ISRCTN22343024 https://doi.org/10.1186/ISRCTN22343024

Investigating if an internet delivered therapy (ACT) can improve the quality of life for adults living with two or more health conditions (multimorbidity)

Submission date
14/06/2016

Recruitment status
No longer recruiting

Registration date
11/01/2017

Overall study status
Completed

Last Edited
17/04/2020

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
The progress of modern medicine has substantially increased life expectancy and improved changes of survival from previously fatal diseases. This has led to a rise in multimorbididy (MM), where a person lives with two or more long term diseases in which neither condition is considered primary. For example, a person may be living with chronic pain (CP) and obesity. MM can greatly affect quality of life as well as being distressing for the patient involved. In terms of MM, CP is one of the most frequent co-morbid chronic conditions for people in this cohort. To assist people living with chronic conditions long term, psychotherapies including Acceptance and Commitment Therapy have been employed by researchers to reduce distress and improve quality of life. ACT is a type of taking therapy that uses acceptance and mindfulness (a way of observing experiences in the present moment, without judgment) strategies, together with commitment and behaviour change strategies, to help a person to deal with difficult situations they may face. The aim of this study is to determine whether an online Acceptance and Commitment Therapy (ACT) programme is effective among people living with multimorbidity, where chronic pain is a feature in Ireland.

Who can participate?
Adults who live in the Republic of Ireland who live with chronic pain and at least one other chronic long-term medical condition will be invited to participate.

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives access to the online therapy immediately and the other group will be part of a waiting list group that will receive access to the therapy at the end of the study. The online therapeutic intervention consists of eight sessions that are designed to run over eight weeks. Each session should last approximately 30-40 minutes. It will be delivered online and will progress at the convenience of participants. The program consists of information, mindfulness exercises, homework assignments and learning relevant metaphors. Throughout the trial, participants receive a

weekly email to remind them to complete their therapy. On three occasions, after session one, three and seven, participants receive a phone call from the researchers, should they have any questions, and to motivate them. These phone calls are structured and are not considered part of the treatment regimen. At the start of the study and again after eight weeks and three months, participants in both groups complete a number of questionnaires designed to measure their quality of life, pain interference and physical and mental wellbeing.

What are the possible benefits and risks of participating?
Participants benefit from having access to a free online psychological ACT programme, receiving useful information on multimorbidity and long-term conditions, and a greater understanding of the individual's role and training in tailored mindfulness techniques. There are no notable risks involved with participating in this study.

Where is the study run from?
Centre for Pain Research, National University of Ireland Galway (Ireland)

When is the study starting and how long is it expected to run for?
March 2018 to July 2019 (updated 04/06/2019, previously: December 2018)

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
Dr Brian Slattery
brian.slattery@nuigalway.ie

Contact information

Type(s)
Public

Contact name
Dr Brian Slattery

Contact details
Centre for Pain Research
National University of Ireland Galway
Galway
Ireland
H91 EV56
+353 91 495832
brian.slattery@nuigalway.ie

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Brian McGuire RLA/2013

Study information

Scientific Title
Comparing the effectiveness of an internet-delivered Acceptance and Commitment Therapy (ACT) intervention with a waiting list control on health related quality of life and pain interference among adults with chronic pain and multimorbidity

Study objectives
Current study hypothesis as of 15/02/2018:
Participants in the ACT treatment group will report significant improvements in health-related quality of life, pain interference, physical functioning, emotional functioning and rating of overall improvement, and reductions in symptom reporting relative to a wait-list control group.

Previous study hypothesis:
People in the ACT treatment group will report significant improvements in health-related quality of life, physical functioning, emotional functioning and rating of overall improvement, and reductions in symptom reporting relative to a wait-list control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the National University of Ireland, Galway, 16/01/2016, ref: 'NUI Galway Research Ethics Committee 16/JAN/01'

Study design
Single-blind randomised wait-list controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Multimorbidity

Interventions
When a participant agrees to take part in the trial they will be randomly assigned to the intervention or waiting list control group using random permuted blocks to ensure groups are balanced. The randomisation process will be performed by a web-based password secured and encrypted data management system designed specifically for the randomisation of participants into clinical trials.

Experimental Group: Participants receive the Acceptance and Commitment Therapy (ACT). This consists of eight sessions over an eight week period and will be hosted on the NUI Galway, Centre for Pain Research Website. The programme will be delivered via an interactive online

platform, and it will consist of information, homework assignments, relevant metaphors and mindfulness exercises. The focus of this treatment protocol is on increasing psychological flexibility by developing acceptance, present-focused awareness and engagement in values-based action. Over the course of the trial, those participants in the experimental group will be prompted to complete each session weekly by a reminder sent to their email via the online ACT platform. As in the Hayes et al. protocol, participants will be contacted by phone three times (i. e., after session one, three, and seven) to motivate participants to continue and to provide them with some contact time with the researchers should they have any questions. The phone calls are structured and are required to maintain participant numbers and avoid participant attrition; the phone calls are not part of the treatment regimen. Adherence to the intervention will be remotely monitored. If a participant wishes to discontinue their involvement they will be withdrawn from the intervention and this will be reported as attrition.

Control Group: Participants in the waitlist control group will be contacted by the study coordinator to explain that they have been allocated to the waiting list control group. The participants will be given the chance to ask any questions they have about the trial at this time. The waitlist control group will be offered the opportunity to use the online ACT intervention following the 3-month follow-up assessment.

Participants in both the intervention and wait-list control groups will complete follow up questionnaires (identical to those administered at pre and post intervention) in order to assess any lasting effects of the intervention.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measures as of 15/02/2018:
Health related quality of life will be measured using the EQ-5D and pain interference will be measured using the Brief Pain Inventory. Both measures will be administered at baseline, post-intervention (week 8) and three months post-intervention.

Previous primary outcome measures:
Health related quality of life will be measured using the SF-36 and will be administered at baseline, post-intervention (week 8) and three months post-intervention.

Key secondary outcome(s))
Current secondary outcome measures as of 15/02/2018:
1. Global improvement with treatment is measured using the Patient Global Impression of Change Scale at baseline, post-intervention (week 8) and three months post-intervention.
2. Psychological inflexibility and experiential avoidance is measured using The Acceptance and Action Questionnaire II at baseline, post-intervention (week 8) and three months post-intervention.
3. Patient illness perceptions in the presence of multimorbidity is measured using The Multimorbidity Illness Perceptions Scale at baseline, post-intervention (week 8) and three months post-intervention.
4. Depression is measured using the Patient Health Questionnaire at baseline, post-intervention (week 8) and three months post-intervention.
5. Anxiety is measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale at baseline,

post-intervention (week 8) and three months post-intervention.
6. Health Care Use is measured using the Client Services Receipt Inventory a baseline, post-intervention (week 8) and three months post-intervention.

Previous secondary outcome measures:
1. Global improvement with treatment is measured using the Patient Global Impression of Change Scale at baseline, post-intervention (week 8) and three months post-intervention
2. Psychological inflexibility and experiential avoidance is measured using The Acceptance and Action Questionnaire II at baseline, post-intervention (week 8) and three months post-intervention
3. Patient illness perceptions in the presence of multimorbidity is measured using The Multimorbidity Illness Perceptions Scale at baseline, post-intervention (week 8) and three months post-intervention
4. Depression is measured using the Patient Health Questionnaire at baseline, post-intervention (week 8) and three months post-intervention
5. Anxiety is measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale at baseline, post-intervention (week 8) and three months post-intervention
7. Pain and the impact of pain on daily life is measured using the Brief Pain Inventory - Short form at baseline, post-intervention (week 8) and three months post-intervention
8. Health Care Use is measured using the Client Services Receipt Inventory a baseline, post-intervention (week 8) and three months post-intervention

Completion date
30/11/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/02/2018:
1. Aged 18 years or over
2. Presence of chronic pain and at least one other chronic conditions reported by the patient as having been diagnosed by a doctor
3. Resident of the Republic of Ireland
4. Access to a computer and the internet
5. Not currently undergoing any form of psychological treatment
6. Sufficiently competent in the English language (as determined by the participant) to complete the various elements of the study
7. Provision of informed consent

Previous inclusion criteria:
1. Aged 18 years or over
2. Presence of two or more chronic conditions reported by the patient as having been diagnosed by a doctor
3. Resident of the Republic of Ireland
4. Access to a computer and the internet
5. Not currently undergoing any form of psychological treatment
6. Sufficiently competent in the English language (as determined by the participant) to complete the various elements of the study
7. Provision of informed consent

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Not fulfilling the inclusion criteria.

Date of first enrolment
15/02/2018

Date of final enrolment
12/07/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Centre for Pain Research
National University of Ireland Galway
Galway
Ireland
H91 EV56

Sponsor information

Organisation
Health Research Board

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Research council

Funder Name
Health Research Board

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/05/2019	17/04/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes