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Place of birth choices for healthy low-risk women: A comparison of a standalone e-learning package or an e-learning package with additional support from a lead midwife to evaluate the knowledge of community midwives

Submission date
02/03/2020

Recruitment status
Suspended

Registration date
06/04/2020

Overall study status
Stopped

Last Edited
28/04/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Informed discussion between community midwives and healthy low risk women about their options for giving birth is important in helping parents decide where to give birth. There is evidence to suggest that this discussion does not always take place. A previous study suggested that a knowledge update session together with ongoing support from a Place of Birth lead midwife in each team improved the knowledge and confidence of community midwives. Four maternity units (Royal Wolverhampton NHS Trust, Walsall Healthcare NHS Trust, Dudley Group NHS Foundation Trust, and Sandwell and West Birmingham Hospitals NHS Trust) that make up the Black Country Local Maternity System (LMS) decided to make completing an e-learning session mandatory for all their community midwives. The Black Country LMS Heads of Midwifery were keen to test whether having a place of birth lead midwife further improves fact based knowledge. The aim therefore of the BEEM study is to evaluate whether a Place of Birth lead in community midwifery teams further improves the fact based knowledge of community midwives compared to completing the e-learning session alone. To do this we are undertaking a cluster controlled randomised trial, which takes account of the issue that using a questionnaire in itself before and after training is likely to improve knowledge.

Who can participate?
All community midwives (Band 5, 6 and 7) working in a specified Local Maternity System.

What does the study involve?
Each community midwifery team in the Black Country LMS will be randomly allocated to one of four possible options:
1. Doing the e-learning package and a post-questionnaire to examine fact-based knowledge and confidence of community midwives six months later
2. Doing a pre-questionnaire to examine fact-based knowledge and confidence of community

midwives before doing the e-learning package and then another questionnaire six months later
3. Having the Place of Birth lead midwife in the team who will support and encourage the midwives as well as doing the e-learning package and post-questionnaire six months later
4. Having a Place of Birth midwife in the team who will support and encourage the midwives as well as doing a pre-questionnaire to examine the fact-based knowledge and confidence of community midwives before they do the e-learning package and then a post-questionnaire six months afterwards

For those teams randomised to having a Place of Birth team lead will appoint a community midwife from the team who will complete an additional e-learning package to train for the role. They will then be responsible for encouraging midwives in their team to complete the e-learning session and questionnaire(s) as well as support and encourage colleagues to talk to women about their place of birth options. They will use provided materials to facilitate six monthly sessions (10 to 20 minutes each) usually as part of the routine team meeting and remind of the importance of the Place of Birth discussions as well as act as an expert for any queries the midwives have.

For the community teams not randomly allocated to having a place of birth lead, the community midwife team lead will encourage team members to complete the elearning package and relevant questionnaire(s). They will not complete any additional follow up sessions.

Following completion of the study, two focus groups will be conducted in each Trust in order to explore the experiences and practices of community midwives in connection with Place of Birth discussions: one for those who have had a Place of Birth lead and one for those who have not. In addition, a further focus group from across the LMS will be conducted for the Place of Birth leads. Each focus group session will be recorded and conducted by a member of the research team, last approximately 30 to 60 minutes and will have a mixture of closed and open questions.

What are the possible benefits and risks of participating?
The potential benefits are improved knowledge and confidence to discuss place of birth options with mothers. There are no risks to taking part in the study.

Where is the study run from?
1. New Cross Hospital (UK)
2. Manor Hospital (UK)
3. Russells Hall Hospital (UK)
4. Birmingham City Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2020 to May 2021

Who is funding the study?
NIHR Applied Research Collaboration (ARC) West Midlands (UK)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
272343

Protocol serial number
Protocol V 2.0 14.01.2020

Study information

Scientific Title
Place of Birth choices for healthy low-risk women: A comparison of a standalone E-Learning package or an e-learning package with additional support from a lead midwife to Evaluate the knowledge of community Midwives- a randomised cluster controlled trial incorporating a modified solomon design: The BEEM trial

Acronym
BEEM

Study objectives
The objective of this research is to evaluate whether a Place of Birth lead midwife in addition to a mandated e-learning session further improves the fact based knowledge of community midwives.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 04/11/2019, University of Birmingham REC (Sue Cottam – Research Ethics Manager Aston Webb Building, University of Birmingham, Edgbaston B15 2TT, UK; +44 (0)121 414 8825; s.l.cottam@bham.ac.uk), ref: ERN_19-1382
2. Approved 16/01/2020, HRA and Health and Care Research Wales (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; no tel. provided; hra.approval@nhs.net), ref: ERN_19-1382

Primary study design
Interventional

Study design
Randomized cluster controlled trial incorporating a modified Solomon design with qualitative follow-up

Study type(s)
Other

Health condition(s) or problem(s) studied
Knowledge of community midwives

Interventions
The intervention is the Place of Birth Lead.

The unit of randomisation will be the community midwifery team within each of the four participating NHS Trusts, stratifying within each to ensure that each Trust has the opportunity to have a Place of Birth lead midwife within a randomised number of teams, as these vary in number and size. Individual randomisation of community midwives to the Place of Birth lead was not feasible due to the nature of the intervention (Place of Birth lead) and risk of contamination during the trial.

To measure the knowledge of the community midwives we will use the same short fact-based questionnaires completed over the three-week period immediately before the e-learning session is undertaken and again six months later. These have been developed by the study team and include key facts which midwives should be aware of in order to speak to healthy low risk women about their place of birth options. The Solomon design has been modified as all teams will complete the e-learning training session.

Each community midwifery team will be randomly allocated to one of four possible arms:
1. Doing the e-learning package and a post-questionnaire to examine fact-based knowledge and confidence of community midwives six months later
2. Doing a pre-questionnaire to examine fact-based knowledge and confidence of community midwives before doing the e-learning package and then another questionnaire six months later
3. Having the Place of Birth lead midwife in the team who will support and encourage the midwives as well as doing the e-learning package and post-questionnaire six months later
4. Having a Place of Birth midwife in the team who will support and encourage the midwives as well as doing a pre-questionnaire to examine the fact-based knowledge and confidence of community midwives before they do the e-learning package and then a post-questionnaire six months afterwards

Qualitative follow-up:

Intervention Type
Other

Primary outcome(s)
Fact based knowledge of community midwives measured using anonymous completion of a fact-based knowledge questionnaire in a three-week period before the e-Learning session is undertaken and again six months afterwards

Key secondary outcome(s)
1. Knowledge improvement with E-Learning session alone by anonymous completion of a fact-based knowledge questionnaire in a three-week period before the e-Learning session is undertaken and again six months afterwards
2. Self-rated confidence of community midwives by anonymous completion of a 5 point Likert scale in a three-week period before the e-Learning session is undertaken and again six months afterwards
3. Experiences of community midwives whose teams are randomised to a Place of Birth lead midwife and those who are not by qualitative data obtained from focus groups with community midwives whose teams had a Place of Birth lead and those who are not. Focus groups will be undertaken after the six-month intervention period
4. Experiences of the Place of Birth lead midwives using qualitative data obtained from focus groups with Place of Birth leads undertaken after the 6 month intervention period
5. Responses to the ‘Safety thermometer’ question ‘Did anyone explain your options for where you could give birth?’ This is a set of questions that are routinely given to a sample of women and which will continue over the six-month intervention period. This information is recorded monthly by the Trust and data will be given to UoB after the six month intervention period

Completion date
31/05/2021

Reason abandoned (if study stopped)
There have now been changes to the community midwifery teams across the participating trusts that do not enable the trial to go ahead as previously planned.

Eligibility

Key inclusion criteria
All community midwives (Band 5, 6 and 7) working in a specified LMS

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Community midwives who are Band 8 and above
2. Student midwives

Date of first enrolment
01/07/2020

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
New Cross Hospital
Royal Wolverhampton NHS Trust
Wolverhampton Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Manor Hospital
Walsall Healthcare NHS Trust
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
Russells Hall Hospital
Dudley Group NHS Foundation Trust
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Birmingham City Hospital
Sandwell & West Birmingham Hospital NHS Trust
Dudley Road
Birmingham
United Kingdom
B18 7QH

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Applied Research Collaboration (ARC) West Midlands

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to limited interest.

IPD sharing plan summary
Not expected to be made available