

# **Mechanisms Of Change in Adolescent Pain Self-management (MOCAS)**

**Unique Protocol Identification Number:**

**National Clinical Trial (NCT) Identified Number: NCT04043962**

**Principal Investigator: Tonya Palermo**

**Sponsor: Seattle Children's Research Institute**

**Grant Title: Role of sleep deficiency in self-management of pediatric chronic pain**

**Grant Number: R21NR017312**

**Funded by: NINR**

**Consent form revision date: 3 May 2019**

---

**PARENTAL PERMISSION FORM**  
**CONSENT FORM: Ages 18 and up**  
**ASSENT FORM: Ages 12-17**

**Study Title: MOCAS Study: Mechanisms Of Change in Adolescent Self- management**

**Principal Researcher: Dr. Tonya Palermo, Ph.D.**

**The Research Team:**

Name/Degree	Title	Department	Phone Number	E-mail
Tonya Palermo, PhD	Principal Investigator	Anesthesiology and Pain Medicine	206-884-4208	tonya.palermo@seattlechildrens.org
Tricia Jessen-Fiddick, BS	Research Supervisor	Child Health, Behavior, & Development	206-884-1308	tricia.jessen@seattlechildrens.org
Homer Aalfs	Research Coordinator II	Child Health Behavior, & Development	206-884-1845	homer.aalfs@seattlechildrens.org
Tanera van Diggelen	Research Coordinator I	Child Health Behavior, & Development	206-884-1488	<a href="mailto:Tanera.vandiggelen@seattlechildrens.org">Tanera.vandiggelen@seattlechildrens.org</a>

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

**24 hour Emergency Contact Number(s):** Call 911

**1. Researchers' Statement:**

You have the option to take part in a research study. The goals of this form are to give you information about what would happen in the study if you choose to take part and to help you decide if you want to be in the study.

Feel free to take notes, write questions or highlight any part of this form.

**Potential Teen Participants:** This form also serves as an assent form. That means that if you choose to take part in this research study, you would sign this form to confirm your choice. Your

parent or guardian would also need to give their permission and sign this form for you to join the study.

**Participant/Guardian Participants:** You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

**Joining the study as a parent:** Parents also have the option to take part in this research study. There is an addendum at the end of this form explaining what it would mean to participate as a parent.

The word “**you**” in this form refers to your child/teen.

## **2. What you should know about this study:**

- This form explains what would happen if your child joins this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to have your child join the study, it will not affect his/her care at Seattle Children's.
- If you say ‘Yes’ now, you can still change your mind later.
- You can choose to have your child leave the study at anytime.
- Your child would not lose benefits or be penalized if you decide not to have your child take part in the study or leave the study later.

## **3. What is the goal of this study?**

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study to learn more about the relationship between pain and sleep.

## **4. Why do I have the option of joining the study?**

You have the option to join this research study because you have chronic pain.

## 5. How many people will take part in the study?

A total of 100 children (and their parents) will take part in this study.

## 6. If I agree to join this study, what would I need to do?

If you join the study, both parent and child will complete a survey at 4 time points and participate in an 8-week pain management program online. Only the child will complete an Actiwatch assessment at 3 time points.

Study time points are:

- At the time of enrolling in the study,
- Half-way through the 8-week Web-MAP program
- Immediately after completing the program
- 3 months following completion of the program

### Surveys:

The surveys will take 30-45 minutes at each time point and will be completed online.

### At-home Sleep Assessments:

**Wear an Actiwatch:** We will send you an Actiwatch in the mail, which looks like a regular watch and measures movement. You will need to wear the Actiwatch on your wrist for 7 days, all day and night. The Actiwatch will help us learn about your activity and sleep. The Actiwatch only assesses movement and does not collect information on your location. You will return the Actiwatch to us using a pre-paid FedEx Ground envelope that we provide.

**Sleep Diary:** Fill out a daily 1-2 minute survey about your sleep and pain every day before going to bed for 8 days.

### Web-MAP Program:

You would receive access to the study website, Web-MAP. You can access this website from your computer at home, or another convenient location. A member of the research team will call you on the phone and would give you instructions about how to access the study website. You will receive a unique password to access the study website.

You would be asked to complete weekly readings and assignments, on the Web-MAP program. Parents and teens will have their own, separate versions of the Internet program. Weekly readings and assignments would take 20 to 30 minutes to complete. You would be using this website regularly for 8 weeks. It would focus on learning pain management skills.

During your participation, a member of the study team would call you to check in with you, and to see if there are any problems using the program.

**7. How long would my child be in the study?**

If you choose to have your child take part in all the study visits, your child would be in the study for **6 months**.

If you join the study, you can decide to stop **at anytime for any reason**. If you decided to stop, you would need to talk with Dr. Tonya Palermo or a member of the study team.

You could also be removed from the study by the research team if we decide that you didn't understand or comply with the study instructions, or if we felt it was important for your safety.

**8. What are the potential harms or risks if my child joins this study?**

Some of the questions you would be asked may seem personal. You may refuse to answer any questions that you do not want to answer.

There is a risk that your confidentiality or privacy could be breached. This would mean that someone other than the research team or our collaborators may find out that you were in the research or see your answers or medical information. However, we will take every precaution to make sure that this does not happen.

**9. What are the potential benefits if my child joins this study?****Potential Benefits for You:**

You may or may not benefit personally from participating in this study. You may find that the Internet program helps you manage pain better.

**Potential Benefits for Others:**

We hope to use information we get from this study to benefit other children who have chronic pain.

**10. What other options do I have?**

Your participation or nonparticipation will not affect your health care. If you wish to withdraw from the study, you should inform the research staff. At that time you will be asked to stop completing the questionnaires and using the study website. In addition, you have the option to not participate in the study.

## 11. What about confidentiality and privacy?

First, parents and children must complete the study separately. Each will choose a password that is kept private. It is important to complete the website privately. Parents cannot review teens' responses to the study website, questionnaires, or consent document. This is to make sure that your responses remain private.

If you join the study, we will keep your information confidential as provided by law.

You have certain privacy rights with regards to your health information, and only with your permission may we collect, use, or share your health information for this study. The following describes the type of information the study will create, use or share, who may use it or share it, and the purposes for which it may be used or shared.

This information may include things like:

- Past or future medical records,
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history
- Medical or laboratory records related to this study, and
- Information specific to your child like his/her name, address, or birthday

This information may be used by or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Review boards (such as Seattle Children's Institutional Review Board), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS), including similar agencies in other countries, and
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.
- If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

This information may be used or shared to:

- Complete and publish the results of the study described in this form,
- Study the results of this research,
- Check if this study was done correctly, and
- Comply with non-research obligations (if we think you or someone else could be harmed).

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of the research information may not be available to you during the study. This does not affect your right to see what is in your medical (hospital) records.

There is no time limit for the use or sharing of your child's information. Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your information will be banked as part of this study, it may be used in the future for other research. We would not ask for your permission prior to this future research.

Your permission for the use or sharing of your information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new information will be collected about you, but information that has already been collected may still be used and shared with others.

The use or sharing of your information will follow privacy laws, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your health information as part of this study may share it with others without your permission if doing so is permitted by the laws they must follow.

If the results of the study are published, information that identifies you would not be used.

Your permission is documented by signing this form below. If you decide that we cannot use or share your information, you cannot participate in this study.

#### **12. Would it cost me money to have my child join the study?**

If you take part in this study, there would be no cost to you and no cost to your insurance company.

#### **13. What if I were injured while in the study?**

If you think you have been harmed from this study, please call Principal Investigator Tonya Palermo, Ph.D. at 206-884-4208

#### **14. Would I be paid if I join this study?**




Your family will receive a \$40 gift card after completing both the parent and child assessment. This would be a total of \$160 per family if you complete all assessment time points.

The IRS has certain rules about paying people who take part in research studies. If you took part in this study, we would ask you to provide your name and mailing address so we could pay you.

You can be in this study even if you do not give us this information. If you decide not to give us this information, you would receive no payment.

The payments you would receive for being in this study might be taxable. Seattle Children's is required to report to the IRS study payments of \$600 or more made to anyone in any year.

### 15. Who do I contact if I have problems, questions or want more information?

 If I have questions or would like to know about ...	 You can call ...	 At ...
<ul style="list-style-type: none"> <li>• Emergencies</li> <li>• General study questions</li> <li>• Research-related injuries</li> <li>• Any research concerns or complaints</li> </ul>	<b>Dr. Tonya Palermo</b>	<b>Emergencies: Dial 911</b>  <b>Other questions:</b> <b>Phone: 206-884-4208</b>
<ul style="list-style-type: none"> <li>• Emergencies</li> <li>• General study questions</li> <li>• Research-related injuries</li> <li>• Any research concerns or complaints</li> </ul>	<b>Homer Aalfs</b>	Phone: 206-884-1845
<ul style="list-style-type: none"> <li>• Your child's rights as a research participant</li> <li>• Study questions, concerns or complaints.</li> <li>• Contacting someone outside of study team</li> </ul>	<b>Institutional Review Board</b> This is a group of scientists and community members who make sure research meet legal and ethical standards.	Phone: (206) 987-7804

### 16. If my child joins the study, can my child or I decide to leave the study?

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time. We ask that you tell Dr. Tonya Palermo. You can contact this person at **206-884-4208**.

**If you choose to leave the study, it will not affect your care at Seattle Children's. You will not lose any benefits or be penalized if you choose to leave the study.**



**17. What would my verbal and electronic permission mean?**

Your permission would mean:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you or your child may have about the study or your child's rights as a research study participant.
- **Your child has rights as a research participant. We will tell you about new information or changes to the study that may affect your child's health or your willingness to have him or her stay in the study.**
- By typing your name below, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
  - You agree to take part in this research study.
  - If the person reading this form is a parent/guardian, you agree to have your child take part in this research study.
  - You permit the creation, use, and sharing of your health information for the purposes of this research study as described in Section 11 above

**Please Note:** If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

---

## PARENT PARTICIPANT ADDENDUM

### Parent Participants

#### Why do parents have the option of taking part?

Parents have the option to take part in this research study.

If you join the study, you would complete 4 questionnaires.

- At the time of enrolling in the study
- Halfway through the Web-MAP program
- At the end of the 8-week Web-MAP program
- 3 months following completion of the program

The surveys will take about 20-30 minutes to complete each time.

You would also be given access to the study website, Web-MAP. You can access this website from your computer at home, or another convenient location. A member of the research team will call you on the phone and would give you instructions about how to access the study website. You will receive a unique password to access the study website.

Both youth and parents would be asked to complete weekly readings and assignments, on the Web-MAP program. You would each have your own separate and private versions of the Internet-accessible program. Weekly readings and assignments would take 20 to 30 minutes to complete. You would be using this website regularly for 8 weeks. It would focus on learning pain management skills.

During your participation, a member of the study team would call you to check in with you, and to see if there are any problems using the program.

#### Do parents have to take part?

Taking part in research is optional. If you decide not to join you will not be penalized nor lose any benefits that you are otherwise entitled to.

#### What are the possible risks?

The main risk of participating as a parent in this study would be breach of confidentiality.

#### What are the possible benefits?

You may or may not benefit personally from participating in this study. You may find that the Internet program helps you manage your child's pain better.

#### How will you protect my information and privacy?

The same general rules and procedures as discussed above about your child's information will apply to the use and sharing of your information. The information will relate to you and your

health, it may be used by or shared with others involved in these research or in future research studies, and its use or sharing will be consistent with the purpose for which it was collected.

You can find the rules and procedures in the form under section 11 - "What about confidentiality and privacy?"

**Can I change my mind?**

You can decide to take part and change your mind at any time. Research is always voluntary. If you change your mind, your relationship with Seattle Children's and your medical provider will not be impacted in any way. Any information that you have provided will have all identifying information removed thus protecting your identity.

If you have questions about the study, your rights, or feel you have been harmed by the study, please contact the study team members listed on the front of this form.

**What would my verbal and electronic consent mean?**

- You agree to take part in the research study.
- You keep all your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
- You permit the creation, use, and sharing of your health information for the purposes of this research study.