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Early physiotherapy management of back pain in primary care: a comparison of physical treatments versus a back pain management programme

Submission date
01/07/2003

Recruitment status
No longer recruiting

Registration date
01/07/2003

Overall study status
Completed

Last Edited
04/11/2010

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

Protocol serial number
M RB 218233

Study information

Scientific Title

Study objectives
To compare the clinical effectiveness, in primary care, of a brief pain management programme delivered by physiotherapists with that of a programme of spinal manual physiotherapy in the treatment of non-specific low back pain of less than 12 weeks duration.

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
Acute low back pain

Interventions
1. A brief pain management programme with no 'hands on' physiotherapy but focusing on education to change behaviour and attitudes, in addition to exercises to increase fitness.
2. A course of "hands on" spinal manual therapy plus specific back exercises prescribed on the basis of a detailed assessment of spinal pain, mobility and function by the physiotherapist.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome was change in self-reported back pain related disability at 12 months as measured on the Roland and Morris Disability Questionnaire.

Key secondary outcome(s))
1. Participants global assessment of change compared with baseline
2. Pain location (body chart)
3. Rating of pain severity (visual analogue scale [VAS]) and pain nature (short form McGill pain questionnaire)
4. Psychological distress (the distress and risk assessment method [DRAM])
5. Fear of movement (Tampa scale of kinesiophobia), coping strategies (coping strategies questionnaire)

6. Satisfaction with treatment (VAS)
7. Days off work since start of current episode
8. Co-interventions (health care utilisation and medication usage)

Completion date
30/06/2003

Eligibility

Key inclusion criteria
1. Aged 18 - 64 years inclusive
2. Acute episode of low back pain of less than 12 weeks duration
3. First or second consultation with general practitioner (GP)
4. Able to give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. On long term sick leave for low back pain
2. Already seen by other health care professional (e.g. physio) for this episode of back pain prior to randomisation
3. Diagnosis of osteoporosis or inflammatory arthritis
4. Systemic steroid therapy for more than three months duration
5. Pregnancy
6. Undergoing current treatment for cancer
7. Terminal illness
8. Previous hip or back surgery or fracture
9. Abdominal surgery within the last three months
10. Roland and Morris Disability Questionnaire score (primary outcome measure) less than 2

Date of first enrolment
01/07/2000

Date of final enrolment
30/06/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Primary Care Sciences Research Centre
Keele
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
The National Lotteries Charities Board (via North Staffordshire Medical Institute) (UK) - Project No. RB218223, £191,227

Funder Name
North Staffordshire Primary Care Research Consortium (UK) £112,516

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	01/06/2005		Yes	No