

Participant Information Sheet



Stress Education Intervention for IBS

Principal Investigator: Dr Kate MacKrill

Student Researcher: Sophie May

Ethics committee ref.: 24918

Tēnā koe,

You are invited to take part in a research study examining whether different stress education videos influence stress-related beliefs and IBS outcomes. Whether or not you take part is entirely your choice. If you decide not to participate, this will not affect your healthcare or relationship with the University of Auckland. If you choose to participate and later change your mind, you may withdraw at any time without giving a reason.

This study is being conducted by researchers from the Department of Psychological Medicine, University of Auckland: Dr Kate MacKrill and Sophie May, a Master of Health Psychology student. This Participant information sheet explains why we are doing the study, what participation involves, possible risks and benefits, and how your information will be handled. Please take time to read it carefully and discuss it with whānau, family, friends, or healthcare providers if you wish.

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 7 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?

Irritable Bowel Syndrome (IBS) is influenced not only by gastrointestinal processes but also by how individuals respond to stress. This study aims to examine whether two different video-based stress interventions can influence perceived stress, gastrointestinal symptom-specific anxiety, and IBS symptom severity.

HOW IS THE STUDY DESIGNED?

Approximately 48 adults with IBS will take part. Participants will be randomly assigned to one of two groups that provide different information about stress and its management. Random assignment means you cannot choose which group you are placed in.

Participation involves: Completing an online baseline questionnaire (approximately 20 minutes), watching a series of short intervention videos (approximately 60 minutes total), completing a short questionnaire immediately after the video (approximately 15 minutes), and completing a follow-up questionnaire one month later (approximately 15 minutes)

Total participation time is approximately 2 hours across one month.

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 had 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 internet access to complete questionnaires.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you would like to participate in the study, you will first read this Participant Information Sheet and complete an online screening questionnaire to confirm your eligibility to participate. If you are eligible, the student researcher will email you with the opportunity to discuss any questions about the study, and if you would like to participate, you will sign the online consent form via Qualtrics.

After signing the consent form, you will continue to complete the baseline questionnaire. This asks about your stress, IBS symptoms, and general well-being (approximately 20-25 minutes). You will then be randomly assigned (by chance) to one of two groups who will watch a series of short videos providing different information about stress and how to manage it. So as not to influence your responses, we are not able to tell you the content of these videos yet. After watching the videos (approximately 60 minutes in total), you will complete a short questionnaire asking about your management of stress (approximately 15 minutes). One month later, you will receive a final online questionnaire (approximately 20 minutes) to see whether there have been any changes in stress or IBS symptoms.

In total, participation will take about 2 hours spread across one month.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There are no anticipated risks or threats to participants' safety in this study. The questionnaires do ask participants to disclose symptoms they have experienced, which some people could find uncomfortable. If you experience distress, you may skip any question or withdraw from the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may learn different ways to manage stress. This research may help improve future psychological interventions for IBS.

WILL ANY COSTS BE REIMBURSED?

Participating in the study will not cost participants. To acknowledge participation, participants will go into the draw to win one of five \$100 Woolworths gift 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.

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. 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 six 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, stigmatise, 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 trace 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.

Use of New Technologies.

Participation in this study involves completing online questionnaires hosted on Qualtrics, a secure survey platform used by the University of Auckland. You will be asked to provide some identifiable information, such as your name and email address, so that we can send you the study questionnaires. You will also be asked questions about your stress, IBS symptoms, and emotional well-being, which may include health-related information.

Your responses will be stored securely on password-protected University systems. Only the research team will have access to identifiable information. Your questionnaire responses will be linked to a study code rather than your name in any reports or publications.

While all reasonable steps will be taken to protect your information, it is important to note that no method of data transmission over the internet is completely secure. For this reason, absolute confidentiality cannot be guaranteed.

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 Carly Hanna (Health Psychologist) about the collection, ownership, and use of study data.

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 funded by the postgraduate research fund of the Department of Psychological Medicine, University of Auckland.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent body, the Health and Disability Ethics Committee (HDEC), which ensures that studies meet established ethical standards. The Northern B Health and Disability Ethics Committee has 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:

Sophie May, Student researcher
0210471722
smay395@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)

Consent Form

Stress Education Intervention for IBS

Please tick to indicate you consent to the following

I have read the Participant Information Sheet and I fully comprehend what it says.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.

I consent to the possibility of my deidentified information being sent overseas for the purposes of future research.

I consent to the research staff collecting and processing my information, including information about my health.

If I decide to withdraw from the study, I understand that the information collected about me up to the point when I withdraw will continue to be used unless I email the student researcher to have it withdrawn.

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

I understand that I will be asked questions about by IBS and wider physical and emotional well-being, and I have the contact details of support services if I become distressed by any of the questions.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study.

Yes

No

Declaration by participant:

I hereby consent to take part in this study.

Participant's name: _____

Signature: _____

Date: _____