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

Submission date
17/05/2021

Recruitment status
No longer recruiting

Registration date
24/05/2021

Overall study status
Completed

Last Edited
15/10/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

Study website
https://www.birmingham.ac.uk/ABA-feed

Contact information

Type(s)
Scientific

Contact name
Prof Kate Jolly

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

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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)

Secondary outcome measures
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

Overall study start date
01/10/2020

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

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Planned Sample Size: 2730; UK Sample Size: 2730

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
England

Scotland

United Kingdom

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
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Sponsor type
University/education

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
The researchers plan to publish the protocol in the future. The chief investigator will coordinate dissemination of results. Results of this trial will be submitted for publication in a peer-reviewed journal. The manuscript will be prepared by CI or delegate and authorship will be determined by mutual agreement. A publication policy will be developed and approved by the CIG and TSC. Any secondary publications and presentations prepared by Investigators must be reviewed by the CIG. Manuscripts must be submitted to the NIHR in a timely fashion and in advance of being submitted for publication, to allow time for review and resolution of any outstanding issues. The authors must acknowledge that the trial was performed with the support of the NIHR and the University of Birmingham. Intellectual property rights will be addressed in the project agreement between the University of Birmingham and collaborating universities. A plain English summary will be sent to participants and available via the study website.

Intention to publish date
30/06/2025

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?
HRA research summary			28/06/2023	No	No
Protocol article		15/11/2023	16/11/2023	Yes	No