

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

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.

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/04/2000

### **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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

240

### **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**

England

United Kingdom

**Study participating centre**

Kilburn Park Medical Centre

London

United Kingdom

NW6 5AY

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

The West London Research Network (WeLReN) (UK)

## **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