WESTERN SYDNEY
UNIVERSITY

Participant Information Sheet

Project Title: Medicinal Cannabis for Primary Dysmenorrhoea Study (CANN-DYS-HELP)

Project Summary:

Researchers from NICM Health Research Institute, Western Sydney University are running a study on the safety and effectiveness of medicinal cannabis products for period pain (dysmenorrhea). If you are, aged over 20, have regular period pain without an underlying cause (such as endometriosis) and your doctor at Natura Clinic thinks medicinal cannabis products are right for you then you may be eligible to participate. This study will monitor your medicinal cannabis consumption over six months and track any self-reported changes in your period symptoms (e.g. pain, bloating, fatigue, volume of menstrual fluid), as well as any side effects (adverse events) that you may experience such as sleepiness or dry mouth, and any changes in your liver or kidney function. If you live in Sydney you will also be invited to provide a small sample of your menstrual blood so we can look for any changes in the markers of inflammation that are related to how severe period pain can be. This is completely voluntary and you can still participate in the study even if you don't want to do this.

How is the study being paid for?

This study is funded by a Research Partnership Grant between WSU and Cannim Pty Ltd.

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 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 then be required

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Locked Bag 1797 Penrith NSW 2751 Australia
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to attend a telehealth appointment with study doctor at a medicinal cannabis clinic, Natura Clinic.

You will also be asked to attend a Laverty Pathology (or sister site) or collection centre to collect some blood. This is to make sure your liver and kidney function is within normal range, and also to measure levels of inflammation before you start treatment.

On a voluntary basis, you will be asked to donate a sample of menstrual blood before commencing medical cannabis, which will be tested for levels of inflammatory markers. The menstrual blood samples will need to be delivered by you to NICM Health Research Institute in Westmead NSW. A sterile menstrual cup will be provided to you if you participate in this.

Medicinal Cannabis Products

Following telehealth consultation, the doctor will assess your suitability for medicinal cannabis and if suitable, will prescribe the appropriate products from the Project Formulary, individualised to you. You may be prescribed one or more products which may include a high THC formulation, a balanced THC/CBD formulation or a low THC/high CBD formulation. The products prescribed to you may be in the form of cannabis flower, a vape cartridge, or an oil. Your doctor will discuss with you the pros and cons of each formulations to make sure you get the treatment that is right for you.

Purchase of Cannabis Products

You will be responsible for the purchase of MC products (these are supplied by the study sponsor at a substantially reduced price). This will be sent to your home or work address directly by the dispensing pharmacy.

The study doctor will in contact with you within a month to ensure that you have been provided the optimal dose and product. You may see the doctor as often as necessary. After the initial consultation, you may see the doctor for ongoing care in relation to the medicinal cannabis for the duration of the study. The cost of the medicinal cannabis consultations for the time that you are part of the study is provided for free by Natura Clinic.

We ask that during the study you withhold from driving or operating heavy machinery due to safety.

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

Once you have purchased your medicinal cannabis products, you will be sent an email invitation

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to fill in the cannabis product(s) details then complete the baseline questionnaires. These are:

- Menstrual Pain Diary (MPD)
- Revised Short Form McGill Pain Questionnaire (SF-MPQ)
- Premenstrual Symptoms Screening Test (PSST)
- Menstrual flow via a pictorial blood loss assessment chart (PBAC)
- EQ-5D Quality of Life (QoL) questionnaire score
- Pharmaceutical use: rescue medication

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

Logging your Medicinal Cannabis Products and Pharmaceutical Medications

Every month you will receive an email asking you to log what medicinal cannabis products you have used that month along with the average daily dosage. This takes about 3-5 minutes each month to complete.

Monthly Questionnaires and Side Effects Data (10-15 minutes per month)

Each month 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 there will be some other questions about how you felt in that previous month. These should take about 10-15 minutes in total each month. 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.

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, and to track levels of inflammation in your blood. If you have agreed to provide us with a sample of your menstrual blood you will need to provide this during the third month as well.

End of Month 6 (20-30 minutes)

In addition to completing your monthly questionnaires, at the end of month 6, you will complete

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some additional questionnaires:

- Menstrual Pain Diary (MPD) (including Numerical Rating Scale (NRS) of pain severity).
- Revised Short Form McGill Pain Questionnaire (SF-MPQ)
- Premenstrual Symptoms Screening Test (PSST)
- Menstrual flow via a pictorial blood loss assessment chart (PBAC)
- EQ-5D Quality of Life (QoL) questionnaire score
- Pharmaceutical use: rescue medication
- Side effects (positive and negative)
- Modified COMM (cannabis use disorder questionnaire)
- Treatment Satisfaction Questionnaire for Medication (TSQM)
- Patient Global Impression of Change (PGIC) questionnaire

You will also need to visit the pathology center for another blood test, same as at the end of the third month.

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 samples.

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

Despite its high prevalence, primary dysmenorrhoea often remains largely unrecognized and untreated. In addition, available treatment options are not always effectiveness. If you want to use medicinal cannabis for your period pain, participating in this study will provide discounted products and free consultation. In addition if medicinal cannabis looks like it might be effective then this study will provide the information needed to run a randomized controlled trial in future.

If you find medicinal cannabis beneficial for your dysmenorrhoea, you may choose to continue using the products at full cost with continued consultation from a doctor. The study team will not be involved in MC treatment after the conclusion of the study.

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

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with the use of medicinal cannabis that have been or will be discussed with your prescribing doctor. 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-patient-information). It is also important that you should not drive or operate heavy machinery if consuming THC-containing medicines due to safety and legal reasons.

You remain under the care of your medical practitioner in relation to your medicinal cannabis. This study simply tracks and measures a range of patient outcomes in a formal sense.

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 Study Coordinator 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 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, however future consultations through Natura

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Clinic would not be free outside of the study.

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 canndyshelp@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.

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 H*[enter approval number once the project has been approved]*.

Explanation of Consent

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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 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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