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BMJ Open

Effectiveness of a midwife-led continuity of care model on birth outcomes and maternal mental health in vulnerable women: study protocol for a randomised controlled trial with an internal pilot, process evaluation and economic analysis

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ABSTRACT

Introduction Women from social disadvantage are at greater risk of poor birth outcomes. The midwife-led continuity of care (MCC) model, which offers flexible and relational care from a small team of midwives, has demonstrated improved birth outcomes. In the general population, the impact of MCC on socially disadvantaged women and on birth outcomes is still unclear. This protocol describes a pragmatic evaluation of the MCC model in a socially disadvantaged population.

Methods and analysis An open-labelled individual prospective randomised controlled trial with an internal pilot, process evaluation and economic analysis, from 1 April 2022 to 31 March 2024.

Women will be randomly allocated to MCC or standard care as part of usual midwifery practice. Participants and midwives will not be blinded, but researchers will be. An internal pilot will test the feasibility of this process. Participants are those randomised into MCC or standard care, who consent to participate in one of two Born in Bradford (BiB) birth cohort studies. Outcomes are taken from routinely linked health data, supplemented by additional data capture. The sample size is fixed by the capacity of MCC teams, commissioning duration and numbers recruited into the cohort. The estimated maximum fixed sample size is 1,410 pregnancies (minimum 734).

Intention to treat (ITT) analysis will be undertaken to assess the impact of MCC on two independent primary outcomes. An economic evaluation will explore the impact on health resource use and a process evaluation will explore fidelity to the MCC model, and barriers/facilitators to implementation from midwives' and women's perspectives.

Ethics and dissemination Ethical approval has been obtained for the randomisation in midwifery practice, use of the cohort data for evaluation and for the process evaluation. Findings will be published in peer-reviewed journals, presented at conferences and translated into policy briefings.

Trial registration number IsRCTN https://doi.org/10.1186/ISRCTN31836167

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The trial includes participants seldom included in research: a population of ethnically diverse women living in deprived areas who are at greater risk of poor birth outcomes and perinatal mental health difficulties.
⇒ The study is a pragmatic effectiveness evaluation, with randomisation undertaken within standard midwifery practice, and recruitment embedded within a birth cohort.
⇒ Outcomes in the study use linked routinely collected health data, enhanced by additional data capture, meaning that the findings are directly applicable to practice, retention rates are high and there is reduced burden for participants.
⇒ This is a single-site study, therefore findings may be dependent on local context and fidelity to the model.
⇒ The sample size is fixed, and power to detect differences in outcomes is dependent on successful local implementation.

INTRODUCTION

Background and rationale

Women who experience social disadvantage (including being from some ethnic minority backgrounds, and of low socioeconomic status) are at greater risk of

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poor birth outcomes[1] and perinatal mental ill health (including depression, anxiety and a poor mother–child relationship).[2]

In 2017, the UK National Health Service produced the 'Better Births' plan[1] to improve inequalities in midwifery led care in England. Within this plan, the Maternity Transformation Programme aimed to implement the midwife-led 'continuity of carer' (MCC) model to support safer, more streamlined maternity care, while fostering positive relationships between women and their midwives, and resulting in better outcomes for women and their babies.[3]

MCC is a model of midwifery care where women receive seamless care from the same midwife, or a small team of midwives, throughout the antenatal, intrapartum and postnatal stages.[4] The model promotes out of hours cover for labour and birth, safety and sustainability for midwives, and provides a reduced caseload, longer appointment times and flexibility in how care is provided compared with standard midwifery care.

A Cochrane review of the MCC model provided evidence of effectiveness for the model in improving a range of birth-related outcomes.[5] This review reported significant outcomes for regional analgesia, instrumental vaginal birth, preterm birth (less than 37 weeks) and all fetal loss (before and after 24 weeks, plus neonatal death). However, the Cochrane review includes limited evidence on the impact of this model of care on the birth outcomes of women experiencing social disadvantage. Trials of MCC have also focused on birth outcomes, and there is no causal evidence of the potential longer term impact, for example on the identification and treatment of postnatal mental health.

In-depth qualitative evaluations of MCC models of care in socially disadvantaged communities have demonstrated the potential benefit that this model of care may have on reducing the inequalities in birth outcomes and perinatal mental health for socially disadvantaged women for mothers and their babies. In these studies, midwives and women both reported the value of continuity of care in building trusting relationships which in turn increased the likelihood of women disclosing mental health and other concerns.[5 6]

On 1 April 2021, Bradford Teaching Hospitals NHS Foundation Trust began implementation of an MCC model that included continuity in the intrapartum period, for women living in deprived inner-city areas where most pregnancies are to women of ethnic minorities. This protocol describes the planned effectiveness, process and economic evaluation of the Bradford Teaching Hospitals NHS Foundation Trust MCC model in this population. The study comprises two phases: (1) a randomised internal pilot; and (2) a randomised controlled trial (RCT) with embedded process, and economic evaluation.

Aims, objectives and research questions

Aim

The overall aim of this study is to evaluate the impact of an MCC model on birth outcomes, perinatal mental health and health-related resource use for women living in ethnically diverse and deprived areas, compared with standard midwifery care.

Objectives

The study includes an internal pilot, RCT, process and economic evaluations. The main objective of each of these components as follows:

- Internal pilot: to assess the feasibility of implementing randomisation into midwifery practice.
- RCT: to establish the effectiveness of MCC on clinical outcomes.
- Process evaluation: to understand the facilitators of service delivery, and the levels of fidelity and acceptability of the model to midwives and women.
- Economic evaluation: to assess intervention costs, and adult and child health resource use and outcomes.

Research questions

Primary research questions for the study are:

When delivered in areas of high ethnic diversity and deprivation, does MCC, compared with standard care:

- Improve rates of spontaneous vaginal birth?
- Impact on maternal depression (Patient Health Questionnaire, PHQ-8[7] at 6–10 weeks postnatally)?

Secondary research questions are as follows:

When delivered in areas of high ethnic diversity and deprivation, does MCC, compared with standard care:

- Increase midwives' identification of perinatal mental health difficulties?
- Reduce the incidence of clinically significant perinatal mental health difficulties during the first year after birth?
- Impact on the parent–child relationship (Mothers Object Relations Scale, MORS-SF[8] at 6–10 weeks postnatally)?
- Impact on maternal anxiety (Generalised Anxiety Disorder assessment, GAD-7[9] at 6–10 weeks postnatally)?
- Improve breastfeeding initiation rates?
- For whom does the intervention work best (e.g., based on ethnic groups and/or socioeconomic circumstances)?
- Is the addition of the MCC intervention likely to be cost-effective?
- What level of continuity can be achieved in MCC, and what are the organisational, or systems-level, barriers and facilitators to delivering MCC with fidelity?
- What are women's perceptions of MCC care, and is this affected by level of continuity at birth?

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METHODS AND ANALYSIS

Study design

An open-labelled individual prospective RCT comprising an internal pilot, a process and economic evaluation.

The study will run from 1 April 2022 to 31 March 2024. The study intentionally starts one full year after the implementation of the MCC model (1 April 2021), to allow MCC to become established. The internal pilot phase will run from 1 April 2022 to 30 June 2022. The internal pilot data will be combined with the main trial data unless significant design changes are required at the end of the pilot phase that have the potential to influence study outcomes. The final decision will be made by the study governance group. All outcome measures will be collected during the pilot. This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist and utilises Consolidated Health Economic Evaluation Reporting Standards (CHEERS) and consolidated criteria for reporting qualitative research (COREQ) as appropriate.

Study setting

Bradford is a city in the north of England, with the fifth largest local authority in terms of population in England and an increasing birth rate. The MCC model will be delivered in inner-city areas of Bradford where 69% of pregnant women live in the most deprived decile of the Index of Multiple Deprivation (IMD) and the majority of women are from ethnic minority groups (19/20 financial year; data from Bradford Teaching Hospitals NHS Foundation Trust).

All pregnant women booked to give birth at the Bradford Teaching Hospitals NHS Foundation Trust are invited to take part in the BiB4All birth cohort, where women consent to the access and linkage of routinely collected health and education data for them and their child.[10] In the Better Start Bradford areas of the city, pregnant women are invited to participate in Born in Bradford's Better Start (BiBBS) birth cohort, comprising an in-depth questionnaire during pregnancy, a mental health questionnaire 6–10 weeks postnatally and consent to the access and linkage of routine data as above.[11] This evaluation is undertaken as a substudy of the BiBBS interventional cohort, supplemented by BiB4All data which the research team has permission to access.

Intervention

MCC requires a single, named, midwife, supported by a small MCC team, to coordinate and provide care before 29 weeks' gestation, through labour and birth, until postnatal discharge from the service. MCC personalisation includes flexibility in the frequency, duration and location of appointments and in time of discharge postnatally, with tailored public health messages. In standard care, postnatal discharge is fixed at 2 weeks, however in MCC, there is flexibility in the length of the postnatal care depending on a woman's needs and preference. Women identified as high risk for medical or social reasons are not eligible for MCC or standard care. They are allocated to obstetrician or a specialised midwifery team. If a woman is allocated to MCC, but then is identified as high risk, they will be moved out of the MCC model and into the appropriate care pathway.

Bradford Teaching Hospitals NHS Foundation Trust plans to implement two MCC teams, each with 7 whole-time-equivalent midwives and one whole-time-equivalent midwife support worker. The MCC caseload target is 30 women at any one time, with a maximum of 35, women per full-time equivalent midwife per year. This corresponds to a total of 420–490 women per year in the MCC model. The MCC models are cofunded by the hospital and two local initiatives: Better Start Bradford[12] and Reducing Inequalities in Communities.[13]

Community midwives within the comparator, standard care, have caseloads of approximately 100 women per year, with a mandated number, duration and location of appointments and discharge 2 weeks after birth. Standard care women will likely see two or more community midwives throughout their care, and intrapartum care is provided separately by hospital midwives.

Trial randomisation and allocation

Between April 2021 and 2022, women will be allocated on an ad-hoc basis to MCC or standard care based on caseload capacity of the MCC team at the time of booking. As the demand for the service outweighs capacity, midwifery services agreed to embed point of care randomisation within their routine practices to enable them to provide equity of care allocation. The randomisation process has received ethical approval (see ethical approval section). In both the ad hoc and random allocation processes, women are informed of their allocated team rather than being offered a choice, although they remain able to request a different midwife or midwife team.

Referrals to Bradford Teaching Hospitals NHS Foundation Trust's Women's and Newborn Unit are made using an electronic online form, by phone by the patient, or by the general practitioner (GP) on a patient's behalf by email or phone. A central administrator will assess MCC eligibility (gestation of <29 weeks, and no requirement for specialist midwifery care). The details of eligible women will be passed via email to the MCC midwifery support administrators, who will input the required details into the randomisation programme, adhering to a standard operating procedure. Following randomisation, women will be offered their allocated service of either MCC or standard care.

The randomisation programme used is MinimPy2.[14] This manages minimisation using biased-coin minimisation with marginal balance, and a base probability of 0.7 (default). Stratification variables included in the randomisation are ethnicity, midwifery team, first pregnancy and estimated week of birth within expected month (for caseload management).

A randomisation ratio of 4:5 (MCC: Standard care) was agreed for the internal pilot, based on: capacity

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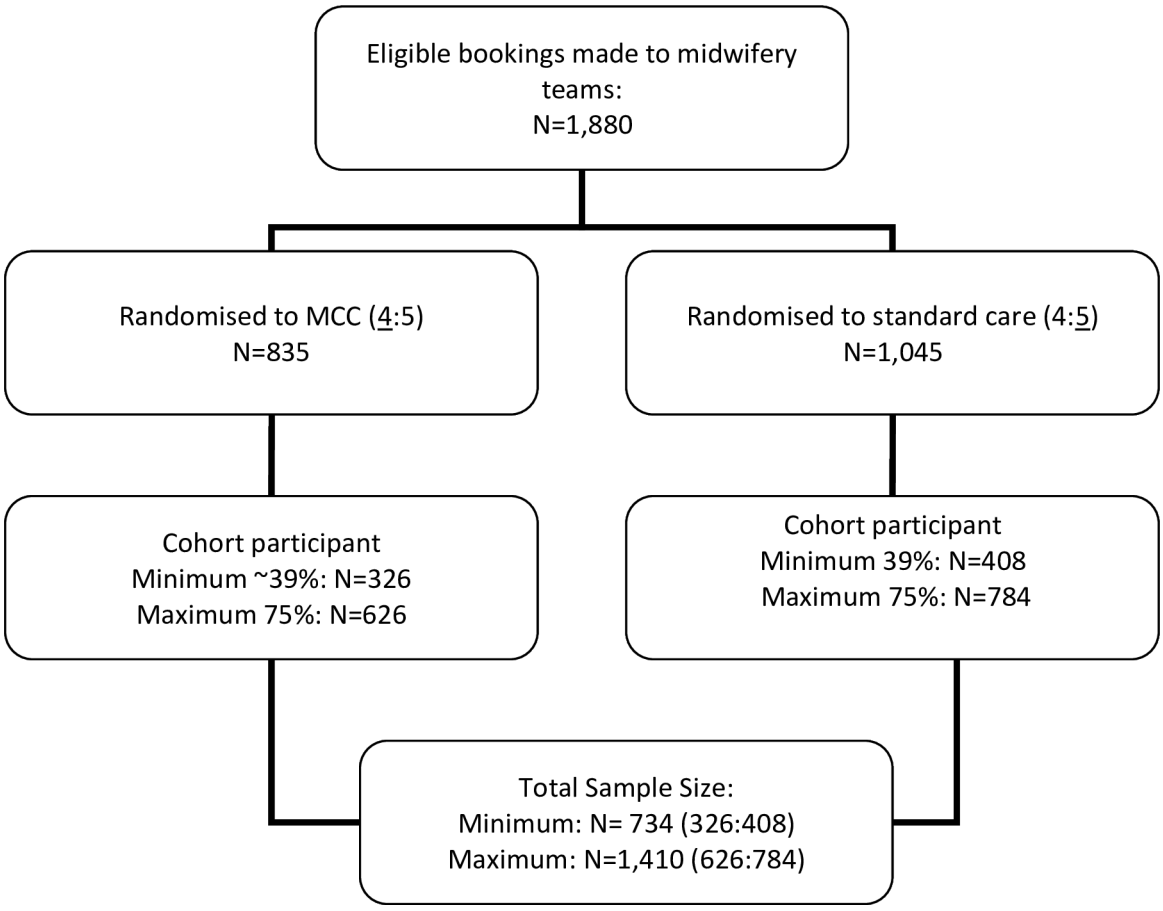

Figure 1 Flowchart of the eligible pregnant population and study sample (based on 2019/2020 pregnancy and cohort data). MCC, midwife-led continuity of care.

to the MCC service, the 2019/2020 eligible pregnant population within the intervention areas and the ability to manage the random allocation service by midwifery administrators (see figure 1). If/when the MCC teams reach their maximum caseload capacity, randomisation will be manually paused and women will automatically receive standard care. Randomisation will recommence when MCC capacity becomes available. This approach provides a pragmatic solution to caseload management while preserving the function of minimisation. Women who receive standard care during paused randomisation will not be included in the trial.

Blinding

Researchers will be blind to allocation although the statistician may become aware of treatment allocation due to the unequal allocation ratio. Participants and those involved in administration or delivery of MCC or standard care will not be blind.

Participants

Internal pilot

Anonymised data on all randomised women will be used to assess the feasibility of the internal pilot. However, to be included in the RCT, all eligibility criteria for the RCT (below) will be required.

Randomised controlled trial

All women booked to give birth at the Bradford Teaching Hospitals NHS Foundation Trust are invited to participate in BiBBS or BiB4All cohort studies during pregnancy. All women who have consented to take part in one of these BiB cohort studies, *and* who have been randomised to receive MCC or standard care, will be trial participants.

Eligibility criteria for trial

Inclusion

- Are randomised to receive either MCC or standard care.
- Consented to take part in the BiBBS or BiB4All cohort studies.

Exclusion

- Have pregnancy loss or termination<24 weeks gestation.
- Are found to be have been >29 weeks gestation at randomisation.
- Move outside of the geographical remit of the care teams following randomisation, but prior to care commencing.
- Were not randomised to MCC or standard care (i.e., if they were allocated their midwifery care during a randomisation pause).

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- Withdraw consent for their research data to be used for the evaluation, before analysis commences.

Process evaluation

Fidelity to the model will be assessed using routinely collected midwifery data for the trial participants. Up to 30 women receiving MCC care will also be invited to take part in in-depth interviews. Women will be sampled based on the level of continuity they received during labour and birth: 10 who received care from their named MCC midwife, 10 who received care from a member of the MCC team and 10 who received care from hospital midwives. Wherever possible, purposive sampling will be used to recruit MCC women from the main ethnic groups within the local population. To avoid any unnecessary distress or burden on women, the process evaluation will not include women who have experienced pregnancy loss, stillbirth or have a baby still receiving inpatient care.

Interviews will take place between 4 and 20 weeks postbirth. MCC midwives (n=14) and team leaders (n=2) will be invited by the research team to complete reflective diaries. Informed consent will be obtained at the start of each reflective diary that is completed.

Eligibility criteria for process evaluation

Women

Inclusion

- Received MCC care.
- Had a live birth between 4 and 20 weeks before recruitment.
- Have completed a 'consent to contact' form (to confirm the research team can get in touch with them).
- Consented to participate in an interview.
- Speak a language accessible to the research team (eg, English, Urdu).

Exclusion

- If their infant is receiving care/treatment in hospital during the recruitment window.
- Have a pregnancy loss.
- Have a stillbirth/infant death.

Midwives

Inclusion

- Have delivered MCC for >9 months
- Consent to complete reflective diaries.

Recruitment process

RCT

Once women have been recruited into a BiB cohort, the research team will be able to access and link mother and child's routine health and education data for research and evaluation purposes (i.e., no further consent is needed for the trial). More details relating to the consent procedures within the cohort studies can be found in the published study protocols.[11 15]

Process evaluation

Women

Consent to contact will be obtained by the woman's midwife who will also give women the participant information sheet. The research team will then contact the women to confirm eligibility, and arrange a time and preferred location (online/in-person) for the interview. Informed consent will be taken before the interview commences.

Midwives

Midwives will be approached and invited to take part by midwifery team leaders. Team leaders will provide all eligible midwives with an information sheet, and informed consent will be taken online at the start of each reflective diary.

Outcomes

Trial internal pilot

The randomisation process will be reviewed on pilot completion using anonymised cumulative trial monitoring data to determine the feasibility of using the randomisation process within usual care for the main trial. The progression criteria for the pilot are 'RAG rated' (red/stop, amber/amend, green/go) as follows:

- The number of women randomised relative to the total number eligible for randomisation: green (90%–100%); amber (80%–90%) and red (<80%).
- The allocation ratio of 4:5 allows the MCC teams to fill their caseload: green (90%–100%); amber (70%–90%); and red (<70%).

Randomised Controlled Trial

Outcome data will be obtained from linked routine health data in the BiB cohorts at trial end (see figure 2 for specific outcome data collection time points). The selection of the primary outcomes used a pragmatic approach based on: the pre-determined sample size of the service; the power to detect a change (see table 1) and the clinical relevance as perceived by local midwifery services. The midwifery service were keen to have one primary outcome relating to birth, and one relating to mental health. The only birth outcome that was significant in the Cochrane review that the fixed sample size in this study was powered to detect was spontaneous vaginal delivery (table 1). The selection of postnatal depression at 6–10 weeks as the primary outcome was based on advice from the perinatal mental health service in Bradford who noted that early detection was likely to reduce the severity of symptoms throughout the postnatal period and therefore have high clinical impact.

Independent primary outcomes: women

- Spontaneous vaginal delivery using maternity service health records.
- Maternal depression measured at 6–10 weeks postnatally using the eight-item Patient Health Questionnaire (PHQ-8).[7]

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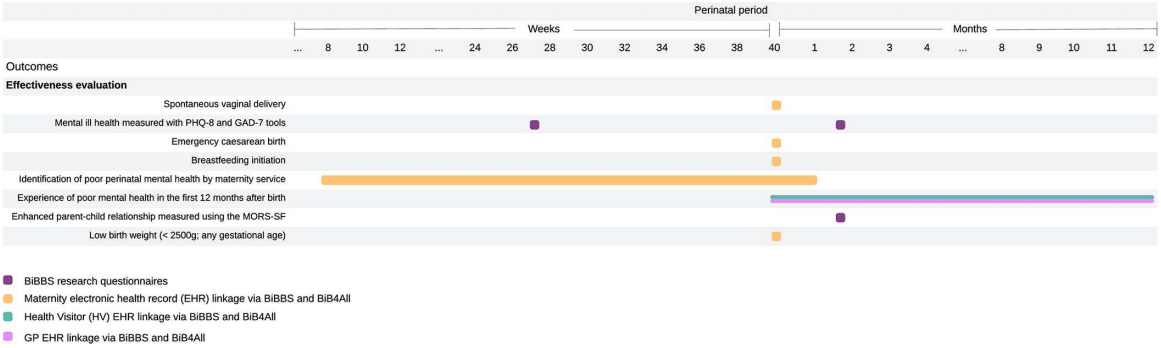

Figure 2 Timepoints of the outcome measurements for the study. BiBBS, Born in Bradford's Better Start; GAD-7, Generalised Anxiety Disorder assessment; GP, general practitioner; MORS-SF, Mothers Object Relations Scale.

Secondary outcomes: women

- Incidence of emergency caesarean birth using maternity service health records.
- Breastfeeding initiation rates using maternity service health records.
- Detection of perinatal mental health by midwives using maternity service health records. Coded maternity data will be examined for detection of poor mental health at any point from time of referral to discharge using predetermined code lists.
- Maternal anxiety measured using the GAD-7[9] at 6–10 weeks postnatally.
- Any indication of perinatal mental health difficulties in the 12 months after birth, identified using health visiting and GP health records. Coded data will be examined for detection of perinatal mental health difficulties using predetermined code lists.
- Parent–child relationship assessed using the MORS-SF[8] at 6–10 weeks postnatally.

Secondary outcome, children

Low birth weight (<2500 g; any gestational age).

Descriptive data

Demographic information, accessible via the cohort data, includes age, ethnicity, socioeconomic status (using the IMD for England and Wales), marital status, housing and family composition. Ethnicity and socioeconomic status will be used to complete subanalyses of the primary outcomes.

Process evaluation

Fidelity to the MCC model will be assessed by considering the number of midwives employed into the teams, their average caseload and the level of continuity achieved within the MCC model overall and separately for antenatal, intrapartum and postnatal elements of the model. Barriers and facilitators to implementation and delivery from midwives perspectives will be obtained through reflective diaries. In-depth interviews with women who received MCC will explore their pregnancy, birth and postnatal experiences.

Economic evaluation

Using a range of economic evaluation methods (cost analysis, cost-consequence and cost-effectiveness), we will examine resource use, costs and health outcomes based on access to health services by parents via the cohorts. We will present data on health-related resource use and postnatal outcomes (including the detection of mental health events) for both intervention and control groups. The primary aim of the economic evaluation will be to

Table 1 Disjunctive power to detect varying minimum important clinical differences (MICD) and sample sizes.

Outcome	N (total)	N (MCC)	N (SC)	Mean (SD) or % (MCC)	Mean (SD) or % (SC)	Difference	Power (%)*
PHQ-8	734	326	408	5 (4.4)	7 (4.4)	2	99.9
	1410	626	784	5 (4.4)	7 (4.4)	2	100
	734	326	408	6 (4.4)	7 (4.4)	1	79.2
	1410	626	784	6 (4.4)	7 (4.4)	1	97.8
Spontaneous vaginal delivery	734	326	408	70.6	65.8	4.8	20.2
	1410	626	784	70.6	65.8	4.8	37.5
	734	326	408	72	65	7	41.6
	1410	626	784	72	65	7	65.0
	734	326	408	73	65	8	53.5
	1410	626	784	73	65	8	83.8

*Power calculated applying the Bonferroni adjustment (p=0.025).
PHQ-8, Patient Health Questionnaire-8.

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inform commissioners of the potential cost and cost-effectiveness of MCC and reflect areas where additional evidence is required before a robust conclusion can be drawn through value of information methodology.

Power and sample size calculations

The maximum number of women to receive the intervention is predetermined by the capacity of the MCC team and the duration of funding. Therefore, a pragmatic approach was taken where the fixed total sample was used to determine the level of confidence in the trial findings.

The target sample for the overall trial (internal and main RCT) was calculated based on: eligible pregnancies (n=1,880) (Bradford Teaching Hospitals NHS Foundation Trust maternity data 1 April 2019 to 31 March 2020, accessed 2 July 2021); MCC service capacity (n=840); the proportion of randomised women also in the BiBBS or BiB4All cohort (estimated at a minimum of 39% and a maximum of 75%), see table 1.

The fixed sample size is therefore estimated as a minimum of 734 (39% of 1,880) and a maximum of 1410 (75% of 1,880).

Effect sizes for spontaneous vaginal delivery were taken from the Cochrane review on continuity of care.[5] The effect size for postnatal depression (PHQ-8) was taken as the minimum clinically important difference of two points on this scale.[7] The two primary outcomes are independent of each other, they are not related and a significant effect of either outcome will deem the intervention effective. To correct for two primary outcomes, the Bonferroni adjustment ($p<0.025$) has been applied to the power calculations.

The calculations show that, with a maximum fixed sample of 1,410, we will have 84% power to detect a difference of 8% in vaginal delivery, and 100% power to detect a change of two points in the PHQ-8 score. Calculations for other sample sizes and effect sizes can be seen in table 1.

ANALYSIS

The statistical analysis plan will be developed before the end of recruitment and will be reviewed and signed off by the study governance team. It will consider necessary adjustments for the inclusion of two independent primary outcomes, and of any changes to allocation ratio that occur after the internal pilot.

Internal pilot

Descriptive statistics will determine whether the anticipated number of women were randomised and the allocation ratio appropriate.

Data from eligible participants will be used as a part of the full trial data set if no substantial design changes are required.[16] The decision as to whether the internal pilot data will be used will be made by the study governance team.

Effectiveness evaluation

Analyses will be fully described in the statistical analysis plan. In summary, ITT analyses using appropriate quantitative methods will be performed for the primary and secondary outcomes. Subgroup analyses will determine whether any outcomes vary by dosage with consideration of the levels of continuity received by women. Mediation and moderator analyses will allow consideration of inequalities including socioeconomic status and ethnicity to establish for whom the intervention works best.

Plans for dealing with missing data will be set out in the analysis plan and handled consistently. Where standardised questionnaires are used, the developer's guidance on handling missing data will be used.

Process evaluation

A mixed-method approach will assess fidelity of the model using descriptive statistics for quantitative data and thematic analysis, utilising a 'realist method' for qualitative data.

Descriptive statistics will describe the fidelity of delivery of the MCC model based on the number of midwives employed and the average caseload of each midwife. The proportion of continuity experienced for women during the antenatal, intrapartum and postnatal periods will be calculated using the number of appointments delivered by MCC. For standard care, the total number of midwives seen and the number of appointments received will be calculated.

Qualitative data will describe the experiences of women, and the barriers and enablers of MCC delivery by midwives. Data will be coded using a hybrid process of inductive and deductive thematic analysis incorporating aspects of grounded theory such as iterative data generation, analysis and constant comparative analysis to enhance the rigour of the analysis.[17]

Economic analysis

We will seek to apply a range of economic evaluation methods using service cost, resource use, health outcome and health-related quality of life at 1 year postnatal data. These data will be obtained from the linked routine health record for cohort participants and information collected by implementation staff. Information captured at any point between referral to midwifery and up to 1 year following birth will be included in analyses.

The methods applied will include costing of the MCC team compared with usual care, cost-minimisation (exploring the comparative resource use of the two treatments), cost-consequence (comparing the respective costs to the primary and secondary outcomes) and cost-effectiveness (comparing the respective cost to the primary mental health outcome measure, i.e., GAD-7). We will further explore the potential to map GAD-7 to a generic measure of health and value of information analysis.

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Patient and public involvement

The approach to randomisation within practice was discussed and planned with MCC team leaders, midwives and administrators. Key outcomes for the trial and process evaluation were also co-produced with the midwifery service to ensure their direct applicability to their future service design and planning. Local families were consulted on the study design through an existing Community Research Advisory Group within BiB. This group will remain involved throughout the study and will help to interpret and disseminate research findings for the public and participants.

Research ethics approval

This study involves human participants. Ethical approvals have been obtained as follows for the different elements of this study: the use of cohort data for cost/effectiveness intervention evaluation (BiBBS: 15/YH/0455 and BiB4All: 17/YH/0202); randomisation in midwifery practice—BiBBS substudy (amendment 12, 20 October 2021); process evaluation (reference: 22/YH/0072). The sponsor for all elements of this study is Bradford Teaching Hospitals NHS Foundation Trust. Participants gave informed consent to participate in the study before taking part.

Ethics and governance

The RCT is evaluating an intervention delivered as a part of standard practice, with data collected through existing cohort processes with no additional burden to participants. We do not anticipate any adverse events or harms relating to the study.

The process evaluation may include discussion of topics that women may find distressing, and/or may result in disclosure of safeguarding concerns. Women will be informed that they do not have to answer any questions they do not want to, and can stop the interview at any time. Any safeguarding concerns will be managed via existing Bradford Teaching Hospitals NHS Foundation Trust policies, and the consent form is explicit that the researcher will follow Bradford Teaching Hospitals NHS Foundation Trust safeguarding policy and as such may have to break confidentiality if any safeguarding concerns are disclosed.

This study does not have a Trial Steering Committee or Data Monitoring committee per se; study procedures, design and data are governed by, and answerable to, Better Start Bradford Innovation Hub programme management group (including lay members), the Better Start Bradford Innovation Hub International Scientific Advisory Group; the BiB executive group, as well as the sponsor and regulatory bodies. Auditing of the randomisation process will be regular undertaken by the study team, auditing of the trial may be undertaken by the study sponsor.

Protocol amendments

Any important protocol changes (e.g., as a consequence of the internal pilot) will be agreed by the management team, submitted as an ethics amendment to the study REC, and will be updated on the trial registry.

Dissemination

Findings will be published in peer-reviewed journals and presented at relevant conferences. Policy briefings will be collated for local services, commissioners and national policy makers. Summary findings for the public and participants will be co-produced with our Community Research Advisory Group who will also advise on the most appropriate modes of dissemination (e.g., videos, social media, newsletters and local press channels).

Data management

All cohort data will be linked, cleaned, quality checked and pseudonymised by the central BiB data team using existing data management procedures described in the BiBBS study protocol[12] before being shared with the research team. Patient data will be handled in accordance with relevant data regulations (e.g, the General Data Protection Regulation (GDPR; 2018)[18] and the 'Confidentiality: NHS Code of Practice'.[19]

Interview recordings will be undertaken on encrypted devices, uploaded to a restricted-access folder on the secure NHS network and the original recording deleted immediately. The consent component will be separated from the rest of the recording and stored in a separate restricted-access folder, accessible only by the study team. The anonymised recordings will be transcribed using an external company with a pre-existing confidentiality agreement. The original recordings will be deleted from the NHS network following analysis.

Data statement

BiB data are available via a managed open access procedure. Guidance for Collaborators is here: https://borninbradford.nhs.uk/research/guidance-for-collaborators/. Data Dictionaries are available here https://borninbradford.github.io/datadict/ and here: https://borninbradford.github.io/datadict/bibbs/. The 'Expression of Interest' form is available here: https://borninbradford.nhs.uk/wp-content/uploads/BiB_EoI_v3.1_10.05.21.doc. Please send this completed form to borninbradford@bthft.nhs.uk. Proposals are reviewed monthly by the BiB Executive Group. A data sharing contract and agreement will be needed: https://borninbradford.nhs.uk/wp-content/uploads/BIHR-Data-Sharing-Contract.docx and https://borninbradford.nhs.uk/wp-content/uploads/BIHR-Data-Sharing-Agreement.docx.

Trial status

To date (17 January 2023), 411 participants have been randomised. It is not yet possible to report on the number also in the BiB cohorts.

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Contributors KW was involved in the conception of this evaluation, has been part of the evaluation development as well as being the lead author of the manuscript. RHM was involved in the development of the process evaluation element of this study and has been assisting with the writing up of this manuscript. GS was involved in the statistics of the piece, assisting the team with the necessary sample size calculations. SA was involved in the conception of this evaluation and has been involved in all elements of evaluation development. MB was involved in the conception of this evaluation, has been involved at all stages of evaluation development and has been involved in writing this manuscript. TB was involved in the conception of this evaluation, has been involved at all stages of evaluation development and has been involved in writing this manuscript. SLB has been involved in the conception and evaluation design of this evaluation. GR, SH and DH have been involved in shaping, designing and understanding the feasibility of conducting an economic analysis evaluation as part of this work. JW contributed to study design and manuscript revisions. JD has been involved in the conception of this evaluation, has been involved in all elements of evaluation development and has been involved in writing this manuscript. All authors edited the final manuscript and are happy to be accountable for this piece.

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Competing interests Yes, there are competing interests for one or more authors and I have provided a Competing Interests statement in my manuscript and in the box.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

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