

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

<b>Submission date</b> 12/08/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/08/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/04/2020	<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

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

yoram.inspector@nhs.net

## Contact information

### Type(s)

Scientific

### Contact name

Dr Yoram Inspector

### Contact details

St Mark's Hospital

London North West University NHS Healthcare Trust

Watford Road

Harrow

London

United Kingdom

HA1 3UJ

+44 02088695936  
yoram.inspector@nhs.net

## **Additional identifiers**

**Integrated Research Application System (IRAS)**  
248751

**Protocol serial number**  
12102018

## **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

### **Study type(s)**

Treatment

### **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(s)**

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.

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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**

United Kingdom

England

**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  
London  
United Kingdom  
SE1 9RT

## **Sponsor information**

**Organisation**

London North West University Healthcare NHS Trust

**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

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No