ISRCTN49955124 https://doi.org/10.1186/ISRCTN49955124

Evaluating acupuncture and standard care for pregnant women with back pain

Submission date
14/03/2012

Recruitment status
No longer recruiting

Registration date
15/03/2012

Overall study status
Completed

Last Edited
10/03/2020

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Acupuncture is a promising treatment for pregnancy-related back pain. Its use for musculoskeletal problems appears to be increasing and it has been recommended within recent UK national guidelines for the management of persistent non-specific low back pain. Although it is already used by some midwives and physiotherapists to treat pregnancy-related back pain, there is only limited, although promising, evidence supporting its usefulness for this patient group. A large study is now needed to test how well acupuncture works for pregnancy-related back pain and whether it is value for money. This study is a pilot study that aims to ensure that the trial processes are acceptable to pregnant women with back pain and to key healthcare professionals.

Who can participate?
Healthy women aged 18 years and over with pregnancy-related back pain.

What does the study involve?
Phase 1 comprises a national survey of physiotherapists to explore their current management of pregnant women with back pain, and focus group and one-to-one interviews with pregnant women, midwives and physiotherapists. Phase 2 is a pilot study with 180 pregnant women with back pain, identified from community and antenatal clinics in North Staffordshire. Participants will be randomly allocated to receive either usual care, or usual care plus one of two different forms of acupuncture. Outcomes will be assessed at baseline and about 12 weeks after random allocation (to be finalised following the interviews).

What are the possible benefits and risks of participating?
Women participating in the study may benefit from reduced pain and improved function. Previous research has found acupuncture to be safe for pregnancy-related back pain in terms of adverse influences on the pregnancy, mother, delivery or the baby.

Where is the study run from?
Arthritis Research UK Primary Care Centre, Keele University (UK)

When is the study starting and how long is it expected to run for?
June 2012 to June 2014

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment Programme (UK)

Who is the main contact?
Prof. Nadine Foster

Contact information

Type(s)
Scientific

Contact name
Prof Nadine Foster

Contact details
Arthritis Research UK Primary Care Centre
Keele University
Keele
United Kingdom
ST5 5BG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 10/69/05

Study information

Scientific Title
Evaluating Acupuncture and Standard carE for pregnant women with BACK pain (EASE BACK): a feasibility and pilot study

Acronym
EASE BACK

Study objectives
More than two-thirds of pregnant women experience back pain that interferes with everyday activities, work and sleep. It appears that most women do not receive much in the way of treatment for this problem but are given advice about self-management and those with the most severe pain and functional problems are referred to physiotherapists in the NHS. Acupuncture appears a safe, promising intervention from previous research and is already used

by NHS physiotherapists for these women but there are no high quality trial data, with long term follow-up, regarding its clinical or cost-effectiveness, in comparison to standard care.

We hope to address the question of the short and long-term clinical and cost-effectiveness of acupuncture versus standard care in a future randomised controlled trial in the NHS. Before we can finalise the plans for the main trial, however, a feasibility and pilot study is needed to ensure the trial recruitment processes, interventions and outcomes are acceptable to pregnant women with back pain and to key health care professionals, and to inform the sample size needed for the future large trial.

This feasibility and pilot study will inform the main EASE BACK trial by:
1. Providing generalisable data on current UK physiotherapy-led standard care and acupuncture treatment for the management of low back pain (with and without pelvic girdle pain) in pregnant women.
2. Exploring the views of pregnant women with low back pain about the acceptability of the proposed interventions (standard care and acupuncture treatment), the content and delivery of participant information to support the randomised trial, the outcomes most important to them and the most appropriate timing of outcome measurement.
3. Optimising the trial information, recruitment and consent procedures by learning what works best from the perspectives of pregnant women with low back pain and midwives in the pilot study.
4. Investigating the views of NHS health care professionals regarding i) the acceptability and feasibility of referring women with low back pain in pregnancy to physiotherapists for acupuncture treatment; ii) the proposed trial design and interventions and iii) ways in which to maximise recruitment and retention to a trial.
5. Testing the trial procedures, training programme for health care professionals, interventions and outcomes with 180 women identified from general practice and antenatal clinics in up to two centres within the West Midlands North Comprehensive Local Research Network, providing data on likely recruitment and follow-up rates for the main trial plus completion rates on key outcomes and an estimate of likely effect size difference between the intervention (standard care plus acupuncture) and control (standard care) arms.
6. Bringing the above findings together, with experts in the fields of standard care, acupuncture and trial design, in a consensus conference event to finalise the design, interventions, sample size, outcome measures and operational aspects (recruitment methods, participant information and consent procedures, randomisation and allocation concealment) of the main EASE BACK trial.

If the feasibility and pilot study shows that acupuncture treatments are felt to be acceptable to these women and health professionals, that our methods for identifying and recruiting eligible women and of assessing their symptoms and responses to treatment are acceptable, and that sufficient proportions of women agree to participate in a trial, then we will have confidence that a future main trial will be achievable in the NHS. The outcome of the feasibility and pilot study will therefore be a clear plan for the main EASE BACK trial that can be submitted for funding.

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/106905/#/

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West, ref: 12/NW/0227

Study design
Feasibility study using survey and focus group or one to one interviews, plus a single centre pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Pregnancy-related back pain

Interventions
1. Standard Care (SC):
A written package of education and advice about self-management plus onward referral, if necessary, for physiotherapy as per usual care.
2. Standard Care (SC) plus True Acupuncture:
The same advice and education package will be provided to women randomised to SC plus true acupuncture, delivered by fully trained NHS physiotherapists over 8 to 10 treatment sessions.
3. Standard Care (SC) plus Non-Penetrating Acupuncture:
This will be the same as SC plus true acupuncture, however, instead of acupuncture needles that penetrate the skin, sham acupuncture needles will be used. These look exactly like a real needle but have a blunted tip, and is tapped onto the skin, held in place by an O ring, and gives the illusion of needle insertion.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pain severity, measured by a pain index (mean of three numerical rating scales (NRS) of least, usual and current pain)
2. Disability, measured by the Oswestry Disability Index and the Disability Rating Index, at baseline and at no later than 12 weeks after randomisation (this will be informed by qualitative research with women)

Secondary outcome measures

1. Worst pain before going to bed
2. Ability to sleep through the night
3. Pain location
4. Global rating of change
5. Pain in other bodily regions
6. Medication
7. Satisfaction with work
8. Work loss
9. Quality of life
10. Health care utilisation since baseline
11. Treatment credibility
12. Satisfaction with care
13. Satisfaction with outcomes and adverse events

Overall study start date
01/02/2013

Completion date
01/12/2013

Eligibility

Key inclusion criteria
1. Healthy women with pregnancy-related back pain (with or without pelvic PGP) as determined by their self-reported pain location on a pain drawing/body chart
2. Aged 18 years and over
3. At 13 to 31 weeks gestation
4. Naïve to acupuncture treatment
5. Able to communicate in English (to complete the baseline and outcome assessments)
6. Willing to participate

Women who have had low back pain episodes before this pregnancy are suitable for inclusion as long as the current episode of low back pain is attributed to this pregnancy.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
180

Total final enrolment

Key exclusion criteria
1. Women who have had acupuncture previously for any health problem
2. Those at high risk of pre-term labour (previous pre-term labour, multiple pregnancies, polyhydramnios, pre-term ruptured membranes)
3. Those with diagnosed pre-eclampsia
4. Previous history of surgery to the spine or the pelvis
5. Women who have contra-indications to any of the treatments (coagulation problems, haemophilia or bleeding disorders)
6. Those at increased risk of infection such as skin infections or loss of skin integrity from burns or
ulcerations at the site of needling)
7. Those with needle phobia
8. Those with pelvic girdle pain (PGP) or pubic symphysis pain

Date of first enrolment
01/02/2013

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele University
Keele
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

Sponsor details
c/o Ms Rhian Hughes
Arthritis Research UK Primary Care Centre
Keele
England

United Kingdom
ST5 5BG

Sponsor type
University/education

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

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	01/04/2016		Yes	No
Results article	results	12/12/2016		Yes	No
Results article	results	25/11/2019	10/03/2020	Yes	No