MASSEY UNIVERSITY

Does the physical form of food influence the absorption of nutrients from the gut

INFORMATION SHEET

Thank you for your interest in the forthcoming study. The information below tells you more about the research project.

Who are we?

I am Ivana Sequeira a post doctoral student undertaking research in the digesta group at Massey University studying gut health and wellbeing. Our group is part of The Institute of Food, Nutrition and Human Health, Massey University. **The current research project investigates the manner in which different forms of food; (a) a solid pellet form/pasta meal, (b) a powdered version of the same, (c) a liquid equivalent of the same meal, affect the rate of absorption in the gut.** This will be measured by the rate at which two harmless sugars , lactulose and mannitol are secreted in your urine. We will also measure the levels of glucose in your blood.

Why are we doing this trial?

We are trying to develop a test that accurately tells food manufacturers how readily nutrients are released on digestion of the foods they make. This information will be useful in them designing healthy foods that do not elevate blood sugars and fats unduly.

How much time will you spend on the trial?

If you are keen on participating you will be asked to attend the laboratory on **four occasions**.

Your first visit will be a *screening session* – you will be asked to provide a fasted urine sample and complete a health questionnaire for us to assess your suitability to participate in the study.

If eligible to participate in the study, you will then be asked to attend our laboratory on *three occasions one week apart*. On each occasion you will be asked to consume **a** different one of each of the following foods:

- a pasta meal
- a powdered version of the pasta meal/porridge consistency
- a liquid drink.

All of the above will have the same levels of macronutrients and also contain two harmless tracer sugars, which the gut does not digest, mannitol and lactulose. You will be asked to empty your bladder every half hour during the six hour period after eating the foods. We will put a small cannula into the vein of your arm and collect 5 ml of blood from it before you eat the meal and every hour for six hours after the meal.

This study will take 18 hours of your time i.e. 6 hours each day you come to the laboratory. As you will be spending considerable time at the laboratory we encourage you to bring along any reading material including study material, laptops etc. We can help you access the WiFi connection while you are at lab and will also provide you with a range of DVDs that you may use on your laptop or the DVD player that is in the lab. If you need a quiet space to work undisturbed, we could provide you with a room that is adjacent to the seating area in the nutrition laboratory.

We will give you a light meal on each day when the urine and blood collection are finished and compensate you for your time at every visit.

Would you like to participate?

We would like to invite women aged between 20 and 40 years to join our study. To be suitable to join in our study you should:

- Be a non smoker
- Have no history of gastrointestinal diseases including recent gut infection evidenced by a recent history of abdominal pain, nausea, vomiting, diarrhea, passage of blood and mucus in stools.
- Not have a recent gut infection leading to diarrhea or suffer from chronic constipation.
- Not have a history of endocrinological disease such as diabetes, renal disorders such as kidney stones and hepatic disorders, i.e. hepatitis.
- Not have had a recent immunisation e.g. flu vaccine in the last month
- Not have had a recent major surgery e.g. abdominal surgery in the last three months
- Not be taking any prebiotic supplements such as lactulose.
- Not be taking any oral steroid inhalants (as in asthmatics).
- Not be taking any ongoing prescription or OTC medication or multivitamins except for contraceptive pills.
- Not consume more than one Standard alcohol drink per day (6 glasses of wine, 3 pints of beer or 4 nips of spirits per week).
- Not have urinary tract infections or genital conditions that cause discharge
- Be able to provide frequent urine samples
- Not have high levels of endogenously produced sugars in the urine

What are we going to measure?

Medical assessment**:**

We will ask you to fill in a form about your health and current medications.

Urine samples:

Each time you come to the Human Nutrition Laboratory we will ask you to collect your urine at the beginning and then every half-hour for 6 hours after you have consumed the meal. The layout in the human laboratory allows for you to use a lavatory immediately adjacent to the seating area and is partitioned from the rest of the area.

Bottles and tubs (whichever convenient for you to use) will be provided and will be left in the lavatory for urine collection by staff so as to save embarrassment.

Blood sample

Each time you come to the Human Nutrition Laboratory we will collect a blood sample at the beginning and then subsequently every hour for 6 hours after you have consumed the meal. A trained medical professional will insert a cannula into your arm so that the venipuncture will be done once. Thereafter samples will be drawn from the cannula at specific time intervals. In the event that you feel faint or are uncomfortable with the procedure we will immediately stop. Additionally, if we are unable to draw blood from the cannula due to clotting of blood, we will no longer collect the remaining samples.

The study will commence at 8:00 am on the morning on each of the three sessions. You are required to refrain from taking any over the counter medication including pain killers and antipyretics (with the exception of contraceptive medication) for at least one week prior to the test, to refrain from alcohol at least three days prior to the test and to fast overnight. We ask you to empty your bladder once when you get up in the morning and not to urinate subsequently so that you can provide a *baseline urine sample immediately on arrival at the laboratory*.

- At each session you will be required to consume one of the three meals along with an additional 150 ml of water.
- Thereafter you will need to provide urine samples every half hour over the next 6 hours. Hence in total over the three sessions you will be asked to provide 13 urine samples. Note, we do not need large volumes - merely the amount that you can produce at a given time. Also note that if you need to urinate between these half-hourly periods you can do so but this will also be collected.
- A cannula will be inserted into the vein of your arm by a medical doctor at the beginning of the study session. A blood sample will be taken before consumption of the test meal and subsequently at hourly intervals after the meal has been consumed. In total you will be required to provide 7 blood samples over the entire study period.

- You will not be allowed to eat during the collection period but will be required to drink a further 200ml water at three hours after the start of the session.

You will attend the laboratory on three occasions from 8.00 am – 2.00 pm when you will receive each 'meal' in a randomised sequence one week apart. The total amount of time you will spend in the laboratory will be 18 hours.

Are any of the procedures harmful or painful?

This procedure is a routine clinical test and should not cause any discomfort. Insertion of the venous cannula will give a temporary discomfort similar to a venipuncture. You should not volunteer for the study if you have difficulties with venepuncture, have a bleeding disorder or take anticoagulants e.g. warfarin.

Who will see the information about you?

When you join the trial you will be given a unique identifier and thereafter all information will be filed with the code number, and stored in a locked filing cabinet accessed by the research team only. When information from all the participants have been pooled, and made anonymous, it will be used in presentations to academic societies, scientific publications. No names will be used, just the designated numbers. We will give you a summary of the findings of our research by email.

All personal data will be destroyed at the end of the trial. Scientific data, filed on paper, will be shredded and electronic data will be deleted from our computer records and databases after 10 years. For the first 5 years it will be stored in a locked filing cupboard within a locked office. For the last 5 years it will be stored in a secure archive where all data is stored in boxes labelled by barcode only. It is accessible by nominated staff only who require pin numbers for ID.

If anything untoward is found in your tests you will be contacted by Professor Roger Lentle, a medically qualified practitioner, informed of the results and asked whether you would like the results to be given to your medical practitioner or sent directly to you.
Any excess blood or urine will be disposed of but you may request that it be returned to you.

Who is funding this research?

This study is funded by 'Return on Science' a government supported committee that funds research that may benefit New Zealand's Industry and economy.

Will I get any financial compensation?

We will give you retail/petrol vouchers of $100 to compensate you for your inconvenience and time at each experimental session.

What are my rights?

You are under no obligation to accept this invitation. If you decide to participate, you have the right to:

- decline to answer any particular question;
- withdraw from the study at any time;
- ask any questions about the study at any time during participation;
- provide information on the understanding that your name will not be used unless you give permission to the researcher;
- be given access to a summary of the project findings when it is concluded.

Compensation for Injury

If physical injury should result from your participation in this study, you should visit a treatment provider to make a claim to ACC as soon as possible. ACC cover and entitlements are not automatic and your claim will be assessed by ACC in accordance with the Accident Compensation Act 2001. If your claim is accepted, ACC must inform you of your entitlements, and must help you access those entitlements. Entitlements may include, but not be limited to, treatment costs, travel costs for rehabilitation, loss of earnings, and/or lump sum for permanent impairment. Compensation for mental trauma may also be included, but only if this is incurred as a result of physical injury.

If your ACC claim is not accepted you should immediately contact the researcher. The researcher will initiate processes to ensure you receive compensation equivalent to that to which you would have been entitled had ACC accepted your claim from Massey University.

If you are interested in participating please contact Ivana Sequeira who will be happy to discuss the project and answer your questions.

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This project has been reviewed and approved by the Massey University Human Ethics Committee: Southern A, Application 15/31.
If you have any concerns about the conduct of this research, please contact Mr. Jeremy Hubbard, Acting Chair, Massey University Human Ethics Committee: Southern A. Telephone 04 801 5799 x 63487, email humanethicsoutha@massey.ac.nz.