WESTERN SYDNEY
UNIVERSITY

Participant Information Sheet – General (Extended)

Project Title: Development of a clinical trial on medicinal cannabis for primary dysmenorrhoea: Co-Design

Project Summary:

You are invited to participate in a research study being conducted by Dr Mike Armour and Mr Justin Sinclair from NICM Health Research Institute at Western Sydney University. The research involves focus groups of women who experience significant period pain, discussing what period symptoms are most bothersome, what role medicinal cannabis might play in the management of their symptoms, and any barriers or concerns about its use for period pain. Period pain can be caused by primary dysmenorrhea, where there is no structural cause but is caused by changes in hormones called prostaglandins, and by secondary dysmenorrhea where there is a structural cause, such as endometriosis or adenomyosis. This study is looking at period pain caused by primary dysmenorrhea.

How is the study being paid for?

This project is funded through a grant from Spectrum Cannabis.

What will I be asked to do?

You will be asked to participate in a focus group conducted online through free video conferencing software (Zoom) with 5-6 other women. If you reside in Australia, are over 18 and experience moderate to severe period pain, and do not have a diagnosis for your period pain (such as endometriosis or adenomyosis) you are eligible to be part of these focus groups. You do not need to be a current or past user of cannabis to participate. The aim of the focus groups is to ensure that our upcoming clinical trial(s) are designed so that the types of interventions we are looking at are relevant and that the outcomes we measure are those that are important to women with period pain. Discussion on the day can vary depending on the group but will cover topics like what are women's current self-management strategies for period pain, any potential barriers or concerns regarding medicinal cannabis usage, what outcomes should we be tracking and how we can make participation in research easiest for you. The facilitator will ensure you have a chance to give your opinion on each topic raised

during the discussion, however, you do not need to participate on every question if you do not wish. We will also collect some demographic information from you like your age, ethnicity, as well as ask you to complete two questionnaires; a quality of life questionnaire (known as the EQ5D) and a questionnaire about cannabis prior to attending the focus group.

How much of my time will I need to give?

The focus groups will take about 60-70 minutes but may go slightly over or under this time depending on the conversation. The anonymous online questionnaire that you will need to fill in prior to the focus groups will take between 5 and 10 minutes.

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

Our goal is to co-design a clinical study to test the effectiveness of medicinal cannabis for the treatment of period pain caused by primary dysmenorrhea. As you are someone who is affected by moderate or severe period pain, your experiences and views will contribute to the design of this future clinical study. It will shape what kind of medicinal cannabis interventions we might investigate, what concerns or barriers to its use would be and what outcomes are important to you, that will later be assessed in the study. This is very important as we want to make sure that it's not just us, the researchers, who decide how the research is done, but that women have a voice and help shape what we do. This will improve how the study can be translated for clinical practice with the ultimate goal to help benefit women affected by primary dysmenorrhoea (period pain). In participating in the focus group, you may benefit from the chance to interact and share common experiences with other women with period pain. You will also be reimbursed for your time, in the form of a $20 fuel/grocery voucher.

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

We do not foresee any risk to you from participating in this study, and all your answers to any cannabis related questions will be completely anonymous. Based on our previous focus group work with this population, there may be some distress while discussing your experience with period pain due to its often significant negative impact on women's lives. We also recognise that some people feel uncomfortable when talking about matters relating to menstruation. Our facilitators are experienced in conducting focus groups on health issues and will ensure that you feel safe and respected during the discussion. During the focus group itself you will be able to take a break and leave the virtual "room" if you find the topic distressing. Should you find discussion about any of the topics in the focus group distressing and would like to speak

with a professional, there is a list of counselling services on: https://www.australiacounselling.com.au.

We recognise that discussion surrounding cannabis usage, which is currently illegal in Australia for those without medicinal access, may make you feel unsafe to share during the session. However, no identifiable information is collected during the focus group as participants are only asked to share their audio, i.e. not video, you can select a completely random User ID when joining the virtual session (to maintain your anonymity), you are also not obligated to share or disclose previous cannabis usage and the resulting audio transcript will be de-identified and kept strictly confidential. Additionally, only the investigator and the participant who consented to be involved in the focus group will have access to the password required to join the session for an added layer of security and due to the de-identified nature of the transcript, any illegal activity you disclose cannot be linked back to you. We also do not collect any identifiable information from the demographic questionnaire nor the quality of life survey, namely the EQ5D.

How do you intend to publish or disseminate the results?

The results of the focus groups are going to be used to develop a clinical trial protocol for an upcoming trial on medical cannabis for primary dysmenorrhoea (period pain). We will publish the trial protocol in journals and may present it at academic conferences. Any publication will not have any information in it that could identify you.

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

We will use your personal history and the focus group transcripts for the purposes of this research but 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. Such projects may include the development of other clinical trials. Please note that minimum retention period for data collection is five years post publication but data may be kept for up to 15 years to allow other researchers access to this data.

Can I withdraw from the study?

Participation is entirely voluntary and you are not obliged to be involved. If you do participate you can withdraw at any time without giving reason. Due to the conversational nature of focus groups, your responses (up until the time of withdrawal) cannot be removed as it may remove

important context from other participants' responses. Whatever your decision, it will not affect your medical treatment or your relationship to anyone involved in this study.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them with Mr Justin Sinclair's details. They can then contact Justin Sinclair to discuss their participation in the research project and obtain a copy of the information sheet.

What if I require further information?

Please contact Mr Justin Sinclair should you wish to discuss the research further before deciding whether or not to participate.

Justin Sinclair, Research Fellow, email j.sinclair@westernsydney.edu.au

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email 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 H13538