



You and your parent are invited to participate in our study entitled:

Early Menstrual Pain Experiences (EMPE) Study

This research is being conducted by:

Michelle Gagnon, Ph.D., R.D. Psych
Associate Professor
Department of Psychology and Health Studies
University of Saskatchewan
Saskatoon, SK,
(306)966-2052

Jennifer Gordon, Ph.D., R. D. Psych
Associate Professor
Department of Psychology
University of Regina
Regina, SK

Krista Baerg, MD, FRCPC
Associate Professor, Pediatrics
University of Saskatchewan
Saskatoon, SK

Marta Erlandson, Ph.D.
Associate Professor
College of Kinesiology
University of Saskatchewan
Saskatoon, SK

The information below is a review of what we talked about in the zoom call with you and your parent.

In this form, we are asking your permission to be involved in two parts of our study:

1. Complete the online questionnaires. Your parent will also be completing an online survey about their perceptions of your experiences.
2. Be contacted twice per month with a reminder to complete a daily diary during your period.

Your participation in this study is not related to your schoolwork or medical treatment and is **completely optional**.

Purpose(s) and Objective(s) of the Research:

- The purpose of this investigation is to better understand what causes menstrual pain in youth and how menstrual pain affects the lives of youth.

Grant Funding

- This study is funded by a grant awarded by Dr. Gagnon from the Canadian Institutes of Health Research.

Procedures:

- It will take up to 45-60 minutes to complete the following online questionnaire.
- You will be given a participant ID that you will be asked to enter in each survey to ensure your responses are private. Your name will not be linked with your survey answers. Your parent will also complete a survey about their perceptions of your experience.
- After you complete the questionnaires, we will send you a reminder email twice per month to remind you to complete daily diaries for at least your next two menstrual periods following the online questionnaire. These diaries should take about 3 minutes each. The study will end two menstrual periods after your final survey time point, and we will send email reminders for two months after completing that final time point.



Potential Risks:

- There are no anticipated risks to completing these questionnaires.

Potential Benefits:

- Your participation will help us understand how menstrual pain changes across early pre-adolescence and adolescence.
- Your participation will also help us understand if there is a relationship between menstrual pain and other pain conditions.
- Your answers may help us develop better treatments for youth who live with menstrual pain.

Compensation:

- You and your parent will each receive a \$25 Amazon gift card for completing the first set of questionnaires.
- For the daily diaries, you will be entered into a draw for a \$50 Amazon gift card, receiving one entry for each daily diary completed for up to four entries per month. Our research team will do a draw every month.
- If you complete more questionnaires down the road, you will be compensated each time you complete questionnaires over the 3 year period. As discussed in our Zoom call, we break this compensation down for you when you complete the consent for this next phase.

Confidentiality:

- Any answers you provide will be kept private. This means that we will not share it with anybody. Answers will not be shared with your teachers, your friends, or anybody outside of the Family Health Lab team.
- We will only use your answers to help us with our research at the University of Saskatchewan.
- We will use your answers and combine them with the answers provided by other youth to present at research conferences and in research articles. By combining your answers with other youth, people who are learning about the research will not be able to identify you as an individual who participated in the study. This helps protect your privacy. Any responses that cannot be aggregated, such as a direct quote from a participant, will not be associated with any information that could identify that participant.
- We will have a list with the names and participant IDs of all the participants in this study. This list, however, will be securely saved and password protected and only seen by researchers and research assistants of the study.
- Some journals require researchers to share a version of the data where the identifying information is removed. This would be shared in a digital library to follow the journal's rules. If this happens, the data will be anonymized; that means that it will be shared in such a way that no one can know who the participants in the data are. This also means that people in and outside Canada can see the anonymized data in the journal's digital library and use it for their own research.
- We ask you to keep in mind that email is not always the safest way to send information. If you contact us by email, we encourage you to not put too much information in the email that you would not want others to find out.

Storage of Data:

- Only the researchers and research assistants will have access to the data.



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- Electronic data will be kept in password protected databases and on password protected computers.
- Assent will be obtained at the beginning of Phase 1 and Phase 3 over Zoom as well as online before surveys. For subsequent Phase 3 surveys, participants will have the choice of reviewing the assent form independently and providing their assent either through an online survey via SurveyMonkey or over Zoom with the assistance of a Research Assistant. We will keep note in our records of whether you gave your assent.
- We will use two online survey platforms to gather data from you.
 - The longer 45-60 minute survey will be completed using REDCap. All data you enter will be stored on servers hosted by the University of Saskatchewan. You can read more about REDCap and privacy here:
 - <https://projectredcap.org/software/mobile-app/privacypolicy/#:~:text=In%20order%20to%20use%20the,must%20be%20at%20version%206.5.&text=A%20REDCap%20project%20that%20needs,collected%20with%20sporadic%20Internet%20access>.
 - The daily diary of your period will be completed using SurveyMonkey. Data entered into SurveyMonkey will be collected, retained, and hosted on a third-party server and not on a University of Saskatchewan server. Your data will be stored in facilities hosted in Canada. Your email address, first name, and participant identification number will be stored in the SurveyMonkey platform. Your information is subject to SurveyMonkey's Privacy Policy. You can read more about SurveyMonkey's Privacy policy here:
 - https://www.surveymonkey.com/mp/legal/privacy/?ut_source=egal&ut_source2=privacy-basics&ut_source3=inline
- Data will be stored for no less than 7 years following publication.
- After this period, all data will be shredded and securely deleted.

Right to Withdraw:

- Your participation in this research study is voluntary. That means that you do not have to participate if you do not want to.
- Even if you start, you can change your mind and choose to stop at any time without giving a reason why.
- If you choose to stop, no one will be upset or angry. There are no consequences to stopping.
- If you chose to withdraw, please exit the survey. We will follow-up with you and your parent to confirm that you want us to remove your information.
- Even if you complete the survey, you can choose to withdraw your answers later. You have until December 2025 to let us know that you do not want your answers used in our research. After this date, it is possible that we may have already used your responses to share our research findings. If you stop participating, but do not let us know whether you would like your previous answers removed, we will keep your answers in our study.

Follow up:

- The goal is to have results from this study available on an ongoing basis as we get more and more information, but starting after April 2023.
- To obtain results from the study, please feel free to contact the Family Health Laboratory at any time at:

Phone: (306) 966-2052; Email: michelle.gagnon@usask.ca

Questions or Concerns:

- If you have any questions or concerns, you can contact the primary researcher, Michelle Gagnon, the following ways:
 - Phone: 306-966-2052
 - Email: michelle.gagnon@usask.ca



- This research project has been approved on ethical grounds by the University of Saskatchewan Research Ethics Board (BEH 2777). Any questions regarding your rights as a participant may be addressed to that committee through the Research Ethics Office ethics.office@usask.ca (306) 966-2975. Out of town participants may call toll free (888) 966-2975.

Assent

- Do you understand what we went through in the form just now?
 - ☐ Yes
 - ☐ No
- Do you understand what you will be doing as a participant in the study?
 - ☐ Yes
 - ☐ No
- Do you understand that your participation is completely voluntary, and you do not have to participate if you don't want to?
 - ☐ Yes
 - ☐ No
- Do you provide your free and informed assent to participate in this study?
 - ☐ Yes
 - ☐ No
- We may contact you for the following reasons throughout this study. Please indicate if we may:
 - Contact you by email to remind you of upcoming questionnaires
 - ☐ Yes
 - ☐ No
 - Contact you by email if you have missed a questionnaire
 - ☐ Yes
 - ☐ No
 - Contact you by email to thank you for completing questionnaire
 - ☐ Yes
 - ☐ No
 - Include an anonymized version of the data in an online repository
 - ☐ Yes
 - ☐ No