

Evaluation of bespoke training to midwifery teams to increase membrane sweeping to reduce induction of labour

Submission date 17/08/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/08/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/02/2018	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A membrane sweep is a medical procedure that can be used to induce labour at the time the baby is due. A midwife usually carries this out by placing her finger into the vagina and up into the cervix. She then makes a sweeping movement with her fingers to separate the sac surrounding the baby from the cervix. It also helps to release natural hormones that help to get the labour started. Membrane sweeps are known to reduce the need to induce labour by other less acceptable means (such as drugs). This study is looking to see whether a bespoke training package for community midwife teams, together with a leaflet for women and a lead midwife for each midwife team would increase the number of women being offered membrane sweeping at term as an alternative to inducing labour by other means.

Who can participate?

Community midwifery teams where it was felt that membrane sweeping wasn't being done according to NICE and Trust Guidance.

What does the study involve?

In order to find out whether the training session works, the date of training for the midwifery teams involved is decided randomly. The training includes practical tips to support practice and a leaflet to be given to pregnant women to make them aware of the procedure. A midwife from each team is selected to be "Champion"; her role is to become the expert in her team for clinical queries and to train and remind the other members of the team. Information from hospital notes about whether women had been offered membrane sweeping for three months before and three months after the training session is then collected for each team.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Birmingham Womens NHS Foundation Trust and the Birmingham Heartlands Hospital (UK)

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

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Sara Kenyon

Contact information

Type(s)
Scientific

Contact name
Dr Sara Kenyon

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12/BWH/SE50

Study information

Scientific Title
Evaluation of bespoke training to midwifery teams to increase membrane sweeping to reduce induction of labour: a stepped wedge cluster randomised trial

Study objectives
Evaluation of a bespoke training package to community midwifery teams, together with a leaflet for women and a lead midwife in each team would improve the numbers of women offered membrane sweeping at term to reduce induction of labour

Ethics approval required

Old ethics approval format

Ethics approval(s)

This was a service evaluation and ethics approval was not required.

Study design

Stepped wedge cluster randomised trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Induction of labour

Interventions

A training session was developed for community midwives to try to improve the numbers of women offered and accepting membrane sweeping to reduce induction of labour when the baby is due (term). National guidance recommends women are offered this at term as evidence suggests that it reduces induction of labour which is associated with more interventions.

The date of training for 10 teams of midwives was randomised and information collected from hospital notes about whether women had been offered membrane sweeping for three months before and three months after the training session.

The intervention consisted of:

1. A generic training package (developed by those leading the evaluation) containing evidence, practical tips to support practice, and a leaflet for women, which addressed issues identified from an earlier discussion group.
2. A lead midwife (Champion) was identified in each team to be an expert for clinical queries, and to train and remind staff.

Randomisation was performed in Stata at a single point in time by the study statistician. Each of the 10 midwifery teams were allocated a unique ID. These ten unique IDs were then randomly allocated to provide the order in which the teams would be trained. The community teams were informed of their allocation date in sequential order once the previous team had set the date for training (a two week period when training should be undertaken).

Intervention Type

Behavioural

Primary outcome measure

1. Proportion of women offered and accepting a membrane sweep
2. Average number of sweeps per women

Data was extracted from hospital notes

Secondary outcome measures

1. Onset of labour
2. Mode of birth
3. Adherence to Trust guidance
4. Sweeps offered but declined
5. Location of the sweep (community or hospital)
6. Reason if sweeping was abandoned

Data was extracted from hospital notes

Overall study start date

01/01/2012

Completion date

01/12/2014

Eligibility**Key inclusion criteria**

1. Community midwifery teams were included in Trusts/ Units where membrane sweeping was felt not to be done according to NICE and Trust Guidance
2. Eligible women included all those who gave birth over 39+3 weeks at BWNFT or BHH within the study period (March to November 2012). Women were included who gave birth after 39+3 weeks (rather than over 40 weeks) as it is plausible that women were not swept on exactly the correct day (i.e. 40 or 41 weeks), so a sweep from 39+4 to 40+3 was considered a sweep at 40 weeks, and 40+4 to 41+3 was considered a sweep at 41 weeks

Participant type(s)

Health professional

Age group

Adult

Sex

Female

Target number of participants

10 community teams. 2,787 women were included in the analysis (1,420 women before training and 1,367 after).

Key exclusion criteria

1. Community midwifery teams already undertaking membrane sweeping or women who were not eligible for membrane sweeping
2. Women were excluded if they were from outside the area or had an elective CS.

Date of first enrolment

05/03/2012

Date of final enrolment

26/11/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Birmingham Womens NHS Foundation Trust

Mindelsohn Way

Birmingham

United Kingdom

B15 2TG

Study participating centre

Birmingham Heartlands Hospital

Bordesley Green E

Birmingham

United Kingdom

B9 5SS

Sponsor information

Organisation

Birmingham Women's NHS Foundation Trust

Sponsor details

Mindelsohn Way

Birmingham

England

United Kingdom

B15 2TG

Sponsor type

Hospital/treatment centre

ROR

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Our intention is to publish in peer-reviewed scientific journals

Intention to publish date

19/08/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/07/2017		Yes	No