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| **PLAIN LANGUAGE STATEMENT AND CONSENT FORM** |  |

TO: Participants

**Plain Language Statement**

Date: 18/01/2019

Full Project Title: Does short term high fat, high calorie feeding impair cardiometabolic outcomes in healthy people?

**Protocol number:** GK00033

Project number: 2019-014

**Principal Researcher:** Dr Gunveen Kaur

**Student Researcher:** Ms Barbara Brayner

**Associate Researcher(s):** A/Prof. Michelle Keske, Dr Lee Hamilton, Dr Lewan Parker, Dr Andrew Betik, Ms Katherine Roberts Thomson and Ms Emily Wordie-Thompson

**1 Your Consent**

You are invited to take part in this research project which will investigate whether short-term (seven days) high fat, high calorie feeding can impair microvascular blood flow (small blood vessels) and glycaemic control (blood sugar regulation) in skeletal muscle and adipose tissue of healthy individuals.

This Plain Language Statement and Consent Form contains detailed information about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research or not.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. Your choice to participate, withdraw, or not participate, will have no effect on your academic grades, employment, memberships or your relationship with Deakin University.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described

You will be given a copy of this Plain Language Statement and Consent Form to keep.

**2 What is the purpose of this research?**

Previous studies have shown that short term (3-7days) overfeeding and overfeeding with high fat (with predominantly saturated fat) can lead to increased fasting glucose, impaired glucose tolerance as well as impaired insulin sensitivity in humans. But it is not known if the impaired glucose tolerance induced by short term high fat overfeeding is linked to impaired microvascular blood flow in skeletal muscle and adipose tissue. This is what we aim to test in this study.

The aims of this project are:

1) To investigate if 7 days of high fat overfeeding (+50% of energy, 50% calories from fat) with high saturated fat leads to impaired glucose tolerance in response to a mixed meal challenge in healthy adults.

2) To investigate if the impaired glucose tolerance is mediated via impaired microvascular blood flow in muscle and adipose tissue.

**3 What is the eligibility criteria to participate in this study?**

You can participate in the study if you meet the following criteria:

* Age 18-45 years.
* BMI 18-24.9 Kg/m2. We need to recruit healthy weight individual to make sure their microvascular blood flow responses are not affected by their obesity status.
* Normotensive (seated brachial blood pressure <140/90 mmHg).
* Have given signed informed consent to participate in the study.
* Have no known food allergies/intolerances.
* Have been weight stable for past 3 months.

You will be excluded from the study if:

* Not meeting the inclusion criteria outlined above.
* Smoking status – regular smoker in the last 10 years and/or >10 years of smoking history.
* History of severe liver disease or any vascular or cardiovascular disease or diabetes.
* Pregnancy/lactation.
* Family history of type 2 diabetes (i.e. a parent with type 2 diabetes).
* Person on a high fat diet (e.g. keto diet).

**4 What does participation in this research involve?**

Prior to enrolment in the study you will be asked to complete a general health and medical history questionnaire to identify conditions that may exclude you from participating. We may also discuss your participation with your current GP or specialist. If there is evidence of risk, this study may not be suitable for you. After you clear the eligibility criteria and provide a written consent you will be invited to the laboratory to undergo/perform the following sessions and procedures:

**Visit 1 Body composition, blood pressure, dietary and physical activity questionnaires**

* + Complete diet and physical activity questionnaires.
	+ Resting heart rate, blood pressure and body composition analysis (height, weight and a DEXA scan).

**Visit 2 Mixed meal challenge and baseline blood flow assessment**

* + Arrive in the laboratory after an overnight fast.
	+ Ingestion of a liquid mixed meal.
	+ Blood sampling and contrast agent infusion via a cannula.
	+ Ultrasound measurement of the forearm and abdomen region (measurement of cardiac function, arterial, skeletal muscle and adipose microvascular blood flow).
	+ Wear a face mask/hood to measure oxygen and fuel metabolism.

**Dietary intervention**

* + Consuming additional foods (on top of your normal diet) for 7 days. The exact calorie and fat intake will be calculated based on your individual dietary and physical activity measurements as well as your height and weight. This will be done under the supervision of an accredited dietitian.

**Visit 3 and 4 Body composition, mixed meal challenge and post-intervention blood flow assessment**

* + On day 4 and day 8 arrive fasted to the laboratory.
	+ Body weight assessment and a DEXA scan.
	+ Ingestion of a liquid mixed meal.
	+ Blood sampling and contrast agent infusion via a cannula.
	+ Ultrasound measurement of the forearm and abdomen region (measurement of cardiac function arterial, skeletal muscle and adipose microvascular blood flow).
	+ Wear a face mask/hood to measure oxygen and fuel metabolism.

The overall time commitment for this study is around 8 hours (spread across 3 visits). All testing sessions will take place at Level 5 Clinical laboratory, Building J, Deakin University (Burwood campus).

**5 Description of study procedures**

If you are interested, please read the following description of what procedures will be used in this research.

**Visit 1:** In your first visit to the Clinical Research Facility, we will measure your height and then get you to stand on a set of scales whilst wearing your shirt and shorts (no shoes or socks) and measure your body weight.

We will then ask you to sit down for 10 mins and then measure your resting heart rate and blood pressure with an automatic blood pressure analyser. This requires you to sit still and wear a cuff around your arm for 2 mins. Three measurements will be taken.

You will then have a DEXA scan to measure the percentage of your body fat mass and fat free mass. To do this you will be asked to lie still on a bed for approximately 15 minutes while a scanner moves above your body from head to toe whilst x-rays are scanned over your body. You will be asked to wear a lab gown for this scan.

**Visit 2:** For each testing visit (visit 2 and 3) you will be asked to avoid exercise and alcohol for 48 hrs prior to attending the Deakin University research facility. You will also be asked to avoid caffeine on the day of the study and do an overnight fast (for at least 10 hrs) before coming into the research laboratory. You will be asked to note the foods consumed 24 hours before each fasting test.

During visit 2 and 3 an intravenous cannula will be inserted into one arm, for blood sampling and to infuse a safe contrast agent solution (detailed later). You will be asked to lay on the bed while we perform cardiac echocardiography(measurement of cardiac function using the ultrasound.

After a baseline blood sample the contrast agent infusion will commence and you will then be asked to consume a liquid meal within 5 minutes. You will then be asked to rest on a hospital bed for 2 hours while blood samples and ultrasound measurements of the forearm and abdomen are taken. In total, visit 2 and 3 may take upto 4.5 hours.

**Mixed meal challenge.** To measure your body’s ability to respond to and metabolise a meal, you will be asked to arrive in the laboratory after an overnight fast and to drink a liquid meal that contains a mixture of fat, carbohydrate and protein. Blood samples (10ml) will be taken at 0, 15, 30, 60, 75, 90, 105 and 120 minutes. This will equate to 90ml of blood which is much less than a single blood donation (500ml). Ultrasound measurements of the forearm and abdomen will be taken before and 60 minutes after meal ingestion.

**Blood Sampling.** Research staff qualified to perform cannulation and venepuncture will collect blood samples via intravenous catheter and venepuncture. Catheters are used when several blood samples are needed from one site over a brief duration such as to be used here. To do this a small plastic tube (catheter/cannula) will be inserted into a vein on your forearm using a needle. The insertion of the needle can be uncomfortable (similar to receiving an injection or donating blood). However, once the catheter is in place the needle is removed. Once the catheter is in place, it is a simple and painless procedure to remove further blood samples. It is possible, although unlikely, that some minor bruising may occur around the site of cannulation.

**Ultrasound measurements.** We will use a specific ultrasound technique to measure how well blood is flowing through the small blood vessels in the muscle of your forearm. This will require infusing a contrast agent (called Definity) into one of your veins so that ultrasound images of these small blood vessels can be taken. The infusion will require cannulation as described in above paragraph.We will also measure how well your heart is pumping blood through the body by placing a non-invasive ultrasound probe on the surface of the skin of your forearm and abdominal region to image the arteries within. You will need to wear shorts and t-shirt/top for this test.

**Resting metabolic rate:** This involves you laying on the clinical bed for 20 mins, breathing normally into a mask/hood that is connected to the oxygen and carbon dioxide sensors.

**Dietary intervention:** You will be asked to consume a high fat, high calorie diet for 7 days. This will involve you consuming your regular diet plus the high fat snacks provided to you. These foods will be provided to you by the research team at no additional cost to you. You will be given clear instructions by the team dietitian on what to eat and you will be asked to fill out diet diaries. During these 7 days the researchers will regularly check up on you via a phone call or mobile text to ensure you are adequately following the diet protocol. While it is anticipated that there will be no serious physiological effects of the 7 days of overfeeding diet, it is likely you will gain a small amount of weight (0-2 kg) over this period. Body weight typically returns to normal within a few days of stopping the intervention.

**Visit 3 and 4:** These visits will be scheduled on day 4 and 8 (after the 3 days and 7 day dietary intervention is completed). For visit 3 and 4 you will undergo same tests as visit 2 and a DEXA scan to determine any changes in body composition.

You will be provided three $ Coles/Myer voucher to compensate for your time, travel, parking and other related expenses that may arise from participation in the research study

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Deakin University.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

**7 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any direct benefits from this research; however, possible benefits may include gaining a better understanding of your general health, your blood glucose, insulin and lipid levels. Furthermore, findings obtained from this research will help improve our understanding of how high fat diet may impact our microvascular blood flow and glucose metabolism.

**8 What are the possible risks and disadvantages of taking part?**

Before you volunteer to be part of this study, there are some important things to understand:

* Having a drug injected or blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, this is low risk and can be easily treated.
* A small number of people (8.4% of people) have side-effects with the infusion of the contrast agent (Definity) during ultrasound imaging. The most common of these side-effects include:
1. Back pain (1.2% of people)
2. Chest pain (0.8%)
3. Headache (2.3%)
4. Dizziness (0.6%)
5. Nausea (1.0%)
6. Flushing (1.1%)

These symptoms usually go away quickly once the infusion is stopped.

* Some people may have an allergic reaction to infusions, plastics or adhesives that we use for testing. Please inform the research team if you have any known allergies.
* It is important that women participating in this study are not pregnant. It is important to let the researchers know if you think you might be pregnant. If you think you might be pregnant then we cannot enrol you into the study.
* Seven days of high fat overfeeding is likely to increase weight and fat mass slightly. It is also likely to induce insulin resistance in the liver and muscle, increasing fasting glucose and insulin. The protocol is not likely to induce changes in blood pressure or LDL-cholesterol. Any negative changes will likely dissipate when a normal diet is resumed.
* This research study will involve exposure to a very small amount of radiation from the DEXA scans. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.06mSv. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure.
1. **How will these risks be managed?**
* We follow approved and pre-tested methods for this study. The research team is trained in first aid, CPR and advanced resuscitation procedures. Two of the trained team members will always be present during testing sessions.
* In the unlikely case of a medical emergency, a call to 000 will be made. The researchers will commence appropriate resuscitation methods or other appropriate procedures (e.g., administration of adrenalin) while waiting for an emergency team to arrive.
* In the event of emergencies, you will need to undergo an additional medical review and consent process before you will be permitted to return to the study.
* For all other adverse events of a physical nature (such as headache or back pain), the testing procedures will be stopped, you will be consulted and reassured and then we will make arrangements for you for appropriate follow-up (e.g. immediate review by a medical practitioner or early referral to an appropriate health professional) at no cost to you.

**10 What will happen to my test samples?**

The collection of venous blood is a mandatory component of the research project and will be utilised for both medical health screening and research purposes. Blood samples and subsequent data will be coded with a re-identifiable ID number and stored for a minimum of 5 years at Deakin University (Burwood Campus). Blood will be analysed for glucose, insulin, and markers of cardio-metabolic and vascular health.

**11 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you may not be able to take some or all of the medications or supplements you have been taking for your condition or for other reasons. It is important to tell the research staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the researchers about any changes to these during your participation in the research project. The researcher will explain to you which treatments or medications may need to be stopped for the time you are involved in the research project or you may be excluded from participation.

**12 What if I withdraw from this research project?**

You can withdraw from the study at any time. If you decide to withdraw from the project, please notify a member of the research team.

With your permission, the information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the research team up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

**13 What happens when the research project ends?**

Following participation in the research project you can request a health report detailing some of the results that have been collected. However, many of the main findings of the research project will not be available until completion of the research project and data analysis of all participants has been completed.

We hope that results from this study will be published in a medical journal. Information will be reported as a group data and you will not be individually identified. We will also be happy to provide you, upon request, with the results of the project and/or relevant publications.

**14 What will happen to information about me?**

By signing the consent form you consent to the relevant research staff to collect and use personal information about you for research purposes. Any information obtained in connection with this research project that can identify you will remain confidential. All information is re-identifiable (coded). Only the research staff will have the code and access to the data. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. We will also ask your permission to use the data in future studies in the same area of research.

Results from your blood tests (glucose, insulin, lipids and gut hormones) will be kept at the pathology lab database however this will be saved using a code that is only identifiable by the research team.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. All data will be presented as the average of the group.

In accordance with relevant Australian and/or Victoria privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. Please contact the study principle researcher if you would like to access your information.

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

This research project is being conducted by Deakin University. By taking part in this research project you agree that samples of your blood or tissue (or data generated from analysis of these materials) will be provided to Deakin University. The research project is funded by Diabetes Australia General Research Grant. Your details or individual identified data will not be shared with Diabetes Australia and only anonymous results in the form of group average may be shared during research presentations.

**16 Who has reviewed the research project and is it approved?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Deakin University Human Research Ethics Committee (DUHREC). This project will be carried out according to the principles of ICH Good Clinical Practice and the National Statement of Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council (NHMRC). This statement has been developed to protect the interests of people who agree to participate in human research studies. Diabetes Australia has also reviewed the project and approved research funding to complete this project.

**17 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the research staff: Dr Gunveen Kaur, +61 3 9246 8288, Gunveen.Kaur@deakin.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au Please quote project number 2019-014.

 **PLAIN LANGUAGE STATEMENT AND CONSENT FORM** 

**TO:** Participants

**Consent Form**

**Date:**

**Full Project Title:** Does short term high fat, high calorie feeding impair cardiometabolic outcomes in healthy people?

**Reference Number: GK00033**

I have read and I understand the attached Plain Language Statement*.*

I freely agree to participate in this project according to the conditions in the Plain Language Statement.

I have been given a copy of the Plain Language Statement and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details, including where information about this project is published, or presented in any public form.

Participant’s Name (printed) ……………………………………………………………………

Signature ……………………………………………………… Date …………………………

**Please post or email this form to:**

 Dr Gunveen Kaur,

Institute for Physical Activity and Nutrition (IPAN),

221 Burwood Highway, Burwood VIC 3125,

Email: Gunveen.Kaur@deakin.edu.au

**PLAIN LANGUAGE STATEMENT AND CONSENT FORM** 

**TO: Participant**

**Consent Form for Sample Storage and Use**

**Date:**

**Full Project Title:** Does short term high fat, high calorie feeding impair microvascular blood flow in healthy people?

**Reference Number: GK00033**

I consent to the storage and use of blood samples taken from me for use in further closely aligned research as described in this Plain Language Statement by Dr. Gunveen Kaur.

Participant's name (printed)…………………………………………………………………..…..

Signature Date

Name of Witness to Participant’s signature (printed)…………………………………………..

Signature Date

Researcher's name………………………………………………………………………………...

Signature Date

Note: All parties signing the Consent Form must date their own signature.

**PLAIN LANGUAGE STATEMENT AND CONSENT FORM** 

**TO: Participant**

**Withdrawal of Consent Form**

*(To be used for participants who wish to withdraw from the project)*

**Date:**

**Full Project Title:** Does short term high fat, high calorie feeding impair cardiometabolic outcomes in healthy people?

**Reference Number: GK00033**

I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardise my relationship with Deakin University.

Participant’s Name (printed) …………………………………………………….

Signature ………………………………………………………………. Date ……………………

**Please post or email this form to:**

 Dr Gunveen Kaur,

Institute for Physical Activity and Nutrition (IPAN),

221 Burwood Highway, Burwood VIC 3125,

Email: Gunveen.Kaur@deakin.edu.au