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

Submission date
16/07/2002

Recruitment status
No longer recruiting

Registration date
16/07/2002

Overall study status
Completed

Last Edited
04/10/2007

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] 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

Contact name
Dr Helen Frost

Contact details
Faculty of Health Sciences
Physiotherapy Department
Queen Margaret University College
Duke Street
Leith
Edinburgh
United Kingdom
EH6 8HF
+44 (0)131 317 3654
hfrost@qmuc.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
01/10/1997

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
286

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
Scotland

United Kingdom

Study participating centre
Faculty of Health Sciences
Edinburgh
United Kingdom
EH6 8HF

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
St Mary's Court
St Mary's Gate
Chesterfield
Derbyshire
United Kingdom
S41 7TD
-
info@arc.org.uk

Sponsor type
Charity

Website
http://www.arc.org.uk

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (UK)

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

Study outputs

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