

Cover page

Project Title: PainTracker Self-Manager (PTSM) : a web-based platform to promote and track chronic pain self-management and other treatment outcomes

Grant ID 19561405

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Abstract

We propose to develop and test a web-based patient empowerment platform, PainTracker Self-Manager (PTSM), that can support integrated multimodal care in a wide variety of specialty and primary care settings. We will adapt PainTracker, a web-based outcome and treatment tracking tool already successfully deployed in multiple University of Washington clinics to create the PTSM self-management tool that helps assess, engage, activate, and support patients' efforts to self-manage their chronic pain in collaboration with their physicians, advanced practice providers, and nurse care managers. PTSM design will be based on 4-phase patient engagement strategy derived from Acceptance and Commitment Therapy. Phase 1 focuses on achieving consensus on the clinical problem definition, treatment goals and timeline. Phase 2 focuses on promoting values-based action and acceptance of pain. Phase 3 focuses on providing skills in chronic pain self-management with close monitoring of patient reported outcomes and actigraphy. Phase 4 focuses on providing autonomy support to promote maintenance of self-management behaviors. Phase 5 involves generating a patient registry with the above data for use in quality improvement research. We will engage patients, providers and investigators in designing PTSM, reviewing prototypes, and conducting usability testing. In a 6-month clinical trial, we will compare 50 intervention patients from the UW Center for Pain Relief who receive PTSM to 50 historical control patients who have received the basic PainTracker. The primary outcome for this trial will be patient activation, with secondary outcomes of: chronic pain self-efficacy, chronic pain acceptance, perceived efficacy in physician-patient interactions, patient and provider satisfaction.

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Reviewer's comments**STRENGTHS:**

1. Meets RFP requisites. LOI measures patient activation, clinical outcomes and perceived efficacy in patient-physician interactions (PEPPI), and Patient and provider satisfaction with care.
2. Definition of Phase 1 elements to define the patient perspective on their clinical problems and goals is excellent.
3. Very good local needs assessment with extensive data about their patient population.
4. Inclusion of non-opioid chronic pain patients; increasing recognition of the adverse effect profile of NSAIDs should make appropriate limitations in their use a goal for many patients and providers.

MAIN PROPOSAL

Overall goal for project: To add patient empowerment and self-management support capabilities to an existing chronic pain treatment outcome tracking web-based and mobile platform. This new content will direct engagement between providers and patients and promote chronic pain self-management through: collaborative goal-setting, multidimensional treatment and outcome tracking, provisional acceptance of pain, guided pain self-management, and enhanced capabilities for collaborative research, education and peer-to-peer support for patients. The web-based and mobile PTSM platform will extend the reach and duration of self-management support currently possible in the pain specialty setting. It will provide the nurse care manager with the ability to reach and support far more patients than is now possible with the self-management class and ad hoc one-on-one patient consultations as is currently the norm. The development of the PainTracker Self-Manager platform will support the dissemination of the multimodal interdisciplinary care for chronic pain that is recommended in the National Pain Strategy.¹ This project builds on the historic leadership of the University of Washington in interdisciplinary chronic pain care. It addresses an acute regional need for chronic pain self-management support in the “post-opioid” era of chronic pain care that we are just entering. The PainTracker Self-Manager platform may help chronic pain care meet the goals of the Triple Aim: better patient experience, better patient outcomes, with lower costs.

Key objectives of project

1. User experience (UX) design and evaluation of PainTracker Self-Manager web-based platform in collaboration with patients and physicians, advance practice providers, and nurse care managers from the University of Washington Center for Pain Relief.
Deliverable: PainTracker Self-Manager platform based on best user centered design research standards.²
2. Testing chronic pain care using PainTracker Self-Manager for 50 patients at the UW Center for Pain Relief compared to 50 patients receiving care using basic PainTracker in a 6-month clinical trial concerning the primary outcome of patient activation, with secondary outcomes of: chronic pain self-efficacy, chronic pain acceptance, perceived efficacy in physician-patient interactions, patient and provider satisfaction.
Deliverable: Test of activation of patients with chronic pain following use of PainTracker Self-Manager platform.

Technical approach

How these objectives address established need for project: The PainTracker Self-Manager (PTSM) platform will be developed and deployed in collaboration with patients and providers. We will involve patients as *development* partners so that we can design a tool that will effectively engage patients as *care* partners. Development of PTSM will be guided by a 5-phase model of patient engagement. These 5 phases of support for patient empowerment and self-management address gaps in chronic pain care as documented in the National Pain Strategy: 1) engagement with patients who are not initially seeking self-management guidance, 2) shifting the focus from pain reduction toward increased engagement in valued activities, 3) skill development to support successful self-management, 4) autonomy support for internalization of motivation for self-management so that self-management actions will be maintained over the long term, 5) generation of analyzable clinical data concerning treatments received, patient-reported outcomes, and self-management engagement to allow Quality Improvement

analyses and health services research on the population of chronic pain patients. This will promote the development of a “learning health care system” that is a crucial part of health system reform. We will test the ability of care supported by this PainTracker Self-Manager platform to improve patient activation, self-efficacy, and satisfaction compared to care supported by Basic Pain Tracker over a period of 6 months at the UW Center for Pain Relief.

Current assessment of need in target area: Engagement in self-management is a crucial unsolved problem in chronic pain management. Many of the innovations of chronic disease management (e.g., care management for populations according to established care metrics, shared medical appointments, software support for care managers) have yet to be developed and disseminated for chronic pain care. As we enter the “post-opioid” era in chronic pain care when patients will be asked to do more than take medications, these tools for patient engagement are needed more than ever before. The National Pain Strategy calls repeatedly for multimodal interdisciplinary care for chronic pain. If this care is to be available outside of academic and other tertiary care medical centers, it must be supported by intelligent software to help coordinate and direct this practice. However, we must begin by developing and testing these tools in the pain specialty setting.

1. Quantitative baseline data summary on QI data, gap analyses, patient-level data

- *Patient population* During 2014 at the UWMC Center for Pain Relief (CPR) we saw: 2,565 new patients, 5,577 return patients. Average number of patients seen per day: 10 new patients, 21 return patients. 70% of these are treated with opioids.
- *Current PainTracker use at CPR:* New patients in 2015 have a 57% completion rate, return patients have a 38% completion rate. This is increasing monthly as providers use PainTracker during their visit and give the patient a copy during visit. PainTracker also used at 9 University of Washington Neighborhood Clinics and the University of Washington Sports Medicine Center at Husky Stadium. Planned deployments of PainTracker within next few months at: Harborview Medical Center’s Sports & Spine Center and the Foot & Ankle Institute. These clinics also lack and need resources for patient self-management support. However, given the scope of this grant award and timeline, our study will focus on Center for Pain Relief only. This will also help us iterate a prototype to effectively translate into successful adoption at other clinics.

Gap Analysis

- A. Current Chronic pain self-management classes at CPR: The class series consists of 6 sessions of 2 hours each. 9 series have been held with an average of 6 patients per series. The goals of the class are to promote a self-management approach and skill development. The class has been successful at increasing confidence and activity level but not as successful at reducing dependence on medication. Among 408 CPR patients referred for the class from 1/17/13 up to 10/30/14, a total of 51 were enrolled and 34 completed the class (67% completion rate). Thus many patients considered eligible for the class are not enrolling. The most common reasons for not enrolling in the class were travel distance and preferring to continue to explore medical treatment. The most common reasons for not completing the class were exacerbations of chronic illness and schedule conflicts. Patients who have completed the class have requested more sessions and opportunities for peer support.

Class attendance is expensive for patients in both time and money. This could be reduced with an accessible web platform.

Table 1 below summarizes the outcomes from the self-management groups.

Table 1. Pain Self-Management Course (Jan 2013 - Apr 2015; N = 31 patients in 9 groups)				
<i>Measures</i>	<i>Mean (Pre)</i>	<i>Mean (Post)</i>	<i>p-values</i>	<i>% Change</i>
Pain Interference with enjoyment of life	6.0	4.8	.006	-20%
Depression (PHQ9)	10.2	8.3	.030	-18%
Pain Interference with General activity	5.7	4.9	.026	-14%
Pain interference with falling asleep	4.4	3.9	.276	-11%
Average Pain Intensity	5.9	5.3	.061	-9%
Anxiety (GAD7)	6.8	6.4	.565	-5%
Pain interference with staying asleep	4.5	4.4	.821	-2%
Pain Management Self Efficacy (PSEQ)	27.1	35.1	.001	29%
Satisfaction with Care	5.1	6.4	.032	25%

Comments from patients who have completed self-management class include: "I have learned to use many coping skills that have helped me very much." "Great materials, great teachers, 100% useful" "I really appreciate everything we have learned and I thank you both so very, very much."

- B. PTSM addresses unmet need for accessible self-management support: The current PainTracker gives patients a broader sense of their progress with chronic pain treatment, but does not explicitly engage them as partners in this process. The reach of the self-management class is limited by patient engagement and the need to attend an in-person class. The web-based and mobile PTSM platform extends the reach and duration of self-management support. It will provide the nurse care manager with the ability to reach and support far more patients than is now possible with the self-management class and ad hoc one-on-one patient consultations as is currently the norm.
- C. Nationwide self-management need: Chronic pain specialty care patients are now lacking any meaningful self-care support apart from Commission on Accreditation of Rehabilitation Facilities (CARF) accredited pain rehabilitation programs. There are now estimated to be approximately 70 CARF-accredited facilities providing chronic pain rehabilitation and/or functional restoration apart from Veterans Affairs and Department of Defense facilities, down from a peak of nearly 1000 CARF-accredited facilities in 1999. Even if more facilities are accredited, there will remain a need for portable form of self-management support such as PTSM that can be adapted to both pain specialty settings and primary care settings.

4. Primary audience for new PTSM platform

- A. The primary and initial audience for PTSM will be specialty care patients with chronic pain. In the UW Center for Pain Relief total= 5500 patients; in US specialty pain care approximately= 20M patients, (based on 20% of 100M patients with chronic pain according to IOM report)³
- B. Another important audience for PTSM are primary care patients prescribed long-term opioid OR non-opioid analgesics for chronic pain. Local estimates based on 2012 data from the UW Neighborhood Clinics indicated ~10,000 long-term opioid therapy patients, as well as ~30,000 non-opioid long-term analgesic patients. . National estimate of US long-term opioid therapy patients is 20M patients, US long-term non-opioid analgesic patients 40M (based on figures in the IOM report). All long-term analgesics carry dose-dependent safety risks that require close monitoring. Long-term analgesic therapy works most effectively and safely as part of a

multimodal and interdisciplinary treatment plan such as can be supported with PTSM. Hence the audience for PTSM includes at least the 40M long-term analgesic therapy patients in the US. While the patients who use long-term analgesics are the primary audience for PTSM, all patients who seek professional healthcare for chronic pain on an ongoing basis could benefit. This is estimated to be 20% of the U.S. primary care population.

- C. Health care payers and systems, as well as providers, patients, and families. Efficient multidimensional pain-related metrics provided by PainTracker have been recognized as valuable throughout the UW Medicine health system, including its Accountable Care Network which is now actively partnering with large regional employers, e.g. Boeing, Washington State Employees. The rise of Accountable Care Networks nationwide will increase in tracking and analyzing patient-reported outcomes of chronic pain care as provided by PTSM.

Objective A: User experience (UX) design & evaluation of PainTracker Self-Manager platform

Pain-Tracker Self-Manager will incorporate the treatment and outcome tracking capabilities of Basic PainTracker, while adding a set of web-based assessments and dashboards to support patient-self management in the context of the multimodal, interdisciplinary care recommended in the National Pain Strategy. Below we have provided a provisional outline of these assessments and dashboards, but all elements are subject to revision during the development process which will include patients and interdisciplinary providers at each step.

Assessments (multiple choice and free-text):

- *Patient pre-visit assessments*: includes both patient-reported outcomes and self-management engagement assessments with editable care plan
- *Provider post-visit assessments*: includes assessment of phase of patient engagement with Editable Care Plan including planned consultations, tests, treatments, treatment goals, and self-management strategies.
- *Nurse care manager assessments*: post-contact (in-person, phone) assessments of progress through tests and consultations, adherence to treatments, participation in self-management, summarized in Editable Care Plan

Dashboards (graphical displays summarizing assessments and patient's clinical situation adherent to visual communication design principles)

- *Patient dashboard*- includes PainTracker graphical/tabular output concerning treatments received and outcomes achieved plus new PainTracker Self-Manager elements: self-management phase and homework, care plan, graphical progress toward self-manager status. Printed copy provided post-visit, also available on-line.
- *Provider dashboard*- includes PainTracker graphical/tabular output concerning treatments received and outcomes achieved plus new PainTracker Self-Manager results of patient assessments, engagement and problem-solving scripts
- *Nurse care manager dashboard*- includes copies of patient and provider dashboards, sortable spreadsheet of all patients actively managed, editable care plan to share with providers, reminders to contact patients according to care plans and most recent outcome assessments, access to mobile text messaging to patients, Fitbit actigraphy data with self-reported outcomes

- *Outcomes/QI dashboard*- spreadsheet with all outcomes, demographics, clinical characteristics searchable and analyzable by patient, provider, clinic, clinical and PTSM care process, or clinical outcome. Programmable to generate monthly or quarterly reports with graphical displays.

PainTracker Self-Manager (PTSM) Resources for Skill Building By Phase Of Patient Engagement

PainTracker Self-Manager will be used as a tool to bind the providers and patient into a team focused on the promotion of patient empowerment and self-management. The nurse care coordinator will coordinate the team's efforts using the PTSM platform to support in-person and telephone contacts with the patient. These will occur in addition to regularly scheduled appointments with MD and PA providers. PTSM will be comprised of three components: 1) Basic PainTracker output concerning treatments, outcomes, alerts, 2) Self-management assessments and supports as described below, 3) Editable Care Plan that specifies planned: tests, consultations, medications, pain procedures, physical therapy/exercise, psychotherapy/behavioral activation. The nurse care coordinator will decide, in consultation with the team, which phase of patient engagement is most appropriate at a given time. As each new phase of engagement is opened, the earlier phases will remain open to be addressed as necessary, but the dashboards will highlight the more recent and most pertinent phase.

PTSM will engage, activate, and support patients in self-management utilizing strategies largely derived from Acceptance and Commitment Therapy (ACT). ACT is a flexible model of intervention with only three core components: 1) increasing patient's awareness, 2) helping them be open to their experiences, and finally 3) promote increase levels of activation in activities they value as a key goal of treatment. Guided by these simple principles ACT can make use of a variety of strategies and techniques to increase patient's quality of life and wellbeing. Such versatility makes ACT an excellent candidate to be adapted to technological means of healthcare delivery, like phone, website and smartphone. To date, ACT has been successfully delivered using technology. For example, among more than 400 smoking cessation apps in the market,⁴ an ACT smartphone app called SmartQuit is the only app for the general population that has shown its potential in a randomized controlled trial for smoking cessation.⁵ ACT has also been successfully delivered using the telephone,⁶ and the website.⁷ Furthermore, ACT's mechanism of change have been directly linked to outcomes in one of these technologically delivered ACT interventions.⁸

The American Psychological Association's Division of Clinical Psychology lists ACT for chronic pain as having "strong" research support, the highest possible positive grading. At present, the effectiveness of ACT for chronic pain has been investigated in a variety of settings, including various age groups (e.g., adolescents, adults, older adults), pain conditions, and levels of intensity (e.g., interdisciplinary and uni-disciplinary) – see the reviews of McCracken & Vowles (2014)⁹ and Vowles & Thompson (2011)¹⁰ for a detailed summary of the literature. Follow-up assessments show excellent maintenance of treatment gains up through follow-up periods of as long as three years post-treatment.¹¹⁻¹⁵ Importantly, and in relation to the present proposal, ACT for chronic pain has been successful in less intensive, self-help oriented interventions.^{16,17}

Basic Pain Tracker vs PainTracker Self-Manager Care Process

Tool	Assessments	Dashboards	Care Process
Basic PainTracker (screenshots in appendix)	Outcomes <ul style="list-style-type: none"> • Symptoms: pain, depression, anxiety, sleep • Function: general activity, enjoyment, selected activity, Oswestry, treatment satisfaction Treatments <ul style="list-style-type: none"> • Medications, opioid MED, overuse days, side effects, procedures, physical and psychotherapy, Alerts <ul style="list-style-type: none"> • opioid risk, suicidal ideation, PTSD, sleep apnea, prescription opioid difficulties 	Patient dashboard: <ul style="list-style-type: none"> • graphs of symptoms, function, sleep, satisfaction overlaid on table detailing treatments received Provider dashboard: <ul style="list-style-type: none"> • alerts, graphs of symptoms, function, sleep, satisfaction over table of treatments received, with scale and item totals 	<ul style="list-style-type: none"> • Completed online prior to each pain clinic appointment. • Copies provided to provider and patient at clinic visit. Discussed at visit.
PainTracker Self-Manager	<i>All of the above plus:</i> Patient pre-visit assessment (staged by phases of patient engagement) <ul style="list-style-type: none"> • collaborative definition of clinical problem and treatment goals • focus on psychological flexibility and values-based action • Self-management importance, confidence and skills • Self-management maintenance and internalization Provider post-visit assessment (staged by phases of patient engagement) <ul style="list-style-type: none"> • summary of patient phase • guidance w scripts to help engage patients • Editable Care Plan Nurse care manager (NCM) assessments: <ul style="list-style-type: none"> • post-contact (in-person, phone) assessments of progress through tests and consultations, adherence to treatments, participation in self-management, summarized in Editable Care Plan 	<i>All of the above plus:</i> Patient dashboard: <ul style="list-style-type: none"> • Patient-friendly summary of phase of engagement • Selected self-management skills and practice schedule Provider dashboard: <ul style="list-style-type: none"> • patient assessments, engagement and problem-solving scripts Nurse care manager (NCM) dashboard: <ul style="list-style-type: none"> • copies of patient and provider dashboards, • sortable spreadsheet of all patients actively managed, • editable care plan to share with providers, • reminders to contact patients according to care plans • most recent outcome assessments • Fitbit data graphed with self-reported outcomes • access to mobile text messaging to patients QI/Outcomes dashboard <ul style="list-style-type: none"> • all data from patient, provider, and care manager assessments in analyzable form 	<ul style="list-style-type: none"> • Completed online prior to or following each pain clinic appointment. • Copies provided to provider and patient at clinic visit. Discussed at visit. Also discussed with NCM between provider visits. • NCM may administer PTSM components as appropriate between provider visits.

Phase 1 Engage patients through collaborative definition of clinical problem and treatment goals

Patient assessment- completed via Web before each visit (or in clinic waiting room for those unable to complete at home)

1. Description of their clinical problem—free text verbatim
2. Treatment goals: cure, comfort, physical function (movement), cognitive function (thinking), social function (relating to others)—endorsement (yes/no) and ranking
3. Time frame of expected/needed improvement: hours, days, weeks, months, years
4. Checklist of possible competing urgent psychological or social concerns: suicide, paranoia, confusion; physical safety, housing, food, childcare, social isolation
5. Basic PainTracker with the following outcome assessments (see screenshots in appendix):
 - a. PEG¹⁸: 3-item pain measure adapted from the Brief Pain Inventory and validated in primary care that assesses: pain severity, pain interference with general activities and with enjoyment of life.
 - b. Personally-important activity disrupted by pain: single item assessing pain interference on 0-10 scale with an activity important to the patient
 - c. PHQ-9¹⁹: 9-item depression measure that follows DSM-V criteria and has become the standard measure of depression in primary care
 - d. GAD-7²⁰: 7-item anxiety measure that follows DSM-V criteria and has become the standard measure of anxiety in primary care
 - e. Oswestry Disability Index²¹: 11-item measure validated as a measure of function in low back pain and other musculoskeletal pain conditions
 - f. Sleep interference: two items assessing interference with getting to sleep and staying asleep adapted from Insomnia Severity Index²²
 - g. Overall quality of life: 10-item PROMIS Global Health ²³measure
 - h. Rate of overuse of pain medication in past month: 0-2, 3-4, ≥ 5 days/month
 - i. Pain medication most important side-effect and severity
 - j. Satisfaction with pain treatment: single-item 0-10 scale
 - k. The following items are screening tools administered only on the initial PainTracker, and then carried forward as alerts on subsequent PainTracker reports:
 1. Opioid Risk Tool (ORT)²⁴: 5-item measure validated for assessment of risk of aberrant behaviors with prescribed opioids
 2. Alcohol Use Disorders Identification Test-Consumption (AUDIT-C)²⁵: 3-item screen for problem alcohol use validated for use in primary care
 3. Primary Care PTSD Screen (PC-PTSD)²⁶: 4-item screen for PTSD validated- primary care
 4. STOP²⁷: 4-item screen for sleep apnea
 5. Prescription Opioids Difficulties Scale (PODS)²⁸: 16-item scale assessing psychosocial problems, opioid control concerns, helpfulness, taper desire for patients on long-term opioid therapy for chronic pain
 - l. The following treatments are assessed and tracked in Basic PainTracker:
 1. prescribed pain medications, total opioid daily dose in morphine equivalent dose (MED)
 2. pain injections or infusions
 3. physical therapy or psychotherapy initiation

After completing each assessment, the patient receives dashboard printout summarizing the above input in graphical format that he/she can bring to the appointment with provider. This

will essentially be a print version of the patient dashboard. This summary will also be emailed to the provider to make sure he/she sees a copy.

Provider dashboard provided at clinic visit-- summarizing patient-provided information

1. Patient description of clinical pain problem verbatim
2. Endorsed patient treatment goals, ranked
3. Time frame of improvement expected
4. Competing urgent social and psychological concerns
5. Tailored engagement scripts supplied to provider to help encourage transitions:
 - a. From definitive diagnosis to ruling out dangerous/progressive conditions
 - b. From cure/no pain to living better with pain
 - c. From short-term to long-term focus on effective living
 - d. Crisis management resources for urgent competing psychosocial concerns

Post-clinic visit assessment by provider:

1. Document consensus about clinical problem definition and treatment goals as achieved OR provide plan to resolve discrepancies concerning problem and goals
2. Editable Care Plan entered into PTSM and copied into Epic electronic health record note
3. Phase 1 assessments and scripts remain active until consensus achieved

Post-clinic visit dashboard for patient

1. Basic PainTracker printout plus description of clinical problem and treatment goals
2. Homework tasks with timeframe, plans for any urgent psychological or social concerns
3. Appended to Epic Electronic Health Record post-visit summary with return clinic date

Nurse care manager dashboard for coordination of care between clinic visits

1. Current patient and provider dashboards including Basic PainTracker printout plus consensus description of clinical problem and treatment goals
2. List of issues that need to be resolved before patient can be effectively engaged in self-management: medical diagnostic questions, diagnostic or treatment procedures, lack of consensus on clinical problem or treatment goals, urgent psychological (suicide, psychosis, dissociation) or social (violence, homelessness, isolation) concerns.
3. Editable Care Plan: planned tests, treatments, consultations, medications, physical/psych therapies

Phase 2: Facilitate patient values-based action and pain acceptance

Patient assessment before visit

I. Values Based Action (assessed by Chronic Pain Values Inventory (CPVI)²⁹)

- a. Consider each area according to your values, the IMPORTANCE at living ways that you most want to live your life in each domain your values (rated 0= not at all, 5=extremely)
- b. Consider each area according to your values, the SUCCESS at living ways that you most want to live your life in each domain your values (rated 0= not at all, 5=extremely)
- c. Patients rate each of the following domains: Family, Intimate relations, Friends, Work, Health, Growth and learning according to Importance and Success at living how they value

II. Barriers to pain acceptance (assessed by STarT Back Tool³⁰ screening questions for fear/avoidance and catastrophizing (agree/disagree)

1. It is really not safe for a person with a condition like mine to be physically active.
2. I feel that my pain is terrible and that it's never going to get any better.

III. Values based action: selection of valued activity for tracking and targeted restoration
Patient will be asked to pick one of 6 domains from above Chronic Pain Values Inventory to work on, with progress tracked within PTSM. Items rated 1 (*Not at all*) to 10 (*Most possible*).

- a. “Rate how effective you were in taking actions that contributed to a better, more vital, quality of living in the past week” (Values Tracker)³¹
- b. “Rate how effective you were this past week in making progress in the areas of your life that matter to you” (Values Progress).

Patient dashboard to bring to clinic visit

Summarizes Phase 1 issues: clinical problem, treatment goals and timeframe, barriers

Summarizes Phase 2 issues: what is important to me, what can I do to achieve this despite pain

Provider dashboard available at clinic visit

Promoting pain acceptance- scripts stratified by CPVI into 3 groups: progressing toward valued activities, no progress, regressing

Countering movement fear- script including PT referral and suggested PT orders

Countering catastrophizing- CBT overgeneralization script, stratified by depression level

Values based action: making a plan to increase valued activity tracked in PainTracker

Post-clinic visit assessment by provider:

Confirm consensus on problem and goals achieved OR plan to resolve discrepancies

Assess patient’s pain acceptance and valued action focus as concrete and feasible

Editable Care Plan: planned tests, treatments, consultations, medications, physical/psych therapies

Post-clinic visit dashboard for patient

Basic PainTracker printout plus consensus description of clinical problem and treatment goals

Editable Care Plan: planned tests, treatments, consultations, medications, therapies

Summary of acceptance status, goals for treatment and activity goals

Homework tasks with timeframe, plans for any urgent psychological or social concerns

Appended to Epic post-visit summary with return clinic date and medication instructions

Nurse care manager dashboard

Updated Basic Pain Tracker plus Phase 1 PTSM components above

Phase 2 personally selected important activity from PainTracker, scores from CPVI, STarT Back

Editable Care Plan planned tests, treatments, consultations, medications, therapies

Phase 3: Promote patient pain-self-management skills through web-based education and mobile text messaging (with FitBit actigraphy monitoring for patient subset)

Patient assessment before visit

Ratings of importance and confidence and barriers concerning core self-management skills:

activity pacing, relaxation training, active pain coping, pain flare survival, pacing, safe opioid/non-opioid use. Repeat assessments of problem areas from Phase 1 and 2

Provider dashboard at visit

Guidance in helping patient select self-management skills to learn, explanation of role of self-management in the overall treatment plan

Problem solve barriers to self-management in light of assessments obtained in Phase 1 and 2

Editable Care Plan

Patient dashboard after visit

Selected self-management strategies to learn with instructions for each, solutions for barriers
Nurse care coordinator dashboard

Selected self-management strategies to learn with instructions for each, text messages to and from patient to assess and reinforce use of self-management strategies; barrier solutions
 Editable Care Plan: with any pending consultations or tests with dates

Patients will receive assessments, prompts, and skill practice guidance through visits with nurse care coordinator and between visits with nurse through mobile text messaging.

Subset of patients will provide observed activity, exercise and sleep data through FitBit Charge to be integrated with PTSM self-report data in nurse care manager and provider dashboards.

Nurse care manager will assist, problem-solve, and monitor self-management importance, confidence and skill development

Phase 4: Maintain self-management skills through autonomy support and skills refreshers

Patient assessment before visit

Will rate progress on resumption of valued activity and describe barriers to further progress
 Will select possible long-term goals in role function

Provider dashboard at visit

Will review progress on valued activity and problem solve concerning barriers
 Will explore role function goals while supporting autonomy, competence, relatedness
 Will continue to track outcomes, treatments and self-management strategies through PTSM

Nurse care manager between clinic visits to providers

Will continue to support resumption of valued activity and role function with refresher plans
 Will provide prompts and reminders to patients through mobile text messaging
 Will select peers for mutual support through PTSM web and mobile interfaces

Phase 5: Analyze PTSM data through registry for provider, clinic, and health system wide data on clinic treatments, patient self-reported and observed outcomes, and patient engagement in self-management

The convenience of web and mobile PTSM assessments should result in high rates of assessment completion, which will provide clinically useful and actionable data to both providers and patients. Once collected, these data will be gathered into a registry that will provide data to monitor not only patient outcomes, but provider-specific and clinic-wide performance on a wide array of outcome measures. *This final phase makes patient-engagement a clinic-wide goal and a measurable focus of Quality Improvement efforts. It makes PTSM part of a "learning health care system."*

Project design and methods

PTSM platform prototype design, development and refinement with four types of users

PTSM implementation builds on three years of experience by the investigators with PainTracker^{32,33}, a web based tool for management of chronic pain. PainTracker is based on a UW-developed, open source, HIPAA-compliant, web/mobile platform for Computerized Patient Reported Outcomes, (cPRO) (<http://cprohealth.org>). Over the past 12 years, cPRO has been the basis for over 30 patient-centered PRO assessments, used in inpatient and outpatient settings for both research and "usual care", and deployed through about a dozen medical centers across the country. The cPRO platform has been used for applications in the domains

of cancer, HIV, mental health, chronic pain, general surgery and orthopedic injury and is actively developed by Dr Lober's Clinical Informatics Research Group.

Rapid development and deployment of PTSM will be achieved by extending the established PainTracker system to include the new content and dashboards described above, using a three step participatory design process that engages both patients and providers from the Center for Pain Relief. Patients will be recruited from graduates of Self-Management Class. Providers will be recruited from the multiple physician specialties and advance practice providers in the clinic.

Step 1 – User-centered Design: Low-fidelity prototypes of the PTSM platform will be developed based on the specifications for the intervention. These “wireframes”, and “storyboards” depicting their sequence, will be used to test PTSM content, interaction design, and dashboards with two focus groups, one comprised of project investigators and close collaborators (pain physician/psychiatrist, psychologist, nurse care manager, outcomes researcher, physician/informatics expert) and the other of patient collaborators. These focus groups will consist of 5-8 individuals,³⁴ and be conducted according to standard practices.^{35,36} The prototypes will be presented using scenario-based use-cases, or simple narrative stories which describe how the system will be used. Facilitated discussion among the group will elicit how well the prototypes reflect user goals, needs, and concerns. Participant feedback will be incorporated into design and development decisions as we enhance PainTracker to form the web-based, functional PTSM system for testing and deployment.

Step 2 -- Usability testing: The ability of the intervention to meet both patients' and providers' expectations, and to be used correctly, will be assessed through usability testing. The use cases from Step 1 will guide both types of users through directly observed testing using the Thinking-Aloud Protocol (TAP), which is the most widely used research method for resolving usability issues. We will engage the same 5-8 individuals who participated in each of the patient and provider focus groups. Research suggests that testing with 5 participants identifies 85% of usability issues.^{37,38} In TAP, users sit individually with a facilitator, in a laboratory setting, and carry out a specified set of tasks while describing aloud their reasoning and actions. The facilitator prompts the participant as needed and notes any difficulties that the participant has with the tasks. Usability testing will assess ease of use, relevance and appeal, efficiency, error frequency and severity, and subjective satisfaction with PTSM as. Iterative improvements will be performed based on usability testing before the product is ready for launch.

Step 3 -- Workflow testing: Providers' use of PTSM in the clinical environment, and of patients' use of PTSM on the device of their own choosing, will be assessed through use of Contextual Design methods.^{39,40} Contextual inquiries are direct observation of users within their environment and as part of their workflow. Our focus group participants will be observed in their own usage contexts: providers in the Center for Pain Relief, and patients using a Mac or Windows PC, or using their own tablet or smartphone. TAP is used in conjunction with the use cases to focus on determining barriers providers may encounter based on their workflow, and on other clinical systems and tasks. Patient testing focuses on barriers encountered in using PTSM in the context of their own devices. Our team has deployed cPRO systems in over 30 clinical and research settings, about half of which have been within the UW Medicine inpatient or outpatient settings. We are very familiar with the processes of moving these systems into production use by patients, and operating and maintaining them consistent is a safe and

reliable way, which we will do for the duration of the project. The information obtained during workflow testing helps ensure a smoother implementation for providers and better access for patients in this particular setting.

Data for analysis We will implement both assessment, dashboard and data extraction features within the cPRO system, to facilitate both monitoring of the usage and outcomes across the system as it is deployed in routine use, and to simplify the at-will extraction of a data set for analysis both of data quality and outcomes. The data are extracted in a standard format (one or more CSV or XML files).

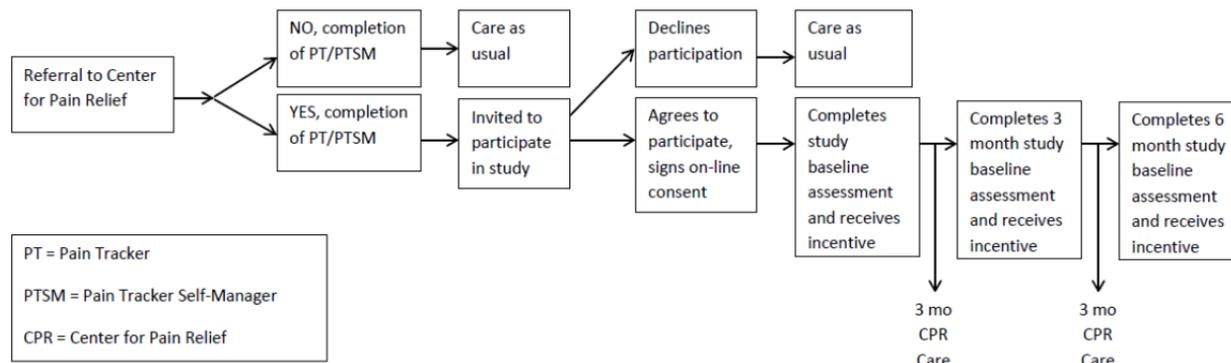
Clinical workflow using the PainTracker Self-Manager (PTSM) platform will involve both patient-provider clinic visits AND separate patient-nurse care manager visits that will occur in clinic or over the phone. In current clinical practice, Basic PainTracker is administered over the web prior to clinic visits. We will continue this practice with PainTracker Self-Manager, but the nurse care manager can elect to have the patient fill out PTSM components between visits. Following their initial clinic visit, patients will be contacted by the nurse care manager to schedule an intake visit, which can occur in the clinic or over the phone. The nurse care manager will have access to patient and provider dashboards. Depending on patient need and desire, contacts between nurse and patient will be scheduled no more frequently than once per week and no less frequently than once per month. The nurse care manager will be supplied with a library of resources to support patient engagement (Phases 1 and 2) and patient self-management (Phases 3 and 4). The nurse care manager will be supervised weekly by Drs. Sullivan and Vilardaga, with monthly participation by Dr. Vowles. PTSM deployment during the trial will be discussed monthly at the regular meeting at 7AM on Monday mornings at UW Center for Pain Relief.

Objective B: Clinical trial of care supported with PainTracker Self-Manager compared to care supported with Basic PainTracker

Evaluation design

Inclusion criteria: All new or returning patients having a diagnosis for one or more chronic pain disorders and planning ongoing pain care by providers at UW CPR, (not one-time consults, not procedure only patients) will be invited to participate in the study after completing their initial PainTracker or PainTracker Self-Manager assessment. Those who agree will complete informed consent, outcome assessments, and receive incentive payment. Those who do not complete PainTracker or PainTracker Self-Manager will receive care as usual through UW CPR. During the study periods, PainTracker or PainTracker Self-Manager will be collected prior to clinic visits, as is currently done. Subjects will receive emails with links to the PainTracker website and asked to complete the measure before coming to clinic. Those who do not complete PainTracker at home will be asked to complete it in the clinic waiting room. The timing of PainTracker completion is tied to the timing of clinic visits and will therefore not be the same for all patients. However, outcome measures will be collected for all subjects at baseline, 3 and 6 months after baseline. The nurse care manager can customize PTSM to allow for collection of any or all measures between clinical visits. All data will be collected via the web platform for PTSM. Outcome measures for this study will be appended to the PainTracker and PainTracker Self-Manager. The primary outcome will be patient activation, supplemented by secondary outcomes of engagement, pain-related self-efficacy, patient-provider communication, and both patient and provider satisfaction with the PTSM platform. **See study design schematic below.**

A. PT/PTSM Study Design



B. Outcomes

Primary Outcome:

- Patient Activation Measure (PAM)^{41,42}. The PAM is a 22-item survey that assesses the knowledge, skills and confidence for managing one's own health and healthcare. It segments survey respondents into one of four progressively higher activation levels: (1) believing the patient role is important, (2) having the confidence and knowledge necessary to take action, (3) actually taking action to maintain and improve one's health, and (4) staying the course even under stress. Previous studies with web-based interventions have been able to produce improvement on the PAM with a medium effect size ($r=0.2$)⁴³. We expect a larger effect size with a combined web/mobile/in-person intervention.

Secondary Outcomes:

- Chronic Pain Acceptance Questionnaire (CPAQ)⁴⁴ is an 8-item survey of (1) engagement in life activities regardless of pain and (2) willingness to experience pain.
- Pain self-efficacy questionnaire (PSEQ)^{45,46} is a 10-item survey assessing patients' self-efficacy with respect to their pain.
- Perceived efficacy in patient-physician interactions (PEPPI)⁴⁷ is a 10-item survey measuring patients' self-efficacy in obtaining medical information and attention to their medical concerns from physicians
- Patient satisfaction with care process and with PTSM specifically
- Provider satisfaction with care process and with PTSM specifically

Other exploratory outcomes:

- PainTracker outcome measures³² (pain, mood, function, sleep, global health)
- FitBit Actigraphy-documented physical activity (on subset of patients willing to wear these)
- Number of contacts with providers, nurse care manager (in-person and phone)
- Number of patients and providers in each phase of PTSM development and deployment

C. How data collected and analyzed

Data will be collected using the Basic PainTracker and PainTracker Self-Manager platforms. These will be augmented with the study outcome measures for the duration of the trial. First, a cohort of 50 patients will be treated and assessed with Basic PainTracker. These patients will be recruited over 3 months (4 patients per week) and followed for 6 months. This will occur while

PTSM is being developed and refined. (see timeline below). After the PainTracker cohort is treated and assessed and after PTSM is finalized, another cohort of 50 patients will be treated and assessed with PTSM. We will assess engagement with both primary and secondary patient-reported outcomes defined above, as well as exploratory outcomes such as actigraphy data and computer-tracked data on usage of the PTSM web-based and mobile platform, including data input and dashboard use.

Longitudinal mixed model regression analyses will be performed to determine if the outcomes change differentially over time for the study groups after controlling for relevant covariates. These analyses are intent to treat and have the advantage of allowing the use of correlated data, and data where observations may be missing. Therefore all patient data will be utilized in the analyses. With three assessments and 50 people in each group, and assuming a two tailed alpha of 0.05, constant correlations across time of 0.70, we will have 80% power to detect a moderate effect size of .54 for examining differential changes between the groups on the outcome variables over time in the mixed models. Data will be collected on all enrolled patients at enrollment and at 3-months and 6-months after enrollment into the basic PainTracker or PTSM program. The historical control consists of a consecutive cohort of patients at the Center for Pain Relief undergoing usual care without PTSM

D. Methods used to control for bias and confounders

Due to limitations in time and budget for the study, we will use a non-randomized historical control design for the trial. Methodological challenges may arise from the use of this design, which include: 1) selection bias, 2) treatment group non-comparability, and 3) temporal bias. Selection bias: In both the PT and PTSM phases of the study, study participants will be limited to those who complete the baseline version of PT or PTSM. This will limit the external validity or the generalizability of our findings to those patients willing and able to complete web-based assessments. However it will allow us to compare longitudinal effects of PT and PTSM between groups that have the technology and the willingness for this type of intervention. This design is appropriate for the study because the research question focuses on the development, implementation and preliminary testing of a patient empowerment tool.

Treatment group non-comparability: Without randomized assignment to treatment groups, it is always possible that the treatment groups will be comprised of patients that differ on important variables. Prior to any statistical analyses, we will examine group differences in patient demographic and clinical characteristics. However, because we will study the PT control sample immediately preceding the PTSM intervention sample and in the same clinic, it is unlikely that the type of patients enrolled will be significantly different. Any significant differences will be used as covariates in the analyses along with baseline outcome measures. We have chosen not to randomize patients because: a) we do not have enough time during the 24-month period of the grant to both develop the PTSM platform and conduct a randomized trial with an adequate number of subjects, and b) randomizing at the patient level would lead to considerable contamination of the treatment received by the PT control group with the strategies and concepts introduced to the providers and nurse care coordinator for the PTSM intervention group. A propensity score comprised of baseline measures that differ between the PT and PTSM groups may be used to assess for group differences and adjust for them in statistical models.

Temporal bias Historical controls will be collected during Phase 1 of the study, while the PTSM platform is being developed and tested. Temporally, this will be roughly 3-to-6 months before launch of PTSM and recruitment of the treatment groups. Given the consecutive nature of data collection in the historical control group and the treatment group, we can reasonably anticipate that there will be no confounds due to changes in medical practice, standards of care, or clinic workflow and policy.

E. Detailed workplan and deliverables schedule

TASKS	Months							
	1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24
Aim 1: Pain Tracker Self-Manager (PTSM) development	■	■	■					
Aim2a: Basic PainTracker (control group) data collection		■	■	■				
Aim2b: PainTracker Self-Manager (intervention group) data collection				■	■	■		
Data Analysis & Reporting							■	■

Aim 1 (9/1/2015- 5/31/2016): 9 month PTSM development period. Deliverable is the PainTracker Self-Manager platform as designed through a collaborative process with patients and providers, iteratively refined with feedback at storyboard, prototype, and fully functional stages, and with demonstrated usability and clinical feasibility. **Deliverable: Usable and feasible PainTracker Self-Manager platform**

Aim 2a (12/1/2015- 9/1/2016): 9 mo data collection on effects of Basic PainTracker on study outcomes. This data collection will occur simultaneously with above PTSM development. We will be able to recruit our proposed sample of 50 patients if we recruit 2 patients per week. **Deliverable: Data on effect of Basic PainTracker on study outcomes: patient activation, self-efficacy, satisfaction, etc.**

Aim 2b (6/1/2016- 5/31/2017): 9 mo data collection on effects of PainTracker Self-Manager on study outcomes. This data collection will occur simultaneously with the final months of collecting outcomes on the Basic PainTracker Cohort. We will be able to recruit our proposed sample of 50 patients if we recruit 2 patients per week. **Deliverable: Data on effect of PainTracker Self-Manager platform on study outcomes: patient activation, self-efficacy, satisfaction, and exploratory outcomes.**

Data analysis and reporting (3/1/2017- 8/31/2017): Data on PTSM development, implementation, and testing will be assembled and analyzed. Papers for professional journals will be prepared. Dissemination through the University of Washington's Training XChange will be arranged. Grant proposals for further testing of PTSM in primary care settings will be prepared. **Deliverable: scientific papers published in peer-reviewed journals, PTSM dissemination plans, studies, and grants.**

PainTracker Instruments

PEG (Pain Severity, Enjoyment of Life, General Activity): Baseline & follow-up ***Sleep Quality (Staying/Falling Asleep): Baseline & follow-up***

We realize that some of the questions might not address your exact situation, but we encourage you to answer them to your best ability.

Please rate your pain by choosing the one number that best describes your pain on **average**, in the last week

0 1 2 3 4 5 6 7 8 9 10
 ← No pain Pain as bad as you can imagine →

Your pain may limit activities that are very important to you (e.g., sport activities, walking, working). We hope your treatment will make it easier for you to do these important activities. Please answer these following questions on your current state compared to pre-injury.

Fill in the circle of the one number that describes how, **during the past week, pain has interfered** with your:

	← Does not interfere						Completely interferes →				
	0	1	2	3	4	5	6	7	8	9	10
General activity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>						
Enjoyment of Life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>						
Falling asleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>						
Staying asleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>						

Important Activity Difficulty: Baseline & follow-up

Please list one important activity that is difficult for you to perform so that we can monitor it during your treatment.

How would you rate the **difficulty** you have had **doing this activity** over the past week? Can do with ...

0 1 2 3 4 5 6 7 8 9 10
 ← No difficulty Extreme difficulty →

Pain Diagram: Baseline & follow-up

Which Areas of Your Body Are Painful?

On the diagrams below of the front and back of the body, choose which areas have pain.

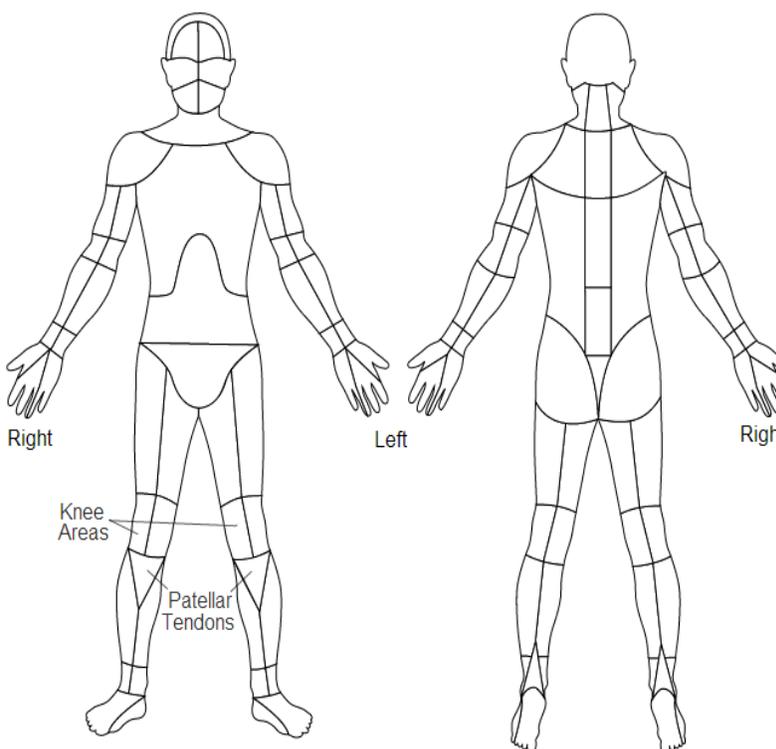
- Click on the area with the worst pain—it will turn red.
- Click on any additional areas that have pain—they will turn yellow.
- If you made a mistake, click on the "Clear Areas" button to start over.
- When you're done, click the "Next" button at the bottom to continue.

Worst Pain Area: Not selected

Other Pain Areas: None selected

Made a mistake?

Clear Selected Areas



PHQ-9: Baseline & follow-up

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling down, depressed, or hopeless	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble falling or staying asleep, or sleeping too much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling tired or having little energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Poor appetite or overeating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling bad about yourself - or that you are a failure or have let yourself or your family down	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble concentrating on things, such as reading the newspaper or watching television	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thoughts that you would be better off dead or of hurting yourself in some way	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Panic Item

In the last 4 weeks, have you had an anxiety attack (a sudden feeling of fear or panic?)

- Yes
 No

GAD-7: Baseline & follow-up

Over the last 2 weeks, how often have you been bothered by the following problems?

	Not at all	Several days	Over half the days	Nearly every day
Feeling nervous, anxious, or on edge	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not being able to stop or control worrying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Worrying too much about different things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble relaxing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being so restless that it's hard to sit still	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Becoming easily annoyed or irritable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling afraid as if something awful might happen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

PC-PTSD: Baseline only

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past month, you:

	Yes	No
Have had nightmares about it or thought about it when you did not want to?	<input type="radio"/>	<input type="radio"/>
Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?	<input type="radio"/>	<input type="radio"/>
Were constantly on guard, watchful, or easily startled?	<input type="radio"/>	<input type="radio"/>
Felt numb or detached from others, activities, or your surroundings?	<input type="radio"/>	<input type="radio"/>

PROMIS Global Health: Baseline and follow-up once every 3 months

PROMIS-GLOBAL-1

Please respond to each item by marking one answer per row

	Poor	Fair	Good	Very good	Excellent
In general, would you say your health is...	<input type="radio"/>				
In general, would you say your quality of life is...	<input type="radio"/>				
In general, how would you rate your physical health?	<input type="radio"/>				
In general, how would you rate your mental health, including your mood and your ability to think?	<input type="radio"/>				
In general, how would you rate your satisfaction with your social activities and relationships?	<input type="radio"/>				
In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	<input type="radio"/>				

AUDIT-C: Baseline only

Alcohol Use

Please tell us about your use of alcohol:

How often do you have a drink containing alcohol?

- Never
 Monthly or less
 2-4 times a month
 2-3 times a week
 4 or more times a week

How many standard drinks containing alcohol do you have on a typical day?

- I don't consume alcohol, or I consume less than 1 drink a month
 1 or 2
 3 or 4
 5 or 6
 7-9
 10 or more

How often do you have six or more drinks on one occasion?

- Never
 Less than monthly
 Monthly
 Weekly
 Daily or almost daily

Procedures (Injections, Physical Therapy, Psychological Therapy: Baseline & follow-up)

Your Procedures

Please enter dates for procedures you've undergone as part of getting treatment for your pain/injury:

- Injections
- Start of physical therapy
- Start of psychological therapy

If you don't remember the exact date, please make your best guess. If none of these apply to you, you can skip this question.

Your Procedures

You haven't added any procedures.

Add New Procedure

Past Treatment History: Baseline only

TRT-1

To the best of your recollection, how many different healthcare providers have you seen in the LAST 6 MONTHS for your pain?

General Practice physicians (e.g., family medicine, internal medicine)

- 0 3 6 9
 1 4 7 10
 2 5 8 More than 10

Medical Specialists (e.g., rheumatologist, allergy specialist, immunologist)

- 0 3 6 9
 1 4 7 10
 2 5 8 More than 10

Pain Specialists

- 0 3 6 9
 1 4 7 10
 2 5 8 More than 10

Surgical Specialists

- 0 3 6 9
 1 4 7 10
 2 5 8 More than 10

TRT-2

To the best of your recollection, how many different healthcare providers have you seen in the LAST 6 MONTHS for your pain?

Psychologists, Psychiatrists and other mental health professionals

- 0 3 6 9
 1 4 7 10
 2 5 8 More than 10

Physical Therapists

- 0 3 6 9
 1 4 7 10
 2 5 8 More than 10

Complementary and Alternative healthcare professionals (e.g., naturopath, massage therapist, acupuncturist)

- 0 3 6 9
 1 4 7 10
 2 5 8 More than 10

TRT-3

To the best of your recollection, how effective were the following treatments for your pain in the LAST 6 MONTHS?

Exercise, physical therapy or occupational therapy?

- Did not have this type of treatment
 It was very effective
 It was moderately effective
 Not at all effective

Physical modalities such as heat, massage, or TENS?

- Did not have this type of treatment
 It was very effective
 It was moderately effective
 Not at all effective

Any behavioral treatment such as cognitive behavioral therapy, distraction, or relaxation?

- Did not have this type of treatment
 It was very effective
 It was moderately effective
 Not at all effective

TRT-4

To the best of your recollection, how effective were the following treatments for your pain in the LAST 6 MONTHS?

Non-opioid medications such as non-steroidal anti-inflammatory medications (like Motrin, Advil, ibuprofen, Celebrex) or "neuropathic pain medications" (like Neurontin, Lyrica, Cymbalta, other anti-depressant)?

- Did not have this type of treatment
 It was very effective
 It was moderately effective
 Not at all effective

Alternative therapies such as acupuncture, hypnosis, yoga or meditation?

- Did not have this type of treatment
 It was very effective
 It was moderately effective
 Not at all effective

Oswestry Disability Index: Baseline & follow-up

Pain and Everyday Activites - Page 1

This questionnaire has been designed to give us information as to how your pain has affected your ability to manage everyday life activities. Please answer every section, and **mark in each section the one box that applies to you**. We realize you may consider that two of the statements in any one section relate to you, but please just mark the box that most clearly describes your present-day situation.

Pain Intensity

- My pain is mild to moderate; I do not need painkillers.
- The pain is bad, but I manage without taking painkillers.
- Painkillers give complete relief from pain.
- Painkillers give moderate relief from pain.
- Painkillers give very little relief from pain.
- Painkillers have no effect on the pain.

Lifting

- I can lift heavy weights without causing extra pain.
- I can lift heavy weights, but it gives me extra pain.
- Pain prevents me from lifting heavy weights off the floor, but I can manage if items are conveniently positioned, i.e. on the table.
- Pain prevents me from lifting heavy weights, but I can manage light weights if they are conveniently proportioned.
- I can lift only very light weights.
- I cannot lift or carry anything at all.

Sitting

- I can sit in any chair for as long as I like.
- I can sit in my favorite chair only, but for as long as I like.
- Pain prevents me from sitting for more than 1 hour.
- Pain prevents me from sitting for more than 1/2 hour.
- Pain prevents me from sitting for more than 10 minutes.
- Pain prevents me from sitting at all.

Personal Care (Washing, Dressing, etc.)

- I can look after myself normally without causing extra pain.
- I can look after myself normally, but it causes extra pain.
- It is painful to look after myself, and I am slow and careful.
- I need some help but manage most of my personal care.
- I need help every day in most aspects of self-care.
- I do not get dressed. I wash with difficulty and stay in bed.

Walking

- I can walk as far as I wish.
- Pain prevents me from walking more than 1 mile.
- Pain prevents me from walking more than 1/2 mile.
- Pain prevents me from walking more than 1/4 mile.
- I can walk only if I use a cane or crutches.
- I am in bed or in a chair for most of every day.

Standing

- I can stand as long as I want without extra pain.
- I can stand as long as I want, but it gives me extra pain.
- Pain prevents me from standing for more than 1 hour.
- Pain prevents me from standing more than 1/2 hour.
- Pain prevents me from standing more than 10 minutes.
- Pain prevents me from standing at all.

Pain and Everyday Activites - Page 2

This questionnaire has been designed to give us information as to how your neck pain has affected your ability to manage everyday life activities. Please answer every section, and **mark in each section the one box that applies to you**. We realize you may consider that two of the statements in any one section relate to you, but please just mark the box that most clearly describes your present-day situation.

Sleeping

- Pain does not prevent me from sleeping well.
- I sleep well, but only when taking medication.
- Even when I take medication, I sleep less than 6 hours.
- Even when I take medication, I sleep less than 4 hours.
- Even when I take medication, I sleep less than 2 hours.
- Pain prevents me from sleeping at all.

Traveling

- I can travel anywhere without extra pain.
- I can travel anywhere, but it gives me extra pain.
- Pain is bad, but I manage journeys over 2 hours.
- Pain restricts me to journeys of less than 1 hour.
- Pain restricts me to necessary journeys under 1/2 hour.
- Pain prevents traveling except to the doctor/hospital.

Social Life

- My social life is normal and causes me no extra pain.
- My social life is normal, but increases the degree of pain.
- Pain affects my social life by limiting only my more energetic interests, such as dancing, sports, etc.
- Pain affects my social life, and I do not go out as often.
- Pain has restricted my social life to my home.
- I have no social life because of pain.

Changing Degree of Pain

- My pain is rapidly getting better.
- My pain fluctuates but overall is definitely getting better.
- My pain seems to be getting better but improvement is slow at present.
- My pain is neither getting better nor worse.
- My pain is gradually worsening.
- My pain is rapidly worsening.

PODS: Baseline only

PODS-1

In the past 2 WEEKS...

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Opiate medicines have caused me to lose interest in my usual activities.	<input type="radio"/>				
Opiate medicines have caused me to have trouble concentrating or remembering.	<input type="radio"/>				
Opiate medicines have caused me to feel slowed down, sluggish or sedated.	<input type="radio"/>				
Opiate pain medications have caused me to feel depressed, down, or anxious.	<input type="radio"/>				

PODS-2

In the past 2 WEEKS...

	Never	Rarely	Sometimes	Often	Always or Almost Every Day
How often have side effects of opiate medicine interfered with your work, family or social responsibilities?	<input type="radio"/>				
How often did opiate medicine make it hard for you to think clearly?	<input type="radio"/>				

PODS-3

In the past year, about how many times did opiate medicines make you sleepy or less alert when you were driving, operating machinery or doing something else where you needed to be alert?

- Never
 Once or Twice
 Three or More Times

Considering the side effects of opiate medicines you experienced *in the past month*, how bothersome were these side effects?

- Not at All Bothersome
 A Little Bothersome
 Moderately Bothersome
 Very Bothersome
 Extremely Bothersome

PODS-4

In the past 2 weeks I have been preoccupied with or thought constantly about use of opiate pain medicines.

- Strongly Disagree
 Disagree
 Neutral
 Agree
 Strongly Agree

PODS-5

In the past YEAR...

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I have felt that I could not control how much or how often I used opiate medicine.	<input type="radio"/>				
I have needed to use a higher dose of opiate pain medicine to get the same effect.	<input type="radio"/>				
I have worried that I might be dependent on or addicted to opiate pain medicines.	<input type="radio"/>				
I have wanted to stop using opiate pain medicines or to cut down on the amount of opiate medicines that I use.	<input type="radio"/>				
Opiate medicines have caused me to have problems with family, friends or co-workers.	<input type="radio"/>				
Family or friends have thought that I may be dependent on or addicted to opiate pain medicines.	<input type="radio"/>				

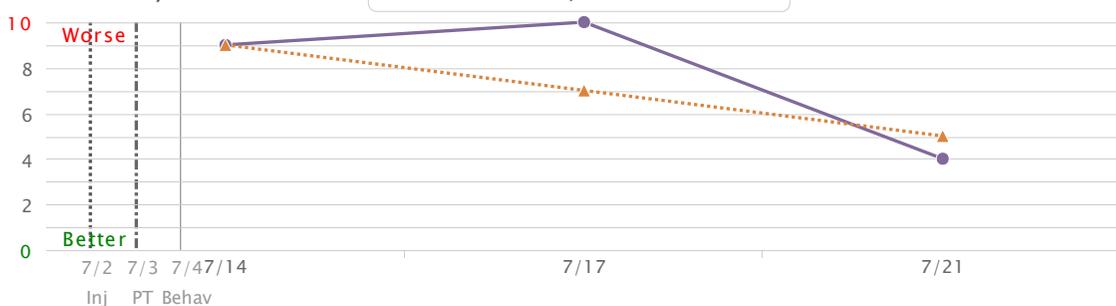
ORT Score	25 (0-26)	⚠️
AUDIT-C	9 (0-12)	⚠️
PHQ-9	13 (0-27)	⚠️
SI	1 (0-3)	⚠️
PTSD	4 (0-4)	⚠️
STOP	0 (0-4)	
Opioids		
Problems	High	⚠️
Concerns	High	⚠️
Helpfulness	No	
Taper	Yes	

Printed: 8/19/2014
Last Completed Session: 7/21/2014 10:27pm

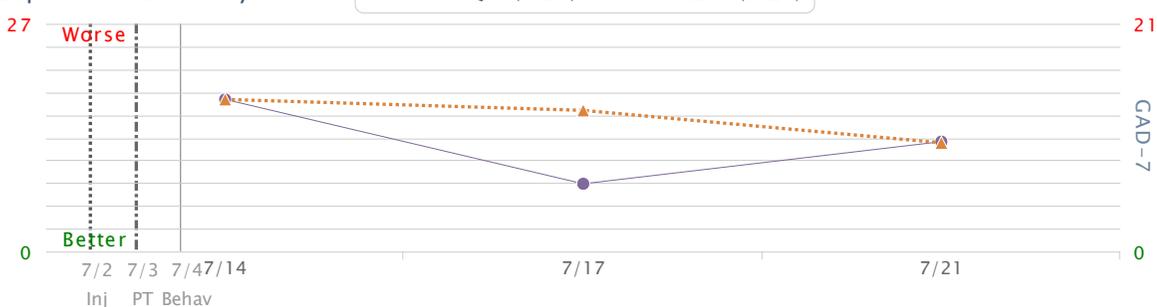


Patient-reported Current Treatments	
..... Injection	7/2/2014
----- Started Physical Therapy	7/3/2014
———— Started Behavioral Therapy	7/4/2014

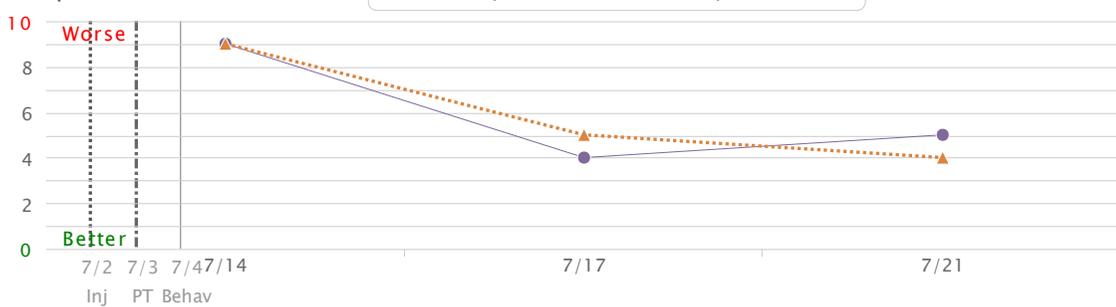
Pain Intensity & Interference



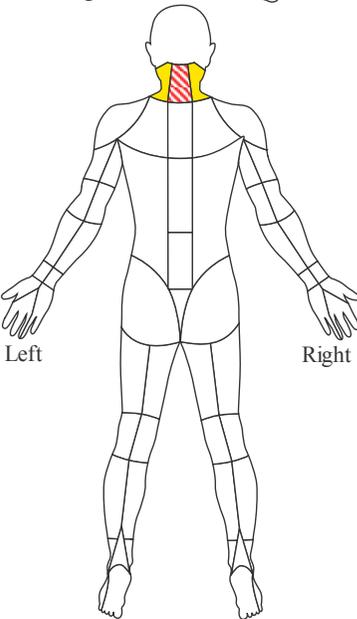
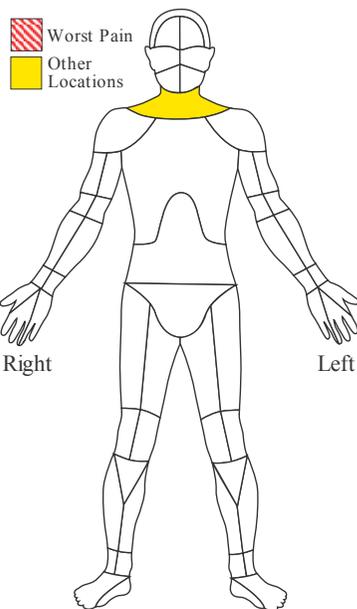
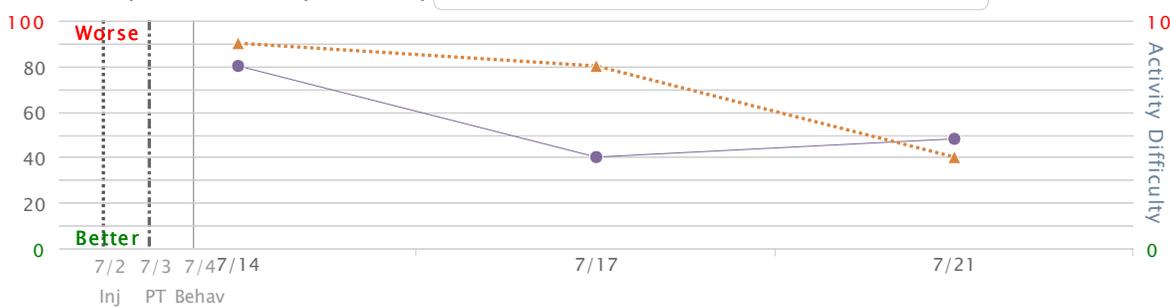
Depression & Anxiety



Sleep Initiation & Maintenance



ODI & Important Activity Difficulty



PT.NO: Test
071414A, 071414A
DOB: 1976-07-04 SEX: M

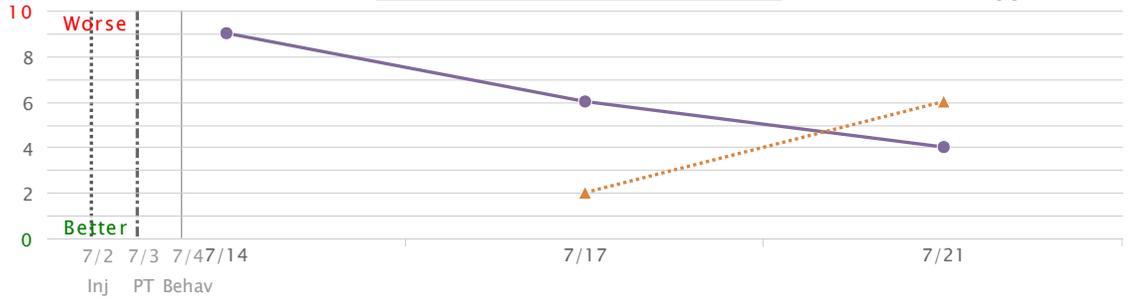
Most Bothersome Side Effect
(From most recent assessment)

dizziness

QOL & Satisfaction

Quality of Life Satisfaction

83



	7/14	7/17	7/21
Days w/ Excess Meds (past month)	3 - 4	1 - 2	1 - 2
Important Activity	Walking briskly	sitting down	walking

Prior Treatment History (In last 6 months—reported in initial assessment)

Providers Seen	
Primary Care	9
Pain Specialists	9
Surgical Specialists	9
Medical Specialists	9
Psychologists/Psychiatrists	9
Physical Therapists	9
Complementary/alt Medicine	9

Treatment Effectiveness	
Phys/Occupational Therapy	Moderately effective
Heat, Massage, TENS	Moderately effective
Behavioral Treatment	Moderately effective
Non-opioid Meds	Moderately effective
Alternative Therapies	Moderately effective

PTSD (Reported in initial assessment)

Have had nightmares about it or thought about it when you did not want to?	Yes
Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?	Yes
Were constantly on guard, watchful, or easily startled?	Yes
Felt numb or detached from others, activities, or your surroundings?	Yes

PainTracker Item Responses (Self-reported from most recent assessment: 7/21/2014)

PHQ-9	
Little interest or pleasure in doing things	Several days
Feeling down, depressed, or hopeless	More than half the days
Trouble falling or staying asleep, or sleeping too much	Several days
Feeling tired or having little energy	More than half the days
Poor appetite or overeating	Several days
Feeling down, depressed, or hopeless	More than half the days
Trouble concentrating on things	Several days
Slow or fidgety	More than half the days
Thoughts that you're better off dead	Several days

GAD-7	
Feeling nervous, anxious, or on edge	Several days
Not being able to stop or control worrying	Over half the days
Worrying too much about different things	Several days
Trouble relaxing	Over half the days
Being so restless that it's hard to sit still	Several days
Becoming easily annoyed or irritable	Over half the days
Feeling afraid as if something awful might happen	Several days

ORT Responses (Reported in initial assessment)

Family history (parents and siblings) of alcohol abuse?	Yes
Family history (parents and siblings) of illegal drug use?	Yes
Family history (parents and siblings) of prescription drug abuse?	Yes
Personal history of alcohol abuse?	Yes
Personal history of illegal drug use?	Yes

Personal history of prescription drug abuse?	Yes
Diagnosis of ADD, OCD, bipolar, or schizophrenia?	Yes
Diagnosis of depression?	Yes
Age 16 - 45 years	No
History of pre-adolescent sexual abuse?	No

PT.NO: Test

071414A, 071414A

DOB: 1976-07-04 SEX: M

UW Medicine

Harborview Medical Center — Northwest Hospital & Medical Center
Valley Medical Center — UW Medical Center
University of Washington Physicians Seattle, Washington

PainTracker

Page 2 of 2



U3303

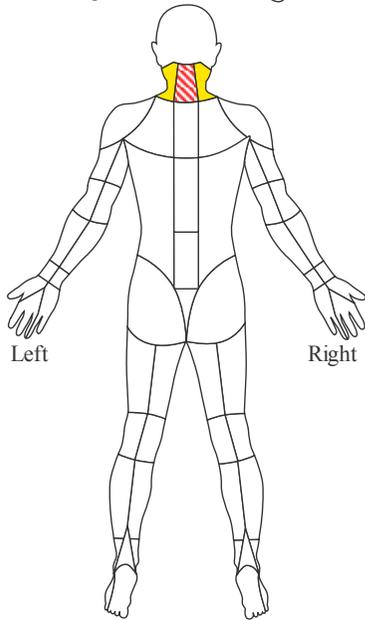
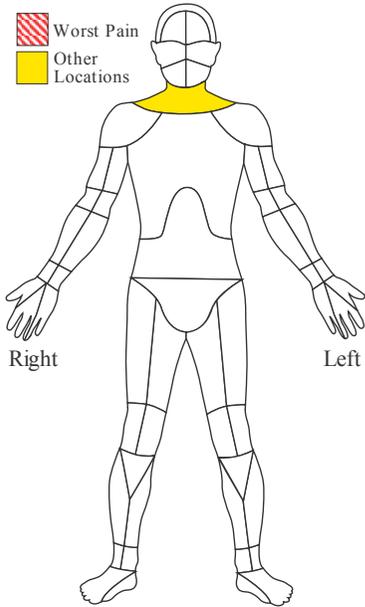
WHITE - MEDICAL RECORD

UH3303 REV JULY 14

Printed: 8/19/2014

Last Completed Session: 7/21/2014

Worst Pain
 Other Locations



Patient-reported Current Treatments	
..... Injection	7/2/2014
----- Started Physical Therapy	7/3/2014
———— Started Behavioral Therapy	7/4/2014

On these charts, lower is better, higher is worse.

