PARTICIPANT INFORMATION SHEET:
DUAL Study

Tēnā koe,

We are a group of researchers interested in improving quality of life for people with irritable bowel syndrome (IBS) and co-existing mental health concerns through dietary management strategies. In this study, we are testing two dietary patterns and their impact both gut and mental health symptoms, as well as overall quality of life.

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 your 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 this mahi (work), 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 pātai (questions) you have.

What is the purpose of the study?

Diet is a key treatment for IBS, but available approaches are gut-centric and do not take mental health concerns into consideration. Current dietary recommendations are not always appropriate for those with mental health concerns, yet they are the only option available. At present, we do not have a dietary treatment which is known to support those with both IBS and mental health concerns.

The purpose of this research is to assess the impact of two different diets on **both** gut and mental health. The dietary patterns being tested appear to be potentially useful in improving symptoms, however these have not been tested across wide populations. Ultimately, we hope this research will allow for more appropriate dietary recommendations to be made for people with IBS and mental health concerns in the future.

Who are the researchers?

This study has been designed by a team of researchers with backgrounds in Nutrition and Dietetics, Psychology, and Gastroenterology. Most of the researchers are affiliated with the University of Auckland, but our team also includes researchers from the University of Otago, Te Wānanga o Aotearoa, and Monash University (Australia). Your main points of contact during the study will be Dr Nicola Gillies (Lead Researcher, pākeha), Olivia Young (Research Assistant, Ngāti Kea Ngāti Tuara), Karis Gordon (Research Assistant, Te Aitanga a Mahaki), Dr Leigh O'Brien (Research Dietitian, pākeha) and Dr Hannah Rapata

(Research Fellow & Dietitian, Kāi Tahu, Ngāti Rahiri tumutumu). 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 100 adults (18-65 years) with IBS and symptoms of anxiety and/or depression will be invited to participate in this 8-week study. Although most of the researchers are based in Tāmaki Makaurau (Auckland), you can take part in this study from anywhere across Aotearoa, New Zealand.

Participants will be randomly assigned to one of two dietary patterns. The study uses a 'double-blinded' design, which means that neither you (the participant) nor the lead researcher will know which dietary pattern you will be allocated to until the results have been analysed. To maintain the integrity of study design and findings, you will not be informed of the name of the diet you are allocated to until the analysis has been completed. Both diets will require a modification of your current diet: both diets include recommended servings of food groups (like protein foods, or fruit and vegetables), and information on what foods to include, have in moderation, or specific foods that we ask you to limit for the trial period.

The study uses a dietary counselling design, which means that you will be provided with guidance on how to follow the dietary pattern, with personalized recommendations based on your preferences and lifestyle. It is your responsibility during the study to follow the recommendations as closely as possible. You will receive a food hamper in the first week of the study which includes food items that will help you follow the diet.

The study lasts for 8 weeks and includes data collection at three key time points (baseline, week-4, week-8) where you will provide information about your symptoms and diet, and fortnightly meetings with the research dietitian which take place over phone or zoom. Some more information about what's involved at each phase is outlined below.

Screening and enrolment

To begin, you will be asked to complete a pre-screening questionnaire online which will take approximately 15 minutes. If you fit the pre-screening criteria, a member of the research team will email you to arrange a phone or video call for a more detailed screening which allows us to confirm if you are eligible to participate or not. The screening call will take approximately 30 minutes to complete, and during this time the research team will also provide a verbal summary of what's involved in taking part in this study, including the requirements and procedures that you need to follow if you are eligible and decide to participate in the trial. You will also have the chance to ask the researcher any questions that you may have regarding the trial.

If you fit the inclusion criteria after this screening meeting and want to take part, you will be asked to provide written consent to take part in the study which is completed through an online form. After this, the researcher will book you in for your first study meeting with the research dietitian.

Preparation for study meeting 1 (baseline data collection)

Before your first study meeting with the research dietitian, we will send you instructions about data collection that needs to be complete **before** the meeting. This includes;

Questionnaires: A series of questionnaires about your gut symptoms, mental wellbeing, and quality of life through a secure online platform. This will take approximately 20 minutes to complete.

- 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.

Food record: 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.

Stool sample: A stool (poo) sample using a home collection kit that will be sent to you, and returned directly to the University of Auckland in a pre-paid courier bag. The kits contain a collection spatula, a collection tube with a stabilizing liquid, and instructions on how to collect and store the sample.

- Providing a stool sample is completely optional. We are collecting data from these samples to assess the gut microbiome. This will help us understand whether the diet can improve symptoms through changing the actions of the gut microbiome.
- If you complete this optional assessment, will be offered the opportunity to receive analysis of your gut microbiome composition. You can still participate in the study if you choose not to provide a stool sample.

First study meeting with research dietitian (45-minute diet consultation).

At this meeting you will meet with the study dietitian to receive information around the diet you have been allocated to, and how to apply it in your own life. You will be given specific targets around servings of each food group to aim for during your meeting, and a full list of the foods to include or limit. The dietitian will discuss how your current diet can be adapted to meet the trial diet.

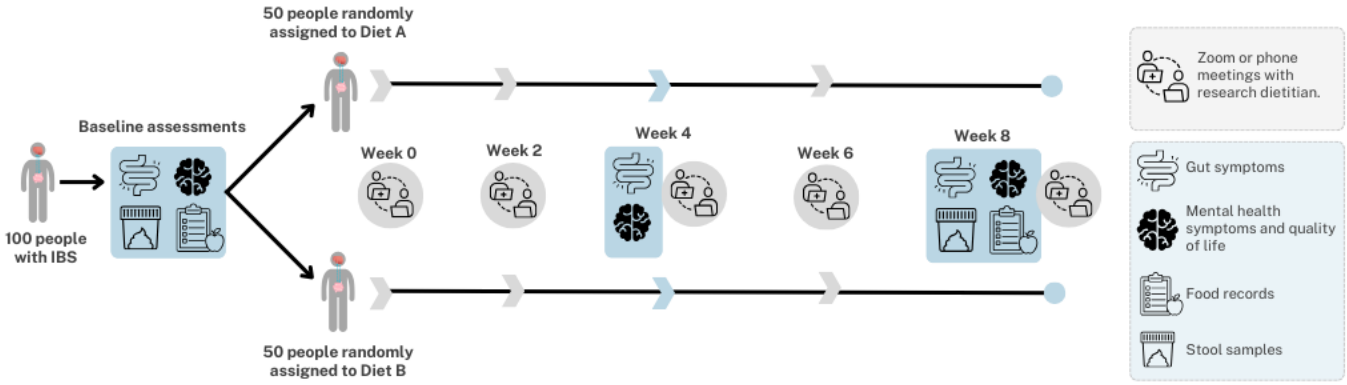
During the study meeting you will set some goals that will help you follow the diet, which we will check in on at later study meetings. You will receive an email after the study which includes written information to support you in following the diet (diet guidelines, meal planning tips, recipe ideas). You will also receive a food hamper valued at $150 during the first week of the study, which will also support you in making dietary changes according to the recommendations provided. We ask that you follow this advice as closely as possible for the 8-week trial.

During the study period

During the 8-week trial period you will attend a 30-minute diet consultation every two weeks to discuss how you are finding the diet, review your previous goals and to set new goals. This will be a time to ask any questions or comment on difficulties that you may have encountered when following the diet. The research dietitian will also ask you some general questions about your health, and whether you have experienced anything unusual that week. Before these sessions you will also be asked to complete a brief questionnaire through the online platform asking how closely you followed the advice over the last week, this should take 2 minutes of your time.

At week 4 you will repeat the questionnaires that you completed at the start of the study, and at week 8 you will repeat the questionnaires, food record, and stool sample assessments again. At week 8 you will complete an additional end of intervention survey which asks you to share your experiences with the diet and taking part in the study overall.

Key aspects of study participation are summarised in the figure below.



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 during screening and on your consent form only. Once you are enrolled in the study, you will be given a unique study ID which will be used moving forward.

De-identified (coded) information): All other study data (questionnaires, food records, stool samples) 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 managed through the University of Auckland. All data storage will comply with local and international data security guidelines, including encryption and controlled access. Data will be kept for 10 years and then deleted or destroyed, which the lead researcher (Dr Gillies) will oversee. 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.

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

- The research team responsible for running the study (Dr Gillies, Dr Rapata, Dr O'Brien, Ms Young, Ms Gordon) will have access to identifiable and coded data.
- Other researchers in the team (e.g., study statistician, co-investigators) or members of the data and safety monitoring committee (responsible for overseeing the safety of the study) will have access to coded data only – they will not be able to identify you or know of your participation.
- If a new member joins the research team or a new collaboration is established with external researchers, these people may also have access to coded data only. The PI Dr Gillies has responsibility for ensuring the safekeeping of your data.
- In certain situations, regulatory bodies, ethics committees, or government agencies may review identifiable data during audits to ensure study compliance.
- With your consent, your GP or healthcare provider may be informed of your participation if you report a high score on mental health questionnaires, which indicates follow-up is needed.
- 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.

Stool samples and microbiome data: Coded stool samples will be stored in a secure freezer at the University of Auckland (Faculty of Medical and Health Sciences).

At this point in time, we do not have funding for the microbiome analysis and cannot confirm where the stool samples will be sent to for microbiome analysis, or specific protocols for this. We will make efforts to complete the microbiome analysis at another research facility in Aotearoa, New Zealand. However, depending on funding and staff availability the analysis may be conducted oversees where our research team has networks (e.g., Australia). Once we know the exact location and protocols involved, you will be informed and asked to provide your consent before the samples are used.

Māori participants

If you self-identify as Māori in the screening questionnaire, a member of the research team can talk through the provisions we have in place to ensure you feel comfortable participating in this trial in line with your cultural values to help provide a positive experience.

Some provisions to support this include:

- Options to meet with a Māori team member at each point of engagement in the trial
- The opportunity for in-person engagements, where possible, to support whakawhanaungatanga
- Where possible, karakia and shared kai will be incorporated into research engagements
- A discussion around your rights to your data in line with Māori data sovereignty, as well as principles of governance.

If you have any pātai please feel free to contact the study team using the contact details at the end of this information sheet.

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

Benefits: You are able to receive personalised advice from a trained dietitian, with supporting written information. Access to dietetic counselling is limited by long wait lists in the public healthcare system or cost in private healthcare. If you take part in the optional stool sample assessments, you are also able receive the results of your microbiome analysis once analysis is completed, which is not routinely available in the healthcare system. You will also receive $100 worth of vouchers (petrol or supermarket), which will be provided as a $50 voucher after you complete data collection at week 4 and another $50 voucher after you complete data collection at week 8. You will also receive a food hamper valued at $150. More broadly, your participation is helping us to develop more effective treatment strategies for people with IBS and related conditions.

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 a mild worsening of gastrointestinal changes with dietary change. 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 Auckland Medical Research Foundation (AMRF). 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.

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, stool samples) 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, and using group-level information. Once complete, the findings from this research will be published in a peer-reviewed journal publication, and may also be shared through a research thesis, reports, and scientific/professional conference presentations. You will not be identifiable in any of these outputs. You are also able to get a summary of the findings of this project once they are published, which we will share as an infographic/short report, 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. We anticipate that the study will be completed in early 2028, and you will receive a summary towards the end of 2028.

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	**Principal investigator** Dr Nicola Gillies, n.gillies@auckland.ac.nz **DUAL study team** gut.research@auckland.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 13/04/2026 for three years. Reference Number 2026 EXP 25317.

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)