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Is it feasible to run a clinical trial of online acceptance and commitment therapy (ACT) for chronic abdominal pain?

Submission date
12/08/2019

Recruitment status
No longer recruiting

Registration date
29/08/2019

Overall study status
Completed

Last Edited
06/04/2020

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Chronic (long-lasting) abdominal pain (CAP) can greatly affect a person's enjoyment of life and their ability to participate in society. Sometimes CAP can result from a medical condition, but in some people doctors have not been able to find a reason for the pain. CAP is among the most common complaints in GP appointments, and is the most common symptom prompting a hospital outpatient clinic visit. Abdominal pain and discomfort can lead to depression, anxiety, and reduced quality of life, as well as substantial healthcare costs.
Psychological treatments like Cognitive Behavioral Therapy (CBT) have been widely used in CAP-related conditions, and have shown improvement in symptoms and reductions in healthcare costs. However, it is unknown if internet-based CBT helps people with CAP. This study will explore whether it is possible and acceptable to offer a newly developed form of online CBT called Acceptance and Commitment Therapy (ACT) to people with CAP.
The researchers are interested in determining how well they can recruit participants and keep them in the trial, whether participants complete the new treatment as intended, and their satisfaction with the treatment. The researchers are also interested in estimating how well participants who receive ACT are functioning compared to those who receive only CAP education. Results from this study will help us determine whether a larger study to test whether the new treatment works is possible and what is the best design for that study.

Who can participate?
People who have had abdominal pain or discomfort for at least 6 months that has interfered with their daily life and who have moderate symptoms of depression. Participants will be recruited primarily from gastroenterology and dietetics clinics, and the psychological unit of St Mark's Hospital, a specialist bowel hospital in London, UK.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive their usual treatment (TAU) plus CAP education or ACT plus CAP education. The treatment lasts for 5-6 weeks. Participants will complete questionnaires to assess pain, gastrointestinal symptoms, functioning, and mood at the beginning of the study and 3 months later.

The ACT treatment starts with a face-to-face or telephone session with a therapist aimed at fostering the therapeutic alliance, exploring the pain problem and current pain management strategies, explaining the treatment model and setting preliminary goals. The therapist will then email the participant a secure weblink to access their online treatment sessions. Participants receive a package of eight online sessions delivered over 5-6 weeks. Treatment finishes with a final face-to-face or telephone session to review progress, set longer-term goals and plan for barriers.

What are the possible benefits and risks of participating?
Participants will contribute to psychological treatment development in this area and will shape the procedures for a larger trial if it is feasible.
Participants may find some of the self-report questionnaires or online treatment materials upsetting. Participants will be made aware of this in the information sheet, and will be informed that they can choose not to answer certain questionnaires or to complete treatment modules if they do not want to. Participants will be instructed to contact the study team if they are concerned about any distress they may have as a result of completing the study procedures.
It is unknown whether the current treatment is effective. However, the psychological procedures used in the online treatment program are standard in cognitive behavioural treatments for pain management, including online delivery formats, and have been shown to have low risks for patients' safety and well-being in studies in patients with chronic pain in general.

Where is the study run from?
St Mark’s Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2018 to March 2020

Who is funding the study?
The Wolfson Foundation (UK)

Who is the main contact?
Dr Yoram Inspector
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Contact information

Type(s)
Scientific

Contact name
Dr Yoram Inspector

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
248751

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
12102018; IRAS 248751

Study information

Scientific Title
Feasibility randomised controlled trial of online acceptance and commitment therapy (ACT) for chronic abdominal pain

Acronym
ACT4GIPain

Study objectives
The study aims to determine the feasibility of a larger randomised controlled trial testing the efficacy of online Acceptance and Commitment Therapy for chronic abdominal pain. This in turn includes three objectives:
1. To examine the feasibility of the treatment by measuring recruitment and retention rates.
2. To determine whether patients with chronic abdominal pain view internet-based ACT, and the format of delivery as acceptable and credible.
3. To determine whether the methods and procedures in treatment can be delivered with fidelity and integrity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/12/2018, London - Brent Research Ethics Committee (80 London Road, Skipton House, London SE1 6LH; 02071048129; nrescommittee.london-brent@nhs.net), ref: 18/LO/2021
2. Approved 27/12/2018, Health Research Authority (hra.approval@nhs.net), ref: 18/LO/2021

Study design
Open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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 abdominal pain

Interventions
Participants will be randomly allocated (1:1 ratio) to the intervention or treatment-as-usual (TAU) condition. This will be done using computer-generated random numbers (http://www.random.org). Sealed, sequentially numbered, opaque envelopes will be used to conceal the sequence, which will be produced by an independent researcher who has no other involvement in the trial.

Participants in the intervention condition will receive the newly developed online Acceptance and Commitment Therapy (ACT) for chronic abdominal pain plus chronic abdominal pain education, while those in the control condition will receive their usual treatment (TAU) plus chronic abdominal pain education.

The online treatment sessions consist of audios and videos providing brief background and guiding participants through experiential exercises and metaphors. The treatment is therapist-supported. Treatment commences with a face-to-face or telephone session with the therapist aimed at fostering the therapeutic alliance, exploring the pain problem and current pain management strategies, explaining the treatment model and setting preliminary goals. The therapist subsequently emails the participant a secure weblink to access their online treatment sessions. Participants received a standardised package of eight online sessions delivered over 5-6 weeks depending on participants' engagement. Treatment finishes with a final face-to-face or telephone session to review progress, set longer-term goals and plan for barriers.

TAU refers to any treatments that potential participants may be receiving for their abdominal pain condition at the assessment time, and during the study period. Opioids are among the most commonly used treatments in this population.

The abdominal pain education will be delivered through an online survey tool, Qualtrics. The education materials include information about the medical, psychological and social aspects of abdominal pain and chronic pain in general, in form of text and videos. These materials are selected from publicly available medical education resources, and the education materials from a published study of a similar psychological treatment for a gastrointestinal condition with abdominal pain as a primary symptom. These materials were reviewed within the research team. It should take 30 to 60 min to complete the education.

Intervention Type

Behavioural

Primary outcome measure
1. Feasibility, calculated using the following measures:
1.1. Recruitment rate calculated by the researcher at completion of data collection
1.2. Retention rate calculated by the researcher at completion of data collection
1.3. Treatment completion rate calculated by the researcher at completion of data collection
1.4. Appropriateness of measures chosen to examine treatment effect calculated from the proportion of missing questionnaire responses
1.5. Credibility of treatment measured by asking participants to rate (on a 1 to 9 scale) in a treatment evaluation questionnaire how logical the therapy seems to them, how successful they think the treatment will be in improving their functioning, and how confident they are in recommending this treatment
The treatment will be considered feasible if 85 participants are recruited and 60 retained at follow-up, a treatment completion rate of 70% is achieved, a rate of <10% missing questionnaire data is achieved, and the majority of the participants in the treatment arm describe the treatment as acceptable.

Secondary outcome measures
1. Pain intensity assessed using 0-10 numerical ratings in a questionnaire at baseline and 12 weeks
2. Patient-reported gastrointestinal symptoms assessed using the Gastrointestinal Symptom Rating Scale (GSRS) at baseline and 12 weeks
3. Patient's belief of efficacy of treatment assessed using the Patients' Impression of Change (PIC) at 12 weeks
4. Depression assessed using the Patient Health Questionnaire (PHQ-9) at baseline and 12 weeks
5. Gastrointestinal symptom-specific anxiety assessed using the Visceral Sensitivity Index (VSI) at baseline and 12 weeks
6. Severity of pain and level of interference of pain in daily life assessed using the Brief Pain Inventory (BPI) at baseline and 12 weeks
7. Functional impairment assessed using the Work and Social Adjustment Scale (WSAS) at baseline and 12 weeks

Overall study start date
14/05/2018

Completion date
31/07/2020

Eligibility

Key inclusion criteria
1. Outpatient aged at least 18 years
2. Presence of continuous or intermittent abdominal pain or discomfort for the last 6 months or more
3. Has reported interference of pain with daily activities over the past 6 months of >4 on scale ranging from 0 (no interference) to 10 (unable to carry out any activities)
4. Has reported at least moderate symptoms of depression in the past 2 weeks, as indicated by a score of >10 on the PHQ-9
5. Willing and able to take part

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
86

Key exclusion criteria
1. Unable to participate due to limits in communicating in English
2. Conditions including:
2.1. Severe depression (as indicated by a PHQ-9 score of >23)
2.2. Suicidal ideation
2.3. Psychiatric disorders (e.g. schizophrenia, bipolar disorder, post-traumatic stress disorder, psychosis, manic episode, and anorexia)
2.4. Cognitive impairment
3. Currently receiving another form of regular psychotherapy weekly

Date of first enrolment
29/08/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London North West University Healthcare NHS Trust
Level 7 Maternity Block
Northwick Park Hospital
Watford Road
Harrow
London
United Kingdom
HA1 3UJ

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Trust Offices
Guy's Hospital
Great Maze Pond
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SE1 9RT

Sponsor information

Organisation
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Level 7 Maternity Block
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Sponsor type
Charity

Website
https://www.lnwh.nhs.uk/

ROR
https://ror.org/04cntmc13

Funder(s)

Funder type
Charity

Funder Name
Wolfson Foundation

Alternative Name(s)

The Wolfson Foundation, wolfsonfdn

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of the study will be submitted for a poster/oral presentation at an international conference and for publication in a peer-reviewed journal.

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No