

## **PARTICIPANT INFORMATION SHEET**

**Project title:** The Acute Effect of Inulin and Non-Inulin based Fibres on Gut Transit Time and Metabolic Biochemistry on Healthy Adults: A Pilot Study on Fibres

**Chief Investigator:** Dr. Ruey Leng Loo

The Australia National Phenome Centre (ANPC) and the Centre for Computational and Systems Medicine (CCSM) invite you to participate in a research study that can help advance our understanding of human health and ingestion of dietary fibres. We are seeking volunteers who are willing to provide breath samples to measure hydrogen gas levels, and biological specimens such as urine, blood, and/or faeces, which will be analysed using cutting-edge analytical techniques.

If you are interested in taking part, or if you would like to find out more about the study, please read the enclosed information leaflet carefully. This leaflet tells you more about the study.

If you decide to take part in the study, you will be asked to sign an electronic consent form (please email [rueyleng.loo@murdoch.edu.au](mailto:rueyleng.loo@murdoch.edu.au) to request a link for the electronic consent to be sent to you) and choose the type of fibres and standardise meal plan. The options will be explained in this leaflet.

If you do not wish to take part, there is nothing you need to do.

**Who are we?**

The Australian National Phenome Centre (ANPC) is a research centre funded by the WA State Government, the Australian Research Council, and Murdoch University. The ANPC is dedicated for developing and delivering metabolic phenotyping (fingerprinting) research to advance human health.

**What is the purpose of the study?**

Inulin is a type of dietary fibre commonly found in plants such as Jerusalem artichoke and garlic. Unlike non-inulin based dietary fibres found in other foods like apple and watermelon, inulin-based fibres are broken down by the gut bacteria in the lower gut, producing compounds that have been shown to improve sugar control and digestive health, aid weight loss and improve lipid profiles.

Although we know inulin has a beneficial effect on human health, we do not know yet if the size of the inulin affects these health benefits in human. Moreover, there is limited research on the effects of inulin when consumed in the form of actual plant products rather than the manufactured inulin powder. Our pilot study is designed to address these knowledge gaps.

In our study, we will investigate how quickly different sizes of inulin from various plant products are digested in the human gut. We will also test how inulin and non-inulin based fibres alter the biochemical changes in the body. Our findings will improve our understanding of how fibres play a role in preventing chronic diseases such as diabetes and obesity; and will allow us to deliver accurate public health messages.

**What are the inclusion criteria?**

During the screening visit, the researcher will check the following:

- You are an adult over the age of 18
- Your body mass index is between 20 -35 kg/m<sup>2</sup>
- You have a positive hydrogen breath test using a positive control substance (in this case e.g. 10 g of inulin).

**What are the exclusion criteria?**

You will be excluded from the study if:

- You have been prescribed a course of antibiotics or undergone colonoscopy procedures four weeks before you take part in this study.
- You have been consuming concentrated probiotics e.g. IBS Support Probiotics, Inner Health Plus, or VSL#3 two weeks before taking part in this study.
- You have been using any enemas for two weeks before taking part in this study.
- You are unable to read or understand English, or follow study protocol.
- You have been considered as someone with difficult intravenous access.
- You are allergic/intolerant to any of the ingredients provided as part of the standardised meals, and the test food that you have selected.

**What is involved in the study?**

This study will involve a screening clinic visit then following a successful eligibility assessment, you will be invited to attend a study clinic visit, on a convenient day. You will need to attend the clinic for both screening and study visits for a duration of 8 hours and have fasted from the night before (at least 8 hours). During the fasting period, you may take sip of water or continue to take your regular medications.

Both the screening and study clinic visit will involve:

- A hydrogen breath test as a proxy for gut transit time. A hydrogen breath monitor is a hand-held device that is used to measure the hydrogen in exhaled breath. The exhaled gases originate from a particular group of bacteria in the gut and will allow us to estimate the quantity and the activity of these bacteria in our gut.

In addition, the study clinic visit will involve:

- The collection of biological specimens (urine, blood, and/or faeces). These specimens will be measured using instruments available at the ANPC in order to compare the changes in the chemicals (fingerprints) before and after the consumption of specific dietary fibres.

On both the screening and study clinic visits, you will be provided standardised meals and protocol, as specified in the study, to minimise the variation in the food that the volunteers' consumed. A standardise meal plan will be provided at the clinics, and you will be given the choice to follow a meat-based or vegetarian-based diet. An example of the meal plan that you will consume at the clinics is as below.

<b>Meal</b>	<b>Meat-based standardised diet</b>	<b>Vegetarian standardised diet</b>
Breakfast	White bread with butter	White bread with butter
Lunch	Roast chicken sandwich	Egg, cheddar cheese sandwich
Dinner	Roast chicken and potatoes	Egg, cheddar cheese sandwich
Snacks	cracker and cheddar cheese	cracker and cheddar cheese

If you agree to take part in this study, the researcher will invite you to attend a screening clinic visit to confirm your eligibility.

**At the screening clinic visit:** The researcher will explain the study protocol and answer any questions that you may have about what is involved. On the day before you attend the screening visit, you will be asked to avoid high-fibre diets (see Appendix A) and having fasted overnight. The researcher will check your eligibility to participate in the study and provide you with 10g of inulin in water together with your chosen standardise breakfast. Standardise lunch will be provided 4 hours later. A hydrogen breath test at baseline (i.e. before consuming inulin) and then hourly for up to 8 hours will be performed. If you show a positive response (i.e. sustained increase of exhaled hydrogen of >20 ppm than baseline), you will be eligible.

If you meet the eligibility criteria of this study, you will have the opportunity to select the specific dietary fibres that you wish to consume as part of the study. You will have the choice of inulin-based fibres including yacon, Jerusalem artichoke, globe artichoke, and Elephant garlic or non-inulin-based fibres including apple, watermelon, orange and tomato. After your dietary preference have been decided, you will be invited to attend a study clinic visit at least one week later at a convenient day. You are allowed to consume you own meal after the end of the screening clinic visit.

**24hr before the study clinic visit:** You will start the standardised diet plan provided at home. The researcher will order it from a local supermarket close to your home and you will then be able to collect the food at a time that is convenient for you. You will be asked to complete a food diary that asks about non-study food that you have eaten, the number of caffeinated and alcoholic beverages consumed,

physical activity, and any intake of medication. You will also need to write down your age, and gender in this food diary. This can be done in your own home.

**Study Clinic Visit:** You will attend the clinic fasted. Once you arrive at the clinic, you will start consuming your chosen standardise breakfast along with up to three portions of your chosen fibres. A portion of fibre is equivalent to the size of an average apple or a large globe artichoke.

The researcher will perform the following assay and specimen collections at baseline (i.e. before consuming the fibres) and then hourly for 8 hours.

1. A serial urine collection at the designated times suggested below, ideally, comprises of the following time points: before consumption of the fibres of interest (U1), within 2hrs after breakfast (U2); before lunch (U3); within 2hrs after lunch (U4), and at the end of the 8 hr (U5). If you do not need to urinate so frequently this is not a problem but as long as you collect a urine specimen every time you urinate and document the time.
2. An hourly hydrogen breath test.
3. An hourly blood collection and in each collection, we will take about 1 tablespoon (4mL) of blood every hour until the end of the study period.
4. A one-off collection of faeces samples (the size of a walnut). It is entirely up to you to decide if you would like to provide faeces samples on the day of the study clinic visit or at home. If you provide a faeces sample, these will be analysed to evaluate the diversity of your gut bacteria.

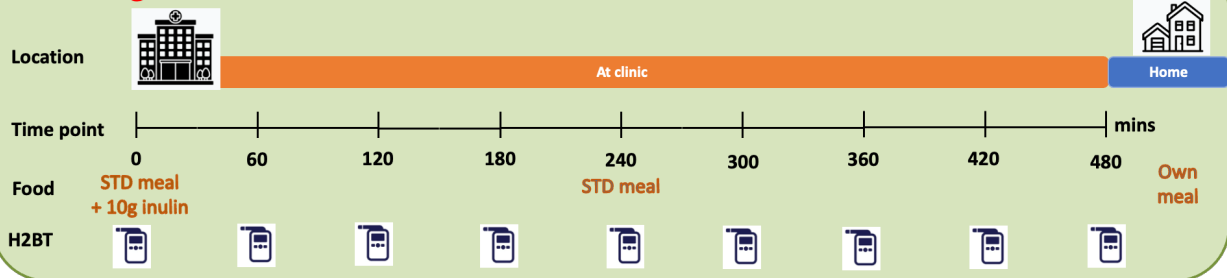
At the end of 8 hours, you are free to go home and consume whatever you like.

For female participants, urine and faeces collection should not be carried out during menstruation. If you are menstruating on your study clinic, please notify the researcher and reschedule your study clinic visit for a later date.

You may choose to be involved in more than one fibre. If this is the case, you will need to repeat the activities described in the 24 hr before the study clinic visit and the study clinic at least one week later.

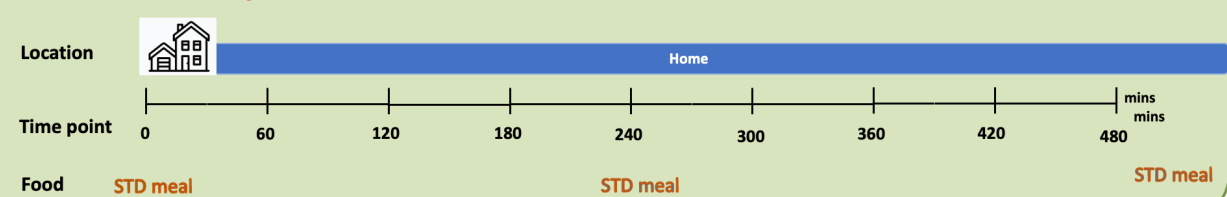
A flow diagram of the study visits including various specimen collections is shown in the next page.

### Screening Clinic Visit

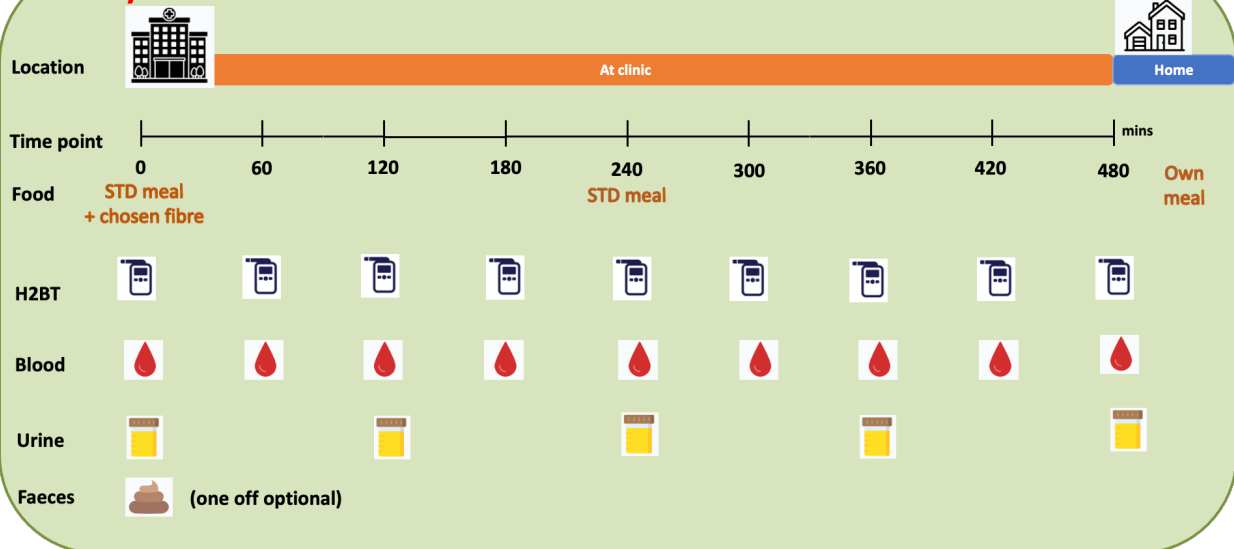


At least one week gap

### 24hr before Study Clinic Visit



### Study Clinic Visit



#### Key:

H2BT = hydrogen breath test

STD meal = standardized meal plan (meat-based or vegetarian) provided by the study

### What are the benefits in taking part in this study?

There are several benefits to taking part in this study. These are:

- You will benefit from the food provided to you on 3 occasions. This will include the screening visit, the day before the study day, and the study clinic visit. During both the screening visit and study clinic visit, food will be provided on-site at the clinic. For the food to be consumed on the day before the study day, you will collect from your local supermarket at a time that is convenient for you.
- You will help to improve the advancement of research into dietary fibres.
- As a token of gratitude, you will be provided a gift voucher worth \$25 after the completion of the screening visit, and \$50 for the study visit. If you travel by car, we will reimburse the parking fees at the Harry Perkin Building and fuel costs at a rate of \$1.2 per 10km based on the shortest distance from your home to the clinic. If you use public transport such as train or bus, we will reimburse your fare. We are unable to reimburse taxi/Uber fare.

- Where appropriate, if any test results with potential relevance to your medical care are identified, your GP will be informed so that further medical tests can be performed (if you have chosen this option on your electronic consent form).
- You will enhance your understanding of the role of dietary fibres and gut health by attending the educational and one-to-one sessions with our team of researcher or dietician. We have designed information session such as "The role of fibres in gut health" and "Metabolic response to food and its impact on health?" to help you learn more about the topic. As part of this study. You will also have the opportunity to visit our laboratory and meet with our team of researchers. During the laboratory visit, you can gain insights into the research process and learn about the various analysis methods we use to study the specimens collected in this study. A one-to-one session will be offered to explain to you the significance of hydrogen breath test and what the results indicate?.

### **What are the risks in taking part in this study?**

- Inconvenience – participation in this research project involves 2 clinic visits, each visit for 8 hrs, and includes multiple blood and urine collections, and breath tests. However, you are advised to bring along items such as laptop, books, magazines or newspapers to help you stay occupied during your time at the clinic. On occasion, we may be able to provide a laptop for your use, if this has been requested in advance. If you usually work from home, you can continue to work at the clinic using your laptop. We will provide temporary WIFI access so that you can stay connected to your work or personal activities.
- Cannulation (blood sample collection) – A clinical research nurse who has experience in performing peripheral cannulation will perform the blood collection. This will be done by inserting a small piece of tube called a cannula in the vein. The cannula will be in-situ for 8 hours. The insertion of a cannula will prevent frequent insertion of a needle but allow the withdrawal of blood from the cannula at each designated time. The nurse will withdraw a maximum of 4 mL of blood (approximately a teaspoon) every hour using the cannula in place. At the end of the study, 480 mins (8 hours), after the nurse has taken the last blood collection, the cannula will be removed. The nurse will perform cannulation according to the WA Department of Health's local policy. Cannulation is safe but occasionally some individuals may experience inflammation of the vein manifesting as pain and redness at the site of cannula insertion and dislodgement of the cannula. However, with good cannulation practice, these risks are minimised. Some individuals may also experience light-headedness, dizziness or fainting from blood drawing but these symptoms usually go away quickly. The risk of these side effects is low as the volume that we are collecting is small (a lot less than blood donation). Snacks will also be provided at the collection clinic to minimise the risk.
- Incidental findings - This research project includes blood and urine testing to identify potential markers related to the consumption of foods. There is a very small chance that these tests may result in the incidental discovery of information that is relevant to your health. Since the samples will be de-identified and analysed in batches, and generally in non-clinical laboratories with investigational techniques, data will be de-identified. If the research team discovers critical information related to your health, they will re-identify the individual concerned and act according to your expressed wishes in the electronic consent form. In this case, you will have the option to either not to be informed of the finding or have the results shared with your GP so that further medical assessment can be taken place.

**What will happen to the samples and information?**

All specimens (urine, blood, and/or faeces) and electronic data will be labelled with a computer-generated random code so it will not be possible to identify you from this computer-generated code. The specimens will be kept in a –80 °C freezer or liquid nitrogen vapour storage facility. Analysis of these specimens will be carried out using various biochemical analytical techniques. All electronic data and samples will be de-identified and stored safely and securely for the duration of the research and for at least 15 years after the final publication of results. Access to the samples and data will be limited to designated researchers who have undergone appropriate training and have been granted permission by the principal investigator.

**What are the withdrawal criteria?**

You are free to choose whether or not to participate in this study or withdraw from it at any point. If you decide to withdraw, we will keep the data (this refers to the information that you have provided, such as your age and gender) and samples (such as urine, blood and/or faeces) that have already been collected as part of the research project. You don't need to take any action regarding the retained data and samples unless you want them to be destroyed. In such case, you can send an email to [rueyleng.loo@murdoch.edu.au](mailto:rueyleng.loo@murdoch.edu.au) with a statement like: "I wish to withdraw from this study, and I request that all my personal data and collected samples be destroyed". Upon receiving your request, the research team will destroy the data and samples, usually within one week. You will be notified via email once this process is complete.

**What will happen to the results of the research study?**

It is likely that the results from this study will be published in a scientific journal or presented at scientific conferences. However, it will not be possible to identify individuals in any results from this study. It is also possible that we will share our analysis with other research collaborators to advance scientific knowledge but they will not be able to identify you. We do not intend to inform you of the results. However, the results of your hydrogen breath test would have been explained to you during the one-to-one session with the researcher/dietitian. Further information on the study will be released on the ANPC webpage, and you can follow updates (e.g. publication of results) on this study via the ANPC webpage.

**Where will the study take place?**

Both the screening and study clinic visits will be conducted at the Harry Perkin South dedicated Clinical Room, 5 Robin Warren Drive, Murdoch 6152.

**Who funds this study?**

This study is funded by the Future Food System Cooperative Research Centre in partnership with Murdoch University and Mt Lindesay Ltd. Mt Lindesay is the provider of the inulin-based food used in this study.

**Who has approved this study?**

This study has been reviewed and approved by the Murdoch University Human Research Ethics Committee (reference number 2023/068).

**What if I have a question?**

If you have any questions regarding any aspect of this study, you can speak to Dr Ruey Leng Loo, who will be happy to answer all your questions.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding this study please contact Dr. Ruey Leng Loo. If you wish to talk with an independent person, you may contact Murdoch University's Research Ethics & Integrity on Tel. 08 9360 6677 (+61 8 9360 6677 for overseas studies) or e-mail [ethics@murdoch.edu.au](mailto:ethics@murdoch.edu.au). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

**How to request an electronic consent form?**

To participate in this study, please email [rueyleng.loo@murdoch.edu.au](mailto:rueyleng.loo@murdoch.edu.au) or call 0893601371 to request a link for the electronic consent form to be sent to you. Once you have completed the electronic consent form, a member of our team will contact you to arrange a suitable date for a screening visit.

**Dr Ruey Leng Loo** (Chief investigator)

**Tel:** 08 9360 1371

**Email:** [rueyleng.loo@murdoch.edu.au](mailto:rueyleng.loo@murdoch.edu.au)

**Address:** Murdoch University, Harry Perkin South Building, 5 Robin Warren Drive, Murdoch, WA 6150





## PARTICIPANT CONSENT FORM



**Project title:** The Acute Effect of Inulin and Non-Inulin based Fibres on Gut Transit Time and Metabolic Biochemistry on Healthy Adults: A Pilot Study on Fibres

**Chief investigator:** Dr. Ruey Leng Loo

1.	I have read the Information Sheet for this study and have had details of the study explained to me.																						
2.	I wish to participate in the study under the conditions set out in the Information Sheet																						
3.	My questions about the study have been answered to my satisfaction and I understand that I may ask further questions at any point.																						
4.	I understand that my participation is voluntary, and I am free to withdraw at any time before and during the collection of biological samples without giving a reason for my withdrawal and that this will not affect my legal rights.																						
5.	I understand that if I withdraw from the study, any collected samples and data can be retained as part of the study. However, I have the option of formally writing to the researchers to request that the samples and/or data be removed.																						
6.	I agree that the research data gathered from the results of the study may be published and that I cannot be identified.																						
7.	I understand that my information can be collected, analysed, reported, and shared internationally with others as part of this research project. However, I understand that my name will not be used, and I will not be identified.																						
8.	I understand that Murdoch University Research Ethics Committee (HREC) has reviewed and approved this study.																						
9.	I understand that my participation will not affect my relationship with Murdoch University.																						
10.	I understand that no individualised results will be provided but the overall results will be published in peer-reviewed journals and/or ANPC webpage. If you wish to be informed of the publication of these results and/or the progress of the study, please provide an email address here:																						
11.	I understand that if the researchers found some abnormalities in their routine analysis, the researcher can ( <i>choose one of the options below</i> ): Contact my chosen general practitioner below to enable appropriate follow-up assessments. My general practitioner's name: _____ My general practitioner's address: _____ _____ I do not wish my GP to be contacted.		<b>Tick one</b> <input type="checkbox"/>  <input type="checkbox"/>																				
12.	Any un-used specimens (please choose one option)  I wish to <b>discard</b> any unused samples.  I give my <b>consent to store any unused</b> samples and they can be used for future analysis relevant to this study.		<b>Tick one</b> <input type="checkbox"/>  <input type="checkbox"/>																				
13.	I would like to participate in the food study involving ( <b>tick those that apply</b> , and you may choose more than one)																						
	<table border="1"><thead><tr><th>Inulin-based fibres</th><th>Tick here</th><th>Non-inulin-based fibres</th><th>Tick here</th></tr></thead><tbody><tr><td>Jerusalem artichoke</td><td><input type="checkbox"/></td><td>Apple</td><td><input type="checkbox"/></td></tr><tr><td>Globe artichoke</td><td><input type="checkbox"/></td><td>Orange</td><td><input type="checkbox"/></td></tr><tr><td>Yacon</td><td><input type="checkbox"/></td><td>Tomato</td><td><input type="checkbox"/></td></tr><tr><td>Elephant garlic</td><td><input type="checkbox"/></td><td>Watermelon</td><td><input type="checkbox"/></td></tr></tbody></table>	Inulin-based fibres	Tick here	Non-inulin-based fibres	Tick here	Jerusalem artichoke	<input type="checkbox"/>	Apple	<input type="checkbox"/>	Globe artichoke	<input type="checkbox"/>	Orange	<input type="checkbox"/>	Yacon	<input type="checkbox"/>	Tomato	<input type="checkbox"/>	Elephant garlic	<input type="checkbox"/>	Watermelon	<input type="checkbox"/>		
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Elephant garlic	<input type="checkbox"/>	Watermelon	<input type="checkbox"/>																				
14.	I would like to provide a faecal sample as part of this study  Yes No		<b>Tick one</b> <input type="checkbox"/> <input type="checkbox"/>																				

**Date:** \_\_\_\_\_

**Participant's Signature:** \_\_\_\_\_ **Participant's Name (printed):** \_\_\_\_\_

**Researcher's Signature:** \_\_\_\_\_ **Researcher's Name (printed):** \_\_\_\_\_