Participant Information Sheet

Mapping of the Care Pathway for Chronic Nausea and Vomiting and Functional Dyspepsia and Pictorial assessment of Upper Gastrointestinal Symptoms

Title: Mapping of the Care Pathway for Chronic Nausea and Vomiting and Functional Dyspepsia and Pictorial assessment of Upper Gastrointestinal Symptoms

Lay Title: Mapping of the Care Pathway and Pictorial Assessment

Locality: Auckland District Health Board

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Email: gutresearch@auckland.ac.nz

You are invited to take part in a study to investigate the experience of patients with functional gastrointestinal disorders (FGIDs) and assess pictograms used to measure gut symptoms. 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 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 take part in this study. Before you decide you may want to talk about the study with other people, such as family, 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?

About 30% of the New Zealand 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 are called functional disorders. These are more difficult to diagnose and to treat because less is known about what the underlying causes are.

Our research team is running studies to look at the electrical activity in the gut because scientists think that when the stomach’s messages to the muscles are not normal, the gut muscles squeeze at the wrong time, in the wrong order, or not at all. You may have already participated in one of these studies (if you have, thank you). We think that these abnormal messages are linked to things people feel like stomach pain, nausea, being unable to finish meals, and feeling bloated. In these studies we use an app to measure the symptoms people are experiencing. One of the purposes of the current study is ask people what they think of the pictograms we are using to assess the severity of symptoms on the app.

We also hope to be able to measure the electrical activity in the stomach to help improve the way that these problems are diagnosed and hopefully to help target treatment options for this condition. To do this, we first need to understand the pathway that patients with these problems currently have to go down and how this affects their lives. Therefore, another aim of this study is to ask patients about their experiences with health care (including tests and treatments for their gut symptoms) and how this might be improved.

We will also be undertaking a similar study asking doctors who are involved with diagnosing these conditions how they do this and what might improve the way this is currently done.

In light of current Covid-19 pandemic, the interviews will be held via a web-based video teleconferencing software if necessary, thus maintaining appropriate levels of physical distancing. We aim to recruit 30 patients 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 or older, be able to speak and read English, and suffer from either nausea and vomiting or dyspepsia which started at least 6 months ago. This means suffering from either bothersome nausea at least 1 day per week and/or 1 vomiting episode per week or suffering from one of the following problems at least 1 day a week; feeling uncomfortably full after a regular sized meal, being unable to finish a regular sized meal, and/or experiencing pain or burning in your upper or mid abdomen (epigastrium). If these problems are related to an eating disorder or due to self-induced vomiting you are not able to take part in this study.

If you are in prison or long-term care, or if you have cognitive impairment you cannot take part in this study.

**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

If you agree to take part in this study, we will ask you to join us for an online interview. In the interview we will ask you about your thoughts and opinions about pictograms (pictures) that have been used to measure the severity of gut symptoms. We will also ask you about your experience living with a gut disorder, including questions about symptoms, tests and treatments, and how these have affected your life.

The interviews will be held via a web-based conferencing platform and will take about 1 hour. 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. You can review the transcripts of your interview if you want to. We will also give you a summary of the outcomes from the study and invite you to give feedback on these outcomes prior to any publication of the results. If there are any significant differences between the group outcomes and your experience you are welcome to discuss this further with us, either by email or by an additional phone or online interview.
You can discuss with the study investigators what time of day would work the best for you to ensure that you have enough time and privacy to complete the interview. Please make sure that you have a private space where others will not over hear you that is available for 1 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 make sure that they have a private place so that your interview will not be overheard.

We will also collect some information about you including your gender, age, ethnicity, but this information will be stored separately to the information from the interview (which will be assigned a participant number). Once the interview has been transcribed the recording will be destroyed and there will be no details that can identify you from the responses that you gave in the interview. If you are based in Auckland and give your permission for one of the study team to access your medical records they will look up which investigations and treatments you have had and when you had them. This is to get more information about the time it takes to go through this pathway.

**WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?**

There are no direct benefits to you taking part in this study. There are however many potential benefits to other people in society. We hope this study will help us learn about the current pathway that patients with these problems have to go down and about how we ask patients about gut symptoms. Our research team is developing a new way to look at the electrical activity of the gut and this study will help us to learn where this device would be best used for patients with these problems. It may also help to improve diagnosis and/or treatment of these problems in other ways as well.

It is possible that discussing your symptoms and medical journey may cause you some distress. If that does happen, we can help direct you to supportive resources, such as your GP and helplines.

Whether you choose to participate or not in this study, it will have no effect on the relationships with your doctors or your further healthcare.

**WHO PAYS FOR THE STUDY AND ARE THERE COMMERCIAL OUTCOMES?**

This study is funded by a New Zealand Health Research Council (HRC) Programme Grant. The data will be owned by the University of Auckland. New technology related to this work is being developed at the University of Auckland and this may be commercialised in future. This could result in a product that may provide improved diagnosis and/or treatment options for unexplained gut problems.

**WHAT ARE MY RIGHTS?**

Participation in this study is **entirely voluntary**. You can decide to not be involved at any time during the study, without providing a reason. After the study, you have the right to withdraw any information collected from you during the study for up to 1 month after your interview.

You have the right to access any information that is collected about you during your enrolment in this study. The information that is gathered from you during your participation in the study will be kept confidential and will be de-identified to ensure your privacy. No material which could personally identify you will be used in any reports on this study. We will send you a
summary of the results of this study upon its completion, if you would like one. Please note it may take time to collect data and provide results for this study.

**WHAT HAPPENS AFTER THE STUDY?**

Your data will be de-identified after the interview is transcribed. This means your data will be assigned a unique code number. This code will not contain any personally identifying information. A separate document will be kept linking these codes to participants' names / NHI identifier. Only the researchers will have access to this document which will be kept under password security.

The information gained from this study will be used in the theses of the student researchers (Nikita Karulkar, Daniel Carson) involved in the current study, and may be presented at academic and clinical forums, but in a way that will not identify any participants.

The research team will store a copy of the data on computer hardware at the University of Auckland. The Principal Investigator will be responsible for the safe keeping of the data. The data will be kept for 15 years following publication and then destroyed.

Members of the research team (present and future) will have access to the raw data and/or your clinical records (if you give permission) during the study, but only where ethical approval has been attained. Future studies may wish to include this data. Where such use goes beyond that outlined in the present application, further ethical approval will be sought.

**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:

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<tr>
<th>Principal Investigator</th>
<th>Study Investigator/Contact Person</th>
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<tr>
<td><strong>Associate Professor Gregory O'Grady</strong></td>
<td><strong>Dr. Celia Keane, Nikita Karulkar</strong></td>
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<td><a href="mailto:greg.ogrady@auckland.ac.nz">greg.ogrady@auckland.ac.nz</a></td>
<td><a href="mailto:gutresearch@auckland.ac.nz">gutresearch@auckland.ac.nz</a></td>
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**Postal Address:**
Department of Surgery, The University of Auckland, Medical and Health Science Building 507, Level 2, Room 2034, 28 Park Avenue, Grafton Auckland 1023

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the He Kamaka Waiora (Māori Health Team) at Auckland DHB by telephoning (09) 307 4949 ext. 29200

If you have any questions or complaints about the study, you may contact the Auckland DHB Māori Research Committee or Māori Research Advisor by telephoning 09 486 8324 ext 42324.

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 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 11/06/2020 for three years. Reference number AH1352.