Information sheet for the Menstrual Pain Intervention Among Students (MPIS) Study

Dear potential study participants,

we invite you to participate in a scientific study exploring well-being in female students, with a focus on evaluating the impact of a simple intervention on menstrual pain. All data will be collected exclusively and entirely anonymously.

Please read this information carefully and then decide if you wish to take part in the study. Your participation is voluntary, and you may withdraw from the study at any time without providing a reason, without any disadvantage to you.

Purpose of the Study

Dysmenorrhea, or painful menstruation, is common among young women, causing cramps, nausea, and fatigue, which impact daily life and productivity. Standard treatments include hormonal contraceptives and non-steroidal anti-inflammatory drugs (NSAIDs), like ibuprofen and naproxen, which help reduce pain by lowering inflammation. While effective, they can often cause several side effects. Physical therapies, like abdominal massage, are promising alternatives with minimal risks. The goal of this study is to explore whether abdominal self-massage can reduce menstrual pain and related symptoms, offering a simple, cost-effective method for managing menstrual discomfort. Additionally, further analysis of the data aims to identify factors that contribute to successful outcomes, including those that may help improve the reliability of N-of-1 trials, allowing for personalized treatment evaluations. This study does not involve the evaluation of a medical device but investigates an existing manual intervention.

Procedure and Duration of Participation

Study Design and Duration

Data for this study will be collected exclusively in an anonymous, electronic format. Menstrual pain and related symptoms vary significantly between individuals, as does the effectiveness of interventions to alleviate them. Therefore, rather than comparing groups, we focus primarily on assessing the intervention's effect within each participant. This design involves alternating phases: in the intervention phase, participants perform the intervention daily, while in the control phase, no intervention is carried out. During both phases, participants will report their daily symptoms regarding menstrual pain, which will then be analyzed quantitatively and qualitatively. In addition to statistical evaluation, we will examine participants' written responses to identify patterns of their symptoms' descriptions. After evaluating individual results, we can also estimate effects at the population level. This study design, known as an "N-of-1 trial," also allows us to provide each participant with a personalized statistical report on the effectiveness of the intervention after the study concludes.

The interventions and daily symptom reporting will be managed through the StudyU app (https://www.studyu.health/), specifically designed for this type of research and freely available on both the App Store and Google Play Store. To enhance understanding and analysis of N-of-1 trial outcomes, a comprehensive baseline questionnaire (approximate completion time:

15 minutes) will be conducted via the UP Survey online tool (https://survey.uni-potsdam.de/) before starting the trial.
Thus, in the beginning, following demographic and menstrual health-related information is gathered through the baseline questionnaire once:

- Age group (18-25, 26-32, 33-39, 40-45 years)
- Work status (yes/no)
- Weight and height
- General health status on a 5-point scale
- Typical frequency and duration of vigorous, moderate, and low-intensity activities both outside of and during menstruation
- Frequency of alcohol consumption
- Smoking status (yes/no/rarely)
- Massage history and expectations
- Age at menarche
- Onset of menstrual cramps
- Cycle duration and regularity
- Typical level of menstrual pain on a scale
- Parity
- Any previous suspected or confirmed diagnoses of endometriosis or adenomyosis

To capture enough data for statistical analysis, each participant should complete at least two menstrual cycles, covering one baseline/control phase, one intervention phase and possibly another control phase. Phase lengths are flexible to accommodate individual, potentially irregular cycles, and the total study period spans 60 days (approximately two months).

During both control and intervention phases, we ask if you are currently menstruating to ensure correct phase assignment and whether you are experiencing menstrual pain (estimated time consumption to respond under 30 seconds). If you answer no, you can skip the remaining questions. If symptoms are present, participants will answer five additional questions, taking approximately 5 minutes. They will be asked to rate their menstrual pain severity on a scale and indicate whether they took any medication for symptom relief, including details about the type of medication and dosage. Additionally, participants are asked to indicate if they experienced any of the following symptoms:

- Cramps
- Lower back pain
- Nausea, vomiting, or diarrhea
- Painful urination
- Painful bowel defecation
- Bloated belly
- Painful intercourse
- Fatigue or brain fog
- Fainting
- Headaches

Participants are also asked to rate how their symptoms affected their mood. Lastly, they have the option to provide a free-text response in a diary-like format to describe their symptoms in their own words, including any details about their physical and emotional well-being, but no identifying information about themselves or others (in particular, no names).
In the intervention phase (one cycle in total), participants are asked to perform the intervention daily for a minimum of 5 and up to 20 minutes. The intervention consists of a gentle abdominal

self-massage with circular motions. The app provides access to a video file with instructions for proper technique.

Participation is voluntary, and you may withdraw from the questionnaire or the study at any time without providing a reason or facing any negative consequences.

Study Procedure

We begin by ensuring that participants have read and understood the study information, given their consent to participate . Next, they go through a screening survey to ensure they meet the eligibility criteria. If so, they receive access to the baseline questionnaire (UP Survey). In this baseline questionnaire you will also find the link to a contact form, which you can use at any time during the study to request correction or deletion of your data. Once they complete the baseline questionnaire, participants are given instructions for downloading and installing the StudyU app. Finally, you receive a unique access code, which you will need to activate the study within the app. This access code links your baseline questionnaire data to the data you enter in the StudyU app. This code will not be associated with identifiable information, such as an email or IP address.

Within the StudyU app, you are asked to confirm your consent once again. Through the StudyU app, participants can access the intervention as a video file and receive regular push notifications reminding them to complete the intervention and record their symptoms. At the end of the N-of-1 trial, participants receive a personalized statistical analysis of their data, delivered directly within the StudyU app. Please note that this analysis can only be generated if enough data points have been recorded.

Requirements for Participation in the Study

Participation in the study is only possible if the following inclusion and exclusion criteria are fulfilled:

Inclusion Criteria

- Female students living in Germany
- Have consistently experienced menstrual pain and other symptoms primarily during menstruation for at least the last three cycles
- Regular access to a smartphone on which the StudyU application (https://www.studyu.health/) can be installed
- Informed consent
- Proficient in English

Exclusion and Termination Criteria

- Age under 18 or over 45 years
- Participation in another intervention study during this study's period
- Use of hormonal treatments affecting the menstrual cycle
- Confirmed or suspected pregnancy
- Presence of contra indicative disorders or diseases for massage (e.g., cancer)
- Severe psychiatric conditions impairing informed consent or reliable participation
- Substance abuse (e.g., alcohol, drugs)
- Recent abdominal surgery, where massage may disrupt healing

- Planned surgery within the next 4–5 months
- Doctor's recommendation or self-assessment not to perform the intervention

Possible Risks

Based on currently available research, this self-administered, short and low-intensity intervention for menstrual pain is generally considered safe, well-tolerated, and free of side effects. The intervention should be performed for one cycle only. Similar techniques are freely available online. The tutorial video used in this study is recorded by a licensed physiotherapist specialized in this field. Therefore, the risk of negative effects is generally considered to be very low. There is a slight chance that the massage may cause physical discomfort, or that increased awareness of symptoms could lead to negative thoughts. In certain situations, strong abdominal massage, deep pressure on the uterus, or unsafe massage techniques may increase the risk of miscarriage, especially in early pregnancy or in high-risk pregnancies. To minimize the risks, clear video instructions are provided for proper technique. A study physician is available and can be contacted at any time for questions and in case of doubts. Participants can withdraw anytime. We have defined specific exclusion criteria to ensure participant safety, similar to other studies in this field. If you suspect you may be pregnant or should not carry out the massage for other reasons, please consult a medical professional or the study physician (philipp.stoffers@hpi.de). Having endometriosis, however, does not generally exclude participation, since this technique can be a viable option for reducing menstrual pain even in those with pre-existing conditions. In all cases, the study physician as well as the principal investigators are available for any concerns or questions. We encourage reporting of any adverse reactions.Possible Benefit for the Study Participants or for the Public

If effective, abdominal self-massage could offer an accessible, simple and non-invasive method to relieve menstrual pain as other research suggests. Furthermore, all participants who have provided a sufficient number of data points will receive an automatic, direct statistical evaluation of their individual study data within the StudyU app. This feedback can enhance their sense of self-efficacy and motivate them to incorporate the intervention into their daily lives over the long term. Participants are also introduced to N-of-1 trials and gain familiarity with the StudyU app as a tool you can continue to use independently and to participate in its further studies.

Information on the Processing of Your Personal Data

Through the contact form (see description on previous page), you can request the correction and deletion of your personal data at any time. Throughout the study, your data can never be linked with any identifying information While we ask for general demographic information, such as age groups, in the baseline questionnaire, these categories are broad and do not allow for the identification of individual participants. The data collected will be used solely for research purposes and analyzed in an anonymized manner.

App

Some data will be collected using the StudyU application, which will be installed on participants' personal smartphones. The app is provided by the Hasso Plattner Institute,

Potsdam, Germany. Its default settings ensure that no data is accessed beyond what is necessary for the study. We ask you to review your device's settings to ensure the app does not access unnecessary data and that other apps cannot access it. Please also ensure your smartphone is properly secured against unauthorized access. Only the study team and authorized personnel at the Hasso Plattner Institute will have access to the app data, ensuring that it is handled securely and in accordance with data protection regulations.

Voluntary Participation

Your participation is voluntary, and you can only participate if you consent. If you choose not to participate, there will be no disadvantages. If you decide to withdraw from the study, the study team will not be able to identify you, as all data is collected anonymously. You may still receive email updates unless you specifically object to the processing and storage of your email address by contacting the study team.

Legal Basis for Data Processing

All data described above will be collected and stored anonymously. Participation in the study is voluntary, and non-participation will not result in any negative consequences. No personal identification will be possible unless you voluntarily provide certain information. Despite strict adherence to the principle of data minimization, a risk of re-identification of a person cannot be completely ruled out, even from anonymous data. In order to further minimize this risk, data should be entered in this study in such a way that it is not possible to draw conclusions about your person. This applies in particular to information input in the form of free text.

Technical and Organizational Measures

Throughout the study, your data can never be linked with any personal identifying information. The data collected will remain anonymous unless you provide specific identifiers. Data from the baseline questionnaire collected over UP Survey will be securely stored on a server of the University of Potsdam, Potsdam, Germany. Data from the StudyU application is securely stored on a backend managed by the Hasso-Plattner-Institute. Only the study team and authorized personnel will have access to your data until the study ends. Afterward, the data will be stored anonymously and published in whole or in part at the earliest possible date. The declaration of consent is stored in electronic form and password-protected on a server of Hasso-Plattner-Institute.

Recipients of Your Data, Right to Access, and Linkage

In order to review the study process or results, it may be necessary for supervisory authorities or appointed monitors/auditors to access the data. However, the data will remain anonymous, and no identification of individuals will be possible.

Responsibility

The principal investigator (Valeria Tisch, Hasso-Plattner-Institute) is responsible for the collection, storage, processing and publication of the anonymous research data.

Publication of the study results

Following the principles of good scientific practice, we will publish the study results in an aggregated form through scientific publications in journals or presentations at conferences. Additionally, in line with open data standards and scientific transparency, we plan to make the anonymized data available, either in full or in part, as early as possible, in a public research data repository, ensuring broad accessibility for further scientific research. Data obtained through the StudyU application is published in its repository (https://designer.studyu.health), which is publicly available.

Data Retention/Deletion

In accordance with the principles of good scientific practice, we are required to ensure that published data can be traced back to the original data for a minimum of 10 years.
Unpublished data will be deleted from the servers of the University of Potsdam as well as the servers of the Hasso-Plattner-Institute six months after the study is completed

Commercial Uses

The interventions made available to the participants in this study are intellectual property. Reproduction, modification, distribution or commercial re-use is prohibited without the express consent and permission of the study management.

Third Parties

The screening and baseline questionnaire are conducted using UP Survey. The data you provide over UP Survey will be transferred to the external service provider Sociolutions GmbH (Ludwigsburg 41, 17291 Schenkenberg, Germany, www.sociolutions.de, Tel.: 039854/63617).

Description of Participants' Rights

In relation to the anonymous data collected and processed during this study, you have the following rights:

Revocation of Consent

You may withdraw your consent at any time. While the data collected is anonymized and cannot be linked back to you, withdrawing consent will ensure that no further data is collected or used for the study. If you decide to withdraw, it will not affect any data that has already been collected and processed. After the study's conclusion, your right to withdraw consent will no longer apply.

Additionally, you have the right to

- request information about all data processed and stored about you, as well as the recipients to whom the data has been shared or will be shared
- request correction of inaccurate data
- request data portability, which allows you to receive the data you have provided to us for research purposes in a commonly used, machine-readable format, assumed we collected this data based on your consent, or you actively submitted the data (e.g., via surveys)

- object to the processing of your data, particularly if it was done without your consent for public interest purposes or the legitimate interests of the data controller. The objection must be justified, clearly demonstrating that specific personal circumstances outweigh the interest in further processing.
- request deletion of your data if certain conditions are met. This applies particularly in cases of unlawful processing or when the data is no longer necessary for the purpose for which it was collected or processed, if you revoke your consent, and no other legal basis for data processing exists.
- Request restriction of the processing of your personal data, especially if the processing is unlawful, and you prefer restriction to deletion, or if there is a dispute regarding the lawfulness of the data processing.

Please note that these rights can only be exercised by contacting the study team directly.

For any questions or to exercise the rights mentioned above, please contact the principal investigator responsible for data processing: Valeria Tisch, Prof.-Dr.-Helmert-Str. 2-3, 14483 Potsdam, Tel.: +49 176 31794830, Email: valeria.tisch@student.hpi.uni-potsdam.de

Alternatively, you may request information directly from the Chief Information Officer of the University of Potsdam (Karl-Liebknecht-Straße 24-25, 14476 Potsdam, Germany). The corresponding request form is available at: https://www.uni-potsdam.de/de/praesidialbereich/praesident-vizepraesidenten/cio.html.

If you have any questions regarding data protection or concerns regarding data processing and compliance with data protection requirements, you can also contact the Data Protection Officer of University of Potsdam:
Dr. Marek Kneis, Campus Am Neuen Palais, Am Neuen Palais 10, Haus 8, Raum 1.52, 14469 Potsdam, Tel.:+49 331 977-124409, Email: datenschutz@uni-potsdam.de

If you believe that data processing is unlawful, you have the option to file a complaint with the supervisory authority responsible for the University of Potsdam and the Hasso-Plattner Institute for Data Engineering gGmbH:
University of Potsdam
represented by the President, Prof. Oliver Günther, Ph.D.
Am Neuen Palais 10
14469 Potsdam, Germany
Phone: +49 331 977-0
Fax: +49 331 977-1089
Website: www.uni-potsdam.de

Hasso-Plattner-Institut für Digital Engineering gGmbH
Prof.-Dr.-Helmert-Str. 2-3
D-14482 Potsdam
Tel.: +49-(0)331 5509-0
E-Mail: hpi-info@hpi.de

You have the right to direct any questions to the principal investigator at any time regarding all matters related to the study, particularly concerning any risks, etc. Valeria Tisch, Prof.-

Dr.-Helmert-Str. 2-3, 14483 Potsdam, Tel.: +49 176 31794830, Email: valeria.tisch@student.hpi.uni-potsdam.de

Insurance Coverage

No specific insurance has been arranged for participants in this study.

Compensation/Costs

Participation in the study does not incur any costs for you. No compensation for expenses will be provided.