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Study Protocol

Patients and Setting

Study participants (N = 99) were patients seeking care for various chronic pain conditions at the UW CPR between April 2016 and March 2017. The target population for the study was patients who had received an initial treatment planning visit, but who were still early in their course of treatment. Therefore, to be eligible for this study, patients were required to have visited the UW CPR at least once, but not more than 5 times. The control subjects were recruited between April 2016 and September 2016 while the intervention was being developed. The intervention subjects were recruited between September 2016 and March 2017. This sequential, nonrandomized design was chosen because of the limited budget and time available for the development and testing of our intervention.

Measures

Demographic and clinical data were extracted from UW CPR electronic medical records. Demographic data collected at enrollment included age, sex, race, ethnicity, and insurance type. Clinical data collected on control and intervention subjects included pain diagnoses, previous and current interventional treatments and therapies for pain, as well as current pain and related medications (opioids, anticonvulsants, antidepressants, anxiolytics, antihistamines, and nonsteroidal anti-inflammatory drugs.

The Pain Self-Efficacy Questionnaire[1, 2] is a 10-item survey that assesses patients' pain self-efficacy, or confidence in their ability to cope with their pain and continue activities of daily living (eg, "I can cope with my pain in most situations."). Items are scored on a 7-point scale from 0 "not at all confident" to 10 "completely confident." Higher scores denote higher pain self-efficacy. The questionnaire is widely used across various chronic pain conditions and has strong psychometric properties.[2] Scores range from 0 to 60. This was pre-specified as our primary outcome measure.

The Chronic Pain Acceptance Questionnaire[3] was used to evaluate chronic pain acceptance. This 20-item survey is composed of 2 factors: 1) "activity engagement": engagement in life activities with pain (11 items), and 2) "pain willingness": willingness to experience pain without trying to engage in unhelpful attempts to control it (9 items). Patients were asked to rate the truth of each item as it applied to them (eg, "My life is going well, even though I have chronic pain."). Items are scored on 7-point scale from 0 "never true" to 6 "always true." Higher scores denote greater levels of pain acceptance. Scores on the "activity engagement" subscale range from 0 to 66; scores on the "pain willingness" subscale range from 0 to 54). The Chronic Pain Acceptance Questionnaire has good psychometric properties[4] as well as evidence of clinical utility.[3]

The Perceived Efficacy in Patient-Physician Interactions[5] is a 5-item survey measuring confidence in obtaining medical information and attention to their medical concerns from physicians. Items are scored on a 5-point Likert scale from 1 "not at all confident" to 5 "very confident." The Perceived Efficacy in Patient-Physician Interactions has established validity and reliability in older adults[5] and patients with osteoarthritis.[6]

Pain and pain interference were evaluated using the 3-item Pain Intensity and Interference With Enjoyment of Life and General Activity (PEG).[7] Pain intensity was rated on an 11-point numeric rating scale, from 0 "no pain" to 10 "pain as bad as you can imagine." For interference items, patients indicated how much pain interfered with enjoyment of life and with general activity from 0 "does not interfere" to 10 "completely interferes." The PEG total score is the mean of these 3 items, where higher values denote a higher level of pain intensity and interference. The PEG has established re- liability and validity in a community and veteran populations with chronic pain and has shown responsiveness to improvement similar to the Brief Pain Inventory.[8] The PEG was completed as part of the participant's regular clinical care. Assessments within 2 months of the primary PTSM outcome assessment were used for these analyses.

To evaluate satisfaction with pain treatment, participants were asked to choose the number between 0 "extremely dissatisfied" and 10 "extremely satisfied" that best reflected how satisfied they are with the results of their pain treatment, in general.

Study Procedures

Consecutive new patients who attended the UW CPR between April 2016 and March 2017 completed a collection of pain-relevant patient-reported outcome questionnaires using PainTracker to facilitate comprehensive multidimensional pain care. All new patients were asked to complete the online questionnaires 1 week before their scheduled appointment. Those who were scheduled for a follow-up appointment at UW CPR and completed the follow-up PainTracker assessment were presented with a question determining interest in the PTSM study. If patients were interested in learning about the study, they were directed to an online information statement outlining the purposes and procedures of the study and given the opportunity to enroll. Patients who chose to not consent at the time were given the options to decide at a later time or obtain more information regarding the study. These patients were then sent a follow- up e-mail by the research team. Intervention and control subjects were compensated with a $100 gift card for completion of all outcome measures.

A controlled, sequential, nonrandomized study design was used. During the first 6 months of the enrollment period, assessment procedures for the control group were conducted. The control group received treatment as usual in the CPR, with no restrictions on treatment received, including medications, procedures, and sessions with pain psychology, pain psychiatry, and social work that provided support for pain self-management. While control subjects were being assessed, the Web-based PTSM platform for the intervention phase of the study was developed by the multidisciplinary research team, which included investigators from psychiatry, internal medicine, psychology, nursing, social work, computer science, and graphic design. During the second 6 months of the study enrollment period, patients were enrolled in the intervention group. Control as well as intervention subjects were followed for 6 months. There was no restriction on treatments received in either group. The study procedures were reviewed and approved by the institutional review board at UW.

Intervention

The intervention included exposure, at the patient's discretion, to a Web-based patient empowerment platform on the basis of ACT principles, as well as phone and text coaching from the research clinicians (trained in nursing and social work, respectively). The flow of the study is shown in Fig 1. The PTSM interactive educational modules covered the following topics: module A: "Introduction to PainTracker" is a brief, non-interactive informational module that was presented to the intervention as well as control patients as an introduction to the first PainTracker assessment. Module B: "What is Pain?," explained that pain is important, unpredictable, and complex. It emphasized that all pain is real and important. It also emphasized that pain may get better and worse for unclear reasons. It did not focus on the difference between acute and chronic pain. Education on the complexity of pain used concepts of "injury" versus "alarm," and incorporated some ideas from *Explain Pain* by Butler and Moseley.[4, 9] Module C: "Life Navigation System," assisted patients with clarifying values and developing an action plan to improve 1 selected life area (ie, free time, relationships, health and self-care, or work and education). This module was adapted from a treatment manual written by Vowles and Sorrell[10] and incorporated the Values Bullseye exercise of Lundgren and colleagues.[11] Module D: "Get Rhythm," focused on pacing, mindful breathing, and sleep rhythms. These 3 areas were selected for skill development because they are often core components of behavioral treatments for chronic pain and because of their relevance with the values focus of the intervention. Participants were encouraged to bring some regular rhythm into their lives, particularly as related to engagement in valued living. Module E: "Life Goes On," the

final module, focused on scheduling value-based activities and managing pain flares over the longer term. These themes were chosen to emphasize the importance of engagement in value- based activities for sustained recovery.[12] Intervention participants were given access to all modules at the outset of the study. They were not forced to complete them on a schedule or in order. The coaches strived to have at least 1 coaching session after the completion of each module. The coaches estimate that patients spent 30 to 40 minutes on each module that they viewed. Module A was especially short and Module B was especially long. Total estimated time for module viewing was 120 to 160 minutes. More precise tracking of viewing time was not possible because of patients' ability to leave the modules open while they attend to other things.

Embedded in each of the interactive modules were open-ended and multiple choice questions and tasks, such as "Of all the things that have happened to you since your pain started, what concerns you the most?" or "Create your own action plan." The responses to these module questions were visible to the coaches and were used to guide and tailor the coaching sessions to the individual patient. Coaching sessions occurred in person (14%), over the phone (85%), or by e-mail and text (1%), on an average of 4 occasions (SD = 1.6) depending on participant preference and availability, with a mean duration of 20 minutes (SD = 8.6, range = 2-50 minutes per session). After each individual coaching session, participants were sent an e-mail summary of the recommendations dis- cussed. At study completion, a final note was sent with a summary of key self-management strategies, and encouragement to continue to incorporate them into daily life.

The patient coach's general approach within each coaching session was to use open, active listening strategies to establish therapeutic rapport. Coaching sessions were focused on incorporating and engaging participants in the PTSM study educational content. Module content was reviewed and questions or concerns were addressed. Participants were asked to identify 1 to 2 simple and achievable goals on the basis of suggestions in the module, and were guided to identify specific strategies to meet the goal. Efforts were made to redirect conversations from excessive review of pain complaints to values, functioning, goal-setting, and self-care. Questions regarding specific diagnoses or medical therapies were directed to the UW CPR provider. Each week, the team met to discuss 1 or 2 challenging cases, and to provide the research clinicians with supervision. Suggestions for strategies to promote engagement in the study educational content were provided by pain psychiatry and psychology. Brief summaries of the coaching session and customized suggestions for engagement of the patient in pain self-management were provided to the patient's UW CPR provider at their next clinic visit on a printed sheet placed on top of the patient's clinical chart.

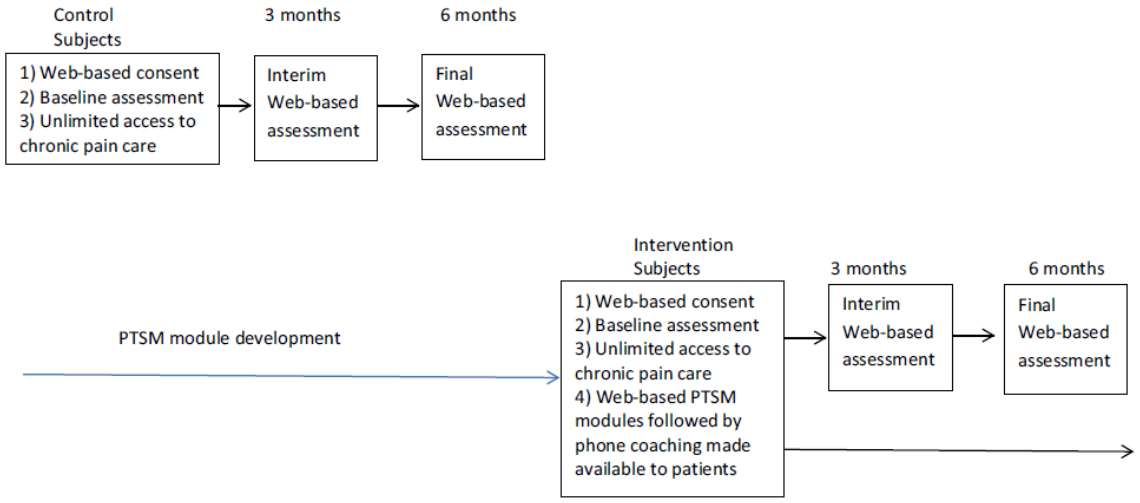

Figure 1. PTSM study flow chart.

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