

# ABA infant feeding study

<b>Submission date</b> 30/01/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/02/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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 to 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)  
c.b.jolly@bham.ac.uk

### **Study website**

<https://www.birmingham.ac.uk/ABA>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Dr Joanne Clarke

### **Contact details**

Room 118c  
Institute of Occupational and Environmental Medicine (IOEM)  
University of Birmingham  
Birmingham  
United Kingdom  
B15 2TT  
+44 121 415 8060  
j.l.clarke@bham.ac.uk

### **Type(s)**

Scientific

**Contact name**

Prof Kate Jolly

**ORCID ID**

<http://orcid.org/0000-0002-6224-2115>

**Contact details**

Institute of Applied Health Research

Public Health building

University of Birmingham

Birmingham

United Kingdom

B15 2TT

+44 121 4147552

[c.b.jolly@bham.ac.uk](mailto:c.b.jolly@bham.ac.uk)

## **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**  
Mindelsohn Way  
Birmingham  
United Kingdom  
B15 2TG

## **Sponsor information**

**Organisation**  
University of Birmingham

**Sponsor details**  
Research Governance Team  
Birmingham  
England  
United Kingdom

B15 2TT  
+44 121 415 8011  
s.jennings@bham.ac.uk

**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?
<a href="#">Protocol article</a>	protocol	23/01/2018		Yes	No
<a href="#">Results article</a>	peer-reviewed results can be requested from STORRE repository at	01/04/2020	18/11/2019	Yes	No
<a href="#">Results article</a>	results	29/09/2020	05/10/2020	Yes	No
<a href="#">Results article</a>		02/12/2019	24/02/2023	Yes	No
<a href="#">Results article</a>	Qualitative results	21/03/2020	24/02/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No