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

Submission date	Recruitment status	[_] Prospectively registered
11/06/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/05/2011	Musculoskeletal Diseases	

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

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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
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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?
Protocol article	protocol	01/05/2010		Yes	No
Results article	results	01/11/2010		Yes	No