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Evaluating the effectiveness of an internet-delivered cognitive behavioural pain course

Submission date
12/01/2016

Recruitment status
No longer recruiting

Registration date
19/01/2016

Overall study status
Completed

Last Edited
16/02/2023

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
Chronic pain is a condition usually defined as any pain lasting for at least 12 weeks. It is very common in Canada, affecting approximately 1 in 5 people. Previous studies have shown that cognitive behavioural therapy (a type of talking therapy designed to help people to change behaviour) can help to reduce the severity of pain and improve general quality of life, however access to this type of treatment is limited. This could be due to a shortage of healthcare providers, difficulty attending appointments due to mobility problems, time constraints and location, or a general negative attitude towards therapy. Therapist-assisted Transdiagnostic Internet-delivered Cognitive Behaviour Therapy (T-ICBT) is a promising approach for overcoming these barriers and improving access for patients. T-ICBT involves patients viewing cognitive behavioural therapy (CBT) materials over the Internet, while receiving support and assistance from a guide. These materials are transdiagnostic, meaning that they cover a range of different problems, such as anxiety and depression, and so can help teach coping skills that are relevant to several different disorders. T-ICBT has now been offered in Saskatchewan by a team specializing in generalized anxiety, depression, and panic disorder, however T-ICBT for the treatment of chronic pain among Saskatchewan residents has yet to be evaluated. The aim of this study is to evaluate the eCentreClinic's (internet service) Pain Course (T-ICBT) among residents of Saskatchewan, Canada.

Who can participate?
Adults living in the province of Saskatchewan who have pain lasting three months or longer that has been assessed by a doctor.

What does the study involve?
All interested participants take part in online screening to determine if T-ICBT matches their needs. Screening takes about 15 to 30 minutes and asks questions about current symptoms and other mental health history. Following the screening, eligible participants receive access to T-ICBT immediately, receiving an 8 week T-ICBT program for chronic pain. The program includes education, different types of coping strategies, as well as information about how to prevent relapse (return to ill health). Participants complete questionnaires at the start of the study, before each lesson of the program, once they have completed the program, and 3 months after completing the program, in order to assess pain levels as well as anxiety and depressive

symptoms. As part of the battery of questionnaires administered after the completion of the program, participants are also asked to rate the program content, the overall service, and their satisfaction with the program.

What are the possible benefits and risks of participating?
Participants could benefit from participating in the Pain Course because it can be completed at any time and location as it is Onternet-based and it may help them to better manage their pain. Participants are able to email their guide at any time at no cost, which may help participants to feel more comfortable disclosing information. Potential risks or challenges of participating difficulty with assessment when visual cues are not present, potential misinterpretation of telephone conversations between the participant and their guide, potential for breaches of confidentiality and for technology failures that may result in messages not being received. 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.

Where is the study run from?
The trial takes place online, and is run from the Online Therapy Unit for Service, Education, and Research, University of Regina (Canada).

When is the study starting and how long is it expected to run for?
June 2015 to September 2020 (updated 06/08/2020, previously: June 2017)

Who is funding the study?
1. Canadian Institutes of Health Research (Canada)
2. Health Research Foundation (Canada)

Who is the main contact?
Dr Heather Hadjistavropoulos
hadjista@uregina.ca

Contact information

Type(s)
Scientific

Contact name
Dr Heather Hadjistavropoulos

Contact details
Department of Psychology
University of Regina
3737 Wascana Parkway
Regina
Canada
S4S 0A2
+1 (0)306 585 5133
hadjista@uregina.ca

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluating the pain course in Canada: A feasibility trial of a guided internet-delivered cognitive behaviour therapy program for managing emotional wellbeing among participants with chronic pain

Study objectives
Participants who receive the Transdiagnostic-Internet-delivered Cognitive Behaviour Therapy (T-ICBT) Pain Course will demonstrate significant improvement from pre- to post-treatment on symptom outcome measures, with moderate to large, significant, and clinically significant reductions in relevant symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Regina Research Ethics Board, ref: REB#2015-053

Study design
Single-group open non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

1. Pain
2. Depression
3. Anxiety

Interventions

All participants receive the transdiagnostic Internet-based CBT, a T-ICBT program designed to treat symptoms of anxiety and depression among adults who have difficulty coping with chronic pain. The program consists of five self-led lessons containing CBT materials that are accessed over the Internet. The lessons include information about the symptoms of anxiety and depression, strategies for identifying and changing unhelpful thoughts, strategies for increasing activity, relaxation techniques, and additional coping strategies relevant to chronic pain management. 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 assertiveness, communication skills, sleep, and problem solving. Participants receive support and assistance from a guide who contacts clients on a weekly basis via telephone to provide general support, encouragement, and to answer questions regarding application of the concepts and skills learned. Participants also receive automated emails to remind them about the Course and direct attention to the content.

Participants who complete the Pain Course will be contacted three months after completing the program to be asked to complete follow-up measures at 3 months.

Intervention Type

Behavioural

Primary outcome measure

1. Depressive symptoms are measured using the Patient Health Questionnaire- 9 Item (PHQ-9) at baseline, immediately following completion of the program (8 weeks), and 3 months
2. Symptoms of generalized anxiety are measured using the Generalized Anxiety Disorder -7 Item (GAD-7) at baseline, immediately following completion of the program (8 weeks), and 3 months
3. Disability associated with chronic pain is measured using the Roland Morris Disability Questionnaire (RMDQ) at baseline, immediately following completion of the program (8 weeks), and 3 months

Secondary outcome measures

Current secondary outcome measures as of 26/11/2020:

1. Pain related disability and interference is measured using the Brief Pain Inventory (BPI) at baseline, immediately following completion of the program (8 weeks), and 3 months
2. Pain self-efficacy is measured using the Pain Self-efficacy Questionnaire (PSEQ) at baseline, immediately following completion of the program (8 weeks), and 3 months
3. Fears of movement and re-injury are measured using theTAMPA Scale of Kinesiophobia (TSK) at baseline, immediately following completion of the program (8 weeks), and 3 months
4. Chronic Pain Acceptance Questionnaire CPAQ-8 at baseline, immediately following completion of the program (8 weeks), and 3 months
5. Pain Medication is determined using an open-ended question which asks participants to list the depression, anxiety, or pain medication that they are currently taking at baseline, immediately following completion of the program (8 weeks), and 3 months
6. Health Service Utilization is determined using open-ended questions which ask participants to

list the total number of visits to a variety of health professionals because of symptoms of anxiety, depression, or pain at baseline, immediately following completion of the program (8 weeks), and 3 months

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Previous secondary outcome measures:

1. Pain related disability and interference is measured using the Brief Pain Inventory (BPI) at baseline, immediately following completion of the program (8 weeks), and 3 months
2. Pain self-efficacy is measured using the Pain Self-efficacy Questionnaire (PSEQ) at baseline, immediately following completion of the program (8 weeks), and 3 months
3. Fears of movement and re-injury are measured using theTAMPA Scale of Kinesiophobia (TSK) at baseline, immediately following completion of the program (8 weeks), and 3 months
4. Catastrophic pain-related cognitions are measured using the Pain Responses Self-Statements (PRSS) at baseline, immediately following completion of the program (8 weeks), and 3 months
5. Pain Medication is determined using an open-ended question which asks participants to list the depression, anxiety, or pain medication that they are currently taking at baseline, immediately following completion of the program (8 weeks), and 3 months
6. Health Service Utilization is determined using open-ended questions which ask participants to list the total number of visits to a variety of health professionals because of symptoms of anxiety, depression, or pain at baseline, immediately following completion of the program (8 weeks), and 3 months

Overall study start date
15/06/2015

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Resident of Saskatchewan
2. Aged 18 years or older
3. Currently experiencing pain for at least the past 3 months
4. Has had pain assessed by a physician or specialist within last 3 months
5. Experiencing symptoms of depression and/or anxiety
6. Has access to a computer and the Internet
7. Has an interest in the Pain Course

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
75

Total final enrolment
293

Key exclusion criteria
1. Not a resident of Saskatchewan
2. Less than 18 years of age
3. Has no regular access to a computer, Internet, and use of printer
4. Is unwilling to have their physician, a medical clinic, or an emergency hospital be notified of their participation in the program
5. High current risk of suicide or attempt in past year
6. Past or present diagnosis of schizophrenia or psychotic disorder
7. Alcohol or drug problem that requires primary treatment
8. Hospitalization for mental health problem in past year
9. Does not complete online or telephone screening
10. Does not consent to treatment or complete pre-treatment questionnaires

Date of first enrolment
01/07/2015

Date of final enrolment
30/01/2017

Locations

Countries of recruitment
Canada

Study participating centre
Online Therapy Unit for Service
Education, and Research
University of Regina
Regina
Canada
S4S 0A2

Sponsor information

Organisation
University of Regina

Sponsor details
c/o Heather Hadjistavropoulos
Department of Psychology
3737 Wascana Parkway
Regina
Canada
S4S 0A2
+1 (0)306 585 5133
hadjista@uregina.ca

Sponsor type
University/education

ROR
https://ror.org/03dzc0485

Funder(s)

Funder type
Government

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, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Health Research Foundation

Alternative Name(s)
Fondation pour la Recherche en Santé, HRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Results and Publications

Publication and dissemination plan
Study information may be used to prepare symposia to be presented at future research conferences. The primary results of this study will be used to prepare a manuscript, which will be submitted for publication in a peer-reviewed journal.

Intention to publish date
01/07/2021

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/09/2021	19/10/2021	Yes	No
Results article		21/03/2018	16/02/2023	Yes	No