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Theoretical Grounds of Pain Tracker Self Manager: An Acceptance and Commitment Therapy Digital Intervention for Patients with Chronic Pain

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Abstract

Objective: To report the theoretical basis and design of a novel digital Acceptance and Commitment Therapy (ACT) intervention for people with chronic pain, the Pain Tracker Self Manager (PTSM), which had promising efficacy in a recent pilot trial.

Methods: Content development by a multidisciplinary panel of experts in psychiatry, clinical psychology, nursing and social work, with feedback from a group of patients with chronic pain and their providers. Materials included paper-based sketching of a story character, visual metaphors, and a series of stories designed to deliver the theory-based components of our behavioral intervention.

Results: This development and design process resulted in 4 digitally delivered clinical modules that combine visual and verbal cues. In addition, it generated a series of novel ACT metaphors specifically tailored to patients with chronic pain: *Pain: Injury vs. Threat, Life Navigation System, The Fog of Pain*, and *Get Rhythm*. Consistent with ACT theory and the contextual behavioral science framework, PTSM utilized: perspective-taking, values clarification, acceptance strategies, and nursing and psychological care recommendations.

Discussion: Reports of the design and theoretical basis of digital health interventions are highly needed to increase the rigor of their development process and more progressively advance our body of knowledge. This pilot study developed and tested a series of ACT metaphors that can be readily used by ACT clinicians working with this population.

Conclusion: PTSM is a novel digital ACT intervention for patients with chronic pain with features directly linked to ACT processes and theory.

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Keywords

Chronic Pain; digital health; Acceptance and Commitment Therapy; Health Coaching; Pain Psychology

BACKGROUND AND SIGNIFICANCE

Patients with chronic pain may be harder to reach than other patient populations with chronic illness. Those with complex chronic pain tend to be highly deactivated physically and socially, and often experience psychiatric conditions, such as depression, anxiety, post-traumatic stress disorder and substance abuse (Gureje et al., 2008; Stanos et al., 2016; Sullivan & Howe, 2013). These experiences may lead patients on protracted searches for care from multiple providers in an effort to seek relief from their pain. Office-based medical care of patients with chronic pain is challenging due to the time-consuming complexity of addressing multifactorial concerns and pervasive deactivation, with resulting low treatment adherence and poor outcomes. These multiple challenges mean that it is important but difficult to bring the insights and techniques of pain psychology into primary care settings -- where pain psychologists are rarely present in person. Therefore, innovative approaches to educate and engage patients with chronic pain are necessary to improve health outcomes in this population and reduce the risks of inadequate care (e.g., Oliva et al., 2017), including medication overuse and possible opioid misuse (Karanges et al., 2018; Kaye et al., 2017).

Digital technology presents an opportunity to deliver chronic pain self-management skills without on-site pain psychologists in order to complement office-based care of these patients. Such digital psychological tools can be accessed by patients from home computers and mobile devices, and/or used to enhance face-to-face encounters with providers. These tools can also deliver behavior change content that can empower patients with chronic pain to reclaim their values and lifestyle in their natural environment.

A number of digital tools have been developed in recent years to support chronic pain self-management, but most of these have not been integrated with office-based clinical care. For example, technology-supported self-management interventions, such as telephone, interactive voice response, and website interventions have shown benefits in this population (Heapy et al., 2015). Specifically, a randomized trial of an internet-delivered intervention showed significant reductions of pain intensity and interference, perceived disability, catastrophizing and fear (Ruehlman, Karoly, & Enders, 2012). However, this intervention was entirely conducted in isolation from office-based clinical care and with online volunteers, who are generally less ill than clinic patients. Another trial investigated an internet intervention in combination with multimodal pain rehabilitation in primary care. The addition of the internet intervention produced significant reductions in pain catastrophizing, but not pain intensity or self-efficacy (Nordin, Michaelson, Gard, & Eriksson, 2016). Thus, there still exists a need to develop and improve digital technology tools to treat the chronic pain population that is cared for in the outpatient care setting.

Given the chronicity and impact of complex chronic pain in a wide range of life domains, Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 2011) is a good

conceptual fit with this patient population (McCracken, 2010). Furthermore, face-to-face ACT interventions for chronic pain have demonstrated promise and are listed as having strong evidence according to Division 12 of the American Psychological Association (APA, 2019). A number of digital ACT interventions have been designed and evaluated for chronic pain. In a previous study the authors developed and pilot tested an online-relapse prevention program based on ACT for chronic pain (Fledderus, Schreurs, Bohlmeijer, & Vollenbroek-Hutten, 2015). The intervention, consisting of self-monitoring of valued-actions, keeping a diary, ACT exercises, tips and the possibility of receiving personalized feedback through a coach function, was administered for two months following a multidisciplinary pain treatment. Nine patients used the program and 5 of them reported that the program was supportive after the in-person treatment. In another study the authors conducted a three-arm randomized controlled trial comparing internet-based guided self-help ACT intervention (“Living with Pain”) with an internet-based control condition (i.e., expressive writing) and a waiting list group (Trompetter, Bohlmeijer, Veehof, & Schreurs, 2015). Results showed that participants in the ACT condition improved on several domains of chronic pain disability compared to both control groups, with psychological flexibility and pain catastrophizing improving during the intervention. Lastly, in another three-arm RCT the authors assessed “ACTonPain” and showed that the ACT-guided intervention reported significantly less pain interference and higher pain acceptance at post-treatment and at 6 month-follow-up compared to waiting list (Lin et al., 2017).

In this paper we describe the design and theoretical basis of a novel digital ACT intervention for chronic pain called Pain Tracker Self Manager (PTSM). PTSM was recently tested in a pilot controlled trial and led to increases in pain self-efficacy, reductions in pain interference in a sample of chronic pain patients that were followed for a period of 6 months, adding to the body of literature in support of digital ACT interventions for chronic pain [Sullivan et al., 2018]. PTSM was informed by the design of a previously developed digital ACT intervention for smoking cessation (Learn to Quit; Vilardaga et al., 2018). Laying out the theoretical rationale of digital health technologies is key to ensure a rigorous treatment development process (Kumar et al., 2013; Vilardaga, Casellas-Pujol, Garrison, & McClernon, 2019) and deserves a dedicated scientific report. Describing the theoretical basis of our digital tool is one key to expanding and advancing the quality and effectiveness of our digital interventions [Vilardaga, Casellas-Pujol, McClernon, & Garrison, 2019]. Therefore, this report describes the design and theoretical rationale of PTSM and provides a conceptual account of each of its modules and their intended function. A secondary aim of this study is to introduce a new set of ACT metaphors and exercises that could be readily used by clinicians during face-to-face interventions.

METHOD

Content Development

PTSM content was developed by a psychiatrist specialized in chronic pain management interventions (MS), a nurse practitioner with more than 15 years of experience with this population (PD), a clinical psychologist specializing in ACT interventions for chronic pain (KV), and a clinical psychologist with expertise in developing acceptance-based digital

health interventions (RV). The group met weekly over a period of 8 months to discuss (a) theory-based components of the intervention, and (b) the specific content and structure of each of the intervention's modules.

Sketching and Visual Design of Digital Modules

Building upon previous work by one of the authors [Vilardaga et al., 2018], modules were inspired by cartoon strips and the presence of two characters who reflected on the module's main narrative. The primary cartoon character was gender, age and race nonspecific who responded to module content with comments such as "That's right. Pain has taken over EVERYTHING in my life!" while the smaller non-verbal 'sidekick' character mirrored emotions with facial expressions, such as frustration, confusion, or laughter. These two characters allowed us to present multiple and nuanced perspectives on the content presented in the program.

Content developed by the expert team was initially laid out in the form of written scripts and paper and pencil sketches of the primary character with chronic pain that conveyed chronic pain management concepts and skills. Work on each module started with a core narrative script laying out central concepts of the intervention. This script included both text and visual content. This script was expanded after the team identified conceptual gaps, potential points of misunderstanding, or the need to include additional examples or metaphors. These scripts and sketches were the basis of a more refined prototype of PTSM using Microsoft PowerPoint. "Low fidelity" prototypes, such as paper and pencil sketches and low quality digital versions of a prototype, are an important process in user-centered design, allowing for a quick iteration of prototypes with different structure, interactions, and layout of theory-based content (Buxton, 2007; Cooper, Reimann, & Cronin, 2007).

Patient Feedback

Patient feedback was incorporated by eliciting comments on a subset of the draft PTSM prototype from 5 patients with chronic pain during 45–60 minute individual user-feedback sessions with the study nurse (PD). These volunteers received clinical care at the University of Washington Center for Pain Relief (UW CPR) and were contacted at the recommendation of clinic providers. Comments and observations were noted, transcribed, and organized for discussion by the expert team. Given the iterative nature of this testing phase, we modified PTSM modules after receiving feedback from the first 3 participants and provided an updated version to the last 2 participants. This iterative process is standard in formative user-centered design research (Rubin, Chisnell, & Spool, 2008).

Pain Clinician Feedback

Pain clinician feedback on the module content was elicited in two ways. First, three members of the Expert Panel (MS, KV, PD) had decades of combined experience working with patients experiencing complex chronic pain. Secondly, we obtained feedback from 6 clinicians working at the UW CPR including 2 attending physicians (anesthesiology and rehabilitation medicine), 2 pain fellows (anesthesiology), 1 physician assistant, and 1 nurse coordinator. Their expertise informed the receptivity of specific PTSM content and images,

and the arrangement within each module. Each patient and clinician volunteer received a \$25 gift card for participation.

RESULTS

We created a total of 232 screens of text and imagery, divided into 4 modules with active interventional content. Completion of each module was expected to take the patient about 30–40 minutes at their home. Study enrollment and viewing of the first module occurred after the initial visit to the pain clinic, but prior to the fourth follow-up visit. We designed the intervention so that module content was gradually presented. That is, modules had to be completed sequentially, as comprehension and incorporation of new content depended upon completion of previous modules. The total length of treatment was 6 months. This digital intervention was not a stand-alone treatment; rather, it was designed to be a “bridge” between pain clinic clinician visits and study telephone or face-to-face coaching sessions with the study clinicians. Overall, our use of characters and the narrative style of the modules throughout were systematically included to increase patient’s pain acceptance and convey empathic concern.

The content of these modules was consistent with the contextual behavioral science (CBS) framework, which posits there is a continuum between traditional behavioral therapy and acceptance and mindfulness-based interventions such as ACT (CBS; Vilardaga, Hayes, Levin, & Muto, 2009). Specifically, PTSM content integrated traditional behavioral techniques (e.g., deep or mindful breathing), with values interventions (e.g., Bullseye exercise). In addition, PTSM also capitalized on Butler and Moseley’s psychoeducation model, which heavily relies on the use of analogy and metaphor to re-contextualize patient’s pain experience as related more strongly to tissue danger than tissue damage (Butler, Moseley, & Sunyata, 2013) and hence transform their function. A recent meta-analysis of this approach suggests it is efficacious at reducing pain-related fear and catastrophizing, and that it improves patient knowledge regarding chronic pain (Watson et al., 2019).

Content related to nurse and social work coaching, and psychological management of chronic pain in a medical setting was also incorporated. All three approaches to chronic pain have shown: (1) efficacy in randomized controlled trials (Pike, Hearn, & Williams, 2016), (2) processes of change linked to treatment outcomes (Vowles, Witkiewitz, Sowden, & Ashworth, 2014) and (3) high levels of acceptability (Butler et al., 2013).

Feedback from both patients and clinicians informed the final PTSM design. For example, the first non-human form of the PTSM character (i.e., an egg like shape) we designed was rejected by some participants after considering it simplified and diminished their experience. Per patient’s suggestion we designed a new character with human-like features. Attempts to demonstrate the cartoon character experiencing pain were abandoned after several pilot patients expressed dissatisfaction given their pain location or pain sensation did not match the drawing (e.g., a lightning bolt hitting the lower back). Specific visual expressions (e.g., the smile of a character on a specific screen) were removed or changed from the cartoon character. A more frequent source of feedback referred to replacing the use of certain terms after some patients found them inadequate or at times offensive. The term ‘overcome’ for

example, was considered to provide false hope about the chronicity of their pain. The term ‘we understand’ caused anger in some patients, who felt it was patronizing. Some patients and providers also provided suggestions to edit the language so that it felt less ‘academic’. Finally, positive feedback about the stories and design of the intervention helped validate elements of the existing design.

In what follows, we will describe each of the Modules developed for this intervention and comment on their development process (see Table 1 for an overall description of modules). Note that at the beginning of each subsequent module, subjects were provided an opportunity to review the concepts from the prior Module to refresh the intervention concepts. Each review section had a few screens with interactive feedback regarding their responses to what they had learned and applied from the prior module.

Module 1: ‘*What is Pain?*’

The first module in the series had the intended function of increasing self-awareness about the interaction between physical injury or disease, the personal context in which it occurs, and the resulting pain that is experienced (See Figure 1). Butler and Moseley’s psychoeducation model was used as inspiration for content (Butler et al., 2013). By establishing a clear link between psychological threat and physical injury, its intricate interaction, and its role in the causation of the chronic pain experience, we laid out the foundation for Modules B, C and D.

The module introduces two unnamed characters, a yellow-orange primary character that is age, gender and ethnically neutral, who shares commentary and questions on the module content via thought bubbles. The second character is a light green humanized caterpillar that adds a second layer of perspective-taking upon the main character’s thoughts via non-verbal expressions. The module starts with an opening question, ‘*What is Pain?*’ (Figure 1, Panel A) that serves the function of prompting the individual to reconsider previously assumed notions of pain. This is followed by a number of statements that reflect on the impact that chronic pain can have at the individual level (Figure 1, Panel B). These statements were included to serve the function of empathizing with the experience of a patient with chronic pain, which is sometimes discarded as ‘not real’ in clinical settings (Chou et al., 2018; Rhodes, McPhillips-Tangum, Markham, & Klenk, 1999).

After this initial introduction, chronic pain is characterized in terms of three primary components: its *Importance*, *Unpredictability* and *Complexity* (Figure 1, Panel C). *Importance* points at both the undeniable experience of chronic pain and its impact on life, including the disruption of valued activities. The module presents multiple exemplars of the impact of pain on activities, relationships, and sleep, and then introduced a text box where the user can describe in writing their own experiences of impact.

Unpredictability is the next key characteristic. This aspect describes how individuals with chronic pain are frequently unable to predict the course of chronic pain, understand the causes of ‘pain flare-ups’, or explain why proven strategies to mitigate the pain fail to help. In this section, perspective-taking and flexible connectedness were the key principles

followed to facilitate empathic concern, increase cognitive defusion and acceptance (Vilardaga, 2009; Vilardaga, Levin, & Hayes, 2014).

Finally, the bulk of this module describes pain's *Complexity*, a key characteristic (Figure 1, Panel D). This concept was introduced with a few examples demonstrating the contextual nature of pain. Inspired by Butler and Moseley's model (2013), the module presents the metaphor of contrasting the pain experience of a football player after winning a game versus a person who is robbed in the street on his way to cash a check, both of whom have similar physical injuries. These examples demonstrated how the *context* in which the injury occurs can have a profound impact on pain experience despite similar trauma. This was further elaborated by bringing up the concept of injuries with high versus low alarm or threat. The differing level of threat means that injuries will be contextualized differently and will result in different pain experiences.

On the whole, this module was designed to increase patient's awareness of how the context of injury and illness can impact the course and severity of chronic pain problems, thereby determining how disruptive they are to patients' quality of life.

Module 2: 'Life Navigation System'

This module introduced two new ACT metaphors: *Life Navigation System* and *The Fog of Pain* (See Figure 2). This module was adapted from a treatment manual written by Vowles and Sorrell (2007) and incorporated the Values Bullseye exercise (Lundgren, Luoma, Dahl, Strosahl, & Melin, 2012). The *Life Navigation System* was elaborated during discussions with the expert team to function as a verbal strategy to apply the adaptive functions of identifying valuable life experiences for patients with chronic pain. Patients with chronic pain often lapse into a 'crisis mode' where they lose sight of what they care about and narrowly focus on the pain they desire to eliminate (e.g., experiential avoidance). Therefore, the narrative asserts that personal values are an essential '*Life Navigation System*' and are especially important to redirect life in a constructive and positive direction aligned with personal values when we feel lost or without a point of reference. The module provides multiple perspective-taking elements enhanced by the module character and companion (See Figure 2).

The *Fog of Pain* metaphor was used to help explain how chronic pain can obscure a patient's most important values as represented by the *Life Navigation System*. As the *Fog of Pain* deepens, patients can become focused on bare survival, forgetting what values define each of them as a unique person. Combined, these two metaphors introduce the idea that chronic pain disrupts our values system and contributes to a narrowly focused emphasis on pain avoidance rather than values-based approach behaviors. The modules then take the patient through a values exercise using a modification of the Bullseye Values Assessment. Rather than an exclusive assessment tool, this ACT exercise can be used as a values clarification intervention. Therefore, we digitally modified the tool to enhance its clinical value. Specifically, we divided the Bullseye into four different sections: (a) Work and Education, (b) Free Time, (c) Health and Self-Care, and (d) Relationships. The user rated their current engagement in each of the 4 value quadrants and then picked one area of focus in order to develop a specific action plan to be discussed with the clinical provider during the next visit.

Examples were provided for each of the 4 quadrants. The bullseye had 7 levels of engagement to choose from. Subjects were instructed that marking the center of the bullseye represented “My life is just as I want it to be,” “I am fully satisfied with how I am living my values in that area.” and “My quality of life in this area is just how I want it.” Whereas a mark furthest from the center means “My life is far from how I want it to be,” “I’ve lost touch with my values in that area,” and “My quality of life would be improved if I were able to move close to the center of the bullseye in this area.” At the end of this module, the user was asked to think about one specific valued area and then create an “Action Plan” (open text section with a maximum of 500 characters) that would lay out specific steps that could be taken in that direction.

As a refresher for Module 3, the user was provided via an interactive interface, their specific responses on the Bullseye exercise from Module 2, including their ratings for all 4 quadrants, the single quadrant they most wanted to focus on, followed by the specific “Action Plan” they had written to increase engagement in that quadrant. At the beginning of Module 3, subjects were asked to write down what they noticed when practiced the “Action Plan” determined in Module 2.

Module 3: ‘*Get Rhythm*’

This module introduced the importance of building a consistent values-based behavioral repertoire by introducing a new metaphor designed to transfer the functions of pace and rhythm -- akin to music -- to daily life activity (See Figure 3). The metaphor for “*Get Rhythm*” resonated because it conveyed in simple and relatable terms the consequences of a common aspect of the chronic pain experience for many, the so-called ‘boom and bust’ cycles. The “boom” cycles occur when pain levels are low, and the patient then engages intensely in valued activities for a short but vigorous period of time lasting hours to days. These cycles often leave the patient exhausted and trigger further episodes of pain. The “bust” cycles occur when the patient withdraws drastically from physical activity, leading to increasing levels of deactivation and social withdrawal, often for several days or weeks at a time (Hadzic, Sharpe, & Wood, 2017). We therefore emphasized the importance of consistent rhythms in life by “pacing” of activities, which as in music, provide a predictable and sustainable foundation for engagement and action. That is, rhythm is to melody what pacing would be to the frequency upon which specific actions (e.g., any valued activity) are taken.

By applying the *Get Rhythm* metaphor we also conveyed a number of important repertoire-building principles: (1) a steady rate of behavior can be more easily sustained, (2) frequent values-based activities are more likely to be reinforced by the environment, and finally, (3) as these repertoires are established, the individual becomes more skillful at contacting external reinforcers. More importantly, the notion of “rhythm” puts the emphasis on frequency and pace rather than the actual outcomes of those behaviors; that is, it puts the emphasis on antecedent control (established routines or cues) rather than consequential control (the rewards that may follow those behaviors).

Once this was described, we extended the metaphor to what we called the “Rhythms of Life” and explained its role as a means to strengthen our *Life Navigation System* to navigate

through the *Fog of Pain*. Key “Rhythms of Life” important to patients with chronic pain were then identified and supported through specific exercises to be completed. Specifically, we presented a section called “Breathing Rhythms” which explained the concepts of diaphragmatic breathing (described as relaxation or “belly breathing” versus “chest breathing” - shallow and short breaths). Subjects were invited to practice “belly breathing” while viewing the module, by clicking on audio breathing exercise recorded by one author (KV). Subjects rated how they felt before and after the breathing exercise. Emphasis was provided on the need to practice these skills regularly.

“Breathing Rhythms” was followed by a section on “Sleeping Rhythms”, which introduced 3 key strategies of sleep hygiene: (1) Get out of bed at the same time every day, (2) Use your bed for sleep and intimacy only, and (3) Try to avoid naps. These sections provided an opportunity to convey the importance of stimulus or antecedent control, such as starting activities at a similar time every day, and rearranging the environment to increase the chances of a target behavior to occur (e.g., removing electronic tablets and screens from the bedroom to increase the chances of initiating sleep).

Finally, subjects were asked to select one of the 4 strategies presented above (e.g. mindful breathing) and practice it in the next few weeks. Participants were encouraged to work on only one of these “Rhythm” strategies at a time.

Module 4: ‘Life Goes On’

The final module in the series, *Life Goes On*, addressed long term maintenance of newly established values-based activity repertoires (See Figure 4). Informed by the values clarification information obtained in the Bullseye Exercise and the previously introduced metaphors, this module helped the patients select and take concrete steps towards establishing a new and chosen life rhythm. This was accomplished by focusing on two strategies: (1) Activity Rhythms and (2) Responding to Pain Flares.

“Activity Rhythms” refers to an important concept in behavioral therapy of scheduling each day to do something pleasurable in the service of one’s values. Because many who struggle with chronic pain feel trapped to an endless experience of suffering, the goal of this exercise was to help them to experience an enjoyable and positive activity on most days. Examples included spending a little time gardening, reading a good book for 30 minutes, or watching a sunset once a week. We also asked participants to consider new “Activity Rhythms” of their own with an open text exercise (i.e., “Please share a few activity rhythms that you would like to do more of in life”).

“Pain flares” are very common in patients with chronic pain, even after treatment. These are episodic worsening of the baseline pain, and may last for days, weeks or months (Daenen, Varkey, Kellmann, & Nijs, 2015). Those with chronic pain are frequently discouraged and frightened by “pain flares”, and often feel helpless to prevent them. Flares leave the patient frustrated and concerned about return to previous pain levels and can inhibit previously reestablished values-based activities. Module content first sought to normalize the experience of “pain-flare,” help identify triggers and warning signs, and provided a

framework to more effectively contextualize them and respond to them, with the goal of preventing a return to previous pain avoidance cycles.

Finally, the last sections of the module provide recommendations about how to interpret pain symptoms and when and how to reach out to a clinical provider. For example, pain flares are common in patients even after a successful intervention. In this context some patients may struggle to distinguish between pain symptoms that require medical attention from symptoms that can be self-managed. Therefore, the module included a section that presents a list of pain symptoms that require medical attention (e.g., unable to control urine or stool), and suggests specific and clear steps to effectively respond to this hypothetical scenario. Inclusion of this content was vetted by clinic leadership and was important in order to integrate PTSM with ongoing clinical care and enhance face-to-face contact with office-based care providers.

DISCUSSION

Chronic pain affects millions of patients worldwide (Jackson et al., 2016). There is a need to develop scalable digital interventions that can enhance the clinical care of these patients in office-based settings -- which rarely offer behavioral treatment -- through the remote delivery of evidence-based self-management tools and support (Lalloo et al., 2017). This work presented the theoretical rationale of a novel ACT-based digital intervention, PTSM, that has shown preliminary efficacy to treat chronic pain patients in a recent pilot trial (Sullivan et al., 2018). This work also introduced a set of new ACT metaphors that can be readily used by clinicians treating patients with chronic pain: *Pain Injury vs. Threat, Life Navigation System, The Fog of Pain*, and *Get Rhythm*.

PTSM built upon previous work to develop an ACT digital intervention for patients with serious mental illness and tobacco use and dependence, Learn to Quit (Vilardaga et al., 2018). Both digital interventions relied on storytelling, graphic design and artistic elements, to deliver ACT concepts and skills in very simple and relatable terms. Furthermore, PTSM's use of art and graphics to convey key psychological concepts in patients with chronic pain is consistent with work by Butler and Moseley (Butler et al., 2013).

In contrast to Learn to Quit, however, PTSM put lesser emphasis on defusion, self-as-context, and contact with the present moment, and more emphasis in ACT's values-based activation components. Our approach to deliver the first two components was indirectly encompassed in our use of visual perspective-taking strategies that are part of the flexible connectedness model. In particular, we used perspective-taking design elements to create a context for defusion and a more flexible sense of self. With regards to contact with the present moment, we focused on the use of traditional mindful breathing techniques, which in turn helped us bridge our approach with traditional cognitive behavioral therapy.

The theoretical rationale and design work presented in this paper has a number of limitations. First, the study used only a few user-centered design strategies (e.g., paper and pencil ideation and sketching, prototyping, patient and clinician input), but did not capitalize on other user-centered design methods (e.g., usability testing), which could have provided

more nuanced data about our specific arrangement of app content, and errors related to navigating the software system. Instead, our module design work relied on the use of a multidisciplinary panel of providers with experience in patients with chronic pain (psychiatry, clinical psychology, nursing, and social work). Alongside those with pain, providers are an important stakeholder when it comes to addressing and managing chronic pain in these patients, therefore, their insights were of critical value for the design of this intervention. In addition, we sought modules' feedback from a selected group of patients with chronic pain receiving care at a tertiary level pain center as well as several clinicians from that clinic. Their input was discussed with the expert panel and used to iterate on different module prototypes. Second, our description of the theoretical basis of PTSM modules relies on ACT and behavioral theory to describe the intended behavioral consequences of the narratives and visual stimuli presented in PTSM. However, we did not attempt to conduct a relational frame theory analysis of each module (Hayes, Barnes-Holmes, & Roche, 2001), which was out of the scope of this report, but could have provided a more rigorous understanding of how each module verbally functioned. Third, the PTSM interface was created for use on a personal computer or tablet, and was not configured as a mobile application due to resource limitations. Unfortunately, a large number of study participants had access only to a mobile phone and were unable to fully view each screen as intended. However, they were able to glean the key information from the module pages, and additional input was provided during the individual coaching sessions. Finally, PTSM's delivery of some ACT components (i.e., defusion, self-as-context, and contact with the present moment) was less emphasized than in previous ACT for chronic pain interventions. Therefore, a potential limitation is that the results of our intervention were limited by the lack of a more extensive use of these ACT techniques.

A previous review of the empirical literature of smoking cessation applications (Vilardaga et al., 2019), identified a key limitation in treatment development of digital smoking cessation interventions (e.g. apps). Specifically, following the four treatment development phases of the Obesity-Related Behavioral Intervention Treatment (ORBIT) model (Czajkowski et al., 2015) for behavioral treatment development, the authors identified a shortage of early-phase research that defined (Phase Ia) and refined (Phase Ib) behavioral interventions. This translational emphasis is consistent with CBS's strategy: the need to directly link behavioral processes with treatment development (Vilardaga et al., 2009). This review also documented a lack of peer-reviewed reports describing the specific features of digital smoking cessation interventions, which can impede the task of assessing the underlying mechanisms of digital behavioral interventions. The present work defines the theoretical components of PTSM (Phase Ia of the ORBIT model), hoping it will contribute to the digital health literature and increase the rigor of the digital health app development process. Given the cost-efficiency and added rigor of early-phase methodologies, we recommend that clinical behavioral scientists interested in digital technologies for behavior change adopt early-phase methodologies for the study and development of their novel tools.

Digital interventions have great potential to enhance the clinical care of patients with chronic pain. For example, PTSM could be more directly targeted to specific groups of patients who express barriers to attend in-person treatment, or who need ongoing reminders to engage in treatment care. Furthermore, digital interventions can provide more robust behavioral

measures of treatment engagement (i.e., minutes of use of specific modules) and hence generate valuable data that could be used by clinicians to adjust and tailor their clinical practice. For future clinicians implementing PTSM we recommend embracing the facilitation of pain self-management as part of their role with patients. PTSM works best when it supports a clinician effort to promote self-management by patients, such as remote communication of patient progress about practice of self-management skills, or the recommendation of specific skills before the next clinic visit. From a research perspective, these digital tools allow for a broad new range of objective measures that can advance clinical behavioral science's measurement armamentarium beyond the sole use of self-report (Newsome, Newsome, Fuller, & Meyer, 2019; Vilardaga & Vilardaga, 2019). Finally, PTSM has shown promising efficacy in a recent pilot trial [Sullivan et al., 2018]. Therefore, consistent with the CBS framework and the ORBIT model, future research should continue to refine the PTSM platform and test its efficacy and/or effectiveness in a large randomized controlled trial.

DISCLOSURES

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HIGHLIGHTS

- Pain Tracker Self-Manager (PTSM) is a novel digital intervention for chronic pain
- PTSM integrates Contextual Behavioral Science and Butler and Moseley's pain model
- PTSM generated new ACT metaphors that can be readily used by clinical providers
- PTSM's design capitalized on verbal and visual perspective-taking
- Describing the theoretical grounds of digital interventions is key

Figure 1.
Module 1: ‘What is Pain?’. Here we selected screens 8 (Panel A), screen 9 (Panel B), Screen 10 (Panel C) and Screen 31 (Panel D).

Figure 2. Module 2, the 'Life Navigation System'. Here we selected screens 16 (Panel A), screen 20 (Panel B), Screen 23 (Panel C) and Screen 38 (Panel D).

Figure 3.

Module 3: 'Get Rhythm'. Here we selected screens 19 (Panel A), screen 23 (Panel B), Screen 26 (Panel C) and Screen 27 (Panel D).

Figure 4.
 Module 4: 'Life Goes On'. Here we selected screens 19 (Panel A), screen 14 (Panel B), Screen 25 (Panel C) and Screen 38 (Panel D).

Table 1.

PTSM Theory-based modules

Modules	Key Metaphors/ Content	Brief Description	Key Behavioral Function	Behavioral Strategies
A: What is Pain (58 screens)	<i>The Football Player and the Robbery Victim</i>	Summarizes and describes chronic pain under three distinct features: personal relevance, complexity and unpredictability	creative hopelessness and flexible connectedness	<p>Visual and verbal perspective-taking cues</p> <p>Eliciting verbal behavior through open text exercises</p> <p>Transfer of stimulus functions through metaphors and analogies</p> <p>Direct and visual verbal instruction to complete behavioral exercises</p>
B: Life Navigation System (45 screens)	<i>Life Navigation System The Fog of Pain</i>	Introduces the importance of identifying and reconnecting with personal values in order to promote behavioral activation and behavior change	Values clarification	
C: Get Rhythm (77 screens)	<i>Life Rhythms</i>	Discusses the mechanics of behavior change and the importance of consistent rates of behavior (i.e., “pacing” and behavioral momentum) in chronic pain management	Establishing specific values-based activities	
D: Life Goes On (52 screens)	Recap of all metaphors	Extends previous metaphors to address long term maintenance of values-based behavioral activation and specific management of pain flares	Maintaining values-based activities over time	