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Evaluation of the Breastfeeding Support project in the Better Start Bradford area

Submission date
07/08/2025

Recruitment status
No longer recruiting

Registration date
14/08/2025

Overall study status
Completed

Last Edited
24/10/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will explore whether a community-based programme to provide breastfeeding Support to new mothers in the Better Start Bradford area helps them to continue breastfeeding their babies 6 to 8 weeks after birth, compared to not if they did not get the support. Research shows that breastfeeding has many benefits for both mothers and babies, but the UK has some of the lowest rates of breastfeeding in the world. Many women stop breastfeeding earlier than they would like to, often due to a lack of timely support. The Breastfeeding Support programme was established to address this by offering direct and emotional support to new mothers through trained breastfeeding support workers. The service was also adaptable, with face-to-face, phone calls, or video calls. During the COVID-19 pandemic, however, support was entirely phone and video contact. The main question is whether women who received support through the programme were more likely to be still breastfeeding at 6–8 weeks compared to similar women who did not receive the intervention. It also explores whether the programme helped with exclusive breastfeeding (where babies receive only breast milk), whether its impact lasted until six months, and whether changes in how the service was delivered during the pandemic affected its success. The study will also check if results are different based on the format of the support (in-person or remote), the spoken primary language of the woman, or their need for an interpreter.

Who can participate?
Mothers (>18 years) who participated in the Breastfeeding Support intervention with at least one support contact, completed the BSB BiBBS baseline questionnaire (the consent and baseline data cohort), and neither mother nor baby was admitted to the ICU/NICU after delivery.

What does the study involve?
For this, researchers are using existing data from a large local project called Born in Bradford's Better Start (BiBBS), which has tracked the health and experiences of thousands of mothers and babies over approximately 10 years. Some mothers in BiBBs received the Breastfeeding Support intervention, and some did not. By using a method called propensity score matching, the researchers will compare women who are similar in key characteristics, such as age, ethnicity, breastfeeding intentions, and depression.

Data to support this study comes from three main sources: a questionnaire completed by mothers during pregnancy, service records from the Breastfeeding Support programme, and health visitor records documenting how babies were fed at 6–8 weeks and 6 months.

In addition to analysing whether the programme helps to promote breastfeeding, the team will consider the cost of delivering the programme. They will compare those costs with the known long-term health benefits of breastfeeding to estimate whether the programme offers good value for money. The evaluation does not involve new data collection; it uses data already gathered through routine care and the BiBBS cohort. Ethical approval for this kind of research was granted when the BiBBS study began, and strict data privacy procedures are followed.

The results of the study will be shared through scientific publications, community newsletters, social media, and other public channels. The goal is to provide useful insights for healthcare providers, local services, and decision-makers about whether this kind of community support program should be continued or expanded.

What are the possible benefits and risks of participating?
There are no anticipated additional risks or benefits, as all processes are part of standard midwifery care, and all data collection has been undertaken as part of the existing BiB/BiBBS studies. Any potential risks from participants completing mental health measures are mitigated through those collecting the measures being trained in Good Clinical Practice, and by providing opportunities for signposting to relevant services.

Where is the study run from?
Better Start Bradford, Better Start Bradford Innovation Hub (UK)

When is the study starting and how long is it expected to run for?
November 2015 to March 2024

Who is funding the study?
The National Lottery Community Fund (UK)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
188581

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 30638

Study information

Scientific Title
A quasi-experimental evaluation of the effectiveness of a community-based breastfeeding support intervention in promoting breastfeeding rates at 6-8 weeks postpartum in the Better Start Bradford cohort.

Study objectives
Primary Hypothesis
Participation in the BFS intervention will increase the likelihood of any form of breastfeeding at 6–8 weeks postpartum compared to standard care in the Better Start Bradford (BSB) cohort.

Secondary Hypotheses
Exclusive Breastfeeding:

Participation in the BFS intervention will increase the likelihood of exclusive breastfeeding at 6–8 weeks postpartum compared to standard care.
Any Breastfeeding:
Mothers who receive the BFS intervention will have higher rates of any breastfeeding at 6 months postpartum compared to those receiving standard care.
Pre- vs. post-pandemic comparison:
The rate of exclusive breastfeeding at 6-8 weeks postpartum will be higher among mothers who received in-person BFS support pre-pandemic, compared to those who received virtual /telephone BFS support during the pandemic.
Intervention Dose:
A higher number of support contacts (intervention dose) will be associated with a greater likelihood of any and exclusive breastfeeding at 6–8 weeks postpartum.
Delivery Format:
Breastfeeding rates at 6-8 weeks postpartum will be higher among mothers who received in-person BFS support compared to those who received telephone support (independent of pandemic)
Interpreter Use:
Mothers who require an interpreter will have lower breastfeeding rates at 6–8 weeks postpartum compared to those who did not.
Participant Characteristics:
Mothers with English as a second language will have lower breastfeeding rates at 6–8 weeks to native English speakers.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/11/2015, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (Room 001, Jarrow Business Centre, Viking Industrial Park Rolling Mill Road, Jarrow, NE32 3DT, United Kingdom; +44 (0)207 104 8083, +44 (0)207 104 8210; bradfordleeds.rec@hra.nhs.uk), ref: 15/YH/0455

Study design
Quasi-experimental evaluation using propensity score matching to compare intervention participants with matched controls

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Maternal and child health, specifically focusing on:
Breastfeeding support
Breastfeeding rates at 6–8 weeks and 6 months postpartum

Interventions
This is a quasi-experimental evaluation using propensity score matching to compare intervention participants with matched controls within the Born in Bradford Better Start cohort.

Participants in the Breastfeeding Support (BFS) Programme are typically enrolled shortly after birth, with the first support contact ideally occurring within the first few days postpartum. The BFS Programme is a community-based behavioural intervention designed to promote and sustain breastfeeding among new mothers. It is particularly relevant in communities with lower breastfeeding rates and among groups who may face social, cultural, or language-related barriers to sustained breastfeeding. The programme is delivered by trained Breastfeeding Support Workers (BSWs), who provide both practical and emotional support tailored to each mother's needs.

Support is offered in a flexible format, including face-to-face home visits, community-based sessions, and telephone or video calls. Each mother receives at least one contact with a BSW, and the number of subsequent contacts varies depending on individual needs. The support includes guidance on breastfeeding techniques, managing common breastfeeding challenges, and encouragement to help mothers meet their breastfeeding goals. In the Better Start Bradford (BSB) area, the BFS Programme was adapted in response to the COVID-19 pandemic in March 2020. All support transitioned to telephone or video delivery during the pandemic period, before gradually returning to a mixed model that included face-to-face support.

Study outcomes are drawn from routine data collected through the Born in Bradford's Better Start (BiBBS) cohort. These include questionnaire data collected during pregnancy, BFS service records documenting support contacts, and health visitor records on infant feeding status at 6–8 weeks and 6 months postpartum. As all data are derived from routine sources, no additional data collection is required for the evaluation. If a participant has relevant data recorded in more than one source, the BiBBS dataset will be prioritised.

Intervention Type
Behavioural

Primary outcome(s)
Any breastfeeding at 6–8 weeks postpartum is measured using linked routine data collected from health visitor records (SystmOne) at one time point (the mandated 6-to-8-week review). This is recorded as a binary measure (any breastfeeding = 1 / no breastfeeding = 0).

Key secondary outcome(s))
1. Exclusive breastfeeding at 6–8 weeks postpartum is measured using linked routine data collected from health visitor records (SystmOne) at one time point (the mandated 6-to-8-week review). Binary measure: exclusive breastfeeding = 1 / not exclusive = 0.
2. Any breastfeeding at 6 months postpartum is measured using linked routine data collected from health visitor records (SystmOne) at one time point (6-month health-visitor contact). Binary measure: any breastfeeding = 1 / no breastfeeding = 0.

Subgroup / secondary analyses:
1. Impact of intervention delivery mode: compare outcomes by delivery mode (face-to-face vs telephone/virtual). Analysis: stratified and interaction analysis within logistic regression models (treatment × mode).
2. Dose–response (number of support contacts): correlation between number of BFS contacts and breastfeeding outcomes; modelled as both continuous and categorised (e.g., above/below median) covariate; trend tests and marginal effects reported.
3. Interpreter use: compare outcomes for participants where an interpreter was used vs not used; adjusted logistic regression and subgroup checks.
4. English language proficiency: subgroup difference (English first language vs English second

language); adjusted models and interaction tests.
5. Pre- vs post-pandemic implementation effects: compare outcomes for participants who received the intervention pre-COVID (in-person) vs during COVID (telephone/virtual), including an assessment of the implementation period as an effect modifier.
6. Cost-effectiveness / economic threshold analysis: planned cost analysis of programme delivery costs plus a threshold analysis linking plausible long-term health benefits to cost-effectiveness (NICE Reference Case framework used where possible). This will be described at a high level in the registry; detailed methods will be in the analysis plan.

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Mothers who participated in the Breastfeeding Support intervention with at least one support contact
2. Completed BSB BiBBS baseline questionnaire (the consent and baseline data cohort)
3. Neither mother nor baby was admitted to the ICU/NICU after delivery

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
1770

Key exclusion criteria
1. Mothers who did not complete the BSB and BiBBS baseline questionnaire
2. Mothers or babies admitted to the ICU/NICU post-delivery

Date of first enrolment
01/10/2018

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Better Start Bradford
Bradford
United Kingdom
BD5 9NP

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Charity

Funder Name
National Lottery Community Fund

Alternative Name(s)
Big Lottery Fund, TNLcommunityfund, TNLComFund, The National Lottery Community Fund

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Researchers are encouraged to make use of the BiB data, which are available through a system of managed open access. Before contacting the researchers, please read the Guidance for Collaborators (https://borninbradford.nhs.uk/research/guidance-for-collaborators/). The BiB executive reviews proposals monthly and will endeavour to respond to requests as soon as possible. Find out about the different datasets in the Data Dictionary (https://borninbradford.github.io/datadict/) or contact a member of the BiB team (borninbradford@bthft.nhs.uk). Once you have formulated your request, please complete the 'Expression of Interest' form available here (https://borninbradford.nhs.uk/wp-content/uploads/BiB_EoI_v3.1_10.05.21.doc) and send it to borninbradford@bthft.nhs.uk. If the request is approved, you will be asked to sign a Data Sharing Contract (https://borninbradford.nhs.uk/wp-content/uploads/BIHR-Data-Sharing-Contract.docx) and a Data Sharing Agreement (https://borninbradford.nhs.uk/wp-content/uploads/BIHR-Data-Sharing-Agreement.docx), and if the request involves biological samples, you will need to complete a material transfer agreement (https://borninbradford.nhs.uk/wp-content/uploads/BiB-Material-Transfer-Agreement-v4-0.docx).

Born in Bradford (BiB) is a longitudinal research project. BiB aims to work out why some people have good health or well-being, while others have difficulties. To do this, BiB collects information from participants about all aspects of their lives at different ages using surveys, research clinics and other assessments. BiB also gathers information about families from other sources, such as health records or environmental records. BiB processes the data to make sure it is accurate, well organised, and to make it so that no person can be identified from the data. BiB then shares this processed data with scientists conducting research with potential public benefit. These scientists can be based anywhere in the world. The data that is available to be shared can be seen here: https://borninbradford.github.io/datadict/bibbs/.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	23/07/2025	13/08/2025	No	No
Statistical Analysis Plan	Statistical Analysis Plan (SAP) & Open Science Framework (OSP)		13/08/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes