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Early physiotherapy for acute low back pain

Submission date 04/09/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/10/2009	**Overall study status** Completed	
Last Edited 18/07/2016	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
715/G18B

Study information

Scientific Title

Early physiotherapy for acute low back pain (LBP) in a working population: a pilot randomised clinical trial

Study objectives
1. To investigate whether early referral to physiotherapy in an occupational health setting for workers with acute low back pain (first onset or recurrent acute), is efficacious in improving disability, pain, work outcome measures and encouraging patients to stay at work or return to work
2. To develop a methodologically sound protocol and provide preliminary data to support a funding application for a large randomised clinical trial (RCT) to an organisation such as the Medical Research Council (MRC), to investigate the effectiveness of the intervention in a large population of workers

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and SW Hampshire Research Ethics Committee A , 07/09/2006, ref: 06/Q1702/79

Study design
Pilot randomised single centre controlled clinical 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute low back pain

Interventions
Control participants will receive the usual treatment from the occupational health nurse based on the Royal College of General Practitioners (RCGP) guidelines, i.e. advice promoting positive attitudes and reducing negative beliefs about low back pain - positive messages; no signs of serious damage; will recover in a few days or weeks; go home; continue to take simple analgesia /anti-inflammatory as needed; activity is helpful and too much rest is not, so just take a little rest when needed; increase physical activities progressively over days or weeks; avoid heavy lifting; maintain a good posture; stay at work or return to work as soon as possible; go to GP if no improvement in 24/48 hours. This usual care will take 15 minutes. Each participant will be given a copy of "The Back Book" that contains this advice and offers a home reference source. Any

treatment received will be recorded, e.g., delayed referral to physiotherapy through their GP; use of private physiotherapy and complementary therapies.

Intervention participants will receive usual treatment from the occupational health nurse as per the control group, plus direct referral to physiotherapy starting within 5 days of randomisation. This will consist of a one-hour initial assessment identifying patient centred problems and any physical examination findings, with agreed functional goals set and decision made on a pragmatic intervention to achieve these goals. Subsequent follow-ups will be for 30 minutes, with an average number of 5 - 6 sessions including the initial assessment. Physiotherapy treatment will aim to further promote positive attitudes and reduce negative beliefs about LBP, enhancing confidence in patients to partake in normal daily activities. It will include advice on self-management, including postural awareness, encouraging functional movement, advice to remain active and advice on aerobic exercise e.g. walking. Where appropriate it will also include specific exercises to mobilise and/or stabilise the trunk and lower limbs, as well as manual therapy low-velocity mobilisation and high-velocity manipulation techniques, but will exclude electrotherapy and traction. Exercise and manual therapy treatment decisions will be based on initial and continued assessment by the physiotherapist. Recording of assessment findings, decision making processes, treatment and response to treatment will be standardised. Discharge of patients in this group will be at the physiotherapists' discretion.

Co-existing treatment: Analgesics and/or non-streoidal anti-inflammatory drugs (NSAID) can be used in both groups at the discretion of the participant, the occupational health nurse, their local pharmacist or their GP. Medication for co-existent conditions will continue as needed. Dosages of all drugs will be recorded.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in the Roland-Morris Disability Questionnaire (RDQ), recorded at the initial baseline assessment and post-randomisation at 6 weeks, 3, 6 and 12 month follow-ups, with the 3-month comparison seen as the primary point of interest in this study.

Secondary outcome measures
Recorded at baseline assessment and 3, 6 and 12 month follow-ups. The Graded Chronic Pain Scale (GCPS) and the Work Limitations Questionnaire (WLQ), will also be recorded at 6 weeks following randomisation:
1. The severity of LBP as defined by pain intensity and interference with daily activities will be assessed using the modified Graded Chronic Pain Scale (GCPS)
2. Work Limitations Questionnaire (WLQ), a generic role-specific measure of work outcome
3. Health Related Quality of Life will be assessed using the EuroQol
4. Fear Avoidance Beliefs Questionnaire (FABQ)
5. Back Beliefs Questionnaire
6. Economic measures; a modified version of the Client Services Receipt Inventory (CSRI)
7. EuroQol will be used to calculate the cost of the interventions per quality adjusted life year (QALY)

Overall study start date

12/10/2006

Completion date
15/05/2010

Eligibility

Key inclusion criteria
1. Non-specific LBP subjects
2. Aged between 18 - 65 years, either sex
3. Had an acute episode of LBP within the last 4 weeks, between the lowest palpable ribs, posterior axillary lines and gluteal folds, with or without referral into the legs
4. A score of 4 or more on the Roland-Morris Disability Questionnaire (RDQ)
5. No acute episode of LBP in the preceding 1 month

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Inability to complete the questionnaires
2. Unable to exercise
3. Unstable co-existing rheumatic, cardiovascular, respiratory, neurological, psychiatric or psychological disorders
4. Use of systemic steroids and anticoagulants
5. Progressive nerve root signs and symptoms
6. Cauda equina symptoms
7. Non-mechanical pain
8. Presently referred to a medical specialist for investigations in relation to LBP
9. Previous attendance or awaiting treatment at a specialist pain management centre
10. Involvement in a litigation process related to LBP

Date of first enrolment
12/10/2006

Date of final enrolment

15/05/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Health Sciences
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
BUPA Foundation (UK) (ref: 715/G18B)

Alternative Name(s)

Funding Body Type
Private sector organisation

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

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