

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	<input type="checkbox"/> Prospectively registered
Registration date 01/07/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/11/2010	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/07/2000

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

402

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

England

United Kingdom

Study participating centre

Primary Care Sciences Research Centre

Keele

United Kingdom

ST5 5BG

Sponsor information

Organisation

Keele University (UK)

Sponsor details

Keele University

Keele

England

United Kingdom

ST5 5BG

Sponsor type

University/education

Website

<http://www.keele.ac.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

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	01/06/2005		Yes	No