Participant information and consent form

Project ID: 25358

Project title: Exploring the use of dietary strategies to provide relief from gastrointestinal symptoms associated with endometriosis

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1. Introduction:

You are invited to take part in this research project. This is because you have been diagnosed with endometriosis and are experiencing gut symptoms such as bloating, diarrhoea and/or constipation, and abdominal pain associated with or relieved by going to the toilet, as well as other symptoms associated with endometriosis. This research project is looking at gut symptoms in people with endometriosis and aiming to determine if dietary therapy can be helpful.

This participant information and consent form tells you about the research project. It explains all the tests and treatments involved. This will help you decide if you want to take part in this research.

Please read this information carefully. Ask questions about anything you do not understand or want to know more about. Before deciding whether or not to take part, you may wish to talk about it with a relative, friend, or your local doctor.

2. What is the purpose of this research?

Endometriosis is a relatively common condition that affects more than 700,000 Australians. Many people have symptoms of chronic abdominal pain and bowel symptoms such as bloating, constipation or diarrhoea, and many people with endometriosis are also diagnosed with irritable bowel syndrome (IBS). It is often difficult distinguishing symptoms between the two conditions. Dietary change is effective in improving symptoms in irritable bowel syndrome but there has been very little research done in reducing symptoms in

endometriosis using dietary strategies, although many people report avoiding certain foods to be helpful. We want to find out if there are specific dietary strategies that improve gut symptoms in these people with endometriosis.

It is also thought that the gut and vaginal bacteria (microbiome) may be related to symptoms in endometriosis. Different dietary strategies are thought to have an effect on these bacteria. We want to see if diet alters the microbiome as well as improving your gut symptoms.

3. What does participation in this research involve?

This study tests the effects of two different diets on gut symptoms in people with endometriosis. One diet is assigned for the 1st month, and the other for a 2nd. This study is known as a "blinded" study, where neither you nor the researchers know which diet you are on first. If you participate you will be assigned a code number. At the end of the study we look at all the results then "unblind" all the codes to see if one diet had better results than the other. We will provide you with all your meals over a 2-month period with the 2 different diets that are equal in nutrients, carbohydrates, proteins and fat, so all your dietary needs are met. These meals are prepared by our chefs and dietitians. For 1 month you will receive one diet provided by our team, followed by a break where, for a month, you prepare and eat what you normally would do. After that month you will receive the other diet prepared by our team for a month, meaning it will take 3 months before you have finished the study.

The majority of foods will be provided for you, packaged appropriately and frozen as required at no cost to you. Food will be prepared for you in commercial kitchens at Monash University by the research chefs with strict adherence to food safety. We will give you a list of what snacks and beverages you can consume while on the study provided diets for those occasions you need something more.

As part of the study we need to get some information from you before, during and after the study. These are in the form of a daily food and symptom diary which will take about 10 mins to complete each day, and some questionnaires on 3 occasions. These ask about your symptoms and how they impact on your daily life. We also ask you to collect a small sample of your bowel motion and to take a swab inside your vagina on 3 occasions so we can look for the different types of bacteria that live on your body and to see if either diet has an effect on these bacteria. Detailed instructions on how to collect these will be given to you.

Enrolment visit (1/2 hr)
If you decide to take part in this study you will first go through a screening process with the study doctor at the enrolment visit to determine if you are eligible to take part. Screening questions include things like what abdominal surgery you may have had and when and how endometriosis was diagnosed. During your enrolment visit the study doctor will check your general health and discuss the study in detail so that if you are eligible, you can decide if this is something you would like to participate in. If you are, and would like to take part we will ask you to sign this consent form. This visit will take around half an hour, where we encourage you to ask lots of questions.

You will only have to be physically seen by us once at the Alfred Centre. After that we will visit you, as convenient, on three occasions to collect your symptom data, samples and deliver your food.

First week-(baseline period)
You will be given some questionnaires to take home and complete at the end of a week. These ask about the types of symptoms, the severity of symptoms and how they affect your quality of life and emotional wellbeing. A small freezer and the specimen collection kit with instructions will also be given to you. You will also be asked to complete a daily food and symptom diary, to note every day what you typically eat and what your symptoms are, as indicated on the diary. We ask you to complete this starting 7 days before you would expect to get your period. If you are taking medication that stops you getting your period you can start this 7-day diary any time. The daily diary will take you about 10 mins each day. On day 7, as well as completing the day 7 questionnaires we ask you to collect a faecal and vaginal sample and put in the freezer we provide. The questionnaires will take you about ½ hour to complete. We will visit you to collect the samples, the daily diary and questionnaires. We will assess your diary and questionnaires. If your symptoms are sufficient to meet the requirement of the study you will be assigned to one of our diets and given your first 4 week's food, a daily diary, the questionnaires and another specimen collection kit. If, however you do not meet the criteria, we will thank you for the information you have given us so far, which is very useful, and recommend follow up with your specialist as desired.

First 4 week study period:
During the time that you are on one of our diets we ask you to complete the food and symptom diary daily again. At the end of the 4-week period we ask you collect the stool and vaginal samples and complete the symptom questionnaires again. We will collect all this from you at a time that suits you.

After this you have a 4 week break from the study and do what you normally do, preparing and eating your own food.

Second 4 week study period:
At the end of the 4 week break we will visit and give you another 4 weeks of food, a freezer and another diary and questionnaires to do as you did in the first 4 weeks. We ask you to again collect stool and vaginal samples at the end of this period and put in the freezer provided where these, along with your diary and questionnaires, will be collected by one of our team.

Over the course of the 2 months you are on our diet, you will receive a reminder phone call to complete your daily diaries, and to check with you that there are no questions or problems.

4. Potential risks and benefits:

The topics of conversation at the enrolment visit and in the questionnaires do ask about you and your body that may be embarrassing for some. Please feel you can avoid certain topics if you need to, for instance in one of the questionnaires it asks about problems with sex related to your endometriosis. You have the option to not answer those questions. You may not like

the food we provide. You are welcome to withdraw any time if you wish to. Anticipated risks may include a possible increase in GI symptoms as you may be on a diet that is different to what you normally eat. Should you be troubled by this please contact the study coordinator. We cannot guarantee you will find benefit from the diets, however, possible benefits of the study include the potential to find a dietary strategy that will give you more control over your gut symptoms and improve your quality of life. You may also gain a better understanding of how endometriosis is affecting you and develop more coping strategies.

Although it is very unlikely that an adverse event occurs, if you do experience an adverse reaction to the study diet please stop the diet immediately and contact the study coordinator. She will advise you on what to do. Alternatively you can contact the chief investigator, Assoc Prof Jane Muir. Details for both are at the beginning of this information sheet.

5. How long does the study run for?

Overall the study will run for 3 months and one week.

6. Source of funding

This research project is funded through a National Health and Medical Research Committee (NHMRC) grant

7. Consenting to participate in the project and withdrawing from the research

Participation in this research is voluntary. If you don't wish to take part you don't have to, and your decisions will not affect your routine treatment, your relationship with those treating you or your relationship with Monash University and the Alfred Centre. If you decide you wish to take part, you will be asked to sign the consent section. By signing you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to do the tests and follow dietary recommendations
- 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.

You may withdraw from this project at any stage. Please let the study coordinator know so she can discuss any issues that may arise from your withdrawing, and can answer any questions you may have. If you do withdraw your consent no additional data will be asked of you. However, personal information already collected will be retained to ensure the results of the study are recorded properly and to comply with the law as we need to retain data (medical events, age, medications, medical history etc…) to ensure correct reporting for the trial.

8. Will I be paid to take part?

You will not be paid to take part in this study, however you will receive reimbursement for parking and reasonable expenses. We will be providing you with all your meals for 2 of the 3 months.

9. Privacy and confidentiality

Any information obtained in connection with this research project that can identify you will remain confidential and securely stored. All data pertaining to you will be allocated a study number or code, which can be re-identified if needed at any stage of the study. It will be disclosed only with your permission, or as required by law. All data will be stored in a locked cabinet and/or password protected server (that only the listed investigators have access to) in the Department of Gastroenterology, Monash University. This information is stored for 7 years after publication of the result after which hard copy documents are shredded and digital data deleted.

All biological samples will be immediately stored in a secured -80^{0}C freezer at the Department of Gastroenterology, Monash University. Any tests on these samples will use study codes only. These samples will be destroyed after 7 years as per typical research protocols.

It is anticipated that the results of this research project will be published and/or presented in scientific seminars and conferences. In any publication or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Only combined data from which no individual can ever be identified will be published. You will be advised of the results of the research study when the data have been analysed and prepared for publication. This can take months to years after the project has finished.

10. **Complaints**:

Should you have any concerns or complaints about the conduct of this project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D
26 Sports Walk, Clayton Campus
Research Office
Monash University VIC 3800
Tel: +61 3 9905 2052 Email: muhrec@monash.edu Fax: +61 3 9905 3831

Thank you,

Assoc Professor Jane Muir

CONSENT FORM

Project title:	*Exploring the use of dietary strategies to Provide relief from gastrointestinal symptoms associated with endometriosis*
Project ID	*25358*
Principal Investigator	*Associate Professor Jane Muir*
Study coordinator	*Dr Judith Moore*
Associate Investigators	*Assoc Professor Rebecca Burgell, Dr Jane Varney, Professor Jane Fisher, Professor Mark Morrison, Dr Roni Ratner*

Declaration by Participant

- I have read the Participant Information Sheet and understand it.
- I understand the purposes of the 2 diets, and faecal and vaginal collection procedures described in the project.
- I understand data collected will be used for the purposes of this 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 study.
- I understand that I will be given a signed copy of this document to keep.

I agree to all of the above:

☐ Yes

☐ No

Name of Participant (please print) _____

Signature _____ Date _____

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

Signature _____ Date _____

Declaration by 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 Researcher (please print) _____

Signature _____ Date _____

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