ISRCTN43733490 https://doi.org/10.1186/ISRCTN43733490

Investigating a psychological intervention for people with long-term lower back pain

Submission date	Recruitment status	[X] Prospectively registered
25/10/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/12/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/06/2015	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Tamar Pincus

Contact details
Royal Holloway, University of London
Egham, Surrey
London
United Kingdom
TW20 0EX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OBI 2010

Study information

Scientific Title

Testing the credibility, feasibility and acceptability of an Optimised Behavioural Intervention for avoidant chronic low back pain patients: pilot study

Acronym
OBI

Study objectives
The aim of the study is to test the acceptability and credibility of an optimal psychological intervention Contextual Cognitive Behavioural Therapy (CCBT) in NHS settings against a known best-practice control (a physiotherapy-led intervention) for people with chronic low back pain (LBP) with associated avoidance of daily activities. The feasibility of implementation will also be assessed to inform the intended follow-on large-scale randomised controlled trial.

A secondary aim is to examine changes in patients' avoidant beliefs and disability when receiving CCBT compared to the best-practice control. This measurement of change in beliefs is an important consideration in the statistical design of the full trial.

Primary objective:
The primary objectives relate to the feasibility of implementing a full-scale randomised controlled trial (RCT). These are:
1. To determine whether CCBT is an acceptable and credible intervention for NHS patients with persistent back pain in comparison to a physiotherapy-led intervention
2. To assess recruitment processes and trial uptake to inform the feasibility of running a full trial
3. To assess the burden of measurement tool completion
4. To gather information about the process of change between the two treatment arms (i.e. is the effect of CCBT in changing avoidant beliefs post-intervention sufficiently promising compared to control to warrant a full trial?)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Phase II multicentre randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Lower back pain

Interventions
Physiotherapy-led treatment (control group):
Chronic low back pain is frequently managed within the physiotherapy departments either through one to one outpatient physiotherapy sessions involving individual advice, exercises, manual therapy and exercise; or group sessions incorporating some form of active exercise or through spine stabilisation training. A number of guidelines, including the recent NICE guidelines (2009), have supported this approach, however no standard treatment system has been defined.

In this study we have taken the pragmatic approach of a class intervention in the form of a "Back to Fitness Class" since these are commonplace in therapy departments across the UK, are supported by the academic literature, and permit a degree of standardisation for the purposes of a randomised controlled trial. We propose to standardise and define the content through standard operating procedures agreed with both recruitment centres and that this content would reflect current practice. We then propose to monitor its delivery through regular observations and assessment.

Currently, the Back to Fitness Class comprises five sessions each lasting two hours, with a maximum of ten patients per class spread out over a period of five weeks. Because classes run several times a week they also offer patients who miss a session the opportunity to re-schedule. Classes will be delivered by a Senior Physiotherapist, and the timing and location of the classes will be in line with each department's routine procedures. The programme of the class will include patient discussion, goal setting and education, stretching and exercises, self management, relaxation, pacing and avoidance of recurrence. This will be spread across the five classes. Whilst patients will be encouraged to attend all classes, this may not be feasible and consequently compliance will be recorded on the basis of attendance and reasons for non-attendance documented, this may include that the patient no longer feels that the classes are required. At the end of the classes the patient will be discharged to the management of their GP.

Contextual Cognitive Behavioural Therapy (CCBT) (intervention group):
Contextual Cognitive Behavioural Therapy (CCBT) is an approach based on a functional contextual theory of human behaviour and a general approach to behavioural treatment called Acceptance and Commitment Therapy (ACT). It seeks to create behaviour change by processes of identifying occasions where behaviour patterns exhibit a quality of psychological inflexibility, and intervening with these occasions to promote psychological flexibility.

Patients randomised to the CCT arm will receive a maximum of eight one-hour sessions with a chartered clinical psychologist specialising in the use CBT methods for treating pain patients. The first session will include initial work on demonstrating an understanding of the patient's problems, building rapport, and clarifying patient's values. The number of subsequent sessions will be determined by agreement between the patient and therapist that patient's goals have been met. Early sessions will focus on "control is the problem" and a letting go of unworkable strategies. Subsequent sessions will alternate between promoting cognitive defusion (a loosening or the dominating influences of thoughts and language), acceptance (willingness to contact negatively evaluated experiential content when this promotes more vital functioning), contact with the present moment (a quality developed by mindfulness methods), and further clarity and direction by values. Goals-based "committed actions" will be promoted regularly, both in session and between sessions, and built into integrated, generalised, and long term patterns of behaviour.

Therapists in the CCBT arm will be trained to competence with an intensive two day experiential workshop, completion of a currently available therapist training workbook under supervision, and supervision of a series of three to five individual cases of chronic pain by one of the research team A 51-item core competency rating form has been devised by the developers of ACT and this will be used in training to track therapist level of developing skill for delivery of CCBT. To maintain faithful treatment delivery throughout the trial weekly supervision will be provided.

Intervention Type
Mixed

Primary outcome measure
Measured at 10 weeks post-registration and 6 months post-registration:
1. An assessment of the acceptability and credibility of CCBT when compared to physiotherapy led intervention
2. An assessment of expectation and satisfaction of the treatment to patients
3. An evaluation of the recruitment rate and feasibility of recruitment process
4. An assessment of the burden associated with the completion of the assessment tools by patients
5. An assessment of the acceptability and credibility of the treatment to therapists
6. An evaluation of process of change between the two treatment arms

Secondary outcome measures
Patient-reported quality of life as measured by a series of different patient completed questionnaires, measured at 10 weeks post-registration and 6 months post-registration.

Overall study start date
01/06/2011

Completion date
01/02/2012

Eligibility

Key inclusion criteria
Patients aged over 18 years (either sex) meeting the following criteria are eligible for trial entry:
1. Suffering from chronic musculoskeletal pain including lower back pain
2. Presenting pain has been present for at least 3 months
3. Suitable for physiotherapy-led treatment
4. Not requiring referral to any other department (e.g. PMP)
5. Classified as "avoidant" - indicated from responses to the Subgroups for Targeted Treatment BACK screening tool (STarT Back), The Photograph Series of Daily Activities - Short Electronic Version (PHODA-SeV) and the Chronic Pain Acceptance Questionnaire (CPAQ) assessment tools

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
92

Key exclusion criteria
1. Actively receiving psychological treatment
2. Presence of sciatica
3. Presence of a progressive disorder such as cancer
4. Pregnancy
5. Insufficient proficiency in English
6. Involved in on-going litigation relating to the pain condition
7. Clinician discretion, where it is felt that treatment would not be appropriate (e.g. following spinal surgery, existing psychiatric condition which would interfere with trial participation)

Date of first enrolment
01/06/2011

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Holloway, University of London
London
United Kingdom
TW20 0EX

Sponsor information

Organisation
Royal Holloway, University of London (UK)

Sponsor details
c/o Dr Hitesh Patel
Orchard Building

Egham, Surrey
London
England
United Kingdom
TW20 0EX

Sponsor type
University/education

Website
http://www.rhul.ac.uk

ROR
https://ror.org/04g2vpn86

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (AR-UK) (UK) (ref: 19401)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Protocol article	protocol	13/06/2013		Yes	No
Results article	results	16/06/2015		Yes	No