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ABA infant feeding study

Submission date
30/01/2017

Recruitment status
No longer recruiting

Registration date
30/01/2017

Overall study status
Completed

Last Edited
24/02/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Breastfeeding can improve the health of mothers and infants, but the UK has one of the lowest rates of breastfeeding in Europe. By the time they are one week old, less than half of babies are exclusively breastfed. Many women stop breastfeeding within the first two weeks and most wish they had breastfed for longer, and would have liked more support to help them continue. Younger mothers, those with only basic secondary school education and from lower income homes are less likely to breastfeed. Women value support from other mothers who have breastfed (peer support) and local areas have set up services to provide this. Many say that this helped to motivate them to continue breastfeeding, but for reasons which are unclear, large high quality UK trials of peer support programs have failed to increase the numbers of women starting or continuing to breastfeed. The failure could be because the timing is not when women most need the help, the way peer supporters are trained, or that the focus on breastfeeding alienates mothers who want freedom to choose. This study is looking at a new infant feeding program called Assets-based feeding help Before and After birth (ABA). The aim of this study is to find out if the ABA program is effective at encouraging women to start and continue breastfeeding their babies.

Who can participate?
Women aged 16 years and over who are pregnant with their first child.

What does the study involve?
Women are randomly allocated to one of two groups. Those in the first group take part in the ABA program. This involves women being put in touch with an 'ABA feeding team member' (specially trained existing peer supporters). The ABA feeding team are be non-judgemental and flexible and work to help mothers identify the feeding experiences of the people they know and the support available to help them, provide information about social, general postnatal and breastfeeding support groups, helplines and websites and information and video clips about infant feeding. They also provide a 'listening ear' when mothers have had their baby. The ABA feeding team contacts women when they are around 30 weeks pregnant and meet them and any family members to talk about infant feeding. They then send monthly texts with relevant messages. Soon after the birth the ABA feeding team member contacts the mother daily for two weeks by brief phone call or text and refer those with particular difficulties to specialist feeding support. Mothers are offered less frequent texts until their babies are five months old. For women who choose to formula feed, the feeding team go through how to prepare bottles

safely. Those in the second group receive usual care available for infant feeding from midwives, health visitors and other groups only. At three days, eight weeks and six months after birth, women are asked how they are feeding their baby and are interviewed about their experiences of the feeding help.

What are the possible benefits and risks of participating?
The potential benefits of this study are an increased number of women who start to breastfeed and women breastfeeding for longer. Another potential benefit is increased satisfaction of women with their feeding choice and the help received. There are no known risks for those taking part in the study.

Where is the study run from?
1. Millenium Medical Centre (UK)
2. Leyhill Surgery (UK)
3. West Heath Surgery (UK)
4. Birmingham Women's Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2016 to November 2018

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

Who is the main contact?
1. Dr Joanne Clarke (public)
j.l.clarke@bham.ac.uk
2. Professor Kate Jolly (scientific)
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Study website
https://www.birmingham.ac.uk/ABA

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33051

Study information

Scientific Title
Assets-based feeding help Before and After birth (ABA): Feasibility study for improving breastfeeding initiation and continuation

Acronym
ABA Study

Study objectives
A new ABA infant feeding intervention (which applies a pro-active, assets-based, person-centred approach) continuing from before to after birth, is effective in improving rates of breastfeeding initiation and continuation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Cornwall & Plymouth Research Ethics Committee, 24/11/2016, ref: 16/SW/0336

Study design

Randomised; Interventional; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

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
Specialty: Reproductive health and childbirth, Primary sub-specialty: Other; UKCRC code/ Disease: Reproductive Health and Childbirth/ Other maternal disorders predominantly related to pregnancy

Interventions
Participants are randomised to one of two groups. Randomisation will be undertaken by a member of the study research team using a secure, web-based randomisation website designed and maintained by CTU data programmers. The randomisation list will be developed by the trial statistician, it will be minimised by site and age group (<25 / 25+ years) and held in a secure database that is unavailable to those who enrol participants or assign interventions. The study research fellow will inform the mother of her allocation at the clinic visit, or if not available, by letter.

ABA Intervention: The intervention will commence antenatally. An ABA feeding team member will telephone the women at about 28-30 weeks gestation and offer a face-to-face discussion at home or location of their choice to discuss infant feeding and find out about their 'assets' for breastfeeding. This will commence with a narrative approach to producing a family tree diagram of infant feeding experiences, widening to the natural social network to enable women to reflect on future feeding relationships. This will allow breastfeeding to be introduced in a narrative way that is woman-centred rather than promotional. Potential topics of discussion include the realities of breastfeeding, barriers to breastfeeding, access to local opportunities for new mothers. Partners and family members will be encouraged to be present so their support role can be emphasised and encouraged.
Further follow-up will be by monthly texts during pregnancy. The key aim of the texts is to establish continuity of care and a strong rapport between woman and ABA feeding team so that engagement immediately after birth is early and effective. In the postnatal period, the aim is for the ABA feeding team to telephone within 24 hours of the woman going home and offer an early face-to-face session with the mother. This will provide the opportunity to observe a breastfeed.
Subsequent support will be brief daily telephone call/texts until the baby is 2-weeks old then reducing in frequency up to 8 weeks based on maternal preference, with final texts at 3, 4 and 5

months. The ABA feeding helpers will be able to choose from a library of texts co-produced with mothers. Women will be able to request that texts and calls stop at any point.

Usual care: Participants receive usual care available for infant feeding from midwives, health visitors and other groups only.

Follow-up for participants in both arms will take place when baby is 3 days, 8 weeks and 6 months old.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcomes:
1. Reach of recruitment of mothers to reflect wide socio-demographic profile is recorded by a comparison of the sociodemographic characteristics of women recruited compared to those not recruited through an analysis of routinely collected local data at the end of the recruitment period
2. Ability to recruit, train and engage current peer supporters to the new ABA infant feeding team role is recorded by the number of peer supporters recruited, and the number of peer supporters attending the training day on 10th February 2017. Engagement will be recorded through analysis of qualitative interviews with peer supporters at the end of the intervention period.
3. Ability to deliver planned number of contacts at a time and location convenient for participants is recorded through analysis of ABA Infant Feeding Team logs and qualitative interviews with peer supporters at the end of the intervention period
4. Acceptability to participants is recorded as positive responses about the intervention in qualitative interviews at the end of the intervention period
5. Fidelity of delivery, as well as whether good practice was achieved in terms of woman-centred care is recorded by analysis of ABA Infant Team logs, and analysis of recordings of contact between mothers and members of ABA Feeding Team at the end of the intervention period
6. Unintended consequences of the intervention is recorded by analysis of qualitative interviews with participants, ABA Infant Feeding Team members and other healthcare professionals at the end of the intervention period
7. The feasibility of a future definitive trial is assessed by recruitment rates (recorded as the number of eligible participants who consent to participate in the study in 4 months), participants' willingness to be randomised, follow-up rates at 3 days, 8 weeks and 6 months and level of completion of assessments by text and email
8. Potential cases of intervention contamination in the control group at 8 weeks is recorded by analysis of qualitative interviews with usual care women at 8 weeks

Secondary outcome measures
1. Any breastfeeding at 8 weeks is measured using a follow-up questionnaire at 8 weeks postnatal
2. Breastfeeding initiation is measured using a text message response at 2-3 days postnatal
3. Exclusive breastfeeding at 6-8 weeks is measured using a follow-up questionnaire at 8 weeks postnatal
4. Any/exclusive breastfeeding at 6 months is measured using a follow-up questionnaire at 6 months postnatal
5. Maternal wellbeing is measured using the Warwick-Edinburgh Mental Well-being Scale using follow-up questionnaires at 8 weeks and 6 months postnatal

6. Self-reported use of health care resources and feeding support services is measured using follow-up questionnaires at 8 weeks and 6 months postnatal

Overall study start date
01/11/2016

Completion date
01/11/2018

Eligibility

Key inclusion criteria
1. Aged 16 years and over
2. Pregnant with first child
3. Residing in study localities

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
103

Key exclusion criteria
Women who have had a previous live birth.

Date of first enrolment
14/02/2017

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Millenium Medical Centre
121 Weoley Castle Road
Birmingham
United Kingdom
B29 5QD

Study participating centre
Leyhill Surgery
101 Holloway
Birmingham
United Kingdom
B31 1TR

Study participating centre
West Heath Surgery
194-196 West Heath Road
Birmingham
United Kingdom
B31 3HB

Study participating centre
Birmingham Women's Hospital
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/03angcq70

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
1. A monograph with an accessible lay summary will be prepared for the NIHR
2. Papers will be submitted to peer-reviewed academic journals and target relevant clinical /public health audiences and those that target policy makers
3. Presentations will be delivered at international conferences directly concerned with infant feeding (e.g. UNICEF UK Baby Friendly Initiative (BFI) Conference, Nutrition and Nurture in Infancy and Childhood: Bio-Cultural Perspectives – International conference led by the Maternal and Infant Nutrition and Nurture Unit (MAINN) at UCLan)
4. Findings will be disseminated at conferences run by national breastfeeding organisations (e.g. NCT, Breastfeeding Network) to service-user groups (e.g. Maternity Services Liaison Committees) and at stakeholder events (e.g. UNICEF UK BFI Stakeholder Group)

Intention to publish date
01/11/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Kate Jolly (c.b.jolly@bham.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/01/2018		Yes	No
Results article	peer-reviewed results can be requested from STORRE repository at	01/04/2020	18/11/2019	Yes	No
Results article	results	29/09/2020	05/10/2020	Yes	No
Results article		02/12/2019	24/02/2023	Yes	No
Results article	Qualitative results	21/03/2020	24/02/2023	Yes	No
HRA research summary			28/06/2023	No	No