

FAMOUS

The Fish and Meat Study

Participant Information Leaflet

We would like to invite you to take part in our research study.

Eating fish can protect against heart disease, but also increase blood levels of a chemical associated with unhealthy diets which has been linked to heart disease. Our study will determine whether this chemical is a cause for concern with those that eat a diet high in fish, or whether fish should be considered a healthy alternative to eating meat-based diets in terms of heart disease.

Please take time to read this short information sheet carefully and discuss it with others if you wish. Ask us if there is anything that is not clear.

If you are interested in finding out more about the study or taking part please let us know by telephone, email, or by using the reply slip and freepost envelope, and we will contact you.

Thank you for reading this

What is the purpose of the study? This research study is trying to find out if trimethylamine oxide (TMAO), a chemical found in the blood and urine and originated from meat- and fish-rich diets, is a genuine marker for heart disease.

Why have I been invited? Your body mass index falls within the range suitable for the study. Further tests for your blood lipid level and blood pressure carried out during the screening visit will determine if you are eligible for the study.

Do I have to take part? No. It is up to you to decide whether to take part. If you take part you are still free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part? If you think you might be interested in taking part we will send you more information, and make plans to see you at the Human Intervention Study Unit at the Rowett Institute on the Forehill site.

At this first study visit we will answer any questions that you have. If you decide you want to take part in the study you will be asked to sign a consent form. We will then review your medical history with you and measure your weight, height, and blood lipids and glucose (using a finger prick test to collect a drop of blood) to make sure you are suitable for the study. If eligible for the study, we will ask you to fill a food diary before next visit. We will also measure the amount of energy your body needs to function while at rest (resting metabolic rate). This is a simple painless non-invasive procedure during which we analyse the air you breathe out. This will allow us to calculate the amount of food we will need to give you during the intervention to match your energy needs.

There would then be 7 more study visits, 3 of which lasting about an hour each, and the others around 1.5 hrs, all in the mornings, over 14 weeks.

You will be asked not to eat anything before each of these visits, but will be given breakfast once we have completed the study tests.

At each of the shorter visits we will:

- Take a small amount of blood (20ml, about 2 dessert spoons)., and ask you to complete a simple questionnaire.
- We will give you urine and stool collection kits to take home with you. We will explain how to use them so you can bring the samples back with you at your next visit. The methods of collecting the urine and stool samples with the kits provided are very simple and clean.

At each of the longer visits, in addition to the to the other procedures listed above we will conduct the following additional measurements:

- We will measure the amount of fat and muscle your have in your body composition using a bodpod machine (lasts 10 min, non invasive and painless procedure).
- We will measure you blood pressure and measure how stiff your blood vessels are, using an ultrasound device (painless and non invasive, like blood pressure measurements)
- We will assess how your body handles sugar. You will be fitted with a continuous glucose monitor which will measure automatically your sugar level over 8 days without having to take blood sample. We will give you also a some sugar to take with you (75g) to consume while fasted in warm water 24 hrs or 48hr after your visit, and stay fasted for 120 min after drinking the sugar solution. The study team will contact you by email or phone several times during the study to check if you have any issues with the study, but you can also contact the investigators at any time.

What will I have to do? You will be given all of the foods you need for the study.

1. For the first week you will be asked to eat a control diet which is similar to what people eat on average in the UK.
2. You will then be asked to eat one of the three study diets, **A**, **B** or **C** for 6 weeks.

Study diet A is a meat-based diet; **Study diet B** is a fish-based diet; **Study diet C** is a plant based diet

3. You would then be asked to eat the control diet for 1 week.
4. You will then switch to another intervention diet (**A** if you started with **B** or **C**, or **B** or **C** if you started with **A**) for 6 weeks.

What are the possible benefits of taking part? The study may not benefit you personally but the information we collect may help find ways of reducing other people's risk of developing diseases such as heart disease.

Will my taking part in the study be kept confidential? All information which is collected about your during the research will be kept strictly confidential and will be held securely. We will tell your GP that you took part in the study and will give your GP your blood pressure and cholesterol results from the study.

Contact for further information If you have any questions or are interested in taking part please contact us using the reply slip and freepost envelope, telephone us or by emailing us. We will then contact you and send you more information.

Further information and contact details:

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THANK YOU FOR TAKING THE TIME TO READ THIS LEAFLET