PARTICIPANT INFORMATION SHEET: PREDICT-FD STUDY

Tēnā koe,

We are a group of researchers interested in improving care for people with gastrointestinal conditions, like functional dyspepsia. In this study, we are interested in seeing if a non-invasive device called Body Surface Gastric Mapping (BSGM) can predict whether someone will respond to dietary intervention or not. By doing so, we aim to understand whether tests like BSGM can be used to better tailor therapies to people.

Participation is **entirely voluntary** (your choice). This information will help you decide if you want to take part in our research or not. If you don't want to take part, you don't have to give a reason. Choosing not to take part won't affect you in any way, won't affect the care you receive or your relationship with your health provider, and won't have any impact on your future involvement in research or health services. If you want to take part now, but you change their mind, you can pull out of the study at any time.

Please take some time to read this information sheet. It tells you why we are doing the study, what you will need to do if you choose to take part, what the benefits and risks are, and what happens after the study ends. Before you decide, you may want to talk about the study with other people such as your healthcare provider, whānau/family, or friends.

Our contact details are at the end of this document, and we are always available to talk about the study and answer any questions you have.

What is the purpose of the study?

Dietary treatments for gut conditions can be difficult to follow and are often restrictive in nature, yet are not always effective. Ideally, people would only need to try these diets if they were going to be provide symptom relief. However, we do not have any approaches or tests to predict whether dietary treatment will be effective or not.

The purpose of this research is to assess whether a non-invasive test called Body Surface Gastric Mapping (BSGM) can be used to predict whether someone with functional dyspepsia will respond to dietary intervention, in this case a low FODMAP Diet. BSGM appears to be useful in determining response to other treatments like medication, but has not been tested in the context of dietary treatment before. Ultimately, we hope that this research will leader to more personalized treatment approaches in the future.

Who are the researchers?

This study has been designed by a team of researchers at the University of Auckland with backgrounds in Nutrition and Dietetics, Health Psychology, and Psychogastroenterology. Charlie Fraser (student researcher) and Dr Nicola Gillies (lead researcher/supervisor) will be running the study, and your main points of contact during the study. We are supported by Dr Mikaela Law, who has an affiliation with

Alimetry Ltd. All the researchers have been involved in designing the study, and you can find our contact details at the end of this document.

What will taking part in the study involve?

Up to 30 individuals will be invited to participate in this study. This is a 4-week study which includes enrolment procedures, a baseline data collection visit (in-person, including the BSGM test and questionnaires), four weeks of a low FODMAP diet, and follow-up data collection (online, questionnaires only). Some more information about what's involved at each phase is outlined below.

Phase 1 – Screening and enrolment

You will be asked to complete an online screening questionnaire, which allows us to confirm if you are eligible to participate or not. If you are eligible, you will be asked to provide written consent to take part in the study which is completed through an online form. You are able to ask the researchers questions about the study and what participation involves at any time during this phase, which we can do over phone, email, or in-person in Grafton if you would prefer.

Phase 2 – Baseline data collection (in-person study visit at Grafton, lasting approx. 4.5h).

At this visit you will complete the BSGM test which takes around 4.5h in total. While you are at the clinic visit you will also complete a series of questionnaires, and be given information about the low FODMAP diet. We appreciate that this is a long clinic visit, but you are still free to read, watch a movie, and do work on a device. You will receive a $50 gift voucher at the end of this visit, and support for travel costs is also available.

The BSGM test

1. *Preparation*

- You may be asked to modify your medications before a gastric mapping test. This will be clearly explained to you prior to each of the study visits and is because these medications affect normal stomach actions.
- You will need to fast overnight (no food or drink except water for at least 6 hours before the gastric mapping test.

2. *The recording*

- A set of non-invasive sensors will be placed on your abdomen using an adhesive gel. These sensors will record your stomach's electrical activity.
- The recording will start after fasting (30 minutes).
- You will then be provided with a standardized meal to eat (this is usually a Cliff bar and an Ensure drink). Afterward, the recording will continue for about 4 hours.
- You will be asked to sit still and quiet during the recording, You will be able to read, watch a movie, work etc.
- You will be given a tablet and be instructed on how to log symptom information throughout the study, using an App.

The questionnaires

- You will complete questionnaires about your gastrointestinal symptoms, mental wellbeing and quality of life. These take about 15 minutes to complete, and will be collected through a secure online platform.
- Some of these questionnaires assess anxiety, depression, and illness perceptions, since these factors have been found to be related to some gastrointestinal conditions and symptoms. Although these questionnaires are not diagnostic for mental health conditions, there are scoring

criteria which indicate the possibility of a mental health condition which requires further investigation by a healthcare provider. If your questionnaire meets this scoring criteria, we will let you know in a letter outlining the finding and who you may contact for help. We will also inform your usual healthcare provider in a letter, with your consent.

- If you are experiencing persistent feelings of low mood or distress, or if you have thoughts of hurting yourself, please reach out for support. Help is available from trained professionals and volunteers by calling 111 or through the helplines listed at the end of this document.

The food record

You will complete a three-day food record prior to the first study visit. This involves recording everything you eat and drink for three days, in as much detail as possible. You will be given a template and instructions for how to complete this.

Phase 3 – Low FODMAP diet (4 weeks)

The low FODMAP diet is a widely used treatment approach for gastrointestinal conditions. The diet involves limiting high FODMAP foods, and choosing mostly low FODMAP foods for the four week period. An example of *some* (not all) high and low FODMAP foods is shown in the table below.

	High FODMAP	**Low FODMAP**
Vegetables	Cauliflower, onion, garlic, green peas	Beans, carrot, cucumber, lettuce, potato, zucchini
Fruits	Apples, cherries, mango, stone fruit	Kiwifruit, mandarin, orange, blueberries
Dairy	Cows milk, fresh cheese	Almond milk, aged cheeses
Proteins	Most legumes	Eggs, firm tofu, plain cooked meat and seafood
Grains	Wheat, rye, barley (and products made from them)	Rolled oats, gluten free grains (and products made from them).
Nuts	Cashews, pistachios	Peanuts, brazil nuts, walnuts, all seeds

You will be given a full list of high and low FODMAP options during your clinic visit, and our student dietitian Charlie will discuss how your current diet can be adapted for the low FODMAP trial. We ask you to follow this advice as closely as possible for the 4-week trial. You will have access to the resource, and may continue utilizing the intervention after the study period if you wish.

During the 4-week trial period you will complete a brief weekly questionnaire asking how closely you followed the advice, this should take 2 minutes of your time.

Phase 4 – Follow-up data collection (online, 20min)

After 4 weeks, you will complete the questionnaires and food record which were completed at baseline. We do not repeat the BSGM test at follow-up, so you can complete this follow-up data collection from home. You will receive another $50 voucher after data collection is complete.

What information is collected and what will happen to this data?

Identifiable information: This includes details like your name and email address, which will be collected on your consent form only.

De-identified (coded) information): All other study data (questionnaires, food records, BSGM testing) will be collected in a de-identified (coded) form, and stored separately to your identifiable information.

Data storage and confidentiality: Our research team takes data storage and confidentiality seriously. The researchers will de-identify (remove) all personal information provided by you, and there is no risk that you will be able to be identified by anyone other than the research team. All records and data collected during the study will be stored on password protected, secure research drives or cloud-based systems. All data storage will comply with local and international data security guidelines,

including encryption and controlled access. Only the research team will have access to these files. Data will be kept for 10 years and then deleted or destroyed. While every effort will be made to protect your privacy, absolute confidentiality cannot be guaranteed.

Withdrawal of consent and data: You may withdraw your consent for the collection and use of your information at any time, by informing the study team. Withdrawal of your data must be requested within one month of your withdrawal from the study – if you withdraw later, then your existing data may still be used in study analyses to maintain research integrity.

Access to data: Access to your information will be restricted as follows;

- The research team (Dr Gillies, Dr Law, Ms Fraser) will have access to identifiable and coded data.
- Regulatory bodies, ethics committees, or government agencies may review identifiable data during audits to ensure study compliance.
- Your GP or healthcare provider may be informed of your participation with your consent, and notified if significant abnormal results are found.
- If a compensation claim is made for a study-related injury, the sponsor or its representatives may access identifiable information to assess the claim.
- No third parties will have access to your information unless required by law, or explicitly stated in this document.

What are the possible benefits or risks from taking part in this study?

Benefits: You are able to receive access to information about the low FODMAP diet, including personalized advice from a trained student dietitian. You are also able to receive the report from your BSGM testing, which is not routinely available in the healthcare system – this can potentially help you understand your body and symptoms better. More broadly, your participation helps us to develop better treatment approaches.

Risks: The study is not expected to cause physical, emotional, social, or spiritual harm to you. The risks associated with the study are minimal. You may experience mild skin irritation or discomfort from the adhesive electrodes used during the test. You may feel uncomfortable filling out the questionnaires which ask about your mental wellbeing and health. If anything difficult arises, the researchers can help you engage with appropriate support services if needed, and a list of support services are available at the end of this document.

Who pays for the study and are there commercial outcomes?

This study is funded by the University of Auckland postgraduate student fund. The study has been designed by the Research Team, with no influence from the study funders. The funders will not have access to the data, or have any role in the analysis, interpretation, or sharing of the study's results. There is no cost to your being part of this study.

The data will be owned by the University of Auckland, but Alimetry Ltd. (a University of Auckland spin-out company) has a data sharing agreement with UniServices at the University of Auckland. Alimetry Ltd produces the recording devices used in this study and, if the study is successful, may use the results to inform future development for commercialisation. The team members may personally benefit from the research in future. All related conflict of interest policies are being followed, including disclosures in presentations in publications. No data will be withheld from publication or presentation for commercial reasons in any way. Only the named researchers of this study will have access to your data.

What are my rights?

Participation is **entirely voluntary** - It is your choice to participate in this study, and you can pull out of the study at any time without giving reason. Whether you take part in this study or not will not affect

your relationship with the University of Auckland or healthcare providers, your usual healthcare, or your opportunity to participate in future research studies.

If you choose to participate, you have the right to withdraw from the study at any time. If you decide to pull out of the study, information contributed (questionnaires, food records, BSGM testing) can be withdrawn for up to one month after you withdraw.

You have the right to access and correct any information about yourself that we have collected as part of the research. No material that could personally identify you will be used in any reports.

What happens after the study?

We will complete data analysis using the de-identified data. Once complete, the findings from this research will be published in a research thesis, and may also be shared through reports, scientific/professional conference presentations, and in peer-reviewed journal publications. You will not be identifiable in any of these outputs. You are also able to get a lay summary of the findings of this project once they are published, and there is space on the Consent Form for you to say whether you would like a copy. There may be a delay between the end of the study and you getting the final results.

Who do I contact for more information or if I have concerns?

If you have questions about the study or would like to participate, please contact the research team	**Principle investigator** Dr Nicola Gillies, n.gillies@auckland.ac.nz **Co-Investigator** Dr Mikaela Law, m.law@auckland.ac.nz **Student investigator** Charlie Fraser, cfra287@aucklanduni.ac.nz
For concerns of an ethical nature, you can contact the Chair of the Health and Disability Ethics Committee	Phone: 0800 400 569 (Ministry of Health general inquiries) Email: hdecs@moh.govt.nz
For Māori cultural support	In the first instance, talk to your whānau. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by phoning 09 486 8624 x 2324
If you wish to talk to someone who isn't involved with the study	**Independent health and disability Advocate** Phone: 0800 555 050 Email: advoacy@advocacy.org.nz

Thank you for taking the time to read about and consider taking part in this study.

This research has been approved by the Health and Disability Ethics Committee on 02/02/2026 for three years. Reference Number 2026 EXP 24951.

Contact details for mental health support

If you are experiencing feelings of stress or anxiety that you think you need more help with you should **make an appointment to see your family doctor** and talk about these feelings with them so that they can discuss support options with you.

The following websites or help numbers can be helpful for people experiencing mental health concerns and needing further support. They have skilled people you can contact to help:

- **1737:** Free call or text 1737 for support from a trained counsellor or peer support worker, this service is available 24 hours a day. Website: https://1737.org.nz/
- **Lifeline Aotearoa Helpline:** Free call 0800 543 354 or text 4357 (HELP) for confidential support, this service is available from 7am – midnight. Website: https://www.lifeline.org.nz/
- **Samaritans**: Free call 0800 726 666 for support for anyone who is lonely or in distress, this service is available 24 hours a day. Website: https://www.samaritans.org.nz/
- Further information and free support can be found at https://www.depression.org.nz/. This includes information for Māori, Pasifika, and LGBTI groups.

If this is an **emergency** and you **require urgent assistance** then please call **111**, or go to your nearest hospital emergency department (ED), or phone your local Mental Health Crisis Team (CATT Team)