Implementation-Effectiveness of the Power Over Pain Portal for Patients Awaiting a Tertiary Care Consultation for Chronic Pain: Pilot Study Protocol

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Abstract

Background: Chronic pain (CP) affects about 8 million people in Canada. Access to CP care is challenging and there is no robust monitoring system to support patient care and decision-making. The Power Over Pain (POP) Portal was developed by people living with CP, healthcare providers, researchers, health system decision makers, policy makers, and community partners to address these concerns. The POP Portal is a comprehensive virtual platform that provides rapid access to a continuum of free, evidenced-informed resources for the self-management of CP, mental health, and substance use health. The POP portal also offers self-assessment tools that enable users to track their progress and receive personalized recommendations.

Objective: This hybrid implementation-effectiveness type III pilot study aims to determine the feasibility (i.e., recruitment, integration, facilitators and barriers, patient engagement, usability, and acceptability) of the POP Portal's implementation for people waiting for care at a tertiary pain clinic.

Methods: A cohort of 80 adults living with pain will be recruited from the waitlist of a tertiary care pain clinic over a 3-month period. Following an orientation to the Portal, participants will be encouraged to use the Portal according to their needs and preferences. They will also be asked to complete questionnaires at baseline (0-months) and 3-month follow-up. Primary feasibility measures will include recruitment and retention rates, and Portal's acceptability using the Acceptability E-Scale. We will also measure usability with the System Usability Scale (SUS), evaluate engagement through Portal analytics, and identify facilitators and barriers via semi-structured interviews with 12-15 study participants. These interviews will further assess participants' acceptability and usability of the Portal. Exploratory measures will include pain severity, pain-related interference, self-efficacy, coping strategies, and symptoms of anxiety and depression.

Results: We will present descriptive data on the cohort's sex/gender, age, rural/urban status, ethnic background, acceptability, usability, and feasibility. Measures of central tendency will be reported for continuous variables and frequencies/proportions for categorical variables. We will also present change to clinical outcomes across time, and a synthesis of qualitative/thematic data.

Conclusions: Most patients awaiting care at a tertiary pain clinic would benefit from improved access to pain education, self-

management resources, and peer support. We will move forward with a multi-site study to evaluate the implementation and effectiveness of the PoP Portal among patients waiting for a tertiary care consultation if the feasibility of recruiting and retaining patients is demonstrated.

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Keywords: chronic pain; self-management; patient portal; virtual care; mental health; substance use; implementation science; feasibility study; protocol; online.

Introduction

Chronic pain (CP) affects about 1 in 5 Canadians, including youth and adults, and costs the Canadian economy an estimated $40 billion CAD per year [1]. Approximately 60% of people with CP have co-occurring mental health disorders [2,3] and about 29% do not use opioids as prescribed [4]. Improving access to care for CP and co-occurring mental health and substance use concerns are among the field's top research priorities [5]. People living with pain (PLWP) often wait for extended periods before receiving specialized pain care. While wait-times in excess of 6 months have been deemed medically unacceptable [6], wait-times to Canadian CP clinics have not changed over the last 10 years [7]. More than 50% of patients are not seen at these clinics within the recommended wait-time, often waiting for several years [7] and as a result they experience concomitant deterioration in function and quality of life [6].

Considering management options for CP, psychosocial interventions delivered virtually have been shown to be effective in improving pain interference, pain severity, psychological distress, and health-related quality of life when comparing to control groups [8]. Currently, no cohesive set of virtually delivered interventions for pain management exist within an integrated framework that augments the current continuum of care. Rather, there has been a reliance on stand-alone mobile apps which present several issues that can impact their effectiveness and user adoption.
One concern is variability in the quality and reliability of the content provided, as not all apps are developed based on evidence-based practices [9]. Additionally, there are privacy and data security concerns to storing information on multiple stand-alone apps, as sensitive health information could be at risk if not properly protected [10]. The lack of personalized feedback, continuous outcome monitoring, and the inability to adapt to individual patient needs can also limit the effectiveness of these apps [11]. Usability and accessibility are also significant concerns, as older adults or those with limited technological proficiency may find these apps difficult to navigate [12]. Further, while some are free, many apps require a purchase or subscription, which can create a financial barrier for some users, limiting equitable access to these potentially beneficial resources [13]. Finally, the engagement and adherence to app-based interventions can be low, as users might lose interest over time without proper motivation and support [12]. Addressing these issues is crucial for the successful integration of mobile apps into pain management strategies.

Our team (i.e., a collaborative group of PLWP, healthcare providers, researchers, health systems decision makers, policy makers, intervention providers and community partners) developed the Power Over Pain (POP) Portal to remedy this gap. The POP Portal offers rapid access to free evidence-informed virtual resources and interventions for the self-management of CP, mental health, and substance use health aligned along a continuum of care. The Portal also facilitates continuous outcome monitoring to provide feedback to PLWP about their progress, promote behaviour change, improve health decision-making, and enhance communication between healthcare providers and PLWP. Importantly, the POP Portal was developed in accordance with the Stepped Care 2.0 model, a framework to integrate resources and interventions along a continuum of care that can support patients and their providers to achieve therapeutic goals. This system is resiliency-based, grounded in recovery-oriented principles and self-corrective [14]. Stepped care approaches have been demonstrated to be acceptable and cost-effective for delivering mental health [15] and substance use [16] care. These approaches have also been studied in managing certain CP conditions such as low back pain [17], musculoskeletal pain [18], and osteoarthritis [19]. However, a 2019 review concluded that stepped care models for CP were inconsistently applied and that studies conducted were of low quality [20]. Our team adapted and implemented Stepped Care 2.0 for adult CP care at our tertiary care institution [21] which led to a substantial reduction in clinical appointment wait-times [22].

Goal of the study

In preparation for an adequately powered multi-site trial to evaluate the implementation and evaluation of the POP Portal, this pilot study aims to determine the feasibility of implementing the POP Portal for PLWP who have been referred to the tertiary pain clinic in Canada and are awaiting their first appointment. The objectives of the pilot study are to determine the: 1) feasibility of recruiting PLWP who are waiting for their first appointment; 2) proportion of patients who agree to have their healthcare number used for a future study (e.g., impact of the POP Portal on healthcare utilization); 3) participant's engagement with, usability, and acceptability of the POP Portal; 4) facilitators and barriers to the POP Portal's implementation; 5) statistical parameters of effectiveness outcomes (outlined below); and 6) preliminary evidence of intervention effectiveness (i.e., estimates of effect and variance for secondary outcome).

Methods

Ethical Considerations

This protocol was reviewed and approved by the Ottawa Health Science Network Research Ethics Board. Any changes to this study protocol will be submitted for ethical clearance and major changes will be reported in study publication. Participants will provide verbal informed consent before participating in the study, and informed that they can withdraw their participation in the study at any time and will not lose access to the Portal if they choose to do so. The Ottawa Health Science Network - Research Ethics Board may review relevant study records under the supervision of Dr. Poulin and their research staff for audit purposes. Adverse events that could reasonably be attributed to use of the PoP Portal will be self-reported by the participants and tracked using an adverse events form.

Study Design

This project is a hybrid implementation-effectiveness type III pilot study using a prospective cohort, mixed method design. We have used the SPIRIT 2013 [23,24] checklist to guide our reporting for this protocol with adaption for feasibility studies [24]. A manuscript reporting on the enacted study will be reported in accordance with the CONSORT guidelines - extension to randomised pilot and feasibility trials [25]. A workflow of the study can be found in **Figure 1**.

Eligibility Criteria

Inclusion criteria include: 1) adult (>18 years of age) referred to a tertiary care pain clinic (i.e., awaiting triage or first appointment); 2) experience of CP (i.e., ongoing, persistent, or recurrent pain for more than 3 months); 3) sufficient fluency in English or French to complete the POP's programs/resources; 4) capacity to provide informed consent in English or French; 5) access to an electronic device with connection to the Internet; and 6) agreed to be contacted for research.

Exclusion criteria include: 1) self-reported barriers to the use of technology during the initial screening appointment; 2) experience cancer-related pain; 3) inability to complete the study questionnaires/assessments; and 4) self-disclose an unmanaged mental health condition or suicidal ideations during the first study visit.

Study Procedures

We will identify prospective participants for this study in two ways: 1) the pain clinic clerk will call patients accepted for care at the pain clinic, and inform them about the study; those who express an interest will be referred to the study coordinator for screening and to discuss participation; or 2) the study coordinator will screen electronic health records to identify those whose consultation request has yet to be triaged and who have provided institutional permission to be contacted for research.

The study coordinator will contact eligible patients via phone. During this call, the coordinator will describe the study background, expectations of participation, voluntariness, rights to withdrawal, risks and benefits, and obtain verbal consent. Additionally, the coordinator will schedule an online orientation session which will introduce the POP Portal and its resources, including: 1) detailed information about navigating the Portal and its resources; 2) creating an account; 3) registering for courses; and 4) completing self-assessments. Participants can ask for guidance on any aspect of the Portal at any time. The study coordinator will ensure verbal consent is recorded during the initial phone call. Consenting participants will be sent a study information sheet along with a weblink to complete a baseline questionnaire on LimeSurvey.

Participants are asked to use the POP Portal for a 3-month period. The participants will not be provided with further instructions on how to use the POP Portal (such as resource recommendations), nor are there restrictions on concomitant care or interventions. The study coordinator will send participants a weblink to complete the follow-up assessment after this 3-month period (**see Figure 1**). Selected participants will be invited to complete follow-up interviews.

Sample Size

We aim to recruit 80 participants from a tertiary care pain clinic over a 3-month recruitment period. We anticipate recruiting 20-30 adults per month. For the qualitative interviews, we will purposively (e.g., sex, gender, pain type, duration with pain, comfort with technology) invite 12 to 15 adults, which we anticipate will be sufficient to achieve saturation [26].

Reimbursement

Study participants will not be compensated for accessing the virtual POP Portal or its resources. Participation will be incentivised in the following ways: participants who complete the 3-month follow-up questionnaire and interview will be provided with a $20, and $30.00 Amazon gift card, respectively. Participants will not be asked to pay fees for any part of this study.

Study Intervention

The POP Portal is a comprehensive virtual platform co-designed by a diverse group of healthcare providers, researchers, decision makers, and Canadians who live with CP. The POP Portal: 1) provides rapid access to free evidence-informed virtual resources for CP, mental health, and substance use health arranged along a stepped care continuum of offerings; and 2) facilitates continuous outcome monitoring through optional self-assessments to allow rapid adjustment to resource recommendations and program evaluation. Recognizing the difference in the needs and preferences of youth and adult populations, two distinct portals were created to better serve each population. This study focuses on an adult population and thus, the adult POP Portal is described below.

Stepped Care Resources

In line with the Stepped Care 2.0 framework, the resources available on the POP Portal are designed to vary in intensity, corresponding to different levels of user commitment. These resources enhance a continuum of care and are accessible at any time, thereby enabling users to engage with them according to their individual preferences and needs.

Step 1 - Educational Resources. Participants who want to learn basic facts about CP, including the relationship between CP, mental health, and substance use, will have access to a range of evidence-informed educational resources (e.g. articles, videos, podcasts) including 1) Pain U Online, developed by the Toronto Academic Pain Medicine Institute, which covers topics on CP mechanisms, factors that influence pain, pharmacological, physical, and psychological strategies for pain management, insomnia, and a healthy lifestyle; and 2) LivePlanBe+, developed by Pain BC which currently hosts 23 modules, including on pain science, nutrition, self-management techniques, sleep, symptom management, and communication.

Step 2 - Virtual Self-Guided CP Self-Management Courses. Participants will be encouraged to create a free account to gain access to free virtual self-guided CP self-management courses including: 1) The Pain Course developed at the eCentreClinic, Macquarie University, and 2) Empowered Management, developed by the Toronto Academic Pain Medicine Institute.

The Pain Course is an online 8-week cognitive behavioural therapy-based self-management program that includes 6 modules: (1) CP education; (2) understanding CP and relationship between pain and emotions; (3) managing unhelpful thoughts; (4) managing uncertainty and problem solving; (5) managing physical symptoms and maintaining physical activity while minimizing fatigue and pain exacerbation; and (6) maintenance strategies and relapse prevention. It has been evaluated among individuals with diverse CP conditions and shown to be acceptable and associated with improved pain, pain interference, depression, and anxiety [27-29].

Empowered Management is an online program specifically designed for patients living with CP who are waiting for tertiary pain care. It aims to improve their readiness for change and provide them with self-management skills that will enhance their interaction with health care providers in CP clinics. The modules include: 1) setting expectations; 2) what is CP; 3) biopsychosocial factors and approaches to CP; 4) empowered management; 5) self-awareness compassion and acceptance; 6) values; 7) goal setting; and 8) communication. The program includes a reflection journal that accompanies the psychoeducational modules and weekly assignments [30]. It was recently tested in two Ontario Chronic Pain Network clinics and found to be acceptable and usable (personal communication, Rosemary Wilson, August 25, 2024).

Step 3 - Peer Support. Participants will have access to different peer support services to help them connect with peers including peer support groups and health coaching.

Participants will be able to connect with different communities of support (i.e. peer support groups) and find a safe space to talk with people who may better know where they are coming from, including People in Pain Network (PIPN). PIPN is a national community of people with persistent pain helping other people with persistent pain to improve the quality of their lives by offering education and support through monthly virtual and in person meetings.

Participants will have access to online health coaching via Ontario Self-Management, a free one-on-one web-based support program to help PLWP manage their condition. Health coaches are people with lived experience trained in self-management support and communication skills.

Step 4 - Live Interactive Workshops. Participants will have access to a suite of live interactive workshops covering various topics related to CP, mental health, and substance use health, some of which including pain neuroscience, sleep, nutrition, gentle movement, communication, pacing/planning, and engaging in meaningful activities.

Step 5 - Individual Counselling. Participants who wish to access individual counselling will be directed to free services available in their jurisdiction.

Self-Assessments

As for other POP Portal uses, participants will have the option to complete self-assessments once every few weeks and be presented with a visual depiction of their results to help them track their symptoms over time. These self-assessments consist of the following valid and reliable patient-reported scales: PROMIS Pain Intensity, Pain Disability Index (PDI), Pain Self-Efficacy Short-Form-2 (PSEQ-2), Patient Health Questionnaire-4 (PHQ-4), PROMIS Sleep Disturbance - Short Form, 1 item modified from the World Health Organization – Alcohol, Smoking and Substance Involvement Screening Test (WHO-ASSIST), and the Global Appreciation of Individual Needs – Substance Use Subscale (GAIN Short Screener). These scales are described in Table 1.

Table 1. Description of the POP Portal self-assessment measures.

Scale	Description
PROMIS Pain Intensity	PROMIS Pain Intensity is a 1-item numerical rating scale from 0 to 10, for measuring pain intensity [31].
PDI	PDI is a 7-item form (including responsibility of home/family; self-care; occupation; sexual behaviour; social activity; recreation; life-support activities) that assesses the magnitude of self-reported pain-related disability of the participant, exclusive from the pain's area or pain-related diagnosis. The pain-related disability questions range on a 11-point numerical rating scale (0–10) [32].
PSEQ-2	PSEQ-2 is a 2-item survey with 7-point numerical rating scale (0-6) to assess patient's pain self-efficacy or believing in one's capability to perform activities, despite having pain. PSEQ-2 has high validity and internal consistency, with evidence for its test-retest reliability, sensitivity to change, and convergent validity [33-35].
PHQ-4	PHQ-4 is a brief 4-item survey of core symptoms/signs of depression and

	anxiety. The total PHQ-4 score provides an overall measure of symptom burden, as well as functional impairment and disability. Its total score (sum of 4 items) measures psychological distress, rated as normal (0-2), mild (3-5), moderate (6-8), and severe (9-12); GAD-2 score ≥3 suggests potential anxiety symptoms and PHQ-2 score ≥3 suggests potential depression symptoms [36].
PROMIS Sleep Disturbance	PROMIS Sleep Disturbance - Short Form is a 4-item form exploring the participant's sleep characteristics/difficulties over the past 7 days. The participant is asked to select, for the first question, from one of 5 options: very poor, poor, fair, good, very good. And for the last 3 questions, from one of the following 5 options for each question: not at all, a little bit, somewhat, quite a bit, very much [37].
WHO-ASSIST	A single item modified from the WHO-ASSIST will be used to evaluate the risk associated with the client's substance use, and whether this use is hazardous and likely to be causing harm (now or in the future) if it continues. We ask patients to indicate whether they have concerns regarding any of the substances from a list provided to them [38].
GAIN Short Screener	GAIN Short Screener will be used to identify individuals who are experiencing challenges or are at risk of developing challenges as it pertains to mental, and substance use issues. We are asking the participants 5 items, each with a 4-point numerical rating scale (0-3) [39,40].

Once the participant completes a self-assessment, their results will be displayed, and feedback will be provided based on where they scored within predefined categorical groupings (e.g. low, moderate, or high). The self-assessments are fully integrated within the POP Portal through an automated electronic data capture system maintained by our technology partner. The goal of the self-assessments is to provide personalized feedback generated by the platform about potential intervention targets for CP, mental health, and/or substance use health. We will ask participants for consent to use their self-assessment data for this study.

Data Collection and Outcomes

Outcomes for this pilot study have been derived through advisory committee meetings with patient partners who are PLWP, previous research in the field, and clinical experience of the multidisciplinary team at the tertiary care pain clinic (e.g., clinicians, nurses, psychologists, social workers).

Primary Feasibility Outcomes and Interpretation

Our primary feasibility outcomes are recruitment rate (i.e., number of patients consenting), 3-month retention rate (i.e., 3-month assessment completion), and participant's acceptability assessed with the Acceptability E-scale 3 months after participant recruitment [41] and through interviews. The Acceptability E-scale is a 6-item questionnaire that uses a 5-point Likert scale to evaluate participant's experiences with the program. The form has shown to have strong psychometric properties to assess participant's acceptance and perception of digital health interventions [41,42].

Secondary Feasibility Outcomes

Secondary feasibility outcomes will consist of: 1) rates of participant accrual, drop-out, screening, eligibility, and 3-month assessment completion; 2) participant's satisfaction assessed with the Acceptability E-scale 3 months after participant recruitment [41]; 3) participant's perceived

barriers/facilitators with the Portal which will be tracked throughout the study and through participant interviews (see below); and 4) portal's usability assessed by the participants with the System Usability Scale (SUS) 3-months after participant recruitment [43]. SUS is a 10-item questionnaire asking participants about the usability of the POP Portal. Each question has a 5-point numerical rating scale (1-5), with 1 indicating strong disagreement and 5 indicating strong agreement. It has shown to be both valid and reliable in giving a global view of subjective assessments of usability [43-45].

We will also explore participant engagement with the Portal and resources on the Portal through system's analytics. We will collect metrics that are maintained by our technology partner, and guided by those that were collected for Wellness Together Canada [46], including: sign-ups, sign-ins, first time user activation (i.e. rate at which new users engage in a meaningful way with the Portal, including a resource, assessment completion or viewing progress over time), type, nature and frequency of resources accessed, number of self-assessments completed, participant retention (e.g. 1 week versus 3 months after study enrollment), and impact (e.g. correlation between participant's improvement in pain, mood or substance use and resource usage).

Interviews

We will conduct semi-structured interviews with a random sample of 12 to 15 participants who use the POP Portal's resources/courses to further assess the acceptability, usability, and impact of the POP Portal. Interviews will span 30-45 minutes in duration, and conducted via Microsoft Teams. We have developed an interview guide using components of the Theoretical Domains Framework [47], Theoretical Framework of Acceptability [48], usability questionnaire [49] and theoretical domains framework questionnaire in implementation research [50]. The interview guide was refined through discussion with pain experts across Canada and with PLWP. The guide is intended to provide structure and context for the participants' responses. Through this interview, we aim to better understand the experience of participants with the resources offered to them by the POP Portal, what they liked or disliked about the Portal, benefits and harms experienced from the Portal, level of confidence and comfort with the portal, barriers to the Portal's implementation or delivery, and potential improvements or additions. Interviews will be conducted by trained study research staff, recorded and transcribed verbatim.

Exploratory Clinical Effectiveness Outcomes

Informed by a consensus-driven minimum dataset [51] for adults with CP from the Centre hospitalier de l'Université de Montréal (CHUM), participant's pain type, location, onset, duration, frequency, and diagnosis will be collected, if known. We will also examine if there are changes in the following clinical outcomes from pre-POP Portal enrollment to 3-months post-enrollment: 1) pain intensity and interference (Brief Pain Inventory; BPI); 2) pain self-efficacy (PSEQ-2); 3) pain coping skills (Chronic Pain Coping Inventory; CPCI); 4) attitudes and beliefs about CP (Survey of Pain Attitudes; SOPA); 5) health-related quality of life (Short Form (SF)-12 v2); 6) symptoms of anxiety (Generalized Anxiety Disorder-7; GAD-7); and 7) symptoms of depression (Patient Health Questionnaire-8; PHQ-8). We will also assess participants' perceived overall effectiveness with the Patients' Global Impression of Change (PGI-C) at the follow-up visit. These scales are described in Table 2.

Table 2. Description of study exploratory clinical effectiveness outcomes.

Scale	Description

BPI	BPI will be used to measure pain severity (4 items on an 11-point numerical rating scales) and pain interference (7 interference items on 11-point numerical rating scales) with daily functioning. Participant's "worst pain" or the arithmetic mean of the 4 severity items can be used as measures of pain severity; the arithmetic mean of the 7 interference (general activity, walking, work, mood, enjoyment of life, relations with others, and sleep) items can be used as a measure of pain interference. BPI has sufficient reliability (Cronbach's alpha coefficients frequently being higher than 0.80), construct validity, and responsiveness in several pain, and other populations [52-57]. Worse pain and average pain scores of 1-4 are viewed as mild pain, 5-6 as moderate pain, and 7-10 as severe pain [58].
PSEQ-2	PSEQ-2 will be as for the Portal's self-assessments described in Table 1.
CPCI	CPCI is an 8-item questionnaire covering use of pain coping skills including Guarding, Resting, Asking for Assistance, Relaxation, Task Persistence, Exercise/Stretch, Seeking and Coping Self-Statements scales. It asks the patient to indicate the number of days during the past week that they used each of the strategies to deal with pain. The questionnaire has been shown to have strong internal consistency reliability, test-retest stability, and validity in CP populations [59,60].
SOPA	SOPA is a 7-item form to assess the patient's attitudes and beliefs about their CP. It includes scales on Pain Control, Disability, Harm, Emotion, Medication, Solicitude and Medical Cure. Patients are asked to indicate how much they agree or disagree with each statement on a 5-point numerical rating scale (0-4). The survey has good internal consistency, test-retest reliability, and convergent/discriminant validity [61].
SF-12 v2	SF-12 v2 is a 12-item survey that measures health-related quality of life, functional health, and well-being across physical and mental health domains. We will be evaluating limitations to participants' physical activities due to their current health using the Physical functioning subscale. SF12 v2 has shown good psychometric validity and reliability for evaluating health-related quality of life in both general [62-65] and specific populations, including those with CP [66], cancer [67], hemophilia [68], mental illnesses and behavioral health diagnosis [69], among others.
GAD-7	GAD-7 is a 7-item scale used to screen for potential signs/symptoms of anxiety and assess the severity of generalized anxiety disorder. Scores range from 0-21 and a clinically meaningful change is 5 points or more. GAD-7 has high internal consistency and convergent validity (alphas frequently above 0.82) across heterogenous psychiatric populations [70,71], as well as sound diagnostic validity, with sensitivity of 0.66-0.89, and specificity of 0.80-0.82 for generalized anxiety disorder and anxiety disorders including social anxiety, post-traumatic stress and panic [72,73].
PHQ-8	PHQ-8 is an 8-item scale to assess frequency of depressive symptoms with scores ranging from 0-24. A total score of 0-4 represents no significant depressive symptoms, 5-9 represents mild, 10-14 represents moderate, 15-19 moderately severe, and 20-24 represents severe depressive symptoms. PHQ-8 has been shown to be reliable and have good construct and criterion validity to screen for depression in patients with heart failure and in the general population [74-76].
PGI-C	PGI-C scale [77] is 1-item scale to evaluate the perceived effect of disease

	management, asking the participants about their overall status at follow-up; it includes 7 options, ranging from “very much worse” to “very much improved”. The scale has demonstrated to have high test-retest reliability and is a potentially clinically-meaningful measure for a variety of pain populations, with evidence of good validity [77-80].

Demographic Characteristics

We will collect age, sex and gender, ethnic background and the first 3 digits of participant’s postal code from medical records to provide basic demographic characteristics.

Data Management

Personal information will be kept confidential unless release is required by law. Participants will be identified in study data by a unique study identification number. Project data will be encrypted, password protected, and stored on the institution’s Microsoft 365 SharePoint/OneDrive. The pre-post questionnaire will be temporarily stored on LimeSurvey. The study coordinator will transfer the data at least biweekly into a spreadsheet securely stored on the institution’s Microsoft 365 SharePoint/OneDrive. Once transferred, questionnaire data will be deleted from LimeSurvey. Only the research team members directly involved in conducting the research will have access to the data. Passwords will be stored in a master list with only the principal investigator, research program manager and study coordinator having access.

The Data Safety and Monitoring Committee will be guided by a charter of roles and responsibilities and consist of a statistical expert, a person with lived experience of CP, a pain medicine specialist and a health psychologist who are independent of the research team. This group will meet with the study steering committee on a monthly basis during study recruitment and intervention to review recruitment, accumulating study data, adverse events and will provide guidance regarding any needed action.

Data Analysis

Quantitative Analyses

The primary feasibility outcomes and secondary outcomes mentioned above, will be described using descriptive statistics (frequencies and proportions), point estimates, and 95% confidence intervals (CI). Even though we will be underpowered for efficacy, we will explore ranges of effect sizes using point estimates of change across time and associated 95% CIs for each resource [81]. Graphs and tables of descriptive data will be prepared. Study data will be imported into SPSS for statistical analysis. Open-text responses will be reviewed by the study team for converging themes. Missing data will be handled using multiple imputation; single point estimates will be determined using parameter estimates and standard errors of 10 imputed data sets.

Qualitative Analyses

Interviews will be transcribed, and analyses/coding will be completed by two research staff members using the software NVivo and following the method described by Saldana [82]. The study staff will acquaint themselves with the data through reading the transcripts independently and start developing the codebook. They will then meet to compare coding, with any disagreement resolved through consensus or discussion with the senior author. We will then use a deductive thematic analysis approach [47] to map emerging categories and themes to constructs within the Theoretical

Framework of Acceptability and Theoretical Domain Framework. Themes that focus on preliminary evidence of effectiveness, acceptability, and usability will be triangulated with quantitative data where possible.

Feasibility Interpretation

Following recommendations for feasibility studies, we developed a-priori criteria on our primary feasibility outcomes to indicate whether progression to an adequately powered trial is feasible. The a-priori criteria are organized through a traffic light system (Textbox 1).

Textbox 1. Feasibility A-Priori Criteria

1. **Green –** Continue without modifications; this will be indicated if: 1) we recruit a minimum of 80 adults at the tertiary care pain clinic over 3 months, 2) we achieve a minimum of 80% retention rate (i.e., participants completing the Pain Course resource delivered through POP) and pre-post outcome measures), and 3) the majority (≥70%) of participants deem the POP Portal to be acceptable for addressing some of their pain and associated health concerns as measured by study questionnaires, Portal self-assessments, and/or interviews.
2. **Yellow –** Continue but modify protocol with close monitoring; this will be indicated if we recruit 40-79 adult participants over 3 months, achieve 50-79% retention rate, and/or 50-69% of participants find the POP Portal acceptable.
3. **Red –** Definitive trial not feasible; this will be indicated if we recruit less than 40 adult participants over 3 months, achieve less than 50% retention rate, and/or < 50% of participants find the POP Portal acceptable.

Results

The Ottawa Health Science Network Research Ethics Board cleared all study procedures and materials for ethical compliance on October 24 2022 in its initial version. The protocol in the current and final version (V2) was cleared on May 16, 2023. Participants were able to enrol in the study between March 25, 2023 and August 7, 2023. Data collection was extended to November 18, 2023. Following ICMJE guidelines for authorship, the results are expected to be published in an open access journal by the end of 2024. Findings will also be disseminated to different knowledge users of the Portal through presentations and webinars offered by POP partners.

Discussion

Most patients referred to tertiary care for pain management have not had access to pain education, self-management and peer support prior to referral. This study will test the feasibility and explore the effects of providing rapid access to a stepped-care continuum of virtual self-management resources to manage CP to patients waiting for their first visit to a tertiary care pain program. Results of this work will inform progression to an adequately powered multi-site trial, including potential modification required before proceeding.

Conclusion

Our ultimate goal is to improve care access for PLWP. The POP Portal aims to empower people

living with CP and associated mental health or substance use health needs with rapid access to flexible, responsive, and individualized resources to improve their overall quality of life and functioning.

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Conflicts of Interest

None declared

Abbreviations

CP: Chronic pain
PLWP: Person living with pain
POP: Power Over Pain

References

1. Canadian Pain Task Force. Chronic pain in Canada: laying a foundation for action. Health Canada. 2019. URL: https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/canadian-pain-task-force/report-2019.html [accessed 2024-07-24].
2. Rayner L, Hotopf M, Petkova H, et al. Depression in patients with chronic pain attending a specialised pain treatment centre: prevalence and impact on health care costs. Pain. 2016;157(7):1472-1479. doi:10.1097/j.pain.0000000000000542.
3. Sagheer MA, Khan MF, Sharif S. Association between chronic low back pain, anxiety and depression in patients at a tertiary care centre. J Pak Med Assoc. 2013;63(6):688-690. PMID: 23901665
4. Tetsunaga T, Tetsunaga T, Nishida K, et al. Drug dependence in patients with chronic pain: A retrospective study. Medicine (Baltimore). 2018;97(40):e12748. doi:10.1097/MD.0000000000012748.
5. Poulin P, Shergill Y, Romanow H, et al. Researching what matters to improve chronic pain care in Canada: a priority-setting partnership process to support patient-oriented research. Can J Pain. 2018;2(1):191-204. doi:10.1080/24740527.2018.1433959.
6. Lynch ME, Campbell FA, Clark AJ, et al. Waiting for treatment for chronic pain - a survey of existing benchmarks: toward establishing evidence-based benchmarks for medically acceptable waiting times. Pain Res Manag. 2007;12(4):245-248. doi:10.1155/2007/891951.
7. Choinière M, Peng P, Gilron I, et al. Accessing care in multidisciplinary pain treatment facilities continues to be a challenge in Canada. Reg Anesth Pain Med. 2020;45(12):943-948. doi:10.1136/rapm-2020-101935.
8. Slattery BW, Haugh S, O'Connor L, et al. An evaluation of the effectiveness of the modalities used to deliver electronic health interventions for chronic pain: systematic review with network meta-analysis. J Med Internet Res. 2019;21(7):e11086. doi:10.2196/11086.
9. Rosser BA, Eccleston C. Smartphone applications for pain management. J Telemed Telecare. 2011;17(6):308-312. doi:10.1258/jtt.2011.101102.
10. Madden M, Gilman M, Levy K, et al. Privacy, poverty and big data: a matrix of

vulnerabilities for poor Americans. Wash U L Rev. 2017;95(1). URL: https://openscholarship.wustl.edu/law_lawreview/vol95/iss1/6 [accessed 2024-07-24].
11. Kumar S, Nilsen WJ, Abernethy A, et al. Mobile health technology evaluation: The mHealth evidence workshop. Am J Prev Med. 2013;45(2):228-236. doi:10.1016/j.amepre.2013.03.017.
12. Birkhoff SD, Smeltzer SC. Perceptions of smartphone user-centered mobile health tracking apps across various chronic illness populations: an integrative review. J Nurs Scholarsh. 2017;49(4):371-378. doi:10.1111/jnu.12298.
13. Elbert NJ, Van Os-Medendorp H, Van Renselaar W, et al. Effectiveness and cost-effectiveness of ehealth interventions in somatic diseases: a systematic review of systematic reviews and meta-analyses. J Med Internet Res. 2014;16(4):e110. doi:10.2196/jmir.2790.
14. Newfoundland and Labrador stepped care 2.0 e-mental health demonstration project. Mental Health Commission of Canada. 2019. URL: https://www.mentalhealthcommission.ca/sites/default/files/2019-09/emental_health_report_eng_0.pdf [accessed 2024-07-24].
15. Ho FYY, Yeung WF, Ng THY, et al. The efficacy and cost-effectiveness of stepped care prevention and treatment for depressive and/or anxiety disorders: a systematic review and meta-analysis. Sci Rep. 2016;6. doi:10.1038/srep29281.
16. Babor TF, McRee BG, Kassebaum PA, et al. Screening, brief intervention, and referral to treatment (SBIRT): toward a public health approach to the management of substance abuse. Subst Abus. 2007;28(3):7-30. doi:10.1300/J465v28n03_03.
17. von Korff M, Moore JC. Stepped care for back pain: activating approaches for primary care. Ann Intern Med. 2001;134(9 Pt 2):911-7. doi:10.7326/0003-4819-134-9_part_2-200105011-00016.
18. Comer C, Glover J, Richardson J, et al. Stratification of treatment in a community-based musculoskeletal service: a mixed-methods study to assess predictors of requiring complex care. Arch Phys Med Rehabil. 2016;97(6):900-911. doi:10.1016/j.apmr.2015.12.013.
19. Smink AJ, van den Ende CHM, Vliet Vlieland TPM, et al. Effect of stepped care on health outcomes in patients with osteoarthritis: an observational study in Dutch general practice. Br J Gen Pract. 2014;64(626):e538-44. doi:10.3399/bjgp14X681337.
20. Palylyk-Colwell E, Wright MD. Tiered care for chronic non-malignant pain: a review of clinical effectiveness, cost-effectiveness, and guidelines. Canadian Agency for Drugs and Technologies in Health. 2019. URL: https://www.ncbi.nlm.nih.gov/books/NBK543512/ [accessed 2024-07-24].
21. Bell L, Cornish P, Gauthier R, et al. Implementation of the Ottawa Hospital Pain Clinic stepped care program: a preliminary report. Can J Pain. 2020;4(1):168-178. doi:10.1080/24740527.2020.1768059.
22. Lynch ME, Williamson OD, Banfield JC. COVID-19 impact and response by Canadian pain clinics: a national survey of adult pain clinics. Can J Pain. 2020;4(1):204-209. doi:10.1080/24740527.2020.1783218.
23. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207. doi:10.7326/0003-4819-158-3-201302050-00583.
24. Thabane L, Lancaster G. A guide to the reporting of protocols of pilot and feasibility trials. Pilot Feasibility Stud. 2019;5. doi:10.1186/s40814-019-0423-8.
25. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot Feasibility Stud. 2016;2. doi:10.1186/s40814-016-0105-8.
26. Baker SE, Edwards R. How many qualitative interviews is enough? National Centre for Research Methods. 2012. URL: https://eprints.ncrm.ac.uk/id/eprint/2273/4/how_many_interviews.pdf [accessed 2024-07-24].

27. Dear BF, Titov N, Perry KN, et al. The Pain Course: a randomised controlled trial of a clinician-guided Internet-delivered cognitive behaviour therapy program for managing chronic pain and emotional well-being. Pain. 2013;154(6):942-950. doi:10.1016/j.pain.2013.03.005.
28. Dear BF, Gandy M, Karin E, et al. The Pain Course: A randomised controlled trial examining an Internet-delivered pain management program when provided with different levels of clinician support. Pain. 2015;156(10):1920-1935. doi:10.1097/j.pain.0000000000000251.
29. Hadjistavropoulos HD, Schneider LH, Hadjistavropoulos T, et al. Effectiveness, acceptability and feasibility of an Internet-delivered cognitive behavioral pain management program in a routine online therapy clinic in Canada. Can J Pain. 2018;2(1):62-73. doi:10.1080/24740527.2018.1442675.
30. Bosma R, Bisson E, Cooper L, et al. Experience-based design: empowering individuals while they wait for interprofessional chronic pain care. Patient Educ Couns. 2023;109. doi:10.1016/j.pec.2023.107623.
31. Askew RL, Cook KF, Revicki DA, et al. Clinical validity of PROMIS® pain interference and pain behavior in diverse clinical populations. J Clin Epidemiol. 2016;73:103-111. doi:10.1016/j.jclinepi.2015.08.035.
32. Giordano PCM, Alexandre NMC, Rodrigues RCM, et al. The pain disability questionnaire: a reliability and validity study. Rev Lat Am Enfermagem. 2012;20(1):76-83. doi:10.1590/s0104-11692012000100011.
33. Dubé MO, Langevin P, Roy JS. Measurement properties of the Pain Self-Efficacy Questionnaire in populations with musculoskeletal disorders: a systematic review. Pain Rep. 2021;6(4):e972. doi:10.1097/pr9.0000000000000972.
34. Nicholas MK, McGuire BE, Asghari A. A 2-item short form of the Pain Self-efficacy Questionnaire: development and psychometric evaluation of PSEQ-2. J Pain. 2015;16(2):153-163. doi:10.1016/J.JPAIN.2014.11.002.
35. Adachi T, Enomoto K, Yamada K, et al. Evaluating the psychometric properties of two-item and four-item short forms of the Japanese Pain Self-Efficacy Questionnaire: a cross-sectional study. J Anesth. 2019;33(1):58-66. doi:10.1007/s00540-018-2583-8.
36. Löwe B, Wahl I, Rose M, et al. A 4-item measure of depression and anxiety: validation and standardization of the Patient Health Questionnaire-4 (PHQ-4) in the general population. J Affect Disord. 2010;122(1-2):86-95. doi:10.1016/j.jad.2009.06.019.
37. Yu L, Buysse DJ, Germain A, et al. Development of short forms from the PROMISTM sleep disturbance and Sleep-Related Impairment item banks. Behavioral sleep medicine. 2011;10(1):6-24. doi:10.1080/15402002.2012.636266.
38. WHO ASSIST Working Group. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): development, reliability and feasibility. Addiction. 2002;97(9):1183-1194. doi:10.1046/j.1360-0443.2002.00185.x.
39. Dennis ML, Feeney T, Stevens LH et al. GAIN-SS Global Appraisal of Individual Needs-Short Screener (GAIN-SS): administration and scoring manual version 2.0.1. Bloomington, IL: Chestnut Health Systems. 2007. URL: https://www.assessments.com/assessments_documentation/gain_ss/GAIN-SS%20Manual.pdf [accessed 2024-07-24].
40. Dennis ML, Chan YF, Funk RR. Development and validation of the GAIN Short Screener (GSS) for internalizing, externalizing and substance use disorders and crime/violence problems among adolescents and adults. Am J Addict. 2006;15(Suppl 1):80-91. doi:10.1080/10550490601006055.
41. Tariman JD, Berry DL, Halpenny B, et al. Validation and testing of the Acceptability E-scale for web-based patient-reported outcomes in cancer care. Appl Nurs Res. 2011;24(1):53-58. doi:10.1016/j.apnr.2009.04.003.

42. Underhill ML, Hong F, Jones T, et al. Feasibility and acceptability of a web site to promote survivorship care in survivors of Hodgkin disease. JCO Clin Cancer Inform. 2017;1:1-10. doi:10.1200/cci.17.00012.
43. Brooke J. SUS - a quick and dirty usability scale Usability and context. In: Usability evaluation in industry. 1st edition. Taylor & Francis; 1996. ISBN: 9780429157011.
44. Peres SC, Pham T, Phillips R. Validation of the system usability scale (SUS): SUS in the wild. Proc Hum Factors Ergon Soc Annu Meet. 2013;57(1):192-196. doi:10.1177/1541931213571043.
45. Sauro J. A practical guide to the system usability scale: background, benchmarks & best practices. 1st edition. CreateSpace Independent Publishing Platform; 2011. ISBN: 1461062705.
46. Wellness Together Canada. Wellness Together Canada. 2023. URL: https://wellnesstogether.ca/ [accessed 2024-07-24].
47. Boyatzis R. Transforming Qualitative Information: thematic analysis and code development. Sage Publications, Inc; 1998. ISBN: 9780761909613.
48. Sekhon M, Cartwright M, Francis JJ. Development of a theory-informed questionnaire to assess the acceptability of healthcare interventions. BMC Health Serv Res. 2022;22. doi:10.1186/s12913-022-07577-3.
49. Brooke J. A quick and dirty usability scale. Iron Steel Technol; 2018;15:41-47. doi:10.5948/Upo9781614440260.011.
50. Huijg JM, Gebhardt WA, Crone MR, et al. Discriminant content validity of a theoretical domains framework questionnaire for use in implementation research. Implementation Sci. 2014;9. doi:10.1186/1748-5908-9-11.
51. Lacasse A, Roy JS, Parent AJ, et al. The Canadian minimum dataset for chronic low back pain research: a cross-cultural adaptation of the National Institutes of Health Task Force Research Standards. CMAJ Open. 2017;5(1):E237-E248. doi:10.9778/cmajo.20160117.
52. Jumbo SU, MacDermid JC, Kalu ME, et al. Measurement properties of the Brief Pain Inventory-Short Form (BPI-SF) and revised Short McGill Pain Questionnaire version-2 (SF-MPQ-2) in pain-related musculoskeletal conditions: a systematic review. Clin J Pain. 2021;37(6):454-474. doi:10.1097/AJP.0000000000000933.
53. Keller S, Bann CM, Dodd SL, et al. Validity of the brief pain inventory for use in documenting the outcomes of patients with noncancer pain. Clin J Pain. 2004;20(5):309-318. doi:10.1097/00002508-200409000-00005.
54. Tan G, Jensen MP, Thornby JI, et al. Validation of the brief pain inventory for chronic nonmalignant pain. J Pain. 2004;5(2):133-137. doi:10.1016/j.jpain.2003.12.005.
55. Gjeilo KH, Stenseth R, Wahba A, et al. Validation of the brief pain inventory in patients six months after cardiac surgery. J Pain Symptom Manage. 2007;34(6):648-656. doi:10.1016/j.jpainsymman.2007.01.010.
56. Jelsness-Jørgensen LP, Moum B, Grimstad T, et al. Validity, reliability, and responsiveness of the brief pain inventory in inflammatory bowel disease. Can J Gastroenterol Hepatol. 2016;2016. doi:10.1155/2016/5624261.
57. Kapstad H, Rokne B, Stavem K. Psychometric properties of the brief pain inventory among patients with osteoarthritis undergoing total hip replacement surgery. Health Qual Life Outcomes. 2010;8. doi:10.1186/1477-7525-8-148.
58. Li KK, Harris K, Hadi S, et al. What should be the optimal cut points for mild, moderate, and severe pain? J Palliat Med. 2007;10(6). doi:10.1089/jpm.2007.0087.
59. Souza LAF, Pereira LV, De Moura LA, et al. Structural validity of the Chronic Pain Coping Inventory-Brazilian version. PLoS One. 2021;16(2). doi:10.1371/journal.pone.0246294.
60. Romano JM, Jensen MP, Turner JA. The chronic pain coping inventory-42: reliability and validity. Pain. 2003;104(1-2). doi:10.1016/S0304-3959(02)00466-9.

61. Jensen MP, Turner JA, Romano JM, et al. Relationship of pain-specific beliefs to chronic pain adjustment. Pain. 1994;57(3). doi:10.1016/0304-3959(94)90005-1.
62. Lam ETP, Lam CLK, Fong DYT, et al. Is the SF-12 version 2 health survey a valid and equivalent substitute for the SF-36 version 2 health survey for the chinese? J Eval Clin Pract. 2013;19(1):200-208. doi:10.1111/j.1365-2753.2011.01800.x.
63. Damásio BF, Andrade TF, Koller SH. Psychometric properties of the Brazilian 12-item short-form health survey version 2 (SF-12v2). Paideia. 2015;25(60):29-37. doi:10.1590/1982-43272560201505.
64. Kim SH, Jo MW, Ahn J, et al. Assessment of psychometric properties of the Korean SF-12 v2 in the general population. BMC Public Health. 2014;14. doi:10.1186/1471-2458-14-1086.
65. Młyńczak K, Golicki D. Psychometric properties of the Polish version of SF-12v2 in the general population survey. Expert Rev Pharmacoecon Outcomes Res. 2022;22(3):465-472. doi:10.1080/14737167.2021.1920401.
66. Hayes C, Bhandari N, Kathe N, et al. Reliability and validity of the medical outcomes study Short Form-12 Version 2 (SF-12v2) in adults with non-cancer pain. Healthcare. 2017;5(2). doi:10.3390/healthcare5020022.
67. Bhandari NR, Kathe N, Hayes C, et al. Reliability and validity of SF-12v2 among adults with self-reported cancer. Research in Social and Administrative Pharmacy. 2018;14(11):1080-1084. doi:10.1016/j.sapharm.2018.01.007.
68. Shah RM, Banahan BF, Holmes ER, et al. An evaluation of the psychometric properties of the sf-12v2 health survey among adults with hemophilia. Health Qual Life Outcomes. 2018;16. doi:10.1186/s12955-018-1059-8.
69. Huo T, Guo Y, Shenkman E, et al. Assessing the reliability of the short form 12 (SF-12) health survey in adults with mental health conditions: a report from the wellness incentive and navigation (WIN) study. Health Qual Life Outcomes. 2018;16. doi:10.1186/s12955-018-0858-2.
70. Rutter LA, Brown TA. Psychometric Properties of the Generalized Anxiety Disorder Scale-7 (GAD-7) in Outpatients with Anxiety and Mood Disorders. J Psychopathol Behav Assess. 2017;39(1):140-146. doi:10.1007/s10862-016-9571-9.
71. Johnson SU, Ulvenes PG, Øktedalen T, et al. Psychometric properties of the General Anxiety Disorder 7-Item (GAD-7) scale in a heterogeneous psychiatric sample. Front Psychol. 2019;10. doi:10.3389/fpsyg.2019.01713.
72. Spitzer RL, Kroenke K, Williams JBW, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166(10):1092-1097. doi:10.1001/archinte.166.10.1092.
73. Dhira TA, Rahman MA, Sarker AR, et al. Validity and reliability of the Generalized Anxiety Disorder-7 (GAD-7) among university students of Bangladesh. PLoS One. 2021;16(12):e0261590. doi:10.1371/journal.pone.0261590.
74. Pressler SJ, Subramanian U, Perkins SM, et al. Measuring depressive symptoms in heart failure: validity and reliability of the patient health Questionnaire-8. Am J Crit Care. 2011;20(2):146-152. doi:10.4037/ajcc2010931.
75. McGuire LC, Strine TW, Allen RS, et al. The patient health questionnaire 8: current depressive symptoms among U.S. older adults, 2006 behavioral risk factor surveillance system. Am J Geriatr Psychiatry. 2009;17(4):324-334. doi:10.1097/JGP.0b013e3181953bae.
76. Kroenke K, Strine TW, Spitzer RL, et al. The PHQ-8 as a measure of current depression in the general population. J Affect Disord. 2009;114(1-3):163-173. doi:10.1016/j.jad.2008.06.026.
77. Ferguson L, Scheman J. Patient global impression of change scores within the context of a chronic pain rehabilitation program. J Pain. 2009;10(4):S73. doi:10.1016/J.JPAIN.2009.01.258.

78. Bobos P, MacDermid J, Nazari G, et al. Psychometric properties of the global rating of change scales in patients with neck disorders: a systematic review with meta-analysis and meta-regression. BMJ Open. 2019;9(11):e033909. doi:10.1136/bmjopen-2019-033909.
79. Eremenco S, Chen WH, Blum SI, et al. Comparing patient global impression of severity and patient global impression of change to evaluate test-retest reliability of depression, non-small cell lung cancer, and asthma measures. Qual Life Res. 2022;31(12):3501-3512. doi:10.1007/s11136-022-03180-5.
80. Rampakakis E, Ste-Marie PA, Sampalis JS, et al. Real-life assessment of the validity of patient global impression of change in fibromyalgia. RMD Open. 2015;1(1):e000146. doi:10.1136/rmdopen-2015-000146.
81. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. 2008;9(2):105-121. doi:10.1016/j.jpain.2007.09.005.
82. Saldaña J. The coding manual for qualitative researchers. 2nd edition. Sage Publications; 2013. ISBN: 1446247376.

Supplementary Files

Figures

Workflow of the study.