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Implementation Evaluation of Multiple Complex Early Years Interventions: An Evaluation Framework and Study Protocol

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Abstract

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Introduction

Implementation evaluations are integral to understanding whether, how and why interventions work. However, unpicking the mechanisms of complex interventions is often challenging in real world settings where multiple services are delivered concurrently. Furthermore, many locally developed and/or adapted interventions have not undergone any evaluation thus limiting the evidence base available. Born in Bradford's Better Start cohort is evaluating the impact of multiple early life interventions being delivered as part of the Big Lottery Fund's 'A Better Start' programme to improve the health and well-being of children living in one of the most socially and ethnically diverse areas of the UK. In this paper, we outline our evaluation framework and protocol for embedding pragmatic implementation evaluation across multiple early years interventions and services.

Methods and analysis

The evaluation framework is based on a modified version of The Conceptual Framework for Implementation Fidelity. Using qualitative and quantitative methods, our evaluation framework incorporates semi-structured interviews, focus groups, routinely collected data and questionnaires. We will explore factors related to content, delivery and reach of interventions at both individual and wider community levels. Potential moderating factors impacting intervention success such as participants' satisfaction, strategies to facilitate implementation, quality of delivery and context will also be examined. Interview and focus guides will be based on the Theoretical Domains Framework to further explore the barriers and facilitators of implementation. Descriptive statistics will be employed to analyse the routinely collected quantitative data and thematic analysis will be used to analyse qualitative data.

Ethics and dissemination

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The Health Research Authority has confirmed our implementation evaluations do not require review by an NHS Research Ethics Committee (HRA decision 60/88/81). Findings will be shared widely to aid commissioning decisions and will also be disseminated through peer-reviewed journals, summary reports, conferences and community newsletters.

Key words: *Implementation Science, process evaluation, early years interventions, prevention, infancy, pregnancy, child health, maternal health, inequalities*

Box 1

What is known about this subject

- Early years interventions are integral to improving the life chances for children and reducing inequalities in health and well-being. However, there is a dearth of evidence examining the impact of interventions and many locally developed and or adapted interventions have not undergone, or are necessarily at a stage in development where they can be subjected to rigorous evaluation.

What this study will add

- Our focus on implementation presents a pragmatic and consistent approach to evaluating multiple early years interventions, including those deemed as not yet ready for evaluations of effectiveness. The mixed methods approach and use of routinely collected data provides an efficient, feasible and manageable evaluation framework that can be easily embedded within services as they are being delivered.

Introduction

The early years of life are integral to promoting positive outcomes throughout the lifespan [3]. Mothers' health in pregnancy and the first two years of life in particular, have been identified as periods that play a vital role in children's emotional, cognitive and physical development [4], [5],[6]. Early years interventions are therefore crucial to reduce inequalities

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and ensure the health and wellbeing of children as they grow. However, many preventative interventions delivered by early years services have not been subjected to rigorous development and evaluation, thus leaving them without a robust evidence base [1, 7]. Born in Bradford's Better Start (BiBBS) experimental birth cohort is currently delivering effectiveness evaluations for multiple complex early years interventions that are being delivered in real-life settings through the Better Start Bradford programme [8, 9]. The cohort will efficiently evaluate multiple complex early life interventions through planned controlled experiments and using quasi-experimental methods. However, effective interventions are those that not only show a positive outcome on key outcomes, but those that are able to recruit and engage participants and can be delivered with fidelity in real-life settings. It is, therefore critical to conduct implementation evaluations to provide evidence of the feasibility, reach, context and short-term impact of interventions [1],[2]. Furthermore, implementation or process evaluations can help allude to the transferability of interventions, providing local commissioners and service providers with guidance on the practical measures they can take to successfully embed interventions within their settings and communities [1].

The limited availability of evidence of effect for many early years interventions means that the majority of Better Start Bradford interventions are considered as being 'science based' with some in the foundational stages of development and/or evaluation [7, 10] (see supplementary table 1 for further details about the interventions) and [9]). Consequently, whilst the long-term goal of BiBBS is to provide effectiveness evaluations of these interventions, many of the interventions are currently not ready for such an evaluation. This paper describes a framework for implementation evaluation and a protocol to evaluate the interventions being delivered as part of the Better Start Bradford programme. This framework can be used by researchers, practitioners, commissioners and service providers across multiple settings to evaluate the quality of implementation of early years interventions being delivered in real-life settings and enhance their readiness for more intensive levels of evaluation.

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Methods

Conceptual framework

Underpinned by the MRC guidance on process evaluations of complex interventions, our implementation evaluations draw on the conceptual framework for implementation fidelity (figure 1) [11, 12].

[Insert figure 1 here]

Adoption of the modified conceptual model of implementation fidelity will help glean the factors affecting the implementation of the Better Start Bradford interventions (independently and collectively) and, in turn examine their impact on outcomes as interventions increase in their potential for evaluation of impact. Whilst drawing on published examples [11], [13] we plan to apply the framework consistently across multiple interventions with much of the data collection being integrated in the routine delivery of interventions to yield an efficient and pragmatic approach to evaluation. Table 1 outlines the evaluation framework including the overarching research questions, corresponding data source and method of collection.

Data collection

Data for the implementation evaluation will be derived from a number of sources:

1. Quantitative data collected by intervention teams

Prior to the implementation of each intervention, a service design process takes place in collaboration with commissioners, intervention delivery teams, academic researchers and other stakeholders including health professionals and community representatives to ensure each intervention meets the needs of the local population. During this process, the appropriate process and outcome data to be collected by each intervention team throughout the delivery period and submitted quarterly to the research team are also agreed. A guide to

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the service evaluation process and templates including a minimum dataset for implementation evaluation is available on our website[14].

2. Satisfaction Questionnaires

We have developed a brief six item satisfaction questionnaire to capture participants' satisfaction across all interventions (see additional file 1). Questions are based on the key constructs of commonly used patient satisfaction surveys[15], [16], but have been adapted following advice from our Community Research Advisory Group (CRAG), comprised of local parents and volunteers alongside intervention team managers, commissioners and the research team to ensure acceptability for the local community. This process resulted in a questionnaire that is brief, incorporates visuals and uses simple language that can be easily understood and translated into other languages.

3. Semi-Structured Interviews and Focus Groups

Semi-structured interviews and/or focus groups where appropriate, will be undertaken with intervention participants and delivery teams to allow more in-depth exploration of elements of the conceptual model. Topic guides will be based on the theoretical domains framework (TDF) [17], [18]. The TDF encompasses a comprehensive range of constructs from theories of behaviour change including beliefs about capabilities, knowledge, skills, emotions and social influences. Furthermore, use of the TDF provides a firm theoretical basis to allow understanding of the mechanisms of action as well as the barriers and facilitators of implementation [19]. It has been extensively applied to investigate and address implementation problems [19]. Whilst the interview questions may differ by intervention, use of the TDF ensures the underlying theoretical concepts explored in all interviews are explored using a consistent approach.

All studies will include data from sources 1 and 2. In-depth qualitative work may be triggered in response to issues identified by interventions such as difficulties in engaging families from

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3 167 particular ethnic groups, low completion rates, and priorities highlighted by the
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5 168 commissioning team.
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10 170 Table 1: Implementation and process evaluation key elements and research questions within
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12

Areas to measure	General process questions	**Example data source** and data collection method
a) Content (Fidelity)	Was the intervention delivered as planned?	**Quarterly monitoring data submitted by intervention teams** e.g, average staff caseload, content of each course session and adherence to manual (for manualised interventions) **Observation of intervention delivery** **Qualitative interviews with staff/facilitators**
b) Frequency/Duration (Dosage, Dose delivery)	What was the duration and frequency of support received by each family?	**Quarterly monitoring data submitted by intervention teams** including: Date of each visit/attendance Duration of visit (where applicable)
c) Reach (coverage)	What were the demographic characteristics of families referred and took up support from each intervention? What were the characteristics of volunteers (*where intervention delivered by volunteers or peer supporters*)	**Quarterly monitoring data submitted by intervention teams** including: Socio-demographic background data on parents including ethnicity, gender, language spoken, religion, disability, number, and age of children Reason for referral, referral source **Quarterly monitoring data submitted by intervention teams** Socio-demographic data on volunteers including gender, ethnicity, languages spoken, appointment start and end dates
d) Participant responsiveness	Were parents' satisfied with the support they received and which elements did they find	**Questionnaire** for parents to measure satisfaction **Qualitative interviews** with

13–60

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Areas to measure	General process questions	**Example data source** and data collection method
	to be most helpful and unhelpful in meeting their needs? What proportion of parents accessed further support? How did staff/volunteers perceive the impact of the intervention?	parents exploring satisfaction **Quarterly monitoring data submitted by intervention teams:** Number and type of referrals made to external agencies **Interviews or focus groups with staff/volunteers**
e) Recruitment	What recruitment procedures were used to engage families and staff? Did the intervention recruit to target? What constituted barriers to maintaining involvement of individuals?	**Quarterly monitoring data submitted by intervention teams including:** Dates of all engagement activities Type of activity Setting/location Target audience and anticipated numbers Number of staff/volunteers present Number of parents/children engaged/attended **Quarterly monitoring data submitted by intervention teams** Anticipated number of staff and volunteers recruited and trained Anticipated number of families supported per year Actual number of families supported per year Reasons for drop-out/non-completion/unplanned ending, service declined Interviews with staff/facilitators **Qualitative interviews with parents** **Qualitative interviews or focus groups with staff/volunteers** **Analysis of quarterly/ annual reports** around the key challenges of implementation and corresponding action plans
f) Strategies to facilitate	What proportion of parents completed the intervention?	**Quarterly monitoring data submitted by intervention**

Areas to measure	General process questions	**Example data source** and data collection method
implementation	 What are the key factors that enabled or were barriers to engagement and completion of intervention?	**teams** Date of each visit/attendance **Qualitative interviews with parents** **Qualitative interviews or focus groups with staff/volunteers**
g) Context	What factors at political, economical, organisational and work group levels affected the implementation?	**Qualitative interviews or focus groups with staff/volunteers** **Analysis of quarterly/annual review reports**, meeting minutes and diary of local/national initiatives

Eligibility

Inclusion Criteria

a. *Intervention participants*

- Reside in a postcode within the Better Start Bradford area
- Enrolled to attend a Better Start Bradford intervention OR
- Were eligible but declined to take part, or dropped out (where relevant)
- Agree for their data to be shared with the research team for evaluation purposes
- Agree to be contacted by the research team, where further qualitative studies maybe planned

b. *Intervention staff, volunteers, stakeholders and/or commissioners.*

- Work/volunteer for an intervention or are actively involved in commissioning or delivering an intervention
- Have delivered at least one full intervention according to the intervention delivery schedule (intervention delivery teams only)
- Agree to take part in an interview / focus group / observation

Exclusion Criteria

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For qualitative studies, participants who have completed an interview/focus group within the past 12 months will not be approached to take part in a second study to avoid unnecessary burden.

Sample Size & Selection

The number of people included in the quantitative data evaluation will be dependent on the number of participants engaged with any given intervention, and the number agreeing to share information with the research team as all data will be collected as part of routine service delivery.

For qualitative evaluation, a purposive sampling method will be used to identify and recruit participants representing key characteristics including ethnicity, number of children, socio-economic deprivation and language. Other characteristics will be included based on their influence on the key objectives of the intervention; for example, maternal mental well-being for interventions relating to social and emotional health; BMI for interventions relating to nutrition. We will continue to recruit until we reach data saturation, with an estimate of 20-30 interview participants per intervention. Where focus groups are undertaken, we would aim to recruit 8-10 participants per group, with potentially separate focus groups depending on participants' ethnicity, gender, language, and/or neighbourhood area. For staff/volunteers, we aim to interview a minimum of 5/6 people per intervention, depending on the size of the intervention delivery team.

Recruitment

Quantitative intervention data & satisfaction questionnaires

Quantitative data will be collected from all participants as a part of the standard service provision.

Qualitative studies

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Participants will be identified and approached by one of two methods:

1) By researchers directly from the BiBBS cohort.

As part of the consent process for our experimental BiBBS cohort study, expectant parents consent to being contacted in the future to learn about participation in further research. Researchers will write to consenting parents, attaching a cover letter and information sheet about qualitative studies and contact them via telephone within two weeks.

2) By intervention delivery staff/managers

Intervention coordinators will be asked to circulate the study information sheet to all participants who have enrolled onto an intervention. Coordinators will share the names and contact details of those individuals who are willing to be interviewed with the research team. Staff and volunteers will first be approached by their service managers and if they agree, their contact details will be passed onto the research team.

In both methods of approach, for those interested in taking part, we will check their eligibility (as described above) and check they have read and understood the information sheet. A convenient date/time/place for an interview will be confirmed if agreed.

Consent

Quantitative data sharing

All intervention participants are given a privacy notice when they enrol for an intervention that explains that data will be shared for service evaluation. The privacy notice and consent form clearly explain how participants can opt out of data sharing/withdraw their consent at any time. All forms were developed with the English language and literacy abilities of the service participants in mind and with guidance from both our CRAG and members of the wider community; the simplified version of the privacy notice has a Flesch reading score of 61 and deemed to be easily understood by individuals aged 12 and above[20]. Information is

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also available in print in Urdu, Bengali and Slovakian, and is translatable to any other language through the Better Start Bradford website[21].

Qualitative data sharing

We will obtain written informed consent from all participants prior to commencing interviews/focus groups. For interviews with non-English speaking participants, the information sheet and consent form will be explained by an interpreter. At every stage of the research process, the right of participants to refuse consent, without giving a reason will be respected.

Data management

a. Quantitative intervention and satisfaction questionnaire data

Data sharing agreements will be in place between intervention teams, Better Start Bradford and the research team before data are shared. For those participants who have agreed to data sharing, the intervention teams will share individual level, identifiable data with the research team using secure transfer methods. Personally identifiable data items will be removed and replaced with a unique intervention identification number prior to analysis.

b. Qualitative Data

Audio recordings will be uploaded to an encrypted and secure network and will be deleted following transcription and verification of transcripts.

Confidentiality

All data shared will be strictly confidential and held securely for the duration of the Better Start Bradford programme. We will comply with all aspects of the General Data Protection Regulation[22], abide by the Caldicott principles and work within NHS Information Governance requirements. Anonymised data and transcripts will be available to the research team for the purposes of service evaluation only.

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Analysis

Quantitative intervention and satisfaction questionnaire data

Data will be summarised using descriptive statistics, including frequencies, summary statistics, confidence interval estimates and ranges for continuous variables (e.g. participant age, referral and recruitment rate, attrition), and proportions/ percentages for categorical variables (e.g. ethnicity, intervention completion). The analysis will also explore whether there are any differences in referrals, recruitment rates, intervention reach, attendance and satisfaction between different groups of participants e.g. by parity, ethnicity, spoken English proficiency.

Qualitative data

Qualitative data will be analysed using thematic analysis (TA), a widely used method in evaluative studies which seeks and reports patterns inherent within the data[23]. TA was chosen as it allows for an understanding of the data to be developed and patterns within the thoughts and views of participants to be examined. Specific barriers and enablers influencing implementation and satisfaction of interventions will be coded according to the TDF[17, 18]. We will also explore any patterning of themes by individuals' ethnicity, socioeconomic circumstances and English language ability. Transcripts will be coded systematically and iteratively until the analysis team are satisfied that the emerging framework adequately captures the data and saturation has been achieved. Ten-percent of the transcripts will be coded by a second researcher to maintain reliability of the coding framework. Any disagreements will be resolved through discussion and revisiting the coding framework. Data will be managed within the Nvivo data management programme (NVivo qualitative data analysis Software; QSR International Pty Ltd).

Patient and public involvement

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Community involvement is integral to the ethos of BiBBS and Better Start Bradford. As such, we have set up a community research advisory group (CRAG) comprised of local community representatives including parents, volunteers, councillors and leaders of local groups and charities. The group have been involved every stage of development including in setting the overall evaluation objectives, development of information sheets, consent forms and satisfaction questionnaires. The CRAG will continue to advise on the development and refinement topic guides, methods for engaging local parents as well as playing a key role in the interpretation and dissemination of findings.

Ethics and Dissemination

The protocol for the BiBBS cohort including consent to contact for other studies has been approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research governance approval has been provided from Bradford Teaching Hospitals NHS Foundation Trust. The Health Research Authority has confirmed that our implementation evaluations do not require review by an NHS Research Ethics Committee (HRA decision 60/88/81). Despite ethical approval not being a formal requirement, we aim to uphold ethical principles, Good Clinical Practice and Research Governance including the provision of participant information sheets and obtaining informed consent.

Findings will be disseminated widely to aid commissioning decisions and ensure shared learning with local partners. Findings will also be shared at local and national conferences, relevant public health events and via publication in academic journals. Summaries of key findings will be shared with participants and the local community via our CRAG, newsletters, and on the Born in Bradford website[24].

Discussion

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In this paper, we have outlined our framework for implementation evaluation across multiple, complex early years interventions. This framework has so far proved invaluable to ensure consistent and manageable data collection across all interventions as well as identifying and resolving issues in the quality of routinely collected data. Through the cyclical transfer of knowledge, findings from our implementation evaluations may also help delivery teams respond to any challenges identified and further optimise the delivery and reach of their interventions. Moreover, the inclusion of a wide range of stakeholders will further help uncover the role of contextual factors, delivery procedures, acceptability and scalability of the interventions.

Our implementation evaluation framework and associated tools[14] are designed to be sustainable beyond our involvement as external service evaluators to allow commissioners and intervention teams to continue monitoring and evaluating the implementation of their services. Whilst in-depth qualitative evaluation may still require input from researchers, the rest of this framework can be applied by service providers and commissioners to embed pragmatic evaluation within the delivery of services whilst taking positive steps towards building a robust evidence base for early years interventions.

List of Abbreviations

BiB - Born in Bradford

BiBBS – Born in Bradford's Better Start

BMI- Body Mass Index

CRAG - Community Research Advisory Group

HRA – Health Research Authority

MRC – Medical Research Council

NHS – National Health Service

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TA – Thematic Analysis

TDF – Theoretical Domains Framework

Declarations

Ethics approval and consent to participate

The protocol for the BiBBS cohort including consent to contact for other studies has been approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research governance approval has been provided from Bradford Teaching Hospitals NHS Foundation Trust. The Health Research Authority has confirmed that our implementation evaluations do not require review by an NHS Research Ethics Committee (HRA decision 60/88/81). However, we will adhere to all ethical principles in the conduct of our evaluations and written informed consent will be obtained from all participants prior to qualitative interviews and/or focus groups.

Consent to publish

Not applicable.

Availability of data and materials

Data sharing is not applicable to this article. However, please note that data collected throughout the course of the study will be available to external researchers and proposals for collaboration will be welcomed. Information on how to access the data can be found at: www.borninbradford.nhs.uk.

Competing interests

The authors declare that they have no competing interests.

Funding

This study has received funding through a peer review process from the Big Lottery Fund as part of the A Better Start programme. The Big Lottery Fund have not had any involvement in the design or writing of the study protocol.

Author contributions

All authors contributed to the design of the study, were involved in drafting this manuscript, approving the final version of this manuscript, and agree to be accountable for this work.

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References

1. Evans R, Scourfield J, Murphy S: **Pragmatic, formative process evaluations of complex interventions and why we need more of them**. *Journal of epidemiology and community health* 2015, **69**(10):925-926.
2. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D *et al*: **Process evaluation of complex interventions: Medical Research Council guidance**. *Bmj* 2015, **350**:h1258.
3. Hickey G, McGilloway S, Furlong M, Leckey Y, Bywater T, Donnelly M: **Understanding the implementation and effectiveness of a group-based early parenting intervention: a process evaluation protocol**. *BMC health services research* 2016, **16**:490.
4. Axford N, Sonthalia, S., Wrigley, Z., Goodwin, A., Ohlsen, C., Bjornstad, G., Barlow, J., Schrader-Mcmillan, A., Coad, J. and Toft, A: **The Best Start At Home: What Works To Improve the Quality of Parent-Child Interactions From Conception to Age 5 Years. A Rapid Review Of Interventions**. In.: The Early Intervention Foundation 2015.
5. Marmot M, Allen J, Goldblatt P, Boyce T, McNeish D, Grady M, Geddes I: **Fair society, healthy lives: strategic review of health inequalities in England post 2010**. London: The Marmot Review; 2010.
6. Tickell D: **The Early Years: Foundations for life, health and learning - An independent report on the Early Years Foundation Stage to Her Majesty's Government**. London: Department for Education; 2011.
7. Axford N BJ: **What works: An overview of the best available evidence on giving children a better start**. Dartington The Social Research Unit at Dartington; 2013.

8. Dickerson J, Bird PK, McEachan RR, Pickett KE, Waiblinger D, Uphoff E, Mason D, Bryant M, Bywater T, Bowyer-Crane C *et al*: **Born in Bradford's Better Start: an experimental birth cohort study to evaluate the impact of early life interventions**. *BMC public health* 2016, **15**:711.
9. **Better Start Bradford** [www.betterstartbradford.org.uk]
10. **EIF Evidence Standards** [http://guidebook.eif.org.uk/eif-evidence-standards]
11. Hasson H: **Systematic evaluation of implementation fidelity of complex interventions in health and social care**. *Implementation science : IS* 2010, **5**:67.
12. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S: **A conceptual framework for implementation fidelity**. *Implementation science : IS* 2007, **2**:40.
13. Hasson H, Blomberg S, Duner A: **Fidelity and moderating factors in complex interventions: a case study of a continuum of care program for frail elderly people in health and social care**. *Implementation science : IS* 2012, **7**:23.
14. **Better Start Bradford Innovation Hub: A Guide for Designing, Implementing and Evaluating Interventions** [https://borninbradford.nhs.uk/what-we-do/pregnancy-early-years/toolkit/]
15. Marshall GNaH, R.D **The Patient Questionnaire Short-form (PSQ-18)**. In. Santa Monica: Rand 1994.
16. Atkinson CaG, T.K.: **The client satisfaction questionnaire (CSQ) scales and the service satisfaction scale**: Williams & Wilkins 1995.
17. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A, Psychological Theory G: **Making psychological theory useful for implementing evidence based practice: a consensus approach**. *Quality & safety in health care* 2005, **14**(1):26-33.
18. Cane J, O'Connor D, Michie S: **Validation of the theoretical domains framework for use in behaviour change and implementation research**. *Implementation science : IS* 2012, **7**:37.
19. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, Foy R, Duncan EM, Colquhoun H, Grimshaw JM *et al*: **A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems**. *Implementation science : IS* 2017, **12**(1):77.
20. Flesch R: **A new readability yardstick**. *J Appl Psychol* 1948, **32**.
21. **Better Start Bradford Privacy notice** [https://betterstartbradford.org.uk/privacy-notice/]
22. EuropeanUnion: **Regulation (EU) 2016/679 of the European parliament and the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing directive 95/46/EC (general data protection regulation).** In.: Office journal of the European Union 2016: 1-88.
23. Braun V, and Clarke, V. : **Using thematic analysis in psychology**. *Qualitative research in psychology* 2006, **3**(2):77-101.
24. **Born in Bradford [www.borninbradford.nhs.uk]**. In.

Figure/Table Titles/Legends

Figure 1: Modified conceptual framework for implementation fidelity Carroll et al 2007, Hasson et al 2010

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5 473 Additional file 1: Satisfaction Questionnaire.pdf
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7 474 Supplementary file 1: Table 1: Interventions to be delivered as part of Better Start Bradford
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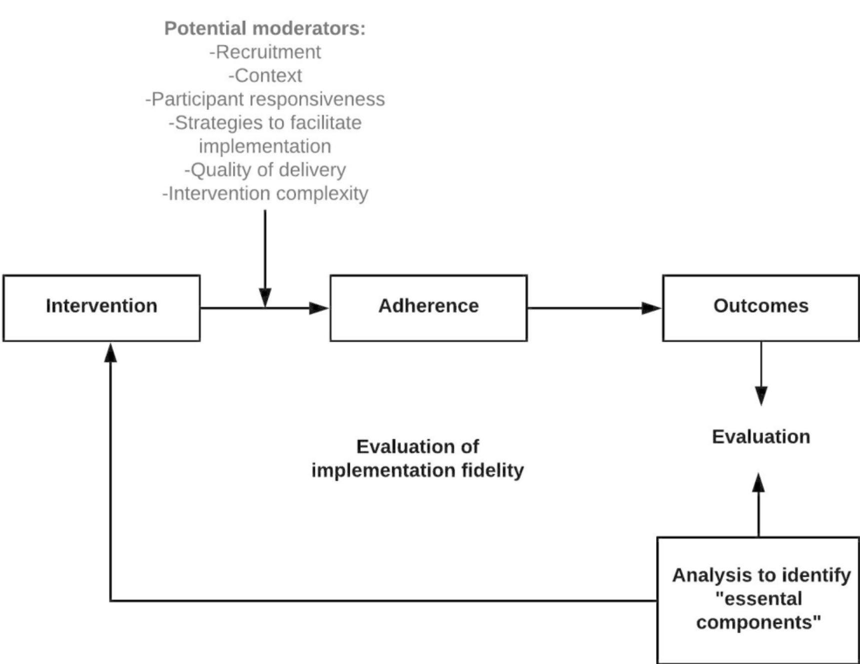

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Table 1: Interventions to be delivered as part of Better Start Bradford

Intervention	**Description**	**Service Provider**	**Estimated Recipients per year**
Antenatal Support			
Personalised Midwifery	Continuous midwife care through antenatal and postnatal period	Bradford Hospitals NHS Foundation Trust Midwifery Services	500
Family Links Antenatal	Universal antenatal parenting skills programme	Local Authority	200
ESOL+	English language course for women with little or no English during pregnancy	Shipley Further Education College	90
Antenatal and Postnatal Support			
Family Nurse Partnership[1]	Intensive home visiting for vulnerable women aged under 25 years	Bradford District Care Trust (BDCT)	100
Baby Steps	Parent education programme for vulnerable parents	Voluntary Community Sector (VCS) – Action For Children	100
Doula	Late pregnancy, birth and post-natal support for vulnerable women	VCS Action For Community Ltd	82
HAPPY	Healthy eating & parenting course for overweight mums with a BMI over 25.	VCS – Barnardo's	120

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Intervention	**Description**	**Service Provider**	**Estimated Recipients per**
Perinatal Support Service	Support for pregnant women and mothers of babies under 1 year old at risk of mild/moderate mental health issues	VCS – Family Action	140
Breast feeding support service	Universal practical and emotional support to breastfeeding mums and their families (this reflects the second part of the service not just peer support)	VCS – Health For All (Leeds)	400
Home-Start	Peer support for vulnerable women	VCS – Home-Start	45
Little Minds Matter	Support and nurturing of parent-infant relationships for those at risk of relationship problems	BDCT/ Family Action	40
HENRY	Universal group programme to improve healthy eating and physical activity in young children	VCS & Schools / HENRY	186
Incredible Years Parenting[1]	Universal parenting programme for parents with toddlers	VCS – Barnardo's	160
Cooking for a Better start	Universal cook and eat sessions	VCS - HENRY	72
Pre-schoolers in the Playground	Pre-schoolers physical activity in the playground	Schools	108

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Intervention	**Description**	**Service Provider**	**Estimated Recipients per**
Forest Schools	Outdoor play in the natural environment for young children & parents	VCS – Get Out More CiC	90
Better Start Imagine	Book gifting & book sharing sessions	VCS – BHT Early Education and Training	1015
I CAN Early Talk	Strengthening parents' and practitioners' knowledge in improving language development	VCS – BHT Early Education and Training	115
Talking Together	Universal screening for language delay of 2 year olds; in home programme for parents with children at risk of delay.	VCS – BHT Early Education and Training	954

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Office ID:

Better Start Bradford Project Satisfaction Questionnaire

Thank you for completing this questionnaire. We really appreciate your feedback about the ESOL+ course. Please note your answers will not affect the support you will receive now or in the future.

Please tick the box which best describes your answer to each question.

1. Overall, I feel that the ESOL+ course was helpful for me

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

2. I am satisfied with the level of support I received

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

3. The information given was useful to me

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

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4. It was easy for me to get onto the ESOL+ course

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

5. I would recommend the ESOL+ course to my friends and family

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

6. Overall, I am happy with the ESOL+ course

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

Thank you for completing this questionnaire. Please place your questionnaire in the envelope provided. If you have any further comments about the ESOL+ course please write them in the box below.

Project satisfaction questionnaire V1: 21.8.17

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BMJ Paediatrics Open

Implementation Evaluation of Multiple Complex Early Years Interventions: An Evaluation Framework and Study Protocol

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Keywords:	Comm Child Health, Data Collection, Health services research, Race and Health, Qualitative research

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Abstract

Introduction

Implementation evaluations are integral to understanding whether, how and why interventions work. However, unpicking the mechanisms of complex interventions is often challenging in usual service settings where multiple services are delivered concurrently. Furthermore, many locally developed and/or adapted interventions have not undergone any evaluation thus limiting the evidence base available. Born in Bradford's Better Start cohort is evaluating the impact of multiple early life interventions being delivered as part of the Big Lottery Fund's 'A Better Start' programme to improve the health and well-being of children living in one of the most socially and ethnically diverse areas of the UK. In this paper, we outline our evaluation framework and protocol for embedding pragmatic implementation evaluation across multiple early years interventions and services.

Methods and analysis

The evaluation framework is based on a modified version of The Conceptual Framework for Implementation Fidelity. Using qualitative and quantitative methods, our evaluation framework incorporates semi-structured interviews, focus groups, routinely collected data and questionnaires. We will explore factors related to content, delivery and reach of interventions at both individual and wider community levels. Potential moderating factors impacting intervention success such as participants' satisfaction, strategies to facilitate implementation, quality of delivery and context will also be examined. Interview and focus guides will be based on the Theoretical Domains Framework to further explore the barriers and facilitators of implementation. Descriptive statistics will be employed to analyse the routinely collected quantitative data and thematic analysis will be used to analyse qualitative data.

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Ethics and dissemination

The Health Research Authority has confirmed our implementation evaluations do not require review by an NHS Research Ethics Committee (HRA decision 60/88/81). Findings will be shared widely to aid commissioning decisions and will also be disseminated through peer-reviewed journals, summary reports, conferences and community newsletters.

Key words: *Implementation Science, process evaluation, early years interventions, prevention, infancy, pregnancy, child health, maternal health, inequalities*

Box 1

What is known about this subject

- Early years interventions are integral to improving the life chances for children and reducing inequalities in health and well-being. However, there is a dearth of evidence examining the impact of early years interventions, especially those that have been developed and/or adapted for local contexts.

What this study will add

- Our focus on implementation presents a pragmatic and consistent approach to evaluating multiple early years interventions, including those deemed as not yet ready for evaluations of effectiveness. The mixed methods approach and use of routinely collected data provides an efficient, feasible and manageable evaluation framework that can be easily embedded within services as they are being delivered.

Introduction

The early years of life are integral to promoting positive outcomes throughout the lifespan [1]. Women's health in pregnancy and the first two years of their children's lives have been identified as critical periods in children's emotional, cognitive and physical development [2-4]. Early years interventions are therefore crucial to reduce inequalities and ensure the

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health and wellbeing of children as they grow. However, many preventative interventions delivered by early years services have not been subjected to rigorous development and evaluation, thus leaving them without a robust evidence base [5-8].

Better Start Bradford is a Big Lottery funded programme that has commissioned and implemented over 20 early years interventions into existing practice in three deprived and ethnically diverse inner-city wards of Bradford. The interventions aim to improve social and emotional development, communication and language development and nutrition and health in 0-4 years olds [8, 9]. The limited availability of evidence of effect for many early years interventions means that the majority of Better Start Bradford interventions are considered as being 'science based' with some in the foundational stages of development and/or evaluation [5, 10] (see table 1 for further details about the interventions) and [9]).

Born in Bradford's Better Start (BiBBS) experimental birth cohort was established to provide independent effectiveness evaluations for these early years interventions through planned controlled experiments and using quasi-experimental methods. However, effective interventions are those that not only show a positive outcome on key outcomes, but those that are able to recruit and engage participants and can be delivered with fidelity in usual service settings. It is, therefore critical to conduct implementation evaluations to provide evidence of the feasibility, reach, context and short-term impact of interventions [6],[11]. Furthermore, implementation or process evaluations can help allude to the transferability of interventions, providing local commissioners and service providers with guidance on the practical measures they can take to successfully embed interventions within their settings and communities [6].

This paper describes a framework and protocol to evaluate the implementation of interventions being delivered as part of the Better Start Bradford programme. Our evaluation framework can be used by researchers, practitioners, commissioners and service providers

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across multiple settings to evaluate the quality of implementation of early years interventions being delivered in usual settings and maximise potential for more intensive levels of evaluation.

Table 1: Interventions commissioned for delivery as part of the Better Start Bradford programme

Intervention	**Description**	**Service Provider**	**Estimated Recipients per year**
Antenatal Support			
Personalised Midwifery	Continuous midwife care through antenatal and postnatal period	Bradford Hospitals NHS Foundation Trust Midwifery Services	500
Family Links Antenatal	Universal antenatal parenting skills programme	Local Authority	200
ESOL+	English language course for women with little or no English during pregnancy	Shipley Further Education College	90
Antenatal and Postnatal Support			
Family Nurse Partnership[1]	Intensive home visiting for vulnerable women aged under 25 years	Bradford District Care Trust (BDCT)	100
Baby Steps	Parent education programme for vulnerable parents	Voluntary Community Sector (VCS) – Action For Children	100
Doula	Late pregnancy, birth and post-natal support for vulnerable women	VCS Action For Community Ltd	82
HAPPY	Healthy eating & parenting course for overweight mums with a BMI over 25.	VCS – Barnardo's	120
Perinatal Support Service	Support for pregnant women and mothers of babies under 1 year old at risk of mild/moderate mental health issues	VCS – Family Action	140

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Intervention	Description	Service Provider	Estimated Recipients per year
Breast feeding support service	Universal practical and emotional support to breastfeeding mums and their families (this reflects the second part of the service not just peer support)	VCS – Health For All (Leeds)	400
Home-Start	Peer support for vulnerable women	VCS – Home-Start	45
Little Minds Matter	Support and nurturing of parent-infant relationships for those at risk of relationship problems	BDCT/ Family Action	40
HENRY	Universal group programme to improve healthy eating and physical activity in young children	VCS & Schools / HENRY	186
Incredible Years Parenting[1]	Universal parenting programme for parents with toddlers	VCS – Barnardo's	160
Cooking for a Better start	Universal cook and eat sessions	VCS - HENRY	72
Pre-schoolers in the Playground	Pre-schoolers physical activity in the playground	Schools	108
Forest Schools	Outdoor play in the natural environment for young children & parents	VCS – Get Out More CiC	90
Better Start Imagine	Book gifting & book sharing sessions	VCS – BHT Early Education and Training	1015
I CAN Early Talk	Strengthening parents' and practitioners' knowledge in improving language development	VCS – BHT Early Education and Training	115
Talking Together	Universal screening for language delay of 2 year olds; in home programme for parents with children at risk of delay.	VCS – BHT Early Education and Training	954

Methods

Conceptual framework

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Underpinned by the MRC guidance on process evaluations of complex interventions, our implementation evaluations draw on the conceptual framework for implementation fidelity (figure 1) [12, 13].

[Insert figure 1 here]

Fidelity, termed as adherence, is defined as a combination of content; frequency and duration of delivery; and coverage [12, 13]. Examining fidelity therefore seeks to establish the extent to which the active ingredients of the intervention were delivered as often and for as long as planned [12, 13]. Also included in the framework are potential moderators of implementation process and fidelity such as intervention complexity, participant responsiveness (including engagement and satisfaction), quality of delivery and strategies that facilitate implementation. Context and recruitment were later added as potential moderators in the modified framework [12]. The moderators are proposed to be intrinsically linked to each other as well as to implementation fidelity.

Adoption of the conceptual model of implementation fidelity will help glean the factors affecting the implementation of the Better Start Bradford interventions (independently and collectively) and, in turn examine their impact on outcomes as interventions increase in their potential for evaluation of impact. Whilst drawing on published examples [12], [14] we plan to apply the framework consistently across multiple interventions with much of the data collection being integrated in the routine delivery of interventions to yield an efficient and pragmatic approach to evaluation. Table 2 outlines the evaluation framework including the overarching research questions, corresponding data source and method of collection.

Data collection

Data for the implementation evaluation will be derived from a number of sources:

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1. Quantitative data collected by intervention teams

Prior to the implementation of each intervention, a service design process takes place in collaboration with commissioners, intervention delivery teams, academic researchers and other stakeholders including health professionals and community representatives to ensure each intervention meets the needs of the local population. During this process, recruitment targets and process and outcome data to be collected by intervention teams throughout the delivery period and submitted quarterly to the research team are also agreed. A guide to the service evaluation process and templates including a minimum dataset for implementation evaluation is available on our website[15].

2. Satisfaction Questionnaires

We have developed a brief six item satisfaction questionnaire to capture participants' satisfaction across all interventions (see additional file 1). Questions are based on the key constructs of commonly used patient satisfaction surveys[16], [17], but have been adapted following advice from our Community Research Advisory Group (CRAG), comprised of local parents and volunteers alongside intervention team managers, commissioners and the research team to ensure acceptability for the local community. This process resulted in a questionnaire that is brief, uses visual cues and simple language that can be easily understood and translated into other languages.

3. Semi-Structured Interviews and Focus Groups

Semi-structured interviews and/or focus groups where appropriate, will be undertaken with intervention participants and delivery teams to allow more in-depth exploration of elements of the conceptual model. Topic guides will be based on the Theoretical Domains Framework (TDF) [18], [19]. The TDF encompasses a comprehensive range of constructs from theories of behaviour change including beliefs about capabilities, knowledge, skills, emotions and social influences. Furthermore, use of the TDF provides a firm theoretical basis to allow understanding of the mechanisms of action as well as the barriers and facilitators of

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179 implementation [20]. It has been extensively applied to investigate and address
180 implementation problems [20]. Whilst the interview questions may differ by intervention, use
181 of the TDF ensures the underlying theoretical concepts explored in all interviews are
182 explored using a consistent approach.
183
184 All studies will include data from sources 1 and 2. In-depth qualitative work may be triggered
185 in response to issues identified by interventions such as difficulties in engaging families from
186 particular ethnic groups, low completion rates, and priorities highlighted by the
187 commissioning team.
188
189 Table 2: Implementation and process evaluation key elements and research questions within
190 Better Start Bradford

Areas to measure	General process questions	Example data collection method	Example data
a) Content (Fidelity)	Was the intervention delivered as planned?	Quarterly monitoring data submitted by intervention teams Observation of intervention delivery Qualitative interviews with staff/facilitators	e.g, average staff caseload, content of each course session and adherence to manual (for manualised interventions)
b) Frequency/Duration (Dosage, Dose delivery)	What was the duration and frequency of support received by each family? What proportion of families completed an intervention? (as per the definition of completion agreed during service design for each	Quarterly monitoring data submitted by intervention teams	Date of each visit/attendance Duration of visit (where applicable)

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Areas to measure	General process questions	Example data collection method	Example data
	intervention)		
c) Reach (coverage)	What were the demographic characteristics of families referred and taking up support from each intervention? What were the characteristics of volunteers (*where intervention delivered by volunteers or peer supporters*)	**Quarterly monitoring data submitted by intervention teams**	Socio-demographic background data on parents including ethnicity, gender, language spoken, religion, disability, number, and age of children Reason for referral, referral source Socio-demographic data on volunteers including gender, ethnicity, languages spoken, appointment start and end dates
d) Participant responsiveness	Were parents' satisfied with the support they received? How did parents perceive the impact of the intervention e.g. which elements did they find to be most helpful and unhelpful in meeting their needs? What proportion of parents accessed further support? How did staff/volunteers perceive the impact of the intervention?	Questionnaire survey and/or qualitative interviews with parents Quarterly monitoring data submitted by intervention teams Interviews or focus groups with staff/volunteers	**Questionnaire** for parents to measure satisfaction **Qualitative interviews** with parents exploring satisfaction Number and type of referrals made to external agencies
e) Recruitment	What recruitment procedures were used to engage families and staff?	Quarterly monitoring data submitted by intervention teams	Dates of all engagement activities Type of activity Setting/location Target audience and numbers

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Areas to measure	General process questions	Example data collection method	Example data
	Did the intervention recruit to target (targets as agreed in service design)? What constituted barriers to maintaining involvement of individuals?	Qualitative interviews with parents including Qualitative interviews or focus groups with staff/volunteers Analysis of quarterly/ annual reports	Number of staff/volunteers present Number of parents/children engaged/attended Target number of staff and volunteers recruited and trained Target number of families supported per year Actual number of families supported per year Reasons for drop-out/non-completion/unplanned ending, service declined Key challenges of implementation and corresponding action plans
f) Strategies to facilitate implementation	What proportion of parents completed the intervention? What are the key factors that enabled or were barriers to engagement and completion of intervention?	Quarterly monitoring data submitted by intervention teams Qualitative interviews with parents Qualitative interviews or focus groups with staff/volunteers	Date of each visit/attendance
g) Context	What factors at political, economical, organisational and work group	Qualitative interviews or focus groups with staff/volunteers	Meeting minutes and diary of local/national initiatives

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Areas to measure	General process questions	Example data collection method	Example data
	levels affected the implementation?	Analysis of quarterly/annual review reports	

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192 ***Eligibility***

Box 1: Inclusion criteria for all participants
a. Intervention participants
• Reside in a postcode within the Better Start Bradford area
• Are enrolled to attend a Better Start Bradford intervention OR
• Eligible but declined to take part, or dropped out (where relevant)
• Agree for their data to be shared with the research team for evaluation purposes
• Agree to be contacted by the research team, where further qualitative studies are planned
b. Intervention staff, volunteers, stakeholders and/or commissioners.
• Work/volunteer for an intervention or are actively involved in commissioning or delivering an intervention
• Have delivered at least one full intervention according to the intervention delivery schedule (intervention delivery teams only)
• Agree to take part in an interview / focus group / observation

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194 *Exclusion Criteria*

195 For qualitative studies, participants who have completed an interview/focus group within the
196 past 12 months will not be approached to take part in a second study to avoid unnecessary
197 burden.

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199 ***Sample Size & Selection***

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Quantitative process and demographic data will be collected for all participants who consent for their data to be shared with the evaluation team. Sample sizes will not be determined in advance as this will be dependent on the uptake of interventions.

For qualitative evaluation, a purposive sampling method will be used to identify and recruit participants representing key characteristics including ethnicity, number of children, and primary language to represent the different ethnic and cultural groups in Bradford. Other characteristics will be included based on the key objectives of the intervention as defined during the service design process; for example, maternal mental well-being for interventions relating to social and emotional health; BMI for interventions relating to nutrition. We will continue to recruit until we reach data saturation, with an estimate of 20-30 interview participants per intervention. Where focus groups are undertaken, we would aim to recruit 8-10 participants per group, with potentially separate focus groups depending on participants' ethnicity, gender, primary language, and/or neighbourhood area. For staff/volunteers, we aim to interview a minimum of 5/6 people per intervention, depending on the size of the intervention delivery team.

Recruitment

Quantitative intervention data & satisfaction questionnaires

Quantitative data will be collected from all participants as a part of the standard service provision.

Qualitative studies

Participants will be identified and approached by one of two methods:

1) By researchers directly from the BiBBS cohort.

As part of the consent process for our experimental BiBBS cohort study, expectant parents consent to being contacted in the future to learn about participation in further studies.

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Researchers will write to consenting parents, attaching a cover letter and information sheet about qualitative studies and contact them via telephone within two weeks. Where a participant speaks a language other than English, the initial phone call will be made by a bilingual researcher or an interpreter.

2) By intervention delivery staff/managers

Intervention coordinators will be asked to circulate the study information sheet to all participants who have enrolled onto an intervention. Coordinators will share the names and contact details of those individuals who are willing to be interviewed with the research team. Staff and volunteers will first be approached by their service managers and if they agree, their contact details will be passed onto the research team.

In both methods of approach, for those interested in taking part, we will check their eligibility (as described above) and check they have read and understood the information sheet. A convenient date/time/place for an interview will be confirmed if agreed.

Consent

Quantitative data sharing

All intervention participants are given a privacy notice (that complies with GDPR) when they enrol for an intervention that explains that data will be shared for service evaluation. The privacy notice and consent form clearly explain how participants can opt out of data sharing/withdraw their consent at any time. All forms were developed with the English language and literacy abilities of the service participants in mind and with guidance from both our CRAG and members of the wider community; the simplified version of the privacy notice has a Flesch reading score of 61 and deemed to be easily understood by individuals aged 12 and above[21]. Information is also available in print in Urdu, Bengali and Slovakian, and is translatable to any other language through the Better Start Bradford website[22].

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Qualitative data sharing

We will obtain written informed consent from all participants prior to commencing interviews/focus groups. For interviews with non-English speaking participants, the information sheet and consent form will be explained by an interpreter. At every stage of the research process, the right of participants to refuse consent, without giving a reason will be respected.

Data management

a. Quantitative intervention and satisfaction questionnaire data

Data sharing agreements will be in place between intervention teams, Better Start Bradford and the research team before data are shared. For those participants who have agreed to data sharing, the intervention teams will share individual level, identifiable data with the research team using secure transfer methods. Personally identifiable data items will be removed and replaced with a unique intervention identification number prior to analysis.

b. Qualitative Data

Audio recordings will be uploaded to an encrypted and secure network and will be deleted following transcription and verification of transcripts.

Confidentiality

All data shared will be strictly confidential and held securely for the duration of the Better Start Bradford programme. We will comply with all aspects of the General Data Protection Regulation[23], abide by the Caldicott principles and work within NHS Information Governance requirements. Anonymised data and transcripts will be available to the research team for the purposes of service evaluation only.

Analysis

Quantitative intervention and satisfaction questionnaire data

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Data will be summarised using descriptive statistics, including frequencies, summary statistics, confidence interval estimates and ranges for continuous variables (e.g. participant age, referral and recruitment rate, attrition), and proportions/ percentages for categorical variables (e.g. ethnicity, intervention completion). The analysis will also explore whether there are any differences in referrals, recruitment rates, intervention reach, attendance and satisfaction between different groups of participants e.g. by parity, ethnicity, spoken English proficiency.

Qualitative data

Qualitative data will be analysed using thematic analysis (TA), a widely used method in evaluative studies which seeks and reports patterns inherent within the data[24]. TA was chosen as it allows for an understanding of the data to be developed and patterns within the thoughts and views of participants to be examined. Specific barriers and enablers influencing implementation and satisfaction of interventions will be coded according to the TDF[18, 19]. We will also explore any patterning of themes by individuals' ethnicity, socioeconomic circumstances and English language ability. Transcripts will be coded systematically and iteratively until the analysis team are satisfied that the emerging framework adequately captures the data and saturation has been achieved. Ten-percent of the transcripts will be coded by a second researcher to maintain reliability of the coding framework. Any disagreements will be resolved through discussion and revisiting the coding framework. Data will be managed within the Nvivo data management programme (NVivo qualitative data analysis Software; QSR International Pty Ltd).

Patient and public involvement

Community involvement is integral to the ethos of BiBBS and Better Start Bradford. As such, we have set up a community research advisory group (CRAG) comprised of local community representatives including parents, volunteers, councillors and leaders of local groups and charities. The group have been involved every stage of development including in setting the

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overall evaluation objectives, development of information sheets, consent forms and satisfaction questionnaires. The CRAG will continue to advise on the development and refinement topic guides, methods for engaging local parents as well as playing a key role in the interpretation and dissemination of findings.

Ethics and Dissemination

The protocol for the BiBBS cohort including consent to contact for other studies has been approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research governance approval has been provided from Bradford Teaching Hospitals NHS Foundation Trust. The Health Research Authority has confirmed that our implementation evaluations constitute service evaluations rather than research and as such, do not require review by an NHS or other Research Ethics Committee (HRA decision 60/88/81). We uphold ethical principles, Good Clinical Practice and Research Governance including the provision of participant information sheets, informed consent, data protection and confidentiality.

Findings will be disseminated widely to aid commissioning decisions and ensure shared learning with local partners. Findings will also be shared at local and national conferences, relevant public health events and via publication in academic journals. Finally summaries of key findings will be shared with participants and the local community via our CRAG, newsletters, and on the Born in Bradford website[25].

Discussion

In this paper, we have outlined our framework for implementation evaluation across multiple, complex early years interventions. This framework has so far proved invaluable to ensure consistent and manageable data collection across all interventions as well as identifying and resolving issues in the quality of routinely collected data. Through the cyclical transfer of knowledge, findings from our implementation evaluations may also help delivery teams

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respond to any challenges identified and further optimise the delivery and reach of their interventions.

Understanding the key components of interventions and local context are integral to ensuring the successful implementation of public health interventions. However, setting up evaluations for interventions being delivered as part of usual practice is challenging, particularly where adaptations are required to ensure interventions can be integrated into the complex systems they are being delivered in. Through partner working with a wide range of stakeholders including service providers, commissioners and community representatives, our evaluation approach will also consider the role of contextual factors, delivery procedures, acceptability and scalability of the interventions. We have shared our learning on the practicalities of translating research into practice, the challenges encountered and the strategies adopted to address them elsewhere[26].

Our implementation evaluation framework and associated tools[15] are designed to be sustainable beyond our involvement as external service evaluators to allow commissioners and intervention teams to continue monitoring and evaluating the implementation of their services. Whilst in-depth qualitative evaluation may still require input from researchers, the rest of this framework can be applied by service providers and commissioners to embed pragmatic evaluation within the delivery of services whilst taking positive steps towards building a robust evidence base for early years interventions.

List of Abbreviations

BiB - Born in Bradford

BiBBS – Born in Bradford's Better Start

BMI- Body Mass Index

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CRAG - Community Research Advisory Group

HRA – Health Research Authority

MRC – Medical Research Council

NHS – National Health Service

TA – Thematic Analysis

TDF – Theoretical Domains Framework

Declarations

Ethics approval and consent to participate

The protocol for the BiBBS cohort including consent to contact for other studies has been approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research governance approval has been provided from Bradford Teaching Hospitals NHS Foundation Trust. The Health Research Authority has confirmed that our implementation evaluations do not require review by an NHS Research Ethics Committee (HRA decision 60/88/81). However, we will adhere to all ethical principles in the conduct of our evaluations and written informed consent will be obtained from all participants prior to qualitative interviews and/or focus groups.

Consent to publish

Not applicable.

Availability of data and materials

Data sharing is not applicable to this article. However, please note that data collected throughout the course of the study will be available to external researchers and proposals for collaboration will be welcomed. Information on how to access the data can be found at: www.borninbradford.nhs.uk.

Competing interests

The authors declare that they have no competing interests.

Funding

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Author contributions

ND, JD, KW, AD, SA, DN, RRCM, NU contributed to the design of the study, were involved in drafting this manuscript, approving the final version of this manuscript, and agree to be accountable for this work.

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References

1. Hickey G, McGilloway S, Furlong M, Leckey Y, Bywater T, Donnelly M: **Understanding the implementation and effectiveness of a group-based early parenting intervention: a process evaluation protocol**. *BMC health services research* 2016, **16**:490.
2. Axford N, Sonthalia, S., Wrigley, Z., Goodwin, A., Ohlsen, C., Bjornstad, G., Barlow, J., Schrader-Mcmillan, A., Coad, J. and Toft, A: **The Best Start At Home: What Works To Improve the Quality of Parent-Child Interactions From Conception to Age 5 Years. A Rapid Review Of Interventions**. In.: The Early Intervention Foundation 2015.
3. Marmot M, Allen J, Goldblatt P, Boyce T, McNeish D, Grady M, Geddes I: **Fair society, healthy lives: strategic review of health inequalities in England post 2010**. London: The Marmot Review; 2010.
4. Tickell D: **The Early Years: Foundations for life, health and learning - An independent report on the Early Years Foundation Stage to Her Majesty's Government**. London: Department for Education; 2011.
5. Axford N BJ: **What works: An overview of the best available evidence on giving children a better start**. Dartington The Social Research Unit at Dartington; 2013.

6. Evans R, Scourfield J, Murphy S: **Pragmatic, formative process evaluations of complex interventions and why we need more of them**. *Journal of epidemiology and community health* 2015, **69**(10):925-926.
7. Hurt L, Paranjothy S, Lucas PJ, Watson D, Mann M, Griffiths LJ, Ginja S, Paljarvi T, Williams J, Bellis MA *et al*: **Interventions that enhance health services for parents and infants to improve child development and social and emotional well-being in high-income countries: a systematic review**. *BMJ open* 2018, **8**(2):e014899.
8. Dickerson J, Bird PK, McEachan RR, Pickett KE, Waiblinger D, Uphoff E, Mason D, Bryant M, Bywater T, Bowyer-Crane C *et al*: **Born in Bradford's Better Start: an experimental birth cohort study to evaluate the impact of early life interventions**. *BMC public health* 2016, **15**:711.
9. **Better Start Bradford** [www.betterstartbradford.org.uk]
10. **EIF Evidence Standards** [http://guidebook.eif.org.uk/eif-evidence-standards]
11. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D *et al*: **Process evaluation of complex interventions: Medical Research Council guidance**. *Bmj* 2015, **350**:h1258.
12. Hasson H: **Systematic evaluation of implementation fidelity of complex interventions in health and social care**. *Implementation science : IS* 2010, **5**:67.
13. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S: **A conceptual framework for implementation fidelity**. *Implementation science : IS* 2007, **2**:40.
14. Hasson H, Blomberg S, Duner A: **Fidelity and moderating factors in complex interventions: a case study of a continuum of care program for frail elderly people in health and social care**. *Implementation science : IS* 2012, **7**:23.
15. **Better Start Bradford Innovation Hub: A Guide for Designing, Implementing and Evaluating Interventions** [https://borninbradford.nhs.uk/what-we-do/pregnancy-early-years/toolkit/]
16. Marshall GNaH, R.D **The Patient Questionnaire Short-form (PSQ-18)**. In. Santa Monica: Rand 1994.
17. Atkinson CaG, T.K.: **The client satisfaction questionnaire (CSQ) scales and the service satisfaction scale**: Williams & Wilkins 1995.
18. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A, Psychological Theory G: **Making psychological theory useful for implementing evidence based practice: a consensus approach**. *Quality & safety in health care* 2005, **14**(1):26-33.
19. Cane J, O'Connor D, Michie S: **Validation of the theoretical domains framework for use in behaviour change and implementation research**. *Implementation science : IS* 2012, **7**:37.
20. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, Foy R, Duncan EM, Colquhoun H, Grimshaw JM *et al*: **A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems**. *Implementation science : IS* 2017, **12**(1):77.
21. Flesch R: **A new readability yardstick**. *J Appl Psychol* 1948, **32**.
22. **Better Start Bradford Privacy notice** [https://betterstartbradford.org.uk/privacy-notice/]
23. EuropeanUnion: **Regulation (EU) 2016/679 of the European parliament and the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing directive 95/46/EC (general data protection regulation).** In.: Office journal of the European Union 2016: 1-88.
24. Braun V, and Clarke, V. : **Using thematic analysis in psychology**. *Qualitative research in psychology* 2006, **3**(2):77-101.
25. **Born in Bradford [www.borninbradford.nhs.uk]**. In.
26. Dickerson J, Bird PK, Bryant M, Dharni N, Bridges S, Willan K, Ahern S, Dunn A, Nielsen D, Uphoff EP *et al*: **Integrating research and system-wide practice in**

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public health: lessons learnt from Better Start Bradford. *BMC public health* 2019, **19**(1):260.

Figure/Table Titles/Legends

Figure 1: Modified conceptual framework for implementation fidelity Carroll et al 2007, Hasson et al 2010

Additional file 1: Satisfaction Questionnaire.pdf

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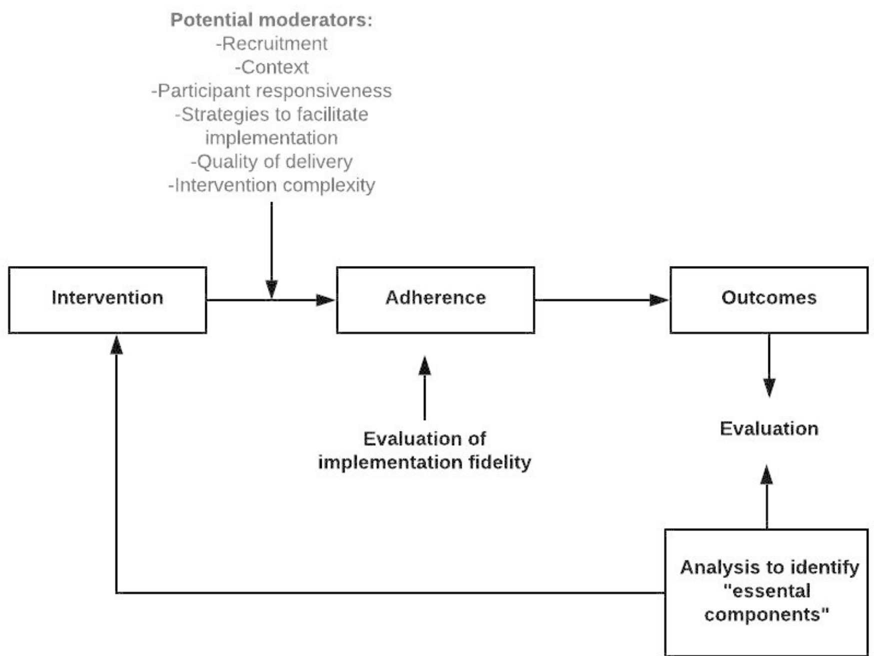

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Better Start Bradford Project Satisfaction Questionnaire

Thank you for completing this questionnaire. We really appreciate your feedback about the [NAME OF PROJECT]. Please note your answers will not affect the support you will receive now or in the future.

Please tick the box which best describes your answer to each question.

1. Overall, I feel that the [NAME OF PROJECT] was helpful for [me/my family/my child]

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

2. I am satisfied with the level of support [I/my family/child] received

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

3. The information given was useful to [me/my family/my child]

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

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4. It was easy for me to get onto the [NAME OF PROJECT]

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

5. I would recommend the [NAME OF PROJECT] to my friends and family

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

6. Overall, I am happy with the [NAME OF PROJECT]?

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

Thank you for completing this questionnaire. Please place your questionnaire in the envelope provided. If you have any further comments about [NAME OF PROJECT] please write them in the box below.

Project satisfaction questionnaire V1: 21.8.17

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