

Early physiotherapy for acute low back pain

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

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
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

United Kingdom

England

Study participating centre

School of Health Sciences

Southampton

United Kingdom

SO17 1BJ

Sponsor information

Organisation

University of Southampton (UK)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration