

The efficacy of exercises for the treatment of chronic low back pain.

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/07/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
N0060055840

Study information

Scientific Title

Study objectives

Experimental hypothesis: A specific exercise protocol will be clinically more beneficial as well as being more cost effective than other forms of treatment for chronic low back pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised single-blind placebo-controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Chronic low back pain

Interventions

Eighty patients with chronic low back pain (> 3 months) were randomized to one of the following treatments, involving 8 treatments over 8 weeks:

1. one to one treatment involving 30 minutes of manual therapy (mobilizations to the spine) and spinal stabilization exercises
2. a 10 station exercise class involving aerobic exercises, spinal stabilization exercises and manual therapy.

Three physiotherapists lead the hour long group with a maximum of 10 patients. Questionnaires were completed and physical measurements were taken by a blinded observer before randomization, at the completion of treatment, at 6 months and 12 months after the completion of treatment. The intention to treat principle was used in data analysis.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Prior to July 2008:

Visual analogue scale (pain intensity). Objective measures (lumbar range of movement, straight leg raise, Biering-Sorenson test). Functional test.

Modified July 2008 to:

Quebec back pain disability questionnaire

Key secondary outcome(s)

Added July 2008:

1. Subjective rating of change
2. Visual analogue scale for pain
3. Perceived level of fitness
4. Analgesic use
5. Number of cigarettes / day
6. Level of confidence relating to back pain
7. Lumbar range of movement
8. Range of straight leg raise

Completion date

01/08/2003

Eligibility

Key inclusion criteria

Added July 2008:

1. Subjects between the ages of 18 to 75 years
2. Fluency in English
3. Mechanical low back pain for more than 3 months (of a non-radicular nature). Mechanical pain was defined as LBP which increased with movement.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients with cardiac, respiratory, kidney, blood pressure or blood circulatory problems, spinal surgery, fracture, inflammatory or infectious diseases of the spine, metabolic disease, neurological deficit, rheumatoid arthritis or diabetes
2. Health professionals and staff members at the institution where data was collected
3. Potential subjects who were pregnant or attempting to become pregnant
4. Patients who were not capable of participating in a graded exercise program were also excluded

Date of first enrolment

01/01/2000

Date of final enrolment

01/08/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Physiotherapy Dept**

London

United Kingdom

SW10 9NH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Chelsea and Westminster Healthcare NHS Trust (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				

[Results article](#)

01/04/2005

Yes

No