ISRCTN12196131 https://doi.org/10.1186/ISRCTN12196131

Effectiveness evaluation of a universal antenatal parenting programme: Baby Steps

Submission date
13/04/2022

Recruitment status
No longer recruiting

Registration date
22/04/2022

Overall study status
Completed

Last Edited
06/10/2026

Condition category
Mental and Behavioural Disorders

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

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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Additional identifiers

Protocol serial number
01

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

Primary study design
Interventional

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

Study type(s)
Prevention

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

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
552

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
United Kingdom

England

Study participating centre
Better Start Bradford
-
Bradford
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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 (previously the Big Lottery Fund; Ref 10094849)

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 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
Basic results		06/10/2026	06/10/2026	No	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan		30/08/2024	06/10/2026	No	No