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Does the midwife-led continuity of carer model improve birth outcomes and maternal mental health in vulnerable women?

Submission date
31/03/2022

Recruitment status
No longer recruiting

Registration date
08/06/2022

Overall study status
Completed

Last Edited
23/04/2025

Condition category
Pregnancy and Childbirth

[_] 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
Midwife-led continuity of carer (MCC) is a model of maternity care in which women receive the majority of their care from a named midwife. Features of this model of care include a reduced caseload for midwives, longer appointment times and flexibility in how care is provided. The named midwife is supported by other members of a small team, with the aim of ensuring that flexible working including out of hours cover for labour and birth is safe and sustainable for midwives. There is strong evidence that the MCC model improves birth outcomes. However, we do not know if this model has the same impact on birth outcomes for women from ethnic minority backgrounds or who live in deprived areas. Research has not looked at other impacts of this MCC model, such as on the mental health of women.
In Bradford, the MCC model of care has been implemented in inner-city areas where a large number of pregnancies are to ethnic minority women, and those living in deprived areas. There are more women than there are spaces for women to receive MCC care, so women are selected by chance (randomised) at the time that they are referred into midwifery care to either receive the MCC model or standard maternity care. Many women in these areas are taking part in existing Born in Bradford studies which link together participants' routinely collected health information from midwifery and other services.
This study aims to explore whether women who receive the MCC model have better birth and mental health outcomes than women who receive standard midwifery care. All women in the study live in ethnically diverse and deprived areas. The study will also use qualitative methods to understand midwives perspectives on the key components for implementing and delivering the MCC model, and explore whether women's experiences of birth vary depending on whether they had their MCC midwife with them or not. Additionally, the study will conduct an economic evaluation to identify the cost effectiveness of the MCC model to compare the costs relative to SC.

Who can participate?
Pregnant women referred for maternity care at BTHFT between the 1st April 2022 and the 31st March 2024, who were randomised to receive their care from the MCC community midwifery teams or a standard care midwifery team, and who are a part of existing Born in Bradford

research studies.
To be selected for an interview with researchers, women must have received the MCC care, had a live birth and have given consent to take part (by completing a 'consent to contact' form and giving verbal consent at the start of their interview).

What does the study involve?
For women who have been randomised to MCC or standard care, and who are a part of the BiB studies, the research team will compare information about their birth and mental health outcomes. The research team will also speak to a small number of women who received MCC care to understand more about their experiences, and how these differed based on the level of continuity received at birth. Midwives will complete diaries to provide insight about the key components to successfully deliver MCC care.

What are the possible benefits and risks to participants?
There are no anticipated additional risks or benefits for this trial as all processes are a part of routine midwifery care, and all data collection has been undertaken as a part of existing BiB studies.
For the qualitative interviews, women will be asked to relive their experience of birth, and talk about their wellbeing, which may bring up difficult memories or emotions.
MCC midwives and team leaders will be asked to keep reflective diaries, which may be challenging if describing a distressing situation.

Where is the study run from?
Born in Bradford, Bradford Teaching Hospitals NHS Foundation Trust (BTFHT) (UK)

When is the study starting and how long is it expected to run for?
April 2021 to September 2025

Who funds the study?
The National Lottery Community Fund (Better Start Bradford), Reducing Inequalities in City Bradford District and Craven CCGs, NIHR ARC Yorkshire & Humber (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309549

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 309549, CPMS 52348

Study information

Scientific Title
Effectiveness of a midwife-led continuity of carer model on birth outcomes and maternal mental health in vulnerable women: study protocol for a randomised controlled trial with an internal pilot and process and economic evaluations.

Study objectives
A midwife-led continuity of carer model (MCC) improves birth outcomes and reduces the prevalence of poor maternal mental health in women from ethnically diverse and deprived backgrounds, compared to standard midwifery care.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Approved 07/12/2021, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), BiBBS, ref: 15/YH/0455
2. Approved 04/10/2018, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), BiB4All, ref: 17/YH/0202
3. Approved 07/06/2023, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), qualitative process evaluation, ref: 22/YH/0072

Study design
Single-centre open labelled individual prospective randomized controlled trial with an internal pilot phase and qualitative process and economic evaluations

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of negative birth outcomes and poor perinatal mental health in vulnerable pregnant women.

Interventions
The MCC model of care provides women with a full continuity of carer service throughout the antenatal, intrapartum and postnatal periods, delivered by a named midwife and support team. Compared to standard care, MCC midwives are given smaller caseloads, can offer longer appointment times and prioritise discussion surrounding public health messages. Point-of-care randomisation with minimisation and multiple stratification variables will be employed. Women will be randomised by administration staff in the MCC teams. Random allocation to either the control (standard care) or intervention arm (MCC) will be completed before patients are contacted by the care provider.

Eligible women will be randomised at the point of referral to the maternity service to receive either the MCC (midwife-led continuity of care) intervention or to receive standard community midwifery care (SC). Those who are randomised to receive MCC will experience a relationship-based, continuity of carer approach where a single midwife plans and provides care for a woman throughout the antenatal, intrapartum and postnatal stages. MCC midwives are responsible for smaller caseloads (maximum of 35 women per full-time equivalent midwife) or more (depending on staffing pressures in SC) and therefore, can offer a personalised care service, with longer appointment times and tailored discussion surrounding public health messages.

Women receiving MCC care will receive this type of care if they are less than 29 weeks gestation at the time of referral for maternity care, up until postnatal discharge from the service (the timing of which may be different for each woman), when their MCC midwife transfers their care to their health visitor (via their GP). SC aims to provide team-based antenatal care though women may be seen by midwives from other community teams if necessary, and intrapartum

care is provided by hospital midwives only. Given the larger caseload size in the SC arm, the duration and location of appointments are restricted, and women are discharged 2 weeks postnatal unless they are in need of specialist care.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 28/02/2023:
1. Spontaneous vaginal delivery indicated at birth, measured using data obtained via the linked routine health (maternity) record for cohort participants
2. Maternal depression measured using the PHQ-8 assessment tool at 6-10 weeks postnatal

Previous primary outcome measures:
Internal Pilot:
1. Number of women randomised relative to the total number eligible using data obtained from the maternity service and cumulative trial monitoring data at 3 months
2. Allocation ratio measured using cumulative trial monitoring data at 3 months

Effectiveness Evaluation:
Primary outcome measures: Parent
1. Spontaneous vaginal delivery indicated at birth, measured using data obtained via the linked routine health (maternity) record for cohort participants
2. Mental ill health measured using the PHQ-8 and GAD-7 assessment tools at 6-10 weeks postnatal

Process Evaluation:
Midwifery teams:
1. Number of reflective diaries completed by MCC midwives (maximum 2 per individual) and team leaders (maximum 4 per individual) using research team study records on 31/03/2024
2. Detail of the challenges and barriers staff within the MCC midwifery team faced when providing this model of care, obtained qualitatively (i.e., free text) through the study-specific reflective diaries completed either twice (for midwives) or 4 times (for team leaders) per year

Women:
1. Number of interviews completed by women who received MCC care during (at least) the antenatal and postnatal periods assessed using research team study records on 31/03/2024
2. Pregnancy, birth and postnatal experiences of women who received MCC care assessed using qualitative interviews. A study-specific topic guide will explore the thoughts and experiences of women who received MCC care at different stages of their pregnancy journey; these will take place between 4-20 weeks post-birth

Economic Evaluation:
1. Health-related quality of life at 1 year postnatal, measured using data obtained from the linked routine health record for cohort participants. Information captured at any point between referral to maternity and up to one year following birth will be included in analyses
2. Health-related resource use at 1 year postnatal, measured using data obtained from the linked routine health record for cohort participants. Information captured at any point between referral to maternity and up to one year following birth will be included in analyses

Key secondary outcome(s))

Current secondary outcome measures as of 28/02/2023:
Effectiveness Evaluation
Secondary outcome measures: Parent
1. Emergency caesarean birth indicated at birth, using data obtained via the linked routine health (maternity) record for cohort participants
2. Breastfeeding initiation (first feed) indicated within the first 24 hours after birth, using early postnatal data obtained via the linked routine health (maternity) record for cohort participants
3. Identification of poor perinatal mental health while receiving midwifery care by a member of the maternity service. This will be measured using data obtained from the linked routine health (maternity) record for cohort participants; information captured at any point between referral and discharge will be included in analyses. Coded data will be examined for indication of poor mental health, with reference to predetermined code lists.
4. Experience of poor mental health in the first 12 months following birth, identified via routine data linkage of the health visiting and GP records of cohort participants. Coded data will be examined for indication of poor mental health, with reference to predetermined code lists.
5. Parent-child relationship assessed using the Mothers Object Relations Scale (MORS) at 6-10 weeks postnatal
6. Maternal anxiety measured using the GAD-7 assessment tools at 6-10 weeks postnatal

Secondary outcome measure: Child
1. Low birth weight (<2500 g; any gestational age) indicated at birth using data obtained via the linked routine health (maternity) record for cohort participants

Previous secondary outcome measures:
Effectiveness Evaluation
Secondary outcome measures: Parent
1. Emergency caesarean birth indicated at birth, using data obtained via the linked routine health (maternity) record for cohort participants
2. Breastfeeding initiation (first feed) indicated within the first 24 hours after birth, using early postnatal data obtained via the linked routine health (maternity) record for cohort participants
3. Identification of poor perinatal mental health while receiving midwifery care by a member of the maternity service. This will be measured using data obtained from the linked routine health (maternity) record for cohort participants; information captured at any point between referral and discharge will be included in analyses. Coded data will be examined for indication of poor mental health, with reference to predetermined code lists.
4. Experience of poor mental health in the first 12 months following birth, identified via routine data linkage of the health visiting and GP records of cohort participants. Coded data will be examined for indication of poor mental health, with reference to predetermined code lists.
5. Parent-child relationship assessed using the Mothers Object Relations Scale (MORS) at 6-10 weeks postnatal

Secondary outcome measure: Child
1. Low birth weight (<2500 g; any gestational age) indicated at birth using data obtained via the linked routine health (maternity) record for cohort participants

Completion date
30/09/2025

Eligibility

Key inclusion criteria

Current inclusion criteria as of 28/02/2023:
Effectiveness Evaluation
1. Have been randomised to receive intervention or control care
2. Have consented to take part in Born in Bradford (BiB) cohort studies: BiBBS (Born in Bradford Better Start) study or BiB4All (Born in Bradford for all) cohort study

Process Evaluation
1. Have received the MCC model of care
2. Had a live birth a minimum of 4 weeks and a maximum of 20 weeks before the time of recruitment
3. Have completed a 'consent to contact' form (to confirm the research team can get in touch with them)
4. Have given informed consent to participate in a qualitative interview
5. Speak a language accessible to the research team

Previous inclusion criteria:
Randomisation for MCC care
1. Be referred or make a self-referral to the BTHFT Women's and Newborn Unit for pregnancy care, between the 1st April 2022 and the 31st March 2024.
2. Reside in the BSB area or be registered with a general medical practice (GP) associated with the RIC programme, and within the geographical remit of the standard care teams forming the eligible population for the trial.
And:
3. Be less than 29 weeks gestation at the time of referral for maternity care.
4. Have no requirement for a referral to a specialist midwifery team or consultant care.

Effectiveness Evaluation
1. Have been randomised to receive intervention or control care
2. Have consented to take part in Born in Bradford (BiB) cohort studies: BiBBS (Born in Bradford Better Start) study or BiB4All (Born in Bradford for all) cohort study

Process Evaluation
1. Been randomised to receive MCC model of care
2. Had a live birth a minimum of 4 weeks and a maximum of 20 weeks before the time of recruitment
3. Have completed a 'consent to contact' form (to confirm the research team can get in touch with them)
4. Have given informed consent to participate in a qualitative interview

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
663

Key exclusion criteria
Effectiveness evaluation
1. Have pregnancy loss or termination (<24 weeks gestation)
2. Have not registered their pregnancy <29 weeks gestation
3. Move outside of the geographical remit of the care teams following randomisation
4. Withdraw consent for data linkage via the BiB4All/BiBBS cohorts before the end of the evaluation period

Process Evaluation
1. Have pregnancy loss
2. Have a stillbirth/infant death
3. Their child is still receiving care/treatment in hospital

Date of first enrolment
05/04/2022

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

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 (Better Start Bradford)

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

Funder Name
Reducing Inequalities in Communities (Bradford District and Craven CCG)

Funder Name
NIHR ARC Yorkshire and Humber

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 you contact us, please make sure you have read our Guidance for Collaborators (https://borninbradford.nhs.uk/research/guidance-for-collaborators/). The BiB executive review proposals on a monthly basis and we will endeavour to respond to your request as soon as possible. You can find out about the different datasets in our Data Dictionary (https://borninbradford.github.io/datadict/). If you are unsure if we have the data that you need please 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 to borninbradford@bthft.nhs.uk. If your request is approved we will ask you 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 your request involves biological samples

we will ask you to complete a material transfer agreement (https://borninbradford.nhs.uk/wp-content/uploads/BiB-Material-Transfer-Agreement-v4-0.docx).
IPD sharing summary
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 publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/11/2023	24/11/2023	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No
Other files	OSF Registry	20/12/2024	13/01/2025	No	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