# The PASSAGE Program: a structured multicomponent interdisciplinary group intervention for the self-management of chronic low back pain

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
26/08/2014	No longer recruiting	∐ Protocol
Registration date	Overall study status	Statistical analysis plan
08/10/2014	Completed	☐ Results
Last Edited	Condition category	Individual participant data
08/10/2014	Musculoskeletal Diseases	Record updated in last year

## Plain English summary of protocol

Background and study aims

Chronic low back pain (CLBP) is a widespread health problem associated with significant costs. The aim of this study is to assess the performance of an intervention called the PASSAGE programme, which has been developed as a series of group therapy sessions to both alleviate symptoms and help patients to self-manage their symptoms.

# Who can participate?

Patients who are aged 18 or over with a medical diagnosis of non-specific CLBP and motivated to fully participate in the PASSAGE programme.

#### What does the study involve?

Participants are randomly allocated to one of two groups: either the intervention group or the waitlist group. Participants in the intervention group attend eight group sessions (with eight people in each group). Each session covers practical and emotional techniques for coping with CLBP (psycho-education), cognitive behavioral therapy-related techniques and exercise activities. A follow-up group session then takes place six months after the completion of the programme. Participants in the waitlist group continue with their usual treatment until the first group completes the PASSAGE programme, after which they also take part. A series of questionnaires completed by both groups are used to assess how well the intervention performs.

What are the possible benefits and risks of participating?

Possible benefits include better self-management of CLBP and alleviation of symptoms. There is little risk in taking part in the study, the only inconvenience being giving up time and resources to participate in the research (e.g. traveling, completing questionnaires).

Where is the study run from? The University of Sherbrooke (Canada).

When is the study starting and how long is it expected to run for? January 2010 to October 2011.

Who is funding the study?

Community Alliances for Health Research and Knowledge Exchange in Pain of the Canadian Institutes of Health Research (CIHR) in partnership with AstraZeneca Canada Inc (Grant # 86787), and by Pfizer Canada Inc.

Who is the main contact? Dr Manon Choinière manon.choiniere@umontreal.ca

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Manon Choinière

#### Contact details

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# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

# Scientific Title

Multicomponent interdisciplinary group intervention for the self-management of non-specific chronic low back pain: A multicenter randomized controlled trial

#### Acronym

**PASSAGE** 

## **Study objectives**

The aim of the present study was to evaluate the efficacy of the PASSAGE Program-a multicomponent interdisciplinary group intervention for the self-management of non-specific chronic low back pain for improving the clinical condition of patients suffering from this type of disorder.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics Committees of the University of Sherbrooke (Université de Sherbrooke), 15/05/2009, ref. 09-034

University of Québec in Abitibi-Témiscamingue (Université de Québec en Abitibi-Témiscamingue) 26/05/2009

# Study design

Multicenter open-label randomized wait-list controlled trial

#### Primary study design

Interventional

# Secondary study design

Randomised controlled trial

## Study setting(s)

Other

# Study type(s)

Treatment

#### Participant information sheet

N/A

# Health condition(s) or problem(s) studied

Non-specific chronic low back pain

#### **Interventions**

- 1. Intervention group: The PASSAGE program is a structured multicomponent interdisciplinary group intervention aimed at reducing CLBP symptoms and maintaining optimal function through the use of self-management strategies and patient education. The intervention consists of 8 group sessions with 8 participants lasting 2.5h each. Each session involved 3 major components:
- 1.a. Psycho-educational tools
- 1.b. Cognitive behavioral therapy-related techniques
- 1.c. Patient-tailored exercise activities. A follow-up group session is schedule 6 months after the end of the intervention
- 2. Waitlist group: Participants randomized to the waitlist group were instructed to continue their treatment as usual until they could take part in the PASSAGE Program i.e., 3 months after the intervention group had completed the program.

#### Intervention Type

#### Other

#### Phase

Not Applicable

## Primary outcome measure

Pain intensity, measured with a standardized numerical rating scale (NRS)

# Secondary outcome measures

- 1. Progress during rehabilitation treatment (Quebec Back Pain Disability Scale)
- 2. Pain interference (Brief Pain Inventory)
- 3. Impact of pain on sleep quality (Chronic Pain Sleep Inventory)
- 4. Pain coping strategies and (Coping Strategy Questionnaire)
- 5. Tendency to catastrophize (Pain Catastrophizing Scale)
- 6. Depressive symptoms (The Beck Depression Inventory)
- 7. Health-related quality of life (SF-12v2)
- 8. Patient global impression of change (PGIC)
- 9. Perceived pain relief (0 to 100% Pain Relief Scale)

Quantitative data were collected in both study groups at baseline (T0), after the intervention group completed the eight sessions of the PASSAGE Program (T1), and 3 months later (T2).

## Overall study start date

01/01/2010

# Completion date

01/10/2011

# **Eligibility**

# Key inclusion criteria

- 1. Aged 18 years or older
- 2. Had a medical diagnosis of non-specific CLBP based on recognized criteria.
- 3. Reported pain of at least moderate intensity (at least 4/10) in the seven days prior to enrolment
- 4. Were motivated to attend all group sessions and to integrate the proposed self-management strategies
- 5. Agreed to not introduce new medications or treatments/therapies over the course of the PASSAGE program

#### Participant type(s)

Patient

# Age group

Adult

#### Lower age limit

18 Years

#### Sex

# Target number of participants

64 (32 per study site)

### Key exclusion criteria

- 1. Subjects who reported major pain syndromes other than CLBP such as arthritis or life threatening diseases such as cancer
- 2. Physical/psychiatric disorders that could compromise their participation in the study

#### Date of first enrolment

01/01/2010

## Date of final enrolment

01/10/2011

# Locations

#### Countries of recruitment

Canada

#### Study participating centre

Centre de recherche du Centre hospitalier de lUniversité de Montréal

Montreal

Canada

H2X 0A9

# Sponsor information

#### Organisation

Centre de recherche du Centre hospitalier universitaire de Sherbrooke (Canada)

#### Sponsor details

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#### Sponsor type

Hospital/treatment centre

#### Website

http://cr.chus.qc.ca/en/axes/sante-population/chercheurs/patricia-bourgault-ph-d/

#### **ROR**

https://ror.org/020r51985

# Funder(s)

# Funder type

Other

#### **Funder Name**

Community Alliances for Health Research and Knowledge Exchange in Pain of the Canadian Institutes of Health Research (CIHR) (Canada)

#### Funder Name

AstraZeneca Canada Inc. (Grant # 86787) (Canada)

#### **Funder Name**

Pfizer Canada Inc. (Canada)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration