Title: Mobile-Based Contingency Management to Promote Daily Self-monitoring in Primary Care Patients

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Mobile-Based Contingency Management to Promote Daily Self-Monitoring of Pain Severity and Related Measures in an Online Sample of Individuals with Chronic Pain

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Introduction

The opioid epidemic has spurred urgent and widespread legal, medical, and behavioral approaches to promote effective opioid prescribing. Between 21-29% of chronic pain patients misuse prescription (Rx) opioids (Vowles et al., 2015). Responsible opioid prescribing depends on accurate and early identification of misuse as well as comprehensive understanding of predictors of pain treatment seeking and successful pain management (Dowell et al., 2016). One promising and practical pain management solution is remote self-monitoring, a state-of-the-art assessment tool shown to be superior to retrospective assessment (e.g., Heron & Smyth, 2010). Unfortunately, low rates of adherence have impeded the use of remote self-monitoring among chronic pain patients (e.g., Jamison et al., 2016), even when non-monetary rewards were included (Jamison et al., 2017). One robust strategy for improving adherence is contingency management (CM). While CM has been widely used in research, translation to clinical practice has been limited, due to practical barriers (e.g., costs) and counselor concerns (e.g., Polak et al., 2020; Carroll, 2014).

This Stage 1 behavioral therapies development project (Rounsaville et al., 2001) will pilot test a novel, fully automated CM app (DynamiCare Rewards) for promoting daily self-monitoring of pain symptom severity and related variables (e.g., sleep, mood), as well as Rx opioid and alcohol use in a sample of chronic pain patients. This study is the first to customize the DynamiCare Rewards app to target survey completion, followed by a pilot controlled trial, comparing participants randomized to receive CM for completing daily self-monitoring surveys (CM group) or receive only electronic daily reminders to complete the survey (control group) over a 28-day period. Primary outcome measures include number of daily surveys completed and longest period of sustained adherence to survey completion. The study tested the hypothesis

that CM group participants will complete more daily self-monitoring surveys and will have a longer sustained period of daily survey completion compared to control group participants. Secondarily, the study examined feasibility; acceptability; and accuracy of Rx opioid and alcohol use reporting.

This dissertation will provide benchmark data on the efficacy and feasibility of CM to promote self-monitoring of pain severity, related factors, and Rx opioid use. More comprehensive information about pain experience and Rx opioid use has the potential to help clinicians provide better care and make better opioid prescribing decisions. Additionally, findings will inform future research on early identification, prevention, and intervention for Opioid Use Disorders.

Statement of Problem and Aims

Problems and Clinical Relevance

Prescription (Rx) opioid misuse is a significant public health problem and the CDC has declared an opioid epidemic (Dowell et al., 2016). Chronic pain patients, often prescribed opioids for pain management, represent a particularly vulnerable population (e.g., Boscarino et al., 2011). Responsible opioid prescribing depends on effective identification of misuse and comprehensive understanding of pain-related variables (Dowell et al., 2016; Tong et al., 2019). Self-report tracking via smartphone apps is a promising solution, but difficulties with adherence have been found to impede the use of remote self-monitoring among chronic pain patients (e.g., Jamison et al., 2016), even with the inclusion of non-monetary rewards (Jamison et al., 2017). One robust strategy for improving adherence is contingency management (CM). While CM has been widely used in research, the translation to clinical practice has met with resistance due, in large part, to practical barriers (e.g., Carroll, 2014).

As a Stage 1 behavioral therapies development project (Rounsaville et al., 2001), the goal of this dissertation was to examine the efficacy and feasibility of CM, delivered using a novel, fully automated CM app (DynamiCare Rewards), to promote daily self-monitoring of pain symptom severity and related variables (e.g., mood, sleep), as well as quantity and frequency of Rx opioid and alcohol use in a sample of chronic pain patients. The target behavior was objectively defined as completing daily self-monitoring surveys via the app within a 12-hour window (8am-8pm) for which those randomized to CM earned incentives.

The DynamiCare Rewards app was customized for the study, followed by RCT data collection. Participants completed baseline assessment, followed by random assignment to either the experimental (CM) or control (C) group. All participants then downloaded the app onto their

smartphone and were provided with instruction in its use. Based on the work of Petry et al. (2005a) and Olmstead and Petry (2009), the CM group received reinforcement escalating with continuous performance of the target behavior while the C group was asked to complete the survey, but did not receive incentives. Both groups received reminders to complete the daily survey. Follow-up assessments (including behavioral and psychological measures) occurred at intervention completion and both CM and C group members were compensated for their time and effort.

Aims

The specific aims of this Phase 1 therapy development project are to:

Aim 1: Compare number of completed daily self-monitoring surveys in CM and C groups. One hypothesis was tested:

Hypothesis 1: CM group participants will complete more daily self-monitoring surveys compared to control group participants.

Aim 2: Compare longest sustained period of daily survey completion in CM and C groups. One hypothesis was tested:

Hypothesis 1: CM group participants will have a longer sustained period of daily survey completion compared to control group participants.

Aim 3: Examine agreement between daily survey and follow-up visit reports of alcohol and Rx opioid use in CM and C groups.

Aim 4: Examine feasibility and acceptability of CM app implementation targeting self-monitoring of pain severity, related factors, and use of Rx opioids and alcohol.

Aim 5: Estimate effect-size to be used to perform power analyses and sample size calculations as part of the design of a larger RCT.

Review of the Literature

Opioid Epidemic

Prescription (Rx) opioid misuse is a significant public health concern and there is currently an epidemic of opioid overdose (CDC, 2014) **(**see Table 1 for definitions of relevant concepts)**.** Overdose deaths from Rx opioids have almost quadrupled since 1999, paralleled by a similar increase in emergency department visits, falls and fractures, and sales of Rx opioids (CDC, 2011; SAMHSA, 2016; WONDER, 2020). In 2019, almost 50,000 people in the U.S. died as a result of an opioid-involved overdose (CDC/NCHS, 2019), representing a 4.6% increase from 2018 (SAMHSA, 2020). The total economic burden of the opioid epidemic in the U.S. has been estimated at $631 billion from 2015-2018 (AHA, 2019).

The landscape of the opioid epidemic is complicated and changing over time. Findings from the 2019 National Survey on Drug Use and Health found that 10.1 million people in the U.S. reported past year opioid misuse (3.7% of the total population) (SAMHSA, 2020). From 2018 to 2019, Rx opioid misuse rates declined for each type of Rx opioid except fentanyl, which appears to be the primary contributor to the increases in opioid-involved overdoses (SAMHSA, 2020). Rx opioid misuse (9.7 million), Opioid Use Disorder involving Rx opioids (1.4 million), and opioid misuse initiation (1.6 million) remained unchanged (SAMHSA, 2020). While heroin initiation (50,000) significantly declined by 57%, heroin use (745,000) and Heroin Use Disorder (438,000) remain unchanged (SAMHSA, 2020). Additionally, there has been an increase in the use of methamphetamines in combination with opioids (O'Donnell et al., 2020).

The COVID-19 pandemic appears to be exacerbating the opioid epidemic. Over 40 U.S. states have reported increases in opioid-related mortality, mainly attributable to illicitly manufactured fentanyl and fentanyl analogs (AMA, 2021). Wainwright et al. (2020) compared

urine drug screen results ordered by health care professionals nationwide four months before and after the COVID-19 national emergency declaration and found increases in fentanyl (3.80% to 7.32%), heroin (1.29% to 2.09%), methamphetamine (5.89% to 8.16%), and cocaine (3.59% to 4.76%).

Table 1

Common Definitions of Relevant Concepts

Concept	Definition
Opioid misuse	Use of any kind of opioids (prescription or illicit), including heroin and a variety of pain-relieving medications (e.g., oxycodone, morphine, and codeine) in a way other than how they were prescribed.
Prescription (Rx) opioid misuse	National Survey on Drug Use and Health (NSDUH) defines it as use "in any way that a doctor did not direct you to use them," including (1) taking someone else's prescription; (2) taking one's own prescription more frequently, at a higher dosage, or for longer than prescribed; (3) taking the prescription in any other way not directed by a doctor; or (4) getting the same prescription from more than one doctor (SAMHSA, 2016).
Opioid Use Disorder (OUD)	A type of DSM-5 Substance Use Disorder (SUD); DSM-IV categories of substance abuse and substance dependence were combined in favor of a broader conceptualization of SUDs on a continuum of severity, ranging from mild to severe (APA, 2013).
Aberrant drug-related behavior (AB)	Any behavior outside of the boundaries of the agreed-on treatment plan between a doctor and patient (Gourlay & Heit, 2008).
Prevention	Interventions intended to prevent the development of a substance use problem, such as prescription medication misuse (SAMHSA, 2017).
Early intervention	While there is no standard definition, early intervention generally refers to the middle ground between prevention and treatment for SUDs (SAMHSA, 2017).

Tolerance	A state of physiologic adaptation in which increased doses of a drug are required to produce the same effects over time (Savage et al., 2003).
Physical dependence	A state of physiologic adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist (Savage et al., 2003).
Long-term opioid therapy (LTOT)	Prescription use of opioid medications for an extended period of time, generally considered to be >1 year (e.g., Chou et al., 2015).

Chronic Pain Epidemic

In addition to opioids, a twin "epidemic" facing providers is chronic pain and the challenge of managing it safely. Chronic pain, generally defined as pain lasting at least 3 months or past the normal injury healing time (IASP, 1986), interferes with sleep, employment, social functioning, and activities of daily living. It is the most significant contributor to disability globally (Rice et al, 2015). As a result, chronic pain imposes the greatest economic burden of all health conditions (Phillips, 2006), with an annual cost of $560-635 billion in direct medical expenses and lost productivity (Institute of Medicine, 2011).

Between 11% and 40% of the US population report some level of chronic pain, with millions suffering from daily, severe, costly, and disabling pain (e.g., Carr, 2016; Johannes et al., 2010; Nahin, 2015). Based on the 2016 National Health Interview Survey data, 20.4% of U.S. adults endorsed chronic pain, with 8.0% reporting high-impact chronic pain (i.e., chronic pain that frequently limits life or work activities) (Dahlhamer et al., 2018). The following groups had higher rates of both chronic pain and high-impact chronic pain: females, older adults, previously employed but currently unemployed individuals, those living in poverty, individuals with public health insurance, and those living in rural areas (Dahlhamer et al., 2018).

Types of chronic pain vary widely, with definitions and categories often insufficient or inconsistently used (IASP, 1986). Chronic pain encompasses a wide range of conditions, with pain most frequently variably categorized according to perceived location (e.g., headache), etiology (e.g., cancer pain), or the primarily impacted anatomical system (e.g., neuropathic pain). However, some pain categories do not adhere to these classification principles (e.g., fibromyalgia; Rolf-Detlef Treede et al., 2015).

Prescription Opioids

Chronic pain patients represent a population particularly vulnerable to opioid misuse. About 21-29% of chronic pain patients misuse Rx opioids (Vowles et al., 2015). Additionally, more than one-third meet criteria for a lifetime Opioid Use Disorder (Boscarino et al., 2011).

The prescribing of opioids for chronic pain has played a significant role in the opioid epidemic. Prescribers have traditionally been the source of most misused Rx opioids (SAMHSA, 2013) and the majority of individuals with Rx opioid dependence report being initially exposed to Rx opioids by a physician (Back et al., 2010). Between 2007 and 2012, the rate of opioid prescribing progressively increased among providers managing pain (increased 7.3%; Levy et al., 2015), with about one-fifth of pain patients prescribed opioids in outpatient medical settings (Daubresse et al., 2013). In 2012, 259 million opioid prescriptions were written, enough for every US adult to have a bottle of pills (Paulozzi et al., 2012). Despite a dose-dependent risk for negative consequences and insufficient evidence of the effectiveness of long-term opioid therapy (LTOT), discontinuation was historically uncommon (Chou et al., 2015; Martin et al., 2011; Vanderlip et al., 2014). In fact, Larochelle et al. (2016) found that nearly all (91%) patients who experienced a nonfatal opioid overdose on LTOT continued to receive Rx opioids after the overdose.

The use of prescription opioids has been linked to other potential harms. Having a lifetime history of at least one Rx for opioids increases the risk for having an Opioid Use Disorder (OUD; Edlund et al., 2014; Zedler et al., 2014; Bohnert et al., 2011). Higher dose of Rx opioids has been linked with risk for overdose (Bohnert et al., 2011; Gomes et al., 2011). Furthermore, misuse of Rx opioids is a significant risk factor for future or concurrent use of heroin (Cicero et al., 2014), with heroin initiation being 19 times more likely among Rx opioid misusers compared to non-misusers (Muhuri et al., 2013).

Effective Opioid Prescribing

Despite its traditionally widespread use, the evidence supporting the effectiveness of long-term opioid use for chronic pain management is limited. Busse et al. (2018) conducted a meta-analysis of 96 randomized clinical trials of patients with chronic noncancer pain and found that when compared with placebo, opioids were linked with significantly less pain and improved physical functioning, however, the magnitude was small. They also found that opioids and nonopioid alternatives may have similar benefits for pain and functioning, but these studies were of low to moderate quality (Busse et al., 2018). When paired with the risks associated with Rx opioid use, these findings highlight the need for providers to be judicious in the prescribing of opioids for pain management.

Effective opioid prescribing is highly individualized and dependent upon identification of misuse and comprehensive understanding of clinically-relevant variables, such as pain severity, quality of life, function, mental health, and other substance use (e.g., alcohol use; CDC, 2016). However, opioid prescribing often relies upon generalizations, which do not adequately capture patients' experience (e.g., Giske et al., 2010).

Identification of Prescription Opioid Misuse

Identification and measurement of Rx opioid misuse is problematic. There is no current gold standard for Rx opioid risk assessment and identification (Smith et al., 2015). Disparate definitions of Rx opioid misuse exist across the literature (Cochran et al., 2015). Little is known about risk factors for Rx opioid misuse and there have been no studies to date on protective factors. Using biological measures to identify potential Rx opioid misuse is more difficult among chronic pain patients prescribed opioids as they would be expected to test positive for opioids (e.g., on a urine drug screen). Furthermore, inconsistencies exist in measurement and categorization of Rx opioid use. For instance, a recent review by Frank et al. (2017) examining outcomes in dose reduction or discontinuation of LTOT found measurement of opioid dose reduction is inconsistent, with no widely accepted standard for meaningful dose reduction.

Problems associated with measurement of Rx opioid misuse have broad implications. Intervention for Rx opioid misuse and effective and responsible opioid prescribing depend upon provider ability to identify misuse (Dowell et al., 2016). Providers, however, have few tools to determine which patients may abuse Rx medication (Rosenblatt et al., 2015; Tong et al., 2019). Despite recognizing misuse as a problem in their patients, providers report feeling unprepared to screen for and address Rx opioid misuse (e.g., Ceasar et al., 2016; Miller et al., 2001). Primary care providers also report a lack of confidence in prescribing opioids safely (Keller et al., 2012), and predicting (Payne et al., 2011) and discussing (Hagemeier et al., 2013) misuse with their patients. Additionally, practices intended to decrease risk for misuse (e.g., opioid treatment agreements) are inconsistently used (Green et al., 2012; Ringwalt et al., 2015; Pergolizzi et al., 2010; Starrels et al., 2014). As a result, misuse often goes undetected, potentially leading to increased severity and consequences (Smith et al., 2015). Not surprisingly, high-risk opioid

prescribing practices have been identified as contributing to the opioid epidemic (e.g., Bohnert et al., 2011; Liu et al., 2013).

Role of Non-Pharmacological Interventions

Treatment approaches that balance chronic pain management and mitigation of Rx opioid misuse are sorely needed. Pharmacological interventions, such as abuse-deterrent formulations, play an important and well-established role in Rx opioid risk mitigation (e.g., Coplan et al., 2016). Abuse-deterrent formulations create barriers to abuse by making crushing or chewing medication difficult and/or including an opioid antagonist to block opioid effects (e.g., euphoria) (Cicero & Ellis, 2015). However, such interventions are not a comprehensive solution to the problem of Rx opioid misuse as abuse-deterrent formulations are not abuse-proof (Becker & Fiellin, 2017). In contrast, whereas clinical guidelines for chronic pain management generally include recommendations for non-pharmacological interventions as important components of Rx opioid risk mitigation (Dowell et al., 2016), few studies have empirically tested such interventions.

Self-Monitoring

Self-monitoring is a core element of self-regulation and self-management (e.g., Bandura, 1991), and is well-established as an integral component of effective chronic pain management (Adams et al., 2017). Pain severity is typically assessed at one time point during medical visits, which has been shown to be less reliable and more inaccurate as a result of recall bias compared to more frequent reporting (Coughlin, 1990; Adams et al., 2017; Giske et al., 2010). Additionally, such assessments are not sensitive to the variable nature of pain severity over time (Jensen & McFarland, 1993; Adams et al., 2017).

While self-monitoring as a stand-alone intervention has not received much research attention, self-monitoring as a component of other effective interventions (Daniëls et al., 2021) is a burgeoning area of research. Self-management interventions have been shown to be effective in decreasing pain and improving physical functioning among individuals with chronic widespread pain (Geraghty et al., 2021). Consistent utilization of self-management strategies is predictive of improved outcomes (pain, disability, and depressive symptoms) among individuals with chronic pain, even after controlling for baseline core pain experience factors (e.g., pain catastrophizing and self-efficacy) (Nicholas et al., 2012). Additionally, the integration of ecological momentary assessment (EMA) and ecological momentary interventions (EMIs) provides opportunities for targeted treatment (Shaefer et al., 2020). For example, one promising approach for the treatment of eating disorders is EMIs that utilize EMA to identify high risk moments then trigger delivery of interventions (Shaefer et al., 2020; Juarascio et al., 2018).

Remote Self-Monitoring

In the US, over two-thirds of individuals own smartphones (Pew Research Center, 2014). There is a plethora of apps used to track health data and assist in management of chronic diseases, with multiple apps specifically developed for pain patients (Hundert et al., 2014; Stinson et al., 2013; Reynoldson et al., 2014; Vega et al., 2014). Health apps provide an ideal platform for self-monitoring.

There is substantial evidence that electronic monitoring via apps is significantly better than paper-and-pencil diaries with respect to compliance, user-friendliness, patient satisfaction, and test reliability and validity (e.g., Jamison et al., 2002; Hufford et al., 2002). Momentary electronic assessment methods, including current symptom ratings, are considered to be state-of-the-art measures for the evaluation of pain and other health-related outcomes and have been

shown to be superior to retrospective assessments (e.g., Heron & Smyth, 2010). Thus, remote self-monitoring is a potentially promising solution to improving tracking of pain severity, related factors, and Rx opioid use, with effective use of such methods leading to more informed practitioners.

Self-Monitoring Adherence

Low rates of adherence have impeded the use of health apps and resulted in reduced utility across a range of behaviors, such as weight loss (e.g., Laing et al., 2014) and sleep disturbance (e.g., Huberty et al., 2021). Poor adherence has also been a major barrier to the more frequent self-monitoring that is essential for effective pain management (Bolger et al., 2003; Adams et al., 2017), including the use of smartphone apps promoting self-monitoring among chronic pain patients (e.g., Jamison et al., 2016), even when non-monetary rewards were included (i.e., supportive text messages; Jamison et al., 2017). Investigation into strategies to promote intervention adherence are thus needed.

Contingency Management

A robust strategy for promoting and maintaining behavior change is CM, systematic reinforcement of target behaviors based on principals of operant conditioning (e.g., Higgins et al., 1994a; Higgins et al., 1994b; Svikis et al., 1997; Kirby et al., 1998). CM has long been used in Substance Use Disorder (SUD) treatment research and is one of the most effective strategies for promoting drug abstinence (Higgins et al., 1994a; Silverman et al., 1996; Polak et al., 2020; Benishek et al., 2014; Prendergast et al., 2006). It does so by activating the brain's reward and inhibitory systems through both positive and negative reinforcement using immediate, concrete incentives. CM involves reinforcing a specific target behavior with tangible rewards (e.g., cash or vouchers). CM has been used for a range of target behaviors, ranging from take-home doses

in methadone programs (Iguchi et al., 1988; Kidorf et al., 1994) to negative urine drug screens (Stitzer et al., 1986; Jones et al., 2001; Peirce et al., 2006), to attendance of counseling (Svikis et al., 1997; Svikis et al., 2007) or job-skills training (Wong & Silverman, 2007; Silverman et al., 2001) sessions.

Use of CM for Health Behavior Targets

More recently, use of CM to promote health-related behavior change has received considerable attention (e.g., Higgins et al., 2012; Herrmann et al., 2017; Stitzer et al., 2020). CM has been found effective at promoting physical activity (Kurti & Dallery, 2013; Pope & Harvey-Berino, 2013) and medication adherence (Rigsby et al., 2000; Sorensen et al., 2007). Despite its effectiveness, CM is underutilized (Herbeck et al., 2008). Practical barriers to adoption include lack of funds, lack of training for staff, and difficulty in managing the rewards (Carroll, 2014; Polak et al., 2020).

CM and Cost Effectiveness

One barrier to use of CM has been that the monetary costs of incentives can be prohibitive. Petry et al. (2000) developed and empirically tested a method for making CM more cost effective. It was an escalating variable-ratio schedule of reinforcement such that costlier rewards are provided less frequently. Using a lottery-based reward system, participants who continuously maintain drug abstinence earn the right to draw increasing numbers of tokens from a "fishbowl" containing hundreds of tokens. With this prize-based approach, the monetary value of incentives remains more modest, thereby increasing the potential for translation to "real life" clinical settings. Multiple studies have highlighted the potential of CM protocols that use variable-ratio reinforcement schedules as a cost-effective CM strategy (e.g., Petry et al., 2005b; Olmstead & Petry, 2009; Peirce et al., 2006).

Remote Delivery of CM

An effective CM intervention requires frequent and objective monitoring of the target behavior, which has traditionally been cumbersome on staff and patients and can limit the range over which health services can be delivered (Kurti et al., 2016). The use of technology in remotely monitoring behaviors and delivering incentives eliminates the practical barriers associated with in-person monitoring (Kurti et al., 2016; Dallery et al., 2019). This emerging CM intervention strategy has been used for studies targeting substance abuse (e.g., Alessi & Petry, 2013; Meredith et al., 2011; Oluwoye et al., 2020), weight loss (e.g., Unick et al., 2015), as well as medication adherence (Defulio et al., 2021a) and home-based health monitoring (Kurti et al., 2016). While they provide ample evidence that a mobile-based CM procedure can work in practice, all still require human involvement.

DynamiCare Rewards App

DynamiCare is an iOS and Android app that provides several highly innovative features that overcome barriers to CM adoption, including fully automating CM methodology (monitoring/incentivizing of target behavior and dispersal of rewards). In addition to Virginia Commonwealth University, this app is currently being used at multiple research universities, such as Johns Hopkins University, Massachusetts Institute of Technology, University of Chicago, Western Michigan University, and University of Vermont. DynamiCare Health, Inc. has been awarded several grants and prizes for the development and implementation of the DynamiCare Rewards app, including Small Business Innovation Research (SBIR) Phase I and Phase II grants from NIH – NIAAA. To date, use of this app has focused exclusively on SUDs.

Recent trials using the DynamiCare Rewards app have demonstrated its efficacy and utility in delivering CM. Kurti et al. (2020) conducted a pilot study of the DynamiCare Rewards

app targeting cigarette smoking in pregnant women. They demonstrated feasibility and found that those in the CM group had higher quit rates compared to controls (Kurti et al., 2020). DeFulio et al. (2021b) found CM delivered via the DynamiCare Rewards app significantly increased clinic appointment attendance and drug abstinence compared to matched controls among patients with Opioid Use Disorder. They also concluded that the DynamiCare Rewards app was usable, acceptable, and similarly effective to in-person CM (DeFulio et al., 2021b).

Incentives for Self-Reporting of Prescription Opioid Use

Finan et al. (2017) recently investigated the variability of Rx opioid use and associations with pain and related factors in patients with sickle cell disease who received incentives for completing a daily electronic diary (N=45). They found that greater pain and pain catastrophizing were associated with greater use of short-acting opioids, and negative affect was associated with greater use of long-acting opioids. Adherence to self-monitoring was problematic in their study, with one-fourth (25%) of the sample excluded for having <25% of self-reports, with an additional 25% of the remaining sample having missing data. These findings highlight the value of remote self-monitoring of pain severity, related factors, and Rx opioid use for providing information that aids effective opioid prescribing. Results also demonstrate the need to better understand how to improve adherence to self-monitoring of these variables.

Summary

Adherence is a problem in many fields of behavioral medicine and while CM has had the biggest impact, practical barriers have limited implementation in “real life” care. The present study sought to bridge the gap with an RCT of the DynamiCare Rewards app for promoting daily self-monitoring of pain severity, related factors, and Rx opioid and alcohol use in a sample of individuals with chronic pain. Comprehensive information on pain severity and medication use

has the potential to help physicians make better opioid prescribing decisions, addressing the opioid epidemic and improving public health.

Methods

Participants

Participants will be individuals seeking to participate in research studies through ResearchMatch.org. Individuals will be eligible to participate in the study if they meet the following criteria: 1) at least 18 years of age; 2) own a study-compatible smartphone (iPhone or Android device); 3) report non-cancer related chronic pain of at least 3 months' duration; 4) able to provide informed consent for study participation; 5) report having chronic pain as part of their ResearchMatch.org profile; and 6) prescribed ≥1 opioid medication(s) for pain management in their lifetime. Individuals will be excluded from study participation if they meet any of the following criteria: 1) currently pregnant; 2) presenting with language barriers, cognitive impairment, or serious medical or psychiatric illness that in the opinion of the Investigator would preclude them from providing informed consent or participating in the study; and 3) visual impairment or motor impairment that would interfere with use of a smartphone.

Study Procedures

Recruitment

Participants will be recruited through ResearchMatch.Org. ResearchMatch.Org is an online platform that allows researchers to recruit from a pool of people who have signed up to receive emails about potential research study participation opportunities. A recruitment email will be distributed one to two times per week to 20 to 400 unique ResearchMatch.org participants each time from this potential research participation pool who listed chronic pain conditions as part of their ResearchMatch.org profile. The recruitment email will include a

description of the study and a link to the REDCap screening survey imbedded in a button labeled "Yes, I'm interested."

Screening

Individuals who indicate that they are interested in potentially participating will first be brought to the REDCap Screener Introduction. At this point, they will be asked if they want to be screened for study eligibility. Those who screen eligible for the study and are interested in study participation will be asked for contact information. No further data will be collected from those who screen ineligible or state they are not interested in study enrollment. The screening process will take approximately 5-10 minutes.

Informed Consent

Individuals who meet eligibility criteria, indicate that they want to participate in the study, and provide their contact information will be emailed a link to the REDCap study informed consent form within one business day of completing the screener. The VCU IRB granted a waiver for signed informed consent. This consent form describes the purpose of the study, involvement in the study (e.g., randomization to two study groups, completion of daily surveys for 28 days, baseline and follow-up assessments, compensation, etc.); the voluntary nature of the study; limits of confidentiality; as well as risks, benefits, and costs of participation. Additionally, participants will be told that they could stop participation at any point without negative repercussions. Participants select one of the following options: “Yes, I understand this and want to participate in the PROMOTING MONITORING: A PILOT TEST study” or “No, I do not want to participate in the study.” Those who provide consent to participate in the study will proceed to baseline assessment, followed by randomization to either the contingency management (CM) or control (Co) group.

Baseline Assessment

Following informed consent, participants will complete a series of computer-administered questions via REDCap (demographic information; medical and mental health history; The Brief Pain Inventory; Pain Self-Efficacy Questionnaire; Pain Catastrophizing Scale; Hospital Anxiety and Depression Scale; Pittsburgh Sleep Quality Index; and 28-day Timeline Followback). Baseline assessment will take approximately 30-45 minutes to complete. If participants do not complete the baseline survey within two days of completing the screener, they will be sent a reminder email to complete the survey. If participants do not complete the baseline survey within three days post screening, they will be called. At the end of their baseline survey, participants will be asked their preference for a 5-10-minute telephone or Zoom call to finish their baseline visit. They will then be informed that within the next business day they would receive a call or email from study staff to set up their Zoom or phone appointment to complete the baseline visit. Participants will be called daily for one week following baseline survey completion until they are reached to complete the baseline call. Participants who can not be reached by telephone or Zoom within one week of completing the baseline survey will not be enrolled or randomized into the study.

Baseline Visit Call

During the 5-10-minute Zoom or telephone call RAs will review the following with all study participants: verify study eligibility; complete randomization to CM or Co groups; set up the DynamiCare Rewards app on the participant's smartphone; and remind them that they would receive daily text message reminders to complete the daily survey. RAs also will encourage participants to set an alarm or some other reminder of their own. In addition, for participants randomized to the CM condition, RAs will review CM procedures, including their debit card,

and they explain that they will receive an initial draw and reward for setting up the app. Participants will also be offered handouts summarizing the information discussed in the call.

Randomization. Participants who complete the baseline visit call and are verified as eligible for the study will be randomly assigned to either the CM (n = 46) or Co (n = 35) condition. To determine group assignment, study staff will use an Excel spreadsheet with randomization groups determined by a random numbers app and prepared by Dr. Svikis in advance of study launch. Each row with a randomization group will be numbered sequentially and correspond to a participant's study ID number. Study staff will not see the randomization group until they indicate that the participant is enrolled in the study and ready to be randomized. No stratification variables are proposed for this Stage I pilot study (see Rounsaville et al., 2001).

DynamiCare Rewards App. DynamiCare is an iOS and Android app which fully automates CM methodology. The app will be customized for the present study, incorporating the daily self-monitoring survey and incentives plan. After randomization, all participants will be added to the DynamiCare Analytics portal and received an email with the link to download the app on their smartphone. Once participants successfully downloaded the app, RAs instructed them in the use of the app.

All Participants. Day 1 of the daily surveys will start the day after the app isdownloaded and the account is set up. Participants will be encouraged to complete the daily survey and pick a time of day to set a personal reminder. They will receive a text reminder around noon each day from a study smartphone. The daily survey data will automatically be uploaded to the DynamiCare HIPAA-compliant server. Participants' DynamiCare Rewards accounts will be manually archived after they completed the 28-day survey period.

CM Group. Participants randomized to the CM group will have the chance to receive incentives for complying with the target behavior (completing daily self-monitoring surveys within a 12-hour window (8am-8pm) over a 28-day period. Daily self-monitoring surveys and the delivery of incentives were completed using the DynamiCare Rewards app. The escalating variable-ratio reinforcement schedule used for the study was modeled after the fishbowl method developed by Petry et al. (2005a) and Olmstead and Petry (2009).

Behavioral incentives will be managed remotely via the app to facilitate extrinsic motivation for participant follow-through with self-monitoring. Participants will be able to draw from a fishbowl via the app to determine their monetary prize. Participants will be given an initial draw for downloading the app and completing training during the baseline call, which will be set to $8. When they meet the target behavior, participants will be awarded additional draws through the app. The number of draws they earn will increase by one for every day they completed the survey. The maximum number of draws they could earn over the course of the 28-day period was 236. Failure to complete a daily self-monitoring survey, however, resulted in a reset to baseline (1 draw per completed daily self-monitoring survey) and 3 consecutive completed daily self-monitoring surveys will be required for a participant to return to the highest level achieved prior to reset. Additional engagement with the app will not result in additional monetary reinforcement.

Incentives. Specifically, reward amounts ranged from $0-50 in value. Half (50%) of incentives will be "good job" and not associated with a monetary reward. The app will be connected to reloadable debit cards (The Next Step debit card, provided by True Link Financial, Inc.), which will be activated and mailed to CM participants within one to two weeks of their baseline call.

Co Group. The Co group will be asked to download the DynamiCare Rewards app during the baseline visit call and to complete the same daily self-monitoring survey as the CM group, but will not be provided with incentives for completing the survey. They also will receive the same reminders to complete the daily survey as the CM group. The only difference between the CM and Co groups will be the receipt of incentives for the 28-day trial.

Post-Daily Survey Period Follow Up

At the end of the 28-day self-monitoring survey period, participants will be emailed a link to the REDCap follow-up survey (approximately 30-45 minutes), including The Brief Pain Inventory; Pain Self-Efficacy Questionnaire; Pain Catastrophizing Scale; Hospital Anxiety and Depression Scale; acceptability questions; Pittsburgh Sleep Quality Index; Timeline Followback (TLFB); and self-report validity and accuracy questions. If participants do not complete the survey within two days, they will be sent a reminder email. If participants do not complete the survey after three days, they will be called. Participants will be asked if they would like to be provided with a document summarizing their daily survey ratings in the follow-up survey. Once participants complete their participation in the study, we will remove their contact information from the study database to protect their privacy.

Participant Compensation

Participants will be compensated with a 20-dollar Amazon electronic gift card for completing the baseline visit and a 30-dollar Amazon electronic gift card for completing the follow-up survey. Electronic gift cards will be distributed via email within 1-2 weeks of completing their visit.

Measures

Assessment measures were carefully selected, based on domains to be studied, psychometric properties of existing measures, previous research in this population, and personal experiences from preliminary studies with the target population. The battery will take approximately 30-45 minutes to complete. Screening, baseline, and follow-up data will be collected and managed using REDCap hosted at Virginia Commonwealth University. Table 3 provides an overview of measures and the baseline and follow-up surveys can be found in Appendix B.

Baseline Survey Only

Demographic Information. Participants were asked about race, ethnicity, age, gender, marital status, employment status, highest grade completed in school, and living situation.

Medical and Mental Health History. Participants were asked about the number of days they experienced medical problems in the past 30 days; previous and current mental health and medical conditions; and if they were currently prescribed opioid, benzodiazepine, and other types of pain medications in the last 28 days.

28-Day Monitoring Period

Daily Self-Monitoring Survey. Once daily, all participants were asked to complete a self-monitoring survey using the app, which was designed to take approximately 5 minutes to complete. Survey items were derived from validated measures and previously tested pain self-monitoring apps/electronic diaries and include the following domains: pain experience; impact of pain on function; sleep; mood; pain catastrophizing; prescription medication use (opioids and sedatives); alcohol use; marijuana use, cannabidiol (CBD) use (Cleeland & Ryan, 1994; Jamison et al., 2016; Finan et al., 2017; Watson et al., 1988; McNair et al., 1992; Sullivan et al., 1995). See Appendix A for the complete daily self-monitoring survey.

Mean Daily Self-Monitoring Survey Completion Time. The app measured the time it took participants to complete the daily self-monitoring survey; all survey completion times were averaged.

Baseline & Follow-Up Survey

Brief Pain Inventory (BPI; Cleeland & Ryan, 1994). The BPI is a well-known measure of clinical pain and has demonstrated sufficient reliability and validity. This self-report questionnaire asks about pain history, severity, and its impact on functioning. Participants rate the intensity of pain at its worst from the past 24 hours, at its least from the past 24 hours, on average, and "right now" on a 0-10 scale. Participants also rate how much pain has interfered with various aspects of their life on a 0-10 scale.

Pain Catastrophizing Scale (PCS; Sullivan et al., 1995). The PCS is a 13-item measure of catastrophizing, including rumination, magnification, and helplessness. Each item is rated on a 0-4 scale. Item responses are summed to generate a total score; higher scores indicate increased pain catastrophizing. It has been found to have adequate reliability and validity (Osman et al., 1997).

Pain Self-Efficacy Questionnaire (PSEQ; Nicholas, 1989; Nicholas, 2007). The PSEQ is a 10-item measure of pain self-efficacy. Each item is rated on a 0-6 scale. Items are summed to generate a total score, with a greater total score indicating increased pain self-efficacy. The PSEQ has been shown to be reliable and valid (Gibson & Strong, 1996; Asghari & Nicholas, 2001).

Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983; Bjelland et al., 2002). The HADS is a widely used 14-item measure of past-week presence and severity of anxious and depressive symptoms. Response options range from 0-3. Two scores are summed

from the responses, a depression score and an anxiety score, with higher values indicating heightened experience of symptoms. The HADS has adequate reliability and validity, and an optimal balance between sensitivity and specificity.

Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989). The PSQI is a reliable and valid measure of sleep quality and disturbances over the past month. The questionnaire contains 19 items focusing on subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction.

Follow-Up Survey Only

TLFB (Sobell & Sobell, 1992). The TLFB is a widely-used, semi-structured interview that uses a calendar to retrospectively collect daily information about substance use. It has been shown to have good reliability and validity and is widely considered the "gold standard" of quantity and frequency substance use assessment. To accommodate the remote study procedures, the TLFB was adapted from interviewer to computer administered (via REDCap), which has been found to be reliable and valid (e.g., Martin-Willett et al., 2020). The TLFB was used to obtain detailed past 28-days frequency of opioid pain medication and alcohol use information.

Acceptability. Participants were asked to answer questions about satisfaction, acceptability, and feasibility on a 0-10 scale based on those used in a previous RCT investigating an app developed for chronic pain patients (Jamison et al., 2017).

Validity and Accuracy of Responses. All participants were asked how honest they were in completing the daily survey (response options: I was very honest, I was honest most of the time, I was honest some of the time, I was honest once in a while, I was not honest at all). CM participants were additionally asked how much the rewards made a difference in how accurately

they reported information in the daily survey (response options: Not at all, very little, little, somewhat, much, to a great extent, completely).

Self-Report of Impact of Behavioral Incentives to Adherence. CM participants were asked how much the rewards made a difference in whether they completed the daily survey (response options: Not at all, very little, little, somewhat, much, to a great extent, completely).

Table 3

Overview of Study Measures

Measure	Baseline Survey	28-Day Monitoring Period	Follow-Up Survey
Demographic information, medical/mental health history	X		
BPI, PCS, PSEQ, HADS, PSQI	X		X
Daily self-monitoring survey (via app), daily self-monitoring survey completion time		X	
TLFB, acceptability survey, validity of responses			X

Data Analysis Plan

Effect Size Estimation

The major goal of this Stage I pilot RCT is to estimate the effect size of the primary outcome variables (Rounsaville et al., 2001). This will be done by using the means and variances of the CM and Co groups on the primary outcome variables. This estimated effect-size will then be used to perform power analyses and sample size calculations to be used in the design of a larger clinical trial.

Sample Size Justification

As this is a Stage I pilot study and no preliminary data are available, a power analysis is not provided. Sample size was determined by anticipating a medium effect size (.05), 80% power, alpha level=.05 (Cohen, 1988). For two-sided *t*-tests, 32 participants/group are needed. This would allow us to detect an effect size of *d*=.711, which falls between medium, *d*=.05 and large, *d*=.8 effect sizes. Recruitment of 80 subjects with 80% retention was expected to achieve this effect size.

Assessing Randomization Success

Randomization should ensure that no differences are found at baseline between the two conditions. However, the CM and Co groups will compared on core baseline measures (demographics and medical and mental health history) using *t*-tests for continuous and chi-square analyses for categorical variables to ensure no differences occurred by chance on important measures.

Outcome Measures

As shown in Table 4, the primary outcome measures are the number of completed daily self-monitoring surveys and the longest period of sustained adherence to survey completion. It is hypothesized that those in the CM group will complete more daily self-monitoring surveys and have a longer sustained period of daily survey completion compared to controls. The number of completed daily surveys and duration of continuous daily survey completion will be compared between CM and Co groups using independent *t*-tests.

Secondarily, descriptive statistics will be used to summarize CM participants' self-report of the impact of behavioral incentives on adherence. Mean time to complete the daily surveys between CM and Co groups will be compared using an independent *t*-test. Pain experience and

related variables from baseline will be compared to follow up responses for the total sample using paired *t*-tests. The daily survey item responses will be summarized for the overall sample using descriptive statistics. Associations between daily survey and follow-up TFLB for alcohol and prescription opioid use data for the overall sample and each study group will be examined using Spearman's correlations. Descriptive statistics will be used to summarize self-report validity and accuracy of responses. Feasibility and acceptability of CM app implementation will be examined by comparing follow-up acceptability survey ratings for each group using independent *t*-tests.

Table 4

Outcome Measures Overview

Name	Time Frame	Brief Description
Number of daily surveys completed	28-day daily survey period	This primary outcome is consistent with previous CM studies.
Longest period of sustained adherence to daily survey completion	28-day daily survey period	Largest number of consecutive days wherein daily surveys were completed. This primary outcome is consistent with previous CM studies.
Mean frequency of alcohol and prescription opioid use (days of use)	28-day daily survey period to follow up	Spearman's correlations between daily survey and TLFB data for alcohol and prescription opioid frequency (days of use) were conducted for the entire sample, the CM group, and the Co group.
Mean time to complete the daily surveys	28-day daily survey period	Daily survey completion time (the amount of time from daily survey start to finish).

Name	Time Frame	Brief Description
Mean CM app feasibility and acceptability survey ratings	Follow up	CM app satisfaction, acceptability, and feasibility survey ratings (on a 0-10 scale; administered at follow-up) based on those used in a previous RCT investigating an app developed for chronic pain patients (Jamison et al., 2017).
Self-report validity and accuracy of responses	Follow up	Ratings of how honest participants were in completing the daily survey and how much the rewards made a difference in how accurately CM participants reported information in the daily survey.

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Appendix A

Daily Self-Monitoring Survey (via DynamiCare Rewards app)

How were you yesterday?

1. What was your average pain? (rated on a 0-10 scale; 0=no pain, 10=worst pain)

2. How much did your pain interfere with your daily activities? (rated on a 0-10 scale; 0=did not interfere, 10=completely interfered)

3. Overall, how much have things changed? (rated on a 0-10 scale; -5=worse; 0=the same; 5=better)

4. How would you rate your sleep quality? (Very good (0) Fairly good (1) Fairly bad (2) Very bad (3))

5. How sad were you yesterday? (rated on a 0-10 scale; 0=not at all and 10=very much)

6. How anxious were you yesterday? (rated on a 0-10 scale; 0=not at all and 10=very much)

7. How irritable were you yesterday? (rated on a 0-10 scale; 0=not at all and 10=very much)

8. Did you take any prescription medications yesterday? (Yes or No)

9. [If yes to the above] Which prescription medications did you take? (check all that apply)
    - Prescription opioid pain reliever (for example: Percocet, Vicodin)
    - Prescription medication for anxiety or sleep (for example: Xanax, Ativan, or Klonopin)
    - Other prescription medication (free response)

10. [For those checked above] How did you take the [type of medication]?
    - Took as prescribed
    - Took less than prescribed
    - Took more than prescribed
    - It was not prescribed for me

11. How many 12-ounce beers containing alcohol did you have? (free response)

12. How many 5-ounce glasses of wine did you have? (free response)

13. How many shots of liquor did you have (straight or in a mixed drink)? (free response)

14. Did you use marijuana? (Yes or No)

15. Did you use cannabidiol (CBD)? (Yes or No)

Appendix B

Computer-Administered Survey

Demographic Information [Baseline Visit Only]

1. Of what race do you consider yourself?
    a. White or Caucasian
    b. American Indian or Alaskan Native
    c. Asian
    d. Black or African American
    e. Native Hawaiian or other Pacific Islander
    f. Other

2. What is your ethnicity?
    a. Hispanic
    b. Not Hispanic

3. What is your gender? (Female; Male; Other)

4. What is your age? Click in the box, type your age, and click submit. (free response)

5. What is your current marital status?
    a. Single
    b. In a relationship
    c. Married
    d. Divorced/separated
    e. Widowed

6. What is your current employment status?
    a. Full time, 40 hours per week
    b. Part time
    c. Not working due to medical or mental health disability
    d. Retired
    e. Unemployed
    f. Student
    g. Homemaker or stay-at-home mom

7. What is the highest grade you completed in school?
    a. Grades 1 through 8
    b. Grades 9 through 11
    c. Grade 12 or GED
    d. Some college
    e. Associate's degree
    f. Bachelor's degree
    g. Technical training (ex: cosmetology, computer, trade school)

h. Graduate degree (Master's or Doctorate)

12. Who do you currently live with?
    a. With my children and significant other/spouse
    b. With my significant other/spouse only
    c. With my children only
    d. With other family
    e. With friends
    f. Alone
    g. I move around a lot or am homeless
    h. Group home or assisted living facility

Medical and Mental Health History [Baseline Visit Only]

1. How many days have you experienced medical problems in the past 30 days? (response 0-30)

2. Check all of the following medical conditions that a doctor, nurse, or other health professional has told you that you have.
    a. Heart disease (e.g., angina, heart attack, or congestive heart failure)
    b. High blood pressure
    c. High cholesterol
    d. Migraines
    e. Diabetes

3. As before, check all of the following medical conditions that a doctor, nurse, or other health professional has told you that you have.
    a. Hepatitis
    b. Liver disease
    c. Pancreatitis
    d. Asthma
    e. Chronic obstructive pulmonary disease (COPD) (e.g., emphysema or bronchitis)
    f. Arthritis
    g. Other (free response)

4. Check all of the following mental health conditions that a doctor, psychologist, or other health professional has told you that you have.
    a. Depression
    b. Anxiety
    c. Bipolar Disorder
    d. Attention-Deficit/Hyperactivity Disorder
    e. Substance Use Disorder
    f. Other (free response)

5. Are you currently prescribed any opioid medications (such as OxyContin, Vicodin, Tylenol 3, Percocet, or morphine)? (yes or no)

6. Are you currently prescribed any other types of pain medications (such as ***Gabapentin or*** Pregabalin***)***? (yes or no)

7. Are you currently prescribed any benzodiazepine medications (such as Xanax, Ativan, Valium, or Klonopin)? (yes or no)

The Brief Pain Inventory (BPI) [Baseline & Follow-Up Visits]

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

☐ Yes ☐ No

3. Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the average.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have right now.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐ No Relief	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐ Complete Relief

9. Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

B. Mood

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

C. Walking ability

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

D. Normal Work (includes both work outside the home and housework)

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

E. Relations with other people

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

F. Sleep

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

G. Enjoyment of life

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

Pain Self-Efficacy Questionnaire (PSEQ) [Baseline & Follow-Up Visits]

Please rate how **confident** you are that you can do the following things at present, **despite the pain**. To indicate your answer circle one of the numbers on the scale under each item, where 0= not at all confident and 6= completely confident.

Remember, this questionnaire is **not** asking whether of not you have been doing these things, but rather **how confident you are that you can do them at present, despite the pain**.

1. I can enjoy things, despite the pain.
2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.
3. I can socialise with my friends or family members as often as I used to do, despite the pain.
4. I can cope with my pain in most situations.
5. I can do some form of work, despite the pain. ("work" includes housework, paid and unpaid work).
6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite pain.
7. I can cope with pain without medication.
8. I can still accomplish most of my goals in life, despite the pain.
9. I can live a normal lifestyle, despite the pain.
10. I can gradually become more active, despite the pain.

Pain Catastrophizing Scale (PCS) [Baseline & Follow-Up Visits]

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain. (0=not at all; 1=to a slight degree; 2=to a moderate degree; 3=to a great degree; 4=all the time)

When I'm in pain…

1. I worry all the time about whether the pain will end.
2. I feel I can't go on.
3. It's terrible and I think it's never going to get any better.
4. It's awful and I feel that it overwhelms me.
5. I feel I can't stand it anymore.
6. I become afraid that the pain will get worse.
7. I keep thinking of other painful events.
8. I anxiously want the pain to go away.
9. I can't seem to keep it out of my mind.
10. I keep thinking about how much it hurts.
11. I keep thinking about how badly I want the pain to stop.
12. There's nothing I can do to reduce the intensity of the pain.
13. I wonder whether something serious may happen.

Hospital Anxiety and Depression Scale (HADS) [Baseline & Follow-Up Visits]

Tick the box beside the reply that is closest to how you have been feeling in the past week. Don't take too long over you replies: your immediate is best.

1. I feel tense or 'wound up':
   3 Most of the time
   2 A lot of the time
   1 From time to time, occasionally
   0 Not at all

2. I still enjoy the things I used to enjoy:
   0 Definitely as much
   1 Not quite so much
   2 Only a little
   3 Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen:
   3 Very definitely and quite badly
   2 Yes, but not too badly
   1 A little, but it doesn't worry me
   0 Not at all

4. I can laugh and see the funny side of things:
   0 As much as I always could
   1 Not quite so much now
   2 Definitely not so much now
   3 Not at all

5. Worrying thoughts go through my mind:
   3 A great deal of the time
   2 A lot of the time
   1 From time to time, but not too often
   0 Only occasionally

6. I feel cheerful:
   3 Not at all
   2 Not often
   1 Sometimes
   0 Most of the time

7. I can sit at ease and feel relaxed:
   0 Definitely
   1 Usually
   2 Not Often
   3 Not at all

8. I feel as if I am slowed down:
   3 Nearly all the time
   2 Very often
   1 Sometimes
   0 Not at all

9. I get a sort of frightened feeling like 'butterflies' in the stomach:
   0 Not at all
   1 Occasionally
   2 Quite Often
   3 Very Often

10. I have lost interest in my appearance:
   3 Definitely
   2 I don't take as much care as I should
   1 I may not take quite as much care

0 I take just as much care as ever

11. I feel restless as I have to be on the move:
    3 Very much indeed
    2 Quite a lot
    1 Not very much
    0 Not at all

12. I look forward with enjoyment to things:
    0 As much as I ever did
    1 Rather less than I used to
    2 Definitely less than I used to
    3 Hardly at all

13. I get sudden feelings of panic:
    3 Very often indeed
    2 Quite often
    1 Not very often
    0 Not at all

14. I can enjoy a good book or radio or TV program:
    0 Often
    1 Sometimes
    2 Not often
    3 Very seldom

Pittsburgh Sleep Quality Index (PSQI) [Baseline & Follow-Up Visits]

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. When have you usually gone to bed? (free response option)

2. How long (in minutes) has it taken you to fall asleep each night? (free response option)

3. What time have you usually gotten up in the morning? (free response option)

4. A. How many hours of actual sleep did you get at night? (free response option)

   B. How many hours were you in bed? (free response option)

5. During the past month, how often have you had trouble sleeping because you	Not during the past month (0)	Less than once a week (1)	Once or twice a week (2)	Three or more times a week (3)
A. Cannot get to sleep within 30 minutes				
B. Wake up in the middle of the night or early morning				
C. Have to get up to use the bathroom				
D. Cannot breathe comfortably				
E. Cough or snore loudly				
F. Feel too cold				
G. Feel too hot				
H. Have bad dreams				
I. Have pain				
J. Other reason (s), please describe, including how often you have had trouble sleeping because of this reason (s):				
6. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
8. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?				
9. During the past month, how would you rate your sleep quality overall?	Very good (0)	Fairly good (1)	Fairly bad (2)	Very bad (3)

Acceptability & Feedback Questions [Follow-Up Visit Only]

Please rate the following questions on a 0-10 scale:

1) How easy was it to use the smartphone app?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Completely difficult — Completely easy

2) Overall, how satisfied were you using the DynamiCare app?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

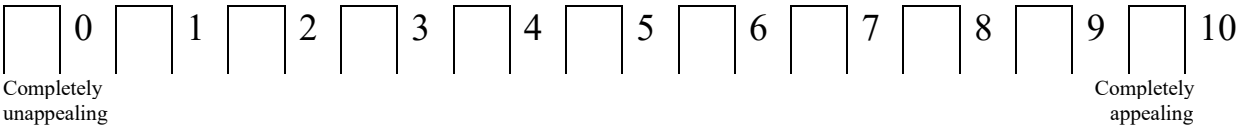
Extremely dissatisfied — Extremely satisfied

3) How useful were the daily surveys?

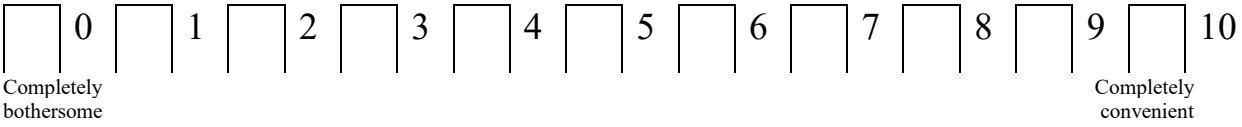
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Completely useless — Completely useful

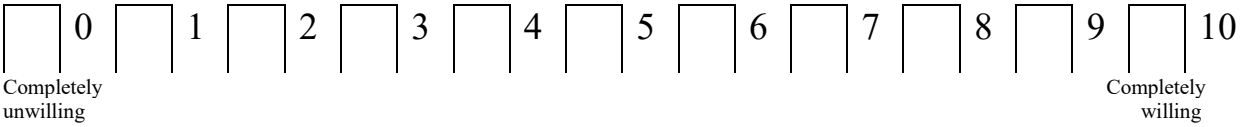
4) How appealing was the smartphone app?



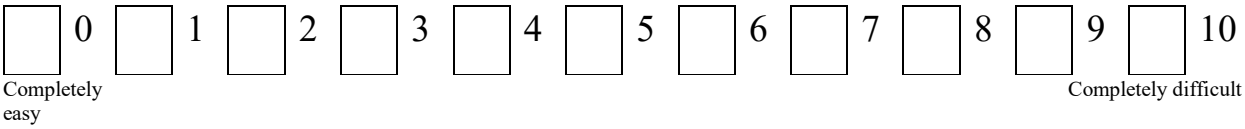
5) How bothersome were the daily surveys?



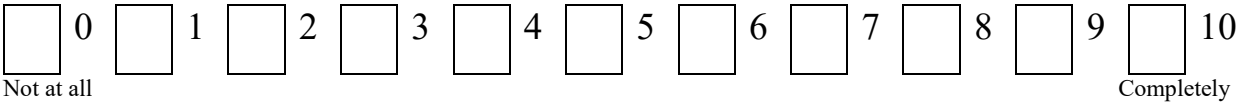
6) How willing were you to use the app every day?



7) How easy was is to complete the daily surveys?



8) How much did the app help you to cope with your pain?



9) How honest were you in completing the daily survey? (I was very honest, I was honest most of the time, I was honest some of the time, I was honest once in a while, I was not honest at all)

10) [for CM group pts only] How much did the rewards make a difference in whether you completed the daily survey? (Not at all, very little, little, somewhat, much, to a great extent, completely)

11) [for CM group pts only] How much did the rewards make a difference in how accurately you reported information in the daily survey? (Not at all, very little, little, somewhat, much, to a great extent, completely)