Can the Roland and Morris disability questionnaire be used to predict the response to physiotherapy treatment in chronic low back pain patients?

Submission date 28/09/2007	Recruitment status Stopped	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Stopped	Results
Last Edited	Condition category	Individual participant data
05/10/2011	Musculoskeletal Diseases	Record updated in last year

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 N0283184549

Study information

Scientific Title

Study objectives

The aim of the pilot study is to see if it is possible to predict which patients with low back pain respond best to certain types of physiotherapy treatment. These treatments will be manipulation plus exercise, a spinal stability class and a general back class.

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)

Treatment

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Low back pain

Interventions

- 1. Manual therapy and exercise
- 2. Stability class
- 3. General back class

Added 21 August 2008: the trial was stopped before it started, firstly due to a staffing issue locally, then due to a change in clinical practice/evidence base.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Roland and Morris Disability Questionnaire.

Key secondary outcome(s))

- 1. Visual Analogue Scale (for pain)
- 2. Patient Specific Functional Scale
- 3. Self-Efficacy Questionnaire

Completion date

01/06/2007

Reason abandoned (if study stopped)

Lack of staff and change in clinical practice/evidence base

Eligibility

Key inclusion criteria

- 1. Aged 18-65
- 2. Non-specific LBP>3 month duration
- 3. Non-specific LBP or leg symptoms of spinal origin>3 months
- 4. Acute exacerbation of chronic LBP
- 5. Patients with longstanding, stable neurological deficit from LBP eg sensory loss, minor motor weakness at one level, loss of reflex at one level
- 6. Medically fit to exercise
- 7. Ability to understand spoken and written English
- 8. Suitable for working in group environment
- 9. Consented to participate

These are recognised inclusion criteria for similar trials with similar cohorts of patients, making the study and its findings potentially reflective of other work in this field.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

Not Specified

Key exclusion criteria

- 1. Pregnancy
- 2. Acute nerve root signs and symptoms
- 3. Spinal red flags as defined by RCGP and ARMA guidelines
- 4. Not meeting inclusion criteria

Date of first enrolment

01/09/2006

Date of final enrolment

01/06/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Worthing & Southlands Hospitals NHS Trust
Worthing
United Kingdom
BN11 2DH

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Sussex NHS Research Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration