# Pragmatic randomised controlled trial of yoga for the treatment of chronic low back pain

Submission date [X] Prospectively registered Recruitment status 02/02/2007 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 30/03/2007 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 18/02/2014 Musculoskeletal Diseases

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

#### Type(s)

Scientific

#### Contact name

**Prof David Torgerson** 

#### Contact details

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#### Additional identifiers

Protocol serial number 17727

# Study information

Scientific Title

#### **Acronym**

Yoga Trial

#### **Study objectives**

To assess the effectiveness of yoga therapy on the quality of life and pain of patients with chronic low back pain.

Aims and purpose of the proposed research:

- 1. To produce a package of yoga care agreed by a cross-section of yoga practitioners
- 2. To undertake a trial of the agreed yoga care package on patients with low back pain (LBP)
- 3. To undertake a cost effectiveness analysis of yoga treatment for LBP
- 4. To produce a manual for yoga teachers for the treatment of LBP

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the Leeds East Research Ethics Committee on the 20th June 2007 (ref: 07/Q1206/35).

#### Study design

Pragmatic randomised controlled trial.

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Chronic low back pain

#### **Interventions**

We will compare the yoga regime with standard care. The yoga intervention will be 12 weekly 75 minute classes. There are a number of recommended yoga practices for people with low back pain, which are delivered by practitioners of different yoga traditions. Among the applicants are representatives of the two most popular styles of yoga within the UK: Integral yoga (sometimes known as Hatha) and Iyengar yoga. Within the first three months of the study, whilst we get ethics permission and NHS Research and Development approval, we will conduct a series of meetings between experienced practitioners of yoga in order to agree on a basic package of yoga that can be delivered by yoga practitioners of these two styles. Yoga therapists taking part in the study will be trained in this package as well as low back pain assessment procedures. This will take place at the Yoga Biomedical Trust, London. As part of the study we will develop a manual for yoga practitioners and their patients. The manual will describe an agreed series of yoga techniques that can be readily used by any experienced yoga teacher and can be practised at home by patients receiving yoga.

The patients allocated to the control group will receive any ongoing treatment they would normally receive. Intervention patients will also receive in addition their normal treatments if

these are deemed necessary. Both groups will receive the Back Book which is an evidence based booklet written by a group of international back pain experts and is aimed at patients who have chronic low back pain.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

Roland and Morris back pain questionnaire.

#### Key secondary outcome(s))

- 1. Quality of life as assessed by 12-item Short Form health survey (SF12)
- 2. Aberdeen Back Pain Scale
- 3. EuroQol
- 4. Costs

#### Completion date

31/03/2010

# **Eligibility**

#### Key inclusion criteria

The target population will be aged between 18 - 65 presenting with low back pain, which is defined as pain of a musculoskeletal origin bounded by the lowest ribs and gluteal folds. Patients with referred pain will be included as long as it does not go below the knee.

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Patients over 65 as they are more likely to have serious spinal pathology
- 2. Clinical indications of serious spinal or neurological pathology
- 3. Previous spinal surgery
- 4. History of psychosis or alcohol abuse (due to difficulty in assessing outcomes)

# Date of first enrolment 01/04/2007

# Date of final enrolment 31/03/2010

### Locations

#### Countries of recruitment

United Kingdom

England

Study participating centre
York Trials Unit, Department of Health Sciences
York
United Kingdom
YO10 5DD

# Sponsor information

#### Organisation

University of York (UK)

#### **ROR**

https://ror.org/04m01e293

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

Arthritis Research Campaign (ARC) (UK)

# **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	01/11/2011		Yes	No
Results article	results	01/09/2014		Yes	No
Protocol article	protocol	01/05/2010		Yes	No
Other publications	economic evaluation	15/08/2012		Yes	No