

Does an infant feeding helper service increase infant feeding practices in firstborn babies?

| | | |
|--|---|---|
| Submission date 17/05/2021 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 24/05/2021 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 08/10/2025 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Breastfeeding can improve the health of mothers and babies, but fewer women breastfeed in the UK compared to other European countries. Many women stop breastfeeding within the first 2 weeks. Most wish they had breastfed for longer, and would have liked more support to help them continue. Younger mothers and those from lower-income homes are less likely to breastfeed.

The aim of this study is to find out whether a promising 'feeding helper' service to support women to feed their babies helps them to breastfeed for longer, improves how babies are formula fed and whether it is good value for money.

Who can participate?

Women expecting their first baby up until they are 35 weeks pregnant

What does the study involve?

Mothers will be allocated by chance to either receive usual care for feeding or the additional new 'feeding helper' service. 'Feeding helpers' will respect women's feeding choices. They will help mothers identify friends and family who may be able to help and will provide information about local groups, helplines and high-quality websites about infant feeding. They will provide a 'listening ear' when women have had their baby. All participants complete questionnaires at the start of the study and at 8, 16 and 24 weeks after the baby's birth.

What are the possible benefits and risks of participating?

Participants may have additional support in feeding their baby, and will at the same time be contributing to the design and delivery of services that could benefit other mothers in the future. As a thank you for taking part in the study and for completing the questionnaires, the researchers will send participants shopping vouchers after they have completed the follow-up questionnaires at 8 and 16 weeks. There are no known risks in taking part in the study.

Where is the study run from?

Birmingham Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
October 2020 to March 2025

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

Who is the main contact?
Prof. Kate Jolly, c.b.jolly@bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Kate Jolly

ORCID ID
<https://orcid.org/0000-0002-6224-2115>

Contact details
University of Birmingham
Institute of Applied Health Research
Murray Learning Centre
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 7552
c.b.jolly@bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 46651

Study information

Scientific Title
The effectiveness and cost-effectiveness of Assets-based feeding help Before and After birth (ABA-feed) for improving breastfeeding initiation and continuation

Acronym

ABA-feed

Study objectives

The aim of the ABA-feed trial is to assess the clinical and cost-effectiveness of the ABA-feed infant feeding intervention compared to usual care in first-time (nulliparous) mothers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 18/05/2021, East of Scotland Research Ethics Service REC 1 (Tayside Medical Science Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; +44 (0)1382 383878; tay.eosres@nhs.scot), REC ref: 21/ES/0045

Study design

Randomized; Interventional; Design type: Process of Care, Other

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Breastfeeding initiation and continuation

Interventions

The study design is a randomised controlled trial with women randomised to receive the additional ABA-feed intervention or usual feeding support.

The researchers aim to recruit women, 2730 women aged at least 16 years, pregnant with their first baby, and not expecting a multiple pregnancy.

Women will receive study information from 16 weeks gestation, with recruitment between 20 and 35+6 weeks

gestation. They will be approached when attending their 20-week scan or at routine antenatal clinics to see whether they would be interested in taking part in the study. If COVID-19 restrictions are in place then processes are in place for entirely remote recruitment.

Two weeks before they are due to give birth, participants will receive an SMS text to remind them to let the study team know when they have given birth. This can be by phone or text. This will enable the researchers to collect information about the initiation of breastfeeding at 3 days after their baby is born.

At 3 days after their baby is born women will receive a text asking about how they have fed their baby. At 8 and 16 weeks postnatally, they will receive an email/text with a link to an online questionnaire, or a postal questionnaire (in line with request at recruitment). These questionnaires will ask about infant feeding. Women will receive a final text/weblink at 24 weeks asking about how they are feeding their baby.

Women allocated to the ABA infant feeding team intervention will be offered information and support from about 30 weeks of pregnancy up until 8-weeks postnatally. Before the birth, women will be offered a face-to-face contact (in person or remotely) followed by texts with links to useful sources of infant feeding information and local social groups for mothers. After birth women will receive daily texts or calls for up to 2 weeks after birth, with reducing frequency to 8 weeks postnatally as participant preference. Once a mother is fully formula feeding and is confident in her ability to do this, the feeding team will cease to proactively contact the mother, but will be available for advice if it is required. The infant feeding team members will be trained peer supporters with additional training to include an assets-based approach. Some exemplar SMS texts were developed with input from women from socio-economically disadvantaged communities, to enhance their acceptability.

The main outcome of the study is any breastfeeding at 8-weeks postnatally from self-report, or, in the case of non-response, from the routinely collected data by health visitors.

The researchers will interview approximately 30 women in the intervention group to find out their experience of the ABA feeding support and to find out whether the ABA intervention was delivered as planned. Women will have the choice of where these interviews take place and whether they would prefer them to take place over the phone or by video call.

The researchers will also interview key informants from five case recruiting centres (e.g. lead midwives, health visitors, Children's Centre managers, and infant feeding leads) at the start and end of the study to 'map' the usual care pathway and at the end to find out whether there were any issues with referral or delivery or contamination and to explore differences in implementation between recruiting centres. At every recruiting centre the infant feeding helpers and their trainers will be asked to complete a brief questionnaire about the training and at the end of the study all infant feeding helpers will be invited to a focus group to explore their experience of delivering the intervention.

Overall the study will take 38 months, with the training the trainers, training the peer supporters and the mapping of community assets taking place in the first six months. Recruitment will start from April 2021 in each locality and last for up to 14 months. Women will be followed up until 24 weeks after they have had their babies. After follow-up is finished there are 6 months to complete the analyses and to write the final report.

There will be public involvement in the development of study materials, design of the study methods, advising during the study and contributing to how the researchers disseminate the findings of the study. One public involvement member is a study co-investigator. Two public partners will be members of the study management group and two lay members will sit on an oversight group to monitor the progress of the study.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measure as of 15/10/2024:

Any breastfeeding at 8 weeks post birth, measured by self-report in the 8-week questionnaire (or subsequent text message for non-responders) with missing data supplemented from health visitor records

Previous primary outcome measure:

Any breastfeeding at 8 weeks post birth, measured by self-report in the 8-week questionnaire (or subsequent text message for non-responders)

Key secondary outcome(s)

1. Any breastfeeding measured using infant feeding status, self-reported formula feeding practices at 16 weeks post birth
2. Any breastfeeding measured using infant feeding status, self-reported formula feeding practices at 24 weeks post birth
3. Exclusive breastfeeding measured using infant feeding status, self-reported formula feeding practices at 16 weeks post birth
4. Exclusive breastfeeding measured using self-reported formula feeding practices at 24 weeks post birth
5. Time to cease exclusive feeding with breastmilk measured using infant feeding status, self-reported formula feeding practices up to 16 weeks
6. Time to cease feeding with any breastmilk measured using infant feeding status, self-reported formula feeding practices up to 16 weeks
7. Maternal anxiety measured using the Generalised Anxiety Disorder Assessment (GAD-7) at 8 weeks post birth
8. Maternal anxiety measured using the GAD-7 at 16-weeks post birth
9. Maternal health-related quality of life measured by the EuroQol (EQ-5D-5L) at 8 weeks
10. Maternal health-related quality of life measured by the EQ-5D-5L at 16 weeks
11. Maternal social support measured by Medical Outcomes Study (MOS) Emotional/Informational Support domain at 8-weeks post birth
12. Maternal social support measured by MOS Emotional/Informational Support domain at 16 weeks post birth
13. The following maternal formula feeding practices measured using infant feeding status, self-reported formula feeding practices at 8 and 16 weeks post birth:
 - 13.1. Making one feed at a time
 - 13.2. Correct water temperature
 - 13.2. Adding formula powder before water
 - 13.3. Making up formula when needed when out of the home
 - 13.4. Keeping milk chilled when out of the home
 - 13.5. Making formula with hot water when out of the home
 - 13.6. Sterilising bottles using recommended methods
14. Maternal use of support for infant feeding (e.g. national breastfeeding helpline; peer support; breastfeeding groups) measured using infant feeding status, self-reported formula feeding practices, health and social resource use at 8 and 16 weeks post birth

Completion date

31/03/2025

Eligibility

Key inclusion criteria

1. Pregnant with their first child
2. Singleton pregnancy

3. Aged 16 years or over
4. Provided informed consent
5. Gestation age from 20+0 to 35+6 (inclusive) weeks gestation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

Female

Key exclusion criteria

1. Women who have had a previous live birth
2. Non-English speaking pregnant women with no Infant Feeding Helper in their locality able to speak their language are not eligible to be randomised into the ABA-feed Trial

Date of first enrolment

10/01/2022

Date of final enrolment

12/01/2024

Locations**Countries of recruitment**

United Kingdom

England

Scotland

Wales

Study participating centre**New Cross Hospital**

The Royal Wolverhampton NHS Trust

Wolverhampton Road

Heath Town

Wolverhampton

United Kingdom

WV10 0QP

Study participating centre

Southport and Formby District General Hospital

Southport and Ormskirk Hospital Nhs Trust

Town Lane

Southport

United Kingdom

PR8 6PN

Study participating centre

Hollins Park Hospital

Mersey Care NHS Foundation Trust

Hollins Park House

Hollins Lane

Warrington

United Kingdom

WA2 8WA

Study participating centre

Southmead Hospital

North Bristol NHS Trust

Southmead Road

Westbury-On-Trym

Bristol

United Kingdom

BS10 5NB

Study participating centre

Bristol Royal Infirmary

University Hospitals Bristol and Weston NHS Foundation Trust

Trust Headquarters

Marlborough Street

Bristol

United Kingdom

BS1 3NU

Study participating centre

Bronllys Hospital

Powys Teaching LHB

Glasbury House

Bronllys Hospital

Brecon
United Kingdom
LD3 0LS

Study participating centre

Dewi Sant Hospital

Cwm Taf Morgannwg University Local Health Board
Albert Road
Pontypridd
United Kingdom
CF37 1 LB

Study participating centre

NHS Dumfries and Galloway

Grierson House
The Crichton
Bankend Road
Dumfries
United Kingdom
DG1 4ZG

Study participating centre

University of Bristol

Bristol Population Health Science Institute
Bristol
United Kingdom
BS8 1NU

Study participating centre

University of Stirling

Nursing, Midwifery and Allied Health Professions Research Unit
Stirling
United Kingdom
FK9 4LA

Study participating centre

University of Central Lancashire

School of Community Health and Midwifery
Lancaster
United Kingdom
PR1 2HE

Study participating centre
Cardiff University
School of Healthcare Sciences
Cardiff
United Kingdom
CF14 4XN

Study participating centre
University of Birmingham
Institute of Applied Health Research
Edgbaston
Birmingham
United Kingdom
B15 2TT

Study participating centre
The Dudley Group NHS Foundation Trust
Pensnett Road
Dudley
United Kingdom
DY1 1HQ

Study participating centre
NHS Lanarkshire
East Kilbride
Glasgow
United Kingdom
G75 8NH

Study participating centre
Swansea Bay University Health Board
Port Talbot
United Kingdom
SA12 7BR

Study participating centre
Royal Blackburn Teaching Hospital
East Lancashire Hospitals NHS Trust

Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Macclesfield District General Hospital

East Cheshire NHS Trust
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre

Leighton Hospital
Mid Cheshire Hospitals NHS Foundation Trust
Crewe
United Kingdom
CW1 4QJ

Study participating centre

St Catherine's Health Centre
Wirral Community Health & Care NHS Foundation Trust
Derby Road
Birkenhead
United States of America
CH42 0LQ

Sponsor information

Organisation

University of Birmingham

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR129182

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon reasonable request from Professor Kate Jolly (c.b.jolly@bham.ac.uk) after the study is completed and the findings published. The anonymised quantitative data and transcribed qualitative transcripts from participants who have given consent to their anonymised data being stored for use in future ethically approved research will be available. Data requests will be considered by the research team and Birmingham Clinical Trials Unit, who will hold the data.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Protocol article | | 15/11/2023 | 16/11/2023 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Other publications | | 21/09/2025 | 22/09/2025 | Yes | No |
| Other publications | Qualitative study | 07/10/2025 | 08/10/2025 | Yes | 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 |