# The UK Back pain, Exercise Active management and Manipulation trial

| Submission date   | Recruitment status  No longer recruiting | Prospectively registered       |  |  |
|-------------------|--|--------------------------------|--|--|
| 23/10/2000        |  | ☐ Protocol                     |  |  |
| Registration date | Overall study status                     | Statistical analysis plan      |  |  |
| 23/10/2000        | Completed                                | [X] Results                    |  |  |
| Last Edited       | Condition category                       | [] Individual participant data |  |  |
| 06/07/2009        | 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 G9628230

# Study information

Scientific Title

#### Acronym

**UK BEAM** 

## **Study objectives**

To evaluate the effectiveness of different physical interventions for back pain in primary care.

## 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)

**Not Specified** 

## Health condition(s) or problem(s) studied

Primary care

#### Interventions

General practices randomised between:

I. An active management training programme and conventional management

#### Patients within practices randomised between:

II. A spinal manipulation package agreed recently by representatives of the chiropractic, osteopathy and physiotherapy professions and delivered in private premises, the same package delivered in NHS premises and conventional management

III. A promising progressive exercise package supported by representatives of the physiotherapy profession and conventional management

Please note that, as of 14/02/2007, the anticipated end date of this trial has been updated to 31/08/2004.

## Intervention Type

Other

#### Phase

**Not Specified** 

## Primary outcome(s)

The primary outcome measure is the change in Roland Disability Questionnaire (RDQ) score at 3 and 12 months. A change of 2.5 points on the scale has been agreed by the UK BEAM Working Party and Trial Steering Committee as clinically significant.

## Key secondary outcome(s))

Not provided at time of registration

## Completion date

30/04/2001

# **Eligibility**

#### Key inclusion criteria

- 1. Primary care back pain consultors aged between 18 and 65 years
- 2. Non-specific back pain
- 3. Referred leg pain must be predominantly above knee
- 4. Fluent in English able to read and write
- 5. No physical therapies in previous 3 months
- 6. Duration at least 4 weeks
- 7. Roland Disability Questionnaire (RDQ) score of 4 or more

#### Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

## Lower age limit

18 years

#### Upper age limit

65 years

#### Sex

All

#### Key exclusion criteria

- 1. People over 65
- 2. Clinical indications for the investigation of possible serious spinal or neurological pathology, or for urgent surgical referral
- 3. Nerve root pain
- 4. Previous spinal surgery
- 5. Major psychological complication or abnormal illness behaviour, referred to a tertiary pain management programme
- 6. Other musculoskeletal disorders which would interfere with therapy
- 7. History of psychosis or major alcohol abuse
- 8. Other concurrent medical conditions, including cardiovascular disease
- 9. Moderate to severe hypertension
- 10. Long-term steroid use
- 11. Anti-coagulant therapy
- 12. Perceived inability to walk 100 metres when free of pain
- 13. Unable to get up and down off floor unaided

- 14. Physical therapy (including acupuncture) in the previous 3 months
- 15. Unable to read and write fluently in English
- 16. Roland Disability questionnaire score of 3 or less on the day of randomisation

## Date of first enrolment

01/09/1997

## Date of final enrolment

30/04/2001

## Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre University of Kent

Kent United Kingdom CT2 7NF

# **Sponsor information**

## Organisation

Medical Research Council (UK)

# Funder(s)

## Funder type

Research council

#### Funder Name

Medical Research Council (UK)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## **Funding Body Type**

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# **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 article | results                       | 01/08/2003   |            | Yes            | No              |
| Results article | results on cost effectiveness | 11/12/2004   |            | Yes            | No              |
| Results article | results on effectiveness      | 11/12/2004   |            | Yes            | No              |
| Results article | results                       | 01/06/2006   |            | Yes            | No              |
| Results article | results                       | 11/06/2009   |            | Yes            | No              |