

Comparing the clinical- and cost-effectiveness of an internet-delivered Acceptance and Commitment Therapy (ACT) intervention with a waiting list control among adults with chronic pain

Submission date 04/02/2014	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 14/02/2014	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 25/06/2020	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Internet-delivered psychological interventions for people with chronic pain may help increase access to evidence-based psychological treatment in the Irish health service. While the use of internet-delivered cognitive behavioural therapy programmes have been consistently shown to have small to moderate effects in the management of chronic pain, there is a lack of research regarding the effectiveness of an internet-delivered Acceptance and Commitment Therapy (ACT) programme among people with chronic pain. The current study will compare the clinical- and cost-effectiveness of an online ACT intervention with a waiting list control group in terms of the management of pain-related functional interference among people with chronic pain.

Who can participate?

People who are aged 18 years or over, living in Ireland, who report the presence of pain for at least three months duration, and have regular access to a computer and to the internet.

What does the study involve?

The people who decide to take part will be randomly assigned to one of two groups. The experimental group will undergo an eight-session internet-delivered ACT programme over an 8-week period. The ACT programme aims to increase a persons' daily functioning and reduce the interfering effect of pain on doing what matters to him/her. The control group will not receive the internet-delivered ACT intervention at this time, but will be offered the chance to participate in the online ACT programme after the 6-month follow-up assessment. All of the participants will be asked to fill out questionnaires (online) before and after the intervention and at a 6-month follow-up.

What are the possible benefits and risks of participating?

Benefits to the participants include access to a free internet-delivered psychological pain

management programme; receiving information relating to the management of chronic pain; a greater understanding of the individual's role in pain management; and training in mindfulness techniques tailored for chronic pain. We do not envisage any adverse effects of this treatment.

Where is the study run from?

This study has been organised by National University of Ireland Galway.

When is the study starting and how long is it expected to run for?

This study is anticipated to start in March 2014 and end in March 2015. Participants will be recruited until September 2014.

Who is funding the study?

Heath Research Board, Dublin (Ireland).

Who is the main contact?

Dr Brian McGuire

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

ICE/2011/19

Study information

Scientific Title

Comparing the clinical- and cost-effectiveness of an internet-delivered Acceptance and Commitment Therapy (ACT) intervention with a waiting list control among adults with chronic pain: study protocol for a randomised controlled trial

Study objectives

1. The people in the ACT treatment group will report significant improvements on measures of pain intensity, physical functioning, emotional functioning and rating of overall improvement,

relative to the waiting list control group

2. The people in the ACT treatment group will report significantly less direct and indirect costs related to their chronic pain relative to the waiting list control group

Ethics approval required

Old ethics approval format

Ethics approval(s)

The National University of Ireland, Galway Research Ethics Committee (REC), 05/04/2012

Primary study design

Interventional

Study design

Single-blind randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

People with chronic pain

Interventions

The participants will be randomly allocated to one of two conditions:

1. ACT internet-delivered psychological intervention

Eight sessions over an 8-week period. Delivered via the interactive online platform Lifeguide, consisting of information, homework assignments, relevant metaphors and mindfulness exercises. The participants will be reminded to complete each session weekly via a prompt to log on dispatched through the online delivery platform. Participants will also receive three phone calls from a member of the research team throughout the duration of the intervention, after their completion of sessions one, three and seven, respectively.

2. Waiting list control condition

Participants will not receive the internet-delivered ACT intervention at that time. The participants will be contacted by the post-doctoral researcher to explain that they have been allocated to the waiting list control group, at which time the participants will be given an opportunity to ask questions regarding the trial. The waiting list control group will be offered the opportunity to use the online ACT intervention after the 6-month follow-up assessment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Pain intensity and pain-related functional interference: Brief Pain Inventory (BPI) - Short form

People in both groups will be assessed pre-treatment, post-treatment (or after 8 weeks for the controls) and there will be a 6-month follow-up for both groups

Key secondary outcome(s)

1. Depression: Beck Depression Inventory (BDI)
2. Pain-related anxiety: Pain Anxiety Symptoms Scale-20 (PASS-20)
3. Patient Global Impression of Change: Patient Global Impression of Change scale (PGIC)
4. Acceptance of chronic pain: Chronic Pain Acceptance Questionnaire-8 (CPAQ-8)
5. Health-related quality of life: EQ-5D
6. Health care usage: Client Service Receipt Inventory (CSRI)

All secondary outcomes will be assessed at pre-intervention, post-intervention (or after 8 weeks for the control group) and at 6-month follow-up.

Completion date

01/03/2015

Eligibility**Key inclusion criteria**

1. Aged 18 years or over
2. The presence of pain for at least three months duration
3. Pain has been assessed by a general practitioner or specialist within the last three months
4. Resident of Ireland
5. Regular access to a computer and to the internet
6. Adequate English language ability

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Not currently undergoing any other form of psychological intervention for chronic pain
2. Not currently experiencing a psychotic illness
3. Not experiencing chronic pain due to malignancy

Date of first enrolment

01/03/2014

Date of final enrolment

01/09/2014

Locations

Countries of recruitment

Ireland

Study participating centre

National University of Ireland, Galway

Galway

Ireland

N/A

Sponsor information

Organisation

National University of Ireland, Galway (Ireland)

ROR

<https://ror.org/03bea9k73>

Funder(s)

Funder type

Government

Funder Name

Heath Research Board, Dublin (Ireland)

Results and Publications

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?
Protocol article	protocol	02/07/2014		Yes	No