

Official Study Title: PainTracker Self-Manager: a Web-based Platform to Promote and Track Chronic Pain Self-Management

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UNIVERSITY OF WASHINGTON
CONSENT FORM
PainTracker Self-Manager Study

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APPROVED

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UW Human Subjects
Review Committee

Researchers' statement

We are asking you to be in a research study. The purpose of this Consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "Informed Consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Standard patient care at the University of Washington (UW) Center for Pain Relief includes a web-based pain assessment system called PainTracker. We want to see if a web-based education system called PainTracker Self-Manager will be more effective than the basic PainTracker in helping people manage their chronic pain.

STUDY PROCEDURES

As a patient in the Center for Pain Relief, you will be asked to complete the standard online PainTracker before each visit, as part of your regular care. If you agree to be in the study, your participation will last about 6 months. The additional research activities differ depending on the date of your second visit to our clinic.

Group 1--If your second visit is before October 1, 2016:

- Answer an additional questionnaire at "baseline" (when you join the study) and again 3 months and 6 months after that.
- Allow us to use for research your PainTracker answers and other information from your medical record.

Group 2—If your second visit is on or after October 1, 2016:

- Answer an additional questionnaire at "baseline" (when you join the study) and again 3 months and 6 months after that. You will also complete PainTracker at the same time you complete the 3-month and 6-month questionnaires.
- Allow us to use for research your PainTracker answers and other information from your medical record.
- Receive and review 4 online PainTracker Self-Manager educational modules over the 6-month study period. Each module will take about 40 minutes to view; you can look at

them as often as you wish. Viewing these modules is an important part of learning chronic pain self-management skills.

- As part of PainTracker Self-Manager study, have regular check-ins with the Research Coordinator by email, text, telephone, or in-person visits. The Research Coordinator will find answer your questions, and give you personalized coaching for chronic pain self-management skills.
- Check-ins will be every few weeks over the 6-month study period, will take 5 to 20 minutes each time, and we will schedule them at your convenience. Based on the check-ins and a review of your medical record, the Research Coordinator will update the PainTracker Self-Manager study database about your progress in learning self-management skills. We will share this information with your regular provider at the UW Center for Pain Relief.
- Communication with the Research Coordinator is an important part of the study. We will ask you to call or e-mail the Research Coordinator every 2-3 weeks in order to receive regular coaching.

As part of your enrollment in the PainTracker Self-Manager study, you will be asked not to participate in the 6-week Pain Support Groups at the Center for Pain Relief or at Harborview Medical Center for the duration of the 6 month study. This is to avoid duplication of self-management skills being taught as part of each program, and will help us test the effectiveness of the PainTracker Self-Manager Study educational modules only. After completion of the study you may enroll in the Pain Support Group, if you desire.

The study “Outcome Measures” questionnaires (both groups): Each of the 3 questionnaires (baseline, 3-months, 6-months) will take about 15 minutes to complete. They ask about how active you are in your life and in your chronic pain care, how well you get on with your life despite your pain, how effective you feel in communicating your needs to your doctor and nurses, and how satisfied you are with your care.

You may refuse to answer any question that you do not wish to answer. Your answers to these questionnaires **WILL NOT** be shared with your doctor or nurses.

Research use of your regular medical information (both groups): We will ask you to sign an additional form that allows us to access information from your regular (non-research) medical record. These data will include your pain-related diagnoses, provider notes, PainTracker scores, as well as upcoming appointment dates at the Center for Pain Relief.

RISKS, STRESS, OR DISCOMFORT

The risks of being in this study include stress in answering the questions and a possible breach in confidentiality that would allow someone not on the research team to see your information. Although a possibility, the breach is not likely as the PainTracker system and study questionnaire data are stored in a secure, password-protected server with encrypted connections to the web.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you decide not to be in the study, you would still complete the PainTracker questionnaire as part of your regular care at the UW Center for Pain Relief. You would not complete the additional study questionnaires and would not experience PainTracker Self-Manager study check-ins and coaching (if your second clinic visit was on or after October 1, 2016).

BENEFITS OF THE STUDY

You might not directly benefit from this study. However, your participation may help improve chronic pain care for others. We hope to learn whether the PainTracker Self-Manager education and coaching by the Research Coordinator can help patients with chronic pain have greater ability to self-manage their pain, better quality of life, and more satisfaction with their care.

SOURCE OF FUNDING

The study team and/or the University of Washington are receiving financial support from Pfizer Inc. through a research grant to conduct this study.

CONFIDENTIALITY OF RESEARCH INFORMATION

The data collected for this study will be confidential. It will be stored in password protected computer files separate from your electronic medical record. The links between your data and your name/other identifiers will be destroyed after the study is complete and data analyzed.

Your identifiable study data will not be given to the study sponsor or your clinical team. Completely de-identified data from this study may be shared with our research partners, or presented as grouped data at national conferences and professional society meetings.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at risk of harm.

OTHER INFORMATION

You will receive a total of \$100, in the form of Amazon gift cards, for completing all 3 study “Outcome Measures” questionnaires: \$25 for the “Baseline”, \$25 for the 3-month, and \$50 for the 6-month questionnaire. If you withdraw early from the study, we will pay you only for the “Outcome Measures” questionnaires that you completed. If you are in Group 2, you must also check in with the Research Coordinator by phone (206-221-8631) or in person. This will provide you with the study “coaching” to help you learn pain self-management skills. Study payments will be made based on regular check-ins with the Research Coordinator, viewing the educational modules, and completing PainTracker reports and the study “Outcome Measures.”

Specifically, to receive the 3-month study payment, you must:

- View educational Modules B and C,
- Check in with the Research Coordinator by phone or in person at least once,
- Complete a 3-month PainTracker report, and
- Complete the 3-month “Outcome Measures.”

To receive the final 6-month study payment, you must:

- View educational Modules D and E,
- Check in with the Research Coordinator by phone or in person at least once,
- Complete a 6-month PainTracker report, and
- Complete the 6-month "Outcome Measures."

Study participation is entirely voluntary. You may refuse to be in the study or decide to withdraw from it at any time, without penalty or loss of benefits to which you are otherwise entitled. This includes care you receive from the UW Center for Pain Relief or other UW Medicine services and facilities. You can continue in the study even if you have stopped receiving care at the UW Center for Pain Relief.

Study Staff Signature:

Printed Name of Study Staff Obtaining Consent	Signature	Date
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Subject's statement

The PainTracker Self-Manager Study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Subject Signature:

Printed Name of Subject	Signature of subject	Date
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Copies to: Researcher
 Subject

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INFORMATION STATEMENT
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PTSM@uw.edu; or thuyc22@uw.edu.

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You may refuse to answer any question that you do not wish to answer. Your answers to these questionnaires **WILL NOT** be shared with your doctor or nurses.

Research use of your regular medical information (both groups): During the course of this study, we will access information from your regular (non-research) medical record. These data will include your pain-related diagnoses, provider notes, PainTracker scores, as well as upcoming appointment dates at the Center for Pain Relief.

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SOURCE OF FUNDING

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CONFIDENTIALITY OF RESEARCH INFORMATION

The data collected for this study will be confidential. It will be stored in password protected computer files separate from your electronic medical record. The links between your data and your name/other identifiers will be destroyed after the study is complete and data analyzed.

Your identifiable study data will not be given to the study sponsor or your clinical team. Completely de-identified data from this study may be shared with our research partners, or presented as grouped data at national conferences and professional society meetings.

Government or university staff sometimes reviews studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at risk of harm.

OTHER INFORMATION

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Study participation is entirely voluntary. You may refuse to be in the study or decide to withdraw from it at any time, without penalty or loss of benefits to which you are otherwise entitled. This includes the care you receive from the UW Center for Pain Relief or other UW Medicine services and facilities. You may continue in the study even if you have stopped receiving care at the UW Center for Pain Relief.

If you have questions about the research, or if you have been harmed by participating in this study, you can contact one of the researchers listed on the first page of this form. If you have questions about your rights as a research subject, you may call the Human Subjects Division at (206) 543-0098. By agreeing to be in the study, you give permission to the researchers to use your medical records as described in this Information Statement. You may print a copy of this form for your records, or you may request that we mail you a paper copy.

DECISION FOR STUDY PARTICIPATION

If you agree to join the PainTracker Self-Manager Study, click “YES” below; if you do not want to be in the study, click “NO” below; if you are not certain if whether you want to join the study or not, click “I don’t want to decide right now.”

Do you volunteer to take part in the PainTracker Self-Manager study?

“YES”
 “NO”
 “I don’t want to decide right now”