supplementary lecithin emulsifier or
- a diet free of any known emulsifiers.

Food scales will be provided with instruction on how to complete the weighed intake food diaries. All foods provided by the Rowett will be individually prepared in the Human Nutrition Unit as ready to eat meals.

Collection of the Rowett meals will be required from the HNU on Monday, Wednesday and Friday mornings during dietary periods 2) and 4). Breakfast will be provided at the HNU on these mornings.

**Study Diagrams**

*Figure 1: Study Timeline*
Figure 2: Test Day Timeline

What are the measurements?

1. Baseline visit (day 0, duration ~ 1½ hours):
   - Body weight (measured in dressing gown)
   - Blood pressure
   - Waist and hip circumferences (measured using a 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.
   - Eating behaviour, motivation to eat, physical activity and energy levels - assessed by questionnaires
   - RMR (resting metabolic rate): This consists of breath sample collection for 30 minutes whilst you are lying on a bed.

2. On the blood sample test days (days 8, 22, 29 and 43 of the study, duration ~ 2½ hours) we will measure:
   - Body weight (measured in dressing gown)
   - Blood Pressure
   - Oral Glucose Tolerance Test (OGTT) conducted over 2 hours - five blood samples will be collected during the 2 hours (every 30 mins) using a cannula.
     - Fasted glucose, insulin & lipid profile will be analysed from the first blood sample (0 mins)
   - Faecal samples be required to be brought to the HNU. These will be collected at home (on the morning of the visit) using specific containers which are provided for the collection & transportation of these samples.
   - Gastrointestinal symptoms, appetite and motivation to eat - assessed by questionnaires.
### What if you find something in my samples?

If we find a blood test result that is out with the normal range, we will inform you and your GP in writing.

### 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 up to a further 5 years to allow for potential additional analysis. After this time, all samples will be destroyed. Some coded samples will be sent to the University of Liverpool for analysis and they will be destroyed at the end of the study, once analysis is complete.

### 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 £50. We will also provide you with feedback on your own body composition, habitual food intake and blood results.

### 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.

### 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 De Roos, 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. 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.

### Who has reviewed this study?

The Rowett Ethics Review Panel has approved the study.

### Who is organising and funding the research?

The Medical Research Council
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.

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

The Rowett Institute
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD

Prof Alex Johnstone
Email: Alex.Johnstone@abdn.ac.uk
Tel: 01224 438614

Dr Alan Walker
Email: A.Walker@abdn.ac.uk
Tel: 01224 438739

Dr Dom Partridge
Email: dominic.partridge1@abdn.ac.uk
Tel: 01224 438748

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.
I have read and understood the information summarised on these sheets and I had an interview with the main investigators. I have been given a copy of the information sheet to keep. I have also signed a consent form.

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*When completed: 1 copy for participant, 1 copy for case report file*