

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

Submission date 02/02/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/03/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2014	Condition category Musculoskeletal Diseases	<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

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