

A randomised controlled trial of the effect on chronic low back pain of a naturopathic osteopathy intervention

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 28/03/2018	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Paul Thomas

Contact details

Kilburn Park Medical Centre

12 Cambridge Gardens

Kilburn

London

United Kingdom

NW6 5AY

+44 (0)20 7624 2414

p.r.thomas@imperial.ac.uk

Additional identifiers

Protocol serial number

M0001078851

Study information

Scientific Title

A randomised controlled trial of the effect on chronic low back pain of a naturopathic osteopathy intervention

Study objectives

Does a naturopathic osteopathy intervention improve pain, disability and sense of well being in chronic low back pain?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Back pain

Interventions

Questionnaire inquiry of disability, pain and sense of well being administered at recruitment, 3, 6, 12 months, and at 5 years. Half will be randomised to an intervention arm that comprises treatment at the British College of Naturopathy and Osteopathy (BCNO) by third/fourth year students under the supervision of experienced trainer practitioners. This intervention will be naturopathic osteopathy and include patient diaries. Up to seven treatments will be given, expecting an average of five weekly treatments.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Assessment of:

1. Disability using the Roland Morris Score
2. Self competence using the Perceived Pain Management Competence Scale
3. Beliefs using the Back Beliefs Questionnaire
4. Pain using the Von Korff questionnaire
5. Well-being using the SF12.

All of these are self-administered questionnaires.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/06/2003

Eligibility

Key inclusion criteria

240 clients aged between 20 and 65 presenting at ten general practices in Brent in the summer of 2000 with low back pain of over three months duration. Random allocation to an intervention arm and usual care.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/04/2000

Date of final enrolment

01/06/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Kilburn Park Medical Centre

London

United Kingdom

NW6 5AY

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Research organisation

Funder Name

The West London Research Network (WeLReN) (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration