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Co-design Interview Study for A Functional Dyspepsia Wellbeing App

PARTICIPANT INFORMATION SHEET (Patient)

It is important to read this document carefully to make an informed decision about whether you would like to participate in this study.

Lead Investigator:	Professor Elizabeth Broadbent, Department of Psychological Medicine, The University of Auckland, Medical and Health Science Building 507 28 Park Avenue Grafton Auckland 1023
Study Personnel:	Isabella Pickering, Professor Greg O'Grady, Dr Mikaela Law, Dr Stefan Calder, Professor Chris Andrews, Dr Armen Gharibans
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You are invited to take part in a study investigating the opinions of patients and clinicians on a wellbeing app for the management of functional dyspepsia. This study counts towards part of a doctoral degree and is run by Isabella Pickering, a doctoral candidate in the Department of Psychological Medicine, and supervised by Professor Elizabeth Broadbent, Professor Greg O'Grady, Dr Mikaela Law, and Dr Stefan Calder.

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.

This Participant Information Sheet will help you decide whether to participate. It sets out why we are doing the study, what your participation would involve, the benefits and risks to you, and what would happen after the study ends. We will review this information with you and answer any questions before the study commences. You do not have to decide today whether you will participate in this study. Before you decide, you may want to discuss the study with others, such as 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 study Consent Form. You will be given a copy of the Participant Information Sheet to keep.

WHAT IS THE PURPOSE OF THE STUDY?

Functional dyspepsia is a condition where patients have chronic stomach symptoms, such as upper abdominal pain, uncomfortable fullness after a meal and inability to finish a normal-sized meal without structural or biochemical issues within the stomach (e.g. normal blood tests and scopes). Functional dyspepsia is estimated to affect at least 10% of the general population and is difficult to define, diagnose, and manage, as little is known about its underlying causes.

Poor mental wellbeing is common in patients with functional dyspepsia, often due to the persistent symptoms and lack of treatment options. Stress, anxiety, and depression have also been found to worsen these patients' symptoms and quality of life, whilst improving mental wellbeing has improved symptoms. Therefore, wellbeing, stress management, and coping skills are a potential way to help improve the quality of life in patients with functional dyspepsia. Recent patient interviews have shown openness to trying and using wellbeing interventions.

We think the best way to deliver wellbeing resources to patients is through a digital app on a smartphone or tablet to improve accessibility. Similar apps have already been created to help patients manage irritable bowel syndrome (IBS), with successful reductions in patients' symptoms and improvements in their mental wellbeing. However, no tested or tailored app exists for patients with functional dyspepsia.

Therefore, this study aims to gain the opinions of patients with functional dyspepsia and clinicians who treat them on developing a wellbeing app to manage stomach symptoms and mental wellbeing. We aim to recruit up to 30 patients and ten clinicians for this study. Each interview will be held separately, with one participant at a time.

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 following diagnostic criteria for functional dyspepsia.

Functional Dyspepsia: You must have at least one of the following symptoms over the past three months, with the onset of symptoms at least six months prior:

- Bothersome postprandial fullness: feeling uncomfortably full after a regular-sized meal more than one day a week
- Bothersome early satiation: being unable to finish a regular-sized meal more than one day a week
- Bothersome epigastric pain or burning: having pain or burning in the middle of the abdomen at least one day a week

You cannot participate in this study if you vomit because you make yourself vomit (self-induced vomiting) or have an eating disorder.

People from any country can participate, as the interviews will be conducted online. You cannot participate in this study if you are in prison or long-term care or have cognitive impairment. If you are unsure if you meet these criteria, you can complete the screening questionnaire, and the researchers will assess your eligibility.

If you are deemed ineligible for the study based on your questionnaire responses, you will be

contacted by the researchers with the reason why. Your questionnaire data will be deleted, and the researchers will keep only the reason for your ineligibility.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you are eligible for this study and agree to participate, we will ask you to join us for an online interview. Before the interview, you will be asked to complete a short online questionnaire about the eligibility criteria above and your general demographics.

The interviews will be held via Zoom, a web-based conferencing platform, for 30-60 minutes. In the interview, we will ask about your current coping strategies and experience with digital health tools before asking about opinions on possible content and how it can be delivered in our app.

You can discuss with the study investigators what time of day would work best for you to ensure that you have enough time and privacy to complete the interview. Please ensure that you have a private space where others will not overhear you that is available for up to one hour to complete the interview. If during the interview there is an interruption, the study team will work with you to reschedule your interview so that we can ensure your privacy. If you would prefer to have someone else present to support you during the interview, the investigators can work with you to arrange that. The researchers conducting the interview will ensure they have a private place so your interview will not be overheard.

With your permission, the interview will be audio recorded so that it can be transcribed. This is done so that we don't miss any of the things you say. Zoom records audio and video; however, only the audio recordings will be saved for transcription. Only the named researchers will have access to the audio recordings. You can review the transcripts of your interview if you want to. Your transcript will be emailed to you for review, and you will have two weeks to respond with any changes you would like to make. If you indicate so on the consent form, we will also give you a summary of the outcomes from the study.

After the interview, you will be reimbursed a $30NZD e-voucher for agreeing to participate in this research. International participants will be given an equivalent voucher from their country of residence. You will receive this irrespective of whether you withdraw during the study. Your participation will help us design an app. You can choose whether or not to participate in follow-up interviews or questionnaires to give us further feedback after we have developed a preliminary app. If consented to, we will contact you about this at a future date.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

There are no immediate benefits to you regarding diagnosis or treatment for participating in this study. However, there may be some benefits related to being able to share your experiences and have these acknowledged. Benefits include helping to advance the scientific understanding of managing gastric symptoms and wellbeing in patients with functional dyspepsia. Information from the interviews will enable the development of targeted digital wellbeing interventions for patients with functional dyspepsia, which may have therapeutic benefits for these patients.

It is possible that discussing your physical or psychological symptoms may cause you some distress. If that does happen, we can help direct you to supportive resources, such as your GP and helplines. We have also listed contact details at the end of this information sheet if

you would like to talk to a qualified counsellor or trained volunteer who can support you.

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 Alimetry Ltd. Auckland UniServices managing this spinout per University of Auckland Guidelines. The team members and the University of Auckland may personally benefit from the research in future. The data will be owned by the University of Auckland, but only de-identifiable data will be made available to Alimetry Ltd. via a data-sharing agreement with Uniservices.

Conflicts of interest will be managed following University of Auckland guidelines at all times. No data will be withheld from publication or presentation for commercial reasons in any way. No identifying information will be linked to the interview transcripts or disseminated for publication or the app development. The University of Auckland team will control the data and the analysis without 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 anytime, including during your interview, without giving a reason or negative consequences. After the interview, you have the right to withdraw any information collected from you during the study for up to one month after your interview, in which case the data will be securely destroyed.

WHAT HAPPENS AFTER THE STUDY?

The information gathered from you during your participation in the study will be de-identified to ensure your privacy. This means your data will be assigned a unique code number that contains no personally identifying information. This identification number de-identifies all other data, keeping your identity confidential. Your data will only be referred to or labelled with this number. A separate document will be kept linking these codes to participants' names. Only the researchers will have access to this document, which will be kept under password security at the University of Auckland. No data will be stored internationally.

Your email address will only be used for organising an interview time, sending you your interview transcript for review, re-contacting about future interviews/questionnaires, and organising the delivery of your voucher. Your email address and name will be stored separately from the interview data, and these will not be linked.

All data will be destroyed after ten years by shredding physical data and permanently deleting electronic data.

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 study's results, 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	Study Investigator/Main Contact Person
Professor Elizabeth Broadbent e.broadbent@auckland.ac.nz	**Isabella Pickering** isabella.pickering@auckland.ac.nz
Co-supervisors	Co-investigators
Professor Greg O'Grady greg.ogrady@auckland.ac.nz **Dr Mikaela Law** m.law@auckland.ac.nz **Dr Stefan Calder** stefan@alimetry.com	**Dr. Armen Gharibans** armen@alimetry.com **Professor Chris Andrews** candrews@ucalgary.ca

Head of Department, Psychological Medicine: Professor Trecia Wouldes, t.wouldes@auckland.ac.nz, +64 (0) 9 923 6221

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

If you want to talk to a qualified counsellor or trained volunteer about any distress during the interview, you can contact your GP or any helplines below in New Zealand. These helplines are available 24/7. If you are from somewhere other than New Zealand, you can talk to your GP, or the researchers can help direct you to an appropriate service available in your country.

Need to talk?

Freephone: Call or text 1737

Lifeline Aotearoa Helpline

Freephone: Call 0800 LIFELINE (543354) or Text HELP (4357)

Website: https://www.lifeline.org.nz/

National Depression Helpline

Freephone: Call 0800 111 757 or Text 4202

Website: https://depression.org.nz/

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

APPROVED BY THE AUCKLAND HEALTH RESEARCH ETHICS COMMITTEE ON 8/1/24 for 3 years, Reference Number AH27084.