BMJ Open

The INternet ThERapy for deprESsion Trial (INTEREST): protocol for a patient-preference, randomised controlled feasibility trial comparing iACT, iCBT and attention control among individuals with comorbid chronic pain and depression

Louise V Bell,[1] Peter Cornish,[2] David Flusk,[3] Sheila N Garland,[4] Joshua A Rash [1]

For numbered affiliations see end of article.

Correspondence to
Dr Joshua A Rash;
jarash@mun.ca

ABSTRACT

Introduction Approximately one-third of adults with chronic pain also report clinically relevant levels of depression. Internet-delivered psychological therapies such as Cognitive Behavioural Therapy (iCBT) and Acceptance and Commitment Therapy (iACT) have been developed to overcome barriers of access to services and ensure the timely delivery of care. The objective of this trial is to collect data on feasibility, acceptability and range of probable effect sizes for iCBT and iACT interventions tailored towards the treatment of depression and chronic pain using a randomised controlled patient-preference design.

Methods and analysis Community dwelling adults with chronic non-cancer pain (CNCP) and major depression will be recruited from pain clinics and primary care providers in Newfoundland and Labrador, Canada. The study is a randomised controlled patient-preference trial. Eligible patients will be randomly assigned to a 'preference' or 'no-preference' arm during the first step of randomisation and to intervention or control in the second step of randomisation. Two interventions (ie, iCBT or iACT) will be evaluated relative to attention control. iCBT and iACT involve the completion of 7-weekly online modules augmented with one session of motivational enhancement and weekly therapy sessions. Primary outcomes include (1) feasibility and acceptability parameters and (2) change in symptoms of depression. Secondary outcomes include pain, physical function, emotional function and quality of life. We will recruit 60 participants and examine the range of effect sizes obtained from the trial but will not conduct significance testing as per recommendations for behavioural trial development.

Ethics and dissemination Ethics was approved by the provincial Health Research Ethics Board. Dissemination of results will be published in a peer-reviewed academic journal and presented at scientific conferences.

Trial registration number NCT04009135.

Strengths and limitations of this study

- ► This feasibility trial has been planned in accordance with best practices in behavioural trial design.
- ► Treatment fidelity and processes of change theorised to underly therapeutic effects will be evaluated.
- ► Trial interventions will be administered using an online format designed to facilitate engagement and minimise attrition.
- ► Neither the internet-delivered cognitive behavioural therapy and internet-delivered acceptance and commitment therapy interventions nor the supplementation of such interventions with principles of chronic pain self-management have been previously evaluated using rigorous randomised controlled trials.
- ► Sample size could vary across intervention if the majority of patients express a strong preference for one intervention.

INTRODUCTION

Chronic pain, defined as pain that persists longer than 3 months, or beyond the typical duration of healing,[1] is a prevalent chronic disease. While estimates vary depending on survey methodology, nationally representative data from Canada, the USA, Germany and other European countries indicate that 20%–30% of adults (≥18 years of age) suffer with chronic non-cancer pain (CNCP).[2–6] Chronic pain confers a substantial burden on patients. A Canadian sample of 728 patients with chronic pain awaiting multidisciplinary pain treatment reported poorer health-related quality of life than patients with major medical conditions, including advanced coronary artery disease, diabetes and stroke.[7]

Moreover, individuals living with chronic pain are four times more likely to experience anxiety or depressive disorders,[8] and the prevalence of depression among individuals with chronic pain was estimated at 27% in primary care and 52% in pain clinics.[9] Conversely, major depression has a global point prevalence of 4.7%,[10] and it is considered one salient predictor of persistent pain and heightened pain-related disability.[9 11]

Effective therapies have been developed to treat chronic pain, including cognitive behavioural therapy (CBT) and acceptance and commitment therapy (ACT) with meta-analyses attesting to their effectiveness on outcomes such as depressed mood and pain.[12 13] The primary barrier to treatment is access. At present, more than one-third of publicly funded pain clinics in Canada have wait-times for care exceeding 1 year, with vast areas of the country having no access to appropriate care.[14] A recent national priority setting initiative for the management of chronic pain identified improving access as the no. 4 priority for patients in Canada.[15] Internet-based programs (iCBT and iACT) have been developed to aid individuals who are unable to access face-to-face therapies due to barriers such as long wait lists, or insufficient numbers of appropriately trained health professionals.[16]

The literature reporting on the effects of iCBT for the treatment of depressed mood in patients with chronic pain is equivocal with some,[16–18] but not all,[19 20] studies reporting improvement. Preliminary research reporting on iACT for the treatment of depressed mood in patients with chronic pain is encouraging with the majority of studies reporting improvement in depressive symptoms relative to inactive control groups.[17 21–23] Patient preference may partially account for previous equivocal results and foster improved treatment outcomes. Guidelines on the application of evidence-based practice emphasise the synthesis of empirical evidence and clinical expertise with patient values and preferences in treatment selection and delivery of psychological therapies.[24] A growing body of research indicates that patients who are provided with their preferred treatment report better outcomes than those who are not provided preference.[25 26] The current study will expand on this area of research by exploring the effect of patient preference on outcomes among individuals with chronic pain and depression.

Newfoundland and Labrador is one of the most sparsely populated provinces in Canada with a population of just over 500 000 and a geographical area of just over 4 00 000 km². Under the improved access to publicly funded mental health services initiative, the province has invested in electronic mental health tools which are currently available within the context of usual care, such as Therapist Assisted Online (TAO).[27] The objective of the proposed trial is to collect data on feasibility, acceptability and preliminary effectiveness of offering iCBT and iACT interventions available through TAO that have been tailored towards the treatment of depression and chronic pain using a randomised, attention-controlled, non-blinded, patient-preference design.

METHODS
Research question and objectives
Primary objective
To determine the feasibility of moving to a full trial for the evaluation of iACT and iCBT to manage depression among patients with CNCP. This objective will be accomplished by collecting data on feasibility and acceptability parameters and by evaluating whether the range of effect sizes on symptoms of change in symptoms of depression encompasses the threshold of clinical significance to move to a full trial of d=0.42.

Secondary objectives
(1) To evaluate the range of possible effects of iCBT and iACT on pain severity and physical function measured using the Brief Pain Inventory—Short Form (BPI-SF), symptoms of depression measured using the Patient Health Questionnaire-9 (PHQ-9) and quality of life measured using the Short Form Health Survey (SF-12) (detailed further in the Measures section). (2) To quantify the effect of patient preference on the treatment of depression among individuals with CNCP.

Exploratory objectives
To evaluate whether theorised putative mechanisms of action account for change in symptoms of depression observed within each intervention group. Specifically, to evaluate whether: (1) change in CBT skill utilisation mediates the effect of iCBT on change in symptoms of depression and (2) change in acceptance and committed action mediates the effect of iACT on change in symptoms of depression.

Study design
The study is a randomised, controlled patient-preference trial adhering to CONSORT guidelines.[28 29] Figure 1 depicts a flow diagram of the study design.

Study setting
Community dwelling adults with CNCP and suspected depression (eg, reporting anhedonia or avolition, or demonstrating an elevated score on a screening measure) will be recruited through pain clinics and primary care in Newfoundland and Labrador, Canada. In order to increase the likelihood of recruitment in rural settings, patients will be given the option of completing assessments in-person or over teleconference.

Patient eligibility
Inclusion criteria
Patients will be eligible to participate if they meet the following criteria: (1) fluent in English; (2) are 18 years of age or older; (3) have a primary diagnosis of CNCP; (4) meet DSM-5 criteria for a diagnosis of major depressive disorder. This criterion will be adapted to allow for patients with 'subthreshold' levels of depression if recruitment is slow following the first 6 months of recruitment. Criterion for the full trial will be similarly adapted if recruitment is slow during the feasibility trial; (5) have
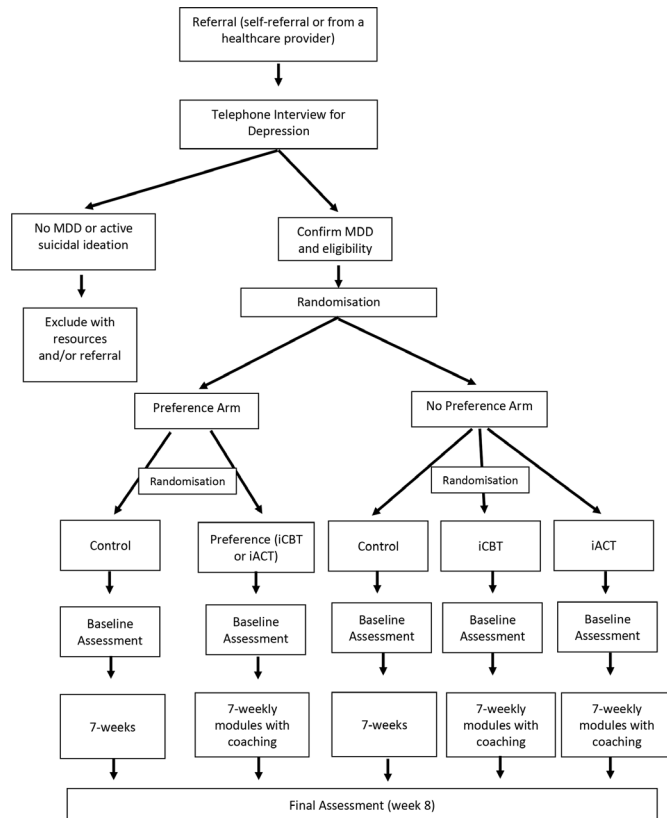
Figure 1 Flow chart of trial design.

access to the internet, email and telephone and (6) can commit to the demands and timelines of the trial. Given high comorbidity in this population, patients with sleep disturbance or comorbid anxiety will also be eligible to participate. Individuals prescribed antidepressant medication for the purpose of managing depressed mood will be eligible to participate so long as the date of initial prescription was sufficiently far removed to allow the establishment of a therapeutic dose (ie, occurring at least 5 weeks before commencing participation).

Exclusion criteria
Exclusion criteria include: (1) diagnosis of cognitive impairment (eg, dementia); (2) active suicidal ideation; (3) severe psychopathology (eg, schizophrenia); (4) unable to sign a safety contract for the duration of the trial and (5) concurrent participation in psychotherapy.

Procedure
Patient screening, recruitment and enrolment
Adults with CNCP and suspected depressed mood (eg, clinician judgement or elevated score on a screening measure, such as the PHQ-9) will be recruited through advertisements throughout the community, and referral from pain and primary care clinics. Recruitment started July 2019 and will continue until 60 patients complete data collection. Patients will be provided with the option of undergoing the screening process in-person, by telephone or over a secure internet connection (ie, Zoom). Screening will be performed by Clinical Psychology

doctoral students supervised by the principal investigator (JR) and consist of (1) provision of trial information; (2) informed consent to undergo screening; (3) completion of screening measures for inclusion/exclusion criteria and (4) clinical interview based on the Structured Clinical Interview for the DSM-5.[30] Eligible patients will be invited to participate in the trial.

Randomisation and blinding
A research assistant not affiliated with the study will use Research Randomizer to generate lists of randomly sequenced numbers to allocate patients to trial arm and group in a manner consistent with CONSORT (http://www.randomizer.org/).[31] One list will be generated for random assignment of patients to the 'preference' or 'no-preference' arm using a 1:1 allocation ratio with random block sizes of 4 and 6. One list will be generated for random assignment of patients in the preference arm to the treatment of their choice or attention control (AC) using a 4:1 allocation ratio with random block sizes of 10 and 15. Patients randomised to 'preference' will complete the Treatment Acceptability and Preferences[32] measure in order to obtain treatment of preference. Finally, one list will be generated to assign patients in the no-preference arm to iCBT, iACT or AC in a random manner with a 2:2:1 allocation schedule and random block sizes of 10 and 15. Thus, each patient will undergo a two-step randomisation procedure: (1) randomisation to preference arm and (2) randomisation to treatment condition. The allocation sequence will be concealed from the researcher using an online portal that allows users to access one allocation per visit. The portal contains one allocation that is deleted following access and replaced with the next allocation in the series. To reduce biases and expectation effects, the research assistant will not be aware of what condition the patients are allocated to when conducting baseline assessments and a research assistant not affiliated with the research will conduct outcome assessments without being aware of allocation. Research assistants delivering telephone coaching will be aware of which group patients are allocated to.

Baseline assessment
Patients who agree to participate will provide informed consent electronically and complete study measures (refer to the Measures section) through Qualtrics.

Intervention
The intervention comprises 7-weekly online modules available through TAO.[27] White papers reporting on the effectiveness of TAO are available online (https://www.taoconnect.org/ask-the-inventor/). The TAO platform can be accessed through a computer or mobile app. Weekly modules include psychoeducation, homework exercises, self-monitoring logs and outcome monitoring. The platform records metrics that can be used to evaluate adherence or engagement, including completion of modules and recording logs, and duration of time spent

Table 1	Content of weekly modules for iACT and iCBT
iACT	**iCBT**
Module 1: *Overview of Depression and Overview of Chronic Pain*	**Module 1: *Overview of Depression and Overview of Chronic Pain***
Module 2: *Introduction to Acceptance and Commitment Therapy* Complete your Mood Survey Module Component 1: Getting Stuck in Our Thoughts Module Component 2: The Six Core Principles of ACT	**Module 2: *Feelings and Thoughts*** Complete your Mood Survey Module Component 1: Feelings and Thoughts
Module 3: *Fusion and Defusion* Complete your Mood Survey Module Component 1: Fusion and Defusion Module Component 2: Defusion Strategies	**Module 3: *Understanding Stress and Relaxation*** Complete your Mood Survey Module Component 1: Stress and Depression Module Component 2: Relaxation Strategies
Module 4: *Thinking Mind vs Observing Mind and Acceptance* Complete your Mood Survey Module Component 1: Thinking Mind vs Observing Mind Module Component 2: Acceptance	**Module 4: *Unhealthy and Healthy Thoughts*** Complete your Mood Survey Module Component 1: Unhealthy and Healthy Thoughts
Module 5: *Mindfulness* Complete your Mood Survey Module Component 1: Mindfulness	**Module 5: *Layers of Thinking*** Complete your Mood Survey Module Component 1: Layers of Thinking
Module 6: *Values* Complete your Mood Survey Module Component 1: Values Module Component 2: Defining your Values	**Module 6: *Core Beliefs*** Complete your Mood Survey Module Component 1: Core Beliefs
Module 7: *Taking Action* Complete your Mood Survey Session 1: Taking Action	**Module 7: *Relationships, Lifestyle, Problem Solving and Relapse Prevention*** Complete your Mood Survey Session 1: Lifestyle Factors Session 2: Social Support Session 3: Problem Solving Session 4: Identifying Early Warning Signs Session 5: Take Action to Continue Recovery

iACT, internet-delivered acceptance and commitment therapy; iCBT, internet-delivered cognitive behavioural therapy.

in the online system. The study team will have access to the weekly activity logs and be aware of adherence to online modules. Patients will be contacted weekly via telephone by their 'online therapy coach' who is expected to: (1) be supportive; (2) ask about progress; (3) provide feedback on symptoms; (4) answer questions; (5) encourage the application of skills in a manner that is consistent with principles of chronic pain self-management (detailed further in the Therapist training section); (6) reinforce progress and skill practice; (7) encourage lesson completion and (8) clarify administrative procedures. Weekly contacts will span approximately 30 min in duration, and actual duration will be recorded.

iCBT

The iCBT consists of seven modules that are depicted in table 1. While consistent with well-established theory and protocols,[33] [34] the iCBT intervention available through TAO has not undergone rigorous empirical evaluation. Patients are also taught thought-challenge logs that they are asked to complete daily.

iACT

The iACT consists of seven modules that are depicted in table 1. While consistent with well-established theory and protocols,[35] [36] the iACT intervention available through TAO has not undergone rigorous empirical evaluation. Patients are also taught 'getting to know your mind' ACT logs obtained from the Association for Contextualized Behavioral Science that they are asked to complete daily.

Attention control

Patients in the control condition will be given online access for psychoeducation about depression and chronic pain. They will be provided weekly phone calls to query symptoms and well-being. Weekly contacts will span approximately 30 min in duration, and actual duration will be recorded. We decided not to use an active common-factor control condition because iACT and iCBT have not been evaluated as a strategy to improve depression among patients with chronic pain relative to attention plus usual care. As such, it would be premature to use a more active common-factor control condition.

Qualitative interviews

At trial completion, patients will complete semistructured interview to obtain information about acceptability; perceived value, benefits, harms, unintended consequences; intervention delivery and dose; intervention components and intervention development.[37 38] Patients who discontinue participation will also be provided the opportunity to complete an interview. Interviews will be conducted by a research assistant who will not otherwise be involved in the conduct of the trial.

Final assessment

Patients will complete study measures at the end of the 7-week intervention and be given access to all TAO modules and content through the programme's self-help library.

Therapist training

Graduate-level trainees of psychology will act as therapy coaches and be provided training and supervision by a registered psychologist with experience in chronic pain management (JR). Training consists of a 2-day workshop that includes: (1) motivational enhancement[39]; (2) management of depression and (3) chronic pain management, including psychoeducation, self-monitoring, overcoming grief and loss, graded activity pacing, assertive communication, cognitive restructuring and active relaxation.[40] Manuals detailing weekly content for iACT and iCBT, and infusion of chronic pain management were created to assist therapy coaches.

Treatment fidelity

Weekly coaching sessions will be conducted by graduate-level trainees of psychology provided supervision by a registered psychologist with experience in chronic pain management (JR). Study personnel complete a 2-day workshop prior to engaging in patient contact and receive weekly supervision thereafter. Coaching sessions will be recorded (with patient consent) and a random 20% will be coded using the therapist rating scale.[41]

Patient engagement

We will use a multipronged approach to encourage patient engagement. First, the timeline and demands of the trial will be explicitly discussed at the outset with patients, who will be asked to sign a behavioural contract to commit to trying to meet the requirements. Second, expectations will be developed for completing weekly coaching sessions. Patients will know our research staff by name and made aware that their research associate has an appointment scheduled with them and will be awaiting their appointment. Third, patients who have difficulties with engagement will be provided with a motivational conversation during which ambivalence towards attending sessions will be openly discussed with the goal of securing commitment to attend sessions. These strategies have been identified by reviews as methods for improving patient recruitment[42] and retention.[43]

Measures

Primary and secondary outcomes were chosen based on recommendations made by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials[44]—an international group of experts who have developed recommendations to improve the design, execution and interpretation of clinical trials of treatments for pain. Refer to table 2 for the schedule of study assessments measured at each phase of the trial.

Primary outcomes
Feasibility and acceptability parameters

Screening rate will be recorded as the number of patients with CNCP and suspected major depression who are referred for screening. *Eligibility rate* will be calculated as the number of patients who meet full inclusion criteria divided by the number of patients referred for screening. The number of patients declining referral for screening and reasons for exclusion will be documented. *Consent rate* will be calculated by dividing the number of patients who consent to undergoing randomisation by the number of patients who met full inclusion criteria. *Attrition* will be recorded and used to calculate the retention rate. *Intervention adherence* is defined by proportion of TAO modules completed. *Intervention engagement* will be defined as length of time spent on the modules. This will be measured using data recorded by TAO and include: (1) frequency of visits to TAO modules and (2) duration of time spent on each module. *Acceptability* data will be collected using semistructured interviews with patients covering recommended content areas.[45 46]

The PHQ-9[47] will be used to measure preliminary effectiveness. It is a nine-item measure of symptoms and severity of depression. Each item is scored from 0 (not at all) to 3 (nearly every day) and scores range from 0 to 27 with scores of ≥5, ≥10 and ≥15 representing mild, moderate and severe levels of depressed mood, respectively.[47] Psychometric properties and sensitivity to change are well documented.[48]

Secondary outcomes

The BPI-SF[49] is a nine-item measure using a 1–10 Numeric Rating Scale assessing pain intensity, impact of pain on seven daily activities (eg, activity, work, sleep) and analgesic use. Test–retest values typically range between 0.72 and 0.98.[49] Evidence indicates that a 1-point reduction in pain or 1-point improvement in interference represents a minimally clinically significant change.[50]

The Depression Anxiety Stress Scale-21[51] is a 21-item scale that measures symptoms of depression, anxiety and stress using a 0 (did not apply to me at all) to 3 (applied to me very much or most of the time) scale. This scale is widely used and has shown high reliability and validity in both clinical and non-clinical samples,[52 53] and among patients with chronic pain.[54 55]

The Coping Strategies Questionnaire-2-Item Version (CSQ-2IV[56]) contains 14 of the original 50 items[57] ranging from 0 (never do that) to 6 (always do that) that

Table 2 Schedule of study assessments randomisation

Testing variables	Randomization					
	Phone screen	↓	Baseline	Weekly assessment	Week 4	Final evaluation
Inclusion and exclusion criteria	X					
SCID-5	X					
Sociodemographics			X			
Medical history			X			
Depression						
PHQ-9			X	X		X
Pain						
BPI-SF (24-hour average pain)			X			X
Function						
BPI-SF (interference)			X			X
Emotional well-being						
DASS-21			X			X
PCS			X			X
MSPSS			X			X
MPFI			X			X
Coping skills						
CSQ			X			X
Quality of life						
SF-12			X			X
Global impression of change						
PGIC						X
Processes of change						
AAQ			X		X	X
CBSTQ			X		X	X
CPAQ-R			X		X	X
CMOTS			X		X	X
URICA			X		X	X
WAI-SF					X	
Expectancy						
CEQ			X			

AAQ, Acceptance and Action Questionnaire; BPI-SF, Brief Pain Inventory—Short Form; CBTSQ, Cognitive Behavioural Therapy Skills Questionnaire; CEQ, Credibility/Expectancy Questionnaire; CMOTS, Client Motivation for Therapy Scale; CPAQ-R, Chronic Pain Acceptance Questionnaire—Revised; CSQ, Coping Strategies Questionnaire; DASS-21, Depression Anxiety Stress Scale-21; MPFI, Multidimensional Psychological Flexibility Inventory; MSPSS, Multidimensional Scale of Perceived Social Support; PCS, Pain Catastrophizing Scale; PGIC, Patient Global Impression of Change; PHQ-9, Patient Health Questionnaire-9; SCID-5, Structured Clinical Interview for the DSM-5; SF-12, Short Form Health Survey; URICA, University of Rhode Island Change Assessment; WAI-SF, Working Alliance Inventory—Short Form.

are divided into seven scales measuring cognitive and behavioural coping strategies typically endorsed by individuals with chronic pain.[18] The two-item CSQ-2IV scale has been shown to have high validity through the strong association (r>0.72) with the corresponding scales of the original 50-item scale.[58]

The SF-12[59] is a 12-item survey measuring mental and physical well-being. Item ranges and anchors vary across the measure. The test–retest reliability of the Physical Component Summary and Mental Component Summary was 0.89 and 0.76, respectively, and correlates highly with the SF-36.[60]

The Insomnia Severity Index[61] is a seven-item measure that assesses the nature, severity and impact of insomnia during the previous 2-week period using a 5-point Likert scale from 0 'no problem' to 4 'very severe'. Adequate psychometric properties have been reported in community samples, primary care patients and chronic pain patients.[62 63]

The Patient Global Impression of Change is a single-item measure of the perception of improvement after an intervention. It is a seven-point rating ranging from 1 'no change, or the condition has worsened' to 7 'a great deal better, and a considerable improvement that has made all the difference'.[64]

The Pain Catastrophizing Scale (PCS[65]) is a 13-item questionnaire that measures how respondents think and feel when they painful experience using a 0 (not at all) to 4 (all the time) Likert scale. The PCS yields a total score and three subscale scores assessing rumination, magnification and helplessness. The PCS has demonstrated adequate test–retest reliability over a mean period of 52 days[66] and excellent internal consistency[67] among individuals with chronic pain.

The Multidimensional Scale of Perceived Social Support (MSPSS[68]) is a 12-item scale that measures the perceived availability and adequacy of emotional and instrumental social support using a 7-point Likert scale ranging between 1 'very strongly disagree' and 7 'very strongly agree'. The MSPSS has demonstrated strong internal consistency (Cronbach's α=0.87–0.94) and test–retest reliability (r=0.73) among adults.[69]

The Multidimensional Psychological Flexibility Inventory[70] is a 60-item scale measuring the 12 dimensions of psychological flexibility as posited by the Hexaflex model. Each item is rated on a 6-point scale ranging from 1 (never or never true) to 6 (always or always true). The internal consistency is strong with Cronbach's α=0.96 for global inflexibility and α=0.97 for flexibility.[70]

Processes of change
The Chronic Pain Acceptance Questionnaire—Revised (CPAQ-R[71]) is a 20-item scale ranging from 0 (never true) to 6 (always true) that measures activity engagement and willingness to accept pain. The CPAQ-R is reliable, with Cronbach's α=0.82 for activity engagement and α=0.78 for pain willingness.[72 73]

The Cognitive Behavioural Therapy Skills Questionnaire (CBTSQ[74]) is a 16-item measure of the frequency with which CBT skills are used. Items range from 1 (I don't do this) to 5 (I always do this). The CBTSQ has two subscales: the seven-item Behavioural Activation subscale and the nine-item Cognitive Restructuring subscale. The scale has demonstrated reliability (α=0.80 for Behavioural Activation and α=0.88 for Cognitive Restructuring) and validity.[74]

The Acceptance and Action Questionnaire (AAQ-II[75]) is a seven-item scale ranging from 1 (never true) to 7 (always true) designed to measure psychological flexibility. The AAQ-II has good internal consistency (α=0.84) and is the most commonly used measure assessing the extent to which patients have developed greater psychological flexibility in ACT.[76]

The University of Rhode Island Change Assessment[77] is a 32-item questionnaire that measures stage of change to engage in treatment. Items on the scale range from 1 (strongly disagree) to 5 (strongly agree). The psychotherapy version measures four subscales with eight items on each scale: precontemplation (α=0.79), contemplation (α=0.84), action (α=0.84) and maintenance (α=0.82).[78]

The Working Alliance Inventory-C[79] is 12-item scale ranging from 1 (never) to 7 (always) that measures the therapist–patient alliance using three facets: goal consensus, task agreement and perceived bond. The internal consistency of the overall alliance (α=0.98) and each subscale (α=0.90 for goal; α=0.90 for task and α=0.92 for bond) is strong.[79]

The Client Motivation for Therapy Scale[80] is a 24-item measure that was developed using self-determination theory[81 82] to measure six facets of motivation (intrinsic, integrated, identified, introjected, external and amotivation) to engage in therapy. Items range from 1 (does not correspond at all) to 7 (corresponds exactly).

The Credibility/Expectancy Questionnaire[83] is a six-item questionnaire designed to capture a patient's perceived expectation for treatment. The questionnaire is divided into two factors: cognitive-based credibility of treatment and affective-based expectancy of treatment. Item ranges and anchors vary across the measure. The measure has strong internal consistency (α=0.84–0.85) and good test–retest reliability (r=0.75–0.82).[83]

Sample size and statistical analysis
Given that the purpose of this study was not to provide a definitive estimate of treatment effect, no formal sample size calculation was performed. Rather, a target sample of 60 patients was chosen based on pragmatic grounds.

Consistent with current best practice recommendations for behavioural trial development,[84] we will examine the range of effect sizes obtained from the trial but will not conduct significance testing. As discussed by Powell *et al*,[85] it is inappropriate to treat pilot studies as 'mini efficacy' studies. As such, statistical evaluation following the completion of 60 patients will serve as an interim assessment to decide the final sample needed to detect observed effects if such effects are of clinical relevance.[86] A full trial will be

warranted if a steady recruitment rate can be established (ie, ≥3 patients enrolled per month), the majority (>50%) of patients describe the intervention as generally acceptable and able to meet their needs with minor or no modification, and the range of effect sizes on the PHQ-9 includes criteria for a reliable and clinically significant change.[87] Interventions will be redesigned if the range of observed effects is not of practical significance.

Risk management strategies

Several strategies will be implemented to mitigate potential risk. First, patients who endorse high risk for suicide or self-harm (eg, endorse suicide intention, unwilling to sign a behavioural contract to keep oneself safe during the trial) will be excluded and provided with resources and/or referral. Second, patients will be queried about suicidal ideation and intention during the study. Patients who endorse active suicidal ideation or suicide intention will undergo a suicide risk assessment.[88] Patients who score elevated will be referred to the emergency department or encouraged to contact the mobile crisis unit. As discussed during informed consent, if necessary, the mobile crisis unit will be contacted on the patient's behalf.

Ethics and dissemination

Results from this feasibility trial will be disseminated to the academic community through conference presentations and the publication of peer-reviewed manuscripts. Results will be posted to our website www.munbehaviourmedicine. ca and made available to patients, providers and the general public.

Data management

Data will be collected, de-identified and stored. Electronic data will be stored on password-protected servers in encrypted files. Paper files will be stored under lock and key in the Memorial University of Newfoundland Behavioural Medicine Centre. De-identified data will be retained indefinitely and made available to members of the investigative team. De-identified data will be made available on reasonable request where such requests are compliant with receipt of ethical approval from the sending and receiving hosts institutional ethics review boards.

Patient and public involvement

Patients with lived experience were consulted in the design of this project and assisted in preparation of study materials. Engagement will continue throughout trial conduction and be emphasised when preparing materials for dissemination.

IMPLICATIONS

The ongoing study represents a phase II-B feasibility trial that will provide proof-of-concept, acceptability and feasibility data to move to a phase III efficacy trial (refer to Czajkowski *et al*[84] for a description of the development of behavioural trials for chronic disease management). Feasibility data will include recruitment rate, timeline to

recruit, retention and adherence. This data will be used to: (1) return to phase I studies for further refinement of the clinical interventions or (2) inform the approach to conducting a phase III efficacy trial. Of note, the effect size calculation for the larger RCT will be based on the probable range of effects observed which must encompass the threshold of clinical significance to proceed to phase III of d=0.42. We have chosen an effect size of d=0.42 because this represents a recommended minimum effect size representing 'practically' significant effects within social sciences and medicine.[86]

The ultimate goal of this programme of research is to provide an efficient and flexible method for improving pain and mood among individuals with chronic pain who would not otherwise be able to access care. Wait-list for admittance to chronic pain clinics in Canada are often in excess of 1 year with vast areas of the country having no access to appropriate care.[89] Protracted waiting periods have been deemed medically unacceptable given that individuals with chronic pain who wait longer than 6 months experience significant deterioration of physical and mental well-being.[14] Interventions evaluated in this trial focus on the treatment of depression while simultaneously improving chronic pain self-management skills in a manner that is flexible and capitalises on patient preferences (ie, fostering motivation and expectancy effects) and readiness to engage in treatment.

Author affiliations
[1]Psychology, Memorial University of Newfoundland, St. John's, Newfoundland, Canada
[2]Student Wellness & Counselling Centre, Memorial University of Newfoundland, St. John's, Newfoundland, Canada
[3]Anesthesia, Memorial University of Newfoundland, St. John's, Newfoundland, Canada
[4]Departments of Psychology and Oncology, Memorial University of Newfoundland, St. John's, Newfoundland, Canada

ORCID iD
Joshua A Rash http://orcid.org/0000-0003-0927-0712

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