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Acupuncture and manual therapy for low back pain

Submission date	Recruitment status	[X] Prospectively registered
02/02/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/03/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/03/2017	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.york.ac.uk/healthsciences/trials-unit/painfreelowback/study/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A cohort design study investigating quality of life and treatment selection for individuals with low back pain incorporating a nested pilot factorial randomised controlled trial of manual therapy and/or acupuncture for individuals with low back pain

Study objectives
The aim of this pilot study is to investigate the recruitement and retention of participants and to assess the feasibility of using two treatments within one treatment session.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds NRES Research Ethics Committee, 05/04/2011, 11/YH/0028

Study design
Cohort recruitment study with a nested pilot factorial randomised controlled trial

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Low back pain

Interventions
1. Usual GP care intervention group (Treatment 0):
All participants entering the cohort who are not randomised to receive active treatment will constitute the usual care group. These participants will receive usual general practitioners (GP) care as would normally be provided. This involves attention from their GP or other health professionals as appropriate and as would be routine, i.e. the same as if they were not involved in the cohort. It will also involve the provision of the Back Book; this is a self help book for LBP

frequently distributed by health care professionals. These participants will not be provided with manual therapy or acupuncture through the trial. Data will be collected on all patients on what constitutes usual care, including receiving any treatment i.e. acupuncture and manual therapy independently to the trial, during the cohort period.

2. Manual Therapy intervention group (Treatment A):
Manual therapy will take place at a local physiotherapy clinic and be delivered by the physiotherapists inducted into the trial only. Participants allocated to this intervention will follow a programme of ten x 30 minute manual therapy treatment sessions, which will occur weekly wherever possible.

The physiotherapists will provide the manual therapy intervention as they see appropriate to their participant, following the guidance of best practice established for the trial and following their professional governance as required by their professional organisation. It is not permitted however for the physiotherapists to provide acupuncture to this intervention group.

All usual standards of care, protocols and practices will continue to be observed. Participants will also be provided with usual GP care, including the provision of the Back Book as would be expected were they not involved in a trial.

3. Acupuncture intervention group (Treatment B):
Acupuncture will take place at a local physiotherapy clinic and be delivered by the recruited appropriately qualified physiotherapists only. Participants allocated to this intervention will follow a programme of ten x 30 minute acupuncture treatment sessions, which will occur weekly wherever possible.

Acupuncture will be provided as the physiotherapist sees appropriate, following the agreed trial guidance and following their professional governance as required by their professional organisation. It is not permitted however for the physiotherapists to provide manual therapy to this intervention group.

All usual standards of care, protocols and practices will continue to be observed. Participants will also be provided with usual GP care, including the provision of the Back Book as would be expected were they not involved in a trial.

4. Combined Manual Therapy and Acupuncture intervention group (treatment AB):
The combined intervention will take place at a local physiotherapy clinic, delivered by physiotherapists inducted into the trial, trained in manual therapy and acupuncture. Participants allocated to this intervention will follow a programme of ten x 45 minute treatment sessions incorporating both manual therapy and acupuncture. The sessions will occur weekly if possible.

The manual therapy intervention will be delivered in exactly the same way as for the manual therapy intervention group and the acupuncture will be delivered in the same way as for the acupuncture intervention group, within the same treatment session. Treatment will be delivered as the physiotherapist sees appropriate following the trial guidance provided prior to the trial and following their professional governance as required by their professional organisation.

All usual standards of care, protocols and practices will continue to be observed. Participants will also be provided with usual GP care, including the provision of the Back Book as would be expected were they not involved in a trial.

Treatment will aim to be once per week for a ten week period; however a two week threshold allows treatment to be completed if any delayed or missed treatment sessions occur due to sickness or unavailability.

A baseline assessment will be completed. This will be followed up by a postal questionnaire at three months. On completion of the three month questionnaire, eligible and willing participants will be randomised to one of the four groups. The next follow-up will occur at six months; this will coincide with the completion of treatment for the active treatment intervention groups. Further follow-up will occur at, 9, 12, 15 and 18 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To investigate recruitment rates and assess any issues with retention to inform a full scale trial

Secondary outcome measures
To determine the main clinical outcome measure:
1. Roland-Morris disability questionnaire, (specific low back pain measure)
2. Modified Oswestry Disability Index, (specific low back pain measure)
Both outcome measures are frequently used in research and both have been shown to be valid and reproducible, however they each have strengths and limitations in different aspects (Longo, Loppini et al. 2010). As this is a pilot study, both of the above measures will be used, to investigate which would be a more favourable and informative measure to use in a full scale study of manual therapy and acupuncture for the treatment of LBP. A comparison of the two questionnaires to assess their reliability to each other as similar measures for LBP will be performed. Additionally the information gained from the questionnaires will be analysed with regard to usable patient information that could inform a full-scale trial, clinical choice and effectiveness.
3. Visual Analogue Scale (VAS) pain scales, (pain specific measure)
4. SF 12, (quality of life questionnaire)
5. Euro-Qol (EQ-5D), (generic measure of health for clinical and economic appraisal)
6. Patient use of body chart and additional treatment information

Measeured every three months for an 18month period, so baseline, then 3months, 6, 9,12,15,18 months.

Overall study start date
04/04/2011

Completion date
30/10/2011

Eligibility

Key inclusion criteria
1. Individuals aged between 18 - 65 years of age, either sex
2. Individuals registered with a GP practice participating in the trial

3. Individuals who have consulted their GP with mechanical or simple low back pain (LBP) in the preceding eighteen months
4. Individuals suffering with LBP for between six weeks and eighteen months
5. Individuals with referred pain into the leg will be included in the study (if there was no indication of any serious neurological conditions when they were assessed by their GP)
6. Individuals with pain present on assessment and pain that is persistent in nature (i.e. occurring at least once daily for eighty percent of the days in the history of their recent painful episode)
7. Individuals who agree to avoid physical treatments other than the study interventions for the ten to twelve week period of the pilot study (active treatment participants only)
8. Individuals with a score of four or more on the Roland-Morris disability questionnaire at baseline (UkBeam 2004)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Individuals with clinical indications of serious spinal or neurological pathology, as assessed by their GP
2. Individuals with a history of spinal surgery (as this may alter clinical outcome)
3. Pregnant women or those who have given birth in the last twelve weeks (as this may alter clinical outcome)
4. Individuals who had received manual therapy or acupuncture in the preceding three months, (as this may alter clinical outcome)
5. Individuals with blood disorders, receiving anti-coagulants or anti-platelets (as a relative contraindication to acupuncture)
6. Individuals who are immuno-compromised, (as a relative contraindication to acupuncture)
7. Individuals with metal allergy (as a relative contraindication to acupuncture)
8. Individuals who are unable to provide consent
9. Individuals who are unable to converse in English, due to funding limitations of the study
10. Individuals with a history of psychosis or alcohol abuse (due to difficulty in assessing outcome)
11. Individuals who have a needle phobia
12. Individuals with valvular heart disease or demand pacemakers (as an absolute contraindication to acupuncture)

Date of first enrolment
04/04/2011

Date of final enrolment

30/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
AARC Building 2nd Floor
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Sponsor information

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Sponsor type
University/education

Website
http://www.york.ac.uk

ROR
https://ror.org/04m01e293

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RP-PG-0707-10186)

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