

Development and validation of a self-report general mental health scale for patients with functional gastroduodenal disorders

PARTICIPANT INFORMATION SHEET

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You are invited to join a study validating a new general mental health screening scale, developed for use in patients with functional gastroduodenal disorders (FGDDs).

Participation is **entirely voluntary (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.

WHAT IS THE PURPOSE OF THE STUDY?

About 30% of the global population have a problem with their stomach or intestines. These problems are split up into two groups by doctors - called structural and functional disorders.

Structural disorders are where the problem can be seen by looking at the gut with a scan, camera, or under a microscope. Generally, doctors are good at treating these disorders because they can see the problem, and treatments have been designed to target the problem that they can see. The other type of gut problems is called **functional disorders or FGDDs**. These are more difficult to diagnose and treat because less is known about what the underlying causes are.

Mental health issues are common in patients with FGDDs, often due to the chronic symptoms and lack of treatment options. Stress, anxiety, and depression have also been found to worsen symptoms and quality of life in these patients. It is possible that referring patients to psychological care, alongside medical treatment, may help improve their stomach symptoms. Therefore, identifying and treating patients most in need of psychological care early on could lead to symptom improvement and reduce the need for extensive medical testing.

One way this could be done is by incorporating mental health questionnaires into routine testing. Although mental health questionnaires already exist, there are no mental health questionnaires specifically designed for use in patients with FGDDs. Our team has therefore developed a new self-report mental health questionnaire for patients with FGDDs.

The aim of this study is to validate this questionnaire in a sample of adult patients with FGDDs. We aim to recruit over 100 patients to complete an anonymous, online survey.

WHO CAN TAKE PART IN THE STUDY?

To take part you must be 18 years or older and be able to speak, read, and write fluently in English. You must also meet the diagnostic criteria for a functional gastroduodenal disorder, such as;

- Gastroparesis
- Functional dyspepsia
- Chronic nausea and vomiting syndrome
- Cyclic vomiting syndrome
- Rumination syndrome
- Cannabinoid hyperemesis syndrome
- A belching disorder

As the survey will be conducted online, people from any country can participate. You cannot take part in this study if you vomit because you make yourself vomit (self-induced vomiting) or have an eating disorder. If you are in prison or long-term care, or if you have cognitive impairment, you cannot take part in this study.

If you are unsure if you meet these criteria, you can complete the screening questionnaire at the start of the survey, which will assess your eligibility.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Participation will involve completing an online questionnaire, which is completely anonymous. This questionnaire will involve completing a series of questions asking about your general demographics, symptoms, and mental health. This should take approximately 15-20 minutes to complete.

After you have submitted your answers, you will be given the opportunity to go into the draw to win 1 of 10 \$50NZD e-vouchers. If you are a winner of one of the e-vouchers, it will be converted to the equivalent value in your local currency.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

There are no immediate benefits to you in terms of diagnosis or treatment for taking part in this study. We hope that in the future, this study will lead to the inclusion of mental health questionnaires in the management of patients with FGDDs, which may enable the development of targeted treatments. This could lead to therapeutic benefits to patients with FGIDs.

There are no anticipated risks to you as a participant in this study. If any of the questions make you feel upset or you would like to contact someone to talk about your mental health further, please contact your general health practitioner, a psychologist, or contact a support service/free support line in your country.

WHO PAYS FOR THE STUDY AND ARE THERE COMMERCIAL OUTCOMES?

This study is funded by a New Zealand Health Research Council Programme Grant. The study investigators are members of the University of Auckland spin-out company Alimetry Ltd. This is a private company that emerged from the University of Auckland and is now commercially selling product for profit. Despite being a private company, Alimetry Ltd. is managed by Auckland UniServices in accordance with University of Auckland Guidelines. The team members and the University of Auckland may personally benefit financially from the research in future. The data will be owned by the University of Auckland but made available to Alimetry Ltd. via a data sharing agreement with Uniservices.

Conflicts of interest will be managed in accordance with University of Auckland guidelines at all times. No data will be withheld from publication or presentation for commercial reasons in any way. The University of Auckland team will control the data and the analysis, with no commercial influence on the analysis or resulting publications.

WHAT ARE MY RIGHTS?

Participation in this study is **entirely voluntary**. If you choose to participate, you can change your mind at any time, including during the survey, without giving a reason and without any negative consequences. Your answers to the questionnaires are completely anonymous and your identity cannot be linked to your survey responses. Due to this, it will not be possible to withdraw your answers after they have been submitted.

WHAT HAPPENS AFTER THE STUDY?

The information that is gathered from the survey is completely anonymous, and your identity can in no way be linked to your survey responses.

You will be provided with the opportunity to enter your email address during the survey to either enter the prize draw or to ask for a summary of the results. Entering your email address for either of these purposes is optional. Your email will only be used to contact you with the results summary or to contact you if you are the winner of the prize draw. It will be stored separately and not linked to your survey answers in any way, ensuring your survey responses

are still anonymous. Once the result summary has been sent/the winners of the prize draw have been contacted, your email will be deleted from the system. All other survey data will be deleted after a period of 10 years.

Research publications and presentations from the study will not contain any information that could personally identify you.

A summary of the research's findings can be emailed to you upon request. As it takes some time to analyse the results of the study, it may be more than one year after your participation that you receive this summary.

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:

Principal Investigator	Contact Person
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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.

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

APPROVED BY THE AUCKLAND HEALTH RESEARCH ETHICS COMMITTEE ON
12/04/2023 for 3 years, Reference Number AH25798