Evaluation of the Oxfordshire Physiotherapy Service for patients with low back pain: a multicentre randomised controlled trial

Submission date	Recruitment status	Prospectively registered		
16/07/2002	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/07/2002	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
04/10/2007	Musculoskeletal Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number F0519

Study information

Scientific Title

Study objectives

To measure the effectiveness of routine physiotherapy compared with an assessment session and advice from a physiotherapist for patients with low back pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Low back pain

Interventions

Group 1: Advice group -

This group will have a single contact with a physiotherapist who will offer self management advice as specified in the advice booklet (see below). Specific exercises will not be advised.

Group 2: Routine physiotherapy treatment -

The physiotherapists will decide on the content of treatment according to their assessment. Treatment will be restricted to a combination of the following techniques depending on the physiotherapists' clinical judgment:

- 1. Mobilisation techniques including manipulation
- 2. Soft tissue techniques
- 3. Individual exercise programmes
- 4. Heat or cold treatment.

No electrotherapy or traction will be used. Trial participants will receive a maximum of six treatment sessions. Information will be recorded on the type of physiotherapy intervention and the level of training and clinical experience of the physiotherapist.

Advice booklet:

Patients in group 1 and group 2 will be given a standardised advice booklet that has been produced by a group of experts in the field of low back pain. The advice in the booklet will be explained by the physiotherapist in a session lasting up to 1 hour. It will encourage activity and discourage bed rest.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Scores on the Oswestry disability index at 12 months: 0% (no disability) to 100% (totally disabled or bed ridden).

Key secondary outcome(s))

- 1. Scores on the Oswestry disability index at two and six months
- 2. Scores on the Roland and Morris disability questionnaire at 2, 6, and 12 months
- 3. General health was measured with the 36-item Short Form health survey (SF-36) at 2, 6, and 12 months (higher scores indicate better health)
- 4. Patient perceived benefit of treatment was measured on a scale from 0 (no benefit) to 10 (maximum benefit) and on a dichotomous scale (perceived benefit or no perceived benefit)

Completion date

01/01/2001

Eligibility

Key inclusion criteria

- 1. Aged 18+ years
- 2. Subacute (more than 6 weeks less than 3 months) or chronic (more than 3 months) mechanical low back pain
- 3. With or without leg pain or neurological signs

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Patients with serious conditions including:
- 1.1. Systemic rheumatological disease
- 1.2. Gynaecological problems
- 1.3. Ankylosing spondylitis
- 1.4. Tumours
- 1.5. Infection
- 2. Past spinal operations

- 3. Treatment for physical problems in the past month
- 4. Referred for intensive functional restoration programmes

Date of first enrolment

01/10/1997

Date of final enrolment

01/01/2001

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre Faculty of Health Sciences

Edinburgh United Kingdom EH6 8HF

Sponsor information

Organisation

Arthritis Research Campaign (ARC) (UK)

ROR

https://ror.org/02jkpm469

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research Campaign (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	25/09/2004		Yes	No