

## PARTICIPANT INFORMATION SHEET

<b>Name of Investigator:</b>	Dr Fiona M. Campbell
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<b>Name of Study:</b>	Do dietary AGEs have an acute effect on metabolism and cognition?
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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?

The Western diet is associated with obesity and type 2 diabetes. As part of this diet, processed foods are high in Advanced Glycation End Products (AGEs) which have been implicated in the damaging effect of this diet on health. The purpose of this study is to find whether dietary AGEs given as part of a milkshake can alter blood glucose, lipids and memory

### Who can take part?

Young (18-30 years) and older (55-75 years) healthy men and women, normal weight and overweight (BMI>19 to 29.9). You cannot take part if you have any milk protein allergy or lactose intolerance, diabetes, thyroid problems, you have heart disease, you smoke, have a history of neurological abnormalities, are taking any current psycho-active, anti-inflammatory or insulin sensitising medication.

### Why have I been chosen?

You are eligible for this study as you fall into the age group with the appropriate BMI who may have different responses to dietary AGEs

### Do I have to take part?

No, it is entirely up to you if you wish to participate in the study. If you agree to take part you will be asked to sign a consent form. You are free to withdraw at any time without giving a reason.

### What will happen to me if I take part?

If you take part in the study all the information collected during the course of the study will be kept strictly confidential. We will ask you questions about your diet and health. Your height, body weight and body fat will be measured. We will ask you to attend the Human Nutrition Unit on 5

separate occasions and you will consume a milkshake on 4 of those visits. We ask for a urine sample at the beginning and end of each visit. We will also take blood samples to measure glucose and lipid levels to tell us how well your body deals with glucose and lipid. We will also measure your body composition and you will be required to fill in some questionnaires about the type of food you generally eat and the level of your physical activity.

#### **What will happen to the samples I give?**

All samples will be stored in an anonymised form, so your identity will only be known to the research team. The blood samples will be analysed for blood glucose and related hormones. The link between volunteer identity and data obtained in this study will be known only to the research team and will be kept strictly confidential. Your samples will be stored by the research team for future use where it is relevant to the study. The samples will be stored in a freezer for 4 years. If we find any clinically relevant out of range results from your samples we will inform your G.P with your consent. Some of the samples will be analysed for genes that are switched on and off by the diet. All data will be kept in a locked filing cabinet. Results from the cognitive tests will be kept in an anonymised format on password protected University of Aberdeen computers.

#### **What do I have to do?**

You will be in the study over a period of 29 days in total. The study visit days are as follows:  
Visit 1. You will come to the Human Nutrition Unit (HNU) after an overnight fast, which means nothing to eat or drink (except water) after 10pm the previous evening. You will meet the study team and have the opportunity to discuss the details of the study in full and sign the consent form. You will undergo a medical examination by a GP to verify your general health and the inclusion/exclusion criteria. You will have your height, weight and body fat measured. You will then have a pinprick blood sample taken. You will be given a short psychological test. This visit will take approximately 2 hours.

Visits 2, 3, 4 and 5: The day before your visit you will be asked to come and collect food for you to eat that day. You will be expected to eat only the food provided that day. The next day we request that you come into the HNU at a prearranged time in the morning after an overnight fast. After arrival at the HNU you will be asked to provide a urine sample then given a milkshake containing different quantities of AGEs. There will be four milkshakes in all. Blood samples (around a tablespoonful in total at each time point) will be taken immediately before the milkshake (0 min) and again after 30, 60, 90, 120, 150 and 180 and 240 min. Computer based memory tests will be carried out at 0, 30 and 90 minutes – there are no right answers to these tests. A urine sample will be requested at the end of the study. You will then be offered lunch. After approximately 4 hours you are free to leave the HNU and live normally until the next week or so when the subsequent test will be run. These visits will be similar to the first.

#### **Expenses and payments**

At the end of the study you will be given the choice of either cash or a voucher for £50 to cover any travel costs and to thank you for your participation in the study.

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

We will let you know aspects of your health status. While there may be no benefit to you personally from taking part in the study but we aim to develop knowledge for future nutrition policy.

**What if there is a problem?**

If during your participation in this study you have reason to complain and you feel unable to resolve this with the P.I., Dr Fiona Campbell Tel. (0)1224 438617, email: [fiona.campbell@abdn.ac.uk](mailto:fiona.campbell@abdn.ac.uk), or the Human Nutrition Manger, Ms Sylvia Stephen Tel. (0)1224 438607, email: [sylvia.stephen@abdn.ac.uk](mailto:sylvia.stephen@abdn.ac.uk), then you can contact Professor Baukje de Roos (Chair of Human Studies). Tel. (0)1224 438636, email: [b.deroos@abdn.ac.uk](mailto:b.deroos@abdn.ac.uk). Aberdeen University carries indemnity insurance for any harm or adverse events.

**Who has reviewed this study?**

This study has been reviewed and approved by the Rowett Institute Human Studies Management Committee and has received ethical approval from the Rowett Ethics Committee.

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

The study was organised by the Rowett Institute and is funded by the Scottish Government (RESAS).

**Will my taking part be kept confidential?**

Yes your participation in this study will be kept confidential.

**CONTACTS FOR STUDY**

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