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The PASSAGE Program: a structured multicomponent interdisciplinary group intervention for the self-management of fibromyalgia.

Submission date
04/07/2014

Recruitment status
No longer recruiting

Registration date
23/07/2014

Overall study status
Completed

Last Edited
18/05/2015

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fibromyalgia syndrome (FMS) is a chronic condition that causes pain all over the body. Other symptoms include an increased sensitivity to pain, extreme tiredness, muscle stiffness, headaches, depression, difficulties sleeping and problems with memory and concentration. The aim of this study is to assess the performance of a new treatment (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 18 years or over, with a medical diagnosis of FMS and motivated to fully participate in the PASSAGE programme.

What does the study involve?
Participants are randomly allocated to one of two groups. The intervention group attend 8 group sessions (with 8 people in each group). Each session covers practical and emotional techniques for coping with FMS (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. 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 FMS 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?
September 2009 to March 2011

Who is funding the study?
1. Community Alliances for Health Research and Knowledge Exchange in Pain of the Canadian Institutes of Health Research (CIHR) (Canada)
2. AstraZeneca Canada Inc. (Canada)
3. Pfizer Canada Inc. (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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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 self-management of fibromyalgia: a mixed-methods randomized controlled trial

Acronym

PASSAGE

Study objectives
The aim of the present study was thus to evaluate, quantitatively and qualitatively, the efficacy of the PASSAGE Program - a multicomponent interdisciplinary group intervention for the self-management of fibromyalgia syndrome (FMS) 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
Mixed-methods multicenter open-label randomized wait-list controlled trial with both a quantitative and a qualitative aspect

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Fibromyalgia syndrome (FMS), chronic pain

Interventions
1. Intervention group : The PASSAGE program is a structured multicomponent interdisciplinary group intervention aimed at reducing FMS 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. Pain intensity was measured with a standardized numerical rating scale (NRS)

Secondary outcome measures
1. Severity of FMS (Fibromyalgia Impact Questionnaire)
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 8 sessions of the PASSAGE Program (T1), and 3 months later (T2). In order to document and further capture the intervention group patients experiences, face-to-face open ended group narrative qualitative interviews were conducted 6 to 9 months after completion of the PASSAGE Program.

Overall study start date
01/09/2009

Completion date
01/03/2011

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Had a medical diagnosis of FMS based on the American College of Rheumatology (ACR) classification criteria for at least 6 months
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
Both

Target number of participants
64 (32 per study site)

Key exclusion criteria
1. Subjects who presented pain-related symptoms commonly associated with FMS (e.g., irritable bowel syndrome, migraine)
2 Those who suffered from chronic pain syndromes other than FMS (e.g., painful diabetic neuropathy)
3. Physical/psychiatric disorders that could compromise their participation in the study

Date of first enrolment
01/09/2009

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
Canada

Study participating centre
Centre de recherche du Centre hospitalier de l'Université de Montréal
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/05/2015		Yes	No