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Adapting an occupational therapy intervention for chronic pain

Submission date
13/11/2025

Recruitment status
Recruiting

Registration date
01/12/2025

Overall study status
Ongoing

Last Edited
17/11/2025

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims:
Living with chronic pain (CP) often implies major lifestyle changes, including modifications of daily routines and work. Few validated and effective interventions specifically target functional outcomes in this population. Redesign your Everyday Activities and Lifestyle with Occupational Therapy [REVEAL(OT)] is a lifestyle-oriented intervention led by occupational therapists that directly targets the daily functional challenges of living with CP. The intervention was initially developed and studied as an add-on to standard treatment delivered by Danish multidisciplinary specialized pain clinics. A series of focus groups and individual interviews with individuals living with chronic pain, clinicians and managers were held to co-develop a first version of the adapted REVEAL(OT) intervention for the Canadian context in tertiary care settings. The current proposed trial will help co-refine REVEAL(OT)/CA by exploring its acceptability, feasibility and mechanisms of action through intervention deliveries and focus groups and/or individual interviews with participating patients and partners.

Who can participate?
To be eligible to participate in the study, participants will be (a) those living with pain for more than 3 months, speaking French and/or English, and who have received treatment at one of the two participating pain clinics within the past 12 months; and (b) health care providers working with individuals with CP at the participating pain clinics for more than 12 months, and managers officially involved in administrative and/or managerial tasks involving the pain clinics.

What does the study involve?
Participation in intervention deliveries and interviews involves:
1. Consultation with one of the occupational therapists who will lead the intervention, in order to verify clinical eligibility criteria and that participation in the program is optimal for participants. This will include questions about pain, functioning and readiness to change their lifestyle.
2. After obtaining written consent, collection of socio-demographic data (patients, clinicians, managers) and self-administered questionnaires (patients) about 2 weeks before the start of the intervention, to document the duration, location and intensity of pain, its functional impact, the quality of sleep, fear of movement and beliefs and attitudes towards your pain.
3. Participation in REVEAL(OT) intervention that will be delivered by 1 or 2 occupational

therapists and will take place over a period of approximately 12 to 15 weeks, including a combination of group sessions (in person and/or online) lasting about 2 hours each, and individual sessions (in person and/or online) lasting about 1 hour each, for a maximum of 20 intervention sessions. Sessions will combine presentations, discussions and experiments. These experiments will consist of graded therapeutic activities aimed at experimenting with symptom management strategies in everyday gestures. Topics covered will include the associations between occupation and health and well-being, energy conservation and pain management in several lifestyle habits, such as sleep, meal preparation, physical activities, work, domestic activities, leisure, etc. A diary will be used (online or written) throughout the intervention to guide a process of change in the ways in which everyday activities are carried out. At the end of each session, a brief appraisal questionnaire (online or in writing) will be completed.
4. Within 2 weeks after the end of the intervention, completion of the same self-administered questionnaires (patients) and a new questionnaire about their global appreciation of the intervention (patients; online or written).
5. The interview (sub-group of participants; in-person or online/individual or focus group) to share feedback about the intervention.

What are the possible benefits and risks of participating?
Participation requires a maximum of 40 hours over a period of around 4 months in order to receive the intervention and share experience in-person and/or online. During the meetings, some people may feel slightly uncomfortable experimenting with activities that they stopped doing or are asked to perform in a different way. Questions about their experiences may embarrass them but the option of skipping treatment sessions, refusing to answer certain questions or withdrawing from the study will always be possible.

Where is the study run from?
This study is carried out in Montreal, Canada. Interviews and intervention deliveries will be done both in-person and online.

When is the study starting and how long it is expected to run for?
December 2025 to December 2027

Who is funding the study?
This study is funded by a research grant from the Canadian Institutes of Health Research

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Cultural adaptation and implementation of an intervention aimed at rethinking daily activities and lifestyle of adults living with chronic pain in occupational therapy

Acronym
REVEAL(OT)CAN

Study objectives
This study aims to define and refine REVEAL(OT)/CA with partners (authors of the original intervention, people with lived experience, clinicians, managers). This overall objective is operationalized in two specific objectives:
1. Optimisation of acceptability of intervention content and format, and feasibility of its delivery; and
2. Exploration of acceptability, feasibility and mechanisms of action of REVEAL (OT)/CA through initial delivery of the intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/06/2023, 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: MP-02-2024-11469

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment

Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Chronic pain

Interventions
Redesign your Everyday Activities and Lifestyle with Occupational Therapy [REVEAL(OT)] is an innovative intervention developed at the University of Southern Denmark and Region Zealand which has undergone three iteration phases to improve delivery, outcomes, and fit within specialized Danish pain clinics. This intervention is based on occupational therapy evidence about CP management through lifestyle changes, population-centered information on motivation for changing lifestyle, and contextual factors related to intervention delivery within a specialized tertiary care pain clinic. This patient-oriented multi-method study will adapt and refine REVEAL(OT) intervention with partners (patients, clinicians and managers) so that it meets the needs of patients living with chronic pain in two Montréal specialized pain clinics. The study will involve the delivery of the program at least two times in each pain clinic. Quantitative and qualitative data will be collected before, during and at the end of the intervention to document its acceptability, feasibility and mechanisms of action through intervention deliveries and focus groups and/or individual interviews with participating patients and partners. Results of this study will generate the intervention manual both in French and English, and established a strategy for the design and funding of a future implementation and efficacy trials.

Intervention Type
Behavioural

Primary outcome(s)
1. Occupational performance and satisfaction measured using Canadian Occupational Performance Measure at baseline (within the 2 weeks prior to start of the intervention) and T1 (within 2 weeks of intervention completion)

Key secondary outcome(s))
1. Pain Interference measured using PROMIS Pain Interference – Short Form 4a, 4 items at baseline (within the 2 weeks prior to start of the intervention) and T1 (within 2 weeks of intervention completion)

2. Pain self-efficacy measured using Pain Self-Efficacy Questionnaire, 10 items at baseline (within the 2 weeks prior to start of the intervention) and T1 (within 2 weeks of intervention completion)

3. Kinesiophobia measured using the Tampa Scale for Kinesiophobia, 6 items at baseline (within the 2 weeks prior to start of the intervention) and T1 (within 2 weeks of intervention completion)

4. Pain catastrophizing measured using the Pain Catastrophizing Scale, 5 items at baseline (within the 2 weeks prior to start of the intervention) and T1 (within 2 weeks of intervention completion)

5. Depressive symptoms measured using the Patient Health Questionnaire, 2 items at baseline (within the 2 weeks prior to start of the intervention) and T1 (within 2 weeks of intervention completion)

6. Anxiety symptoms measured using the Patient Health Questionnaire, 2 items at baseline (within the 2 weeks prior to start of the intervention) and T1 (within 2 weeks of intervention completion)

7. Sleep measured using the PROMIS Sleep Disturbance, 4 items at baseline (within the 2 weeks prior to start of the intervention) and T1 (within 2 weeks of intervention completion)

8. 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 measured at T1 (within 2 weeks of intervention completion)

9. Recruitment rates measured using the number and proportion of eligible patients recruited, reasons for ineligibility, and refusals. Provides feasibility data according to CONSORT recommendations for pilot studies at active recruitment period for the study (up to 12 months)

10. Attendance measured using the number of sessions attended by participants at each session for a total of 12 to 15 sessions (up to 3 months)

11. Adverse events measured using the number and nature of adverse events reported during the study at each session for a total of 12 to 15 sessions (up to 3 months)

12. Retention rates measured using 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 at T1 (within 2 weeks of intervention completion)

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Adults (18 years or more)
2. Able to communicate in French or English
3. Patients living with pain for more than 3 months
4. Patients who have received treatment at one of the two participating pain clinics within the past 12 months
5. Health care providers working with individuals with CP at the participating pain clinics for more than 12 months
6. Managers officially involved in administrative and/or managerial tasks involving the pain clinics

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Not being able to travel to attend in-person sessions
2. Not being able to access the internet with a microphone and camera to participate in online sessions
3. Having cognitive disabilities or emotional distress that prevents participation

Date of first enrolment
01/12/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Canada

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

Study participating centre
Centre universitaire de santé McGill
Montreal
Canada

Sponsor information

Organisation

Centre Hospitalier de l’Université de Montréal

ROR
https://ror.org/0410a8y51

Funder(s)

Funder type

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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
Available on request