

Participant Information Sheet



**MEDICAL AND
HEALTH SCIENCES**

Investigating smartphone tracking apps for IBS

Principal Investigator: Dr Kate MacKrill

Co-Investigator: Professor Keith Petrie

Student Researcher: Grace Lyon

Ethics committee ref.: 2024 EXP 19213

Tēnā koe,

You are invited to take part in a study on the usefulness of food tracking apps for people with irritable bowel syndrome (IBS). Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This study is being conducted by researchers from the Department of Psychological Medicine, University of Auckland: Dr Kate MacKrill, Professor Keith Petrie, and Grace Lyon, a Master of Health Psychology Student. This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Participation in this study is entirely voluntary. If you choose to participate, you can change your mind at any time without any negative consequences. You can withdraw from the study at any time without giving a reason and withdraw any data traceable to you up until one week following your completion of the study. Whether or not you participate in this study will not affect your relationship with the researchers. You will be given a copy of this document to keep. If you withdraw, you will still be eligible to win one of the gift cards.

WHAT IS THE PURPOSE OF THE STUDY?

Keeping track of one's diet is a commonly recommended practice for people with IBS. This is thought to help identify foods that can trigger or worsen IBS symptoms. However, it is unknown what role smart phone tracking apps can play in this process. This study aims to investigate the experience of using food and symptom tracking apps for people with IBS. In particular, we are interested in how people evaluate these apps, how using these apps might impact wellbeing and whether using an app affects how people understand and monitor their IBS symptoms.

HOW IS THE STUDY DESIGNED?

We will be recruiting 140 people to participate in this study. Participation in the study will involve using a smartphone app for four weeks and completing four questionnaires (at baseline, two weeks, four weeks and six months). There will be three different versions of the smart phone app and you will be randomly allocated to use one of these versions. At each time point, the questionnaires will ask about your general health, experience using the app and IBS symptoms.

WHO CAN TAKE PART IN THE STUDY?

To be eligible to participate in this research you must meet the Rome IV criteria for a diagnosis of IBS:

- Have abdominal pain at least once a week for the past three months.
- Have this abdominal pain related to defecation, a change in stool frequency, or stool form.

In addition to this you must:

- Be aged between 18 and 65 years old.
- Be able to read and write in English.
- Have a smartphone.
- Not have used a symptom tracking app in the last twelve months.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you would like to participate in the study, you will first complete an online screening questionnaire to confirm your eligibility to participate. If you are eligible, you will provide your contact details and the student researcher will arrange a time with you to complete a 30-minute baseline study session, either in person at the University of Auckland City or Grafton campuses or over Zoom if that is not possible.

At this session you will complete a baseline questionnaire covering your demographics and health information (physical and emotional well-being). Following this you will be asked to download a food tracking app to use for the next four weeks. There are three versions of the app, which differ in some of the features they track. When you enter your email address into the app followed by a study-specific code, you will be randomly allocated to one of the app versions.

For the next four weeks you will use this smartphone app to track your diet and symptoms. The app will ask you to track the types of food you are eating (i.e., muesli, coffee, rice), but not the amount of food that you eat. Using the app will take about five minutes each day. Two weeks and four weeks after your study session, you will be emailed a link to an online follow-up questionnaire. The questionnaires will ask about your experience of using the app as well as about any symptoms

you have experienced and your physical and emotional well-being. The questionnaires should take about twenty minutes to complete. If you do not complete the questionnaires within 24 hours, a reminder email will be sent. After the four week timepoint you can stop using the app but will still be emailed a final follow-up questionnaire at six months to see if there have been any lasting changes.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There are no anticipated risks or threats to the safety of participants in this study. The questionnaires do ask participants to disclose symptoms they have experienced, which some people could find uncomfortable. Researchers will not have access to the information participants disclose when using the smartphone app, but will be able to see how often participants have used the app. The app being used does not share or sell users' personal information with third party services. To acknowledge the app developer and their involvement in the study, the researchers will email them the anonymised app feedback but this will not be linked to participants' identity or other answers.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Some participants may enjoy the novelty of using the food tracking app. Some participants may also find the app helps them to identify foods that trigger their IBS leading them to understand their IBS better.

WILL ANY COSTS BE REIMBURSED?

Participating in the study will not cost participants. There is a yearly subscription to unlock all features of the app. The cost of a one-year subscription will be covered by the researchers. To acknowledge participation, participants will go into the draw to win one of ten \$100 Prezzy eGift cards.

WHAT IF SOMETHING GOES WRONG?

In the event that some of the questions are upsetting and you would like support, Below is a list of help and support contacts that you can reach out to:

Healthline

0800 611 116

Speak to a registered nurse

1737 Need to talk?

Free call or text 1737 to talk to a counsellor

<https://1737.org.nz/>

Lifeline

0800 543 354

Free text 4357 (HELP)

Available 24/7 for confidential support

Youthline

0800 376 633

Free text 234

WHAT WILL HAPPEN TO MY INFORMATION?

This survey requires you to provide information about yourself in response to the survey questions. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only the researchers will have access to your identifiable information.

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researchers. Instead, you will be identified by a code. The researchers will keep a list linking your code with your name, so that you can be identified by your coded data if needed. Your app feedback will be anonymised (no identifiable information will be included) and provided to the app developer to support their service improvement.

The results of the study may be published in academic papers or presented at conferences and seminars, but not in a form that would reasonably be expected to identify you. The results from the questionnaires will be aggregated (grouped together) so only group data (e.g. means) will be presented.

Security and Storage of Your Information.

Your identifiable information will be held at the University of Auckland during the study. After the study is completed, written information will be transferred to a secure archiving site and stored for ten years, then confidentially destroyed. Your coded information will be entered into an electronic data file and saved on a secure server at the University. This file will be deleted after ten years. All storage will comply with local and/or international data security guidelines.

Risks.

This research includes basic information such as your ethnic group, age, and gender. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. If you have any questions about the collection and use of information about you, you should ask the student researcher.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing the student researcher. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw unless you withdraw after the study analyses have been undertaken.

Future Research Using Your Information.

Your coded information may be used for future research related to people's experiences of health apps for IBS. This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers and added to information from other studies, to form much larger sets of data. You will not get reports or other information about research that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Use of New Technologies.

Participation in this study requires using a health app for four weeks. To create an account in the app you will need to input your email address. You will also be asked to record the food you eat and how you are feeling, which could include health-sensitive information such as bowel movements and symptoms. This information will not be accessible to the researchers. However, this study's researchers will be able to access information about how often you use the app. Your data will be kept secure as per the app's privacy and data security guidelines. This includes data storage on their servers. The app development team and algorithm may analyse your data to find correlations between foods and symptoms common to many users, in line with the app's aim. Still, your data will never be shared in a way that is personally identifiable. No data recorded using the app will ever be traded or sold to third parties. All reasonable steps will be taken to ensure your data is treated securely. However, it is essential to note that no method of data sharing over the Internet is 100% secure, and for this reason, we cannot guarantee its absolute security.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with Meihana Douglas (Health Psychologist) about the collection, ownership, and use of study data.
- We allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

CAN I FIND OUT THE RESULTS OF THE STUDY?

You will be given the option of requesting a summary of the results of this study. If you select on the Consent Form that you would like to receive a summary, it will be sent to you via email once the study has been completed. As it takes some time to analyse the results of studies, it may be more than a year after your participation that you receive this information.

WHO IS FUNDING THE STUDY?

This study is being funded from the postgraduate research fund, Department of Psychological Medicine, University of Auckland, and the Gastroenterology Department of Te Whatu Ora Counties Manukau.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern B Health and Disability Ethics Committee approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Grace Lyon, Student researcher

0210756024

Glyo697@aucklanduni.ac.nz

Or alternatively:

Kate MacKrill, Lecturer | Health Psychologist

k.mackrill@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@advocacy.org.nz

Website: <https://www.advocacy.org.nz/>

For Māori cultural support please contact:

Administrator, Kamaka Waiora (Māori Health Team)

Phone: 09 486 8324 ext 2324.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Email: hdecs@health.govt.nz

Phone: 0800 400 569 (Ministry of Health general enquiries)