WESTERN SYDNEY
UNIVERSITY

## Would you like to participate in a research study?

We are recruiting volunteers with gastroparesis to participate in a dietary trial of low viscosity soluble fibres at the newly established Western Sydney University, Macarthur Clinical School.

You can visit our website for more information about this trial or contact our investigator Harsha

**Website:** https://westernsydney.edu.au/gimotility/our-research/fibre_trial
Or
**Harsha's Email:** 17271790@student.westernsydney.edu.au

# Benefits of low viscosity soluble fibre in gastroparesis patients

## Project Summary

Soluble fibres are an essential part of a healthy diet. When mixed with liquids, soluble fibres form a gel-like substance which allows for slow release of ingested sugars and a low glycaemic index (low GI). In patients with gastroparesis, the high-viscosity of soluble fibre can further increase digestion time and associated symptoms. A range of low-viscosity fibres may offer the some of the benefits without an increase in symptoms. The study is being conducted by Dr Jerry Zhou (Clinical Researcher), Dr Vincent Ho (Gastroenterologist) and Mr Harsha Suresh (PhD student) at the School of Medicine, Western Sydney University.

## How is the study being paid for?

School of Medicine, Western Sydney University

Rotary Health Australia/Rotary Davenport Scholarship

## What will I be asked to do?

The total study will consist of four 3 hour visits, ideally over a 4 week period. Your blood glucose and gastric transit times will be measured using a portable glucose monitor and hydrogen breathalyser, respectively at 30 min intervals. The hydrogen breath analyser measures hydrogen levels in exhaled breathe. You will be asked to exhale into a collection bag periodically throughout the test. Hydrogen is produced by the gut bacteria at the end of the small intestine when they encounter sugars. By observing increase in hydrogen we can calculate the transit time from mouth to large intestine.

You will also be required to fill out a symptom severity form at the same time in accordance with the Gastroparesis Cardinal Symptom Index (GCSI). These tests are not invasive and require minimal effort from the participant. The researchers may ask you general questions relevant to this study (age, gender, BMI, medical history, exercise and diet scheme).



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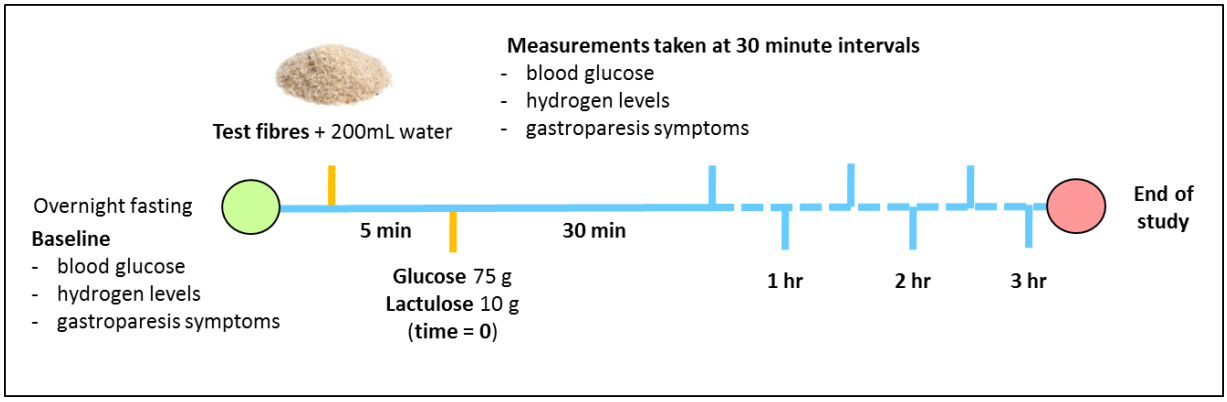
For this study, there will be four tests spread out over consecutive weeks. A test can be re-scheduled if it is missed during that week due to reasons such as sickness, time conflict or emergencies. The trial will be randomised, you will not know which fibre or control is being tested until the information is collected for analysis.

No prescriptions or medicines are required during the test. The procedure will take around 3 hours to complete and you may bring laptops, books, or phone during the intervals to pass the time.




## What benefits will I, and/or the broader community, receive for participating?

There are no direct benefits or incentives to the participants. At the end of this study, the benefits of low-viscosity fibre at managing blood glucose and gastroparesis symptoms will be shared with the participants. The results of this research will also contribute towards understanding dietary options in gastroparesis patients and further medical knowledge.

## Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

Serious complications are extremely rare during these tests and Dr. Ho will be available nearby during any complications or emergencies.

Complications may include:

Bloating & Nausea – Bloating can occur during the test and may be severe. In such cases, the attending physician will be contacted. Nausea can happen during the test and if there is a serious reaction, the test will be stopped and the attending physician informed.

Hyperglycaemia – This is major risk factor for type 1 and type 2 diabetes patients who are consuming a sugar test meal, though it is a rare occurrence. You may be recommended to an endocrinologist by Dr. Ho for insulin therapy.

Hyperosmolar hyperglycaemic nonketotic syndrome (HHNS) – Is extremely rare and happens when your blood glucose levels suddenly spike. You will be taken to an emergency facility at nearby Campbelltown Hospital if this occurs during a test.

You can reduce your risk of complications by carefully following your doctor's instructions for preparing for a prolonged blood glucose test, such as fasting and eschewing certain medications.



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How do you intend to publish or disseminate the results?

All aspects of the study, including results, will be strictly confidential and only the investigators in this form will be able to access the information about the participants. A report of the study may be submitted for research publication and the participants will not be identifiable in the report.

Will the data and information that I have provided be disposed of?

Please be assured that only the researchers will have access to the raw data you provide. During analysis and publication the data will not be identifiable. All information will be held for a maximum of 15 years before being properly disposed of.

Can I withdraw from the study?

Participation is entirely voluntary, if you do sign the form and wish to withdraw any time later, your data will be removed and excluded from the study. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with medical staff.

What if I require further information?

When you have read this information Harsha Suresh will discuss it with your further and answer any questions you may have.

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is *[enter approval number once the project has been approved]*.

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