

PARTICIPANT INFORMATION SHEET
ONLINE RESEARCH PARTICIPATION

Swinburne University of Technology,
Royal Melbourne Hospital & St Vincent's Hospital (Melbourne)



FULL PROJECT TITLE:

Evaluation of the efficacy of www.gastroparesisclinic.org a 6-week online psychological support program for gastroparesis.

NAME/S OF INVESTIGATORS

Dr Simon Knowles (Swinburne University), Professor David Castle (St. Vincent's Hospital Melbourne), A/Prof Geoff Hebbard (Royal Melbourne Hospital) and Ms Sally Woodhouse (Swinburne University).

1. Introduction

You are invited to take part in this research project. This is because you are currently seeking treatment for gastroparesis and associated psychological distress. Due to the psychological distress often associated with gastroparesis, our research group has developed an online psychological treatment program for gastroparesis.

Funded by Associate Professor Geoff Hebbard, this online support program (www.gastroparesisclinic.org) is now available and we ask if you would volunteer to participate in undertaking the program and provide feedback from a consumer's perspective.

This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research. This consent form is five pages long.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to complete several online questionnaires, an online 6-module treatment program and participate in a telephone interview (further details are provided under 'What does participation in this research project involve').

The return of the consent form will be signalling that you are telling us that you:

- understand what you have read;
- consent to take part in the research project; and,
- consent to participate in the research processes that are described.

2. What is the purpose of this research project?

The purpose of this study is to validate and attain consumer feedback regarding an online psychological support program for individuals with gastroparesis. We are aware that having gastroparesis can have a significant impact on your health, both physiologically and well as psychologically. It is well recognised that individuals undergoing treatment for a medical condition also report anxiety, stress, and even depression. Consequently, our research team has developed an online assessment and psychological treatment service for gastroparesis. We aim to recruit a total of 60 participants.

Your participation in this study will help us to gather important information about the ways in which the online service is used, what changes can be made to improve its relevance and effectiveness for treating common psychological problems identified by individuals with gastroparesis. Under the supervision of the primary investigator, data from this study will also be used by Ms Sally Woodhouse as part of her PhD research.

3. What does participation in this research project involve?

If you wish to join the study, please contact your Gastroenterologist or contact the chief investigator, Dr Simon Knowles (ph +61 3 9214 8206, sknowles@swin.edu.au) who can assess your suitability for this research program (i.e., have gastroparesis and low to mild levels of psychological distress).

Upon creating a login at www.gastroparesisclinic.org and identifying your acceptance of participating in this research you will then be asked to complete:

- (1) an online psychological and well-being assessment (approximately 45 minutes). Assessment involves answering questions relating to your demographic details (age, marital status), physiological symptoms (e.g., pain, nausea) and psychological symptoms (e.g., feeling tense, worried, sad).
- (2) an online 6 module psychological support program (approximately 1.5 hours per module per week) focused around your psychological distress and gastroparesis symptoms. Each module is designed to provide a step-by-step therapeutic program which aims to help you develop strategies to reduce your symptoms. Modules will include a combination of education about

the psychological distress as well as targeted behavioural and psychological strategies (e.g., identifying and challenging thoughts that contribute to your distress, relaxation and breathing retraining), to help you overcome your psychological distress.

- (3) after the 6th module (at the end of week 6) you will be asked to complete the online post-intervention assessment (approximately 30 minutes). You may also be contacted and asked if you would participate in a brief interview via telephone (approximately 30 minutes) regarding your thoughts about the online treatment program and how it could be improved. You will also be contacted 1 and 2 years after completing the intervention to complete the online post-assessment program again.

Further details about the telephone interview:

At the completion of the intervention program (week 6), you will be invited (via email) to take part in a 30 minute telephone interview (conducted by Ms Sally Woodhouse, PhD candidate). The aim of the telephone interview will be to attain qualitative information about your perceptions of the intervention and how it can be improved. The telephone interview is completely voluntary. All information will be transcribed and identifiable information removed. You will be offered a transcript of the interview to review and provide comments on, which should take no longer than an hour of your time.

This research involves the collaboration between the Royal Melbourne Hospital, St Vincent's Hospital, and Swinburne University.

4. Participant Inclusion/exclusion criteria

Inclusion criteria:

- (1) Aged 18 year or older
- (2) Having been diagnosed with Gastroparesis and currently under the care of a gastroenterologist
- (3) English as a first language or able to read English

Exclusion criteria:

- (1) Not currently experiencing severe mental illness
- (2) Not currently seeking support from a mental health expert (i.e., psychologist or psychiatrist)

5. What are the possible risks?

It is recommended that you discuss your participation in this research with your gastroenterologist or health professional. If you become upset or distressed as a result of your participation in the research,

the researcher is able to arrange a referral for counselling and/or other appropriate support. Any counselling or support will be provided by individuals who are not members of the research team.

6. Do I have to take part in this research project?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage. If you do decide to leave this project, the researchers would like to keep the personal and health information about you that has been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the study.

If you are completing this questionnaire from outside of Australia, please be alert to any local restrictions in your home country on participating in foreign research activity.

7. How will I be informed of the results of this research project?

The research group conducting the study plan to write a report, which will be made available to anyone who is interested. The report will be available via www.Gastroparesisclinic.org. The results will also be written for publication in a scientific medical journal. Under the supervision of the primary investigator, data from this study will also be used by Ms Sally Woodhouse as part of her PhD research.

8. What will happen to information about me?

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. No information used in future presentations or written publications like articles or books will identify any participant. This is done through coding all participants using numbers and keeping all documents involved with individuals in a locked cabinet, accessible only to people involved in the project. All information will be kept at Swinburne University of Technology, in a locked filing cabinet (or secured computer) for a period of 7 years after last access/use and subsequently shredded (or deleted).

9. Can I access research information kept about me?

In accordance with relevant Australian and /or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Swinburne University Human Research Ethics Committee (SUHREC).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007 – updated May 2013)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Who can I contact?

If you want further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the Principal Researcher, Dr Simon Knowles, on +61 3 9214 8206 or sknowles@swin.edu.au.

12. Complaints

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Research Ethics Officer, Swinburne Research (H68), Swinburne University of Technology, PO BOX 218, HAWTHORN VIC 3122. Tel +61 3 9214 5218 or +61 3 9214 5218 or reethics@swin.edu.au

Consent

I have read this document and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I can print off or contact the principle researcher to attain a copy of the information and consent form.

If you have read and agree to participant, please click on the AGREE button.