

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

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

<a href="#">Results article</a>		01/04/2005		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes