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Evaluating a self-guided internet-based pain course for individuals with fibromyalgia and anxiety and/or depression

Submission date
30/03/2014

Recruitment status
No longer recruiting

Registration date
15/04/2014

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Most people with fibromyalgia (a long-term condition that causes body pain) have depression and/or anxiety. If untreated, this can affect their health significantly as many fail to seek profession help. This makes it necessary for the development of more accessible treatment methods. There are a lot of studies on internet-based courses in various fields such as mood disorders, anxiety disorders, health conditions, and long-term pain. However, to date, research has not investigated the use of a self-guided internet cognitive behaviour therapy based course for people with fibromyalgia. The Pain Course for Fibromyalgia is based on the Pain Course developed by the eCentreClinic part of the Centre for Emotional Health at Macquarie University in Sydney Australia, which is comprised of five lessons based on cognitive behavioural therapy model. The focus of this study is to find out how effective the Pain Course is for people with fybromyalgia.

Who can participate?
Adults living in Canada who have been diagnosed with Fibromyalgia and are experiencing at least mild symptoms of anxiety and/or depression.

What does the study involve?
All interested participants will participate in an online application and a telephone screening to find out if the Pain Course for Fibromyalgia matches their needs. The screening is a two-part process, online application followed by a telephone screening, that takes about 40 minutes in total. Participants will be asked about their symptoms of pain, anxiety, depression, other mental health history as well as fibromyalgia diagnosis and treatment. Following the screening, eligible participants are randomly allocated to receive the Pain Course for Fibromyalgia immediately or are placed on an eight-week waitlist. Pain Course for Fibromyalgia consists of 5 self-led lessons containing cognitive behaviour therapy (CBT) materials and additional treatment resources that are accessed online. All participants are asked to complete questionnaires at the start of the program, immediately following completion of the program or at 8 weeks, and 1 month

following completion of the program. The waitlist group are asked to complete questionnaires at the beginning of the eight weeks and then at the end of the 8-weeks at which time they will be offered the Pain the Course for Fibromyalgia.

What are the possible benefits and risks of participating?
The potential benefits include: you do not need to schedule an appointment to engage in an online course, you avoid having to visit an office if things like transportation, travel, stigma, medical conditions/symptoms or your own availability are a concern, you can access the online course at a time and location that is convenient to you, you can save and print off program materials for your own review, you can e-mail the coordinator at any time through our secure web application, and this service is provided free of charge. In addition, participating in the Pain Course for Fibromyalgia may help participants manage symptoms of anxiety and depression more effectively. Symptoms of pain, anxiety, and depression may also decrease as a result of learning more helpful coping strategies. The potential risks or challenges include: self-guided online course may require more self-motivation than other forms of therapy, there is a risk for breaches of confidentiality, and there is potential for technology failures that may result in messages not being received by either the client or the coordinator. As with any form of psychological treatment, there is a small risk of temporary discomfort and/or slight increases in negative emotions due to increased focus on and awareness of these emotions. However, with the continuation of Pain Course for Fibromyalgia, these emotions typically lessen and improve as a result of treatment.

Where is the study run from?
The study is run from the Online Therapy Unit for Service, Education, and Research, University of Regina, Regina, Canada.

When is the study starting and how long is it expected to run for?
Recruitment for the study began in January 2014 and is expected to be completed in December 2014.

Who is funding the study?
Canadian Institutes of Health Research, Canada.

Who is the main contact?
Ms Lindsay Friesen, Lindsay.Friesen@uregina.ca
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Study website
https:// www.onlinetherapyuser.ca/fibromyalgia/welcome/

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
A randomized controlled trial of a self-guided internet cognitive behaviour therapy-based course for individuals with fibromyalgia and anxiety and/or depression

Study objectives
1. It is predicted that participants who receive the Pain Course for Fibromyalgia will demonstrate significant improvement from pre- to post-treatment on (a) primary outcome measures of fibromyalgia, pain, anxiety, and depression relative to a standard care group, and (b) secondary outcome measures of quality of life, fear of movement, and fatigue.

2. It is predicted that patients will report a high level of satisfaction with the program.

3. It is expected that that improvements in depression and pain severity will most strongly mediate improvements in Fibromyalgia symptom severity during the Pain Course for Fibromyalgia, in comparison to improvements in anxiety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Regina; 08/01/2014; ref.: 31S1314

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet.

Health condition(s) or problem(s) studied
Fibromyalgia, Major Depressive Disorder, Generalized Anxiety Disorder, Panic Disorder, Social Phobia

Interventions
An online program, Research Randomized (http://www.randomizer.org/), will be used to generate a list of random numbers. Participants will be assigned to the treatment group using a 1:1 ratio using simple randomization (i.e., n = 30 Pain Course for Fibromyalgia; n =30 waitlist control). To prevent selection bias, participants group assignment will be given by a graduate student, who is not involved in this study, to both the participant and study staff only after the completion of the full assessment.

1. Treatment group: Self-Guided Internet Cognitive Behaviour Therapy Based Course.
The intervention is titled Pain Course for Fibromyalgia, which is a self-guided Internet course designed to treat symptoms of pain, anxiety, and depression among adults diagnosed with Fibromyalgia. The program consists of five self-led lessons containing cognitive behaviour therapy materials that are accessed online. The lessons include information about the symptoms of pain, anxiety, and depression, strategies for identifying and changing unhelpful thoughts, strategies for increasing activity, relaxation techniques, and additional coping strategies. Each lesson also includes a Do It Yourself Guide which breaks down central concepts and offers additional practice activities. Participants can access several additional resources outlining topics such as pain treatments, assertiveness, communication skills, sleep, problem solving, and basic information on Fibromyalgia. Participants also receive access to educational stories outlining the experiences of two individuals with chronic pain experiencing pain, anxiety, and depression. During the Pain Course for Fibromyalgia, on a weekly basis participants will receive notification emails to their email address. These emails provide brief but important reminders from the unit about the Lessons that are available each week. In addition, participants will receive weekly messages on the secure message system to provide helpful tips about the Lesson they are working on. Participants will also be briefly contacted via telephone (10-15 minutes) by the coordinator on a weekly basis, to answer any questions you may have about the course and provide participant with encouragement. Participants will also be contacted one month after completing the course to be asked to complete follow-up symptom measures.

2. Control: The control condition in this study will continue to receive the medical interventions used prior to entering the study.

There will be a one month follow-up for the treatment group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Revised Fibromyalgia Impact Questionnaire
2. Brief Pain Inventory
3. Patient Health Questionnaire- 9 Item
4. Generalized Anxiety Disorder 7 Item
These will be administered at baseline, weekly, post-treatment, 1- and 3-month follow-up.

Secondary outcome measures
1. Hopital Anxiety and Depression Scale measured at baseline, post-treatment and at 3-month follow up
2. Pain Self-Efficacy Questionnaire measured at baseline, post-treatment and at 3-month follow up
3. Pain Responses Self-Statements at baseline, post-treatment
4. Visual Analogue Scale for Pain at baseline, weekly, post-treatment
5. Fatigue Symptom Inventory at baseline, post-treatment
6. TAMPA Scale of Kinesiophobia at baseline, post-treatment
7. Medical Outcomes Study Short Form at baseline, post-treatment and at 3-month follow up
8. Treatment Satisfaction Questionnaire measured post-treatment
9. Client Feedback Open-Ended Questions measured post-treatment

Overall study start date
08/01/2014

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Resident of Canada
2. Aged 18 years or older, either sex
3. Currently experiencing clinically significant symptoms of Fibromyalgia, depression, anxiety, social phobia, and/or panic
4. Has regular access to a computer, Internet, and printer
5. Comfortable using the Internet

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60 (30 per condition)

Total final enrolment
60

Key exclusion criteria
1. Not a resident of Canada
2. Less than 18 years of age
3. Has no regular access to a computer, Internet, and use of printer
4. Currently receiving psychotherapeutic treatment for pain, anxiety, or depression elsewhere or in some other form
5. Started a new psychotropic medication within the past month or had a change in dosage within the past month
6. Self-reported current problems with alcohol use or substance use
7. Self-reported current problems with psychotic disorder or bipolar disorder, or severe symptoms of depression, including frequent suicidal ideation

Date of first enrolment
08/01/2014

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Canada

Study participating centre
Department of Psychology
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Canada
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Sponsor information

Organisation
University of Regina (Canada)

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Sponsor type
University/education

ROR
https://ror.org/03dzc0485

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (Canada) Regional Partnership Doctoral Award; Ref. GSD - 228035

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		01/04/2017	10/05/2021	Yes	No