PARTICIPANT INFORMATION SHEET

Ethics reference: 14655

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Full project title

InterSat: Health effects of commercially relevant palmitic versus stearic acid rich interesterified fats: a randomised crossover trial.

The INTERSAT study

We would like to invite you to participate in this original research project undertaken as part of a Malaysian Health Ministry funded project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

This research project is a short-term dietary intervention study to investigate the difference between how two commonly consumed fats are metabolised or broken down by the body and used as an energy source, and their impact on cardiovascular health. After eating a fat rich meal there is an increase in fat in the blood, which is believed to affect processes involved in heart disease. Dietary fat has a defined molecular structure, which the food industry can modify via a process called 'interesterification', in order to make liquid fats more solid. These fats are found in most of the spreads, bakery and confectionary products that we consume but their affects on fat metabolism and therefore processes involved in heart disease risk is unknown. This study aims to look at the differences in which the body metabolises two different types of commonly used interesterified fats.

Why have I been chosen?

You have been contacted as you have expressed an interest in our research. In order to participate in this study, you need to be able to say 'yes' to the following:

- I am a male or female aged between 35-65 years old.
- I consume 2 or more snacks between meals every day
- I do not smoke and have not recently given up smoking (within the last 6 months).
- I have no history of heart attack, stroke, angina, thrombosis, liver or kidney diseases, diabetes, chronic gastrointestinal disorder or cancer.
- I do not take medication to lower blood fats (e.g. statins, fibrates) or to stabilise blood glucose (e.g. acarbose, metformin or sulfonylureas) or blood pressure.
- I am not taking oral antibiotics (and haven't within the last 40 days).
- I do not have a history of excess alcohol intake or substance abuse.

- I do not have food intolerances, allergies or hypersensitivity.
- I am not already participating in a clinical trial.
- I am prepared to follow dietary instructions before and during the study.
- I have not recently donated blood (within the last 3 months).
- I have not recently lost or gained more than 3 kg/7 lb (in the last 2 months).
- I have not participated in night shift work (12am – 6am) during the last 2 weeks, and do not plan to do so for the next 3 months.
- I have not given blood in the last 3 months.

What will happen to me if I take part?
If you would like to participate you would first need to complete a screening questionnaire with us over the telephone or via email (approx. 5 mins), after which potentially eligible volunteers will be invited to attend a clinic screening appointment (approx. 45 mins) in the Metabolic Research Unit on the 4th Floor, Corridor A, Franklin-Wilkins Building, 150 Stamford Street, SE1 9NH.

Summary of screening visit:
1) You should avoid eating or drinking anything, except water, for 12 hours prior to the commencement of your visit.

2) The visit will last approximately 45 mins.

3) We will explain all the details of the study and answer any questions you have. If you are still happy to take part, you will be asked to sign a consent form which asks you to consent to the collection of various measurements in the study.

4) We will ask you questions about your medical history, your food choices and eating habits as well as measuring your weight, height, percentage body fat and blood pressure.

5) We will need to take a small venous blood sample (14 ml, about 2 tsp) to check that your blood biochemistry is normal.

6) After the screening, we will provide you with breakfast.

The results of the screening blood test will be provided within 2 weeks. If any abnormal results are found, we will offer to provide you with a letter for your GP. If, after screening, you are discovered to be unsuitable for the study, your data will be destroyed.

If you are eligible for the study you will attend the Metabolic Research Unit (MRU) at the Franklin-Wilkins Building for four full day study visits, each of these will be 6 weeks apart. You will also need to return used food containers, collect additional food samples and have weight and body fat measurements taken on an additional four visits.

Preparations for your study day visit:

Prior to the first visit you will be given a 4-day diet diary in which we would like you to record everything that you eat and drink for 4 days (three weekdays and one weekend) before the study day. To stabilize your health markers before each study visit, it is important that you eat the same type of low-fat dinner, at approximately the same time, the night before. We will give you information and suggestions on what sort of meal is appropriate. You will be asked to refrain from eating or drinking anything (apart from water) for 12 hours prior to the commencement of your visit. We will then randomly assign you to one of two treatment groups: either the main cohort, or the subgroup.

Summary of study visits:

At the start of the study visit, a blood sample (10 mL, or 2 tsp) will be taken from a vein in your arm. We will also be measuring your blood pressure and the function of the brachial artery in your arm, using a non-invasive, ultrasound technique called flow mediated dilatation (FMD).

Subgroup study visit:

A smaller subgroup of participants will follow the main protocol but continue to have repeat blood samples taken at regular time via a cannula at regular intervals throughout the day (a total of 98 mL/20 tsp will be taken throughout each study day). The first sample will be taken shortly after you arrive, after which you will be asked to consume a test meal (two muffins and a milkshake containing 50g of the test fat). After five hours, you will be given a cheese muffin (containing 30g of test fat) to eat.

Participants in the subgroup will have FMD measured when you arrive, and at 4.5 and 7.5 hours after your first muffin. This total visit should take approximately 9 hours, including time to consume a snack afterwards.

Once the measurements have been completed, you will be given detailed dietary information on what we would like you to eat over the next 6 weeks. You will also be given a supply of food including muffins and spreads containing the test fats that we would like you to consume as part of your diet. During the 6-week periods, you will be asked to fill in another 4-day food diary, recording everything that you eat and drink for 4 days (three weekdays and one weekend).

Every two weeks during the 6-week intervention, you will be asked to come to the MRU to bring back your empty food containers and collect a refill of your muffins and spreads. At this time, your body weight and body fat percentage will also be measured.

After 6 weeks, we will invite you back to the MRU to repeat the procedures from your first study day visit, e.g. overnight fast, blood samples, blood pressure and FMD.

You will then be asked to return to your normal diet for 4 weeks.

After the 4 week “wash out” period, the second part of the study will commence following the same format as the first 6-week intervention, starting with a visit to the MRU where we will ask you to follow the original study visit guidelines (arriving having fasted since for 12 hours).

During the study, and for 6 months after completion of the trial, we request that you do not donate blood.

Summary of study day visit:

1) Following screening, if your results comply with the study inclusion criteria you will be invited to attend the Metabolic Research Unit in the Franklin-Wilkins Building on 4 further occasions 6 weeks apart; each of these visits will take around 30 mins.
2) We shall also ask you not to consume anything, except water, for 12 hours prior to the commencement of your visit. We will provide you with instructions for consuming a standardised low-fat meal for the night before the visit.
3) You will be asked to report to the Metabolic Research Unit in the Department of Nutritional Sciences between 8:10 and 08.50 am, in a fasted state. **Make sure you drink some water on the morning of the study to avoid dehydration**.
4) At each of the 4 visits, a small needle will be inserted in a vein in your arm and a sample of blood will be taken (at baseline 10 mL, or 2 tsp). Blood pressure and baseline flow mediated dilatation (FMD) will also be measured.
5) Before you leave the MRU, you will be given a small breakfast.

*Summary of **subgroup** study day visit:*

1) Following screening, if your results comply with the study inclusion criteria you will be invited to attend the Metabolic Research Unit in the Franklin-Wilkins Building on 4 further occasions 6 weeks apart; each of these visits will take approximately 9 hours each.
2) We shall also ask you not to consume anything, except water, for 12 hours prior to the commencement of your visit. You will also be asked to avoid tea, coffee, fatty foods, drinking alcohol, and any strenuous exercise the day prior to each visit. We will provide you with a standardised low-fat meal for the night before the visit.
3) You will be asked to report to the Metabolic Research Unit in the Department of Nutritional Sciences between 8:10 and 08.50 am, in a fasted state. **Make sure you drink some water on the morning of the study to avoid dehydration**.
4) At each of the 4 visits, a small flexible tube called a cannula will be inserted in a vein in your arm and a sample of blood will be taken (at baseline 10 mL, or 2 tsp). Blood pressure and baseline flow mediated dilatation (FMD) will also be measured.
5) After the baseline measurements are taken, you will be asked to consume a test meal, consisting of two muffins and a milkshake.
6) Following the test meal, we would ask you to stay in the Metabolic Research Unit but you are free to work/ read/ use your laptop for the remainder of the study day in between measurements.
7) After eating the test meal, further blood samples will be taken at regular intervals up until and includingS 8 hours after the meal. In total you will have 98 mL/ 20 tsp blood taken on each study day.
8) We will also measure FMD 4.5 and 7.5 hours after your first muffin.
9) 5 hours into the study we will provide you with a cheese muffin.
10) Following the final blood sample and after the cannula has been removed, you will be provided with a meal after which you are free to leave the MRU.

How will this benefit me?
You will have a free health check at screening, including liver function tests, full blood count, blood lipid profile and glucose levels, blood pressure measurements and body composition measurements. Should you wish to find out the results of this study you are welcome to contact the study team (using the details below) for a copy of the final report once the study is finished. In recognition of your time commitment, you will be paid an honorarium of £200 on completion of the chronic study (£50 for each completed study visit, exclusive of the screening visit) and an extra £140 for completion of the acute study (£85 for each completed visit). Any reasonable travel expenses will be refunded for the screening and study visits (maximum £10 per visit).

Will my participation be kept confidential?
Any information collected about you during this research will be kept strictly confidential. Your GP will not be told that you are taking part in the study, nor will they receive any results from the study, unless you instruct us to provide a letter for you to pass on to them. Subject confidentiality and anonymity will be observed throughout the study by use of subject codes in place of names, and the storage of subject details in a secure place. Only the investigators have access to this data.

What will happen to my study results?
Your anonymised data will be shared with other researchers at the university of Maastricht, our collaborators in this project, and with the Malaysian Health Ministry. This will pertain only to the results of the study and no personal information will be shared. We hope to publish the results of the whole study in a scientific journal. You will not be identified in any publication. We will be happy to discuss the overall results with you when the study is completed and will let you know how you can get a copy of the published results if you wish. The results may also be used in student project reports (or thesis), presented at conferences and disseminated via public engagement activities. The data will remain fully anonymised and you will not be able to be identified in any of these occasions.

Who is organising and funding the study?
The researchers who are organising this study are Dr. Sarah Berry and Dr. Wendy Hall from the Department of Nutritional Sciences at King's College London. This study is funded by the Malaysian Health Ministry.

Do I have to take part?
It is up to you to decide whether to take part or not. If you do decide to take part, you will be asked to sign a consent form. You can withdraw from the study at any time by informing one of the researchers and you are not obliged to give a reason. You can also withdraw your data from the study if you wish at any time up until two weeks after you complete the study. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you decide to take part, please let us know if you have been involved in any other study in the last year.

For further information, please contact: The InterSat study team on 020 7848 4345; intersat@kcl.ac.uk; Department of Nutritional Sciences, King's College London, Franklin Wilkins Building, 150 Stamford Street, London SE1 9NH.

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information.

Participant Information Sheet

Chair of Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (BDM RESC) *rec@kcl.ac.uk*