

# A pilot randomised controlled trial of yoga for chronic low back pain

<b>Submission date</b> 11/06/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/05/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.york.ac.uk/healthsciences/centres/trials/>

## 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

15/08/06 Version 3

# Study information

## Scientific Title

### Acronym

Yoga Pilot

### Study objectives

To assess recruitment, practicality and feasibility of a randomised controlled trial of yoga for chronic low back pain in order to inform a larger multicentre trial.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

MREC approval was granted in October 2006. Research Governance approval was given on 09/032007

### Study design

Pragmatic single site randomised controlled trial with equal allocation

### 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

Chronic low back pain

### Interventions

As well as receiving their usual care patients receiving this treatment will be offered 12 weekly sessions of yoga plus the Back Book (a small information booklet aimed at patients with back pain and is based on current evidence). Each session will last 75 minutes with a Hatha and Iyenga yoga programme of relaxing, toning, stretching and breathing. The yoga package of care has been developed by several yoga specialists with the aid of GPs and physiotherapists to provide an optimal regime.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Back pain, measured using the Roland and Morris Back pain Questionnaire (RDQ) and the Aberdeen Back Pain Scale.

Primary and secondary outcomes will be measured at baseline, 3 months, 6 months and 12 months.

**Secondary outcome measures**

1. Quality of life, measured using the 36-item Short Form health survey (SF-36)
2. Pain self-efficacy, measured using the Pain Self-Efficacy Questionnaire (PSEQ)
3. Practicality and feasibility

Primary and secondary outcomes will be measured at baseline, 3 months, 6 months and 12 months.

**Overall study start date**

21/05/2007

**Completion date**

18/09/2007

**Eligibility****Key inclusion criteria**

1. Aged 18 to 65 years
2. Attended General Practice (GP) for a consultation of back pain in previous 18 months
3. Scoring four or more on the Roland and Morris back pain scale

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

20

**Key exclusion criteria**

1. Pregnant women
2. Life-threatening co-morbidities
3. Severe documented psychiatric problems (other than mild to moderate unipolar depression or a simple anxiety state) or alcohol dependency
4. Have participated in yoga in the previous six months
5. Are currently involved or have recently been in another trial for their back pain
6. Previous spinal surgery
7. Clinical indications of serious spinal or neurological pathology

**Date of first enrolment**

21/05/2007

**Date of final enrolment**

18/09/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Department of Health Sciences**

York

United Kingdom

YO10 5DD

## **Sponsor information**

**Organisation**

University of York (UK)

**Sponsor details**

c/o Ms Sue Final

Intellectual Property manager

Research Support Office

Heslington

York

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**Sponsor type**

University/education

**Website**

<http://www.york.ac.uk/>

**ROR**

<https://ror.org/04m01e293>

## Funder(s)

**Funder type**

University/education

**Funder Name**

York Trials Unit (UK) - Department of Health Sciences, University of York

## 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?
<a href="#">Protocol article</a>	protocol	01/05/2010		Yes	No
<a href="#">Results article</a>	results	01/11/2010		Yes	No