

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

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Registration date 16/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/05/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes