PARTICIPANT INFORMATION SHEET

"CANNABIDIOL (CBD) TAMPONS FOR SELF-MANAGEMENT OF PERIOD PAIN IN WOMEN WITH CHRONIC PELVIC PAIN: A PROSPECTIVE VOLUNTEER STUDY"

You are being invited to try CBD tampons during your period and complete questionnaires on whether you found CBD tampons acceptable and if you felt they helped your pelvic pain.

Before you decide if you would like to take part, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask any member of the research team if there is anything that is not clear or if you would like more information.

We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to. Thank you for taking the time to read this information sheet.

Why are we doing the study?

Chronic pelvic pain (CPP) is pain felt in the lower tummy that lasts for three months or more. This pain can be constant, or it may come and go. It is very common, affecting over 1 million women in the UK. The cause of CPP is often unknown but may be due to gynaecological conditions, such as endometriosis (where tissue similar to the lining of the womb is found outside the womb), or non-gynaecological conditions, such as irritable bowel syndrome.

Living with CPP can have a negative impact on women emotionally, socially, and financially, affecting their day-to-day life. Current treatment options are painkillers, hormonal treatments, and surgery. During periods the pelvic pain can worsen and become more difficult to manage. Many women try other therapies such as heat, acupuncture, dietary changes, and cannabis-based products to help with their pain. We need more treatments that women can use to manage their CPP. This study will explore if cannabidiol (CBD) tampons are a suitable and practical option for women with CPP that worsens during their periods.

What is CBD?

CBD comes from the cannabis plant but does not cause the sensation of feeling high. In the UK, CBD products are widely available as gummies, drinks, and even tampons. Some surveys suggest that women with CPP find CBD products helpful for pain relief, with few side effects.

Why have I been chosen and do I have to take part?

You're invited as a healthy volunteer but joining the study is completely your choice, and there is no pressure or obligation to take part.

What will happen if I take part?

You will be asked to fill out a consent form and a health questionnaire to check if you're eligible for the study. It is important for the study you are not using any other CBD based products at the same time. You will then be provided with **Daye® CBD tampons** to use during the daytime over two days

of your menstrual period. You can use the CBD tampons as needed and change them whenever you like.
You'll be asked to record your pain levels at these times:

1. Before using the tampons
2. While using the tampons
3. After removing the tampons

At the end, you'll fill out a short questionnaire to share your thoughts on using the CBD tampons.

What are the possible benefits of taking part?
We don't expect you to get any direct benefits from this study, but your participation will help improve our understanding and contribute to research on treatments for CPP.

What are the possible disadvantages of taking part?
The CBD tampons, supplied by Daye and available in the UK, are safe to use and come in regular and super absorbencies. While serious side effects are rare, if you do experience any, we advise stop using the tampons, seek medical advice, and let the research team know.

How will my data be used?
The University will handle your personal data as part of its research in line with its goal of supporting education, learning, and research for the public good.

Under UK data protection law, the University is responsible for your personal data collected during the research. Dr. Nicola Tempest, the main investigator, will manage the data for this study. If you have any queries about how your data is handled, you can contact Dr. Tempest Nicola.tempest@liverpool.ac.uk.

Further information on how your data will be used can be found in the table below:

How will my data be collected?	Through questionnaires, including your name, contact details, and information about your treatments and general health.
How will my data be stored?	In a password protected University server Drive.
How long will my data be stored for?	Maximum 10 years.
What measures are in place to protect the security and confidentiality of my data?	Your data will be stored on a secure, password-protected server, and only the researchers will have access to it.
Will my data be anonymised?	Your name and contact details will be kept private. Instead, a code will be used to protect your identity. Only the researchers will have access to this code to link the data back to you.
How will my data be used?	Your data may be used in student projects, journal articles, websites, and conferences, but it will always be anonymous..
Who will have access to my data?	Only the researchers relevant to the study.
Will my data be archived for use in other research projects in the future?	Yes.
How will my data be destroyed?	After 10 years, we will delete your data from the server and shred any paper records.

What will happen to the results of the study?
The results will be shared on request and may be published in journals or presented at conferences. Your data will be anonymised, so it won't be identifiable.

What will happen if I want to stop taking part?
You can stop at any time before the study results are anonymised and analysed, and you don't need to give a reason. If you want, your data up to that point can still be used, or you can ask for it to be deleted. Just let the researchers know if you want to withdraw.

What if I am unhappy or there is a problem?
If you're unhappy or there's an issue, let us know by contacting Aisha Anwar (Aisha.anwar@liverpool.ac.uk) and we'll help. If you're still not satisfied, you can contact the Research Ethics and Integrity Office at research@liverpool.ac.uk with the study details and your complaint.

The University works hard to ensure your data is handled properly. However, if you have concerns about how your personal data is processed, you have the right to file a complaint with the Information Commissioner's Office by calling 0303 123 1113.

Who is organising and funding the research?
The University of Liverpool is the sponsor of this research and is conducting the research.

Who has reviewed the study?
The study has been reviewed by University of Liverpool members for scientific and ethical approval.

Who can I contact if I have further questions on the study or about how my information is used?
You should contact Aisha Anwar, Aisha.anwar@liverpool.ac.uk.

Thank you for taking the time to read and consider this information sheet.