Participant Information Sheet

Health/Social Science Research - *Adult providing own consent*

Title	*Cluster randomised controlled trial of a decision aid for ulcerative colitis patients: Enhancing patients' quality of life, empowerment, quality of decision making and disease control*
Protocol Number	*Version 2*
Coordinating Principal Investigator/ Principal Investigator	*A/Prof Susan Connor*
Location	*Enter site details*

Part 1 What does my participation involve?

1 Introduction

You have been invited to take part in this research project because you have been diagnosed with Ulcerative Colitis (UC) and as such, should be able to help in evaluating the effectiveness of the Ulcerative Colitis Patient Decision Aid (UCPDA) as an intervention in the treatment of UC. You can also help identify preferences, challenges and barriers to decision making choices between you and your specialist regarding your treatment for UC. Your contact details were obtained from your gastroenterologist.
This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.
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 local health worker.
Participation in this research is voluntary. If you do not wish to take part, you do not have to.
Once you have decided you want to take part in the research project, you will be forwarded to a web link where you will complete an online survey from your computer at home, or on a computer in the gastroenterology clinic.
You will be able to print a copy of this Participant Information Sheet to keep or you can request a copy be sent to you from the study coordinator.

2 What is the purpose of this research?

The researchers hope that an internet-based decision aid will help patients with UC better understand their disease and options for treatment, lead to more informed treatment decisions, better quality of decision making and better long-term disease control.
It is expected that the UCPDA will improve communication between patients and their treating physicians and it is hoped that by using input from patients with UC a more useful and relevant decision aid will be developed.

This research is being coordinated by Gastroenterologists in the Department of Gastroenterology & Hepatology at Liverpool Hospital with participating sites from throughout New South Wales, South Australia, Victoria, Queensland and Western Australia.

3 What does participation in this research involve?

You will be required to complete online surveys at the time points of baseline, two weeks after your first consultation, 2 months, 6 months and 12 months post consultation. The surveys will take approximately 30 minutes to complete. You will be required to enter data such as your age, gender and how long you have had UC, but not your name or any other details that may directly identify you. You are also required to provide a stool sample for faecal calprotectin (FC) at baseline, 2 months, 6 months and 12 months to assess your UC disease activity. By providing your consent for this study you will also allow the project team to access demographic and treatment data that exists in the hospital system, including information about your medical condition, current medications and other medical information from your health care team.

Task	Baseline Time point	2 Week Time point	2 Month Time point	6 Month Time point	12 Month Time point
Survey (completed online)	✓	✓	✓	✓	✓
FC Stool Sample	✓		✓	✓	✓

The FC stool sample is to be returned to any SONIC Pathology Centre. You will be advised of the name and location of your nearest pathology centres. You will also be provided with the necessary equipment, request forms and information needed to return the stool samples. It is critical that this sample be provided within a few days of completing the respective time point survey. There are no costs associated with participating in this research project, nor will you be paid.

4 Other relevant information about the research project

You will be allocated with a number upon recruitment; this is how you will be identified throughout the study. The coordinating investigators and study coordinator will be the only member of the study team that will be able to identify you. There will be 460 participants recruited from Inflammatory Bowel Disease (IBD) Services in South Australia, New South Wales, Victoria, Queensland and Western Australia.

5 Do I have to take part in this research project?

Participation in any 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 any stage. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with Liverpool Hospital or your treating physician.

6 What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this research. However, possible benefits may include more useful and effective treatment for patients with UC and better communication with their physicians in the future.

7 What are the possible risks and disadvantages of taking part?

Though unlikely, you may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

9 What happens when the research project ends?

Once you have completed the online surveys and stool samples at required time points your participation in the study will be complete. As this is a part of an ongoing study, a summary of the results may not be available for a period of time. When the research project is completed and a summary of the results are available, you will have the opportunity to access these through your gastroenterologist or a member of the research team.

Part 2 How is the research project being conducted?

10 What will happen to information about me?

The coordinating investigators and study coordinator will be able to identify you by matching your identification number. However none of the treating physicians nor anyone else will have access to your personal information. Although you are answering personal questions about your disease and experience, all responses are de-identified (anonymous). Your information will only be used for the purpose of this research project and will only be disclosed with your permission, except as required by law.

The personal information that the research team collect and use relates to: your age, gender & duration of disease, your general health rating, other diseases you have besides UC, your general feelings about UC and therapy for UC, your feelings about your relationship with your doctor, your adherence with your treatments and what types of information you would like to help you make decisions about your treatment for UC. Data from the survey will be analysed and summarised for future reports. All results will be reported as an aggregate (a large number of findings, not individual) to protect patient confidentiality. Data will be stored on a password-protected, secure system to prevent unauthorised access.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information about you that is collected and

stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

11 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

12 Who is organising and funding the research?

This research project is being conducted by A/Prof Susan Connor, Professor Afaf Girgis and Professor Jane Andrews.

You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from your information proves to be of commercial value to the researchers.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

13 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The ethical aspects of this research project have been approved by the HREC of South Western Sydney Local Health District.
This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

14 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any 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 research coordinator Sasha Ruban on (02) 8738 9247 or IBD.Liverpool@sswahs.nsw.gov.au.

15 Complaints contact person

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee – 15/199 (Local Project Number). Any person with concerns or complaints about the conduct of this study should contact the Ethics and Research Governance Office, Locked Bag 7279, LIVERPOOL BC, NSW, 1871 on 02 8738 8304, fax 02 8738 8310,
Email: research.support@sswahs.nsw.gov.au,
Website: http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html

Thank you for taking the time to consider this study.