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

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SCHOLARONE™
Manuscripts

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3 1 **Implementation Evaluation of Multiple Complex Early Years Interventions: An**
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5 2 **Evaluation Framework and Study Protocol**
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57
58 27 **Abstract**
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5 **29 Introduction**

6
7 30 Implementation evaluations are integral to understanding whether, how and why
8
9 31 interventions work. However, unpicking the mechanisms of complex interventions is often
10
11 32 challenging in real world settings where multiple services are delivered concurrently.
12
13 33 Furthermore, many locally developed and/or adapted interventions have not undergone any
14
15 34 evaluation thus limiting the evidence base available. Born in Bradford's Better Start cohort is
16
17 35 evaluating the impact of multiple early life interventions being delivered as part of the Big
18
19 36 Lottery Fund's 'A Better Start' programme to improve the health and well-being of children
20
21 37 living in one of the most socially and ethnically diverse areas of the UK. In this paper, we
22
23 38 outline our evaluation framework and protocol for embedding pragmatic implementation
24
25 39 evaluation across multiple early years interventions and services.
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31 **41 Methods and analysis**

32
33 42 The evaluation framework is based on a modified version of The Conceptual Framework for
34
35 43 Implementation Fidelity. Using qualitative and quantitative methods, our evaluation
36
37 44 framework incorporates semi-structured interviews, focus groups, routinely collected data
38
39 45 and questionnaires. We will explore factors related to content, delivery and reach of
40
41 46 interventions at both individual and wider community levels. Potential moderating factors
42
43 47 impacting intervention success such as participants' satisfaction, strategies to facilitate
44
45 48 implementation, quality of delivery and context will also be examined. Interview and focus
46
47 49 guides will be based on the Theoretical Domains Framework to further explore the barriers
48
49 50 and facilitators of implementation. Descriptive statistics will be employed to analyse the
50
51 51 routinely collected quantitative data and thematic analysis will be used to analyse qualitative
52
53 52 data.
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55 **Ethics and dissemination**

1
2
3 56 The Health Research Authority has confirmed our implementation evaluations do not
4
5 57 require review by an NHS Research Ethics Committee (HRA decision 60/88/81). Findings
6
7 58 will be shared widely to aid commissioning decisions and will also be disseminated
8
9 59 through peer-reviewed journals, summary reports, conferences and community
10
11 60 newsletters.
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15
16 62 **Key words:** *Implementation Science, process evaluation, early years interventions,*
17
18 63 *prevention, infancy, pregnancy, child health, maternal health, inequalities*
19

20
21 64

22 65 **Box 1**

23 24 66 *What is known about this subject*

- 25
26 67 • Early years interventions are integral to improving the life chances for children and
27
28 68 reducing inequalities in health and well-being. However, there is a dearth of evidence
29
30 69 examining the impact of interventions and many locally developed and or adapted
31
32 70 interventions have not undergone, or are necessarily at a stage in development where
33
34 71 they can be subjected to rigorous evaluation.
35

36 37 72 *What this study will add*

- 38
39 73 • Our focus on implementation presents a pragmatic and consistent approach to
40
41 74 evaluating multiple early years interventions, including those deemed as not yet ready for
42
43 75 evaluations of effectiveness. The mixed methods approach and use of routinely
44
45 76 collected data provides an efficient, feasible and manageable evaluation framework that
46
47 77 can be easily embedded within services as they are being delivered.
48

49
50 78

51 79 **Introduction**

52
53 80 The early years of life are integral to promoting positive outcomes throughout the lifespan
54
55 81 [3]. Mothers' health in pregnancy and the first two years of life in particular, have been
56
57 82 identified as periods that play a vital role in children's emotional, cognitive and physical
58
59 83 development [4], [5],[6]. Early years interventions are therefore crucial to reduce inequalities
60

1
2
3 84 and ensure the health and wellbeing of children as they grow. However, many preventative
4
5 85 interventions delivered by early years services have not been subjected to rigorous
6
7 86 development and evaluation, thus leaving them without a robust evidence base [1, 7].
8
9 87 Born in Bradford's Better Start (BiBBS) experimental birth cohort is currently delivering
10
11 88 effectiveness evaluations for multiple complex early years interventions that are being
12
13 89 delivered in real-life settings through the Better Start Bradford programme [8, 9]. The cohort
14
15 90 will efficiently evaluate multiple complex early life interventions through planned controlled
16
17 91 experiments and using quasi-experimental methods. However, effective interventions are
18
19 92 those that not only show a positive outcome on key outcomes, but those that are able to
20
21 93 recruit and engage participants and can be delivered with fidelity in real-life settings. It is,
22
23 94 therefore critical to conduct implementation evaluations to provide evidence of the feasibility,
24
25 95 reach, context and short-term impact of interventions [1],[2]. Furthermore, implementation or
26
27 96 process evaluations can help allude to the transferability of interventions, providing local
28
29 97 commissioners and service providers with guidance on the practical measures they can take
30
31 98 to successfully embed interventions within their settings and communities [1].
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36

37 100 The limited availability of evidence of effect for many early years interventions means that
38
39 101 the majority of Better Start Bradford interventions are considered as being 'science based'
40
41 102 with some in the foundational stages of development and/or evaluation [7, 10] (see
42
43 103 supplementary table 1 for further details about the interventions) and [9]). Consequently,
44
45 104 whilst the long-term goal of BiBBS is to provide effectiveness evaluations of these
46
47 105 interventions, many of the interventions are currently not ready for such an evaluation.
48
49 106 This paper describes a framework for implementation evaluation and a protocol to evaluate
50
51 107 the interventions being delivered as part of the Better Start Bradford programme. This
52
53 108 framework can be used by researchers, practitioners, commissioners and service providers
54
55 109 across multiple settings to evaluate the quality of implementation of early years interventions
56
57 110 being delivered in real-life settings and enhance their readiness for more intensive levels of
58
59 111 evaluation.
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3 1124
5 113 **Methods**6
7 114 ***Conceptual framework***8
9 115 Underpinned by the MRC guidance on process evaluations of complex interventions, our
10 116 implementation evaluations draw on the conceptual framework for implementation fidelity
11 (figure 1) [11, 12].
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13

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15 118
16 [Insert figure 1 here]

17 119

18 120
19
20 121 Adoption of the modified conceptual model of implementation fidelity will help glean the
21 122 factors affecting the implementation of the Better Start Bradford interventions (independently
22 123 and collectively) and, in turn examine their impact on outcomes as interventions increase in
23 124 their potential for evaluation of impact. Whilst drawing on published examples [11], [13] we
24 125 plan to apply the framework consistently across multiple interventions with much of the data
25 126 collection being integrated in the routine delivery of interventions to yield an efficient and
26 127 pragmatic approach to evaluation. Table 1 outlines the evaluation framework including the
27 128 overarching research questions, corresponding data source and method of collection.
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40 130 ***Data collection***

41 131 Data for the implementation evaluation will be derived from a number of sources:

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43 133 ***1. Quantitative data collected by intervention teams***44 134 Prior to the implementation of each intervention, a service design process takes place in
45 135 collaboration with commissioners, intervention delivery teams, academic researchers and
46 136 other stakeholders including health professionals and community representatives to ensure
47 137 each intervention meets the needs of the local population. During this process, the
48 138 appropriate process and outcome data to be collected by each intervention team throughout
49 139 the delivery period and submitted quarterly to the research team are also agreed. A guide to
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3 140 the service evaluation process and templates including a minimum dataset for
4
5 141 implementation evaluation is available on our website[14].
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9 143 *2. Satisfaction Questionnaires*

10
11 144 We have developed a brief six item satisfaction questionnaire to capture participants'
12
13 145 satisfaction across all interventions (see additional file 1). Questions are based on the key
14
15 146 constructs of commonly used patient satisfaction surveys[15], [16], but have been adapted
16
17 147 following advice from our Community Research Advisory Group (CRAG), comprised of local
18
19 148 parents and volunteers alongside intervention team managers, commissioners and the
20
21 149 research team to ensure acceptability for the local community. This process resulted in a
22
23 150 questionnaire that is brief, incorporates visuals and uses simple language that can be easily
24
25 151 understood and translated into other languages.
26
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30 153 *3. Semi-Structured Interviews and Focus Groups*

31
32 154 Semi-structured interviews and/or focus groups where appropriate, will be undertaken with
33
34 155 intervention participants and delivery teams to allow more in-depth exploration of elements
35
36 156 of the conceptual model. Topic guides will be based on the theoretical domains framework
37
38 157 (TDF) [17], [18]. The TDF encompasses a comprehensive range of constructs from theories
39
40 158 of behaviour change including beliefs about capabilities, knowledge, skills, emotions and
41
42 159 social influences. Furthermore, use of the TDF provides a firm theoretical basis to allow
43
44 160 understanding of the mechanisms of action as well as the barriers and facilitators of
45
46 161 implementation [19]. It has been extensively applied to investigate and address
47
48 162 implementation problems [19]. Whilst the interview questions may differ by intervention, use
49
50 163 of the TDF ensures the underlying theoretical concepts explored in all interviews are
51
52 164 explored using a consistent approach.
53

54
55 165 All studies will include data from sources 1 and 2. In-depth qualitative work may be triggered
56
57 166 in response to issues identified by interventions such as difficulties in engaging families from
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167 particular ethnic groups, low completion rates, and priorities highlighted by the
 168 commissioning team.

169

170 Table 1: Implementation and process evaluation key elements and research questions within
 171 Better Start Bradford

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 (<i>where intervention delivered by volunteers or peer supporters</i>)	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

Areas to measure	General process questions	Example data source and data collection method
	<p>to be most helpful and unhelpful in meeting their needs?</p> <p>What proportion of parents accessed further support?</p> <p>How did staff/volunteers perceive the impact of the intervention?</p>	<p>parents exploring satisfaction</p> <p>Quarterly monitoring data submitted by intervention teams: Number and type of referrals made to external agencies</p> <p>Interviews or focus groups with staff/volunteers</p>
e) Recruitment	<p>What recruitment procedures were used to engage families and staff?</p> <p>Did the intervention recruit to target?</p> <p>What constituted barriers to maintaining involvement of individuals?</p>	<p>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</p> <p>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</p> <p>Qualitative interviews with parents Qualitative interviews or focus groups with staff/volunteers</p> <p>Analysis of quarterly/ annual reports around the key challenges of implementation and corresponding action plans</p>
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

172

173 **Eligibility**174 *Inclusion Criteria*175 *a. Intervention participants*

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

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

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

188 *Exclusion Criteria*

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3 189 For qualitative studies, participants who have completed an interview/focus group within the
4
5 190 past 12 months will not be approached to take part in a second study to avoid unnecessary
6
7 191 burden.
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11 193 **Sample Size & Selection**

12
13 194 The number of people included in the quantitative data evaluation will be dependent on the
14
15 195 number of participants engaged with any given intervention, and the number agreeing to
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17 196 share information with the research team as all data will be collected as part of routine
18
19 197 service delivery.
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24 199 For qualitative evaluation, a purposive sampling method will be used to identify and recruit
25
26 200 participants representing key characteristics including ethnicity, number of children, socio-
27
28 201 economic deprivation and language. Other characteristics will be included based on their
29
30 202 influence on the key objectives of the intervention; for example, maternal mental well-being
31
32 203 for interventions relating to social and emotional health; BMI for interventions relating to
33
34 204 nutrition. We will continue to recruit until we reach data saturation, with an estimate of 20-30
35
36 205 interview participants per intervention. Where focus groups are undertaken, we would aim to
37
38 206 recruit 8-10 participants per group, with potentially separate focus groups depending on
39
40 207 participants' ethnicity, gender, language, and/or neighbourhood area. For staff/volunteers,
41
42 208 we aim to interview a minimum of 5/6 people per intervention, depending on the size of the
43
44 209 intervention delivery team.
45
46

47 210

48 49 211 **Recruitment**

50 212 *Quantitative intervention data & satisfaction questionnaires*

51
52 213 Quantitative data will be collected from all participants as a part of the standard service
53
54 214 provision.
55

56 215

57 216 *Qualitative studies*

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3 217 Participants will be identified and approached by one of two methods:
4

5 218

6
7 219 1) By researchers directly from the BiBBS cohort.
8

9 220 As part of the consent process for our experimental BiBBS cohort study, expectant parents
10
11 221 consent to being contacted in the future to learn about participation in further research.

12
13 222 Researchers will write to consenting parents, attaching a cover letter and information sheet
14
15 223 about qualitative studies and contact them via telephone within two weeks.
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20 225 2) By intervention delivery staff/managers
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22 226 Intervention coordinators will be asked to circulate the study information sheet to all
23
24 227 participants who have enrolled onto an intervention. Coordinators will share the names and
25
26 228 contact details of those individuals who are willing to be interviewed with the research team.

27
28 229 Staff and volunteers will first be approached by their service managers and if they agree,
29
30 230 their contact details will be passed onto the research team.
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34 232 In both methods of approach, for those interested in taking part, we will check their eligibility
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36 233 (as described above) and check they have read and understood the information sheet. A
37
38 234 convenient date/time/place for an interview will be confirmed if agreed.
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41

42 236 **Consent**

43 237 *Quantitative data sharing*

44
45 238 All intervention participants are given a privacy notice when they enrol for an intervention
46
47 239 that explains that data will be shared for service evaluation. The privacy notice and consent
48
49 240 form clearly explain how participants can opt out of data sharing/withdraw their consent at
50
51 241 any time. All forms were developed with the English language and literacy abilities of the
52
53 242 service participants in mind and with guidance from both our CRAG and members of the
54
55 243 wider community; the simplified version of the privacy notice has a Flesch reading score of
56
57 244 61 and deemed to be easily understood by individuals aged 12 and above[20]. Information is
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245 also available in print in Urdu, Bengali and Slovakian, and is translatable to any other
246 language through the Better Start Bradford website[21].

247

248 *Qualitative data sharing*

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

254

255 **Data management**

256 *a. Quantitative intervention and satisfaction questionnaire data*

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

262

263 *b. Qualitative Data*

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

266

267 **Confidentiality**

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

273

274 Analysis**275 Quantitative intervention and satisfaction questionnaire data**

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

283

284 Qualitative data

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

298

299 Patient and public involvement

1
2
3 300 Community involvement is integral to the ethos of BiBBS and Better Start Bradford. As such,
4
5 301 we have set up a community research advisory group (CRAG) comprised of local community
6
7 302 representatives including parents, volunteers, councillors and leaders of local groups and
8
9 303 charities. The group have been involved every stage of development including in setting the
10
11 304 overall evaluation objectives, development of information sheets, consent forms and
12
13 305 satisfaction questionnaires. The CRAG will continue to advise on the development and
14
15 306 refinement topic guides, methods for engaging local parents as well as playing a key role in
16
17 307 the interpretation and dissemination of findings.
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19
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21 22 309 ***Ethics and Dissemination***

23
24 310 The protocol for the BiBBS cohort including consent to contact for other studies has been
25
26 311 approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research
27
28 312 governance approval has been provided from Bradford Teaching Hospitals NHS
29
30 313 Foundation Trust. The Health Research Authority has confirmed that our implementation
31
32 314 evaluations do not require review by an NHS Research Ethics Committee (HRA decision
33
34 315 60/88/81). Despite ethical approval not being a formal requirement, we aim to uphold
35
36 316 ethical principles, Good Clinical Practice and Research Governance including the
37
38 317 provision of participant information sheets and obtaining informed consent.
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41 318

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43 319 Findings will be disseminated widely to aid commissioning decisions and ensure shared
44
45 320 learning with local partners. Findings will also be shared at local and national conferences,
46
47 321 relevant public health events and via publication in academic journals. Summaries of key
48
49 322 findings will be shared with participants and the local community via our CRAG, newsletters,
50
51 323 and on the Born in Bradford website[24].
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58 327 **Discussion**
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3 328 In this paper, we have outlined our framework for implementation evaluation across multiple,
4
5 329 complex early years interventions. This framework has so far proved invaluable to ensure
6
7 330 consistent and manageable data collection across all interventions as well as identifying and
8
9 331 resolving issues in the quality of routinely collected data. Through the cyclical transfer of
10
11 332 knowledge, findings from our implementation evaluations may also help delivery teams
12
13 333 respond to any challenges identified and further optimise the delivery and reach of their
14
15 334 interventions. Moreover, the inclusion of a wide range of stakeholders will further help
16
17 335 uncover the role of contextual factors, delivery procedures, acceptability and scalability of
18
19 336 the interventions.
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24 338 Our implementation evaluation framework and associated tools[14] are designed to be
25
26 339 sustainable beyond our involvement as external service evaluators to allow commissioners
27
28 340 and intervention teams to continue monitoring and evaluating the implementation of their
29
30 341 services. Whilst in-depth qualitative evaluation may still require input from researchers, the
31
32 342 rest of this framework can be applied by service providers and commissioners to embed
33
34 343 pragmatic evaluation within the delivery of services whilst taking positive steps towards
35
36 344 building a robust evidence base for early years interventions.
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42 43 347 **List of Abbreviations**

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46
47 349 BiB - Born in Bradford

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49 350 BiBBS – Born in Bradford’s Better Start

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51 351 BMI- Body Mass Index

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53 352 CRAG - Community Research Advisory Group

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55 353 HRA – Health Research Authority

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57 354 MRC – Medical Research Council

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59 355 NHS – National Health Service
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3 356 TA – Thematic Analysis
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5 357 TDF – Theoretical Domains Framework
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11 360 **Declarations**

12
13
14 361 ***Ethics approval and consent to participate***

15
16 362 The protocol for the BiBBS cohort including consent to contact for other studies has been

17
18 363 approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research

19
20 364 governance approval has been provided from Bradford Teaching Hospitals NHS Foundation

21
22 365 Trust. The Health Research Authority has confirmed that our implementation evaluations do

23
24 366 not require review by an NHS Research Ethics Committee (HRA decision 60/88/81).

25
26 367 However, we will adhere to all ethical principles in the conduct of our evaluations and written

27
28 368 informed consent will be obtained from all participants prior to qualitative interviews and/or

29
30 369 focus groups.
31

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33

34
35 371 ***Consent to publish***

36
37 372 Not applicable.
38

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41 374 ***Availability of data and materials***

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43 375 Data sharing is not applicable to this article. However, please note that data collected

44
45 376 throughout the course of the study will be available to external researchers and proposals for

46
47 377 collaboration will be welcomed. Information on how to access the data can be found

48
49 378 at: www.borninbradford.nhs.uk.
50

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53 380 ***Competing interests***

54
55 381 The authors declare that they have no competing interests.
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3 384 **Funding**
4

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6
7 386 part of the A Better Start programme. The Big Lottery Fund have not had any involvement in
8
9 387 the design or writing of the study protocol.
10

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13
14 389 **Author contributions**

15 390 All authors contributed to the design of the study, were involved in drafting this manuscript,
16
17 391 approving the final version of this manuscript, and agree to be accountable for this work.
18
19

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21
22 393 **Acknowledgements**

23
24 394 We are grateful to all the participants, all members of the Community Research Advisory
25
26 395 Group, Born in Bradford staff, the Better Start Bradford staff and projects, health
27
28 396 professionals and researchers who have supported the development and set-up of this
29
30 397 evaluation study.
31

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34
35 399 **References**

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54 469 **Figure/Table Titles/Legends**
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56 470 Figure 1: Modified conceptual framework for implementation fidelity Carroll et al 2007,
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58 471 Hasson et al 2010
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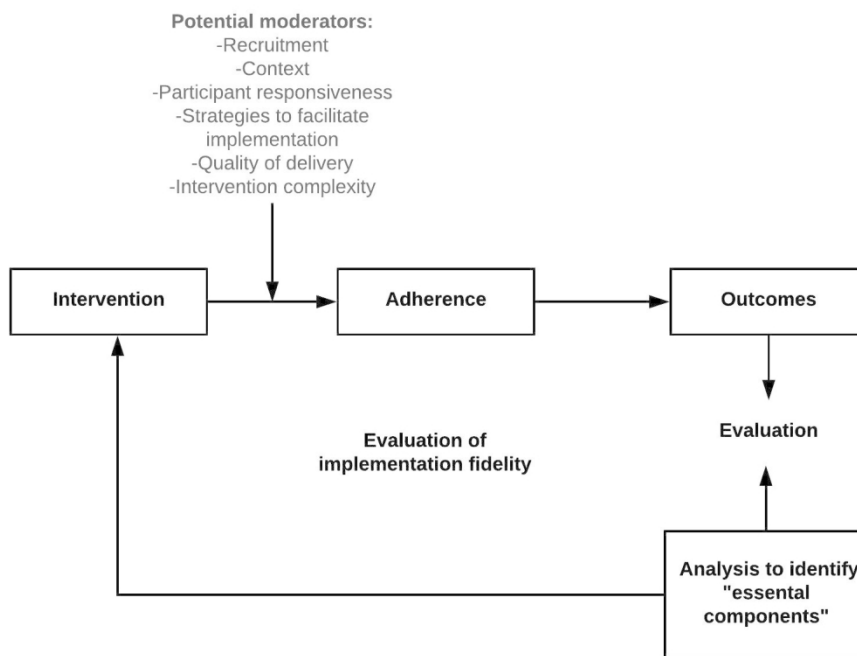
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473 Additional file 1: Satisfaction Questionnaire.pdf

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

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

<i>Intervention</i>	<i>Description</i>	<i>Service Provider</i>	<i>Estimated Recipients per year</i>
<i>Antenatal Support</i>			
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
<i>Antenatal and Postnatal Support</i>			
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

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

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








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.

BMJ Paediatrics Open

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

Journal:	<i>BMJ Paediatrics Open</i>
Manuscript ID	bmjpo-2019-000479.R1
Article Type:	Protocol
Date Submitted by the Author:	28-May-2019
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Keywords:	Comm Child Health, Data Collection, Health services research, Race and Health, Qualitative research

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Manuscripts

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3 **28 Abstract**
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7 **30 Introduction**
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9 31 Implementation evaluations are integral to understanding whether, how and why
10
11 32 interventions work. However, unpicking the mechanisms of complex interventions is often
12
13 33 challenging in usual service settings where multiple services are delivered concurrently.
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15 34 Furthermore, many locally developed and/or adapted interventions have not undergone any
16
17 35 evaluation thus limiting the evidence base available. Born in Bradford's Better Start cohort is
18
19 36 evaluating the impact of multiple early life interventions being delivered as part of the Big
20
21 37 Lottery Fund's 'A Better Start' programme to improve the health and well-being of children
22
23 38 living in one of the most socially and ethnically diverse areas of the UK. In this paper, we
24
25 39 outline our evaluation framework and protocol for embedding pragmatic implementation
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27 40 evaluation across multiple early years interventions and services.
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32 **42 Methods and analysis**
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35 43 The evaluation framework is based on a modified version of The Conceptual Framework for
36
37 44 Implementation Fidelity. Using qualitative and quantitative methods, our evaluation
38
39 45 framework incorporates semi-structured interviews, focus groups, routinely collected data
40
41 46 and questionnaires. We will explore factors related to content, delivery and reach of
42
43 47 interventions at both individual and wider community levels. Potential moderating factors
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45 48 impacting intervention success such as participants' satisfaction, strategies to facilitate
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47 49 implementation, quality of delivery and context will also be examined. Interview and focus
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49 50 guides will be based on the Theoretical Domains Framework to further explore the barriers
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51 51 and facilitators of implementation. Descriptive statistics will be employed to analyse the
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53 52 routinely collected quantitative data and thematic analysis will be used to analyse qualitative
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55 53 data.
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56 **Ethics and dissemination**

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

62
63 **Key words:** *Implementation Science, process evaluation, early years interventions,*
64 *prevention, infancy, pregnancy, child health, maternal health, inequalities*

66 **Box 1**

67 *What is known about this subject*

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

72 *What this study will add*

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

79 **Introduction**

80 The early years of life are integral to promoting positive outcomes throughout the lifespan
81 [1]. Women's health in pregnancy and the first two years of their children's lives have been
82 identified as critical periods in children's emotional, cognitive and physical development [2-
83 4]. Early years interventions are therefore crucial to reduce inequalities and ensure the

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3 84 health and wellbeing of children as they grow. However, many preventative interventions
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5 85 delivered by early years services have not been subjected to rigorous development and
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7 86 evaluation, thus leaving them without a robust evidence base [5-8].
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11 88 Better Start Bradford is a Big Lottery funded programme that has commissioned and
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13 89 implemented over 20 early years interventions into existing practice in three deprived and
14
15 90 ethnically diverse inner-city wards of Bradford. The interventions aim to improve social and
16
17 91 emotional development, communication and language development and nutrition and health
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19 92 in 0-4 years olds [8, 9]. The limited availability of evidence of effect for many early years
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21 93 interventions means that the majority of Better Start Bradford interventions are considered
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23 94 as being 'science based' with some in the foundational stages of development and/or
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25 95 evaluation [5, 10] (see table 1 for further details about the interventions) and [9]).
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30 97 Born in Bradford's Better Start (BiBBS) experimental birth cohort was established to provide
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32 98 independent effectiveness evaluations for these early years interventions through planned
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34 99 controlled experiments and using quasi-experimental methods. However, effective
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36 100 interventions are those that not only show a positive outcome on key outcomes, but those
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38 101 that are able to recruit and engage participants and can be delivered with fidelity in usual
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40 102 service settings. It is, therefore critical to conduct implementation evaluations to provide
41
42 103 evidence of the feasibility, reach, context and short-term impact of interventions [6],[11].
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44 104 Furthermore, implementation or process evaluations can help allude to the transferability of
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46 105 interventions, providing local commissioners and service providers with guidance on the
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48 106 practical measures they can take to successfully embed interventions within their settings
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50 107 and communities [6].
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55 109 This paper describes a framework and protocol to evaluate the implementation of
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57 110 interventions being delivered as part of the Better Start Bradford programme. Our evaluation
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59 111 framework can be used by researchers, practitioners, commissioners and service providers
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3 112 across multiple settings to evaluate the quality of implementation of early years interventions
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5 113 being delivered in usual settings and maximise potential for more intensive levels of
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7 114 evaluation.
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10
11 116 Table 1: Interventions commissioned for delivery as part of the Better Start Bradford
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14 117 programme
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<i>Intervention</i>	Description	Service Provider	Estimated Recipients per year
<i>Antenatal Support</i>			
<i>Personalised Midwifery</i>	Continuous midwife care through antenatal and postnatal period	Bradford Hospitals NHS Foundation Trust Midwifery Services	500
<i>Family Links Antenatal</i>	Universal antenatal parenting skills programme	Local Authority	200
<i>ESOL+</i>	English language course for women with little or no English during pregnancy	Shipley Further Education College	90
<i>Antenatal and Postnatal Support</i>			
<i>Family Nurse Partnership¹</i>	Intensive home visiting for vulnerable women aged under 25 years	Bradford District Care Trust (BDCT)	100
<i>Baby Steps</i>	Parent education programme for vulnerable parents	Voluntary Community Sector (VCS) – Action For Children	100
<i>Doula</i>	Late pregnancy, birth and post-natal support for vulnerable women	VCS Action For Community Ltd	82
<i>HAPPY</i>	Healthy eating & parenting course for overweight mums with a BMI over 25.	VCS – Barnardo's	120
<i>Perinatal Support Service</i>	Support for pregnant women and mothers of babies under 1 year old at risk of mild/moderate mental health issues	VCS – Family Action	140

<i>Intervention</i>	Description	Service Provider	Estimated Recipients per year
<i>Breast feeding support service</i>	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
<i>Home-Start</i>	Peer support for vulnerable women	VCS – Home-Start	45
<i>Little Minds Matter</i>	Support and nurturing of parent-infant relationships for those at risk of relationship problems	BDCT/ Family Action	40
<i>HENRY</i>	Universal group programme to improve healthy eating and physical activity in young children	VCS & Schools / HENRY	186
<i>Incredible Years Parenting¹</i>	Universal parenting programme for parents with toddlers	VCS – Barnardo's	160
<i>Cooking for a Better start</i>	Universal cook and eat sessions	VCS - HENRY	72
<i>Pre-schoolers in the Playground</i>	Pre-schoolers physical activity in the playground	Schools	108
<i>Forest Schools</i>	Outdoor play in the natural environment for young children & parents	VCS – Get Out More CiC	90
<i>Better Start Imagine</i>	Book gifting & book sharing sessions	VCS – BHT Early Education and Training	1015
<i>I CAN Early Talk</i>	Strengthening parents' and practitioners' knowledge in improving language development	VCS – BHT Early Education and Training	115
<i>Talking Together</i>	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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121 **Methods**122 **Conceptual framework**

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3 123 Underpinned by the MRC guidance on process evaluations of complex interventions, our
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5 124 implementation evaluations draw on the conceptual framework for implementation fidelity
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7 125 (figure 1) [12, 13].
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11 127 [Insert figure 1 here]
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15 129 Fidelity, termed as adherence, is defined as a combination of content; frequency and
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17 130 duration of delivery; and coverage [12, 13]. Examining fidelity therefore seeks to establish
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19 131 the extent to which the active ingredients of the intervention were delivered as often and for
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21 132 as long as planned [12, 13]. Also included in the framework are potential moderators of
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23 133 implementation process and fidelity such as intervention complexity, participant
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25 134 responsiveness (including engagement and satisfaction), quality of delivery and strategies
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27 135 that facilitate implementation. Context and recruitment were later added as potential
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29 136 moderators in the modified framework [12]. The moderators are proposed to be intrinsically
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31 137 linked to each other as well as to implementation fidelity.
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37 139 Adoption of the conceptual model of implementation fidelity will help glean the factors
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39 140 affecting the implementation of the Better Start Bradford interventions (independently and
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41 141 collectively) and, in turn examine their impact on outcomes as interventions increase in their
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43 142 potential for evaluation of impact. Whilst drawing on published examples [12], [14] we plan
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45 143 to apply the framework consistently across multiple interventions with much of the data
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47 144 collection being integrated in the routine delivery of interventions to yield an efficient and
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49 145 pragmatic approach to evaluation. Table 2 outlines the evaluation framework including the
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51 146 overarching research questions, corresponding data source and method of collection.
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55 148 **Data collection**

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57 149 Data for the implementation evaluation will be derived from a number of sources:
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3 151 *1. Quantitative data collected by intervention teams*
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5 152 Prior to the implementation of each intervention, a service design process takes place in
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7 153 collaboration with commissioners, intervention delivery teams, academic researchers and
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9 154 other stakeholders including health professionals and community representatives to ensure
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11 155 each intervention meets the needs of the local population. During this process, recruitment
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13 156 targets and process and outcome data to be collected by intervention teams throughout the
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15 157 delivery period and submitted quarterly to the research team are also agreed. A guide to the
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17 158 service evaluation process and templates including a minimum dataset for implementation
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19 159 evaluation is available on our website[15].
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24 161 *2. Satisfaction Questionnaires*
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26 162 We have developed a brief six item satisfaction questionnaire to capture participants'
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28 163 satisfaction across all interventions (see additional file 1). Questions are based on the key
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30 164 constructs of commonly used patient satisfaction surveys[16], [17], but have been adapted
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32 165 following advice from our Community Research Advisory Group (CRAG), comprised of local
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34 166 parents and volunteers alongside intervention team managers, commissioners and the
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36 167 research team to ensure acceptability for the local community. This process resulted in a
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38 168 questionnaire that is brief, uses visual cues and simple language that can be easily
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40 169 understood and translated into other languages.
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45 171 *3. Semi-Structured Interviews and Focus Groups*
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47 172 Semi-structured interviews and/or focus groups where appropriate, will be undertaken with
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49 173 intervention participants and delivery teams to allow more in-depth exploration of elements
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51 174 of the conceptual model. Topic guides will be based on the Theoretical Domains Framework
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53 175 (TDF) [18], [19]. The TDF encompasses a comprehensive range of constructs from theories
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55 176 of behaviour change including beliefs about capabilities, knowledge, skills, emotions and
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57 177 social influences. Furthermore, use of the TDF provides a firm theoretical basis to allow
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59 178 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)

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

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

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

191

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

193

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.

198

199 **Sample Size & Selection**

1
2
3 200 Quantitative process and demographic data will be collected for all participants who consent
4
5 201 for their data to be shared with the evaluation team. Sample sizes will not be determined in
6
7 202 advance as this will be dependent on the uptake of interventions.
8

9 203

10
11 204 For qualitative evaluation, a purposive sampling method will be used to identify and recruit
12
13 205 participants representing key characteristics including ethnicity, number of children, and
14
15 206 primary language to represent the different ethnic and cultural groups in Bradford. Other
16
17 207 characteristics will be included based on the key objectives of the intervention as defined
18
19 208 during the service design process; for example, maternal mental well-being for interventions
20
21 209 relating to social and emotional health; BMI for interventions relating to nutrition. We will
22
23 210 continue to recruit until we reach data saturation, with an estimate of 20-30 interview
24
25 211 participants per intervention. Where focus groups are undertaken, we would aim to recruit 8-
26
27 212 10 participants per group, with potentially separate focus groups depending on participants'
28
29 213 ethnicity, gender, primary language, and/or neighbourhood area. For staff/volunteers, we
30
31 214 aim to interview a minimum of 5/6 people per intervention, depending on the size of the
32
33 215 intervention delivery team.
34
35

36 216

37 217 **Recruitment**

38 218 *Quantitative intervention data & satisfaction questionnaires*

39 219 Quantitative data will be collected from all participants as a part of the standard service
40
41 220 provision.
42

43 221

44 222 *Qualitative studies*

45 223 Participants will be identified and approached by one of two methods:
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47 224

48 225

49 226 1) By researchers directly from the BiBBS cohort.

50 227 As part of the consent process for our experimental BiBBS cohort study, expectant parents
51
52 consent to being contacted in the future to learn about participation in further studies.
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3 228 Researchers will write to consenting parents, attaching a cover letter and information sheet
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5 229 about qualitative studies and contact them via telephone within two weeks. Where a
6
7 230 participant speaks a language other than English, the initial phone call will be made by a
8
9 231 bilingual researcher or an interpreter.
10

11 232

12
13
14 233 2) By intervention delivery staff/managers

15
16 234 Intervention coordinators will be asked to circulate the study information sheet to all
17
18 235 participants who have enrolled onto an intervention. Coordinators will share the names and
19
20 236 contact details of those individuals who are willing to be interviewed with the research team.
21
22 237 Staff and volunteers will first be approached by their service managers and if they agree,
23
24 238 their contact details will be passed onto the research team.
25

26 239

27
28 240 In both methods of approach, for those interested in taking part, we will check their eligibility
29
30 241 (as described above) and check they have read and understood the information sheet. A
31
32 242 convenient date/time/place for an interview will be confirmed if agreed.
33

34 243

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36
37 244 **Consent**

38
39 245 *Quantitative data sharing*

40
41 246 All intervention participants are given a privacy notice (that complies with GDPR) when they
42
43 247 enrol for an intervention that explains that data will be shared for service evaluation. The
44
45 248 privacy notice and consent form clearly explain how participants can opt out of data
46
47 249 sharing/withdraw their consent at any time. All forms were developed with the English
48
49 250 language and literacy abilities of the service participants in mind and with guidance from
50
51 251 both our CRAG and members of the wider community; the simplified version of the privacy
52
53 252 notice has a Flesch reading score of 61 and deemed to be easily understood by individuals
54
55 253 aged 12 and above[21]. Information is also available in print in Urdu, Bengali and Slovakian,
56
57 254 and is translatable to any other language through the Better Start Bradford website[22].
58
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60 255

1
2
3 256 *Qualitative data sharing*
4

5 257 We will obtain written informed consent from all participants prior to commencing
6
7 258 interviews/focus groups. For interviews with non-English speaking participants, the
8
9 259 information sheet and consent form will be explained by an interpreter. At every stage of the
10
11 260 research process, the right of participants to refuse consent, without giving a reason will be
12
13 261 respected.
14

15
16 262

17
18 263 **Data management**

19
20 264 *a. Quantitative intervention and satisfaction questionnaire data*

21
22 265 Data sharing agreements will be in place between intervention teams, Better Start Bradford
23
24 266 and the research team before data are shared. For those participants who have agreed to
25
26 267 data sharing, the intervention teams will share individual level, identifiable data with the
27
28 268 research team using secure transfer methods. Personally identifiable data items will be
29
30 269 removed and replaced with a unique intervention identification number prior to analysis.
31

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33 270

34
35 271 *b. Qualitative Data*

36
37 272 Audio recordings will be uploaded to an encrypted and secure network and will be deleted
38
39 273 following transcription and verification of transcripts.
40

41 274

42
43 275 **Confidentiality**

44
45 276 All data shared will be strictly confidential and held securely for the duration of the Better
46
47 277 Start Bradford programme. We will comply with all aspects of the General Data Protection
48
49 278 Regulation[23], abide by the Caldicott principles and work within NHS Information
50
51 279 Governance requirements. Anonymised data and transcripts will be available to the research
52
53 280 team for the purposes of service evaluation only.
54

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56 281

57
58 282 **Analysis**

59
60 283 *Quantitative intervention and satisfaction questionnaire data*

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3 284 Data will be summarised using descriptive statistics, including frequencies, summary
4
5 285 statistics, confidence interval estimates and ranges for continuous variables (e.g. participant
6
7 286 age, referral and recruitment rate, attrition), and proportions/ percentages for categorical
8
9 287 variables (e.g. ethnicity, intervention completion). The analysis will also explore whether
10
11 288 there are any differences in referrals, recruitment rates, intervention reach, attendance and
12
13 289 satisfaction between different groups of participants e.g. by parity, ethnicity, spoken English
14
15 290 proficiency.
16
17

18 291

19 292 *Qualitative data*

20
21
22 293 Qualitative data will be analysed using thematic analysis (TA), a widely used method in
23
24 294 evaluative studies which seeks and reports patterns inherent within the data[24]. TA was
25
26 295 chosen as it allows for an understanding of the data to be developed and patterns within the
27
28 296 thoughts and views of participants to be examined. Specific barriers and enablers influencing
29
30 297 implementation and satisfaction of interventions will be coded according to the TDF[18, 19].
31
32 298 We will also explore any patterning of themes by individuals' ethnicity, socioeconomic
33
34 299 circumstances and English language ability. Transcripts will be coded systematically and
35
36 300 iteratively until the analysis team are satisfied that the emerging framework adequately
37
38 301 captures the data and saturation has been achieved. Ten-percent of the transcripts will be
39
40 302 coded by a second researcher to maintain reliability of the coding framework. Any
41
42 303 disagreements will be resolved through discussion and revisiting the coding framework. Data
43
44 304 will be managed within the Nvivo data management programme (NVivo qualitative data
45
46 305 analysis Software; QSR International Pty Ltd).
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50 306

51 307 *Patient and public involvement*

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53 308 Community involvement is integral to the ethos of BiBBS and Better Start Bradford. As such,
54
55 309 we have set up a community research advisory group (CRAG) comprised of local community
56
57 310 representatives including parents, volunteers, councillors and leaders of local groups and
58
59 311 charities. The group have been involved every stage of development including in setting the
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1
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3 312 overall evaluation objectives, development of information sheets, consent forms and
4
5 313 satisfaction questionnaires. The CRAG will continue to advise on the development and
6
7 314 refinement topic guides, methods for engaging local parents as well as playing a key role in
8
9 315 the interpretation and dissemination of findings.
10

316

317 ***Ethics and Dissemination***

15 318 The protocol for the BiBBS cohort including consent to contact for other studies has been
16
17 319 approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research
18
19 320 governance approval has been provided from Bradford Teaching Hospitals NHS
20
21 321 Foundation Trust. The Health Research Authority has confirmed that our implementation
22
23 322 evaluations constitute service evaluations rather than research and as such, do not
24
25 323 require review by an NHS or other Research Ethics Committee (HRA decision 60/88/81).
26
27 324 We uphold ethical principles, Good Clinical Practice and Research Governance including
28
29 325 the provision of participant information sheets, informed consent, data protection and
30
31 326 confidentiality.
32
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36 328 Findings will be disseminated widely to aid commissioning decisions and ensure shared
37
38 329 learning with local partners. Findings will also be shared at local and national conferences,
39
40 330 relevant public health events and via publication in academic journals. Finally summaries of
41
42 331 key findings will be shared with participants and the local community via our CRAG,
43
44 332 newsletters, and on the Born in Bradford website[25].
45
46

333

334 **Discussion**

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49 335 In this paper, we have outlined our framework for implementation evaluation across multiple,
50
51 336 complex early years interventions. This framework has so far proved invaluable to ensure
52
53 337 consistent and manageable data collection across all interventions as well as identifying and
54
55 338 resolving issues in the quality of routinely collected data. Through the cyclical transfer of
56
57 339 knowledge, findings from our implementation evaluations may also help delivery teams
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59
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3 340 respond to any challenges identified and further optimise the delivery and reach of their
4
5 341 interventions.
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7 342
8
9 343 Understanding the key components of interventions and local context are integral to
10
11 344 ensuring the successful implementation of public health interventions. However, setting up
12
13 345 evaluations for interventions being delivered as part of usual practice is challenging,
14
15 346 particularly where adaptations are required to ensure interventions can be integrated into the
16
17 347 complex systems they are being delivered in. Through partner working with a wide range of
18
19 348 stakeholders including service providers, commissioners and community representatives,
20
21 349 our evaluation approach will also consider the role of contextual factors, delivery procedures,
22
23 350 acceptability and scalability of the interventions. We have shared our learning on the
24
25 351 practicalities of translating research into practice, the challenges encountered and the
26
27 352 strategies adopted to address them elsewhere[26].
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29

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32 354 Our implementation evaluation framework and associated tools[15] are designed to be
33
34 355 sustainable beyond our involvement as external service evaluators to allow commissioners
35
36 356 and intervention teams to continue monitoring and evaluating the implementation of their
37
38 357 services. Whilst in-depth qualitative evaluation may still require input from researchers, the
39
40 358 rest of this framework can be applied by service providers and commissioners to embed
41
42 359 pragmatic evaluation within the delivery of services whilst taking positive steps towards
43
44 360 building a robust evidence base for early years interventions.
45
46

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48 362

49 363 **List of Abbreviations**

50 364

51 365 BiB - Born in Bradford

52 366 BiBBS – Born in Bradford's Better Start

53 367 BMI- Body Mass Index

1
2
3 368 CRAG - Community Research Advisory Group
4

5 369 HRA – Health Research Authority
6

7 370 MRC – Medical Research Council
8

9 371 NHS – National Health Service
10

11 372 TA – Thematic Analysis
12

13 373 TDF – Theoretical Domains Framework
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16 374

17
18 375 **Declarations**

19
20 376 ***Ethics approval and consent to participate***

21
22 377 The protocol for the BiBBS cohort including consent to contact for other studies has been

23
24 378 approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research

25
26 379 governance approval has been provided from Bradford Teaching Hospitals NHS Foundation

27
28 380 Trust. The Health Research Authority has confirmed that our implementation evaluations do

29
30 381 not require review by an NHS Research Ethics Committee (HRA decision 60/88/81).

31
32 382 However, we will adhere to all ethical principles in the conduct of our evaluations and written

33
34 383 informed consent will be obtained from all participants prior to qualitative interviews and/or

35
36 384 focus groups.
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39 385

40
41 386 ***Consent to publish***

42
43 387 Not applicable.
44

45 388

46
47 389 ***Availability of data and materials***

48
49 390 Data sharing is not applicable to this article. However, please note that data collected

50
51 391 throughout the course of the study will be available to external researchers and proposals for

52
53 392 collaboration will be welcomed. Information on how to access the data can be found

54
55 393 at: www.borninbradford.nhs.uk.
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57

58 394

59
60 395 ***Competing interests***

1
2
3 396 The authors declare that they have no competing interests.
4

5 397

6
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8
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10
11 400 part of the A Better Start programme. The Big Lottery Fund have not had any involvement in
12
13 401 the design or writing of the study protocol.
14

15 402

16
17
18 403 **Author contributions**

19
20 404 ND, JD, KW, AD, SA, DN, RRCM, NU contributed to the design of the study, were involved
21
22 405 in drafting this manuscript, approving the final version of this manuscript, and agree to be
23
24 406 accountable for this work.
25

26 407

27
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29
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31
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33
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35
36 412 evaluation study.
37
38

39 413

40
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8 490 **Figure/Table Titles/Legends**
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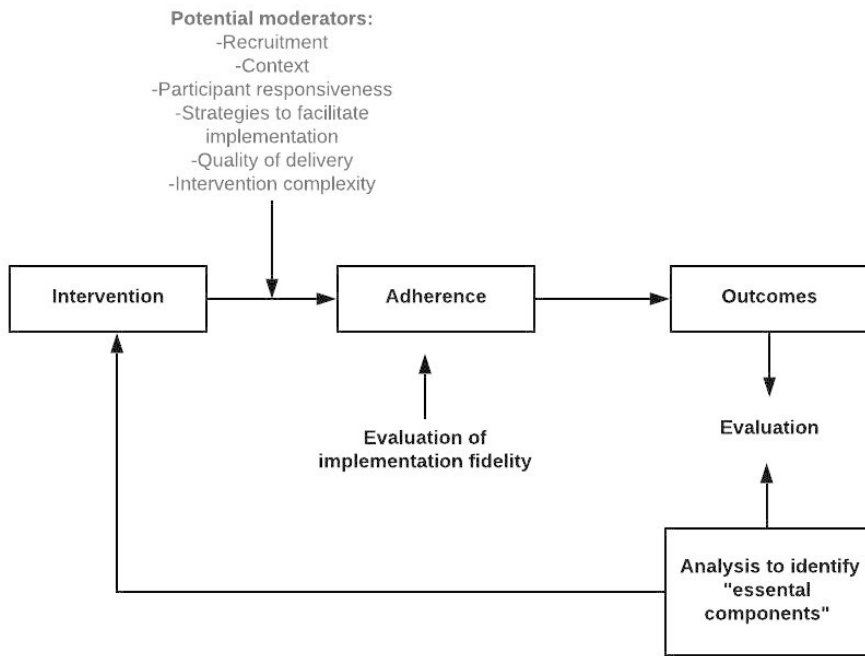
10 491 Figure 1: Modified conceptual framework for implementation fidelity Carroll et al 2007,
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16 494 Additional file 1: Satisfaction Questionnaire.pdf
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145x107mm (160 x 160 DPI)








Office ID:

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






1
2
3 4. It was easy for me to get onto the [NAME OF PROJECT]
4
5

 Strongly disagree	 Disagree	 Neither agree nor disagree	 Agree	 Strongly agree

12
13
14
15
16 5. I would recommend the [NAME OF PROJECT] to my friends and family
17
18

 Strongly disagree	 Disagree	 Neither agree nor disagree	 Agree	 Strongly agree

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28
29 6. Overall, I am happy with the [NAME OF PROJECT]?
30
31

 Strongly disagree	 Disagree	 Neither agree nor disagree	 Agree	 Strongly agree

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39
40 Thank you for completing this questionnaire. Please place your questionnaire in the
41 envelope provided. If you have any further comments about [NAME OF PROJECT] please
42 write them in the box below.
43
44