ISRCTN18018389 https://doi.org/10.1186/ISRCTN18018389

Antenatal Care Education (ACE): The co-design and piloting of interventions to improve patient and staff experience through better birth preparedness

Submission date
15/07/2019

Recruitment status
Suspended

Registration date
16/07/2019

Overall study status
Completed

Last Edited
21/05/2020

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
Many women have a positive experience of birth, however some identify a gap between their expectations of birth and what happens. This mismatch has been linked with poor experience, distress and anxiety. Being well informed, having coping strategies and feeling in control during labour can enable a positive birth experience. Antenatal education is available. However, not all women attend the NHS classes and the content varies. As there is limited time to deliver this education, it is important that it is evidence-based, effective and efficient.

Who can participate?
To understand the current antenatal education, we will gather the opinions of women and staff about antenatal education.
To develop the intervention, we will invite women, their birth partners and staff from North Bristol NHS Trust, to take part in public patient involvement, alongside organisations advocating for women.

What does the study involve?
We will talk with patients about the current antenatal education at North Bristol NHS Trust
We will collaborate with women, birth-partners, organisations and staff to co-design a two hour antenatal education session and a short intervention to enable staff to support the coping strategies discussed in the session.
To understand antenatal education there will be 1-2 hour long focus groups with women and staff.
To test the intervention and compare it to standard care we will ask women to complete questionnaires before and after their session and 2 and 6 weeks after the birth of their baby. Birth partners will be asked to complete a questionnaire. We will ask staff to complete a questionnaire before and after attending a session, and one at 2 months.

What are the possible benefits and risks of participating?
Benefits of participating: Women, partners and staff will be participating in a study that may directly benefit their pregnancy experience. However, as the classes will only run in three of the community midwifery sites, it may be that women and partners are participating to benefit women in future.
Risks of participating: Women and staff will be asked to give their time. Women will be asked questions about their experience and levels of anxiety, depression and trauma. This may mean that women think about these issues more, or identify that they are struggling with them. As part of their clinical care team, we will take steps to support women if this happens.

Where is the study run from?
Southmead Hospital, Bristol, UK

When is the study starting and how long is it expected to run for?
July 2019 to August 2020

Who is funding the study?
1. Health Foundation
2. The David Telling Charitable Trust

Who is the main contact?
Dr Abi Merriel
abi.merriel@bristol.ac.uk

Study website
https://www.nbt.nhs.uk/research-innovation/our-research/current-research

Contact information

Type(s)
Scientific

Contact name
Dr Abi Merriel

ORCID ID
http://orcid.org/0000-0003-0352-2106

Contact details
Population Health Sciences
University of Bristol
Department of Women's and Children's Health
The Chilterns
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
07740334922
abi.merriel@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
41821

Study information

Scientific Title
Antenatal Care Education (ACE): The co-design and piloting of interventions to improve patient and staff experience through better birth preparedness

Acronym
ACE

Study objectives
A co-designed antenatal and staff intervention can be implemented into practice and improve women's experience.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/06/2019, NHS HRA (South West - Frenchay Research Ethics Committee, Level 3, Block B
Whitefriars, Lewins Mead, Bristol, BS1 2NT; nrescommittee.southwest-frenchay@nhs.net; 0207 104 8210), ref: 19/SW/0073

Study design
Non-randomised; Both; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Management of Care, Qualitative

Primary study design
Other

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

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
Childbirth

Interventions
There are 5 parts to this study, which will enable us to build up a clear picture of antenatal education in the UK. The multiple designs have been selected carefully to ensure that we develop a detailed picture of what women want locally. Further to this, we will ensure that we situate the design of the final interventions in the national situation. The contact these work packages enable with other NHS organisations and stakeholders in antenatal education will try to ensure that we harness existing resources.
Work package 1: focus group sessions: women from antenatal classes
Work package 2: qualitative study of staff's perspectives of antenatal education
Work package 3: cognitive interviewing and testing of pilot tool for measuring expectations
Work package 4: controlled pilot study of antenatal education session for women
Work package 5: pilot study of intervention for staff

Focus Groups with Women (Work Package 1), Research and clinical staff on the research team from NBT and UoB at an NBT/Community site
Focus Groups with Staff (Work Package 2), Research and clinical staff on the research team from NBT and UoB at an NBT/Community site
Think Aloud Interviews with Women (Work Package 3), Research and clinical staff on the research team from NBT and UoB at an NBT/Community site; Expectations of birth questionnaire (Work Package 4), The women will complete a questionnaire on paper or online before the session and 1-2 weeks after the session.
Staff Intervention feedback (Work Package 5), Staff will be asked to complete a feedback form immediately following the intervention, in whichever clinical area the intervention takes place. A member of the study team will collect these responses.
Staff satisfaction with work scale (Work Package 5), Staff will be asked to complete the questionnaire twice either on paper prior to the session or online. They will then be asked to complete it again 2-3 months after the intervention.
Staff pilot intervention (Work Package 5), Staff will be invited to attend a brief intervention about coping strategies delivered at NBT in the clinical areas in which staff work. The intervention will be delivered by a member of the research team.
Feedback about sessions from women and birth partners (Work Package 4), We will ask women to complete the questionnaire immediately following the session which takes place at at an NBT /Community site
Clinical Information about delivery (Work Package 4), This will be collected from case notes by clinical members of the research team. However, for women who have their baby outside of NBT, we will phone the women at the same time as the follow up questionnaires and ask them for the information.
Outcome assessment (Work Package 4), This will be a paper, online or telephone completion of a questionnaire by the women whilst they are at home at 2 and 6 weeks postnatal.
Staff debrief (Work Package 4), Members of the research team will debrief community midwifery staff delivering the intervention using a structured debrief form at an NBT /Community site where the session has taken place
Staff delayed intervention feedback (Work Package 5), Staff will be asked to complete a feedback form 2-3 months following the intervention, either on paper or online.

Pilot or standard antenatal education intervention (Work Package 4), Community Midwives who will routinely deliver care, will deliver either their standard or the new intervention at an NBT /Community site

Intervention Type
Other

Primary outcome measure
The main outcome for the study will be the production and piloting of the interventions, there will be no primary outcome as the study is not powered to detect any differences, as it is pilot work.

Secondary outcome measures
For WP1 & 2 the outcomes will be an understanding of the current landscape of women's antenatal education, coping strategies and expectations.
For WP3 we will produce an expectations questionnaire.
For WP 4:
Process Measures:
4.1 Number of women and partners attending the sessions
4.2 Immediate feedback on the intervention from women and partners
4.3 Delayed feedback on the utility of the intervention via a postnatal survey at 2 and 6 weeks.
4.4 Debrief with staff delivering the intervention for 10 minutes post intervention recorded on a structured form by a member of the research team.
Intervention Fidelity:
4.5 Length of session delivered, as timed by the research team member
4.6 Content delivered as reported by the community midwife
4.7 Research team assessment of fidelity of intervention via audio-recording.
Outcome Assessment
4.8 expectations of labour and birth questionnaire - change pre-post intervention
4.9 birth outcomes
4.10 2 and 6 weeks questionnaire to record the childbirth experience questionnaire, Edinburgh postnatal depression scale, the Generalised Anxiety Disorder Scale, and a PTSD Scale.
For WP 5:
Process Measures:
5.1 Number of staff attending the intervention will be collected
5.2 Immediate feedback on the intervention from staff
5.3 Delayed feedback on the utility of the intervention via a survey at 2-3 months
Outcome Assessment
5.4 All staff consenting to participate in the sessions will be asked to complete a satisfaction with work scale before the study and 3 months later

Overall study start date
01/01/2019

Completion date
31/07/2020

Eligibility

Key inclusion criteria

There are five work packages (WPs), with separate inclusion criteria:
WP1: Aged > 16, invited to attend/attended ANE Class in North Bristol NHS Trust (NBT)
WP2: Any clinical role, involved in labour/delivery care at NBT
WP3: Aged > 16, either antenatal or postnatal NBT patient
WP4: Women and partners attending ANE at NBT, willing to participate and can complete an english questionnaire
WP5: All clinical staff involved in labour and delivery care at NBT

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 611; UK Sample Size: 611

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
16/07/2019

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
United Kingdom
BS10 5NB
0117 41 49330
researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
Health Foundation; Grant Codes: 1109133

Funder Name
The David Telling Charitable Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No