

# 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

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<b>Registration date</b> 14/02/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/06/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Dr Brian McGuire

### Contact details

School of Psychology and Centre for Pain Research

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### **Study design**

Single-blind randomised 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 patient information sheet

### **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 measure**

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

### **Secondary outcome measures**

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.

### **Overall study start date**

01/03/2014

### **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

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

126; 63 people per condition

**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)

**Sponsor details**

c/o Dr Brian McGuire

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N/A

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**Sponsor type**

University/education

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

Heath Research Board, Dublin (Ireland)

## 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?
<a href="#">Protocol article</a>	protocol	02/07/2014		Yes	No