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Online acceptance and commitment therapy for chronic pain

Submission date
15/04/2015

Recruitment status
No longer recruiting

Registration date
15/04/2015

Overall study status
Completed

Last Edited
17/08/2018

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Acceptance and commitment therapy (ACT) is associated with clinically meaningful long-term improvements in function and quality of life among patients with chronic pain. However, much of the research to date on ACT for chronic pain has been done in the tertiary care setting (for example, specialist hospitals or clinics), and research is needed to determine whether ACT can be given to patients in a cost-effective way in a community setting (for example, at a patients home). To address these challenges, this study aims to test a newly developed therapist-assisted online ACT treatment for patients with chronic pain.

Who can participate?
Adults with chronic pain recruited from Guy's and St. Thomas' Pain Management Centre

What does the study involve?
Initially, ten patients are asked to test how easy it is to use the online ACT treatment. Participants are then randomly allocated into one of two groups. Those in group 1 are given access to the online ACT treatment in addition to medical treatment as usual. Those in group 2 are given just treatment as usual. The online ACT treatment is then compared with treatment as usual. All participants complete assessment questionnaires online before they are allocated into one of the two groups and then again at three months and nine months after the start of the study.

What are the possible benefits and risks of participating?
We expect that participation in this research will help improve treatment access and outcomes for people with chronic pain in the future. The study procedures are not expected to have a negative impact on participants' safety and well-being. The risks associated with the study procedures are standard in studies evaluating psychological treatments. To maintain the security of participant data, we will use an encrypted online survey system to collect questionnaire responses.

Where is the study run from?
St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2015 to April 2017

Who is funding the study?
International Association for the Study of Pain (USA)

Who is the main contact?
Dr Whitney Scott

Contact information

Type(s)
Scientific

Contact name
Dr Whitney Scott

Contact details
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Institute of Psychiatry
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18687

Study information

Scientific Title
Testing the feasibility of internet-administered acceptance and commitment therapy for patients with chronic pain: a randomized controlled trial

Study objectives
The online ACT intervention will be feasible according the following criteria:
1. We expect to recruit and retain 35 participants per treatment arm to provide assessment data at the three month follow-up
2.Seventy percent of participants in the online ACT treatment will complete seventy percent of treatment sessions

3.The majority of participants will score in the upper end (i.e., 5 or more) on the self-report items assessing treatment acceptability
4. Less than 10% of data will be missing from participants' assessment data
A secondary objective of the study is to provide a stable estimate of the variance for clinical outcome and theoretically-relevant treatment process measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London (United Kingdom) - Central, 26/01/2015, ref: 14/L0/1936

Study design
Single-centre randomized-controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic non-malignant pain

Interventions
1. Online Acceptance and Commitment Therapy: The therapist-assisted online treatment program is based on principles of Acceptance and Commitment Therapy (ACT) for chronic pain. Patients will receive a standardized treatment package of two face-to-face sessions plus eight online sessions with the online component delivered over five weeks and the total treatment time including about eight weeks. This core package may be augmented with additional exercises by the therapist, depending on each patient's progress. Online therapy sessions consist primarily of videoclips of therapists providing information and guiding patients through experiential exercises (e.g., meditation, values clarification, goal-setting) and metaphors. Following each session, patients will be asked to respond to several questions assessing their experiences in session, which will be sent by email to their therapist for feedback. Patients will have a face-to-face meeting with their therapist before and after the online treatment to establish the therapeutic relationship, set expectations, and review progress. Participants in this condition will also continue to receive medical treatment as usual.
2. Treatment as usual. All patients will receive usual medical care as deemed appropriate by their treating clinicians at the Guy's and St. Thomas' Pain Management Centre.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment and retention rates will be recorded by a researcher.
2. Treatment adherence: Adherence to the online treatment will be determined through a count of the number of sessions for which patients submit post-session email reflections to their therapists and attendance at the two face-to-face sessions. Therapists will record whether patients have submitted these responses and attended the face-to-face sessions (yes/no) following each scheduled session.
3. Treatment acceptability: Immediately following treatment, participants will respond to several questions asking them to rate how satisfied they were with the treatment they received on an 11 point Likert scale ranging from 0 (not at all) to 10 (completely). These items were created specifically for the purpose of the present study.
4. Completeness of data acquisition: Response rates on all questionnaires and the number of missing data points will be identified and recorded by a researcher following the final follow-up assessment.

Secondary outcome measures
The following clinical outcome and treatment process measures will be completed by all participants prior to randomization, and at 3 and 9 month follow-up intervals:
1.Daily Functioning: Brief Pain Inventory--Interference subscale (Cleeland et al., 1994).
2. Depressive Symptoms: Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001)
3. Pain intensity: Current and average pain intensity and pain-related distress will be rated from 0 to 10.
4. Health Care utilization: Participants will report on their number of GP visits, specialist visits, accident and emergency visits, and days hospitalized over the preceding three-month period.
5. The single-item Patient Global Impression of Change rating will be used to examine patients' self-reported overall impressions of change.
6. Treatment process: The short version of the Chronic Pain Acceptance Questionnaire (Fish et al., 2010), the Experiences Questionnaire (Fresco et al., 2007), and the short version of the Committed Action Questionnaire (McCracken et al., 2014) will be used to measure theoretically-relevant processes of psychological flexibility.

Overall study start date
01/09/2014

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. Adults aged 18 years and older
2. Outpatients at St. Thomas' Pain Management Centre
3. Chronic pain non-malignant pain (at least 3 months duration), associated with significant distress and/or disability
4. Medical appropriateness for an online psychological treatment as determined by the referring clinician
5. Access to the Internet for the duration of the study
6. Ability to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90 recruited, 70 retained

Key exclusion criteria
1. History of ACT or traditional CBT for chronic pain
2. Currently receiving another form of psychological treatment
3. Presence of a serious, uncontrolled psychiatric disorder (e.g., schizophrenia, bipolar, etc.) or other impediments to treatment engagement (e.g., neuropsychological impairment)
4. Inability to complete study procedures in English
5. Inability to complete study procedures using a computer

Date of first enrolment
10/04/2015

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St. Thomas' Pain Management Centre
INPUT Pain Management Unit
Gassiot House
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London

Sponsor details
Room 1.8
Hodgkin Building
Guy's Campus
London
England
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SE1 4UL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
International Association for the Study of Pain

Alternative Name(s)
The International Association for the Study of Pain, IASP

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Results and Publications

Publication and dissemination plan

Following completion of the trial, data concerning primary and secondary feasibility outcomes will be analysed and the results will be prepared for submission to a peer-reviewed journal and for presentation at scientific conferences.

Intention to publish date
30/04/2018

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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018		Yes	No