Participant Information Sheet

Understanding patients' mindsets about gastrointestinal conditions

Locality: Te Whatu Ora Counties Manukau
Lead investigator: Dr Kate MacKrill
Contact: kate.mackrill@middlemore.co.nz
Ethics committee ref: AH27179

Tēnā koe,

You are invited to take part in a study investigating people's mindsets about their gastrointestinal condition. Mindsets are broad beliefs we all have about many different areas of life e.g. mindsets about stress, work or sport. Research has now started to look at people's mindsets about their health and illness, and this study is specifically interested in how people think about Inflammatory Bowel Disease and Irritable Bowel Syndrome. Whether or not you take part in this study 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.

The study is being conducted by Dr Kate MacKrill, a Health Psychologist in the Gastroenterology Department at Middlemore Hospital and Lecturer in the Department of Psychological Medicine at the University of Auckland. This Participant Information Sheet will help you decide if you'd like to take part. It sets out why the study is being conducted, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. 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.

This study is an anonymous online survey. If you agree to take part in this study, completing and submitting the survey will be taken as your informed consent to participate.

This document is 5 pages long. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Participation in the study is entirely voluntary. You may consult with whānau or a support person before taking part in the study. You are free to decline to participate. If you decide to participate in this study, you can stop completing the survey at any time and your response won't be recorded. If you complete the survey and submit your response, you will not be able to withdraw your data as the survey is anonymous and the data cannot be traced back to you.

If you are a patient of a gastroenterology service, whether or not you participate in this study will not affect your relationship with your treating physician or the treatment you receive from them. You may wish to discuss the study with your treating physician before deciding if you want to participate.

WHAT IS THE PURPOSE OF THE STUDY?

This study is interested in how people with Inflammatory Bowel Disease or Irritable Bowel Syndrome think about their health condition (their mindsets) and the relationship of this with four domains of well-being: taha tinana/physical, taha hinengaro/emotional, taha whānau/social, and taha wairua/spiritual.

The hope is that the results of this study will improve our understanding of the impact of IBD and IBS on people's well-being and highlight potential strategies to improve this.

HOW IS THE STUDY DESIGNED?

This study consists of a one-off, anonymous online survey. The survey should take around 20-minutes to complete and you will be asked questions about your attitudes towards your gastro condition, the types of symptoms you experience, your mood, anxiety and stress levels, the ways you might cope with this, and wider areas of quality of life. Completing the survey and submitting it will be taken as your informed consent to participate. The study is aiming for 200 people to complete the survey.

WHO CAN TAKE PART IN THE STUDY?

To be able to participate in this study, you must:
- Be 18 years of age or older.
- Be able to read and write in English.
- Have the ability to give informed consent to participate.
- Have one or more of Crohn's disease, Ulcerative Colitis, or Irritable Bowel Syndrome.
- Have access to a computer, laptop, tablet or smartphone with a Wi-Fi connection to complete the online questionnaire.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If after reading this information sheet you are interested in participating in this study, you can click the survey link at the end of this document. You will first complete the screening questions to check that you are eligible to participate. If you are eligible, you will be able to continue to the rest of the survey.

The survey will take around 20 minutes to complete and will ask you about your beliefs and attitudes about your IBS/IBD, the types of symptoms you experience from it, its impact on various aspects of your life and emotional well-being, and how you cope with challenges. The survey will also assess basic demographic factors, such as gender, age, and ethnicity. To thank you for completing the survey, you can go into the draw to win one of ten $100 Prezzy eGift cards.

No identifying information will be taken like your name or address. As the survey is anonymous, completing and submitting the survey will be taken as your informed consent to participate. After submitting your survey response, you will be redirected to a separate webpage where you can request to be put into the gift card draw and to receive a summary of the study results. So that you can be contacted by the investigator, this will require you to provide your email address, which will not be linked to your survey response.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The procedures in this study are non-invasive and any possible risks are minimal. The study survey will be measuring your mood and well-being. If your scores indicate that you may have anxiety or depression, you will receive a specific message at the end of survey advising you to speak to your GP for support and will be informed of links to mental health services in the community.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Direct benefits of this study may include an improved understanding of your gastrointestinal condition. Future benefits of this study may include a greater understanding of the role of mindsets in health and a new target for interventions to improve well-being.

WILL ANY COSTS BE REIMBURSED?

You will not incur any costs for participating in this study. As a thank you for your help with the research, you can request to 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

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). No identifiable information will be collected in this study as the online survey is anonymous. 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

All survey information will be stored in electronic format on a password-protected server at Te Whatu Ora Counties Manukau during the study. Access to these electronic files will be restricted to the investigator only. After completion of the study, all data, including computer data files, will be stored for a minimum period of six years to allow for publication and re-analysis, after which time it will be securely and confidentially disposed of. Once the result summary has been sent and the winners of the prize draw have been contacted, your email will be deleted from the system. 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

As the survey is anonymous, your answers will not be able to be linked back to you, so you will not be able to access your information held by the research team. If you have any questions about the collection and use of information about you, you should ask the investigator.

Rights to Withdraw Your Information

If you decide to participate in this study, you can stop completing the survey at any time and your response won't be recorded. If you complete the survey and submit your response, you will not be able to withdraw your data due to the survey being anonymous.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you change your mind about participating in this study, you are able to stop completing the survey at any time and your response will not be recorded. If you submit your response at the end of the survey, you will not be able to withdraw your data as the survey is anonymous and your response will not be able to be linked to you.

CAN I FIND OUT THE RESULTS OF THE STUDY?

This research is expected to finish by the end of 2024. You can request a summary of the study results by providing your email address after completing the survey. The results from this study will be published in peer-reviewed scientific journals and academic conferences.

WHO IS FUNDING THE STUDY?

This study is funded by 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 the Auckland Health Research Ethics Committee, who check that studies meet established ethical standards.

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:

Dr Kate MacKrill, Lead Investigator
kate.mackrill@middlemore.co.nz

Head of Department:
Professor Trecia Wouldes, Department of Psychological Medicine
The University of Auckland
Private Bag 92019, Auckland 1142
Email: t.wouldes@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.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at +64 9 373 7599 x 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

If after reading this document you would now like to complete the study survey, you can access it at this link: https://auckland.au1.qualtrics.com/jfe/form/SV_9o7xD5nG6PHs0Xs

Approved by the Auckland Health Research Ethics Committee on 27/02/2024 for three years.
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