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Assessing the medium-term impact of a home-visiting programme on child maltreatment through routine data linkage to a trial cohort: The protocol for the Building Blocks 2-6 study.



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3 1 Assessing the medium-term impact of a home-visiting programme on child
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7 3 Building Blocks 2-6 study.
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2
3 **23 ABSTRACT**
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5 **24 Introduction:** Child maltreatment involves acts of omission (neglect) or commission (abuse)
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8 often by caregivers that results in potential or actual harm to a child. The Building Blocks
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trial [ISRCTN 23019866] assessed the short-term impact of an intensive programme of antenatal and postnatal visiting by specially trained nurses to support young pregnant women in England. The Building Blocks: 2-6 study will assess the medium-term impacts of the programme for mothers and children (n=1562), through the linkage of routinely collected data to the trial data, with a particular emphasis on the programme's impact upon preventing child maltreatment.

32 Methods and analysis: We have developed bespoke model of data linkage whereby
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outcome data for the trial cohort will be retrieved by linked anonymous data abstraction from NHS Digital, Office for National Statistics and the Department for Education's National Pupil Database. Participants will be given reasonable opportunity to opt-out of this study prior to data transfer. The information centres will match participants to the information held in their databases using standard identifiers, and send extracts to a third party safe haven. The study will have 80% power to detect a 4% difference (4% vs 8%) for the binary primary outcome of Child in Need status (from birth to key stage one) at a two-sided 5% alpha level by following up 602 children in each trial arm. Analysis will be by intention to treat using logistic multilevel modelling. A cost and consequences analysis will extend the time-frame of the economic analysis from the original trial.

43 Ethics and Dissemination: The study protocol has been approved by NHS Wales
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Research Ethics Committee and the Health Research Authority's Confidentiality Advisory Group. Methods of innovative study design and findings will be disseminated through peer-review journals and conferences, results will be of interest to clinical and policy stakeholders in the UK.

48

49 **Strengths and limitations of this study**

- 50 • This study aims to provide much needed evidence about the medium-term benefits of
51 the Family Nurse Partnership programme in England. This study has the capacity to
52 either confirm the current perspective on the value of the intervention or demonstrate
53 clinically meaningful benefits to children in vulnerable young families.
- 54 • There are distinct benefits associated with using routine data including a reduction in
55 cost and participant burden over prospectively collected data, and relative
56 completeness and therefore minimisation of bias over self-report, particularly for such
57 sensitive outcomes.
- 58 • The establishment of a regulatory secure research database for this cohort of trial
59 participants also offers the prospect of further data being added over the longer term
60 and of broadening the scope of the dataset to other outcome domains relevant to this
61 intervention, such as criminal justice and welfare benefits.
- 62 • The extent of this benefit will be balanced by our ability to adequately access the
63 data from information centres in a timely fashion, the quality of matching conducted
64 as well as the quality of the data ultimately retrieved.

65 **INTRODUCTION**

66 **Maltreatment**

67 Child maltreatment involves acts of omission (neglect) or commission (abuse) often by
68 caregivers that inflict harm, or fail to act to prevent harm to a child.[1] Abuse may be
69 physical, emotional or sexual. Neglect represents persistent failure to meet basic physical or
70 psychological needs, often resulting in serious impairment of the child's health and/or
71 development.[1] Neglect may involve failing to: protect a child from physical and emotional
72 harm or danger; provide adequate supervision; or ensure access to appropriate medical
73 care. In the year ending 31st March 2015 in England there were 635,600 referrals to
74 children's social care services, 403,400 children starting an episode of need (an overall rate

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75 of 348.0 per 10,000) and 62,200 children became subject of a child protection plan.[2] Of
76 children who became subject of a child protection plan, the most common initial category of
77 abuse was neglect (43.2%) followed by emotional abuse (33.7%).

78 **Family Nurse Partnership home-visiting programme**

79 There has been increasing emphasis upon the primary prevention of child maltreatment,
80 including interventions directed at general populations and those targeting high-risk
81 groups.[3] One such intervention is the Family Nurse Partnership (FNP) programme
82 (developed in the US as the Nurse Family Partnership or NFP) – a home-visiting approach
83 with three overarching goals: to improve birth outcomes, optimise child health and
84 development - including reducing maltreatment - and promote economic self-sufficiency of
85 mothers.[4]

86 In three US trials (in Elmira, Memphis and Denver),[5-7] the NFP has demonstrated
87 improvements in prenatal health behaviours and birth outcomes, sensitive child care,
88 maternal life course (e.g. greater workforce participation) and child and adolescent
89 functioning. It has also shown positive effects in relation to reductions in rates of child
90 injuries, abuse and neglect. In the first US trial in 1977, a sub-group analysis of poor
91 unmarried teens (54 families) revealed that by age 2 there was verified abuse / neglect in
92 19% of control children compared to 4% in the group in receipt of NFP in both pregnancy
93 and infancy (treatment difference of 0.15, 95% confidence interval of -0.01 to 0.31) and 56%
94 relative reduction in emergency department encounters for injuries and ingestions during the
95 second year of life.[5] Amongst the sub-group of children (56 families) with a state-verified
96 report of maltreatment by age 4, the NFP group of children exhibited fewer risks for harm
97 than the control group (e.g. fewer attendances with injuries / ingestions, safer home
98 environment) at follow-up points between 25 and 50 months of life.[8] This was considered
99 to be due to the earlier and more comprehensive detection of maltreatment by nurse-visited
100 families.

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2
3 101 The NFP programme was adapted for implementation as the Family Nurse Partnership and
4
5 102 was introduced in England in 2007. Our Building Blocks trial (ISRCTN23019866) was the
6
7 103 first trial of FNP in England and evaluated short-term outcomes to age 2 – the duration of the
8
9 104 FNP programme.[9] The trial reported no difference for four primary outcomes: biomarker-
10
11 105 calibrated self-reported tobacco use by the mother at late pregnancy, birth weight of the
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13 106 baby, the proportion of women with a second pregnancy within 24 months post-partum, and
14
15 107 emergency attendances and hospital admissions for the child within 24 months post-
16
17 108 partum.[10] We observed some differences for secondary child development outcomes
18
19 109 including the rate of safeguarding events reported in primary care records. While the current
20
21 110 evidence does not support continuation of the programme in England, previous evaluations
22
23 111 have demonstrated benefit over the longer-term (e.g. up to 15 years of age).[11] For
24
25 112 maltreatment outcomes this benefit has been increasingly evident after age 4 years,[12]
26
27 113 therefore, the current study will establish whether FNP has moderated maltreatment
28
29 114 outcomes over a medium-term period of follow-up (i.e. to the point where the child is aged
30
31 115 six years old).

35 116 **METHODS AND ANALYSIS**

38 117 **Research objective**

40 118 The Building Blocks: 2-6 Study will use data linkage of routinely collected national datasets
41
42 119 to assess the medium-term impact of the FNP intervention upon child maltreatment
43
44 120 outcomes and key indicators of neglect.

47 121 **Study design**

50 122 This is a data linkage study, which will generate a linked anonymised database hosted by an
51
52 123 independent Trusted Third Party (TTP). Participant mothers and children from Building
53
54 124 Blocks: 0-2 (BB:0-2) will be followed up for a further four years using routine data only. Data
55
56 125 from various routine public sector sources will be retrieved and linked to the trial data to
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3 126 enable children and mothers to be followed until the child reaches key stage one (the two
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5 127 years of schooling when pupils are aged between 5 and 7). A summary of the data sources
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7 128 is provided in Table 1 and the time points for each dataset are shown in Figure 1. Study
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9 129 outcomes are summarised in Table 2.

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For peer review only

131 Table 1. Summary of data sources

BB: 0-2	BB: 2-6	Provided by	Dataset	Time period*	Eligibility / Coverage	Mother	Child	Indicative / key data items
✓		Trial participants maternal self-report	Baseline	2009-2013	Trial participants	Yes	No	Socioeconomic; Maternal health & well-being; Health behaviour; pregnancy complications, Neonatal outcomes; Feeding & development.
✓	Late Pregnancy							
✓	6 month		Post-birth					
✓	12 month							
✓	18 month							
✓		24 month						
✓		Maternity records	Maternal outcomes	2009-2010	UK	Yes	Yes	Maternal health & well-being; Neonatal outcomes
✓		GP records	GP consultations	2009-2013	UK	Yes	Yes	Immunisations; safeguarding
✓		PCTs	Immunisation	2009-2013	England	No	Yes	Immunisations
✓	✓	DoH	Abortions	2009-2013	England and Wales All abortions performed in the NHS or an approved independent sector	Yes	No	Abortions
✓	✓	ONS	Mortality records	2009 - 2017	UK	Yes	Yes	Mortality data
✓	✓	NHS Digital / HES	Inpatient;	2009 - 2017	Any NHS hospital in England	Yes	Yes	Injuries and ingestions; subsequent pregnancies;
✓	Outpatient;							
✓	A&E							
	✓	Dept. for Education / NPD	CIN;	2009 - 2017	< 18 years Registered with social services in England	Yes	Yes	Child in need status and child looked after status
	✓		CLA					
	✓		EYFSP	2013-2017	Public Schools in England	No	Yes	Indicators of maltreatment; educational development and attainment; eligible for free school meals;
	✓		Census					
	✓		Alt Provision					
	✓		PRU					
	✓		Key stage One	2016-2017		No	Yes	

132 *Trial started 2009; 2 year follow up ended 2013; 6 year follow up ends in 2017. PCTs – Primary Care Trusts ONS- Office for National
 133 Statistics; HES-Hospital Episode statistics; NPD-national pupil database; CIN-child in need; CLA-child looked after; PRU-pupil referral unit;
 134 EYFSP-Early Years Foundation Stage Profile DoH – Department of Health

135 Table 2. Study Outcomes

Domains	Outcomes	HES	ONS	NPD
<i>Primary:</i> Child in Need status recorded at any time during the follow-up period.	CIN status as of 31 March each year			✓
<i>Secondary:</i>				
(i) Objective measures of maltreatment	Child Protection registration			✓
	Details of a child protection plan			✓
	CIN categorisation			✓
	CIN duration			✓
	Looked after status			✓
	CLA period of care			✓
	Legal status of CLA			✓
	Cause of death		✓	
(ii) Associated measures of maltreatment	DNA appointments	✓		
	Injuries and ingestions	✓		
(iii) Intermediate FNP programme outcomes	Subsequent pregnancies	✓		
(iv) Costs	Health and Social Care resource use	✓		✓
(v) Child health, developmental and educational outcomes	Special Educational Needs			✓
	Disability	✓		✓
	Day care attendance			✓
	Early Years assessment			✓
	School attendance			✓
	Key stage one attainment			✓

136 CIN – Child in Need; CLA – Child Looked After; DNA – Did not attend; FNP – Family Nurse
 137 Partnership; HES – Hospital Episode Statistics; NPD – National Pupil Database; ONS –
 138 Office for National Statistics

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140 **Data providers and datasets**

141 The BB:0-2 Trial Data

142 Data collected for the initial trial will be used in the present study.[9-10] A baseline home
 143 assessment was conducted upon trial entry using Computer-Assisted Personal Interview
 144 (CAPI). Follow-up was by computer-assisted telephone interview (CATI) at 34-36 weeks
 145 gestation and 6, 12 and 18 months postnatal. A final home-based CAPI was conducted at 2
 146 years after birth. Several routinely collected datasets were accessed and data obtained from
 147 the following sources: maternity records (medical and obstetric history items, antenatal

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3 148 attendances and maternal and neonatal outcomes), primary care notes for each mother and
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5 149 child dyad (consultations, immunisations, pregnancies, safeguarding), abortions data from
6
7 150 the Department of Health Abortions Statistics Team, and immunisation data via COVER
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9 151 (Cover of Vaccination Evaluated Rapidly) contacts.

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12 152 NHS Digital

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14 153 The Hospital Episode Statistics (HES) datasets hold records on over 125 million hospital
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16 154 admissions, outpatient and accident and emergency episodes each year. Data can be
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18 155 requested from NHS Digital (formerly known as the Health and Social Care Information
19
20 156 Centre), the executive non-departmental public body established under the Health and
21
22 157 Social Care Act 2012.[13] All available records belonging to cohort members (mothers and
23
24 158 children) will be obtained from study entry of the mother, which occurred between June 2009
25
26 159 and July 2010 until the date the child turns six. The data requested include diagnoses,
27
28 160 procedures, length of episode and external causes of injuries coded according to the 10th
29
30 161 revision of the International Statistical Classification of Diseases and Related Health
31
32 162 Problems [ICD-10] codes.[14]

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35 163 NHS Digital has responsibility for collecting these data from across the health and social
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37 164 care system to allow NHS hospitals to be paid for the care they deliver. At the end of the
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39 165 financial year (March) a final dataset is collated. This dataset is cleaned and validated
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41 166 before being available for research at the end of the year (December).

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44 167 Office for National Statistics (ONS)

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47 168 The Office for National Statistics (ONS) collects information on cause of death from civil
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49 169 registration records. Mortality data can be accessed through NHS Digital. For registered
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51 170 deaths, the underlying cause of death is derived from the sequence of conditions leading
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53 171 directly to the death and is recorded on the death certificate. Deaths are subsequently coded
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55 172 in line with the ICD-10.

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3 173 Department for Education (DfE)
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5 174 The Department for Education (DfE) holds information on pupils throughout the different
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7 175 phases of education. Records are sourced from publicly funded schools, local authorities
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9 176 and awarding bodies and held in the National Pupil Database (NPD). Datasets are available
10
11 177 on various aspects of education such as school census data, absence data, and school
12
13 178 attainment.[15] All available records for the children in the cohort will be obtained from the
14
15 179 various datasets held. The data requested includes the number of hours attended, early
16
17 180 educational development, eligibility for free school meals, and special educational needs
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19 181 (SEN) provision type. Datasets are collated throughout the year and are available at set
20
21 182 time points annually.
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24 183 Social Care Data
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27 184 Social care data from local authorities is available through the NPD via two datasets, Child in
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29 185 Need (CIN) and Child Looked After (CLA). The CIN census captures individual level
30
31 186 information on children referred to and assessed by children's social care services within
32
33 187 each 12month period.[16] CLA is collected in the SSDA903 return – an annual statutory
34
35 188 data collection for all local authorities.[17] Any child in the cohort who is in one of these
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37 189 datasets will be identified. Mothers who were <18 years at the time of participation in the
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39 190 BB:0-2 trial will also be identified in these datasets.
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42 191 **Study participants: Inclusion and exclusion criteria**
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45 192 Eligible participants are those mothers and children exiting the BB:0-2 trial. Women were
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47 193 recruited as nulliparous women aged 19 or under, living in one of 18 local authority FNP
48
49 194 catchment areas; recruited by 24⁺⁶ weeks gestation, have conversational level of English
50
51 195 and were able to consent to research.[10]
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53 196 Children in medium-term foster placements or adopted within the six year study period can
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55 197 be linked up to the date of adoption. Maternal or child death will be captured as an outcome.
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3 198 **Recruitment / Dissent**
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5 199 Participants previously consented to enter into the BB:0-2 trial and provide self-report and
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7 200 access to their routine records for the period up to two years postpartum. In order to obtain
8
9 201 an unbiased estimate of the medium-term effect of FNP on objective and associated
10
11 202 maltreatment outcomes we have received section 251 (s251) support of the 2006 NHS Act
12
13 203 approval from the Health Research Authority's Confidentiality Advisory Group (HRA CAG) to
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15 204 pass identifiable participant data legally held by Cardiff University to the information centres
16
17 205 (IC) to link to routine data. This is without obtaining further consent from participants,
18
19 206 instead using an opt-out/dissent model.
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21
22 207 Justification of approach
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25 208 Consent for longer-term follow-up (i.e. beyond 24 months postpartum) was originally
26
27 209 proposed in the BB:0-2 trial. However, upon ethical review it was considered that greater
28
29 210 specificity about exact outcomes than could be provided at recruitment was required.
30
31 211 Additionally, providing meaningful consent for much longer follow-up was also challenging,
32
33 212 particularly on behalf of yet to be born children.
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35 213 Developing the opt-out approach was necessary due to (i) the child protection focus of the
36
37 214 study and the consequent sensitivity and impracticality in asking directly for consent, (ii) the
38
39 215 mobility and relative difficulty in ongoing direct access to these participants (iii) the
40
41 216 consequent introduction of non-ascertainment bias on sample representativeness – resulting
42
43 217 in a non-random sample, and (iv) the likely cost and logistical requirements of securing even
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45 218 modest levels of additional consent.
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48 219 Methods of notifying participants
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51 220 We discussed the issue of dissent and fair processing with the HRA CAG and have
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53 221 subsequently attempted to contact all mothers recruited to the original BB:0-2 trial to inform
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55 222 them that medium-term follow-up using anonymised records will be undertaken.
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3 223 Details of participants' residential addresses were updated using their most recent address
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5 224 registered with their GP. Where available, mobile number and email addresses collected
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7 225 for the trial were used to send SMS and emails to participants. All three modes of contact
8
9 226 were used over a two-day period and participants were provided with a two-month window in
10
11 227 which to contact the project team to discuss the project and opt-out if they wished. A
12
13 228 website was also available with the same information which directed participants to contact
14
15 229 the project team if they wished.

16 17 18 230 *Development of opt-out letter*

19
20 231 A group of care-experienced young people (CASCADE Voices)[18] advised on the layout,
21
22 232 wording and tone of a letter to be sent to all participants. A key consideration was to
23
24 233 communicate the focus of this follow-on study in a sensitive manner. The final letter was
25
26 234 approved by both an NHS Research Ethics Committee and CAG committee as part of
27
28 235 overall governance approval for the study. The letter contained both information on the trial,
29
30 236 the follow-on study and a flowchart for what to do if women wished to discuss the project
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32 237 and/or opt out.

33 34 35 238 *Process to manage dissent*

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37 239 Women notifying the study team of their dissent will be recorded as "opted out", removed
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39 240 from all project datasets for this follow-up work and identifiable datasets to be sent to ICs.
40
41 241 They will not be included in any of the datasets or analyses for this follow-on study.

42 43 44 242 **Governance and compliance**

45
46 243 Following Ethical approval (14/WA10062) and s251 support (CAG 10-08(b)/2014), data
47
48 244 request applications were submitted to DfE, NHS Digital and ONS.

49
50
51 245 In order to satisfy the requirements of the s251 support and NHS Digital contract, the
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53 246 Information Governance (IG) Toolkit self-assessment[19] (commissioned by the Department
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55 247 for Health for NHS Digital to develop and maintain) was required. This organisation-level
56
57 248 assessment provides reassurance of satisfactory information governance within the host
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3 249 trials unit. Both the s251 support and IG Toolkit are assessed and renewed on an annual
4
5 250 basis. The opt-out model was also required to satisfy s251 support as well as the DfE
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7 251 assessment of compliance with principle one of the Data Protection Act 1998. Governance
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9 252 and IC requirements prior to application approval are shown in Figure 2.

11 253 **Data matching**

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13
14 254 Maternal and child identifiers will be sent to both NHS Digital and DfE for matching with their
15
16 255 databases. Each IC holds differing identifiers including a unique identifier for each individual
17
18 256 (NHS Number; Unique Pupil Number UPN).

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20
21 257 Matching with HES data will be by exact matching on NHS Number; Date of Birth; Postcode
22
23 258 and Gender. This was conducted for BB:0-2 and achieved a high match rate where 99.6%
24
25 259 of mothers and babies' records were matched fully (i.e. matched on all identifiers provided)
26
27 260 or partially (i.e. matched on a reduced, but acceptable number of identifiers provided). This
28
29 261 will be repeated for this study. NHS Digital will then exact match with ONS using NHS
30
31 262 number in order to obtain mortality data.

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34 263 As the NPD does not include NHS numbers, initially exact matching on first name and
35
36 264 surname, date of birth and postcode (of both mother and child for social care data; all other
37
38 265 datasets just child) will be undertaken. Further matching required will be by fuzzy matching
39
40 266 of first name. The CIN and CLA datasets do not contain names or postcodes therefore the
41
42 267 matching will be in two phases: i) Participants will be matched with the NPD, the UPN added
43
44 268 to all participants and ii) this will be used to identify individuals in the CIN and CLA datasets.

45
46 269 Data matching at DfE and NHS Digital/ONS are independent therefore match rates at the
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48 270 participant level are expected to vary (some may match to NPD but not HES). Educational
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50 271 records should be available for all children in the trial cohort whereas health and social care
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52 272 derived data will only exist where the child has received a relevant episode of care.
53
54 273 Participants will be compared using trial baseline data to check for any bias between those
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3 274 who are matched and not-matched for those datasets where they would all be expected to
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5 275 be present (e.g. school census for all children).
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8 276 The Pseudonymised Dataset

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10 277 A unique study ID will be attached to each participant's record prior to data transfer to ICs.

11
12 278 Once ICs have matched records to their database, only the unique study ID is retained.

13
14 279 Data extracts from both ICs plus data files from the trial (following a process of de-

15
16 280 identification and standardisation in Cardiff to reduce risk of later unintentional participant

17
18 281 level identification) will all be securely transferred to a data safe haven,[20] the Secure

19
20 282 Anonymised Information Linkage (SAIL) databank, for linking and storage. The data flow is

21
22 283 shown in Figure 3.
23

24
25 284 A SAIL data analyst will re-assign the study ID with a new anonymous linking field [ALF] and

26
27 285 store the corresponding ID in a separate encrypted password protected file.[21]
28

29
30 286 Participants will not be identifiable to the study team, or to the SAIL analyst, but incoming

31
32 287 datasets can be linked at the individual level using the ALF. The study team will have

33
34 288 controlled remote access to these data thus ensuring the security of the pseudonymised

35
36 289 database.[22] All data cleaning and analysis will be carried out via the remote portal by the

37
38 290 study data manager and statistician.
39

40
41 291 Data from NHS Digital and NPD will be requested at two time points. The first data extract

42
43 292 will confirm the data flow model, assess data quality and the suitability of data for answering

44
45 293 key study analyses. The second data request will be made once all children in the study

46
47 294 have reached key stage one (April 2017) and on which the study findings will be reported on

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49 295 (in 2018).
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3 297 Control of data
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5 298 Cardiff University control under contract the identifiable trial data that are being transferred to
6
7 299 the ICs and to the safe haven. Data held by NHS Digital, ONS and DfE, for which they are
8
9 300 the controllers, are de-identified and then sent to SAIL to be linked and held (including the
10
11 301 de-identified trial data) in a secure anonymised standalone database for use by nominated
12
13 302 study team members. SAIL will control the safe haven environment, and will process the
14
15 303 pseudonymised data for secure use by study team. Cardiff University will control the
16
17 304 purposes to which the data are put in answering research questions as per the study
18
19 305 protocol. Once linked in the data safe haven, the ability to submit queries to each IC about
20
21 306 individual records will be more limited than if identifiable data were returned to the research
22
23 307 team in Cardiff. Data cleaning will remain possible however as will generic queries about
24
25 308 data provided in batch. The quality of matching conducted by NPD and NHS Digital/ONS will
26
27 309 be a key factor in the success of the study.
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31 **Analysis**

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35 311 Power Calculation
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37 312 Primary outcome (CIN status at any point between birth and six years): For CIN status,
38
39 313 available UK data on rates are not specific to the age-range of interest, but the rate in the
40
41 314 general population aged 5-9 years is 4.6% (for local authorities comprising study sites in
42
43 315 BB:0-2). The rate would be expected to be greater in the specific study sample, and
44
45 316 therefore we have assumed a rate of 8%. To detect a difference of 4% (FNP: 4% vs Usual
46
47 317 Care: 8%) would require 602 children in each arm (1204 in total) using 80% power and a
48
49 318 two-sided 5% alpha level.
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55 320 BB:0-2 recruited 1645 women, with 1562 available for follow-up (i.e. excluding those subject
56
57 321 to a mandatory withdrawal). Follow-up through medical records (assuming 10% loss in
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3 322 tracking & linkage) would result in 1405 participants, thus securing enough data to test the
4
5 323 primary outcome and the key secondary outcome
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8 324 Main analysis
9

10 325 Analyses will be conducted on an intention-to-treat basis and due emphasis placed on
11
12 326 confidence intervals for the between-arm comparisons. Descriptive statistics of demographic
13
14 327 and baseline measures will be used to ascertain any marked imbalance between the trial
15
16 328 arms. The primary comparative analysis on CIN status at any point between birth and six
17
18 329 years will use logistic multilevel modelling to investigate differences between the groups,
19
20 330 and odds ratios alongside 95% confidence intervals (CIs) will be reported. Multilevel
21
22 331 modelling will allow for clustering of effect within a site and family nurse. Modelling the
23
24 332 impact of key subgroups and different intervention elements (e.g. gestational age at
25
26 333 programme entry, dosage) on outcome will be undertaken by extending the primary models
27
28 334 and testing for interaction effects. The role of potential moderators of programme effect (e.g.
29
30 335 domestic violence) will also be explored.
31
32

33
34 336 Although the study will be powered to examine a 4% difference in CIN status, secondary
35
36 337 analyses will assess group differences in referral rates to CSC, maltreatment profile, and
37
38 338 child protection outcomes. Levels of concern will be examined by looking at extent of action
39
40 339 taken. A state transition model using Markov chains will be used to assess the probabilities
41
42 340 of moving from one stage marker (states) to another.[23] The transition probabilities (the
43
44 341 probability of the various state-changes) in our model will be derived from our data and
45
46 342 compared between groups.
47

48
49 343 Bias in the followed-up BB:2-6 sample will be quantified by examining group differences
50
51 344 (participants and non-participants) in baseline variables such as age, deprivation, gestational
52
53 345 age, and education. Surveillance bias in detection of maltreatment during the child's infancy
54
55 346 and toddlerhood can be assessed by examining subsequent reporting.[24] The duration
56
57 347 between birth and the date of first referral to CSC will be calculated and group differences
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3 348 examined using Cox regression analysis to calculate hazard ratios for referral, together with
4
5 349 95% CIs. Surveillance bias is most likely to occur during the intervention phase, although
6
7 350 improved handover to other services at 2 years may lead to higher identification in the
8
9 351 following year. Severity of the referral will also be compared between the two groups (an
10
11 352 approach used in US trials of NFP to explore surveillance bias).

13 353 Health economics

14
15 354 The economic evaluation will consider costs and consequences of the FNP over the full
16
17 355 follow-up period (BB:0-2 & BB:2-6). The current BB:0-2 study reported 1) a within trial cost
18
19 356 utility analysis assessing NHS costs against quality adjusted life years (QALY) from the
20
21 357 perspective of the mother, and 2) a within trial cost consequences analysis relating all costs
22
23 358 (including those to the social care, education and criminal justice sectors as well as health)
24
25 359 against the full range of effects.[10] Cost and consequences framework is deemed the most
26
27 360 appropriate economic evaluation framework for public health interventions[26] and preferred
28
29 361 by NICE[27] because it enables to capture equity consideration as well as intersectoral costs
30
31 362 and consequences[28] yet applications are still limited.[26]

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33
34 363 The absence of additional data on Health Related Quality of Life within the BB2 study means
35
36 364 that it will not be possible to estimate QALYs beyond 24 months postpartum and hence
37
38 365 extend the within trial cost utility analysis. However, the within trial cost consequences
39
40 366 analysis will be extended from 0-2 to 0-6 years through collection of resource use data from
41
42 367 medical and education records (including from the latter, data related to social care usage).
43
44 368 These will be summarised against the range of outcomes collected within BB2 without
45
46 369 aggregation to allow weighing up changes in the various outcomes reported in BB2 against
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48 370 the changes in costs in a consistent and transparent manner.[29] This will contribute to
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50 371 providing more robust and valid medium-term estimates within the extended period.

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54 373 **ETHICS AND DISSEMINATION**

55 374 **Legal & Ethical considerations**

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3 375 The potential for using routine data in health and social care research has been greatly
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5 376 publicised and study designs utilising these data are encouraged by funders.[30] There are,
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7 377 however, many inherent challenges in working with secondary-use data, in particular for this
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9 378 project the ethical and legal requirements/responsibilities which have fundamentally
10
11 379 informed this study design.

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13 380 Although BB:0-2 linked trial data to HES and ONS data via NHS Digital, the governance
14
15 381 requirements around the two applications have differed between the two studies not least
16
17 382 because of the difference in consent models. Trial data were provided by NHS Digital and
18
19 383 ONS after participant consent to prospective collection and for specified purposes limited to
20
21 384 the time-frame of that study. The current follow-on study uses a dissent model under which
22
23 385 we are only able to send trial participant identifiers to ICs for matching to outcome data
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25 386 records if there is no objection received from mothers. The study will require all clinical,
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27 387 social and educational data to be held in a data safe haven using encrypted record
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29 388 identifiers and analysis via a securely managed and monitored remote portal. The legal
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31 389 bases for transfer of identifiable data to ICs without explicit consent are as follows; s251 of
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33 390 the 2006 NHS Act 2006 for HES data from NHS Digital, s42(4) of the Statistics and
34
35 391 Registration Service Act 2007 through NIHR funding for ONS data via NHS Digital, and 6(1)
36
37 392 of Schedule 2 of the 1998 Data Protection Act for NPD data.

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40 393 *Dissemination of findings* The Building Blocks: 2-6 Study will generate policy-relevant
41
42 394 findings describing the medium-term impact of FNP on measurements of child maltreatment.
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44 395 The findings will also include other policy relevant outcomes from the programme such as
45
46 396 health care use, education attainment and changes in social care use over the 6 years of
47
48 397 follow up. Such medium-term evaluation remains important as some outcomes for the
49
50 398 intervention are expected to arise only after the child's second birthday, including
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52 399 maltreatment. This study will either confirm the largely negative trial findings from BB:0-2
53
54 400 further weakening the justification for FNP Programme continuation or provide a balance to
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56 401 the early measurable outcomes.

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3 402 In addition to reporting the findings to the funder for this study, the funder for the BB:0-2 trial
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5 403 (DH Policy Research Programme) will also be informed and the FNP National Unit (FNPNU).
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7 404 All local authorities in England will be notified of the results, as (since October 2015) they
8
9 405 have responsibility for commissioning public health services for children aged 0-5.
10
11 406 Participants will receive a summary of the results and all reports and publications will be
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13 407 made publicly available in full on the Cardiff University website. The research team have
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15 408 previously convened and met twice with a stakeholder group, including relevant policy leads
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17 409 from each country in the UK delivering FNP (England, Scotland, Northern Ireland). We will
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19 410 stage a similar event to present and discuss the implications for practice and policy of the
20
21 411 results of this medium-term follow up of participants.
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24 412 In addition to policy and public outputs, academic outputs will include (i) this protocol paper
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26 413 providing visibility of this medium-term follow up, (ii) a methods paper describing the piloting
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28 414 process of the study (including data quality and success of data matching) and (iii) main
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30 415 study findings. We aim to disseminate in high-quality, peer reviewed journals and present in
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32 416 key conferences.
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34 417 A particular benefit of this study is understanding of, and learning from, the governance
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36 418 challenges. There is potential to use this method for future trials looking at longer term
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38 419 follow-up. Therefore this study has the potential to add to the understanding of routine data
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40 420 and data linkage methods in future public health and clinical trials and these planned
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42 421 publications will provide a basis for the dissemination of the success of these methods.
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423 **Declarations**

424 *List of abbreviations*

ALF: anonymous linking field;
ALF-E: encrypted ALF;
BB:0-2: Building Blocks trial;
CAPI: computer-assisted personal interview;
CATI: computer-assisted telephone interview;
CIN: Child in Need;

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3	CLA: Child Looked After;
4	DfE: Department for Education;
5	DNA: Did not attend;
6	DoH: Department of Health;
7	EYFSP: Early Years Foundation Stage Profile;
8	FNP: Family Nurse Partnership;
9	FNPNU: Family Nurse Partnership National Unit;
10	HES: Hospital Episode Statistics;
11	HRA CAG: Health Research Authority's Confidentiality Advisory Group;
12	HSCIC: Health and Social Care Information Centre;
13	IC: information centres;
14	IG: Information Governance ;
15	NFP: Nurse Family Partnership;
16	NPD: National Pupil Database;
17	ONS: Office for National Statistics;
18	PCT: Primary Care Trusts;
19	PRU: pupil referral unit;
20	QALY: Quality adjusted life years;
21	s251: Section 251 of the NHS 2006 Act;
22	SAIL: Secure Anonymised Information Linkage;
23	SEN: special educational needs;
24	TTP: trusted third party;
25	UPN: Unique Pupil Number.
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426 *Ethics approval and consent to participate* - Ethics approval of the study has been given by
 427 the Research Ethics Committee for Wales (14/WA10062) and the transfer and use of
 428 identifiable data has been approved by the Health Research Authority [HRA] Confidentiality
 429 Advisory Group [CAG] (CAG 10-08(b)/2014).

430 *Consent for publication* - Not Applicable

431 *Availability of data and material* - Not Applicable

432 *Competing interests* - The authors declare that they have no competing interests

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 436 the NIHR PHR Programme or the Department of Health.

437 *Authors' contributions*

1
2
3 438 MR is the chief investigator of the study. All authors have contributed to and are responsible
4
5 439 for the final design of the study. FLW and GM are responsible for study and data
6
7 440 management. RCJ is responsible for statistical planning and for data analysis. DF is
8
9 441 responsible for the health economics. All authors read and approved the final manuscript.

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17
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21
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23
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25
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3 533 *(Title)* Figure 1. Follow up and datasets over the six years

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5 534 *(Legend)* A&E Accident and Emergency; PRU Pupil Referral Unit

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11 537 *(Title)* Figure 2. Governance and Information centre requirements prior to application

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13 538 approval.

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15 539 *(Legend)* s251 Section 251 of the NHS 2006 Act; ONS Office for National Statistics; NPD

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17 540 National Pupil Database; IG Information Governance

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21
22 542 Figure 3. Data Flow

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24 543 *(Legend)* ¹Participant identifiable information securely transferred for linkage; ²De-

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26 544 identification and Standardisation applied (e.g. date of birth to week of birth); ³Information

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28 545 centres confirm matching of participant identifiers; ⁴Hosted on SAIL secure platform. ALF-

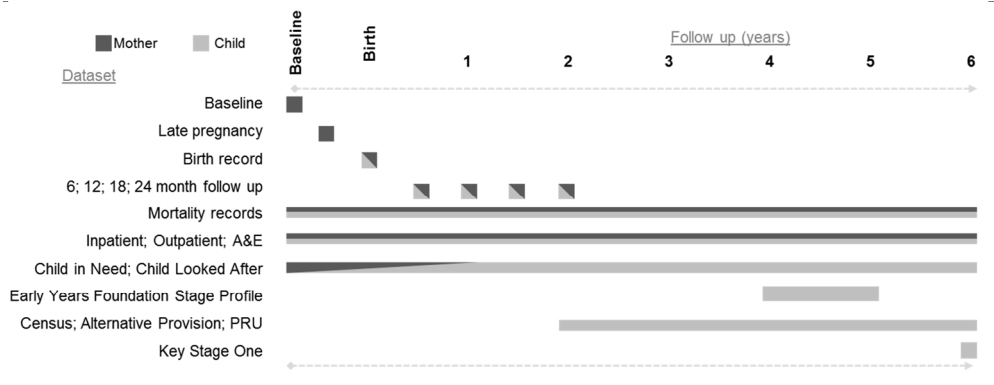
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30 546 Anonymised Linking Field; BB:0-2 – The Building Blocks trial; DfE – Department for

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32 547 Education; DPO – Data Providing Organisation; HES – Hospital Episode Statistics; ONS –

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34 548 Office for National Statistics; SAIL – Secure Anonymised Information Linkage.

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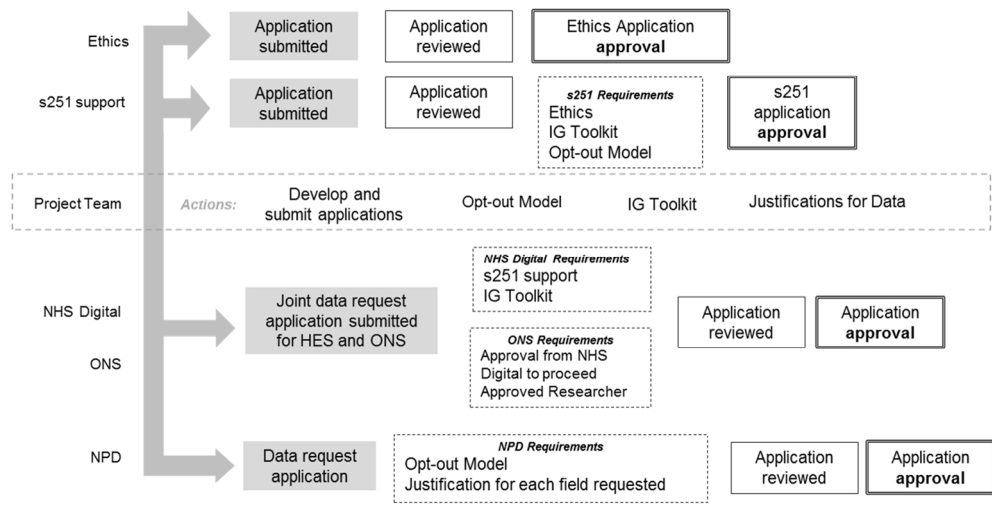


(Title) Figure 1. Follow up and datasets over the six years
(Legend) A&E Accident and Emergency; PRU Pupil Referral Unit

252x98mm (150 x 150 DPI)

Peer review only

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(Title) Figure 2. Governance and Information centre requirements prior to application approval.
 (Legend) s251 Section 251 of the NHS 2006 Act; ONS Office for National Statistics; NPD National Pupil Database; IG Information Governance

236x127mm (150 x 150 DPI)

Review only

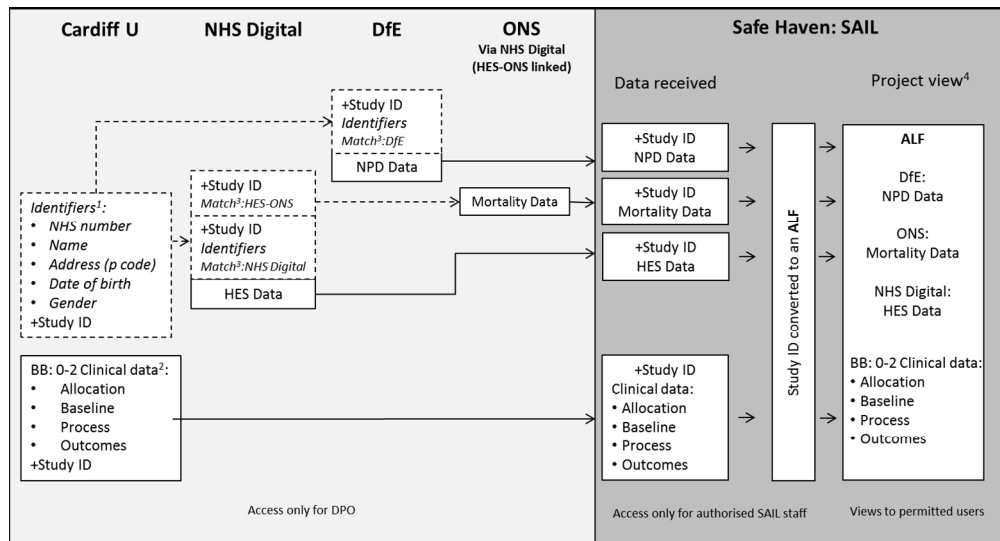


Figure 3. Data Flow

(Legend) 1Participant identifiable information securely transferred for linkage; 2De-identification and Standardisation applied (e.g. date of birth to week of birth); 3Information centres confirm matching of participant identifiers; 4Hosted on SAIL secure platform. ALF- Anonymised Linking Field; BB:0-2 – The Building Blocks trial; DfE – Department for Education; DPO – Data Providing Organisation; HES – Hospital Episode Statistics; ONS – Office for National Statistics; SAIL – Secure Anonymised Information Linkage.

266x143mm (150 x 150 DPI)

view only

BMJ Open

Assessing the medium-term impact of a home-visiting programme on child maltreatment in England: protocol for a routine data linkage study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015728.R1
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3 1 Assessing the medium-term impact of a home-visiting programme on child
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5 2 maltreatment in England: protocol for a routine data linkage study
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18

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21 Medical Record Linkage, Follow-Up Studies

1
2
3 **22 ABSTRACT**
4

5 **23 Introduction:** Child maltreatment involves acts of omission (neglect) or commission (abuse)
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often by caregivers that results in potential or actual harm to a child. The Building Blocks trial [ISRCTN 23019866] assessed the short-term impact of an intensive programme of antenatal and postnatal visiting by specially trained nurses to support young pregnant women in England. The Building Blocks: 2-6 study will assess the medium-term impacts of the programme for mothers and children (n=1562), through the linkage of routinely collected data to the trial data, with a particular emphasis on the programme's impact upon preventing child maltreatment.

31 Methods and analysis: We have developed bespoke model of data linkage whereby
32 outcome data for the trial cohort will be retrieved by linked anonymous data abstraction from
33 NHS Digital, Office for National Statistics and the Department for Education's National Pupil
34 Database. Participants will be given reasonable opportunity to opt-out of this study prior to
35 data transfer. The information centres will match participants to the information held in their
36 databases using standard identifiers, and send extracts to a third party safe haven. The
37 study will have 80% power to detect a 4% difference (4% vs 8%) for the binary primary
38 outcome of Child in Need status (from birth to key stage one) at a two-sided 5% alpha level
39 by following up 602 children in each trial arm. Analysis will be by intention to treat using
40 logistic multilevel modelling. A cost and consequences analysis will extend the time-frame of
41 the economic analysis from the original trial.

42 Ethics and Dissemination: The study protocol has been approved by NHS Wales
43 Research Ethics Committee and the Health Research Authority's Confidentiality Advisory
44 Group. Methods of innovative study design and findings will be disseminated through peer-
45 review journals and conferences, results will be of interest to clinical and policy stakeholders
46 in the UK.

47

48 **Strengths and limitations of this study**

- 49 • This study aims to provide much needed evidence about the medium-term benefits of
50 the Family Nurse Partnership programme in England. This study has the capacity to
51 either confirm the current perspective on the value of the intervention or demonstrate
52 clinically meaningful benefits to children in vulnerable young families.
- 53 • There are distinct benefits associated with using routine data including a reduction in
54 cost and participant burden over prospectively collected data, and relative
55 completeness and therefore minimisation of bias over self-report, particularly for such
56 sensitive outcomes.
- 57 • The establishment of a regulatory secure research database for this cohort of trial
58 participants also offers the prospect of further data being added over the longer term
59 and of broadening the scope of the dataset to other outcome domains relevant to this
60 intervention, such as criminal justice and welfare benefits.
- 61 • The extent of this benefit will be balanced by our ability to adequately access the
62 data from information centres in a timely fashion, the quality of matching conducted
63 as well as the quality of the data ultimately retrieved.

64 **INTRODUCTION**

65 **Maltreatment**

66 Child maltreatment involves acts of omission (neglect) or commission (abuse) often by
67 caregivers that inflict harm, or fail to act to prevent harm to a child.[1] Abuse may be
68 physical, emotional or sexual. Neglect represents persistent failure to meet basic physical or
69 psychological needs, often resulting in serious impairment of the child's health and/or
70 development.[1] Neglect may involve failing to: protect a child from physical and emotional
71 harm or danger; provide adequate supervision; or ensure access to appropriate medical
72 care. In the year ending 31st March 2015 in England there were 635,600 referrals to
73 children's social care services, 403,400 children starting an episode of need (an overall rate

1
2
3 74 of 348.0 per 10,000) and 62,200 children became subject of a child protection plan.[2] Of
4
5 75 children who became subject of a child protection plan, the most common initial category of
6
7 76 abuse was neglect (43.2%) followed by emotional abuse (33.7%).
8

9
10 77 In the UK, preventing maltreatment is an important focus of Government concern. The
11
12 78 Children Act 1989 specifies agencies' responsibilities to cooperate in the interests of
13
14 79 vulnerable children, for Children in Need (section 17) and children suffering or likely to suffer
15
16 80 from significant harm (section 47). A child in need is defined as a child who is unlikely to
17
18 81 achieve or maintain a reasonable level of health or development, or whose health and
19
20 82 development is likely to be significantly or further impaired, without the provision of services;
21
22 83 or is a child who is disabled. Local authority provisions may include supervision of activities,
23
24 84 financial help, provision of family accommodation, respite or home help in addition to advice
25
26 85 and guidance from social workers.
27

28 86 **Family Nurse Partnership home-visiting programme**

29
30
31 87 There has been increasing emphasis upon the primary prevention of child maltreatment,
32
33 88 including interventions directed at general populations and those targeting high-risk
34
35 89 groups.[3] One such intervention is the Family Nurse Partnership (FNP) programme
36
37 90 (developed in the US as the Nurse Family Partnership or NFP) – a home-visiting approach
38
39 91 with three overarching goals: to improve birth outcomes, optimise child health and
40
41 92 development - including reducing maltreatment - and promote economic self-sufficiency of
42
43 93 mothers.[4]
44

45
46 94 In three US trials (in Elmira, Memphis and Denver),[5-7] the NFP has demonstrated
47
48 95 improvements in prenatal health behaviours and birth outcomes, sensitive child care,
49
50 96 maternal life course (e.g. greater workforce participation) and child and adolescent
51
52 97 functioning. It has also shown positive effects in relation to reductions in rates of child
53
54 98 injuries, abuse and neglect. In the first US trial in 1977, a sub-group analysis of poor
55
56 99 unmarried teens (54 families) revealed that by age 2 there was verified abuse / neglect in
57
58 100 19% of control children compared to 4% in the group in receipt of NFP in both pregnancy
59
60

1
2
3 101 and infancy (treatment difference of 0.15, 95% confidence interval of -0.01 to 0.31) and 56%
4
5 102 relative reduction in emergency department encounters for injuries and ingestions during the
6
7 103 second year of life.[5] Amongst the sub-group of children (56 families) with a state-verified
8
9 104 report of maltreatment by age 4, the NFP group of children exhibited fewer risks for harm
10
11 105 than the control group (e.g. fewer attendances with injuries / ingestions, safer home
12
13 106 environment) at follow-up points between 25 and 50 months of life.[8] This was considered
14
15 107 to be due to the earlier and more comprehensive detection of maltreatment by nurse-visited
16
17 108 families.

19
20 109 The NFP programme was adapted for implementation as the Family Nurse Partnership and
21
22 110 was introduced in England in 2007. Our Building Blocks trial (ISRCTN23019866) was the
23
24 111 first trial of FNP in England and evaluated short-term outcomes to age 2 – the duration of the
25
26 112 FNP programme.[9] The trial reported no difference for four primary outcomes: biomarker-
27
28 113 calibrated self-reported tobacco use by the mother at late pregnancy, birth weight of the
29
30 114 baby, the proportion of women with a second pregnancy within 24 months post-partum, and
31
32 115 emergency attendances and hospital admissions for the child within 24 months post-
33
34 116 partum.[10] We observed some differences for secondary child development outcomes
35
36 117 including the rate of safeguarding events reported in primary care records. While the current
37
38 118 evidence does not support continuation of the programme in England, previous evaluations
39
40 119 have demonstrated benefit over the longer-term (e.g. up to 15 years of age).[11] For
41
42 120 maltreatment outcomes this benefit has been increasingly evident after age 4 years,[12]
43
44 121 therefore, the current study will establish whether FNP has moderated maltreatment
45
46 122 outcomes over a medium-term period of follow-up (i.e. to the point where the child is aged
47
48 123 six years old).

52 124 **METHODS AND ANALYSIS**

55 125 **Research objective**

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2
3 126 The Building Blocks: 2-6 Study will use data linkage of routinely collected national datasets
4
5 127 to assess the medium-term impact of the FNP intervention upon child maltreatment
6
7 128 outcomes and key indicators of neglect.
8
9

10 129 **Study design**

11
12 130 This is a data linkage study, which will generate a linked anonymised database hosted by an
13
14 131 independent Trusted Third Party (TTP). Participant mothers and children from Building
15
16 132 Blocks: 0-2 (BB:0-2) will be followed up for a further four years using routine data only. Data
17
18 133 from various routine public sector sources will be retrieved and linked to the trial data to
19
20 134 enable children and mothers to be followed until the child reaches key stage one (the two
21
22 135 years of schooling when pupils are aged between 5 and 7). The study formally started in
23
24 136 February 2014 and will report to the funder in May 2018. Participants were recruited to the
25
26 137 trial between June 2009, and July 2010 and the six year follow up ends (i.e. the last child will
27
28 138 have turned six) in March 2017. A summary of the data sources is provided in Table 1 and
29
30 139 the time period for each dataset are shown in Figure 1. Study outcomes are summarised in
31
32 140 Table 2.
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142 Table 1. Summary of data sources

BB: 0-2	BB: 2-6	Provided by	Dataset	Time period*	Eligibility / Coverage	Mother	Child	Indicative / key data items	
✓		Trial participants maternal self-report	Baseline	2009-2013	Trial participants	Yes	No	Socioeconomic; Maternal health & well-being; Health behaviour; pregnancy complications, Neonatal outcomes; Feeding & development.	
✓	Late Pregnancy								
✓	6 month		Post-birth						
✓	12 month								
✓	18 month								
✓		24 month							
✓		Maternity records	Maternal outcomes	2009-2010	UK	Yes	Yes	Maternal health & well-being; Neonatal outcomes	
✓		GP records	GP consultations	2009-2013	UK	Yes	Yes	Immunisations; safeguarding	
✓		PCTs	Immunisation	2009-2013	England	No	Yes	Immunisations	
✓	✓	DoH	Abortions	2009-2013	England and Wales All abortions performed in the NHS or an approved independent sector	Yes	No	Abortions	
✓	✓	ONS	Mortality records	2009 - 2017	UK	Yes	Yes	Mortality data	
✓	✓	NHS Digital / HES	Inpatient;	2009 - 2017	Any NHS hospital in England	Yes	Yes	Injuries and ingestions; subsequent pregnancies;	
✓	Outpatient;								
✓	A&E								
	✓	Dept. for Education / NPD	CIN;	2009 - 2017	< 18 years Registered with social services in England	Yes	Yes	Child in need status and child looked after status	
	✓		CLA						
	✓		EYFSP	2013-2017	Public Schools in England	No	Yes	Indicators of maltreatment; educational development and attainment; eligible for free school meals;	
	✓		Census						4 yrs
	✓		Alt Provision						2-19 yrs
	✓		PRU						2-19 yrs
	✓		Key stage One	2016-2017		No	Yes		

143 *Trial started 2009; 2 year follow up ended 2013; 6 year follow up ends in 2017. PCTs – Primary Care Trusts ONS- Office for National
 144 Statistics; HES-Hospital Episode statistics; NPD-national pupil database; CIN-child in need; CLA-child looked after; PRU-pupil referral unit;
 145 EYFSP-Early Years Foundation Stage Profile DoH – Department of Health

146 Table 2. Study Outcomes

Domains	Outcomes	HES	ONS	NPD
<i>Primary:</i> Child in Need status recorded at any time during the follow-up period.	CIN status as of 31 March each year			✓
<i>Secondary:</i>				
(i) Objective measures of maltreatment	Child Protection registration			✓
	Details of a child protection plan			✓
	CIN categorisation			✓
	CIN duration			✓
	Looked after status			✓
	CLA period of care			✓
	Legal status of CLA			✓
	Cause of death		✓	
(ii) Associated measures of maltreatment	DNA appointments	✓		
	Injuries and ingestions	✓		
(iii) Intermediate FNP programme outcomes	Subsequent pregnancies	✓		
(iv) Costs	Health and Social Care resource use	✓		✓
(v) Child health, developmental and educational outcomes	Special Educational Needs			✓
	Disability	✓		✓
	Day care attendance			✓
	Early Years assessment			✓
	School attendance			✓
	Key stage one attainment			✓

147 CIN – Child in Need; CLA – Child Looked After; DNA – Did not attend; FNP – Family Nurse
 148 Partnership; HES – Hospital Episode Statistics; NPD – National Pupil Database; ONS –
 149 Office for National Statistics

150

151 Data providers and datasets

152 The BB:0-2 Trial Data

153 Data collected for the initial trial will be used in the present study.[9-10] A baseline home
 154 assessment was conducted upon trial entry using Computer-Assisted Personal Interview
 155 (CAPI). Follow-up was by computer-assisted telephone interview (CATI) at 34-36 weeks
 156 gestation and 6, 12 and 18 months postnatal. A final home-based CAPI was conducted at 2
 157 years after birth. Several routinely collected datasets were accessed and data obtained from
 158 the following sources: maternity records (medical and obstetric history items, antenatal

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2
3 159 attendances and maternal and neonatal outcomes), primary care notes for each mother and
4
5 160 child dyad (consultations, immunisations, pregnancies, safeguarding), abortions data from
6
7 161 the Department of Health Abortions Statistics Team, and immunisation data via COVER
8
9 162 (Cover of Vaccination Evaluated Rapidly) contacts.

10
11
12 163 NHS Digital

13
14 164 The Hospital Episode Statistics (HES) datasets hold records on over 125 million hospital
15
16 165 admissions, outpatient and accident and emergency episodes each year. Data can be
17
18 166 requested from NHS Digital (formerly known as the Health and Social Care Information
19
20 167 Centre), the executive non-departmental public body established under the Health and
21
22 168 Social Care Act 2012.[13] All available records belonging to cohort members (mothers and
23
24 169 children) will be obtained from study entry of the mother, which occurred between June 2009
25
26 170 and July 2010 until the date the child turns six. The data requested include diagnoses,
27
28 171 procedures, length of episode and external causes of injuries coded according to the 10th
29
30 172 revision of the International Statistical Classification of Diseases and Related Health
31
32 173 Problems [ICD-10] codes.[14]

33
34
35 174 NHS Digital has responsibility for collecting these data from across the health and social
36
37 175 care system to allow NHS hospitals to be paid for the care they deliver. At the end of the
38
39 176 financial year (March) a final dataset is collated. This dataset is cleaned and validated
40
41 177 before being available for research at the end of the year (December).

42
43
44 178 Office for National Statistics (ONS)

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46
47 179 The Office for National Statistics (ONS) collects information on cause of death from civil
48
49 180 registration records. Mortality data can be accessed through NHS Digital. For registered
50
51 181 deaths, the underlying cause of death is derived from the sequence of conditions leading
52
53 182 directly to the death and is recorded on the death certificate. Deaths are subsequently coded
54
55 183 in line with the ICD-10.

1
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3 184 Department for Education (DfE)
4

5 185 The Department for Education (DfE) holds information on pupils throughout the different
6
7 186 phases of education. Records are sourced from publicly funded schools, local authorities
8
9 187 and awarding bodies and held in the National Pupil Database (NPD). Datasets are available
10
11 188 on various aspects of education such as school census data, absence data, and school
12
13 189 attainment.[15] All available records for the children in the cohort will be obtained from the
14
15 190 various datasets held. Data coverage will vary depending on the dataset in question. For
16
17 191 example, the School Census returns data on maintained schools (funding and oversight is
18
19 192 through the local authority) which represents the majority of schools, Academies (funding
20
21 193 and oversight is from the Department for Education), City Technology Colleges, maintained
22
23 194 and non-maintained special schools and hospital special schools. Schools that are entirely
24
25 195 privately funded and home education are not included in the data, this represents 7% of
26
27 196 English students.[16]

28
29
30 197 In the UK education is mandatory from the first school term after their 5th birthday. Prior to
31
32 198 this, some children may not have received formal early years provision and therefore may
33
34 199 not appear in the datasets. A survey conducted in 2014-15 commissioned by Department
35
36 200 for Education reported that 25 per cent of children aged 0-4, were not in receipt of any early
37
38 201 years' provision. Older preschool children (aged 3 to 4) however, were far more likely to
39
40 202 receive early years provision (92%) than younger pre-school children (aged 0 to 2)
41
42 203 (61%).[17] We would therefore expect similar coverage rates for this study.

43
44
45 204 The data requested includes the number of hours attended, early educational development,
46
47 205 eligibility for free school meals, and special educational needs (SEN) provision type.
48
49 206 Datasets are collated throughout the year and are available at set time points annually.

50
51
52 207 Social Care Data

53
54
55 208 Social care data from local authorities is available through the NPD via two datasets, Child in
56
57 209 Need (CIN) and Child Looked After (CLA). The CIN census captures individual level
58
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1
2
3 210 information on children referred to and assessed by children's social care services within
4
5 211 each 12month period.[18] CLA is collected in the SSDA903 return – an annual statutory
6
7 212 data collection for all local authorities.[19] Any child in the cohort who is in one of these
8
9 213 datasets will be identified. Mothers who were <18 years at the time of participation in the
10
11 214 BB:0-2 trial will also be identified in these datasets. There will not be the coverage issues as
12
13 215 seen in the education data returns and importantly, the primary outcome will be sourced
14
15 216 from these social care datasets.

17 **217 Study participants: Inclusion and exclusion criteria**

18
19
20 218 Eligible participants are those mothers recruited to the BB:0-2 trial and their first child (or
21
22 219 twins, if relevant) and who were not mandatorily withdrawn from the study, or electively
23
24 220 withdrew including their consent for use of their data. Women were recruited as nulliparous
25
26 221 women aged 19 or under, living in one of 18 local authority FNP catchment areas; recruited
27
28 222 by 24⁺⁶ weeks gestation, have conversational level of English and were able to consent to
29
30 223 research.[10]

31
32
33 224 Children in medium-term foster placements or adopted within the six year study period can
34
35 225 be linked up to the date of adoption. Maternal or child death will be captured as an outcome.

36 37 38 226 **Recruitment / Dissent**

39
40
41 227 Participants previously consented to enter into the BB:0-2 trial and provide self-report and
42
43 228 access to their routine records for the period up to two years postpartum. In order to obtain
44
45 229 an unbiased estimate of the medium-term effect of FNP on objective and associated
46
47 230 maltreatment outcomes we have received section 251 (s251) support of the 2006 NHS Act
48
49 231 approval from the Health Research Authority's Confidentiality Advisory Group (HRA CAG) to
50
51 232 pass identifiable participant data legally held by Cardiff University to the information centres
52
53 233 (IC) to link to routine data. This is without obtaining further consent from participants,
54
55 234 instead using an opt-out/dissent model.

56
57 235 Justification of approach
58
59
60

1
2
3 236 Consent for longer-term follow-up (i.e. beyond 24 months postpartum) was originally
4
5 237 proposed in the BB:0-2 trial. However, upon ethical review it was considered that greater
6
7 238 specificity about exact outcomes than could be provided at recruitment was required.
8
9 239 Additionally, providing meaningful consent for much longer follow-up was also challenging,
10
11 240 particularly on behalf of yet to be born children.

12
13 241 Developing the opt-out approach was necessary due to (i) the child protection focus of the
14
15 242 study and the consequent sensitivity and impracticality in asking directly for consent, (ii) the
16
17 243 mobility and relative difficulty in ongoing direct access to these participants (iii) the
18
19 244 consequent introduction of non-ascertainment bias on sample representativeness – resulting
20
21 245 in a non-random sample, and (iv) the likely cost and logistical requirements of securing even
22
23 246 modest levels of additional consent.

24
25
26 247 Methods of notifying participants

27
28
29 248 We discussed the issue of dissent and fair processing with the HRA CAG and have
30
31 249 subsequently attempted to contact all mothers recruited to the original BB:0-2 trial to inform
32
33 250 them that medium-term follow-up using anonymised records will be undertaken.

34
35 251 Details of participants' residential addresses were updated using their most recent address
36
37 252 registered with their GP. Where available, mobile number and email addresses collected
38
39 253 for the trial were used to send SMS and emails to participants. All three modes of contact
40
41 254 were used over a two-day period and participants were provided with a two-month window in
42
43 255 which to contact the project team to discuss the project and opt-out if they wished. A
44
45 256 website was also available with the same information which directed participants to contact
46
47 257 the project team if they wished.

48
49
50 258 *Development of opt-out letter*

51
52
53 259 A group of care-experienced young people (CASCADE Voices)[20] advised on the layout,
54
55 260 wording and tone of a letter to be sent to all participants. A key consideration was to
56
57 261 communicate the focus of this follow-on study in a sensitive manner. The final letter was
58
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1
2
3 262 approved by both an NHS Research Ethics Committee and CAG committee as part of
4
5 263 overall governance approval for the study. The letter contained both information on the trial,
6
7 264 the follow-on study and a flowchart for what to do if women wished to discuss the project
8
9 265 and/or opt out.

10
11 266 *Process to manage dissent*

12
13
14 267 Women notifying the study team of their dissent will be recorded as “opted out”, removed
15
16 268 from all project datasets for this follow-up work and identifiable datasets to be sent to ICs.
17
18 269 They will not be included in any of the datasets or analyses for this follow-on study.

19
20
21 270 **Governance and compliance**

22
23 271 Following Ethical approval (14/WA10062) and s251 support (CAG 10-08(b)/2014), data
24
25 272 request applications were submitted to DfE, NHS Digital and ONS.

26
27
28 273 In order to satisfy the requirements of the s251 support and NHS Digital contract, the
29
30 274 Information Governance (IG) Toolkit self-assessment[21] (commissioned by the Department
31
32 275 for Health for NHS Digital to develop and maintain) was required. This organisation-level
33
34 276 assessment provides reassurance of satisfactory information governance within the host
35
36 277 trials unit. Both the s251 support and IG Toolkit are assessed and renewed on an annual
37
38 278 basis. The opt-out model was also required to satisfy s251 support as well as the DfE
39
40 279 assessment of compliance with principle one of the Data Protection Act 1998. Governance
41
42 280 and IC requirements prior to application approval are shown in Figure 2.

43
44
45 281 **Data matching**

46
47 282 Maternal and child identifiers will be sent to both NHS Digital and DfE for matching with their
48
49 283 databases. Each IC holds differing identifiers including a unique identifier for each individual
50
51 284 (NHS Number; Unique Pupil Number UPN).

52
53
54 285 Matching with HES data will be by exact matching on NHS Number; Date of Birth; Postcode
55
56 286 and Gender. This was conducted for BB:0-2 and achieved a high match rate where 99.6%
57
58 287 of mothers and babies' records were matched fully (i.e. matched on all identifiers provided)

1
2
3 288 or partially (i.e. matched on a reduced, but acceptable number of identifiers provided). This
4
5 289 will be repeated for this study. NHS Digital will then exact match with ONS using NHS
6
7 290 number in order to obtain mortality data.

8
9
10 291 As the NPD does not include NHS numbers, initially exact matching on first name and
11
12 292 surname, date of birth and postcode (of both mother and child for social care data; all other
13
14 293 datasets just child) will be undertaken. Further matching required will be by fuzzy matching
15
16 294 of first name. The CIN and CLA datasets do not contain names or postcodes therefore the
17
18 295 matching will be in two phases: i) Participants will be matched with the NPD, the UPN added
19
20 296 to all participants and ii) this will be used to identify individuals in the CIN and CLA datasets.

21
22 297 Data matching at DfE and NHS Digital/ONS are independent therefore match rates at the
23
24 298 participant level are expected to vary (some may match to NPD but not HES). Educational
25
26 299 records should be available for all children in the trial cohort whereas health and social care
27
28 300 derived data will only exist where the child has received a relevant episode of care.
29
30 301 Participants will be compared using trial baseline data to check for any bias between those
31
32 302 who are matched and not-matched for those datasets where they would all be expected to
33
34 303 be present (e.g. school census for all children).

35 36 37 304 The Pseudonymised Dataset

38
39
40 305 A unique study ID will be attached to each participant's record prior to data transfer to ICs.
41
42 306 Once ICs have matched records to their database, only the unique study ID is retained.
43
44 307 Data extracts from both ICs plus data files from the trial (following a process of de-
45
46 308 identification and standardisation in Cardiff to reduce risk of later unintentional participant
47
48 309 level identification) will all be securely transferred to a data safe haven,[22] the Secure
49
50 310 Anonymised Information Linkage (SAIL) databank, for linking and storage. The data flow is
51
52 311 shown in Figure 3.

53
54 312 A SAIL data analyst will re-assign the study ID with a new anonymous linking field [ALF] and
55
56 313 store the corresponding ID in a separate encrypted password protected file.[23]
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3 314 Participants will not be identifiable to the study team, or to the SAIL analyst, but incoming
4
5 315 datasets can be linked at the individual level using the ALF. The study team will have
6
7 316 controlled remote access to these data thus ensuring the security of the pseudonymised
8
9 317 database.[24] All data cleaning and analysis will be carried out via the remote portal by the
10
11 318 study data manager and statistician.

12
13 319 Data from NHS Digital and NPD will be requested at two time points. The first data extract
14
15 320 will confirm the data flow model, assess data quality and the suitability of data for answering
16
17 321 key study analyses. The second data request will be made once all children in the study
18
19 322 have reached key stage one (April 2017) and on which the study findings will be reported on
20
21 323 (in 2018).

22
23
24 324 Control of data

25
26
27 325 Cardiff University control under contract the identifiable trial data that are being transferred to
28
29 326 the ICs and to the safe haven. Data held by NHS Digital, ONS and DfE, for which they are
30
31 327 the controllers, are de-identified and then sent to SAIL to be linked and held (including the
32
33 328 de-identified trial data) in a secure anonymised standalone database for use by nominated
34
35 329 study team members. SAIL will control the safe haven environment, and will process the
36
37 330 pseudonymised data for secure use by study team. Cardiff University will control the
38
39 331 purposes to which the data are put in answering research questions as per the study
40
41 332 protocol. Once linked in the data safe haven, the ability to submit queries to each IC about
42
43 333 individual records will be more limited than if identifiable data were returned to the research
44
45 334 team in Cardiff. Data cleaning will remain possible however as will generic queries about
46
47 335 data provided in batch. The quality of matching conducted by NPD and NHS Digital/ONS will
48
49 336 be a key factor in the success of the study.
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3 337 **Analysis**
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5
6 338 Power Calculation
7

8 339 Primary outcome (CIN status at any point between birth and six years): For CIN status,
9
10 340 available UK data on rates are not specific to the age-range of interest, but the rate in the
11
12 341 general population aged 5-9 years is 4.6% (for local authorities comprising study sites in
13
14 342 BB:0-2). The rate of CIN status would be expected to be greater in the specific study
15
16 343 sample, and therefore we have assumed a rate of 8%. We hypothesise that FNP would
17
18 344 reduce the detection of CIN in the first six years and thus assumed a difference of 4% as
19
20 345 being important. To detect a difference of 4% (FNP: 4% vs Usual Care: 8%) would require
21
22 346 602 children in each arm (1204 in total) using 80% power and a two-sided 5% alpha level.
23
24

25 347 BB:0-2 recruited 1645 women, with 1562 available for follow-up (i.e. excluding those subject
26
27 348 to a mandatory withdrawal). Follow-up through medical records (assuming 10% loss in
28
29 349 tracking & linkage) would result in 1405 participants, thus securing enough data to test the
30
31 350 primary outcome.
32
33

34 351 Main analysis
35
36

37 352 Analyses will be conducted on an intention-to-treat basis and due emphasis placed on
38
39 353 confidence intervals for the between-arm comparisons. Descriptive statistics of demographic
40
41 354 and baseline measures will be used to ascertain any marked imbalance between the trial
42
43 355 arms. The primary comparative analysis on CIN status at any point between birth and six
44
45 356 years will use logistic multilevel modelling to investigate differences between the groups, and
46
47 357 odds ratios alongside 95% confidence intervals (CIs) will be reported. Multilevel modelling
48
49 358 will allow for clustering of effect within a site and family nurse. Modelling the impact of key
50
51 359 subgroups (deprivation, looked after status of mother, adaptive functioning, Not in Education,
52
53 360 Employment, or Training (NEET) status and age) and different intervention elements (e.g.
54
55 361 gestational age at programme entry, dosage) on outcome will be undertaken by extending
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1
2
3 362 the primary models and testing for interaction effects. The role of potential moderators of
4
5 363 programme effect (e.g. domestic violence) will also be explored.
6
7

8 364 Secondary outcomes will assess group differences in objective and associated measures of
9
10 365 maltreatment, intermediate FNP programme outcomes as well as child health, development
11
12 366 and educational outcomes (as detailed in table 2). The majority of these are binary outcomes
13
14 367 (presence/absence of a status, meeting the Key stage one standard or not)) and will be
15
16 368 analysed using a multilevel logistic regression model. The distribution of potential continuous
17
18 369 outcomes such as Early Year assessment scores will be assessed before analysing using
19
20 370 linear regression. Count data such as the number of attendances for injuries and ingestions
21
22 371 will be analysed using a Poisson or negative binomial multilevel regression modelling. A
23
24 372 detailed statistical plan will be written and signed off prior to any analysis.
25
26

27 373 A state transition model using Markov chains will be used to assess the probabilities of
28
29 374 moving from one stage marker (states) to another.[25] The transition probabilities (the
30
31 375 probability of the various state-changes) in our model will be derived from our data and
32
33 376 compared between groups.
34
35

36 377 Bias in the followed-up BB:2-6 sample will be quantified by examining group differences
37
38 378 (participants and non-participants) in baseline variables such as age, deprivation, gestational
39
40 379 age, and education. Surveillance bias in detection of maltreatment during the child's infancy
41
42 380 and toddlerhood can be assessed by examining subsequent reporting.[26] The duration
43
44 381 between birth and the date of first referral to CSC will be calculated and group differences
45
46 382 examined using Cox regression analysis to calculate hazard ratios for referral, together with
47
48 383 95% CIs. Surveillance bias is most likely to occur during the intervention phase, although
49
50 384 improved handover to other services at 2 years may lead to higher identification in the
51
52 385 following year. Severity of the referral will also be compared between the two groups (an
53
54 386 approach used in US trials of NFP to explore surveillance bias).
55

56
57 387 Health economics
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3 388 The economic evaluation will consider costs and consequences of the FNP over the full
4
5 389 follow-up period (BB:0-2 & BB:2-6). The current BB:0-2 study reported 1) a within trial cost
6
7 390 utility analysis assessing NHS costs against quality adjusted life years (QALY) from the
8
9 391 perspective of the mother, and 2) a within trial cost consequences analysis relating all costs
10
11 392 (including those to the social care, education and criminal justice sectors as well as health)
12
13 393 against the full range of effects.[12] Cost and consequences framework is deemed the most
14
15 394 appropriate economic evaluation framework for public health interventions[27] and preferred
16
17 395 by NICE[28] because it enables capture of equity consideration as well as intersectoral costs
18
19 396 and consequences[29] yet applications are still limited.[27]
20
21 397 The absence of additional data on Health Related Quality of Life within the BB2 study means
22
23 398 that it will not be possible to estimate QALYs beyond 24 months postpartum and hence
24
25 399 extend the within trial cost utility analysis. However, the within trial cost consequences
26
27 400 analysis will be extended from 0-2 to 0-6 years through collection of resource use data from
28
29 401 medical and education records (including from the latter, data related to social care usage).
30
31 402 Costs will be summarised against the range of outcomes collected within BB2 without
32
33 403 aggregation to allow weighing up changes in the various outcomes reported in BB2 against
34
35 404 the changes in costs in a consistent and transparent manner.[30] This will contribute to
36
37 405 providing more robust and valid medium-term estimates within the extended period.
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407 **ETHICS AND DISSEMINATION**

408 **Legal & Ethical considerations**

409 The potential for using routine data in health and social care research has been greatly
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48
49 410 publicised and study designs utilising these data are encouraged by funders.[31] There are,
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51 411 however, many inherent challenges in working with secondary-use data, in particular for this
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53 412 project the ethical and legal requirements/responsibilities which have fundamentally
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55 413 informed this study design.
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3 414 Although BB:0-2 linked trial data to HES and ONS data via NHS Digital, the governance
4
5 415 requirements around the two applications have differed between the two studies not least
6
7 416 because of the difference in consent models. Trial data were provided by NHS Digital and
8
9 417 ONS after participant consent to prospective collection and for specified purposes limited to
10
11 418 the time-frame of that study. The current follow-on study uses a dissent model under which
12
13 419 we are only able to send trial participant identifiers to ICs for matching to outcome data
14
15 420 records if there is no objection received from mothers. This is especially important, as
16
17 421 following an opportunity to object to being included in the current study, those women who
18
19 422 withdrew from the original Building Blocks will be retained. The study will require all clinical,
20
21 423 social and educational data to be held in a data safe haven using encrypted record
22
23 424 identifiers and analysis via a securely managed and monitored remote portal. The legal
24
25 425 bases for transfer of identifiable data to ICs without explicit consent are as follows; s251 of
26
27 426 the 2006 NHS Act 2006 for HES data from NHS Digital, s42(4) of the Statistics and
28
29 427 Registration Service Act 2007 through NIHR funding for ONS data via NHS Digital, and 6(1)
30
31 428 of Schedule 2 of the 1998 Data Protection Act for NPD data.

32
33
34 429 *Dissemination of findings* The Building Blocks: 2-6 Study will generate policy-relevant
35
36 430 findings describing the medium-term impact of FNP on measurements of child maltreatment.
37
38 431 The findings will also include other policy relevant outcomes from the programme such as
39
40 432 health care use, education attainment and changes in social care use over the 6 years of
41
42 433 follow up. Such medium-term evaluation remains important as some outcomes for the
43
44 434 intervention are expected to arise only after the child's second birthday, including
45
46 435 maltreatment. This study will either confirm the largely negative trial findings from BB:0-2
47
48 436 further weakening the justification for FNP Programme continuation or provide a balance to
49
50 437 the early measurable outcomes.

51
52
53 438 In addition to reporting the findings to the funder for this study, the funder for the BB:0-2 trial
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55 439 (DH Policy Research Programme) will also be informed and the FNP National Unit (FNPNU).
56
57 440 All local authorities in England will be notified of the results, as (since October 2015) they
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1
2
3 441 have responsibility for commissioning public health services for children aged 0-5.
4
5 442 Participants will receive a summary of the results and all reports and publications will be
6
7 443 made publicly available in full on the Cardiff University website. The research team have
8
9 444 previously convened and met twice with a stakeholder group, including relevant policy leads
10
11 445 from each country in the UK delivering FNP (England, Scotland, Northern Ireland). We will
12
13 446 stage a similar event to present and discuss the implications for practice and policy of the
14
15 447 results of this medium-term follow up of participants.
16

17
18 448 In addition to policy and public outputs, academic outputs will include (i) this protocol paper
19
20 449 providing visibility of this medium-term follow up, (ii) a methods paper describing the piloting
21
22 450 process of the study (including data quality and success of data matching) and (iii) main
23
24 451 study findings. We aim to disseminate in high-quality, peer reviewed journals and present in
25
26 452 key conferences.
27

28
29 453 A particular benefit of this study is understanding of, and learning from, the governance
30
31 454 challenges. There is potential to use this method for future trials looking at longer term
32
33 455 follow-up. Therefore this study has the potential to add to the understanding of routine data
34
35 456 and data linkage methods in future public health and clinical trials and these planned
36
37 457 publications will provide a basis for the dissemination of the success of these methods.
38

39 458 Finally, publishing protocol papers in medical journals were an important innovation for trials.
40
41 459 They convey a number of benefits including transparency about what was intended by
42
43 460 researchers and therefore comparison to what was actually reported. While protocols are
44
45 461 more commonly published for trials, we consider that the protections afforded are similar for
46
47 462 other study types. This may include inhibiting 'data dredging' and post-hoc revisions to
48
49 463 original study plans. In our study, which links a trial cohort to routine data we consider that
50
51 464 this is especially important, particularly because of the broad range of outcomes that are
52
53 465 potentially impacted by this complex home visiting intervention.
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467 **Declarations**468 *List of abbreviations*

ALF: anonymous linking field;
ALF-E: encrypted ALF;
BB:0-2: Building Blocks trial;
CAPI: computer-assisted personal interview;
CATI: computer-assisted telephone interview;
CIN: Child in Need;
CLA: Child Looked After;
DfE: Department for Education;
DNA: Did not attend;
DoH: Department of Health;
EYFSP: Early Years Foundation Stage Profile;
FNP: Family Nurse Partnership;
FNPNU: Family Nurse Partnership National Unit;
HES: Hospital Episode Statistics;
HRA CAG: Health Research Authority's Confidentiality Advisory Group;
HSCIC: Health and Social Care Information Centre;
IC: information centres;
IG: Information Governance ;
NEET: Not in Education, Employment, or Training
NFP: Nurse Family Partnership;
NPD: National Pupil Database;
ONS: Office for National Statistics;
PCT: Primary Care Trusts;
PRU: pupil referral unit;
QALY: Quality adjusted life years;
s251: Section 251 of the NHS 2006 Act;
SAIL: Secure Anonymised Information Linkage;
SEN: special educational needs;
TTP: trusted third party;
UPN: Unique Pupil Number.

469

470 *Ethics approval and consent to participate* - Ethics approval of the study has been given by
 471 the Research Ethics Committee for Wales (14/WA10062) and the transfer and use of
 472 identifiable data has been approved by the Health Research Authority [HRA] Confidentiality
 473 Advisory Group [CAG] (CAG 10-08(b)/2014).

474 *Consent for publication* - Not Applicable475 *Availability of data and material* - Not Applicable476 *Competing interests* - The authors declare that they have no competing interests

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2
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6
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8
9 480 the NIHR PHR Programme or the Department of Health.

10
11 481 *Authors' contributions*

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13
14 482 MR is the chief investigator of the study. All authors have contributed to and are responsible
15
16 483 for the final design of the study. FLW and GM are responsible for study and data
17
18 484 management. RCJ is responsible for statistical planning and for data analysis. DF is
19
20 485 responsible for the health economics. All authors read and approved the final manuscript.

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24
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3 577 *(Title)* Figure 1. Follow up and datasets over the six years

4
5 578 *(Legend)* A&E Accident and Emergency; PRU Pupil Referral Unit

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9
10
11 581 *(Title)* Figure 2. Governance and Information centre requirements prior to application

12
13 582 approval.

14
15 583 *(Legend)* s251 Section 251 of the NHS 2006 Act; ONS Office for National Statistics; NPD

16
17 584 National Pupil Database; IG Information Governance

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21
22 586 Figure 3. Data Flow

23
24 587 *(Legend)* ¹Participant identifiable information securely transferred for linkage; ²De-

25
26 588 identification and Standardisation applied (e.g. date of birth to week of birth); ³Information

27
28 589 centres confirm matching of participant identifiers; ⁴Hosted on SAIL secure platform. ALF-

29
30 590 Anonymised Linking Field; BB:0-2 – The Building Blocks trial; DfE – Department for

31
32 591 Education; DPO – Data Providing Organisation; HES – Hospital Episode Statistics; ONS –

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34 592 Office for National Statistics; SAIL – Secure Anonymised Information Linkage.

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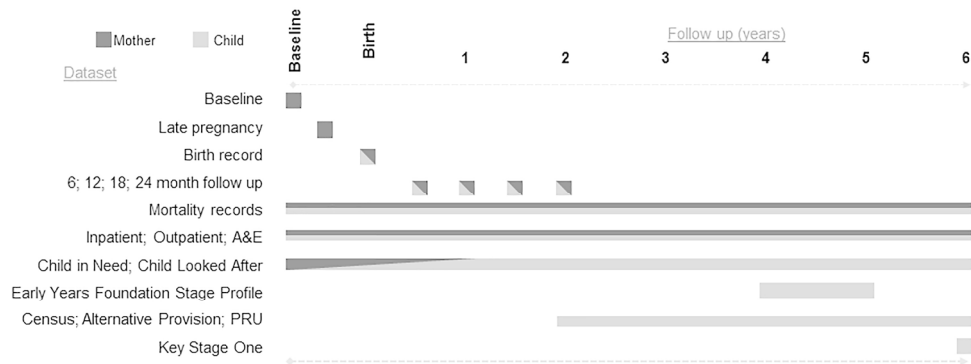


Figure 1. Follow up and datasets over the six years.
A&E - Accident and Emergency; PRU - Pupil Referral Unit

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Peer Review Only

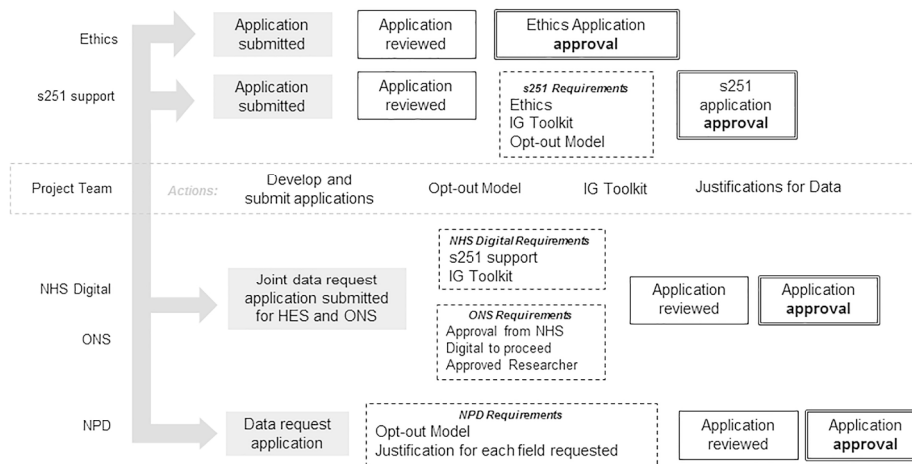


Figure 2. Governance and Information centre requirements prior to application approval. s251 - Section 251 of the NHS 2006 Act; ONS - Office for National Statistics; NPD - National Pupil Database; IG - Information Governance

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For peer review only

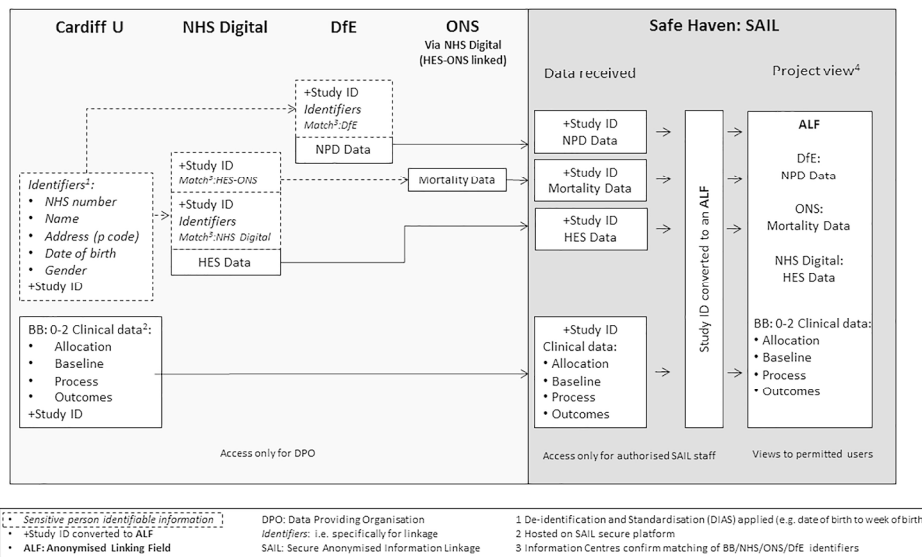


Figure 3. Data Flow.

1 - Participant identifiable information securely transferred for linkage; 2 - De-identification and Standardisation applied (e.g. date of birth to week of birth); 3 - Information centres confirm matching of participant identifiers; 4 - Hosted on SAIL secure platform. ALF- Anonymised Linking Field; BB:0-2 – The Building Blocks trial; DfE – Department for Education; DPO – Data Providing Organisation; HES – Hospital Episode Statistics; ONS – Office for National Statistics; SAIL – Secure Anonymised Information Linkage.

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