PARTICIPANT INFORMATION SHEET

Swinburne University

&

Royal Melbourne Hospital, St Vincent's Hospital, The Austin Hospital, Box Hill Hospital, and Tasmanian North West Regional Hospital.

FULL PROJECT TITLE:

A validation trial of the IBSclinic.org.au online assessment and psychological support program.

NAME/S OF INVESTIGATORS

Dr Simon Knowles (Swinburne University) and A/Prof David Austin (Deakin University), Prof Michael Kamm (St. Vincent's Hospital), Dr David Castle (St. Vincent's Hospital), Dr Kaveh Monshat (St. Vincent's Hospital), Prof Findlay Macrae (Royal Melbourne Hospital), A/Prof Geoff Hebbard (Royal Melbourne Hospital), Chris Leung (Royal Melbourne Hospital, The Austin Hospital), Dr Suresh Sivanesan (Royal Melbourne Hospital), Dr Jason Tye-din (Royal Melbourne Hospital, Box Hill Hospital), Dr Jarrad Wilson (Tasmanian North West Regional Hospital), and Mrs Felicity Wood and Ms Sarina Cook (Swinburne University).

1. Introduction

You are invited to take part in this research project. This is because you are currently seeking treatment for Irritable Bowel Syndrome and have ongoing psychological distress. Due to the high prevalence of psychological distress in IBS cohorts, our research group has developed an online psychological treatment program for IBS.

We have now developed this online support program (www.IBSclinic.org.au) and 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 12-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 IBS. We are aware that having Irritable Bowel Syndrome 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 have developed an online assessment and psychological; treatment service for IBS. We aim to recruit a total of 80 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 IBS. Under the supervision of the primary investigator, data from this study will also be used by Mrs Felicity Wood as part of her 4th year 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 92148206, sknowles@swin.edu.au) who can assess your suitability for this research program (i.e., have IBS and low to mild levels of psychological distress).

Upon identifying your acceptance of participating of this research online at www.IBSclinic.org.au you can create your own username and password. You will then be asked to log onto the system and complete:

(1) an online psychological and well-being assessment (approximately 30 minutes). Assessment involves answering questions relating to your demographic details (age, marital status), physiological symptoms (e.g., pain, bowel activity) and psychological symptoms (e.g., feeling tense, worried, sad).

(2) an online 12 module psychological support program (approximately 1.5 hours per module per week) focused around your psychological distress and IBS 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 retaining), to help you overcome your psychological distress.

(3) after the 12th module (at the end of week 12) 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.

This research involves the collaboration between the Royal Melbourne Hospital, St Vincent's Hospital, The Austin Hospital, Box Hill Hospital, Tasmanian North West Regional Hospital and Swinburne University.

4. What are the possible risks?

There are no foreseeable risks from participating in this study. If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team.

5. 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.

6. 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.IBSclinic.org.au The results will also be written for publication in a scientific medical journal.

7. 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 and subsequently shredded. Information about you may be obtained from your health records held at this health service for the purposes of this research.

8. 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 researches 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.

9. Is this research project approved?

The ethical aspects of this research project have been approved by the Swinburne University Human Ethics Committee (SUHREC), Royal Melbourne Hospital Human Research Ethics Committee-A and other hospital specific ethics committees involved in this research.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* 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 resethics@swin.edu.au

Consent

I have read, or have had read to me in a language that I understand, 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.