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Self-Hypnosis for Intrapartum Pain management (SHIP) trial

Submission date
29/01/2011

Recruitment status
No longer recruiting

Registration date
25/03/2011

Overall study status
Completed

Last Edited
25/07/2016

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
Self-hypnosis is a way of training the mind and body to experience things differently. It usually involves listening to a voice on a tape or CD which gives hints and suggestions about how to change unhelpful ways of thinking. By listening to the CD regularly the belief is that the listener will 'absorb' the suggestions and their experience will change. It is sometimes used by health professionals to help people give up smoking or to reduce their fear of flying. Recent studies have shown that self-hypnosis can be used successfully to treat the pain associated with chronic gastro-intestinal complaints like Irritable Bowel Syndrome and Crohn's Disease. In this study we would like to find out if self-hypnosis could help women to deal with the pain associated with labour and childbirth. Our theory is that if women feel more relaxed and in control during labour then they are less likely to experience intense pain and less likely to need medical assistance or even surgery. So far there have been few studies conducted in this area and most of them have been small or of poor quality. However, the results have been encouraging and we would like to find out if this would be an effective way of providing pain relief to pregnant women in the UK.

Who can participate?
The study will be open to women who are pregnant with their first baby. Most women over the age of 18 and under 40 who do not have any serious medical conditions will be given information about the study and asked if they would like to take part.

What does the study involve?
We are going to offer a group of pregnant women the opportunity to attend a short course explaining how to use self-hypnosis to control the pain associated with childbirth. The course will involve two one hour training sessions with an experienced midwife as well as a self-hypnosis CD to take home and practice with. This group of women will be compared with another (similar) group of pregnant women who will not receive any self-hypnosis training. By comparing the childbirth experiences of the two groups, and paying particular attention to the type of pain relief they receive, we should be able to tell whether self-hypnosis is a useful way of reducing and controlling the pain associated with giving birth.

What are the possible benefits and risks of participating?
There is some evidence to suggest that the more relaxed a woman feels when she goes into

labour then the less likely she is to need pain relief. In theory, women who are able to achieve a deep state of relaxation by using self-hypnosis should need less pain relief. This means they are less likely to require more risky medical or surgical assistance and more likely to make a quick recovery following the birth of their baby. Because self-hypnosis is a simple and natural way of achieving a relaxed state it is a safe technique with little or no side-effects and, as far as the NHS is concerned, it is a much cheaper way of providing pain relief.

Where is the study run from?
The study will be organized by East Lancashire Hospitals NHS Trust which provides maternity services at two locations in Blackburn and Burnley. The University of Central Lancashire in Preston will provide support and research expertise.

When is the study starting and how long is it expected to run for?
The study starts in August 2010 and is expected to be completed by June 2013. Participants will be recruited into the study over a 2 year period beginning in December 2010 and ending in December 2012.

Who is funding the study?
The National Institute of Health Research (NIHR)

Who is the main contact?
Professor Soo Downe
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PB-PG-0808-16234

Study information

Scientific Title
Self-Hypnosis for Intrapartum Pain management (SHIP): a single organisation, two-site pragmatic exploratory non-blinded randomised controlled trial with blinded analysis based on intention to treat, and contextualised by interviews, focus groups, logs, and questionnaires

Acronym
SHIP Trial

Study objectives
There will be no difference in rates of epidural usage in labour for maternal request between women randomised to an antenatal group self-hypnosis programme and those randomised to usual care.

Please note that as of 08/01/2013, the following changes were made to the record:
1. The overall trial end date was changed from 31/07/2012 to 01/06/2013.
2. The target number of participants was updated from 800 to 600.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NHS IRAS Ethics Committee System approved
2. University of Central Lancashire Faculty of Health Ethics Committee approved

Study design
Multicentre pragmatic exploratory non-blinded 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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Intrapartum maternity care

Interventions
Intervention group:
1. Each group hypnosis programme will be provided by one of 4 midwives with appropriate training
2. They will not be present during the labour and birth of study participants
3. The programmes will be provided in addition to usual care
4. Each programme will be delivered on one of the two Trust sites, with evening or weekend options, to groups of 5 - 10 women and their planned birth companions (a total maximum of 20 people) in 2 sessions separated by 3 weeks (32 weeks gestation, 35 weeks gestation
5. Each session will last 90 minutes
6. Four sets of hypnosis programmes will be run every 4 weeks with evening and weekend options
7. The hypnosis scripts will be adapted from those tested in the current Australian Hatch Trial
8. The sessions will include self-hypnosis induction techniques, exercises relating to confidence, coping and strength in labour, suggestions for time distortion, a labour rehearsal involving recurrent fractionation and staircase imagery, and pain control and dissociation techniques. Participants will also be asked to listen to a CD of reinforcement exercises at least once a day until their baby is born

Control group:
'Usual care' will consist of attendance at any antenatal classes usually offered to nulliparous women, and standard clinical care

Women in both groups will be free to request any additional pain relief they require during labour, and this will be emphasised in the information leaflets.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rates of epidural usage in labour for maternal request

Secondary outcome measures
1. Mode of birth and other maternal labour outcomes
2. Neonatal wellbeing
3. Participants preferences relating to hypnosis
4. Anxiety and fear about labour
5. Recall of labour pain
6. Ability to manage labour
7. Satisfaction with self during labour
8. Clinical and psychological morbidity and well-being
9. Economic cost-benefit analysis
10. Experiences of women, their birth companions, and their caregivers
11. Follow up will continue to 6 weeks postnatal

Overall study start date

01/08/2010

Completion date
01/06/2013

Eligibility

Key inclusion criteria
All nulliparous women who:
1. Have a singleton, viable, cephalic pregnancy
2. Are planning a vaginal birth in hospital
3. Have no current history of being under treatment for psychiatric disorders or of hypertensive disorders
4. Speak and read English
5. Consent to take part
6. Who are available to attend the intervention sessions
7. Aged between 18 and 45 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
600 (680 by end of recruitment, 343 randomised to the self-hypnosis intervention and 337 in the control group)

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/12/2010

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Central Lancashire
Preston
United Kingdom
PR1 2HE

Sponsor information

Organisation
East Lancashire Hospitals NHS Trust (UK)

Sponsor details
Research and Development Office
Level 3, Royal Blackburn Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.elht.nhs.uk/

ROR
https://ror.org/002pa9318

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0808-16234)

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	18/11/2015		Yes	No