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UK-Back Skills Training Trial (UK-BeST) A multi-centred randomised controlled trial of a primary-care based cognitive behavioural program (CBP) for low back pain (LBP)

Submission date
17/09/2003

Recruitment status
No longer recruiting

Registration date
23/09/2003

Overall study status
Completed

Last Edited
30/09/2014

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 01/75/01

Study information

Scientific Title

Acronym
UK-BeST

Study objectives
The problem:
Low Back Pain (LBP) is a major public health problem. In any year, about 37% of the UK population report LBP, but not all people consult their general practitioner, or have long lasting symptoms. LBP has a substantial impact on the UK economy. Direct health care costs associated with LBP were estimated to be £1,628 million in 1998. Indirect costs, including lost production are even higher.

Cognitive Behavioural Therapy (CBT):
Over the recent years there has been considerable interest in CBT as a treatment for LBP, but few large controlled trials. CBT aims to empower people to better manage their back pain by learning skills of self-management. Important components of CBT are learning coping and pacing skills, non-pharmacological management of pain, countering negative beliefs about back pain and a graded activity programme in which people learn how to set themselves realistic goals. We have decided to use a group setting to deliver CBT as opposed to an individual treatment. We hope that people will be able to gain benefit from talking to one another, as has been shown in CBT programmes designed for other conditions.

The study:
Up to 700 people with a diagnosis of LBP, resulting in at least moderately troublesome symptoms and of at least 6 weeks duration will be identified through 93 practices of the Medical Research Council's General Practice Research Framework http://www.mrc-gprf.ac.uk/index.html. Potential participants will be invited to participate in a trial in which they will be allocated on a random basis to one of two treatment arms:
1. Advice from their general practice
2. Advice plus a group based cognitive behavioural program.

The costs of each strategy, and the clinical effects of the treatment will be monitored for a year.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/017501
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0016/50614/PRO-01-75-01.pdf

On 15/01/2008 the anticipated start and end date of this trial were changed from 01/10/2003 and 30/09/2006 to 06/10/2003 and 05/10/2008, respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Multi-Centred Research Ethics Committee, Birmingham UK (MRC/03/7/04) provided the ethical review and approval.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Low Back Pain

Interventions
Group CBP, utilising an individualised assessment and promotion of self-management by
1. Patient education to counter negative beliefs about LBP
2. Use of cognitive re-structuring techniques to improve coping skills and self-efficacy (focusing on occupation and activity)
3. Goal setting, led by the paticipants
4. Pacing skills
5. Graded physical activity programme
6. Effective communication with health professionals.

Groups will allow for up to 6 hours of face-to-face contact with therapists, and will be conducted in a community or primary care facility.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Pain and Disability measured using the Roland and Morris Questionnaire at months 0, 3, 6, 12
2. Pain measured using the Von Korff Scale at months 0, 3, 6, 12

Key secondary outcome(s)
Secondary outcome measures:
1. Occupational and other limitations measured by the numbers of days off work, reduced activity and bed rest at months 0, 3, 6, 12
2. Health-related quality of life including physical and mental health measured by Short Form 12 version 2 at months 0, 3, 6, 12
3. Back Pain Beliefs measured using Fear avoidance scale (1st five items only)* at months 0, 3, 6, 12
4. Self-efficacy measured using the Pain self-efficacy questionnaire at months 0, 3, 6, 12
5. Satisfaction with treatment measured using the single item rating of satisfaction with treatment at months 12

Economic analysis:
1. Resource Use measured using the resource use questionnaire at months 6 and 12
2. Health related quality of life; time trade off score measured using the EQ-5D (health utility) at months 0, 6, 12

Completion date
05/10/2008

Eligibility

Key inclusion criteria
1. People with at least moderately troublesome low back pain of six weeks duration
2. Able to give informed consent
3. Aged over 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Exclusions will be based on pre-specified factors associated with serious pathologies.

Date of first enrolment
06/10/2003

Date of final enrolment
05/10/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Primary Health Care Studies
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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	13/03/2010		Yes	No
Results article	results	01/09/2011		Yes	No
Results article	results	01/02/2012		Yes	No
Results article	results	14/01/2014		Yes	No
Protocol article	protocol	22/02/2007		Yes	No
Other publications	description of development of intervention	01/06/2010		Yes	No