

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/07/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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

Dr Vari Wileman

Contact details

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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