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Complementary and Alternative Medicine (CAM) for the management of low back and/or pelvic pain (LBPP) in pregnancy

Submission date
14/11/2012

Recruitment status
No longer recruiting

Registration date
06/12/2012

Overall study status
Completed

Last Edited
06/07/2018

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
More than two thirds of women experience low back pain and one fifth experience pelvic pain during pregnancy. At present there is no treatment guideline for managing low back and/or pelvic pain (LBPP) in pregnancy and as a result treatment and management strategies vary considerably. Complementary and Alternative Medicine (CAM) is a popular method of managing LBPP with 1 in 4 of women using at least one form of CAM despite the limited evidence demonstrating the effectiveness of CAM for LBPP in pregnancy. The aim of this study is to determine the feasibility of completing a fully powered study investigating the effectiveness of reflexology as an addition to usual care in the management of low back and/or pelvic pain in pregnancy.

Who can participate?
The CAM in pregnancy study aims to recruit 90 first time expectant mothers experiencing LBPP from ante-natal clinics in the South Eastern Health and Social Care Trust (SEHSCT).

What does the study involve?
Over a period of 18 months, first time expectant mothers experiencing LBPP will be invited to take part in the CAM in pregnancy study in the third trimester of their pregnancy. All potential participants will be invited to an initial meeting with the research team, where they will be asked to complete a series of questionnaires and assessments relating to low back and/ or pelvic pain in their pregnancy. At the end of this meeting participants will be randomly allocated to a specific group either reflexology, footbath or usual care only. Participants allocated to the reflexology group will receive six weekly reflexology treatments. Participants allocated to the footbath group of the study you will receive six weekly foot bath treatments. At the first and last reflexology and footbath treatments participants will be asked to provide a 2ml saliva sample before and after treatment. This will be stored and tested in the laboratory at the University of Ulster for natural bodily substances that may indicate levels of stress and pain. Before and after every reflexology or footbath treatment blood pressure, heart rate and foetal heart rate will be measured. Participants in the reflexology and footbath groups will be asked at each weekly treatment to complete two questionnaires, one about the intensity and frequency

of their pain and another on the type of pain they experienced in the past week. Those allocated to the usual care group will receive the usual care for low back and/or pelvic pain, there will be no additional intervention (treatment) provided from this research team. Participants in the usual care group will be asked to provide two saliva samples, one 2ml saliva sample at the initial meeting with the research team and another six weeks later. They will be asked to complete two questionnaires each week at home, one on the intensity and frequency of their low back and/ or pelvic pain and the other on the type of pain they experienced that week. They will also be asked to keep a weekly log of any treatments used to manage low back and/ or pelvic pain. A complimentary reflexology treatment will be offered to usual care participants at the end of the six week study period in appreciation for their participation in the study. At the end of six weeks all participants will be required to repeat the questionnaires from the initial meeting. Reflexology and footbath participants will repeat these at their last treatment. Usual care participants will be asked to return to the hospital to complete these. Further follow ups will take place 6 weeks and 6 months post-delivery.

What are the possible benefits and risks of participating?
The main possible benefit of taking part in this research is that low back and / or pelvic pain in pregnancy may be reduced. Also reflexology and footbaths are known to be relaxing and pleasant experiences, so by taking part in this study participants may feel more relaxed. Reflexology and footbaths are safe and natural treatments and there are no obvious disadvantages or risks to taking part in the study. The reflexologist in this study is an experienced and fully qualified maternity reflexologist. The footbath that will be used is completely natural and is not an electrical appliance. Those in the usual care group will continue with the usual treatment for low back and/ or pelvic pain within the maternity hospital, which poses no risk.

Where is the study run from?
The CAM in pregnancy study has been set up by the University of Ulster, in collaboration with South Eastern Health and Social Care Trust.

When is the study starting and how long is it expected to run for?
The study began in July 2012 and is expected to run until end of December 2013. Participants will be enrolled in the study for a period of 10 months approximately.

Who is funding the study?
Funding has been provided by the Department of Employment and Learning in Northern Ireland.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Dr Elaine Madden

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Complementary and Alternative Medicine (CAM) as an addition to usual care for the management of low back and/or pelvic pain in pregnancy: A feasibility randomised controlled trial (RCT) investigating the effectiveness of reflexology as an addition to usual care for the management of low back and/or pelvic pain (LBPP) in the third trimester of pregnancy

Study objectives
It is hypothesised that it is feasible to carry out a fully powered randomised controlled trial (RCT) to determine the effectiveness of reflexology as an addition to usual care in the management of LBPP in pregnancy, in a maternity department in Northern Ireland.

The null hypothesis is that it is not feasible to carry out a fully powered RCT to determine the effectiveness of reflexology in the management of low back and/ or pelvic pain in pregnancy in a maternity department in Northern Ireland.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Univerity of Ulster School of Health and Rehabilitation Sciences Filter Committee, 06/02/2012
2. Office of Research Ethics Northern Ireland, 05/07/2012, ref: 12/NI/0052
3. South Eastern Health and Social Care Trust, 19/07/2012, ref: SET/12/10

Study design
Single-centre feasbility randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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 and/or pelvic pain in pregnancy

Interventions
Three groups in the study, reflexology (intervention), footbath (sham) and usual care only (control)

Reflexology and footbaths will be administered once a week over a 6 week period and will last a maximum of 45 minutes.

Folllow up will take place at the end of the intervention period, 6 weeks and 6 months post delivery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pain - using a 0-10 visual analogue scale where 0= no pain and 10 = worst pain possible, at baseline, end of 6 week intervention period, 6 weeks and 6 months post delivery

Secondary outcome measures
1. Back specific function using the Roland Morris Disability Questionnaire at baseline, end of 6 week intervention period, 6 weeks and 6 months post delivery
2. Quality of life using The Pregnancy Mobility Index at baseline, end of 6 week intervention period, 6 weeks and 6 months post delivery
3. Type of pain using the McGill Pain Questionnaire at baseline, end of 6 week intervention period, 6 weeks and 6 months post delivery
4. Stress and anxiety using The State Trait Anxiety Inventory at baseline, end of 6 week intervention period, 6 weeks and 6 months post delivery

Overall study start date
01/07/2012

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. First time pregnant women
2.18 years of age or older
3. Presence of low back pain and/or pelvic pain
4. 20-29 weeks gestation
5. Able to understand written and verbal English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
90

Key exclusion criteria
1. Women pregnant with more than one baby
2. Smokers
3. Women with neurological diseases
4. Deep Vein Thrombosis (DVT) sufferers
5. Women with fungal foot infections or verrucae
6. Women currently using CAM therapies
7. Placenta Previa (low lying Placenta) Grade 3 or 4
8. Women already participating in a research study
9. Women with any serious spinal pathology e.g. cancer, Cauda Equina, infection in the spine
10. Those in a previous road traffic accident which resulted in LBPP or unresolved symptoms

Date of first enrolment
01/07/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Ulster Hospital
Belfast
United Kingdom
BT16 1RB

Sponsor information

Organisation
University of Ulster (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name

Department of Employment and Learning Northern Ireland (UK)

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	01/12/2017		Yes	No