Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	Effectiveness of a lacto-ovo vegetarian diet compared to omnivorous diet in ulcerative colitis: a randomised trial of two dietary interventions
Short Title	LOVUC
Protocol Number	5
Project Sponsor	Edith Cowan University, Ferring Pharmaceuticals, St John of God Subiaco Hospital
Coordinating Principal Investigator/ Principal Investigator	Charlene Grosse, ECU PhD candidate, St John of God Subiaco Hospital
Associate Investigator(s)	• Dr Claus Christophersen, Edith Cowan University • Professor Amanda Devine, Edith Cowan University • Professor Ian Lawrance, St John of God Subiaco Hospital & The University of Western Australia • Dr Johnny Lo, Edith Cowan University • Dr Lena Thin, Fiona Stanley Fremantle Hospitals Group & The University of Western Australia • Daniel Lightowler, Fiona Stanley Fremantle Hospitals Group & The University of Western Australia • Associate Professor Susan Connor, Liverpool Hospital • Dr Graham Radford-Smith, Royal Brisbane and Women's Hospital
Location	St John of God Subiaco Hospital Fiona Stanley Hospital Liverpool Hospital Royal Brisbane and Women's Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project 'Effectiveness of a lacto-ovo vegetarian diet compared to omnivorous diet in ulcerative colitis: a randomised trial of two dietary interventions'. You have been identified as a potential participant because you have mild to moderately active ulcerative colitis. The current treatment options ulcerative colitis include medications such as steroids (Prednisolone and Budesonide), 5-ASA medications such as Mesalazine, immunosuppressants and/or biologics. These medications are not without risks such as acquiring an infection and can also be expensive. There is a need to investigate the safe and cost effective alternatives including diet. The majority of patients with Inflammatory Bowel Disease (IBD) use dietary modifications to manage their symptoms, despite limited research to support these changes. Little research, however, has been undertaken into the role, and effect, that diet can play on intestinal inflammation and in the management of Ulcerative Colitis (UC). A Westernised diet, low in dietary fibre and high in sugar, animal fats and proteins is associated with increased prevalence of IBD and there is emerging data that a plant-based diet may be of benefit to IBD patients.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. 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 your local doctor.

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 or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

This study aims to determine whether a lacto-ovo vegetarian diet is effective in improving gastrointestinal symptoms, quality-of-life, intestinal inflammation and gut microbiota composition in mild-to-moderate UC compared to an omnivorous (meat) diet. The outcome of this study will provide insight into understanding diet in UC and to give recommendations into potential future directions for the use of diet as a supporting treatment to medical therapy.

The results of this research will be used by the study Chief Investigator Charlene Grosse to obtain a Doctor of Philosophy degree supervised by experienced researchers and supported by gastroenterologists. .

This research has been funded by St John of God Subiaco Hospital, Edith Cowan University and Ferring Pharmaceuticals.

3 What does participation in this research involve?

You will be participating in a randomised controlled trial. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). There is a one in two chance of being randomised to either group.

If you are eligible and agree to participate in this study, we will obtain your signed informed consent. We will then randomise you into one of two intervention diets. Each group will be educated by the dietitian on following the intervention diet they were randomised too (lacto-ovo vegetarian or omnivorous diet as per the Australian Guide to Health Eating). Five dinners a week can be provided via Hello Fresh or similar. The treating gastroenterologist will be blinded to which diet you have been placed on and it is requested that you do not discuss your diet with your doctor. The IBD nurse at your participating Hospital will be your first point of contact during the eight weeks.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

Your participation will require you to be evaluated by your gastroenterologist, IBD nurse and chief investigator at baseline and week 8 for a clinical symptom assessment, inflammatory blood markers (ESR and CRP), stool markers (FCP), gut microbiota composition, metabolome analysis and quality of life measures via questionnaires. You will also be contacted fortnightly by the chief investigator to complete bloods and questionnaires at week 2 and 4 and for a faecal calprotectin at week 4. This study requires a stool sample for gut microbiome analysis and a 3-day weighed food record prior to commencing the study and at the completion of the study. An optional routine flexible sigmoidoscopy or colonoscopy is included at baseline and at the end of the study

There are no additional costs associated with participating in this research project, nor will you be paid. You may be provided with a paid parking ticket for any appointments that require Hospital parking.

This study will require the following

- Complete a 3 day- weighed food record at the beginning and end of the study (including one weekend day). You will be given scales, measuring cups, spoons, recording sheets and instructions.
- Complete questionnaires on IBD, quality of life and food related quality of life.
- Complete blood tests at your routine visits to the IBD clinic
- Complete a stool sample at the beginning and end of the study to assess your microbiota composition and metabolome (pending funding).
- Complete an interview with an Accredited Practising Dietitian.

Please ensure you let the researcher know of any food allergies or special diets you follow as this may affect your eligibility to participate in the study.

5 Other relevant information about the research project

This study is a collaborative research project that will be recruiting 30 participants across four Hospitals in Western Australia, Brisbane and Sydney. Each intervention diet will have 15 participants each. This is a randomised control trial that is following on from an initial pilot study of 10 participants. This study will help to validate if an improvement of diet is important overall or if a plant based diet is more effective in UC.

6 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. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with your gastroenterologist or hospital.

7 What are the alternatives to participation?

If you chose not to participate in the project you will continue to receive standard clinical care as prescribed by your gastroenterologist.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, this research may help us to understand the role diet may play in ulcerative colitis activity, inflammation, gut flora, symptoms and quality of life.

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

There are no known health risks of the new diet. A flexible sigmoidoscopy poses few risks with rare complications including bleeding from the site the tissue sample was taken or a tear in the colon or

rectal wall. In addition, risks associated with blood sampling are infrequent and may include local bruising, inflammation of the vein, local thrombosis and possible infection of the sampling site. If this happens, it can be easily treated.

If you have a colonoscopy as part of your usual medical care you will have anaesthetic. The risks of anaesthesia will be discussed with you by your anaesthetics team.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

All clinically indicated blood and faecal samples will be collected and analysed at your local pathology centre. Stool samples and RNA biopsies taken during your flexible sigmoidoscopy will be transferred, stored and analysed at St John of God Hospital Subiaco and Curtin University of Technology. Some of these samples may be stored for future research purposes. This will enable gene expression patterns within our RNA to be analysed and further contribute to understating the role diet plays in managing UC.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you your treatment options.

12 Can I have other treatments during this research project?

No, you cannot be on other treatments during this research project until you have completed the 8 week study duration, as these treatments will affect the results of the study that determine whether the study diet is truly effective or not.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss the withdrawal process. If you do withdraw your consent during the research project, the study doctor and relevant study staff will ask you if you are happy to provide final blood and faecal samples and complete the questionnaires when you have participated for four weeks or more. 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 by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This study is unlikely to be stopped unexpectedly however, if it is you will be informed about this as soon as practical as well as what will happen with the data captured about you.

15 What happens when the research project ends?

When the study ends no further diet therapy will be provided by the study team. The results of the study will be available in summary form that will not contain any of your identifying personal or clinical information. The summarised results will be presented firstly, at an IBD conference such as ECCO (European Crohn's and colitis organisation), and then we will submit the results for publication in a reputable gastroenterology/ IBD journal. Your clinical care will be handed back to your IBD physician.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

All personal and clinical information about you will be stored on secure, password encrypted data files stored on the hospital desktops of the principal investigator at each hospital. By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. All of the information collected about you will be stored for a period of 15 years as directed by the NHMRC guidelines.

Any data collected on paper forms will be stored at St John of God Subiaco Hospital within a locked office in a secure area which is access controlled and only accessible by investigator staff. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the research team accessing any health records that are relevant to your participation in this research project.

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, except with your permission. Only summary data will be presented or published.

Information about your participation in this research project may be recorded in your health records.

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

Any information obtained for the purpose of this research project and for the future research that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If you suffer any complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research project is funded by Edith Cowan University, St John of God Subiaco Hospital and Ferring Pharmaceuticals.

19 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 South Metropolitan Area Health Service Human Research Ethics Committee.

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.

20 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 medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal investigator [PI Name] [contact number] or any of the following people:

Clinical contact person

Name	
Position	
Telephone	
Email	

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	
Position	
Telephone	
Email	

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	South Metropolitan Health Service Human Research Ethics Committee
HREC Executive Officer	Ethics Coordinator
Telephone	(08) 6152 2064
Email	SMHS.HREC@health.wa.gov.au

Local HREC Office contact (Single Site -Research Governance Officer)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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Consent Form - *Adult providing own consent*

Title	Effectiveness of a lacto-ovo vegetarian diet compared to omnivorous diet in ulcerative colitis: a randomised trial of two dietary interventions
Short Title	LOVUC
Protocol Number	5
Project Sponsor	Edith Cowan University, Ferring Pharmaceuticals, St John of God Subiaco Hospital
Coordinating Principal Investigator/ Principal Investigator	Charlene Grosse, ECU PhD candidate, St John of God Subiaco Hospital
Associate Investigator(s)	• Dr Claus Christophersen, Edith Cowan University • Professor Amanda Devine, Edith Cowan University • Professor Ian Lawrance, St John of God Subiaco Hospital & The University of Western Australia • Dr Johnny Lo, Edith Cowan University • Dr Lena Thin, Fiona Stanley Fremantle Hospitals Group & The University of Western Australia • Daniel Lightowler, Fiona Stanley Fremantle Hospitals Group & The University of Western Australia • Associate Professor Susan Connor, Liverpool Hospital • Dr Graham Radford-Smith, Royal Brisbane and Women's Hospital
Location	St John of God Subiaco Hospital, Fiona Stanley Hospital Liverpool Hospital and Royal Brisbane and Women's Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Charlene Grosse, Principal Investigator concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Other research that is closely related to this research project
- Any future research.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required*

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is <u>not</u> to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may <u>not</u> act as a witness to the consent process. Witness must be 18 years or older.

<u>Declaration by Study Doctor/Senior Researcher†</u>

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Optional Consent Form - *Adult providing own consent*

Title	Effectiveness of a lacto-ovo vegetarian diet compared to omnivorous diet in ulcerative colitis: a randomised trial of two dietary interventions
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Location	St John of God Subiaco Hospital, Fiona Stanley Hospital Liverpool Hospital and Royal Brisbane and Women's Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission to undergo flexible sigmoidoscopy or colonoscopy as outlined within the Participant Information Sheet.

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

I consent to the storage and use of tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Other research that is closely related to this research project
- Any future research.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required*

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Effectiveness of a lacto-ovo vegetarian diet compared to omnivorous diet in ulcerative colitis: a randomised trial of two dietary interventions
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Location (where CPI/PI will recruit)	St John of God Subiaco Hospital, Fiona Stanley Hospital Liverpool Hospital and Royal Brisbane and Women's Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Fiona Stanley.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.