ISRCTN11292570 https://doi.org/10.1186/ISRCTN11292570

The Pain Course: Examining the effectiveness of an online chronic pain management programme, in adults with chronic pain, living in Ireland

Submission date
30/10/2017

Recruitment status
No longer recruiting

Registration date
24/01/2018

Overall study status
Completed

Last Edited
10/06/2020

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Lots of research shows that large numbers of people have pain that lasts longer than three months. Treatments such as drugs or surgery do not provide relief for this chronic pain condition. For many of the people concerned, the inability to find a cure for the pain can lead to disability, depression and anxiety. Psychological therapies such as cognitive behavioural therapy (a type of talking therapy), can help people to cope with their disability and distress despite continuing pain. These pain management treatments are mainly delivered face-to-face but many people with chronic pain cannot obtain them because of the scarcity of treatment centres. People don't always live close to a treatment centre and sometimes the cost and discomfort of such a journey prevents them from availing of these treatments. More recently, psychological therapies have been developed for delivery over the internet. This allows people to receive treatment in their own home. This research examines how well an online treatment, called the Pain Course, works for a group of people with chronic pain, who live in Ireland. The Course was developed at, and is managed from Macquarie University, in Sydney, Australia. It aims to provide information and teach practical skills to help manage chronic pain, low mood and anxiety. Research shows that having good information about pain and how to manage it can make a difference in how much pain affects peoples' lives. Results from Australia found that most people who completed the Pain Course showed improvements in their pain symptoms and levels of disability. A majority of people also reported improvements in their emotional wellbeing. The aim of this study is to apply the research to an Irish setting.

Who can participate?
Adults aged 18 and older who have chronic pain for at least six months.

What does the study involve?
Participants are allocated to one of two groups. Those in the first group have immediate access to the Pain Course. Those in the second group receive treatment as usual and join a waiting list, and obtain access to the Course after the Treatment Group complete the course. The pain

course includes online lessons over eight weeks, homework with each lessons, case studies based on previous participation, additional resources and weekly contact with a clinician. Participants are followed up with questionnaires before, during and after the course to monitor their symptoms and safety.

What are the possible benefits and risks of participating?
Benefits to the participants include access to a free online psychological CBT programme and useful information on chronic pain. It is expected that participants will experience improvements in coping with their pain and in feelings of wellbeing. By using techniques taught in this programme, it is hoped that participants will find it easier to manage their symptoms.

Where is the study run from?
The study is administered from the Centre for Pain Research, NUI Galway (Ireland) and the eCentre Clinic, Macquarie University (Australia).

When is the study starting and how long is it expected to run for?
November 2016 to May 2020

Who is funding the study?
NUI Galway (Ireland)

Who is the main contact?
1. Gary McKenna
2. Ms Catherine Navin (Public)
3. Professor Brian McGuire (Scientific)

Contact information

Type(s)
Public

Contact name
Ms Catherine Navin

Contact details
Centre for Pain Research
School of Psychology
Arts Millenium Building Extension
NUI Galway
Galway
Ireland
N/A

Type(s)
Scientific

Contact name
Prof Brian McGuire

ORCID ID
http://orcid.org/0000-0002-3540-6639

Contact details
Centre for Pain Research
School of Psychology
Arts Millenium Building Extension
NUI Galway
Galway
Ireland
N/A

Type(s)
Scientific

Contact name
Dr Blake F. Dear

Contact details
Department of Psychology
Macquarie University
New South Wales
Sydney
Australia
2109

Type(s)
Scientific

Contact name
Mr Gary McKenna

Contact details
Clinical Psychology Dept.
National University of Ireland
Galway
Ireland
N/A
+353 (0)86 3242357
g.mckenna5@nuigalway.ie

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized controlled trial (RCT) of the Pain Course, an internet-based chronic pain management programme, in adults with chronic pain, living in Ireland

Study objectives
Individuals in the intervention group will report significant improvements on measures of disability, depression, anxiety, and pain severity relative to the control group, together with a high level of satisfaction with the Course.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NUI Galway Research Ethic Committee, 20/03/2017, ref: 17-March-27
2. Macquarie University HREC, 14/07/2017, ref: 5201700731

Study design
Randomised controlled cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

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

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

Interventions
This study involves a collaboration between researchers at NUI Galway and a research team at the eCentreClinic at MacQuarie University, Sydney, who developed the Pain Course. The programme comprises a secure web platform, assessment procedures, and treatment content, and is maintained at the eCentreClinic.

Intervention:
The Pain Course comprises:
1. Five online lessons provided over 8 weeks
2. A homework summary with assignments for each lesson

3. Additional resources which deal with topics and skills that are potentially relevant for the participants, such as managing sleep, problem solving, and assertive communication
4. Case Studies based on previous participants
5. Weekly contact with a clinician via email or telephone

Individuals who are selected for the trial are randomly allocated to receive the Pain Course or to a treatment-as-usual waitlist control condition, who receive the course after the Active Treatment Group has finished. The randomisation process is carried out through the generation of a list of random numbers, using an independent website, www.random.org, corresponding to the two groups.

All data is collected online via the eCentreClinic secure software platform. Participants are asked to complete questionnaires prior to starting the Course (pre-treatment), nine weeks after starting the Course, and three months post-intervention.

Intervention Type
Behavioural

Primary outcome measure
1. Disability associated with chronic pain is measured using the Roland Morris Disability Questionnaire (RMDQ) at baseline, post-intervention (week 9), 3 months post-intervention and 2-year follow-up

Updated 27/03/2020 to add 2-year follow-up

Secondary outcome measures
1. Symptoms and severity of depression is measured using the Patient Health Questionnaire – 9 Item (PHQ-9) at baseline, weekly, post-intervention (week 9), 3 months post-intervention and 2-year follow-up
2. Symptoms of anxiety is measured using the Generalized Anxiety Disorder Scale – 7 Item (GAD-7) at baseline, post-intervention (week 9), 3 months post-intervention and 2-year follow-up
3. Duration, severity and location of a person's pain as well as level of interference associated with pain is measured using the Wisconsin Brief Pain Questionnaire (WBPQ) at baseline, post-intervention (week 9), 3 months post-intervention and 2-year follow-up
4. A person's beliefs about their ability to undertake a number of daily tasks with pain is measured using the Pain Self-Efficacy Questionnaire (PSEQ) at baseline, post-intervention (week 9), 3 months post-intervention and 2-year follow-up
5. A person's fear of movement and re-injury is measured using the Tampa Scale of Kinesiophobia (TSK) at baseline, post-intervention (week 9), 3 months post-intervention and 2-year follow-up
6. A person's acceptance in the context of chronic pain is measured using the Chronic Pain Acceptance Questionnaire (CPAC) at baseline, post-intervention (week 9), 3 months post-intervention and 2-year follow-up
7. Pain severity and impact on health-related quality of life (HRQOL) domains is measured using the Pain Impact Questionnaire (PIQ-6) at baseline, post-intervention (week 9), 3 months post-intervention and 2-year follow-up
8. Treatment satisfaction and acceptability is measured using Treatment Satisfaction Questionnaire (TSQ) at post-intervention (week 9), and 2-year follow-up
9. Post Traumatic Stress Disorder (PTSD) and Complex PTSD measured using Complex Trauma Inventory (CTI) at 2-year follow-up (added 27/03/2020)

Updated 27/03/2020 to add 2-year follow-up

Overall study start date
24/11/2016

Completion date
14/05/2020

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. The presence of chronic pain for at least 6 months duration
3. Resident of Ireland
5. Sufficient computer and internet literacy/have internet access
6. Not currently experiencing an unmanaged psychotic illness or severe symptoms of depression (indicated by a total score > 22, or a score > 2 on item 9 of the PHQ-9)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 140 participants will be recruited with 70 in each group.

Total final enrolment
36

Key exclusion criteria
1. Chronic pain due to malignancy
2. Person unable to engage with the treatment intervention due to insufficient English language

Date of first enrolment
08/08/2017

Date of final enrolment
16/10/2017

Locations

Countries of recruitment
Australia

Ireland

Study participating centre
NUI Galway
Centre for Pain Research
Galway
Ireland
N/A

Study participating centre
Macquarie University
Sydney
Australia
-

Sponsor information

Organisation
NUI Galway

Sponsor details
University Road
Galway
Ireland
N/A

Sponsor type
University/education

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
University/education

Funder Name
NUI Galway

Results and Publications

Publication and dissemination plan
The findings of the trial will be submitted for publication in peer-reviewed journals and will be disseminated through conference presentations.

Intention to publish date
14/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Participant data will be anonymized i.e. each participant will be assigned a specific number. All data will be stored in a password protected Microsoft Excel spreadsheet on a password protected and restricted-access clinical network drive, which is secured.

IPD sharing plan summary
Stored in repository