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A randomised controlled trial of brief physiotherapy informed by Acceptance and Commitment Therapy for chronic low back pain: the PACT study

Submission date
22/10/2014

Recruitment status
No longer recruiting

Registration date
22/10/2014

Overall study status
Completed

Last Edited
30/07/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic low back pain (CLBP) is very common and causes much pain and disability. It costs the NHS billions of pounds in treatment every year and is the second leading cause of time off work. There are various treatments for CLBP, but the most effective are still only moderately helpful. Most people with CLBP receive physiotherapy, with varying results. Cognitive behaviour therapy (CBT) may offer more long-term help than current treatments because it enables people to self-manage their condition. A new type of CBT, called Acceptance and Commitment Therapy (ACT), has produced particularly good results for chronic pain. However, a shortage of clinical psychologists means that most patients never receive CBT. Physiotherapists can successfully use CBT techniques with extra training, but this is not standard practice and ACT-based physiotherapy treatment has never been tested. A short ACT-based treatment (PACT) has been developed for physiotherapists to deliver and the aim of this study is to compare it with usual physiotherapy care.

Who can participate?
People aged over 18 with CLBP from three hospitals in South East London

What does the study involve?
Participants are randomly allocated into two groups, with one group receiving PACT and the other group ordinary physiotherapy. PACT consists of two hour long sessions and one follow-up phone call, meaning fewer hospital visits for patients and more time during sessions for individualised treatment. It aims to encourage people to focus less on getting rid of their pain and more on moving forward with what is most important in their lives. PACT is compared with usual physiotherapy to see which is most successful at improving people's ability to function and their quality of life and which approach helps them to manage their back pain best in the long term.

What are the possible benefits and risks of participating?
If PACT is effective, it could reduce the considerable burden of CLBP to patients, the NHS and society

Where is the study run from?
Guy's and St Thomas' NHS Foundation Trust Physiotherapy Service and Kings' College Hospital NHS Foundation Trust Physiotherapy Service (UK)

When is the study starting and how long is it expected to run for?
October 2014 to October 2016

Who is funding the study?
NIHR Research for Patient Benefit (UK)

Who is the main contact?
Dr Vari Wileman
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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
NCT02409420

Secondary identifying numbers
16805

Study information

Scientific Title
A randomised controlled trial of brief physiotherapy informed by Acceptance and Commitment Therapy for chronic low back pain: the PACT study

Acronym
PACT

Study objectives
It is hypothesised that the group receiving PACT will have improved self-reported functioning at the primary end point of 3 months follow-up compared to the treatment as usual group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/SC/0277; First MREC approval date 26/06/2014

Study design
Randomised; Interventional and Observational; Design type: Process of Care, Treatment, Qualitative

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 participant information sheet

Health condition(s) or problem(s) studied
Topic: Musculoskeletal disorders; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
PACT: a brief physiotherapy intervention based on ACT principles optimised to promote self-management, consisting of two 60 minute face-to-face sessions one week apart, of assessment, individualised treatment and exercise prescription, plus one follow-up phone call (lasting 20 minutes), one month after the last treatment session.

Intervention Type
Behavioural

Primary outcome measure
Self-report of disability due to low back pain, assessed using the Roland-Morris Disability Questionnaire (RMDQ; Roland and Morris, 1983) at baseline, 3 months and 12 months

Secondary outcome measures
Measured at baseline, 3 months and 12 months:
1. Quality of life, measured using the Work and Social Adjustment Scale and EQ-5D-5L
2. Pain, measured using the visual analogue scale
3. Function, measured using Patient Specific Functional Scale
4. Mood, measures using Generalised Anxiety Disorder-7 and Patient Health Questionnaire-9
5. Acceptance, measures using Chronic Pain Acceptance Questionnaire-8
6. Committed action, measured using Committed Action Questionnaire-8
7. Pain self efficacy, measured using pain self-efficacy questionnaire
8. Satisfaction, measured using Satisfaction with Life, Global Improvement and Treatment Credibility scales
9. Health economics, measured using EQ-5D-5L and SF-6D

Overall study start date
01/10/2014

Completion date
01/07/2017

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Back pain including associated leg pain of greater than 12 weeks duration
3. Scoring 3 points or more on the Roland-Morris Disability Questionnaire (RMDQ)
4. Able and willing to give informed consent and attend treatment
5. Adequate understanding of spoken and written English to complete trial data collection and participate in programme

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 240; UK Sample Size: 240

Total final enrolment
248

Key exclusion criteria
1. Medically diagnosed lumbar spine pathology (e.g. inflammatory arthritis, fracture, cancer).
2. Deteriorating neurological signs (stable neurological signs and pain of apparently neuropathic origin are not exclusion criteria).
3. Previous or awaiting spinal surgery.
4. Psychiatric illness (e.g. extremely distressed/severe depression, personality disorders, posttraumatic stress disorders).
5. Drug or alcohol misuse.
6. Prior multidisciplinary or CBT pain management at any time.
7. Other physiotherapy in previous 6 months.

Date of first enrolment
01/11/2014

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Physiotherapy Service
United Kingdom
-

Study participating centre
Kings' College Hospital NHS Foundation Trust
Physiotherapy Service
United Kingdom
-

Study participating centre
Ashford & St Peter's Hospitals NHS Foundation Trust
London
United Kingdom
-

Sponsor information

Organisation
Guy's & St Thomas' NHS Foundation Trust (UK)

Sponsor details
16th Floor, Tower Wing
Guy's Hospital
Great Maze Pond
London
England
United Kingdom
SE1 9RT

Sponsor type
University/education

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-1112-29055

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The results of this study will be communicated to participants at the end of the study and disseminated via peer reviewed publications, patient interest groups and conference presentations. Key publications are planned as follows:

1. Study protocol (Spring 2016)
2. Efficacy trial and primary outcomes (2018)
3. Intermediary and process evaluations (2018)
4. Clinician experiences of PACT training and delivery (2017)
5. Cost-consequences analysis (2018)

Intention to publish date
01/09/2017

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 Emma Godfrey (emma.l.godfrey@kcl.ac.uk). The data will become available on publication of the results of the primary efficacy analyses. Individual level data will be made available upon request for use in academic research e.g. individual patient data meta analyses. Summary level data will be made available with the primary efficacy analyses and made available open access via the institutional website. Consent from participants was obtained. Data is pseudo anonymised. Detailed information that risks breaking anonymity will not be shared outside the research group. No ethical or legal restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/06/2016		Yes	No
Results article	results	01/01/2019	30/07/2019	Yes	No
HRA research summary			28/06/2023	No	No