Evaluating the Effectiveness of the Breastfeeding Support Program in Promoting and Sustaining Breastfeeding at 6-8 Weeks Postpartum: A Quasi-Experimental Study

Funding bodies: National Lottery Community/Fund Better Start Bradford

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1. Introduction

The benefits of breastfeeding are well documented, with strong evidence of benefits for both mothers and children. On the basis of this, the World Health Organisation (WHO) recommends exclusive breastfeeding until at least six months of age, and continued breastfeeding until children are at least two years old (Fomon S, 2001). In contrast to these recommendations, breastfeeding rates in the UK are among the lowest in the world (Kendall et al., 2023). Recent national data suggests that although nearly 72% of babies have breastmilk as their first feed, only 49% of babies continue to receive any breast milk at 6 months (OHID, 2024). This is in line with the findings from the Infant Feeding Survey conducted in the UK in 2010, which found that although 81% of infants were breastfed directly after birth, only 69% were receiving breast milk at one week, 55% at six weeks, and only 1% were exclusively breastfed at 6 months old (McAndrew et al., 2012).

Breastfeeding is a complex behaviour, influenced by factors at the level of the mother, the baby, and the interaction in the dyad, as well as factors within the wider familial, community, and cultural environment (Rollins et al., 2021). Aggregated figures on breastfeeding rates hide large variations in outcomes by individual and geographical characteristics. The Infant Feeding Survey revealed that, within the UK context, mothers who were older, more affluent, living in the least deprived areas, had higher levels of education, were employed in professional roles, and were from minority ethnic backgrounds were more likely to breastfeed (McAndrew et al., 2012). This mirrors international evidence that suggests the influence of demographic variables including race, age, marital status, education levels, and socioeconomic situation, as well as biological, social, and maternal psychological variables on breastfeeding duration (Thulier & Mercer, 2009). While many of these variables are constants, there is also evidence that there are important modifiable factors that are associated with breastfeeding outcomes, including breastfeeding knowledge and support factors in women' s environments (Xu et al., 2022). These modifiable factors are the key targets of interventions.

Many women encounter challenges when initiating and attempting to sustain breastfeeding, and evidence suggests that breastfeeding rates can be improved by interventions at all levels of the socioecological model (Pérez-Escamilla, et al., 2023). For example, in their review of reviews, Tomori and colleagues (2021) found evidence that interventions that provided breastfeeding information and counselling support, including via home visits, were associated with longer durations of breastfeeding and increased rates of exclusive breastfeeding. The WHO has previously set out guidance on what should be included in breastfeeding counselling interventions, including recommendations on when and how to provide care, the minimum dosage, and the appropriate people to provide the support (WHO, 2018). Given the low rates of breastfeeding in the UK, as well as the evidence that interventions can be effective in improving breastfeeding outcomes, it is important to understand whether interventions may work within UK contexts. One such intervention was the Breastfeeding Support service, that provided

postnatal breastfeeding support through trained community-based supporters in a diverse, urban community.

The Breastfeeding Support intervention was co-designed with key stakeholders as part of the Better Start Bradford programme to meet the needs of the specific community. The intervention was designed to be a universal education and counselling service to provide information, support and advice to new mothers on the arrival of their baby. Health for All, a local health promotion charity, provides the service through a team of trained breastfeeding support managers and staff.

The Breastfeeding Support intervention was co-designed with key stakeholders as part of the Better Start Bradford programme, which began in 2015, to meet the needs of the specific community. The project was co-designed with key stakeholders, including mothers and community members, to ensure it met the specific needs of the local community. The intervention was designed to be a universal education and counselling service to provide information, support, and advice to new mothers on the arrival of their baby. Health for All, a local health promotion charity, provides the service through a team of trained breastfeeding support managers and staff. The intervention was created through a partnership approach, involving trained Breastfeeding Support Workers who provided practical and emotional support to women and their families to help them breastfeed for longer. This collaborative effort aimed to address the high rates of early breastfeeding cessation in the area. In Bradford, the intervention complements the Baby Friendly Initiative (BFI), a UNICEF-led programme designed to support breastfeeding in health services by training healthcare staff to deliver evidence-based support. Unlike the BFI, which focuses on establishing a breastfeeding-supportive environment within hospitals and health services, the Breastfeeding Support intervention extends into the community and provides tailored, ongoing postnatal support directly to mothers in their homes or preferred settings.

The public protections put in place to control the spread of Covid-19 impacted the Breastfeeding Support intervention in ways similar to many health interventions at the time. Face-to-face delivery was stopped and all support was moved to either telephone or online delivery. Given that these changes impacted on key design features that were developed in line with the WHO recommendations for breastfeeding counselling interventions (Pérez-Escamilla, 2020), another key objective of this evaluation is to investigate whether these implementation changes were associated with changes in the impact of the intervention.

As the service was designed specifically for the Better Start Bradford programme, it has not been subject to any previous quantitative evaluation beyond standard monitoring processes. Monitoring of the program over the duration of its delivery (5.5 years) in the Better Start Bradford area revealed that it supported over 1500 women, and rates of enrollment, participation, and completion were high. A qualitative evaluation revealed that the intervention

was delivered as intended and was valued by the participants who received the service. Together this suggests that the intervention was successfully delivered and acceptable to the community, and this provides support for the assumption that sufficient data will be available for a quantitative evaluation.

Based on the Early Intervention Foundations evidence scales, Breastfeeding Support would be rated as 'not level 2' (NL2), as it has not yet met the threshold for preliminary evidence of achieving outcomes for children (see https://guidebook.eif.org.uk/about-the-guidebook/other-programmes.

It is not yet known whether receiving the Breastfeeding Support intervention has an impact on women's breastfeeding rates, and whether participation in the intervention is associated with an increase in the duration of breastfeeding.

Objectives

The main objective of this study is to evaluate the effectiveness of the Breastfeeding Support intervention in promoting and sustaining breastfeeding among women in the Better Start Bradford area, and to identify factors that may influence its impact.

Primary research question:

Does participating in the Breastfeeding Support intervention increase the chances that women will be breastfeeding (any breastfeeding) their baby at 6-8 weeks, as compared to receiving standard care in the BSB area ?

Secondary research questions:

Effectiveness Evaluation

Exclusive Breastfeeding: What is the difference in exclusive breastfeeding rates at 6-8 weeks, and any breastfeeding rates at 6 months postpartum between mothers who received the BFS intervention and those who received standard care?

Pre- and Post-Pandemic comparison: How do exclusive breastfeeding rates at 6-8 weeks postpartum compare between mothers who received in-person BFS support pre-pandemic and those who received virtual/telephone BFS support during the pandemic?

Implementation/Process Evaluation

Intervention dose: Is there a correlation between the number of BFS support contacts and the rate of any breastfeeding at 6-8 weeks postpartum?

Mode of delivery: How do breastfeeding rates at 6-8 weeks postpartum differ between mothers who received in-person BFS support and those who received telephone support?

Interpreter use: What is the impact of interpreter use on breastfeeding rates at 6-8 weeks postpartum among mothers receiving BFS support?

Subgroup Analyses:

Language background: How do breastfeeding rates at 6-8 weeks postpartum differ between mothers with English as a first language and those with English as a second language receiving BFS support?

1 Methods

2.1. Study design

The study is a quasi-experimental evaluation using data from an intervention group of women in the Born in Bradford's Better Start (BiBBS) cohort who received Breastfeeding Support compared to a matched control group of similar women from BiBBS who did not receive the intervention. . This design is chosen because it allows for the assessment of the intervention in a real-world setting where random assignment is not feasible. By using propensity score matching, we aim to create comparable groups based on observed characteristics, thereby reducing selection bias and approximating the conditions of a randomized controlled trial. This approach helps to isolate the effect of the intervention on breastfeeding outcomes by ensuring that the intervention and control groups are similar in terms of key covariates (Harris et al. 2006). Stakeholders within the wider project team considered universal delivery to be the most important priority for the service. Propensity score matching will be used to match participants within the BiBBS cohort who did and did not receive the intervention, and multiple case controls will be matched to intervention cases. More details on the planned statistical analyses are available in section 2.8 of this document. As such, a retrospective evaluation of existing data is necessary. We have utilised the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE; 2021) guidelines for reporting methods in this protocol **(Appendix 2)**.

The Born in Bradford Better Start (BiBBS) cohort is an interventional birth cohort of women and their children born within the Better Start Bradford area between 2016 - 2024. It was specifically established in order to evaluate the interventions implemented as part of Better Start Bradford, and the cohort recruits pregnant women who are eligible for the interventions, regardless of whether they go on to participate in them. An interim analysis of the profile of the cohort suggests that the cohort is representative of the community Better Start Bradford serves (Dickerson et al, 2023). All parents recruited into the cohort consent to data linkage of their own and their child's routine health and education data, intervention data, and cohort baseline questionnaire, and they also consent to all of this data being used to evaluate interventions (including as either a participant or a control). As such, additional consent processes are not necessary once parents join the cohort.

Within this cohort, in the years 2016 to 2024, baseline cohort questionnaire data provided by >5,600 participants during pregnancy revealed that 81% of women intended to at least try to initiate breastfeeding with their baby, and 68% went on to give breastmilk as their baby's first feed (Dickerson et al., 2023). Once women were discharged from hospital, 52% were exclusively breastfeeding, 17% were breastfeeding in combination with feeding formula milk, and 32% were providing only formula milk. Additionally, interim analysis of the cohort revealed that 48% of BiBBS mothers participated in the Breastfeeding Support intervention (Dickerson et al., 2023), demonstrating that the intervention was accessible to the specific mothers involved in this evaluation.

2.2. Study registration

This study will be registered on ISRCTN, which is a clinical trial registry open to all clinical research trials. Details of this registration will be added to this protocol once available.

2.3. Study setting

Bradford is a city in the North of England, with a highly diverse population and high levels of poverty. Poor childhood health outcomes and large health inequalities contributed to the city's selection as a recipient of funding for a programme of work to implement interventions for young families called Better Start Bradford (https://www.betterstartbradford.org.uk/). The aim of this programme was to provide a range of interventions and services to pregnant women, their families and their babies to improve the early life experiences of these children, with support to improve children's language, socioemotional development, and health and nutrition.

2.4. Intervention

The Breastfeeding Support (BFS) intervention was developed in 2017 as part of the Better Start Bradford (BSB) programme. Its design involved collaboration between BSB programme staff, academic researchers, local midwives, infant feeding specialists, and community representatives. The intervention was informed by both research evidence on the characteristics of effective breastfeeding support and by local knowledge of the needs, preferences, and resources within the BSB target communities and the wider health system.

BFS was a universal intervention, offered to all new mothers in the area. It provided proactive, tailored breastfeeding support from birth until six months postpartum, delivered via a combination of telephone and face-to-face contacts. Mothers were first approached either on postnatal hospital wards or by phone shortly after discharge. Once enrolled, they received support in their preferred format, with the goal of helping them achieve their own breastfeeding intentions and extending the duration of breastfeeding where possible.

The service began delivering support in October 2018 and concluded its contract with Better Start Bradford in March 2024. Further details of the intervention's content, delivery model, and

implementation fidelity can be found in the TIDieR checklist (Appendix 1). The intervention was particularly intensive in the first six weeks, recognizing the critical period for establishing breastfeeding. During this time, mothers received frequent contact from trained Breastfeeding Support Workers, who provided practical and emotional support. This included help with latch and positioning, addressing common breastfeeding challenges, and offering reassurance and encouragement. The support was delivered through a flexible mix of home visits, telephone calls, and in-person contacts, tailored to each mother's individual needs and preferences.

2.5 Participants

Participants in this study are mothers of infants, and data have been collected at the level of the mother and child. The participants allocation to the intervention and matched comparison group are via self-selection. Where mothers had multiple pregnancies in the cohort, the first pregnancy and baby will be selected for analysis.

The eligibility criteria for the intervention group are:

- Participants engaged with the Breastfeeding Support service, with at least one support contact.
- Completion of the Born in Bradford's Better Start (BiBBS) baseline questionnaire.
- Neither mother nor infant was admitted to ICU/NICU following delivery.
- No documented medical reason for refusal, such as:
    - Maternal or infant health complications
    - Contraindicated medications
    - NICU admission (not already covered above)
- Breastfeeding support was offered within 6–8 weeks postpartum (i.e., not offered later than 8 weeks).

The eligibility criteria for the matched comparison group are:

- Mother delivered during the Breastfeeding Support intervention delivery period.
- Mother did not participate in the Breastfeeding Support intervention.
- Completed the BiBBS baseline questionnaire.
- Neither mother nor infant was admitted to ICU/NICU following delivery.
- No documented medical reason for refusal, such as:
    - Maternal or infant health complications
    - Contraindicated medications
    - NICU admission
- Did not receive a late offer of breastfeeding support (i.e., no offer made after 6–8 weeks postpartum).

2.5.1 Selection of participant

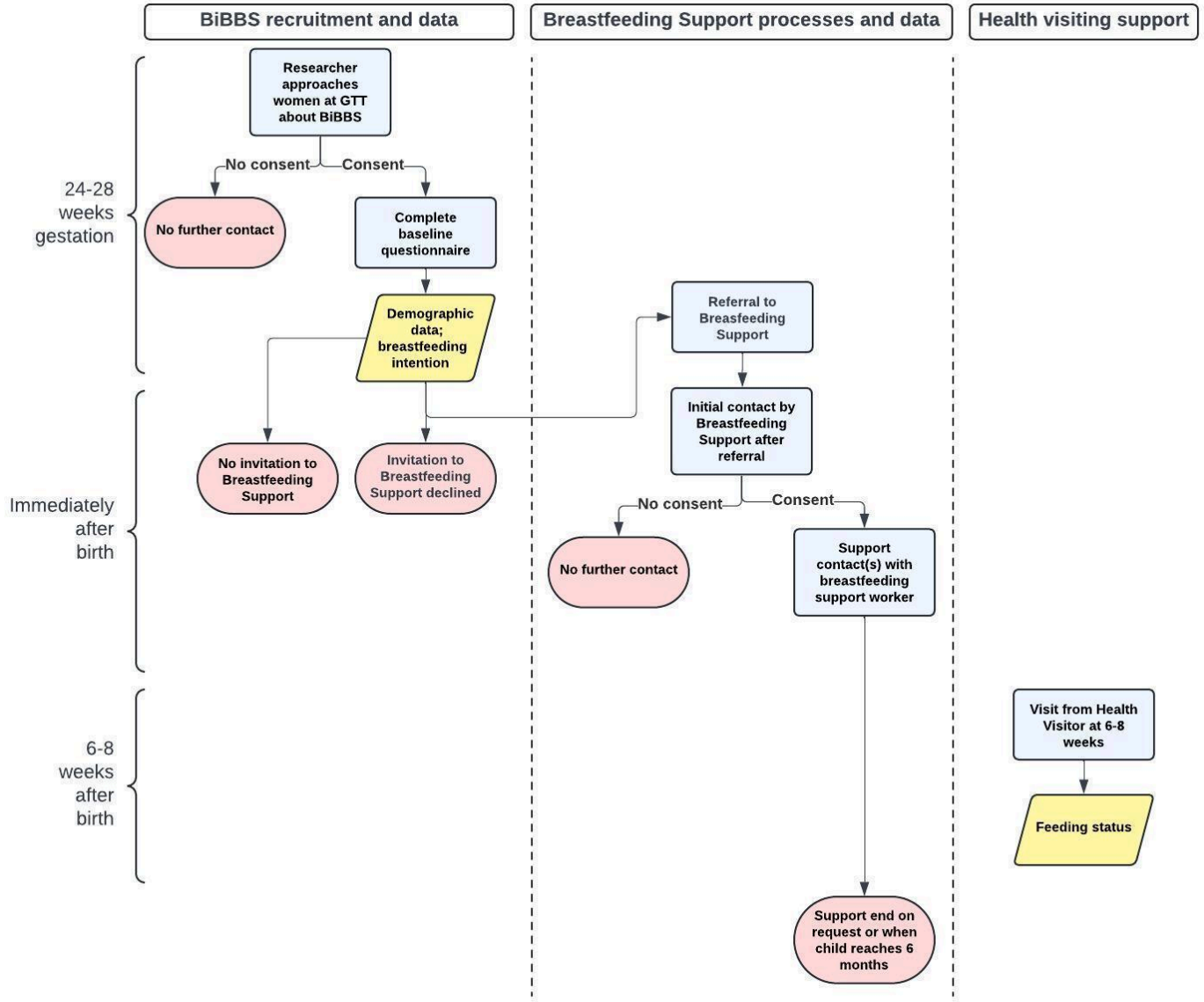

Figure 1. Participant pathway through BiBBS and Breastfeeding Support, and data sources and collection points

Figure 1 shows how participants are recruited into BiBBS and the Breastfeeding Support intervention. Data sources are shown in yellow boxes; baseline data is recruited from participants during pregnancy as they are recruited into the BiBBS cohort, data on intervention engagement is collected by the Breastfeeding Support service, and the outcome data is collected by health visitors as part of the mandated 6-8 week visit for all children.

It was possible for women to be part of BiBBS and not receive Breastfeeding Support, and it was also possible for women to receive Breastfeeding Support and not be part of BiBBS. Of all the

women who received Breastfeeding Support, only those who were also signed up to BiBBS, and for whom baseline survey was completed, will be included in this evaluation.

2.5.1.1 Recruitment to BiBBS and Breastfeeding Support

For more information on how women were recruited to BiBBS, please see the description of the cohort provided by Dickerson and colleagues (Dickerson et al., 2016). For more information on the recruitment process into Breastfeeding Support, please see the TIDierR checklist (Appendix 1).

2.6 Sample size calculations

Sample size calculations for the primary objective were conducted using Stata 18 to estimate required sample sizes for detecting differences in proportions between two groups. The analysis focused on the effectiveness of the Breastfeeding Support intervention in improving the probability of any breastfeeding at 6–8 weeks postpartum.

Assumptions used for the calculation:

- Baseline breastfeeding rate of **55%** at 6 weeks (based on local data)
- **Two-tailed alpha = 0.05**
  Power = 80%
- **Risk difference (effect size): 5% to 10%**
- **Equal and unequal group allocation scenarios**

Using a conservative **8% risk difference**, the following sample sizes were estimated:

- **For equal group sizes (1:1 allocation)**:
  A total of **1,186 participants** (593 per group) are required to detect an 8% difference in breastfeeding rates with 80% power.
  OR
- **For unequal group sizes (1:2 allocation)**:
  A total of **1,329 participants** (443 in the intervention group and 886 in the comparison group) are required to detect the same 8% difference with 80% power.

Allocation Ratio	Total Participants	Intervention Group	Comparison Group
1:1	1,186	593	593
1:2	1,329	443	886

Given that 984 women have attended the breastfeeding intervention, who are also part of BiBBs, our sample size is based on an equal ratio 1:1, requiring a total sample of 1186 participants, with equal sized intervention and comparison groups of n=593.

2.7 Data sources

Data for this study will come from three sources; the BiBBS baseline questionnaire, the Breastfeeding Support project data, and health visiting data records. Timings for when each of these data sources are collected can be seen in Figure 1.

BiBBS baseline questionnaire

Women who are recruited from 1st Nov 2018, up until the end of the delivery of the service (March 2024) into the BiBBS cohort, completed a baseline questionnaire that includes a large amount of demographic information in addition to measures of mental health, socioeconomic status, and family background. This questionnaire data will be the source of the variables for the propensity score matching, and further details on which variables will be used can be found in section 2.9.4.

Breastfeeding Support project data

The service collects data on participants who engage with the project, including when they were referred, contacted, enrolled, dates of each support contact, format of each support contact, and discharge date. This information will be used to identify women within BiBBS who did and did not engage with the service, and to understand when and how women received support, as this information will be used to consider whether differences in receipt of the intervention may impact on outcomes (secondary research questions). Project data is held on SystmOne, and so can be linked to BiBBS and health visiting data via NHS number.

Health visiting data

Data from women's health records held on SystmOne will be used to collect information on feeding status at 6-8 weeks. This data is collected as part of the mandated 6-8 week health visiting visit, and feeding status at 6-8 weeks is a nationally collected health outcome. For this reason, it is hoped that data quality and completeness for this variable will be better than breastfeeding status data in mothers and babies health records at other times.

2.8 Data management

The BiBBS protocol establishes a comprehensive approach to data management. Data from various routine data systems (e.g. Cerner and SystmOne) are stored in the central database, managed by Bradford Teaching Hospitals NHS Foundation Trust (BTHFT). The unique identifier links the data at the individual BiBBS participant level. Nightly backups are performed on the

linked and comprehensive database for security and integrity. Baseline BiBBS data and routine data from the health visiting data (SystmOne) are linked to the person-level information from the maternity server (Cerner) is linked to baseline information for consenting BiBBS participants. Additionally, breastfeeding project data, collected and stored in SystmOne, can be linked to BiBBS baseline information for participants involved in the program. All data is stored within a cohort-specific Relational Database Management System (RDBMS) and managed using Microsoft SQL Server 2018 Management Studio. The Better Start Bradford Innovation Hub receives exported data from these sources for cleaning and combination. The existing data-sharing agreement must be completed to share with collaborators at the University of York. Further information is available on the Born in Bradford website (https://borninbradford.nhs.uk/research/).

2.9 Statistical methods

The descriptive analysis will be conducted to summarise the characteristics of the study population and evaluate the balance between the intervention and control groups after matching. For continuous variables, data will be reported as either the mean and standard deviation (SD) or the median and interquartile range (IQR), depending on the underlying distribution. Categorical variables will be presented as frequencies and percentages. To assess balance between groups, standardised mean differences (SMD) will be calculated for each variable. An SMD of less than 0.2 will be considered indicative of adequate balance between the intervention and control groups, ensuring that any potential confounding variables are minimised in the analysis (Andrillon, et al. 2020).

A matched control group for the intervention group will be generated using the propensity score matching method. The propensity score represents the likelihood of a subject receiving the treatment, given a set of covariates (Benedetto et al., 2018). We will employ one-to-many matching with the propensity score method to enhance statistical power (Barth et al., 2008). The propensity scores will be created using the matching variables. After specifying the propensity score, a critical aspect of any propensity score analysis is evaluating whether the model has been appropriately specified. To determine if the model is properly specified, the following steps will be undertaken:

1. The distribution of baseline covariates between treated and untreated subjects will be examined. It is essential to compare not only the means but also other distributional characteristics, such as medians and standard deviations, across treatment groups (Austin, 2011).

2. If systematic differences in baseline covariates persist between the groups after conditioning on the propensity score, this suggests that the propensity score model may be misspecified. In

such cases, the model can be refined by incorporating additional covariates, interaction terms, or nonlinear terms (Austin, 2011).

Propensity Score Matching steps:

Step 1: Estimating Propensity Scores: A logistic regression (i.e., the probability of receiving the intervention given baseline covariates).

Step 2: Matching algorithms by Kernel matching

Step 3: Assessment of matching quality by standardised mean differences (SMDs).

After performing propensity score matching and creating matched control groups, we will address missing data in the outcome measures using multiple imputation (MI), which remains a practical approach when the probability of missingness can be reasonably explained by observed covariates. In this study, we assume that missingness in breastfeeding outcomes is at least partially related to baseline characteristics used in the propensity score model—such as maternal age, ethnicity, socioeconomic status, breastfeeding intention, and relevant health variables.

A sensitivity analysis using complete cases (i.e., those participants with no missing outcome data) will be conducted alongside the imputed datasets. The goal of this sensitivity analysis is to compare the treatment effect estimates derived from the imputed datasets with those from complete cases. This will help assess whether the imputation approach affects the interpretation of the intervention's effectiveness.

After matched groups have been created and outcomes have been imputed, regression analyses will be run using group assignment as the independent variable, and the outcomes as the dependent variables, adjusted for any residual imbalances in covariates post-matching.

We will also conduct secondary outcome analyses to evaluate the rate of exclusive breastfeeding at 6-8 weeks and any breastfeeding at 6 months postpartum, and whether the impact of the Breastfeeding Support intervention differs by potential parameters (e.g. amount of intervention support contacts, i.e. dosage), the format of intervention delivery (face-to-face vs. telephone only vs. virtual meetings), use of interpreters, and changes in intervention implementation due to the Covid-19 pandemic).

2.9.1 Directed Acyclic Graph

To identify the matching variables associated with the intervention and the outcome, we designed the Directed Acyclic graph, a tool for indicating the causal relationships between variables (Shrier & Platt, 2008; Williams et al., 2018). A literature review was conducted to examine the factors associated with breastfeeding outcomes, and identified variables were added into the dagitty tool (Textor et al., 2016). This allowed for the identification of those

factors that were necessary to control for (through group matching) based on the theoretical, evidence-based relationships identified in the literature. An example of evidence supporting the link between each identified factor and breastfeeding outcomes is shown in Table 2.

Based on the DAG in Figure 2 we will match groups based on the eleven characteristics on the left-hand side of the graph to estimate the effect of treatment on outcome. Regression analysis will be employed to assess the relationships between group assignment (independent variable) and the primary and secondary outcomes (dependent variables). Specifically, linear regression will be used for continuous outcomes, while logistic regression will be used for categorical variables.

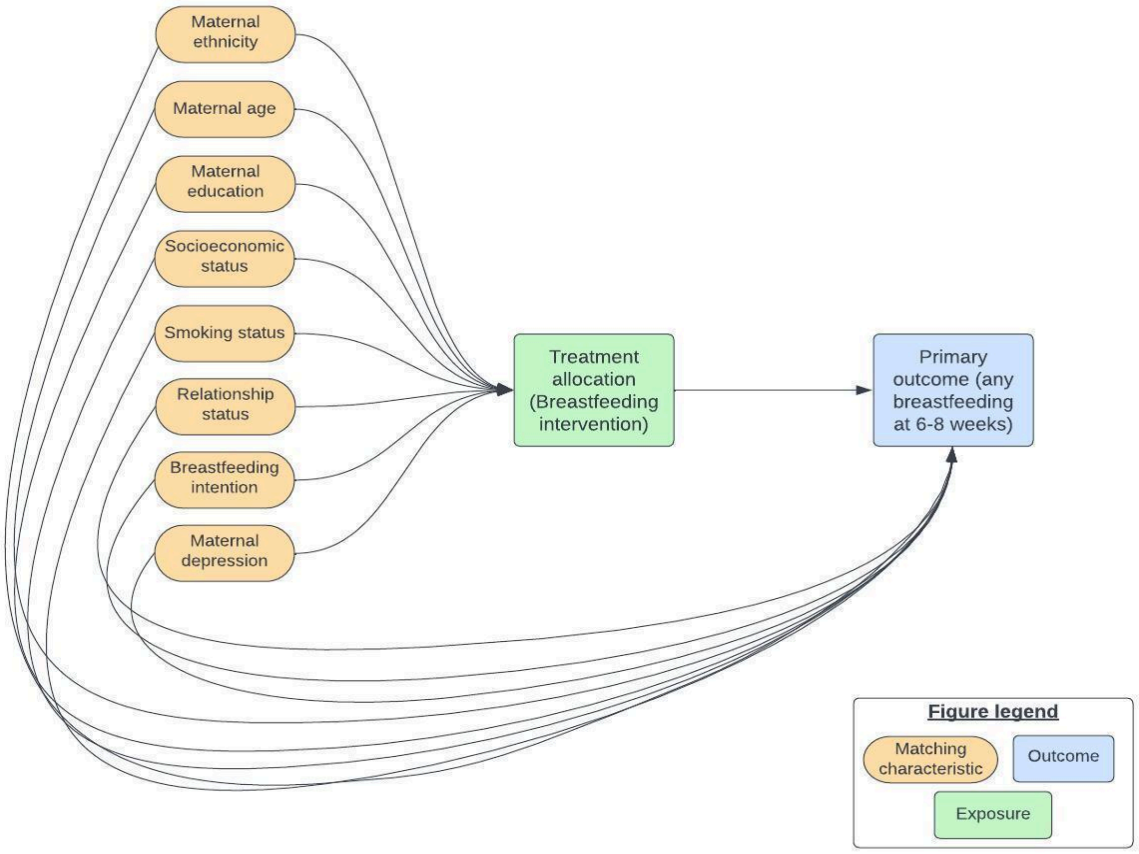

Figure 2. Directed acyclic graph showing relationships between matching variables (confounders), intervention exposure, and outcome

2.9.2 Variables

Exposure (intervention)

The exposure is the Breastfeeding Support intervention (treatment allocation), defined as a binary variable (participated, did not participate). We will also create a matched control group, based on the propensity score method as described above.

Primary outcomes

The primary outcome will be feeding status as recorded by health visitors at 6-8 weeks, defined as a binary variable (any breastfeeding, no breastfeeding).

Secondary outcomes

We will evaluate if there is any difference in rate of exclusive breastfeeding at 6-8 weeks and any breastfeeding at 6 months postpartum between participants with regards to the observed effectiveness of the intervention.

Moreover, by analysing the data from before, during, and after the COVID-19 pandemic, we will evaluate the impact of the pandemic on the changes in intervention implementation and the effectiveness of the intervention. The number of contacts (dose) each participant received and the format in which the intervention was delivered (face-to-face vs. telephone/online) will be recorded and examined to assess their impact on the effectiveness of the intervention. Additionally, as the population is linguistically diverse, we will evaluate whether receiving the intervention through an interpreter impacts its effectiveness. We will also assess if there is any difference in effectiveness of the intervention among participants whose first language is English and those for whom English is a second language.

Table 1. Summary of Breastfeeding Support data sources, collection, measurement methods.

Variable	**Data Source & Collection Method**	**Measurement**
Exposure	Breastfeeding support project data	Binary (participated/did not participate)
Primary Outcome	Health visiting records (routine health data)	Binary (any breastfeeding/no breastfeeding) at 6–8 weeks
Secondary Outcomes	Health visiting records (routine health data)	Binary (exclusive breastfeeding/no breastfeeding) at 6–8 weeks and at 6 months - any breastfeeding at 6 months
Implementation Context	BFS project data	Categorical (intervention received before COVID-19 / during COVID-19 / not during COVID-19)

Intervention Dose	BFS project data	Continuous (number of support contacts); may also be categorized (e.g. above/below average)
Format of Delivery	BFS project data	Categorical (in-person/telephone/virtual)
Use of Interpreters	BFS project data	Binary (interpreter used/not used)
Primary Language	BiBBS baseline data	Categorical (English as first language / English as second language)

2.9.2.1 Covariates

Table 2. Covariates for matching obtained from the BiBBS baseline questionnaire*

Covariates	**Measurement**
Maternal ethnicity	Categorical
Maternal age	Continuous
Socioeconomic status	Categorical
Relationship status	Categorical
Smoking status	Categorical
Breastfeeding intention	Binary/Categorical
Maternal Depression	Binary/Categorical

*The variables in this propensity score matching were selected based on the previous studies and associations with the intervention or outcomes of previously published evidence (van Dellen et al. 2019; Thulier and Mercer 2009; van Rossem et al. 2009; Lanting et al. 2005; Scott et al. 2001; Merten and Ackermann-Liebrich 2004; Ojofeitimi et al. 2000; Moore et al. 2007; Lisi et al. 2020)

Outcome analysis

After matched groups have been created, binomial logistic regression analyses will be run using group assignment as the independent variable, and breastfeeding status as the dependent variables.

2.10 Process evaluation

A qualitative evaluation of the Breastfeeding Support intervention has already been conducted, and results from that study will be submitted for publication elsewhere. No additional formal process evaluation will be conducted as part of this evaluation study. However, some operational data related to the implementation of the intervention—such as referral numbers (reach), service uptake, and participant retention—are available and may be used to help contextualize the findings of the current evaluation.

2.11 Health economic analysis

A health economic analysis will be conducted consisting of three elements:

1) Investigation of the costs associated with delivering the Breastfeeding support programme, including staff time, training, and deliverables. This will make use of financial returns available from the BSB finance team. Where possible we will seek to distinguish between sunk setup costs of the programme from ongoing variable costs.

2) A pragmatic literature review of the previously estimated long term health impact of increasing uptake and continuation of breastfeeding on the mother and child. This will explore existing evidence on the long term costs and benefits of breastfeeding with a focus on a healthcare perspective. The review will utilise online journal databases (e.g. Cochrane Library and Medline) to conduct a key work search which will be supplemented via reference and citation searching of relevant studies. An exploration of the grey literature will also include leveraging known policy resources (e.g. National Institute for Health and Care Excellence (NICE) Guidance, World Health Organisation) and online search engines.

3) A threshold analysis considering the scale of additional benefits that would need to be achieved for an intervention like that delivered through the BSB programme to be considered cost saving or cost-effective under conventional analytical perspectives such as the NICE Reference Case. This analysis will utilise the findings of the previous two elements in addition to wider evidence on the cost and impact of diseases that have been purported to be affected by breastfeeding such as obesity rates.

3 Ethics and dissemination

3.5 Research ethics approval

The protocol for BiBBS recruitment and collection of routine outcome data was approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research governance approval was gained from Bradford Teaching Hospitals NHS Foundation Trust. The existing ethics includes approval for the evaluation of Better Start Bradford interventions using quasi-experimental methods, including the use of cohort participants to create control groups. protocol for the current evaluation is covered by this previous ethical approval.

Breastfeeding Support is delivered as a part of usual practice. Ethical considerations with regards to the delivery of the programme can be found in Breastfeeding Supports' service design plan, and issues arising are managed by the service delivery team and BSB as service commissioners, in accordance with local guidance, e.g. such as safeguarding procedures, access to appropriate mental health support. Key members of the research team are trained in good clinical practice.

3.6 Data monitoring and auditing

This study evaluates an intervention that was already commissioned by Better Start Bradford and implemented independently from this study and the evaluation team. The Innovation Hub conducted regular monitoring of the intervention including reporting on progression criteria that were agreed with the intervention and Better Start Bradford teams. This information was used by Better Start and the intervention team to inform commissioning and implementation decisions. There are also a number of project management groups for BiBBS conducted within BTHFT described in Additional File 1 in the BiBBS protocol (Dickerson et al., 2016). The sponsor is the BTHFT Research Management and Support Office who may conduct independent auditing of the study.

3.7 Harms

This is a post-hoc evaluation of a previously delivered intervention. Although the intervention and associated data collection have already been completed, the evaluation protocol was developed and agreed prior to any analysis being undertaken. The study uses observational data drawn from the BiBBS cohort, including questionnaire responses and data linked from routine sources. The BiBBS study protocol was approved by the Bradford and Leeds Research Ethics Committee (15/YH/0455), and all researchers adhere to Bradford Teaching Hospitals NHS Foundation Trust's Safeguarding Adults and Safeguarding Children policies.

Given the non-invasive nature of the evaluation and the fact that the intervention was delivered by trained practitioners operating under established safeguarding procedures, the risk of harm to participants is considered minimal. As such, no formal identification or assessment of harms will be conducted as part of this evaluation.

3.8 Confidentiality

All information collected during the cohort is kept strictly confidential. BiBBS comply with all aspects of the 1998 Data Protection Act. Where possible, consent and baseline questionnaires are completed electronically using tablet devices. The data collected is then saved onto the BTHFT secure computer server. Data is only stored with personal identifiers if absolutely necessary and is not stored on local drives. Where electronic data collection is not possible, paper consents and questionnaires are used and then entered onto the database held within the

BTHFT secure computer server. Paper files containing personal identifiers are stored in locked cabinets within BIHR, separate from all other data.

Data collection will be observed by an independent observer on a regular basis for quality assurance. Researchers will have up to date Good Clinical Practice (GCP) training and will be trained in administering the questionnaire. They will be provided with detailed instructions and background information. Researchers will be supported by the BiB research midwife who will be available for advice and guidance. They will also be trained in BTHFT wide policies on lone working and safeguarding of adults and children.

3.9 Declaration of Interests

The authors declare no conflict of interest.

3.10 Dissemination policy

Findings will be produced in reports for publication in scientific journals, as conference abstracts, on websites, and will be shared amongst relevant BSB partners and commissioners in Bradford and England. Summaries of findings will be widely reported in local BSB communities using: BiBBS and BSB newsletters, social media, and local press. The evaluation report will also be shared with BSB project participants. No participants will be identifiable in any reports or publications produced from this work.

Whilst services and BSB may contribute to the interpretation of findings, the data and results will be produced independently by the BSBIH, without the influence of the service, BSB or the funding body.

3.11 Access to data

Information on how to access the data can be found at: www.borninbradford.nhs.uk

4.0 References

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Appendix 1. TIDierR checklist

1. Brief name	Breastfeeding Support
2. Why	While it is well known that breastfeeding confers benefits for both babies and their mothers, initiating and sustaining breastfeeding can be very challenging for women and their families. Often support for breastfeeding can be difficult to access in a timely manner, which can result in families making the decision to stop breastfeeding earlier than they hoped and intended. The goal of the Breastfeeding Support intervention was to provide informational and emotional support for breastfeeding to women and their families during the first 6 months of their child's life. The goal of this support was to help women reach their breastfeeding goals, and to make it more possible for women to continue to breastfeed for longer.
3. What – Materials	1. Initial contact and referral The main sources of referrals came from Perinatal Project Administrators (PPAs; see below) who used scripts to initiate conversations with women on hospital wards or via telephone calls. These scripts were agreed with the intervention provider, *Health for All*. 2. Ongoing support In some instances support workers provided women with leaflets or other written material to reinforce or remind women of information covered in their discussions. The information in these written materials was specific to the type of support that women requested or needed. 3. Support ending Once babies reached six months, or when their contact with the service had ended by request or a lack of ongoing need, women were contacted and asked a series of standardised questions about their experiences of breastfeeding. The content of these questions remained the same for all women, but they were asked in a semi-structured way as part of natural conversation between support workers and women.

4. What – Procedures	1. Referral and initial contact Most women are offered the intervention either on the hospital wards or shortly after discharge through a telephone call by Perinatal Project Administrators (PPAs). PPAs are administrators based within maternity services specifically tasked with identifying appropriate interventions and support services for women and families with new babies, and proactively offering these services to them. If women accept the offer of referral, their details are passed onto the intervention team, who then contact them via telephone call as soon as possible to offer support. They ask some baseline questions and establish what women would need and like from the service in terms of support, and they then provide support accordingly. 2. Ongoing support Women can choose to receive support either via telephone, home visit, or face-to-face meeting at a site of their choosing. Support is available 6 days a week (Mon - Sat), including during evenings. Women can contact the service either through their designated support worker or the service's open contact line. Support workers also actively contact women to check in with them until women are discharged from the service. There is no limit to the number of support contacts women can receive, and so support can increase or decrease over time in a way that suits families changing needs. 3. Support ending Support ends when women indicate that they no longer feel it is necessary, when they stop breastfeeding, or when the baby reaches 6 months (whichever comes first). If a woman is discharged but then needs support again before their baby turns 6 months, they can self-refer back into the service. Women complete a short set of questions about the support they received and their breastfeeding goals on discharge.

5. Who provided	The intervention is run by *Health for All*, a registered charity providing a range of health and community interventions in West Yorkshire. Breastfeeding Support is provided by breastfeeding support workers with extensive training in breastfeeding (Unicef Baby Friendly Initiative training), parent infant relationship training, and motivational interviewing. This training background was specifically designed in order that support workers can provide accurate breastfeeding information in a way that is sensitive and responsive to women and their families' needs.
6. How	Support is provided either face-to-face or via the telephone, and during Covid-19 related national lockdowns, via online video meetings. Support contacts were provided individually.
7. Where	Support for women was provided either over the telephone or in women's homes or a place of their choosing, depending on women's preferences. It could also be arranged to happen in community based settings; the offer was designed to be flexible and responsive to women's requests.
8. When and how much	The service has a core offer of three face-to-face support contacts. However, women can request to receive support however they prefer (telephone support, face-to-face support in their homes or at another setting of their choice).
9. Tailoring	The content, timing, and frequency of support was fully tailored to the needs and requests of women.
10. Modifications	Service delivery was adapted during national lockdowns due to Covid-19. During this time (March 2020 – September 2021), all support was offered via telephone or video calls, with no face-to-face delivery option. Although this did impact on the delivery of the service, the central aims of the support (informational and emotional support as frequently as women requested it) remained the same.
11. How well – planned	The service was regularly monitored by the commissioner against progression criteria for the recruitment, implementation, and reach. This identified any ongoing areas of support needed for implementation.
12. How well – actual	No changes were made to the content or structure of the intervention based on the ongoing monitoring (with the exception of changes necessitated by the Covid-19 national lockdowns). However, after the Covid-19 lockdowns, the core offer was changed to include three support contacts in any format (telephone, video call, or face-to-face) rather than three face-to-face contacts as it originally entailed.