ISRCTN49827391 https://doi.org/10.1186/ISRCTN49827391

Contextual Cognitive-Behavioural Therapy (CBT) for the Self-Management of Chronic Pain in the Community

Submission date 29/09/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2011	**Overall study status** Completed	
Last Edited 21/07/2015	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
The aim of the research is to see whether a treatment for the management of chronic pain which currently takes place in an intensive hospital-based program could be helpful for patients in the community. The treatment is a psychological therapy and the sessions would help you to gain a more careful understanding of experiences related to pain and the actions taken in relation to these.

Who can participate?
You can take part if you are over 18 and have had pain for more than 3 months.

What does the study involve?
To take part in the research we will ask you to complete some forms and questionnaires about your pain and health. You will then either be put into the group that takes part in four, four hour treatment sessions over two weeks, or the group that is asked to continue with their current treatment as usual. This will be done randomly. You will also be asked to complete the questionnaires a further two times.

What are the possible benefits and risks of participating?
If you are placed in the 'treatment as usual' group you are unlikely to experience any benefit to your health by taking part. However, you will be helping us understand more about chronic pain which may help us develop ways to help manage it. If you are placed in the psychological therapy group we do not know whether you will experience any benefit as this treatment has not been tested under these circumstances before. However, it is beneficial for the average person with chronic pain. There are no known risks in taking part in this research.

Where is the study run from?
This research is run by the Royal National Hospital for Rheumatic Diseases, Bath, and the Centre for Pain Research, University of Bath. If you are invited to take part in treatment sessions this will be at a GP surgery near where you live at set times and dates.

When is the study starting and how long is it expected to run for?
The study is starting in November 2011 and running until September 2012. We will be recruiting participants from different area at different times. Overall, we will be recruiting participants until March 2012.

Who is funding the study?
The study is funded by a National Institute for Health Research (NIHR) 'Research for Patient Benefit' grant.

Who is the main contact?
Dr Charlotte Boichat
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10877

Study information

Scientific Title
Contextual Cognitive-Behavioural Therapy (CBT) for the Self-Management of Chronic Pain in the Community: A Feasibility Study: Phase 2

Study objectives

The proposed study is phase 2 of a study. Phase 1 aimed to develop a psychologically-based treatment for chronic pain called Contextual Cognitive Behavioural Therapy for delivery in community settings. The aim of this second phase is to conduct a pilot and feasibility trial of this treatment which has been developed through phase 1, with patients with chronic pain in primary care to determine whether further study is likely to be useful and to guide the design of this further research. This type of treatment is usually delivered at tertiary care level and so the research question being addressed here is whether this treatment can be translated for use in the community and whether it is effective at this level. Participants will be randomised to either the treatment (approximately 16 hours of treatment total) or a treatment as usual condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/SW/0010

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Charlotte Boichat [C.S.Boichat@bath.ac.uk] to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Contextual CBT: Contextual Cognitive Behavioural Therapy for chronic pain focuses on undermining core processes of suffering and disability, including avoidance, preoccupation with the past or future, verbally-based behavioural rigidity, and failures of values-based action.

Intervention Type
Behavioural

Primary outcome measure
Treatment evaluation: evaluated using measurement of recruitment rates, qualitative interview and a questionnaire to measure acceptability and credibility for patients. Timepoint(s): After treatment (or equivalent for control group)

Secondary outcome measures
1. Depression (PHQ-9); Timepoint(s): Before randomisation, after treatment (or equivalent for control group), and three months later
2. Health Survey (SF-36); Timepoint(s): Before randomisation, after treatment (or equivalent for control group), and three months later
3. Healthcare and medication use; Timepoint(s): Before randomisation, after treatment (or equivalent for control group), and three months later
4. Modified Patient Global Impression of Change Scale (PGIC); Timepoint(s): After treatment (or equivalent for control group), and three months later
5. Pain intensity; Timepoint(s): Before randomisation, after treatment (or equivalent for control group), and three months later
6. Quality of life (EuroQol EQ-5D); Timepoint(s): Before randomisation, after treatment (or equivalent for control group), and three months later
7. Roland Morris Disability Questionnaire (RMDQ); Timepoint(s): Before randomisation, after treatment (or equivalent for control group), and three months later
8. The Acceptance and Action Questionnaire - II (AAQ - II); Timepoint(s): Before randomisation, after treatment (or equivalent for control group), and three months later
9. The Chronic PAin Acceptance Questionnaire (CPAQ); Timepoint(s): Before randomisation, after treatment (or equivalent for control group), and three months later

Overall study start date
03/10/2011

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Living with chronic pain every day or most days for three months or more
2. Having sought treatment for pain from the general practitioner (GP) in the past six months
3. Continuing analgesic use
4. Reporting significant interference with daily social or physical activities or reporting significant depression or anxiety related to pain
5. Aged at least 18 years
6. Willingness and ability to take part

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Inability to participate due to limits communicating in English
2. Inability to participate due to conditions such as severe depression, anxiety disorders, psychotic disorders, or personality disorders, or cognitive impairment
3. Presence of a disease condition that requires specialist medical assessment or treatment (such as a newly diagnosed rheumatologic condition and not currently in maintenance treatment), or cancer, or having a medical condition that makes moderate exercise or increasing activity inappropriate

Date of first enrolment
03/10/2011

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Pain Research
Bath
United Kingdom
BA2 7AY

Sponsor information

Organisation
Bath Royal National Hospital for Rheumatic Diseases (UK)

Sponsor details
Bath Royal National Hospital for Rheumatic Diseases
Upper Borough Walls
Bath
England
United Kingdom
BA1 1RL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05va5gy74

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB)

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?
Results article	results	01/11/2013		Yes	No