

Period Pain Relief Study Participant Instructions

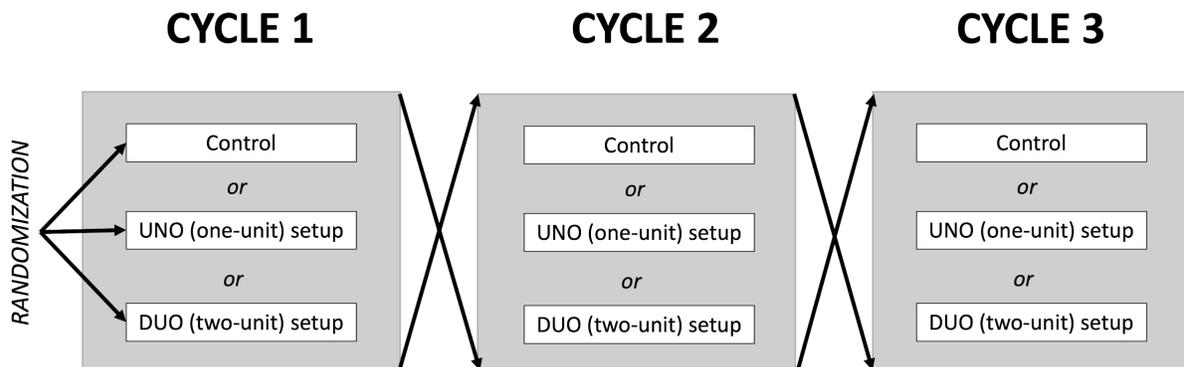
Introduction

Thank you for participating in the USC Period Pain Relief Research Study. Here, you'll find key information about the study procedures, so you'll know exactly what to do and we can ensure accurate data collection.

Purpose

The primary purpose of this study is to determine the influence of transcutaneous electrical nerve stimulation (TENS) on lower abdominal pain during your period. Additionally, we also will be monitoring exercise and physical activity during your period.

Study Design



This study will take place over the course of three cycles (~3 months total) and tests three conditions (listed below). At the beginning of the study, you will be informed of the random order in which you will use each treatment. For instance, you could be randomized to the control treatment during cycle 1, the UNO set-up in cycle 2 and the DUO set-up in cycle 3. Or, you could be randomized to use the DUO set-up in cycle 1, the UNO set-up in cycle 2, and the control cycle for cycle 3. Regardless of your assigned treatment order, you will receive the PowerDot device before the start of the cycle 1.

Study Procedures

Control	UNO (one-unit) setup	DUO (two-unit) setup
<p><u>Procedures</u></p> <ul style="list-style-type: none">• 400mg ibuprofen<ul style="list-style-type: none">• up to 1600mg per 24 hours• Record pain scores before and 30 minutes after ibuprofen in WHOOP app<ul style="list-style-type: none">• Repeat as necessary• Daily Survey/Questions in WHOOP app• Record exercise in WHOOP app	<p><u>Procedures</u></p> <ul style="list-style-type: none">• <i>IF necessary:</i> 400mg ibuprofen<ul style="list-style-type: none">• up to 1600mg per 24 hours• Record ibuprofen intake in WHOOP app• Record pain scores before and 30 minutes after TENS sessions<ul style="list-style-type: none">• Repeat as necessary• Daily Survey/Questions in WHOOP app• Record exercise in WHOOP app	<p><u>Procedures</u></p> <ul style="list-style-type: none">• <i>IF necessary:</i> 400mg ibuprofen<ul style="list-style-type: none">• up to 1600mg per 24 hours• Record ibuprofen intake in WHOOP app• Record pain scores before and 30 minutes after TENS sessions<ul style="list-style-type: none">• Repeat as necessary• Daily Survey/Questions in WHOOP app• Record exercise in WHOOP app

FOR ALL CYCLES

You will first receive a WHOOP wrist sensor. Download the app on your mobile device and follow the directions to connect your sensor. Please wear this constantly throughout the entire study. Please only take it off to charge. It is waterproof up to 10m (32ft), but you may take it off to shower if you want to avoid getting the strap wet.

Please [follow the link here](#) that has instructions on the WHOOP website on how to set-up your device and account.

During each of the cycles, you will also be monitoring your exercise and physical activity using the WHOOP band. Make sure your WHOOP band is charged prior to use during exercise.

Please [follow the link here](#) that has instructions on the WHOOP website on how to accurately track your physical activity.

Control Cycle

This cycle is considered the “control condition” where no TENS therapy will be used. Instead, you will take IBUPROFEN, specifically, for period pain. Please do not use any other therapeutic intervention, medication, or treatment, such as heat, Tylenol, CBD, etc. Only IBUPROFEN. The first cycle starts on the first day of menses (period bleed) and continues until bleeding has stopped. This is typically around 3-7 days.

During this cycle when in pain, you will record your daily ibuprofen use and pain within the “Control Cycle Journal” document. For each day of your period in the control cycle, you will record the date, your pain as a score from 0-10, with 0 being “no pain” and 10 being “severe pain”, and the time of day before you have taken the ibuprofen dose. This will be considered a PRE pain score. Then you will take 400mg of ibuprofen, making sure to record the dosage. After 30 minutes, you will then record your POST pain score (and time of day) to determine how well the ibuprofen has worked. You can record any notes for the study staff in the right column of the table.

If the pain has not changed after 4-6 hours and/or has gotten worse, use the table labeled “Second Dose Ibuprofen” to record another PRE pain score and take another 400mg of ibuprofen. After 30 minutes, you will then record your POST pain score (and time of day) to determine how well the ibuprofen has worked. You can record any notes for the study staff in the right column of the table.

You will continue to record the amount of ibuprofen you intake and you may take up to 1600mg of ibuprofen throughout the day.

Within the WHOOP app, every morning during your period, you will answer the following questions:

- Are you on your period? (Y/N)
- If yes, what day of your period are you on (First day of your period= Day 1)?
- Which condition are you randomized to this cycle?
[control/ibuprofen]
[one-unit set-up]
[two-unit set-up]
- If you are using the one- or two-unit PowerDot set-up this cycle, on average, how long did pain relief last for? (specify using hours and minutes)
- If you are in the control condition taking only ibuprofen, on average, how long did pain relief last for after taking ibuprofen before you needed more? (specify using hours and minutes)
- In the last 24 hours, did you take ibuprofen? (Y/N)
- If yes, how many mg of ibuprofen did you take?
- In the last 24 hours, did you have caffeine? (Y/N)

- If yes, how many mg of caffeine did you consume? (for reference: there are ~96 mg caffeine in 8oz brewed coffee; there is ~47mg caffeine in 8oz brewed black tea)
- Which of the following symptoms are you experiencing while on your period? (check all that apply)
 - Abdominal pain
 - Low back pain
 - Fatigue
 - Bloating
 - Breast tenderness
 - Fatigue
 - Mood swings
 - Trouble sleeping
 - Headaches

PowerDot Uno Cycle

You will be randomized to use the PowerDot UNO (one-unit) during one of the three cycles. Download the app on your mobile device and follow the directions to connect your PowerDot unit. Make sure the PowerDot unit is charged, using the charging cord provided.



Uno Set-Up

The PowerDot Uno cycle starts on the first day of menses (period bleed) and continues until bleeding has stopped. This is typically around 3-7 days. During this cycle, you will open the PowerDot App and select the Period Pain Relief (TENS) Protocol on the lower pelvic area when you feel pain during menstruation. Follow the directions below to use the Period Pain Relief Protocol correctly.

Period Pain Relief (TENS) Protocol Instructions

1. Make sure your PowerDot unit is charged prior to use.
2. Open the PowerDot App on your mobile device, click on the Period Pain Relief Program.
3. Use the slider to select the duration of your session, ranging from 30 to 90 minutes.
4. Just below the slider, you can then select the location you want to use the device. For the cycle with the UNO set-up, you will select “Abdomen Area: Butterfly electrode,” which is the second option.
5. Once you select the appropriate set-up, you will record your pain score on a scale from 0 to 10. There will be descriptions below the number to help you choose the pain score that most closely represents your current pain. Select “continue”. *Please see the video on the Study Support Page about how to use the pain scale.
6. Using the image as a guide, place the electrode pads on your abdomen, turn on your PowerDot unit, and connect the wire(s) to the unit and pads.

7. Select “Start Workout”.
8. Increase the intensity to where you begin to feel a tingling sensation and then increase it further to where it’s tolerable, but not painful. After a few minutes you will get used to the stimulation, this is called accommodation. Be sure you continually increase the intensity throughout the duration of your session to maximize effectiveness. You should continually increase the stimulation throughout your session so that the sensation feels the same throughout the entire session duration.
9. Once your session is complete you will be asked if you feel better or feel the same (meaning you experienced no relief). You will then select what your post session pain score is on the scale from 0 to 10.

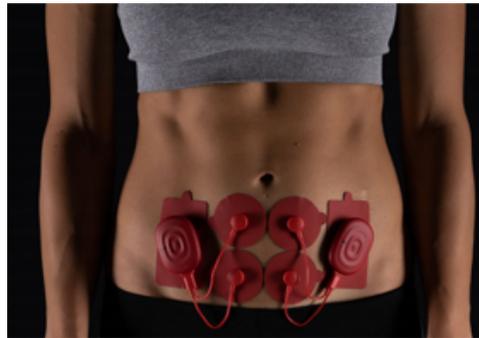
If pain is felt again throughout the day, you will again use the Period Pain Relief (TENS) Protocol in the PowerDot App on the lower pelvic area. Always use the Period Pain Relief (TENS) Protocol whenever you are in pain. And if pain is not relieved after your session, you may start another session (as it’s safe to perform multiple sessions throughout the day) or you may take 400mg of ibuprofen and up to a maximum daily dose of 1600mg ibuprofen. You will record all ibuprofen intake in the WHOOP app.

Every morning during your period, you will also answer the following questions again within the WHOOP app:

- Are you on your period? (Y/N)
- If yes, what day of your period are you on (First day of your period= Day 1)?
- Which condition are you randomized to this cycle?
[control/ibuprofen]
[one-unit set-up]
[two-unit set-up]
- If you are using the one- or two-unit PowerDot set-up this cycle, on average, how long did pain relief last for? (specify using hours and minutes)
- If you are in the control condition taking only ibuprofen, on average, how long did pain relief last for after taking ibuprofen before you needed more? (specify using hours and minutes)
- In the last 24 hours, did you take ibuprofen? (Y/N)
- If yes, how many mg of ibuprofen did you take?
- In the last 24 hours, did you have caffeine? (Y/N)
- If yes, how many mg of caffeine did you consume? (for reference: there are ~96 mg caffeine in 8oz brewed coffee; there is ~47mg caffeine in 8oz brewed black tea)
- Which of the following symptoms are you experiencing while on your period? (check all that apply)
 - Abdominal pain
 - Low back pain
 - Fatigue
 - Bloating
 - Breast tenderness
 - Fatigue
 - Mood swings
 - Trouble sleeping
 - Headaches

PowerDot Duo Cycle

You will be randomized to use the DUO (two-unit) set-up during one of the three cycles. If you have not done so, download the app on your mobile device and follow the directions to connect your PowerDot units. Make sure the PowerDot units are charged, using the charging cord provided.



Duo Set-Up

The PowerDot Duo cycle starts on the first day of menses (period bleed) and continues until bleeding has stopped. This is typically around 3-7 days each. During this cycle, you will open the PowerDot App and select the Period Pain Relief (TENS) Protocol on the lower pelvic area when you feel pain during menstruation. Follow the directions below to use the Period Pain Relief Protocol correctly.

Period Pain Relief (TENS) Protocol Instructions

1. Make sure your PowerDot unit(s) are charged prior to use.
2. Open the PowerDot App on your mobile device, click on the Period Pain Relief Program.
3. Use the slider to select the duration of your session, ranging from 30 to 90 minutes.
4. Just below the slider, you can then select the location you want to use the device. For the cycle with the DUO set-up, you will select “Abdomen Area,” which is the first option.
5. Once you select the appropriate set-up, you will record your pain score on a scale from 0 to 10. There will be descriptions below the number to help you choose the pain score that most closely represents your current pain. Select “continue”. *Please see the video on the Study Support Page about how to use the pain scale.
6. Using the image as a guide, place the electrode pads on your abdomen, turn on your PowerDot unit(s), and connect the wire(s) to the unit(s) and pads.
7. Select “Start Workout”.
8. Increase the intensity to where you begin to feel a tingling sensation and then increase it further to where it’s tolerable, but not painful. After a few minutes you will get used to the stimulation, this is called accommodation. Be sure you continually increase the intensity throughout the duration of your session to maximize effectiveness. You should continually increase the stimulation throughout your session so that the sensation feels the same throughout the entire session duration.
9. Once your session is complete you will be asked if you feel better or feel the same (meaning you experienced no relief). You will then select what your post session pain score is on the scale from 0 to 10.

If pain is felt again throughout the day, you will again use the Period Pain Relief (TENS) Protocol in the PowerDot App on the lower pelvic area. Always use the Period Pain Relief (TENS) Protocol whenever you are in pain. And if pain is not relieved after your session, you may start another session (as it’s safe to perform multiple sessions throughout the day) or you may take 400mg of ibuprofen and up to a maximum daily dose of 1600mg ibuprofen. You will record all ibuprofen intake in the WHOOP app.

Every morning during your period, you will also answer the following questions again within the WHOOP app:

- Are you on your period? (Y/N)
- If yes, what day of your period are you on (First day of your period= Day 1)?
- Which condition are you randomized to this cycle?
[control/ibuprofen]
[one-unit set-up]
[two-unit set-up]
- If you are using the one- or two-unit PowerDot set-up this cycle, on average, how long did pain relief last for? (specify using hours and minutes)
- If you are in the control condition taking only ibuprofen, on average, how long did pain relief last for after taking ibuprofen before you needed more? (specify using hours and minutes)
- In the last 24 hours, did you take ibuprofen? (Y/N)
- If yes, how many mg of ibuprofen did you take?
- In the last 24 hours, did you have caffeine? (Y/N)
- If yes, how many mg of caffeine did you consume? (for reference: there are ~96 mg caffeine in 8oz brewed coffee; there is ~47mg caffeine in 8oz brewed black tea)
- Which of the following symptoms are you experiencing while on your period? (check all that apply)
 - Abdominal pain
 - Low back pain
 - Fatigue
 - Bloating
 - Breast tenderness
 - Fatigue
 - Mood swings
 - Trouble sleeping
 - Headaches