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The UK Back pain, Exercise Active management and Manipulation trial

Submission date
23/10/2000

Recruitment status
No longer recruiting

Registration date
23/10/2000

Overall study status
Completed

Last Edited
06/07/2009

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 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

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
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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