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Cognitive functional therapy for low back pain: a feasibility randomised controlled trial

Submission date
01/05/2019

Recruitment status
No longer recruiting

Registration date
10/05/2019

Overall study status
Completed

Last Edited
14/03/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Low back pain is the number one cause of disability worldwide resulting in a huge financial burden to society with costs estimated to be £12 billion each year in the United Kingdom. Previous treatments for low back pain have failed to reduce this burden. Even the most effective treatments provide only moderate benefits for patients. This may be due to low back pain being a complex condition made up of physical, psychological, social and lifestyle factors. For example, how a person thinks and behaves in response to low back pain can have a significant bearing on their recovery.

To target the complex nature of low back pain, the United Kingdom National Institute for Health Care and Excellence (NICE) guidelines recommend combined physical and psychological treatment programmes for people with persistent low back pain. Despite this recommendation, the Department of Health highlight a 'serious gap' in service provision for people with persistent low back pain in the United Kingdom with disability levels continuing to rise.

Cognitive Functional Therapy is an individualised self-management intervention that meets the recommendations of NICE. Cognitive Functional Therapy targets psychological, physical and lifestyle barriers to recovery, by teaching people to think, move and respond differently to low back pain. It has been shown to be more beneficial than traditional treatments for low back pain in one clinical trial in Norway. To date the clinical and cost effectiveness of Cognitive Functional Therapy has not been evaluated in the United Kingdom National Health Service (NHS). However, before the effectiveness of Cognitive Functional Therapy can be measured in a clinical trial, a number of questions need to be answered. These are;

• Can physiotherapists be trained to deliver Cognitive Functional Therapy within the NHS?
• Can a clinical trial of Cognitive Functional Therapy be completed within the NHS?
• Is Cognitive Functional Therapy acceptable to physiotherapists and people with low back pain?

This study will ask if it is feasible to carry out a future large clinical trial comparing Cognitive Functional Therapy with usual physiotherapy care within the NHS, providing results that are useful for patients, clinicians and service providers.

Who can participate?
People over the age of 18 with persistent low back pain from three hospitals in Leicester, United Kingdom.

What does the study involve?
Eligible and consenting participants will be randomly allocated to receive physiotherapy treatment as usual or Cognitive Functional Therapy for their low back pain. Participants will be asked to complete a series of short questionnaires, about their low back pain and how it affects them, before their treatment begins and again at three, six and twelve months after they entered the study. The questionnaires will take approximately 20 minutes to complete.
Participants allocated to usual physiotherapy care will receive education about low back pain, an exercise programme that may include strengthening, stretching and cardiovascular exercise and they may also receive treatments such as manipulation or massage.
Participants allocated to Cognitive Functional Therapy (CFT) will receive an individualised self-management intervention for low back pain. Management is tailored towards each person's unique clinical presentation and comprises of three integrated components.
1) Education to enable the patient to make sense of their pain from a multi-dimensional perspective. 2) Exposure with control to target feared, painful and or avoided movements and activities, in order to build confidence to engage in valued and personally relevant functional tasks. 3) A lifestyle intervention aimed at increasing physical activity levels based on preference, enhancing sleep habits, regulation of stress (via relaxation techniques) and/or dietary advice where relevant.
Following completion of treatment, ten of participants will be invited to discuss their experiences of participation in the study during a short one-off interview.

What are the possible benefits and risks of participating?
Both interventions are recommended by clinical guidelines and are provided by physiotherapists. Therefore, participants will be receiving interventions based on the best available evidence for managing low back pain. Participants should experience a reduction in pain, disability and an improvement in function. Both interventions will incorporate different forms of exercise (for example, cardiovascular and strengthening) which may cause some short lasting muscle soreness for 2-3 days. Apart from that, there are no known risks of taking part in this research.

Where is the study run from?
University Hospitals of Leicester NHS Trust, Physiotherapy Department (UK).

When is the study starting and how long is it expected to run for?
April 2019 to April 2020.

Who is funding the study?
The study is funded by NIHR Collaboration for Leadership in Applied Health Research and Care (East Midlands) and the Chartered Society of Physiotherapy Charitable Trust.

Who is the main contact?
Mr Christopher Newton
christopher.newton@nottingham.ac.uk

Contact information

Type(s)

Scientific

Contact name
Mr Christopher Newton

ORCID ID
http://orcid.org/0000-0002-0013-4557

Contact details
Physiotherapy Department
Balmoral Building, Level 0
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW
+44116 258 5816
christopher.newton@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
113690

Study information

Scientific Title
Cognitive functional therapy for persistent low back pain: a mixed methods feasibility randomised controlled trial

Study objectives
This study aims to determine the feasibility of completing a future large scale randomised controlled trial that will evaluate the clinical and cost-effectiveness of Cognitive Functional Therapy in comparison to usual physiotherapy care for people with persistent low back pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/2019, East Midlands - Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 0207 104 8101; NRESCommittee.EastMidlands-Nottingham1@nhs.net) ref: 18/EM/0415

Study design
Pragmatic two arm parallel feasibility randomised controlled trial

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
Low back pain

Interventions
Eligible and consenting participants will be randomly allocated to receive either usual physiotherapy care or Cognitive Functional Therapy.

Cognitive Functional Therapy (CFT) is an individualised self-management intervention for low back pain. CFT employs a multidimensional clinical reasoning framework to identify and target the biopsychosocial complexity of low back pain. Management is tailored towards each person's unique clinical presentation and context. The intervention comprises three integrated components:
1. Making sense of pain: a reflective process that combines the person's own narrative (interview) and experience (during guided behavioural experiments) to developing a personally-relevant, multidimensional understanding of pain for the patient. In this process, unhelpful beliefs are dispelled.
2. Exposure with 'control': a process of graded movement exposure to feared, painful and or avoided movements and activities, in order to build self-efficacy to engage in goal orientated functional tasks.
3. Lifestyle change: a process of behavioural modification addressing unhelpful lifestyle factors aimed at increasing physical activity levels based on preference, enhancing sleep habits, regulation of stress (via relaxation techniques) and/or dietary advice where relevant.

Usual physiotherapy care
Participants will receive usual physiotherapy care in keeping with standard assessment procedures and decision making by the treating physiotherapist. Physiotherapy treatment for low back pain typically includes education, manual therapy and stretching, strengthening and cardiovascular exercise.

Both interventions will be delivered over three months with no restriction on the number of sessions undertaken during this period. The first appointment will be for 1 hour and follow-up appointments for 30 minutes for both interventions.

Participants will be randomly allocated to receive Cognitive Functional Therapy or usual physiotherapy care. An online randomisation schedule has been generated using www.randomization.com on 8th February 2019 with variable block sizes of 2, 4, 6 and 8 for 60 participants. Assignment has been enclosed in sequentially numbered opaque envelopes with participants drawing the next envelope in sequence. Participants will take the envelope to physiotherapy reception to book their appointment for their allocated intervention to commence. A researcher responsible for recruitment will be concealed to group allocation. It is not possible to blind participants or the physiotherapists.

The therapy in both arms of the trial is led by physiotherapists.

Data will be collected at baseline during a face to face appointment by a blinded assessor. At 3, 6 and 12-month follow-up questionnaires will be posted to participants who will be provided with a stamp-addressed envelope to return them. Data will be inputted by a researcher blinded to group allocation.

Intervention Type
Behavioural

Primary outcome measure
To determine the feasibility of completing a future fully powered randomised controlled trial by;
1. Measuring eligibility, recruitment and retention rates of participants.
2. Measuring response rates to patient-reported outcome measures.
3. Decide the primary outcome measure for a definitive trial.
4. Calculate the sample size for the definitive RCT, should feasibility be assured.
5. Record any arising adverse events.
6. Evaluate intervention adherence.
7. Explore the acceptability of the intervention and the research process as experienced by participants and physiotherapists.

Secondary outcome measures
The following patient-reported outcome measures will be collected at baseline, three, six and twelve-month follow-up periods;
1. Roland Morris Disability Questionnaire
2. Numeric Pain Rating Scale
3. Fear Avoidance Beliefs Questionnaire
4. Keele STarT Back Screening Tool
5. Pain Self-efficacy Questionnaire
6. Pain Catastrophising Scale
7. Distress, Anxiety and Stress Scale (DASS 21)
8. Euro-Qol (Eq-5D-5L)
9. Global Rating of Change and participant satisfaction will be collected at three, six and twelve-month follow-up only.
10. Working Alliance Theory of Change Inventory will be collected at three-month follow-up only.

Overall study start date
01/08/2018

Completion date
17/04/2021

Eligibility

Key inclusion criteria
1. Dominant low back lasting for more than three months
2. Activity and/or functional limitations due to low back pain
3. A Numeric Pain Rating Scale (NPRS) score ≥3/10 during the last week
4. Being independently mobile to be capable of participating in a rehabilitation programme

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Leg pain as the primary problem (e.g. nerve root compression or disc prolapse with radicular pain/radiculopathy, lateral recess or central spinal stenosis)
2. Pain relieving interventional procedures in the preceding 3 months (e.g. facet joint denervation, caudal epidural injections)
3. Less than six months after lumbar spine, lower limb or abdominal surgery
4. Red flag disorders (malignancy/cancer, spinal fracture (less than six months ago), spinal infection or cauda equina syndrome)
5. Pregnancy or less than six months post-partum
6. Diagnosed psychiatric disorder that prevents engagement in a self-management intervention
7. Rheumatologic/inflammatory disease (e.g. rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis)
8. Progressive neurological disease (e.g. multiple sclerosis, Parkinson’s disease, motor neuron disease)
9. Unstable cardiac conditions

Date of first enrolment
17/04/2019

Date of final enrolment
17/04/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
Physiotherapy Department
Balmoral Building, Level 0
Infirmary Square
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

Sponsor details
Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW
+44116 258 4109
RIAdmin@uhl-tr.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.leicestersresearch.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name

Chartered Society of Physiotherapy Charitable Trust

Alternative Name(s)
CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
National Institute for Health Research

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 study results will be be communicated to participants in a short report, disseminated through peer review journal publications and presented at scientific conferences. Planned open-access publications include;
1) Study protocol (Summer 2019)
2) Feasibility RCT results (Summer 2021)
3) Qualitative process evaluation (Winter 2021)

Intention to publish date
01/07/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		12/02/2024	14/03/2024	Yes	No