Seattle Children's
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Study Title: Web-MAP 2
Principal Researcher: Dr. Tonya Palermo, Ph.D.
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Seattle Children's
Seattle, Washington
Institutional Review Board
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APPROVED

CONSENT FORM & ASSENT FORM: Ages 14-16

Study Title: Web-MAP 2: Internet CBT for Adolescents with Chronic Pain

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

The Research Team:

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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.

Parent/Guardian Participants: This consent form is for you to provide consent for your own participation in the study, as well as provide consent for your child's participation. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in the study and that you will allow your child to take part in this research study, you would sign this form to confirm your decision. You would then receive a signed copy of this form for your records.

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.

The word **"you"** in this form refers to you and/or your child in this consent form.

2. What you should know about this study:

- This form explains what would happen if you join 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 be in the study, it will not affect your care at your hospital.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at any time.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

3. What is the goal of this study?

The goal of any research study is to answer scientific questions. We (the research team listed on the front of this form and our staff) are doing this research study to see if the Internet can be used as a method to teach children with pain (such as headache, abdominal, or muscle pain) and their parents, ways to help deal with the problems related to the pain.

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

You have the option to take part in this research study because your teen (age 11-16) has pain that is getting in the way of some part of his/her life.

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

A total of 300 adolescents and 300 parents of these adolescents will take part at hospitals and clinics around the country. We think that about 120 youth and 120 parents will take part in this research study at Seattle Children's.

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

If you agree to join this study, you would receive access to one of two versions of the study website. You would need to 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.

All study participants would be asked several questions to ensure that they are able to use the computer and the study website. You would be given a unique password to access the study website each time.

All study participants would complete four study assessments during their participation:
Time 1 assessment would happen after enrollment.
Time 2 assessment would happen about 2 months after beginning the study.
Time 3 assessment would happen about 6 months after beginning the study.
Time 4 assessment would happen about 12 months after beginning the study.

During each of the study assessments, all participants (both parents and adolescents) would complete several questionnaires online through the study website. Participants may also be contacted on the phone for reminders.

Adolescents: The questionnaires would ask adolescents about their pain, how much pain interferes with their daily activities, their parent's response to their pain, and if they believe the Internet treatment will help. Adolescents would also complete questionnaires about their mood and sleep.

In addition to these questionnaires, adolescents would be asked to track pain on a daily diary for 7 days during each of the study assessments. This diary would also be completed on the study website.

Each assessment would take about 20-30 minutes to complete.
Parents: The questionnaires would ask parents about family demographics, about their adolescent's pain, how much pain interferes with their adolescent's daily activities, and their responses to their adolescent's pain. Parents would also complete questionnaires about their adolescent's mood, sleep, and health care services.
While another parent is welcome to view the study website, the parent who provides consent must be the parent who visits the study website and completes the questionnaires.

Each assessment would take about 20-30 minutes to complete.

If you join this study, we would randomly assign you to one of two study groups--**Group A** or **Group B**. Randomization means that you will be put into a group by chance. This means whichever group you are in would be decided by chance, like flipping a coin. Neither you nor the researcher will know in advance which group you will be in. People in **Group A** and **Group B** would have access to different versions of the study website that focus on education or skills training. Both groups will continue with standard medical care prescribed by their treating specialist during their participation in the study.

Group A:
If you were randomized into Group A, you would complete study assessments at Time 1, 2, 3 and 4. In addition, both adolescents and their parents would have access the internet program focused on skills training. Both adolescents and parents would be asked to complete weekly readings and assignments on the Internet using 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 to 9 weeks.
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.

Group B:
If you are randomized into Group B, in addition to completing study assessments at Time 1, 2, 3, and 4, both adolescents and their parents would have access to the internet program focused on education about managing chronic pain in youth. Both adolescents and parents would be asked to complete weekly readings on the Internet using their own, separate versions of the Internet program. Weekly readings would take 20 to 30 minutes to complete. You would be using this website regularly for 8 to 9 weeks.

No matter which group you are randomized to, your participation in the study would be complete after the study assessment at Time 4.

7. How long would I be in the study?

If you choose to take part in all parts of the study, you would be in the study for **one year.**

If you join the study, you can decide to stop **at any time for any reason**. If you did decide 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 staff if we decided 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 I join this study?

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

9. What are the potential benefits if I join 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 your teen manage pain better.

Potential Benefits for Others:

We hope to use information we get from this study to benefit children and adolescents with pain in the future.

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 this study.

11. How would you keep my information confidential?

If you take part, we will make every effort to keep your information confidential.

First, parents and teens 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 documents, and teens cannot review parents' responses to the study website, questionnaires, or consent document. This is to make sure that your responses remain private.

If at any time it seems that a teen may hurt himself/herself, or someone else, we would need to follow up on this immediately by contacting that person and, if necessary, connecting them to appropriate crisis services. Depending on what state you live in, the teen's parents may be contacted as well.

We will store all of your research records in locked cabinets and secure computer files. We will not put your name on any research data. Instead, we will label your information with a study number. The master list that links a person's name to their study number is stored in a locked cabinet or on a secure computer file.

If results of this research are published, we would not use information that identifies you.

We would only use your information for research purposes. These are some reasons that we may need to share the information you give us with others:

- If it's required by law.
- If we think you or someone else could be harmed.
- Government agencies or research staff could sometimes look at forms like this and other study records. They do this to make sure the research is done safely and legally. Anyone who reviews study records would keep your information confidential.
    - Agencies that may look at study records include:
        - Hospital Auditors; Government Agencies; others responsible for watching over the safety, effectiveness, and conduct of the research.

We would keep your results for a minimum of seven years.

To further help us protect your and your child's privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (HHS). With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself or your child, or your involvement in this study. If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

You should understand that we will in all cases take the necessary action, including reporting to authorities, to prevent serious harm to your child or others. Fore example, in the case of child abuse or neglect.
A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

12. Would it cost me money to be in 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 because I joined the study?

If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed. No funds have been set aside for this treatment. You or your insurance company would be billed for the treatment.

It is important that you tell the Principal Researcher, Tonya Palermo, if you think that you have been injured as a result of taking part in this study. You can call her at 206-884-4208.

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

We would give you and your adolescent $50 for completing each of four phases of this study to thank you for your time and help. Altogether, this would be $200 for each of you, or $400 total. You will receive credit toward online gift cards for each assessment through the study website.

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

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 can 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 could choose to receive no payment.

15. Who do I call if I have problems or questions?

? If I have questions or would like to know about …	You can call …	☎ At …
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Dr. Tonya Palermo**	**Emergencies:** **Dial 911** **Other questions:** **Phone: 206-884-4208**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Tricia Jessen- Fiddick**	**Phone: 206-884-1308**
• Your rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meet legal and ethical standards.	**Phone: (206) 987-7804**
• Assistance with figuring out what questions to ask the research team • Help understanding the research process	**Research and Family Liaison** A person who works with families to ensure they receive the information they need to make an informed decision about taking part in a research study.	**Phone: (206) 884-7858** **Pager: (206) 469-3983**

16. If I join the study, can I stop?

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 saying 'yes' to being in the study mean?

You saying 'yes' to being in the study 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 may have about the study or your rights as a research study participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
- By saying 'yes' to being in the study, 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.
- I agree to participate in the study.

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.