

The UK Back pain, Exercise Active management and Manipulation trial

Submission date 23/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 06/07/2009	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/1997

Completion date

30/04/2001

Eligibility**Key inclusion criteria**

1. Primary care back pain consultants 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

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

1350

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

England

United Kingdom

Study participating centre

University of Kent

Kent

United Kingdom

CT2 7NF

Sponsor information

Organisation

Medical Research Council (UK)

Sponsor details

20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.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

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	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