WESTERN SYDNEY
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Participant Information Sheet

Project Title: Exploring Medicinal Cannabis Effects on Endometriosis via Gut Microbiome Modulation

Project Summary:

Researchers A/Prof Mike Armour, Ms Toobah Farooqi, Ms Amelia Mardon, Dr Deep Bhuyan and Dr Mitchell Low from NICM Health Research Institute, Western Sydney University are running a study on the safety and effectiveness of medicinal cannabis on endometriosis. If you are, aged over 18, have diagnosed endometriosis and experience regular menstruation (i.e. a 21-35 day cycle), then you may be eligible to participate. This study will monitor your medicinal cannabis consumption over three months, changes in your endometriosis symptoms (e.g. pelvic pain, fatigue, nausea, gastrointestinal symptoms), any side effects (adverse events) that you may experience such as sleepiness or dry mouth, and any changes in your liver or kidney function.

How is the study being paid for?

This study is funded by Western Sydney University as part of Ms Toobah Farooqi's PhD.

What will I be asked to do?

Recruitment and Informed Consent to Participate in the Study

You will need to complete a pre-screening survey, followed by a call with a member of the research team (15-20 minutes). A member of the research team will explain the study to you. If you choose to participate, you will be sent an email with electronic copy of the Participant Information sheet (this document) and an electronic Informed Consent Form to you for signature.

Screening

During the phone call/Zoom teleconference, a member of the research team will assess you against the inclusion/exclusion criteria. If you meet the criteria and are happy to be part of the study, you will then be directed on the process to complete some questionnaires online (20-30 minutes). You will be sent an email invitation with a link to complete these questionnaires.

You will also be asked to attend a Laverty Pathology (or similar collection centre) to collect some blood. This is to make sure your full blood count, liver and kidney function is within normal range.

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Menstrual blood and faecal sample donation

At baseline (1st menstrual cycle; trial entry; before you begin taking the trial medication), end of treatment (3rd menstrual cycle; approx. 3 months after trial entry) and follow-up (2nd menstrual cycle after end of treatment), you will be asked to donate a sample of menstrual blood and faecal samples. These will be tested for levels of inflammatory markers, your gut microbiome, vaginal microbiota and endocannabinoids. The samples will need to be delivered by you to NICM Health Research Institute in Westmead NSW. Sterile containers will be provided to you via post.

Medicinal Cannabis Products

You will then be randomised (the research team does not have any control over which treatment you get, and you will not know which one you are getting during the study) to one of the three groups – Luna Oil (THC and CBD), Elan Oil (CBD only), or a control oil (no active ingredients). The three treatments look and taste the same. Over the first 10 days, you will be asked to slowly increase your treatment dose, and if you get any side effects your dosage can be reduced if needed.

Throughout the study you will take two doses of oil per day for 3 months – one dose in the morning and one dose at night.

We ask that during the study you withhold from driving or operating heavy machinery due to safety reasons, in line with NSW legislation.

Completing Initial (Baseline) Questionnaires (20-30 minutes)

Once you have been provided your medicinal cannabis products, you will be asked to complete some baseline questionnaires. These are:

- Numerical Rating Scale of pelvic pain severity
- Endometriosis Health Profile (EHP-30)
- EQ-5D Quality of Life (QoL) questionnaire score
- Modified COMM questionnaire
- Nausea rating scale (NRS)
- Fatigue severity scale
- Gastrointestinal symptom rating scale
- Patient Global Impression Change (PGIC) questionnaire

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This will take you around 20-30 minutes. All questionnaires are online and can be completed from your phone, tablet or computer.

Questionnaires and Side Effects Data (10-15 minutes each time)

You will be asked to log your period symptoms and menstrual blood flow for the first three days of your period. At the end of your period, you will be asked to complete some questionnaires at midpoint (during your 2nd menstrual cycle after trial entry). These should take about 10-15 minutes in total. You will receive email and/or text reminders to complete these and all can be completed from your phone, tablet or computer.

You will also be asked to choose any positive or negative side effects associated with the use of medicinal cannabis from a drop-down list. You may type in your own also.

End of Treatment (20-30 minutes)

On the last day of taking medication, you will complete some additional questionnaires:

- Numerical Rating Scale (NRS) of pelvic pain severity
- Endometriosis Health Profile (EHP-30)
- EQ-5D Quality of Life (QoL) questionnaire score
- Side effects (positive and negative)
- Modified COMM (cannabis use disorder questionnaire)
- Nausea rating scale
- Fatigue severity scale
- Gastrointestinal symptom rating scale

At the end of three months, you will need to attend a Laverty Pathology (or sister site) or collection centre for another blood test, for us to check your liver and kidney function is still within the normal range.

How much of my time will I need to give?

This study will take approximately 3-4 hours of your time to fill in all the questionnaires, not including the time for blood tests and delivery of menstrual blood and faecal samples.

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What benefits will I, and/or the broader community, receive for participating?

If you are currently suffering from endometriosis, you may experience an improvement in your endometriosis-related symptoms from taking the study medication, although there is no guarantee this will happen. You will also get a blood test for safety monitoring (i.e. to ensure there is no pre-existing and previously non-identified issues with your liver and kidney functions).

If the study medication is found to be more effective, compared to the control, for an improvement in endometriosis-related symptoms, this has the potential to benefit people with endometriosis.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

There are no additional risks of participating in the study above those risks that are associated with the use of medicinal cannabis. Known side effects of medicinal cannabis, both CBD and THC, include fatigue, sedation, vertigo, nausea, vomiting, fever, decreased or increased appetite, dry mouth and diarrhoea. THC and products containing high amounts of THC have also been associated with convulsions, feeling high, feeling dissatisfied, depression, confusion, hallucinations, paranoid delusions, psychosis, and cognitive distortion (having thoughts that are not true) (for more information please see: https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-australia-participant-information). It is also important that you should not drive or operate heavy machinery due to safety and legal reasons.

We will monitor any side effects you may experience through the questionnaires and any changes in your liver or kidney function via the blood tests. Any side effects you report will be checked by the study's Principal Investigator and medical monitor.

How do you intend to publish or disseminate the results?

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 the participant cannot be identified, except with your permission.

Each participant's name is coded, and the Client Code is what is associated with the study data including the questionnaire results, not the participant's name. The Principal Investigator will have access to the Client Code which is assigned to each participant. De-identified, coded data (including completed questionnaires) is what will be collated and analysed by the statistician and

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electronic copies of the de-identified, coded data will be password-protected and stored on a secure site within Western Sydney University. Electronic copies of informed consent forms will be password protected and stored on a secure site at NICM Health Research Institute, Western Sydney University, separate from completed questionnaires.

Will the data and information that I have provided be disposed of?

Please be assured that only the researchers will have access to the raw data you provide. However, your data may be used in other related projects for an extended period of time.

Can I withdraw from the study?

Note that you may withdraw from the study at any time, participation is voluntary. Withdrawal will in no way impact on your ongoing medical care or relationship with the university.

Can I tell other people about the study?

Yes, you can tell other people about the study by sharing social media posts of the study, the study website and/or providing the study email address to a potential participant.

What if I require further information?

Please contact the research team led by Associate Professor Mike Armour on m.armour@westernsydney.edu.au if you would like to discuss any concerns or for more information.

Privacy Notice

Western Sydney University staff and students conduct research that may require the collection of personal and/or health information from research participants.

The University's Privacy Policy and Privacy Management Plan set out how the University collects, holds, uses and discloses personal or health information. Further details about the use and disclosure of this information can be found on the Privacy at Western Sydney webpage.

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may email the Ethics Committee through Research Services: humanethics@westernsydney.edu.au.

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Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep, and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H16068.

Explanation of Consent

What will happen to my information if I agree to it being used in other projects?

Thank you for considering being a participant in a university research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to Extended consent.

What does this mean?

When you agree to extended consent, it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in projects that are

- an extension of this project
- closely related to this project
- in the same general area of this research.

To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use will not have information in it that makes you identifiable. The re-use of the data will only be allowed after an ethics

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committee has agreed that the new use of the data meets the requirements of ethics review.

The researchers want to keep the data for 15 years for possible re-use. After this time the data will be securely destroyed.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the National Statement on Ethical Conduct in Human Research – see Sections 2.2.14 - 2.2.18.

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

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