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Participant Information Form

Survey-only Sub-study

Project title:

Noisy Guts: Preliminary Data Gathering and Analysis (sub-study with online survey))

Names of Researchers:

Prof Barry Marshall, Dr Josephine Muir, Ms Linda Wang and Dr Mary Webberley at the University of Western Australia.

Invitation:

You are invited to participate in the Noisy Guts Project.

You are asked to take part because you have responded to our advertising, and you either have had a diagnosis of Irritable Bowel Syndrome (IBS) or have a healthy gut.

Aim of the Study (What is the project about?)

Our aim is to develop a new, non-invasive tool to help in the diagnosis of gut problems, such as Irritable Bowel Syndrome (IBS). This tool will help screen patients for gut problems without the need for invasive tests.

In this study we will gather responses to a survey about gut symptoms that we can use to build the tool's software.

What does participation involve?

We ask you to

- Provide your GP's details and allow us to contact them to confirm your IBS diagnosis, if you have it.
- Tell us about your age, gender and history of gastrointestinal conditions and diagnoses.
- If you are eligible for our study, we will ask you complete two online surveys – one with 6 questions and one with 16 questions. Both surveys cover your recent gut symptoms and activity.
- In the future we may use your de-identified data in combination with data gathered in new studies to widen the range of diagnoses.

Voluntary Participation and Withdrawal from the Study

Participation is completely voluntary and you can withdraw from the study without giving an explanation. If you wish, your data collected so far will be destroyed after withdrawal. This is possible up until the data is submitted for analysis.

There will be no consequences associated with withdrawal. If you wish to withdraw, contact Dr Mary Webberley on 08 6457 2516 or mary.webberley@uwa.edu.au.

Your privacy

We will protect privacy. Our team are aware of the importance of confidentiality and have signed Confidentiality Agreements. Each participant will be allocated a unique identifier. The software developers will not see your name. We will also take care not to provide a combination of other information (e.g., age and sex) that might allow identification of you.

Similarly, no identifiable data will be included in publications.

We use the REDCap platform to gather data. This is a secure platform that has been specially developed to gather data in clinical trials.

Your data will be kept securely during the study on either the REDCap platform or a UWA, password protected computer in a lockable office and public access will be prevented. One researcher will hold the key to the unique identifiers, and this will be kept as a password locked file.

The final data will be kept securely after the study on the UWA data storage system (IRDS) and public access will be prevented. Your data may be used in combination with data gathered in future studies by the team. However, it will later be destroyed following UWA's guidelines.

Possible Benefits

There are no immediate benefits to participants. However, there are significant longterm benefits relating to improved care for sufferers of gut problems. This is the first step in developing a new non-invasive tool for the diagnosis of gastrointestinal diseases.

Possible Risks and Inconveniences

The study is non-invasive and there are no physical risks. There is inconvenience associated with completing the surveys.

LIMITING RISKS and INCONVENIENCE

The online surveys make data entry easy and secure. These can be completed on a smart phone in approximately 10 minutes.

To ensure your safety, the longer survey will have the following advice included:

“If you are in severe pain, or have experienced over 24 hours of constipation, vomiting or diarrhoea, we advise that you seek help from your doctor or Hospital Emergency.”

Reimbursement

Participants will be offered the chance to win one of three \$50 Coles vouchers for completing the survey.

Contacts

If you would like to participate, or discuss any aspect of this study, please contact Mary Webberley on 08 6457 2516.

Sincerely,

A handwritten signature in black ink that reads "Barry Marshall". The signature is written in a cursive, slightly slanted style.

Prof Barry Marshall

Chief Investigator

Approval to conduct this research has been provided by the University of Western Australia with reference number RA/4/1/8893, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time. In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Ethics office at UWA on (08) 6488 4703 or by emailing to humanethics@uwa.edu.au. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.