

Effectiveness evaluation of a universal antenatal parenting programme: Baby Steps

Submission date 13/04/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/07/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The perinatal period and transition to parenthood marks a significant period in new parents' lives. Whilst it can be a positive experience for many, it can also be a challenging period accompanied by negative experiences – particularly for vulnerable groups of parents. Postnatal depression affects an estimated 10%–19% of women. The women most at risk of depression are those aged below 30 years and those living in the most deprived areas. Parents may also experience difficulties with secure attachment and bonding with their child. Parent-child attachment and parental sensitivity are important for the development of children's social and emotional competence, cognitive functioning, physical health, and mental health.

Within the Born in Bradford's Better Start (BiBBS) cohort (where the current study is based), significant proportions of pregnant women recruited to the study report experiencing mild to severe symptoms of depression (46%) and anxiety (30%). Evidence from six studies suggests that problems with perinatal mental health are less likely to be identified in ethnic minority women living in the UK, in both those who do and do not speak English.

Interventions that potentially improve/stabilise parental mental health and improve the quality of family relationships during the perinatal period have the potential to reduce the economic burden on society and improve outcomes for children. In response to the COVID-19 pandemic, many interventions moved to online delivery. Baby Steps is one such intervention, which is a relationship-based antenatal and postnatal parent education programme.

Born in Bradford's Better Start (BiBBS) is an interventional birth cohort study that runs in parallel to Better Start Bradford (BSB) (<https://www.betterstartbradford.org.uk/>), and is designed to support the evaluation of the effectiveness of early life interventions. All mothers and children in the BiBBS cohort have in-depth baseline data captured during pregnancy and consent to routine linkage to their health and education records. BiBBS are currently designing an additional sweep at 6-10 weeks postnatal, which will include the primary outcomes for Baby Steps. As a part of the consent to BiBBS, mothers agree to the information about them being used to evaluate interventions.

In this study the aim is to investigate the effects of Baby Steps on postnatal outcomes at the parent level, including parent mental health and parent-child sensitivity. The researchers also aim to investigate the feasibility of conducting an economic analysis through routine data. A process evaluation will explore implementation fidelity and the acceptability and feasibility of the intervention.

Who can participate?

1. Pregnant mothers (not exceeding 24 weeks gestation) who live in the Better Start Bradford areas and have consented to a referral to Baby Steps
2. Pregnant mothers who have a child aged between 0 and 3 months, who are not currently receiving and have not already received Baby Steps in the Better Start programme at any time, and provided data in the BiBBS additional sweep at any time in the duration of service delivery

What does the study involve?

This study will compare outcomes for BiBBS mums who take part in Baby Steps to those BiBBS mums who did not take part in Baby Steps. It will explore the effects of taking part in Baby Steps and its impact on postnatal parent-child sensitivity and postnatal parent mental health. It will also look at differences in birth outcomes and assess the feasibility of an economic evaluation of Baby Steps.

What are the possible benefits and risks of participating?

There are no anticipated additional risks or benefits as all processes are a part of standard midwifery care and all data collection has been undertaken as a part of the existing BiB/BiBBS studies. Any risks of participants completing mental health measures are mitigated through those collecting the measured being trained in Good Clinical Practice, and 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?

October 2021 to October 2024

Who is funding the study?

The National Lottery Community Fund (UK)

Who is the main contact?

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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Study information

Scientific Title

Quasi-experimental evaluation of the effectiveness of a universal antenatal parenting programme on parent sensitivity and mental health: a Born in Bradford's Better Start (BiBBS) cohort study

Study objectives

Primary research question:

1. To assess whether the universally delivered, online, Baby Steps programme is effective in improving postnatal parent sensitivity when compared to services as usual

Secondary research questions:

2. To assess whether the universally delivered, online, Baby Steps programme is effective in improving postnatal parent mental health when compared to services as usual

3. To assess whether the effects of Baby Steps on postnatal parent sensitivity are mediated by postnatal parent mental health

4. To assess whether birth outcomes differ in the Baby Steps programme compared to services as usual (e.g. delivery type, weight, gestation, feeding)

5. To assess whether the identification and prevalence of poor perinatal mental ill health inferred through routine data linkage differs in the Baby Steps programme compared to services as usual

6. Estimate the cost of the intervention (including delivery and training to deliver Baby Steps)

7. Assess the feasibility of collecting health-related resource use data for a future full economic evaluation

Ethics approval required

Old ethics approval format

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, UK; +44 (0)207 104 8083, +44 (0)207 104 8210; bradfordleeds.rec@hra.nhs.uk), ref: 15/YH/0455

Study design

Quasi-experimental longitudinal study design using an intervention and matched control group in a single centre

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Prevention

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

Prevention of parental distress, mental health problems, and improvements in parent-child bonding and sensitivity

Interventions

Participants in Baby Steps enrol before they are 24 weeks pregnant, and involvement with the service begins around the 26th to the 30th week of pregnancy.

Baby Steps is a 'relationship-based' antenatal parent education programme, mostly delivered in a group setting. It is particularly suitable for vulnerable and socially excluded parents who often face challenges and 'overload' in pregnancy and early parenting. It was initially developed by the National Society for Prevention of Cruelty to Children (NSPCC) (<https://learning.nspcc.org.uk/services-children-families/baby-steps>) and has previously been delivered by their local service throughout the Bradford district.

Initially there are two one to one visits (one of which is in the participant's home, one of which is virtual) prior to the course commencing to help build relationships between families and practitioners, then there are four weekly group sessions before the baby is born. After the baby is born there is another in-person home visit followed by two online group sessions. Baby Steps sessions are facilitated by an Early Years Practitioner and a Health Practitioner (Midwife or Health Visitor). The curriculum and activities for each group follow a set pattern at specific stages of pregnancy and following each baby's birth (see the Baby Steps manual and the NSPCC implementation handbook for full details). In Better Start Bradford (BSB) (see <https://www.betterstartbradford.org.uk/>), Baby Steps moved to an online delivery model in response to the COVID-19 pandemic in March 2020 and will change from a targeted to a universal offer in May 2022.

The study outcomes are collected in the BiBBS additional sweep, which will take place 6-10 weeks after birth. As some of these BiBBS participants asked to complete questionnaires will be taking part in Baby Steps, this may result in 'double data collection' for some participants – as some of the outcomes collected in Baby Steps are similar to the BiBBS additional sweep. If participants provide data in both collection processes, the outcome data from the BiBBS additional sweep will be used. If a BiBBS participant in Baby Steps has not completed the BiBBS additional sweep but has completed the outcomes in Baby Steps, the data from Baby Steps will be used.

Intervention Type

Behavioural

Primary outcome measure

Parent sensitivity is measured using the Mothers Object Relations Scale - Short Format (MORS-SF) at 6-10 weeks after childbirth

Secondary outcome measures

1. Parent mental health is measured using the Patient Health Questionnaire - 9 (PHQ-9) and Generalised Anxiety Disorder assessment (GAD-7) at 6-10 weeks after childbirth
2. Perinatal mental health will also be explored through routine data linkage. Identification and prevalence of poor perinatal mental health will be assessed through the Whooley questions asked by the health visiting service at 6 to 8 weeks after delivery, and other indicators obtained through routine data.
3. Birth outcomes will be explored through routine data linkage and will be described. The outcomes are delivery method (vaginal vs caesarean), gestation period, and reduced rates of low birthweight (<2500 g; any gestational age). Birth outcomes are collected immediately post-birth.

It is unknown how feasible it is to conduct an economic evaluation through routine data. This study will therefore collate information on the cost of the intervention and routine data on health-related resource use data to inform future economic evaluations. This level of description is not possible for the economic analysis as this will relate to the feasibility of exploring outcomes for an economic analysis, and the outcomes are therefore unknown.

Overall study start date

01/10/2021

Completion date

30/10/2024

Eligibility

Key inclusion criteria

The participants in this study are pregnant mothers, where data are collected at the level of the parent. The participant's allocation to the intervention and matched comparison group is via self-selection (i.e. not randomisation).

Eligibility for the intervention group:

1. Currently pregnant and have not exceeded 24 weeks gestation
2. Live in the Better Start Bradford areas
3. Have consented to a referral to Baby Steps

Eligibility for the matched comparison group:

1. Have a child aged between 0 and 3 months at any time in the duration of service delivery (to ensure that matched cases are comparable)
2. Not currently receiving and have not already received Baby Steps in the Better Start programme at any time
3. Provided data in the BiBBS additional sweep at any time in the duration of service delivery

Participant type(s)

Other

Age group

Adult

Sex

Female

Target number of participants

Key exclusion criteria

Participant is not currently enrolled in BiBBS cohort study

Date of first enrolment

01/05/2022

Date of final enrolment

31/07/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Better Start Bradford

Bradford

United Kingdom

BD5 9NP

Sponsor information

Organisation

Bradford Teaching Hospitals NHS Foundation Trust

Sponsor details

Research Management and Support Office

Bradford Institute for Health Research

Duckworth Lane

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England

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Sponsor type

Hospital/treatment centre

Website

<https://bradfordhospitals.nhs.uk>

ROR

<https://ror.org/05gekvn04>

Funder(s)

Funder type

Charity

Funder Name

National Lottery Community Fund (previously the Big Lottery Fund; Ref 10094849)

Alternative Name(s)

Big Lottery Fund

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

A protocol for this study is being submitted for publication in the coming months. It will be uploaded to ISRCTN if published. An academic publication in a peer-reviewed journal is planned. Findings will also be shared at relevant conferences where possible. Policy briefings will be collated for local services, commissioners, and national policymakers to share key findings. Summary findings for the community and participants will be co-produced with the Community Research Advisory Group to ensure accessibility. Different modes of sharing will be considered (e.g. videos, social media, local press channels).

Intention to publish date

31/01/2025

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 review proposals on a monthly basis 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. The aim of BiB is 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

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/01/2023	30/01/2023	Yes	No
HRA research summary			28/06/2023	No	No