Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

The Alfred/The School of Translational Medicine – Monash University/Monash Biomedicine Discovery Institute – Monash Clayton

Title	Microbial fermentative capacity of individuals with ulcerative colitis with an ileoanal pouch compared to a healthy or UC with intact colons: an in vitro study
Short Title	Fermentation characteristics in UC
Project Number	107983
Project Sponsor	Monash University
Coordinating Principal Investigator/ Principal Investigator	Dr Chu Yao (Alfred Health & Monash University)
Associate Investigator(s)	Dr. Zaid Ardalan, Dr Emma Halmos, Prof Peter Gibson (Monash University/Alfred Health) A/Prof Jonathan Segal (Royal Melbourne/Melbourne University)
Student investigator	Dakota Rhys-Jones (Monash University/Alfred Health)
Location	The Alfred The School of Translational Medicine – Monash University Monash Biomedicine Research Institute – Monash University

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, 'Microbial fermentative capacity of individuals with ulcerative colitis with an ileoanal pouch compared to a healthy or UC with intact colons: an in vitro study'. This is because you are healthy with no pre-existing gastrointestinal disease – results from a healthy colon act as an important comparator in this study. The purpose of this research project is to understand whether, in individuals with ulcerative colitis or with a pouch, there are differences in how the gut bacteria metabolise fibre compared to healthy controls. If we can understand whether these differences exist, the information obtained from this study will help tailor treatment strategies better, particularly with diet, for ulcerative colitis and those with a pouch.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research 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 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 the tests and research 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?

An ileoanal pouch (e.g. a J-pouch) is a surgical procedure used when the colon is removed due to ulcerative colitis that does not respond to treatment. In this surgery, the end of the small intestine is reshaped to create a new storage area for waste, similar to a rectum. Over time, this pouch undergoes changes to function more like a colon. While quality of life is good for majority of individuals, a high proportion of patients will often have symptoms of increased pouch frequency, abdominal pain and cramping due to factors that are poorly understood. Pouchitis is the most common inflammatory condition of the pouch, which interestingly, shares some similarities with UC.

Managing suboptimal bowel/pouch function and symptoms of a pouchitis/UC flare can be challenging. Some patients opt to avoid foods high in fibre, believing it may help ease their symptoms. Yet, recent studies suggest that adhering to a Mediterranean diet, which is rich in fibre, or increasing fruit intake might actually reduce the risk of developing pouchitis in those with a pouch. Similarly, in UC, increasing fibre intake is a common strategy used to treat active disease. The type of fibre consumed also matters. Fibres that ferment quickly may exacerbate symptoms (i.e. onion, garlic, legumes), while those that don't ferment or have less rapid fermentation can be better tolerated (i.e. psyllium).

Studies suggest that microbial fermentation in patients with UC or an ileoanal pouch is different to patients with a healthy colon. Therefore, we aim to assess how various fibres are fermented by microbes in patients with UC, an ileoanal pouch and healthy controls. This study aims to fill gaps in knowledge regarding how fibres are broken down by patients with UC and an ileoanal pouch, to guide dietary recommendations.

The results of this research will be used by Dakota Rhys-Jones to obtain a Doctor of Philosophy degree.

This research has been initiated by the study's Principal Investigator, Dr Chu Yao.

3 What does participation in this research involve?

Participation is voluntary and nothing takes place before you have read and fully understand this consent form, and have signed it. You may qualify to participate in this research as a 'healthy control' if you meet the eligibility criteria below.

Screening:
A phone call will be scheduled with the researcher for screening to ensure you meet the below criteria. After this and once you have read and signed this participant information consent form (PICF) you are ready for participation. Contact details for the research team can be found at the end of this document.

To be included in this trial you are:	You are not eligible for inclusion in this trial if you:
• 18-75 years old • Living in Metropolitan Melbourne • Ability to speak and read English • Eligible for Medicare	• Presence of gastrointestinal diseases i.e. coeliac disease, inflammatory bowel disease • Prebiotic or probiotic supplement in the last 2 weeks • Antibiotic use (including sulfasalazine) in the last 4 weeks • Inability to provide informed consent

All individually identifiable information (name, contact details) will be collected by the study coordinator and stored on a password protected drive on a Monash University server. After this, you will be given a study ID and all of the data collected below will be labelled with this study ID.

Screening call:

Once you have provided consent, the researcher with the study gastroenterologist will undertake a screening assessment via phone call to assess your eligibility. This will take no more than 30 minutes. You will be asked information about your demographics (weight/height, smoking status, age, gender), medical history and current medications.

Collection of identifiable information is obtained in the context of confirming eligibility for participation in the trial.

Procedures

Pre-study day:

You will be asked to refrain from eating foods high in oligosaccharides (garlic, onion, leek, shallots, Jerusalem artichokes, rye products, pistachio/cashews) and resistant starch (green banana flour, cooked and cooled potato/rice/pasta, legumes (chickpeas, red kidney beans), wholegrain cereals) for 24hrs. This will minimise any fibres in the stool that may impact on the way the microbes ferment the fibres.

Study collection day:

You will be provided with a faecal collection kit that includes two tubs for faecal collection. One is for the assessment of faecal calprotectin (an inflammatory marker in the stool).

The other is for the assessment of fermentation of gut bacteria – this sample needs to be collected **fresh** and transported to Monash Biomedicine Discovery Institute, Monash Clayton within **~1.5 hours** of passing. There are two ways in which this can be achieved.

1) **Faecal sample collection at home:**

If you choose to collect your faecal sample at home, you will be sent a faecal collection kit with instructions on how to collect the samples, as well as packaging for safe transport of the samples. An approximate time and day will be agreed upon between yourself and a member of the research team for the samples to be collected by a courier service. As soon as you have taken the sample, we ask that you let a member of the research team know, so that they can arrange a courier service to collect the sample. After you have taken the sample, we ask that you place this into the provided packaging for transportation with a courier service.

2) **Faecal sample collection at The School of Translational Medicine, Monash University (Alfred Centre) or Monash Biomedicine Discovery Institute (Monash Clayton):**

You also have the option of attending for a study visit at The Alfred Centre or Monash University, Clayton for sample collection. You will be met by the study coordinator at The Alfred Centre or Monash Biomedicine Discovery (BDI) Institute, Monash Clayton and be provided with the faecal collection kit. You will also be provided with a $10 food and drink voucher so that you can purchase food and drink whilst waiting for the faecal collection. You will also be provided with a parking voucher or any reasonable travel reimbursement (taxi voucher or parking up to $25). If you are coming into The Alfred Centre, you will be shown to the toilets on level 6, Monash University, School of Translational Medicine. If you are coming into Monash Clayton, you will be shown to the toilets at the ground floor of Monash BDI. Once you feel the urge to use bowels/empty pouch, you will be asked to use the available toilets at level 6 of The Alfred Centre or the ground floor of Monash BDI for sample collection. Once safely collected, these will be provided back to the study coordinator for immediate sample processing.

Table 1 describes the differences between faecal collection methods.

Location of collection	*Study visit required*	*Courier to collect sample*	*Provision of food and drink voucher ($10)*	*Reimbursement for travel (taxi voucher or parking up to $25)*
Home	✗	✔	✗	✗
School of Translational Medicine, Monash University, Alfred Centre	✔	✗	✔	✔
Monash Biomedicine Discovery Institute, Monash University	✔	✗	✔	✔

We expect the faecal collection (excluding any time it takes to travel to The Alfred Centre/Monash Clayton) will take approximately 15-20 minutes, including reading instructions, collecting sample and placing securely into packaging. Note this 15-20 mins is time taken to collect the sample, any time spent waiting to pass a stool is additional.

Dietary data: The day prior to faecal sample collection, you will be asked to document the food you eat for 24 hours. A food diary will be provided to you with instructions. We expect this will take up to 15 minutes total.

After the food diary has been completed and the faecal sample has been collected, your participation in the study is over.

Duration of research project: we expect that this project will go for ~6-12 months.

Reimbursement and costs: There are no costs associated with participating in this research project, nor will you be paid. You will only be provided with a reimbursement if you choose to come into The Alfred Centre or Monash Biomedicine Discovery Institute, Monash Clayton for sample collection which will be $10 food and drink voucher and any reasonable travel (taxi or parking voucher up to $25).

Bias: This research project has been designed to make sure the researchers interpret the results in fair and appropriate way and avoids the research team or participants jumping to conclusions.

4 What do I have to do?

In order to fully participate in this study, you need to be available on two occasions – for a screening phone call that takes up to an hour, and on another day to provide a faecal sample. There are no physical or lifestyle restrictions in terms of participation in physical activity. You should continue to take your regular medications, there are no restrictions in terms of medications you cannot take. You can still donate blood to take part in this study.

Dietary restrictions:

We are looking at how your gut microbes ferment certain fibres, therefore we will ask you to limit these particular fibres. You will be asked to limit the following foods in the 24hrs prior to providing your faecal sample:

- Resistant starch: green banana flour, cooked and cooled potato/rice/pasta, legumes (chickpeas, red kidney beans), wholegrain cereals
- Fructans: garlic, onion, leek, shallots, Jerusalem artichokes, rye products

5 Other relevant information about the research project

We expect that 50 people will be taking part in this study in the following groups:

- Patients living with Ulcerative colitis (10 with ‘active’ disease and 10 in remission)
- Patients living with an ileoanal pouch (10 with active pouchitis and 10 healthy pouch)
- Controls who have no history of inflammatory bowel disease and have an intact colon (10)

Alfred Health will be the predominant site for this study.

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 The Alfred

7 What are the alternatives to participation?

Participation in this study is entirely voluntary. Not participating in this study will have no impact on the course of your pouch or it's management.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any direct benefits from this research. However, your participation in this study will contribute to expanding the existing scientific knowledge base surrounding ileoanal pouches, filling gaps in our understanding of the condition. By contributing your time and effort to this study, your involvement will help us to advance the field of research in ileoanal pouches, and guide the development of future dietary trials, that could use fibre/diet as therapy. As there are no current dietary guidelines or recommendations for patients living with ileoanal pouches, it is expected that this study will add to the limited scientific literature, to one day achieve practical evidence-based strategies to improve quality of life for these patients.

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

It is unlikely that participation in this trial will carry many risks, however, possible risks are as follows:

- There is potential biological hazard (cross-contamination of harmful microorganisms from faecal material to surfaces/objects/skin) risks when collecting faecal samples, however, there are controls in place for this to minimise the risk of harm by providing gloves, easy-to-understand instructions and toilet liners.
- The time taken for the screening phone call prior to the study day, and time taken to collect the faecal sample and record the food diary may be an inconvenience on the day. However, the both the pre-study and study days will be organised on days that work best within your schedule.
- In the event that you experience acute distress as a result of ineligibility with the study during the screening visit or as a result of the study protocol, you can discuss this with the study investigators. The research team will direct you to your GP who will be able to refer you to counselling with an accredited psychologist.

Additionally, the research team will cover the costs associated with psychological care. If you feel that you will benefit from further support, we can provide you with contact details for support services (Lifeline 13 11 14 or Beyond Blue 1300 224 636) should you incur any distress as a result of this. Some of the other external support services are also listed on the website: https://www.alfredhealth.org.au/alfred-mental-and-addiction-health/resources-and-useful-links

10 What will happen to my test samples?

The collection of faecal samples is a compulsory part of this study. Faecal sample collection kits will be labelled with the study ID of the participant which is known only by members of the research team. Faecal samples are therefore re-identifiable.

We are looking at how your gut bacteria ferments fibres, and are assessing gas production in the stool, and this test has to be done on **fresh** stool. These faecal samples will be transported to Monash Biomedicine Discovery Institute, Monash Clayton for analysis immediately. After this test, all samples will be destroyed immediately as per standard lab protocols.

Faecal samples that are used for assessment of faecal calprotectin will be stored at the laboratory at the Department of Gastroenterology, Monash University until analysis. After analysis, samples will be destroyed safely as per standard laboratory protocols.

You have the option for an additional sample to be used for future use, only this sample may be potentially used in future related studies, otherwise, the sample will be destroyed as per protocols above. These optional samples will be retained for 5 years and then destroyed safely as per standard laboratory protocols.

A separate ethics application will be made if the samples are used for future use that is related to the study protocol.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information might become available about fermentation in pouches. If this happens, your study coordinator will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

12 Can I have other treatments during this research project?

During the course of the study, you can continue taking your regular medications and/or commence new medications. It is important to tell your study coordinator and the about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

13 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team when you withdraw. If you do decide to withdraw, you will be asked to complete and sign a ‘Withdrawal of Participation’ form which will be provided to you by the research team.

If you do withdraw your consent during the research project, the study coordinator and relevant study staff 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 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?

It is very unlikely that the project will be stopped unexpectedly, even in the event of new data emerging about diet and pouches. Often, further research is required to either confirm existing findings or provide alternative results. Therefore, we do not have any reasons for this study to stop.

15 What happens when the research project ends?

Once the study concludes, you will continue to be followed up as a standard patient with your usual doctor. There will be no explicit changes to dietary or medical advice from participating in this research. You will not be provided with any individual results for taking part in this study. You will be offered an overall summary of the study outcomes at the completion of the study – please let the study coordinator know if you do not want a summary of results from the study once the study has been completed.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the relevant research staff collecting and using personal information about you for the research project. 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 study team accessing health records if they are relevant to your participation in this research project.

Any information obtained in connection with this research project that can identify you will remain confidential. All personal identifiable data such as name, date of birth collected will be coded with a participant ID and stored separately on the Alfred Sharepoint (that is password protected server) to all data collected in this study. All coded data will be stored on an excel spreadsheet on a password protected drive on a Monash secure server that is password-protected and access will be restricted to research personnel only. Upon completion of the study, this data will be stored for 7 years and then all digital files will be permanently deleted.

Any hard copy identifiable files (including consent forms) will be securely stored by the research team in locked filings cabinets at the Department of Gastroenterology, Alfred Centre. Entry to the Department of Gastroenterology is secured and restricted by swipe access. Following completion of the study, all hardcopy files will be stored for 7 years and then shredded and destroyed safely.

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.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. Furthermore, research findings generated from this project may be shared with other researchers upon request made to the study researchers or used in other data analyses related to this project. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. In any data sharing or analyses, information will be provided in a way that you cannot be identified.

In addition, sharing of re-identifiable data generated from this project with other researchers may be made upon request to the study researchers. Additionally, only re-identifiable data may be used for secondary analyses related to this project.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study 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 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.

A separate ethics application will be made if the samples are used for future use that is unrelated to the study protocol.

17 What if I get injured in this research?

If you suffer any injuries or 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. As 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?

The research project is being conducted by Dr. Chu Yao and Dr. Zaid Ardalan of the Gastroenterology unit of Monash University and Alfred Health.

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

If knowledge acquired through this research leads to discoveries that are of commercial value to the researchers or their institutions, there will be no financial benefit to you or your family from these discoveries.

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 Alfred Hospital Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. 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, you can contact:

Clinical contact person

Name	Dr Zaid Ardalan
Position	Study gastroenterologist
Telephone	0409 730 301
Email	Zaid.ardalan@monash.edu

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 Office/Complaints contact person

Position	Complaints Officer, Office of Ethics & Research Governance, Alfred Health
Telephone	+61 3 9076 3619
Email	research@alfred.org.au
Please quote the following Project ID number: 107983	

Monash University HREC Office/Complaints contact person

Name	Executive Officer
Position	Monash University Human Research Ethics Committee (MUHREC) Office of Research Ethics and Integrity Room 116, Administration Building B (3D) 26 Sports Walk, Clayton Campus Monash University VIC 3800
Telephone	+61 3 9905 2052
Email	muhrec@monash.edu

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	Alfred Health
HREC Executive Officer	[Name]
Telephone	+61 3 9076 3619
Email	research@alfred.org.au

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

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

Consent Form - *Adult providing own consent*

Title	Microbial fermentative capacity of individuals with ulcerative colitis with an ileoanal pouch compared to a healthy or UC with intact colons: an in vitro study
Short Title	Fermentation characteristics in UC
Protocol Number	107893
Project Sponsor	Monash University
Coordinating Principal Investigator/ Principal Investigator	Dr Chu Yao (Alfred Health & Monash University)
Associate Investigator(s)	Dr. Zaid Ardalan, Dr Emma Halmos, Prof Peter Gibson (Monash University/Alfred Health)) A/Prof Jonathan Segal (Royal Melbourne/Melbourne University)
Student investigator	Dakota Rhys-Jones (Monash University/Alfred Health)
Location	The Alfred/The School of Translational Medicine – Monash University/Monash Biomedicine Discovery Institute – Monash Clayton

Declaration by Participant

I have read the Participant Information Sheet

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

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 project without affecting my future health care.

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

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Alfred Health or Monash University concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

☐ Extended consent (optional): I consent to have my samples retained for future use after finishing the study.

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	Microbial fermentative capacity of individuals with ulcerative colitis with an ileoanal pouch compared to a healthy or UC with intact colons: an in vitro study
Short Title	Fermentation characteristics in UC
Protocol Number	107893
Project Sponsor	Monash University
Coordinating Principal Investigator/ Principal Investigator	Dr Chu Yao (Alfred Health & Monash University)
Associate Investigator(s)	Dr. Zaid Ardalan, Dr Emma Halmos, Prof Peter Gibson (Monash University/Alfred Health)) A/Prof Jonathan Segal (Royal Melbourne/Melbourne University)
Student investigator	Dakota Rhys-Jones (Monash University/Alfred Health)
Location	The Alfred/The School of Translational Medicine – Monash University/Monash Biomedicine Discovery Institute – Monash Clayton

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 Alfred Health or Monash University.

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.