

PARTICIPANT INFORMATION SHEET

Menstrual Cramps Ibuprofen Therapy Study



BACKGROUND AND STUDY AIMS

Dr. Jerilynn Prior and the UBC Centre for Menstrual Cycle and Ovulation Research (CeMCOR, www.cemcor.ubc.ca) are inviting teen and young adult women+ (of all genders) with problematic menstrual cramps to participate in a study comparing two ways of taking ibuprofen (brand names Advil®, Motrin® etc.) for menstrual cramps to see if we can decrease menstrual pain.

Ibuprofen is the standard cramp treatment because it prevents formation of prostaglandins (the funny fatty acid hormones) that cause the contractions of the uterus we call “cramps”. Ibuprofen is taken as two (200 mg tablets) at the first hint of cramps. After that it is officially taken every 4-6 hours. However, some find this ineffective. We will see if a different way of taking ibuprofen is better at treating cramps.

Ibuprofen is available on pharmacy shelves so is quite safe for young people. Its most common side effect is heartburn which can be prevented if it is always taken with food.

PURPOSE OF THE STUDY

Our goal is to see if a different way of taking ibuprofen will be more effective for the pain of menstrual cramps than the standard way of taking it.



WHO CAN BE PART OF THIS STUDY?

- We invite teen and young adult women+ aged 16-25 years who have regular about a month-apart periods and who live in Metro Vancouver.
- You need to have problematic cramps that negatively impact your daily life.
- Participants who are sexually active with a man/men need to use non-hormonal contraception, such as condoms, a diaphragm with spermicide, or a copper IUD.

You are not able to participate if:

- you are taking the Pill (combined hormonal contraceptives) or using a hormone-releasing IUD.
- you have had a past unwanted or harmful reaction to ibuprofen, you also are not eligible.



WHAT DOES THE STUDY INVOLVE?

This study invites participants from Metro Vancouver to participate in a two-week randomized trial and two visits that will compare two ways of taking ibuprofen for menstrual cramps. To take part in this study, you need to let us know by calling **604-875-5960** or emailing us at cycles.cemcor@ubc.ca.



You will be contacted and a researcher will see if you are eligible by a short telephone call. Eligible participants will complete a baseline questionnaire via video call.



You will then come for a brief visit in which we will take your height and weight and give you your bottle of 90 ibuprofen tablets, going over with you when and how to take them.

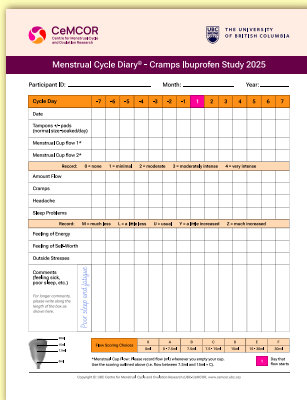


We will then give you two research forms. We'll teach you how to track your cramps in a Daily Diary© and to record what time you take ibuprofen and to note any side effects.

You will record the Daily Diary© for two weeks and the ibuprofen you take for the days you have cramps. We will give you 90 tablets of ibuprofen (provided by Pure Integrative Pharmacies), enough for at least six cycles. You will start recording on the Daily Diary© about a week before you guess your period will start. Whenever cramps start, you will start taking ibuprofen following the instructions on your ibuprofen bottle. After a week of recording in your new cycle (starting with Day 1, the first day of flow), you will return for a second visit...

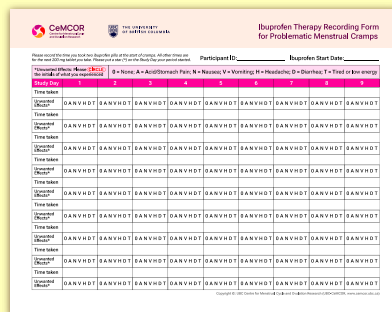
...Please bring 3 things to that visit:

1

A detailed form titled "Menstrual Cycle Diary® - Cramps Ibuprofen Study 2025". It includes fields for Participant ID, Month, and Year. The form is divided into sections for "Daily Diary" (tracking symptoms like cramps, pain, and energy) and "Menstrual Cycle Diary" (tracking cycle details like start date, duration, and flow). It also includes a section for "Other Symptoms" and a legend for symptom coding.

Your completed Diary (that we will copy and return to you).

2

A form titled "Ibuprofen Therapy Recording Form for Problematic Menstrual Cramps". It includes fields for Participant ID and Ibuprofen Start Date. The form is a grid with columns for days 1 through 8 and rows for "Time taken" and "Pain level". A legend at the bottom explains the coding for pain levels (0-3) and time taken (D, A, N, V, H, O, T).

Your completed Ibuprofen Recording form.

3



Your ibuprofen bottle — we just need to count the remaining pills and will then return all of them to you.

Please Note: We will only be able to include your results if you complete the FINAL QUESTIONNAIRE (online or print version). It takes only 2-3 minutes.

If you would like, we want to say thank you by giving you a free menstrual cup (value \$40-50.00) donated to CeMCOR by DivaCup®. We will also show you how to use it.



WHEN IS THE STUDY STARTING AND HOW LONG IS IT?

- **In April 2025.** You will participate for 2-weeks, although we need you to come visit us twice.
- The Centre for Menstrual Cycle and Ovulation Research website (www.cemcor.ubc.ca) will let you know when we are done recruiting for this investigation, but possibly not before the end of 2025.
- We will send you an email telling you that you can access the study results as soon as they are available (since it takes time to clean and analyze the information).

BENEFITS OF PARTICIPATING IN THIS STUDY

By keeping the Daily Diary® and tracking your cramps you may learn a bit about your own body, and how you respond to ibuprofen. We are providing you with free ibuprofen for at least half a year. And we are offering a free menstrual cup and support in using it. Together we are learning something that may help all those with menstrual cramps.

POTENTIAL HARMS AND DISCOMFORTS

This study has been carefully reviewed and approved by UBC Clinical Research Ethics Board. We don't expect anyone will have intense, unwanted ibuprofen effects. However, we are carefully tracking side-effects which will increase knowledge for the future.



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STUDY FUNDING

This study is not funded by any agency or sponsor. Medical students at UBC are providing their time, skills and energy to create this study and to be its research assistants. Any other costs for this research (the person who will randomize you, and analyze results, those making ads, coordinating visits, and making sure you learn your own results) are supported by individual donations to CeMCOR. Ibuprofen is donated by Pure Integrative Pharmacy, creating the labelled bottles and counting out 90 pills and couriering these bottles to us.

STUDY INVESTIGATORS

Jerilynn C. Prior MD—Endocrinology Professor and CeMCOR's Scientific Director

Sonia Shirin MD—CeMCOR Research Associate; randomization and statistics

Dharani Kalidasan MSc—Basic Scientist and Coordinator

Marshall Dahl MD—Endocrinologist; Head-UBC Division of Endocrinology – prescriptions

Azita Goshtasebi MD—Women's health expert; Canadian Family Physician; CeMCOR Scientific Advisory Committee Member

Medical Student Researchers:

Johnny Yip—Pharmacist and fourth year student, nearly ready to graduate

Kate Fitzsimmons—Fourth year student also almost graduating

Maya Geerts—Second year student

Sijia (Scarlett) Qiao—Pharmacist and second year student

Gurleen Mann – Third year student

STUDY CONTACT INFORMATION



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Your participation is voluntary and you may withdraw from the study at any time. Your information is confidential.