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Co-construction of CALM-Pain, a mindfulness-based chronic pain management program for Veterans to improve quality of life

Submission date 28/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/10/2025	**Overall study status** Ongoing	
Last Edited 28/10/2025	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims

Chronic pain (a pain that lasts longer than 3 months) is 2-3 times more prevalent, but also more severe in Veterans than in the general population. It has numerous physical, psychological, and social consequences that adversely impact one's well-being. Chronic pain in Veterans transitioning to civilian life is associated with poor quality of life. Symptoms of anxiety, depression and post-traumatic stress can exacerbate pain, which in turn can worsen psychological states. In this context, interventions that have the potential to impact both chronic pain and psychological distress are desired. Over 50% of Veterans use complementary /alternative approaches to manage chronic pain, anxiety and depression; a third have been exposed to mindfulness. Mindfulness typically helps individuals refocus on the present moment and increase awareness of their surroundings, internal sensations and cognitions, which allow for stepping back and reframing experiences. In military personnel/Veterans, mindfulness programs showed promising preliminary results to reduce psychological distress and improve QoL. These studies are limited however, since they either did not tailor the program to the needs of military personnel/Veterans or did not use a trauma-informed approach essential to this population.

The three study objectives are to: (1) co-construct with Veterans and clinicians CALM-Pain (Cultivating Awareness and Living Mindfully for Veterans – Pain), a mindfulness-based chronic pain management program for Veterans living with chronic pain (CP); (2) analyze the feasibility and acceptability of CALM-Pain using the ORBIT framework; and (3) co-refine the intervention.

Who can participate?

To be eligible to participate in the intervention, individuals must be adult Veterans from the Canadian Armed Forces (18 years old or above), living in the province of Quebec or Ontario (Canada), experiencing pain for over 3 months, speaking English or French, and having access to the Internet. Individuals are not eligible if they have already completed a mindfulness program for chronic pain, have active suicidal ideations or severe psychiatric diagnoses.

What does the study involve?

Participation in the intervention will involve:

1. Consultation with one of the clinicians that will lead the program, in order to verify eligibility criteria and that participation in the program is optimal for participants. This will include questions about pain, physical and mental health, and prior experience with mindfulness.
2. Complete baseline questionnaires about 2 weeks before the start of the intervention, to document pain interference, resilience, posttraumatic stress, psychological distress, pain beliefs, self-efficacy and quality of life
3. Take part in a 12-session online mindfulness-based program for chronic pain adapted to the needs of Veterans. Each session will last 2h30. Some exercises will be assigned to practice in between sessions.
4. Half-way through the program, at the end of the program, and six months later, complete follow-up questionnaires to measure program satisfaction, pain, physical and mental health, and prior experience with mindfulness.
5. For a subset of participants, take part in an online semi-structured interview

What are the possible benefits and risks of participating?
Participation in the intervention will require 30 hours for the program itself, in addition to completing questionnaires for approximately 2 hours and for some participants, taking part in an online interview of 90 minutes. This might cause some inconvenient. Participation in the program could also bring on some discomfort (e.g., increased pain, unpleasant emotions).

Where is the study run from?
This is an Internet-based study carried out in Canada.

When is the study starting and how long it is expected to run for?
October 2024 to December 2027

Who is funding the study?
This study is funded by a research grant from the Chronic Pain Centre of Excellence for Canadian Veterans

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Co-construction of CALM-Pain, a trauma-informed mindfulness-based chronic pain management program for Veterans to improve quality of life: A pilot mixed methods study

Acronym
CALM-PAIN

Study objectives
The three study objectives are to:
1. Co-construct with Veterans and clinicians CALM-Pain (Cultivating Awareness and Living Mindfully for Veterans – Pain), a mindfulness-based chronic pain management program for Veterans living with chronic pain (CP)
2. Analyze the feasibility and acceptability of CALM-Pain using the ORBIT framework
3. Co-refine the intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/06/2025, Research Ethics Board of the Centre hospitalier de l'Université de Montréal (900 St-Denis, Montreal, H2X0A9, Canada; +1 (0)514 890 8000; ethique.recherche.chum@ssss.gouv.qc.ca), ref: 2025-12587

Study design
Multi-center longitudinal multi-methods single-arm interventional study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied

Improvement of quality of life among veterans living with chronic pain

Interventions
Trauma-informed and trauma-sensitive mindfulness-based program for chronic pain in Veterans. This is a single-arm study in order to develop and refine the program so that it meets the needs of Veterans living with chronic pain. Phase 1 will include individual interviews and focus groups with Veterans with and without experience with mindfulness interventions, to gather their feedback on the current intervention format and content. Rapid data analysis will be carried out to improve the program. Phase 2 will involve the delivery of the program four times to Veterans living with chronic pain. Quantitative and qualitative data will be collected before, during and at the end of the intervention to document acceptability, feasibility, satisfaction, and preliminary effectiveness. Phase 3 will use data collected in Phase 2 to finalize the intervention format and content.

Intervention Type
Behavioural

Primary outcome(s)
Health-related quality of life assessed using the Short-Form Health Survey V2 (SF-12v2) at baseline (within the 2 weeks prior to start of the intervention), T1 (session 6 of the intervention), T2 (within 2 weeks of intervention completion) T3 (6 months after intervention completion)

Key secondary outcome(s))
1. Pain self-efficacy measured using the Pain Self-Efficacy Questionnaire at baseline (within the 2 weeks prior to start of the intervention), T1 (mid-way through intervention sessions), T2 (within 2 weeks of intervention completion) and T3 (6 months after intervention completion)
2. Pain catastrophizing measured using the Pain Catastrophizing Scale at baseline (within the 2 weeks prior to start of the intervention), T1 (mid-way through intervention sessions), T2 (within 2 weeks of intervention completion) and T3 (6 months after intervention completion).
3. Pain intensity measured using an 11-point Numeric Rating Scale at baseline (within the 2 weeks prior to start of the intervention), T1 (mid-way through intervention sessions), T2 (within 2 weeks of intervention completion) and T3 (6 months after intervention completion)
4. Psychological distress assessed using the Patient Health Questionnaire-4 at baseline (within the 2 weeks prior to start of the intervention), T1 (mid-way through intervention sessions), T2 (within 2 weeks of intervention completion) and T3 (6 months after intervention completion).
5. Pain resilience measured using the Pain Resilience Scale at Baseline (within the 2 weeks prior to start of the intervention), T1 (mid-way through intervention sessions), T2 (within 2 weeks of intervention completion) and T3 (6 months after intervention completion)
6. Pain interference measured using the Brief Pain Inventory at Baseline (within the 2 weeks prior to start of the intervention), T1 (mid-way through intervention sessions), T2 (within 2 weeks of intervention completion), and T3 (6 months after intervention completion).
7. Posttraumatic stress symptoms measured using the PTSD checklist for DSM-5 (PCL-5) at Baseline (within the 2 weeks prior to start of the intervention), T1 (mid-way through intervention sessions), T2 (within 2 weeks of intervention completion) and T3 (6 months after intervention completion).
8. Recruitment rates: The number and proportion of eligible patients recruited, reasons for ineligibility, and refusals. Provides feasibility data according to CONSORT recommendations for pilot studies. Time Frame: During active recruitment period for the study (up to 12 months)
9. Attendance: Number of sessions attended by participants. Time Frame: Each session for a total of 12 sessions (up to 3 months)
10. Adverse events: The number and nature of adverse events reported during the study. Time

Frame: Each session for a total of 12 sessions (up to 3 months)
11. Acceptability measured using a modified version of the Pain Program Satisfaction Questionnaire . Acceptable level defined as >50% of participants rating moderate-high (>=3/4) satisfaction items. Time Frame: T2 (within 2 weeks of intervention completion)
12. Retention rates: The number and proportion of eligible patients who complete the program and who drop-out. Provides feasibility data according to CONSORT recommendations for pilot studies. Time Frame: (T2) End of intervention (assessed up to 4 weeks)

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Living with pain for more than 3 months
2. Able to communicate in French or English
3. Residing in Canada (Quebec or Ontario for Phase 2)
4. Having access to the Internet

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Having prior experience with a structured mindfulness program for chronic pain (Phase 2 only)
2. Active suicidal ideations or severe psychiatric diagnosis that prevents participation

Date of first enrolment
01/12/2025

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
Canada

Study participating centre
Centre hospitalier de l'Université de Montréal
900 St-Denis
Montreal
Canada
H2X0A9

Sponsor information

Organisation
Centre Hospitalier de l'Université de Montréal

ROR
https://ror.org/0410a8y51

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chronic Pain Center of Excellence for Canadian Veterans

Results and Publications

Individual participant data (IPD) sharing plan
Following recommendations for open access science, denominated data might be made available to other researchers if an official request is sent, pending approbation by the ethics committee.

IPD sharing plan summary
Data sharing statement to be made available at a later date