

## The Implementation Evaluation of *A Better Start*

### EVALUATION PROTOCOL

<b>Protocol Number:</b>	31005332-RMRHW0083
<b>Chief Investigator:</b>	Professor Jane Barlow
<b>Funding Body:</b>	Big Lottery Fund
<b>Sponsor:</b>	University of Warwick
<b>Ethics Committee:</b>	University of Warwick Biomedical and Scientific Research Ethics Committee
<b>Ethics Approval Date:</b>	2 <sup>nd</sup> June 2015
<b>Version Number:</b>	3
<b>Date:</b>	09 November 2017
<b>Stage:</b>	Approved [Ref: REGO:2014-973]

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable UK guidelines.

**Chief Investigator Signature:**



**Print Name:** JANE BARLOW

**Date:** 15.12.16

**Protocol Amendments:**

**Amendment Number:** 2

**Date of Amendment:** 09.11.17

**Amendment Approval:** J Barlow

## Table of Contents

<b>1. Key Roles and Contact information .....</b>	<b>3</b>
<b>2. Introduction .....</b>	<b>7</b>
2.1 <i>Background information.....</i>	7
2.2 <i>Warwick consortium: The team.....</i>	8
<b>3. Rationale for A Better Start .....</b>	<b>9</b>
3.1 <i>Poverty.....</i>	9
3.2 <i>Early years developmental and biological factors .....</i>	9
3.3 <i>Genotypes.....</i>	9
3.4 <i>Epigenetic mechanisms.....</i>	10
3.5 <i>Attachment.....</i>	10
<b>4. Objectives.....</b>	<b>11</b>
4.1 <i>Overall ABS evaluation objectives.....</i>	11
4.2 <i>Overall ABS hypotheses.....</i>	11
<b>5. Design and Methodology of the implementation evaluation .....</b>	<b>12</b>
5.1 <i>Introduction .....</i>	12
5.2 <i>Implementation study research questions .....</i>	13
5.3 <i>Implementation Study Research Objectives .....</i>	13
5.4. <i>Component One: Profiling of Structure and Services.....</i>	16
5.4.1 <i>Aim .....</i>	16
5.4.2 <i>Objectives .....</i>	16
5.4.3 <i>Methods.....</i>	16
5.4.4 <i>Data analysis .....</i>	17
5.4.5 <i>Site involvement.....</i>	17
5.5 <i>Component Two: Core Process Data.....</i>	17
5.5.1 <i>Aim .....</i>	17
5.5.2 <i>Methods.....</i>	17
<b>Appendix 1 – CMO example .....</b>	<b>20</b>
<b>References.....</b>	<b>22</b>

## 1. Key Roles and Contact information

<b>Sponsor:</b>	<a href="#">University of Warwick</a> (Jane Prewett) Coventry, West Midlands CV4 7AL <a href="mailto:Jane.prewett@warwick.ac.uk">Jane.prewett@warwick.ac.uk</a>
<b>Chief Investigator:</b>	<a href="#">Jane Barlow</a> , Warwick Consortium, Professor of Evidence-Based Intervention and Policy Evaluation, Fellow of St Hilda's College, Department of Social Policy and Intervention, University of Oxford, Barnett House, 32 Wellington Square, Oxford OX1 2ER. Tel: 01865 270323 <a href="mailto:jane.barlow@spi.ox.ac.uk">jane.barlow@spi.ox.ac.uk</a>
<b>Co-investigators:</b>	<a href="#">Geoff Lindsay</a> , Warwick Consortium, Professor of Special Educational Needs & Director of Centre for Educational Development, Appraisal and Research (CEDAR), University of Warwick, Coventry CV4 7AL Tel: 024 7652 3213/3638 <a href="mailto:Geoff.lindsay@warwick.ac.uk">Geoff.lindsay@warwick.ac.uk</a> <a href="#">Kathy Sylva</a> , Warwick Consortium, Professor of Educational Psychology, Department of Education, 15 Norham Gardens, Oxford OX2 6HP Tel: 01865 274008 <a href="mailto:Kathy.sylva@education.ox.ac.uk">Kathy.sylva@education.ox.ac.uk</a> <a href="#">Debra Bick</a> , Warwick Consortium, Professor of Evidence Based Midwifery, Room 4.32, James Clerk Maxwell Building, Kings College London, Waterloo, London SE1 8WA Tel: 020 7848 3641 <a href="mailto:debra.bick@kcl.ac.uk">debra.bick@kcl.ac.uk</a>
<b>Senior Project Manager:</b>	<a href="#">Virginia Woolgar</a> , Warwick Consortium, Department of Social Policy & Intervention, University of Oxford, Barnett House, 32 Wellington Square, Oxford OX1 2ER. Tel: 01865 270340 <a href="mailto:virginia.woolgar@spi.ox.ac.uk">virginia.woolgar@spi.ox.ac.uk</a>
<b>Statistician:</b>	<a href="#">Alastair Leyland</a> , Warwick Consortium, Professor of Applied Statistics, University of Glasgow, 200 Renfield Street, Glasgow G2 3QB Tel: 0141 353 7504 <a href="mailto:Alastair.Leyland@glasgow.ac.uk">Alastair.Leyland@glasgow.ac.uk</a>
<b>Health Economist:</b>	<a href="#">Stavros Petrou</a> , Warwick Consortium, Professor in Health Economics, Warwick Clinical Trials Unit, Warwick Medical School, Gibbet Hill Campus, University of Warwick, Coventry CV4 7AL Tel: 024 7615 1124 <a href="mailto:S.Petrou@warwick.ac.uk">S.Petrou@warwick.ac.uk</a>

**Specialist Collaborator(s):**

**Ipsos MORI Social Research Unit**

3 Thomas More Square, London E1W 1YW

Tel: 020 7347 3000

[BetterStartIMTeam@ipsos.com](mailto:BetterStartIMTeam@ipsos.com)

**Bryson Purdon Social Research**

10 Etherow Street, London Se22 0JY

Tel: 07966 167192

[Caroline.bryson@bpsr.co.uk](mailto:Caroline.bryson@bpsr.co.uk)

**ECORYS UK**

Albert House, Quay Place, 92-93 Edward Street, Birmingham B1 2RA

Tel: 0121 212 8877

[Laurie.Day@uk.ecorys.com](mailto:Laurie.Day@uk.ecorys.com)

**Vivette Glover**, Warwick Consortium, Emeritus Professor of Perinatal Psychobiology, Imperial College London

Tel: 020 7594 2136

[v.glover@imperial.ac.uk](mailto:v.glover@imperial.ac.uk)

**Carolyn Summerbell**, Warwick Consortium, Professor of Nutrition, Room A106, Holliday Building, Queens Campus, University of Durham, Stockton-On-Tees TS17 6BH

Tel: 0191 33 40029

[Carolyn.summerbell@durham.ac.uk](mailto:Carolyn.summerbell@durham.ac.uk)

**Steering Committee:**

**Independent Chair: Heather Joshi**, Emeritus Professor of Economic and Developmental Demography, Faculty of Policy and Society, Centre for Longitudinal Studies, Institute of Education, 20 Bedford Way, London WC1H 0AL. Tel: 020 7612 6874 E: [heather.joshi@ioe.ac.uk](mailto:heather.joshi@ioe.ac.uk)

**Sarah Gibbs**, Head of Funding (Investment) England Directorate Big Lottery Fund, 2 St James Gate, Newcastle, Newcastle-upon-Tyne NE1 4BE. Tel: 0191 376 1638 / 07823 551384 E: [sarah.gibbs@biglotteryfund.org.uk](mailto:sarah.gibbs@biglotteryfund.org.uk)

**Paul Mason**, Funding Manager Investments, England Directorate, Big Lottery Fund, Apex House, 3 Embassy Drive, Birmingham B15 1TR. Tel: 0121 345 7702. E: [Paul.Mason@biglotteryfund.org](mailto:Paul.Mason@biglotteryfund.org)

**Scott Greenhalgh**, England Committee Member, Big Lottery Fund. E: [englandsecretariat@biglotteryfund.org.uk](mailto:englandsecretariat@biglotteryfund.org.uk)

**Jean Gross CBE**, Education and Policy Expert, The Dove House, 16 Church Lane, Stetchworth, Newmarket CB8 9TN. Tel: 07748 775902. E: [jean.gross@btinternet.com](mailto:jean.gross@btinternet.com)

**Jeanne Brooks-Gunn**, Professor of Child Development and Education, Co-Director, National Center for Children and Families, Columbia University. Tel: 011 212 678 3369. E: [brooks-gunn@columbia.edu](mailto:brooks-gunn@columbia.edu)

**Jane Barlow**, Warwick Consortium, Professor of Evidence-Based Intervention and Policy Evaluation, Fellow of St Hilda's College, Department of Social Policy and Intervention, University of Oxford, Barnett House, 32 Wellington Square, Oxford OX1 2ER. Tel: 01865 270323. E: [jane.barlow@spi.ox.ac.uk](mailto:jane.barlow@spi.ox.ac.uk)

**Geoff Lindsay**, Warwick Consortium, Professor of Special Educational Needs & Director of CEDAR, University of Warwick, Coventry CV4 7AL. Tel: 024 7652 3213/3638. E: [Geoff.lindsay@warwick.ac.uk](mailto:Geoff.lindsay@warwick.ac.uk)

**Kathy Sylva**, Warwick Consortium, Professor of Educational Psychology, Department of Education, 15 Norham Gardens, Oxford OX2 6HP Tel: 01865 274008. E: [Kathy.sylva@education.ox.ac.uk](mailto:Kathy.sylva@education.ox.ac.uk)

**Laurie Day**, Warwick Consortium, Director of Policy and Research, ECORYS UK, Albert House, Quay Place, 92-93 Edward Street, Birmingham B1 2RA. Tel: 0121 212 8877. E: [Laurie.Day@uk.ecorys.com](mailto:Laurie.Day@uk.ecorys.com)

**Stephanie Bradley**, Vice Chair and Secretary, Community Voice, part of Blackpool Better Start. E: [blackpoolcommunityvoice@outlook.com](mailto:blackpoolcommunityvoice@outlook.com)

**Andrea Joseph**, Parent Champion, Lambeth LEAP. E: [andreajoseph@hotmail.co.uk](mailto:andreajoseph@hotmail.co.uk)

**Max Stanford**, Early Years and Childcare Analysis, Department for Education Tel: 020 7340 7993 Ext. 307993. E: [Max.STANFORD@education.gov.uk](mailto:Max.STANFORD@education.gov.uk)

**Michael E Lamb**, Professor of Psychology, Department of Psychology, University of Cambridge, Free School Lane, Cambridge CB2 3RQ Tel: 0 1223 3 34523. E: [Mel37@cam.ac.uk](mailto:Mel37@cam.ac.uk)

**Helen Duncan**, ChiMat Intelligence Lead, Public Health England. E: [Helen.Duncan@phe.gov.uk](mailto:Helen.Duncan@phe.gov.uk)

**Overall Management Group:**

**Chair: Professor Jane Barlow**

Contact details as listed

Other members as per Co-applicants, Collaborators and Senior Project Manager

Contact details as listed

**External Advisory Group:**

[Professor Jeanne Brooks-Gunn](#), Professor of Child Development and Education, Co-Director, National Center for Children and Families, Columbia University  
Tel: 011 212 678 3369  
[brooks-gunn@columbia.edu](mailto:brooks-gunn@columbia.edu)

[Jean Gross CBE](#), Education and Policy Expert  
The Dove House, 16 Church Lane, Stetchworth, Newmarket CB8 9TN  
Tel: 07748 775902  
[jean.gross@btinternet.com](mailto:jean.gross@btinternet.com)

[Professor Michael E Lamb](#), Professor of Psychology  
Department of Psychology  
University of Cambridge  
Free School Lane  
Cambridge CB2 3RQ  
Tel: 0 1223 3 34523  
[Me137@cam.ac.uk](mailto:Me137@cam.ac.uk)

## 2. Introduction

The purpose of this document is to provide information about the implementation evaluation of *A Better Start*. It complements the protocol of *the Impact and Economic Evaluation of A Better Start* (August 2015).

### 2.1 Background information

There is strong evidence that the first few years of life build the foundations for future health and wellbeing and that taking a preventative approach together with systems changes in local agencies, can improve the life chances of babies and children. However, these interventions have yet to be tested at scale. The Big Lottery Fund has invested £215M in funding A Better Start (ABS) in order to improve understanding about effective early childhood intervention in five competitively selected areas across England: Bradford, (led by Bradford Trident); Blackpool (led by the National Society for the Prevention of Cruelty to Children - NSPCC); Lambeth (led by National Children's Bureau - NCB); Nottingham (led by Nottingham City Care), and; Southend-On-Sea (led by the Pre-School Learning Alliance). These geographical areas have a high level of need in terms of deprivation, and child health.

Big Lottery Fund aims to use the learning from this investment to promote a shift in public policy, public funding and agency culture away from remedial services to greater investment in prevention in pregnancy and the first few years of life. Each area will deliver science- and evidence-based preventative programmes, policies and services, with a focus on the most disadvantaged families. Investment will take place in antenatal and postnatal support programmes that set out to achieve one or more of the following: (i) improve a child's social and emotional development – preventing harm before it happens (including abuse and neglect, perinatal mental health problems and domestic violence) as well as encouraging parenting practices that promote attachment; (ii) improve their language development by encouraging parents to talk, read and sing to, and particularly to praise – their babies and toddlers, and by ensuring local childcare services emphasise language development; and (iii) improve their nutrition and reduce obesity by encouraging breast-feeding and promoting good nutritional practices. The evidence suggests that these three areas can have a significant impact on long-term life chances and outcomes.

Each area will also address systems change across all children and families agencies. The systems changes should deliver less bureaucratic, more joined-up services; services that are prevention-focused; that are needs- and demand-led; that work for a whole family; and that get it right for families first time.

Big Lottery Fund has invested in the Warwick Consortium, led by the University of Warwick, to conduct a 10-year study designed to evaluate the impact of ABS across these five selected intervention areas, compared with matched comparison sites.

In addition to the impact evaluation, Warwick Consortium are also undertaking an implementation evaluation involving the collection of process data from the participating sites, and a learning and dissemination workstream to ensure that the lessons in terms of what works, for whom, and why, are identified and widely disseminated.

## 2.2 Warwick consortium: The team

Warwick Consortium is led by Professor Jane Barlow, and comprises a team that includes both substantive and methodological expertise, and that will enable it to successfully evaluate and disseminate the learning from ABS. Jointly, it has a strong track record in conducting multi-strand evaluations of complex programmes, and in combining the methodologies required for this including: longitudinal surveys, impact analysis using survey and administrative data, randomised controlled trials (RCTs), cost-effectiveness measurement, qualitative interviews, and analysis. The team includes field leaders in terms of socio-emotional development (Jane Barlow), nutrition (Professor Carolyn Summerbell) and early years education (Professor Kathy Sylva). There is also academic expertise in biometric measurement (Professor Vivette Glover), childbirth and the perinatal period (Professor Debra Bick), implementation research (Professor Geoff Lindsay) economic evaluation (Professor Stavros Petrou), and longitudinal evaluation and analysis (Professor Alastair Leyland).

The core team (responsible to the day-to-day running of the evaluation) includes the Universities of Warwick and Oxford, along with Ipsos MORI (evaluation fieldwork), Bryson Purdon Social Research (BPSR) (analysis) and ECORYS UK (learning and dissemination).

The evaluation is project-managed by Virginia Woolgar, based at the University of Warwick.



### 3. Rationale for A Better Start

Big Lottery Fund's decision to invest in preventative early intervention is both important and timely. There is a strong growing body of evidence supporting the need for preventative early intervention, particularly during pregnancy and the first three years of life. Below is a summary of the evidence regarding the factors that are associated with good or compromised outcomes in terms of nutrition, socio-emotional development and educational achievement (including language and speech) during the first three years of life. This research has informed the design of the evaluation, including the proposed choice of outcomes to be measured, and the time points at which these are assessed.

Briefly stated (providing selected references only):

#### 3.1 Poverty

Despite improvements in absolute levels of poverty and universal access to education and healthcare, poverty continues to be a significant predictor of compromised functioning in terms of nutritional and psychological wellbeing and educational outcomes (Marmot 2008). However, the research shows that the effects of poverty on these outcomes are almost entirely mediated by parental care, which provides considerable opportunity for remediation and interventions.

#### 3.2 Early years developmental and biological factors

Research increasingly supports the view that the origins of much adult disease lie in the 'developmental and biological disruptions occurring during the early years of life' (Shonkoff, Boyce, McEwen, 2009), and more specifically as a result of the 'biological embedding of adversities during sensitive developmental periods' (p.2009). This research suggests that the brain plays a central role in this process because it 'interprets and regulates behavioural, neuroendocrine, autonomic and immunological responses to adverse events, serves as a target of acute and chronic psychosocial and physical stress, and changes both structurally and functionally as a result of significant adversity'. For example, children's exposure to the type of 'toxic stress' (i.e. recurrent physical and/or emotional abuse, chronic neglect, parental substance misuse and domestic violence, severe mental health problems) that is more common in families living in poverty, also leads to changed brain architecture and reduced thresholds for stress, that continue throughout the life course, increasing the risk of stress-related disease and cognitive impairment.

The two key sensitive periods are pregnancy and the first three years of life because pre- and post-natal stress cause alterations in the function of the hypothalamic-pituitary-adrenal axis, which makes the hormone cortisol, leading to increased production (Glover, O'Connor & O'Donnell, 2010). This underlies some of the alterations in foetal and child brain neurodevelopment following early exposure to stress, and may also be one of the mediators of an altered epigenetic profile (see below).

#### 3.3 Genotypes

Recent research on differential susceptibility has found that children's genotypes interact with their caregiving environment to influence the impact of early caregiving. For example, gene x environment studies show that children with a short 5-HTTLPR allele have very unfavourable outcomes when parenting is compromised, but that these children also have significantly better outcomes than usual when parenting is better than average (Kochanska et al., 2011).

### **3.4 Epigenetic mechanisms**

There is now good evidence that early experience is associated with altered long-term outcomes, at least in part, by epigenetic mechanisms. These epigenetic (or on top of genetic) changes are functionally relevant modifications to the genome that do not involve a change in nucleotide sequence. They involve the addition of extra chemicals, such as methyl groups to the DNA, that alter whether, or how much, a specific gene is expressed or turned on or off. Such epigenetic changes can persist through the life of an individual and even be passed to the grandchild generation. Several studies have now shown that altered fetal experience in utero, due for example to pregnancy-specific anxiety (Hompeš et al., 2013) or to maternal stress caused by interpersonal violence (Radtke et al., 2011) cause epigenetic changes in the child. Postnatal experience can also cause long-lasting epigenetic changes (McGowan et al., 2009).

Epigenetic changes are therefore the most promising biological markers both for the effects of early experience and the possible effects of intervention, and a recent study has found that the Nurse Family Partnership (Olds, 2008) is associated with an altered epigenetic profile in the adult children, compared with the matched cohorts (O'Donnell and Meaney, personal communication).

### **3.5 Attachment**

Attachment appears to be one of the key mechanisms by which children regulate their emotional states, particularly when they are stressed (e.g. Sroufe, 2005). There is now incontrovertible evidence showing that securely attached children experience a range of improved outcomes, and that insecure and particularly disorganised attachment, are both associated with less optimal functioning. Disadvantaged children have considerably higher rates of both insecure and disorganised attachment.

## 4. Objectives

### 4.1 Overall ABS evaluation objectives

The overall aim of this research evaluation is to provide robust evidence about the impact and cost-effectiveness of the Big Lottery Fund ABS Programme, focusing predominantly on pregnancy and the first three years of life, identifying what interventions work, for whom, and under what circumstances.

The survey tools have been designed using a range of validated and standardised measures across three domains: socio-emotional health; nutrition; speech, language and learning.

The impact and economic evaluation will assess short- (birth – 3 years), medium- (4-5 years) and long-term (7 years) outcomes in each of the three key outcome domains. It will also measure parental outcomes that are strong predictors of infant/child functioning.

The impact and economic evaluation of ABS will address the following research questions:

- I. How effective is ABS in improving children's socio-emotional functioning; nutrition, and language?
- II. How cost-effective is ABS?

The evaluation of the ABS programme will also provide answers to the following questions:

- III. How quickly do we find improvements in outcomes, and how sustainable are these over time?
- IV. How does this compare with families in other areas not supported by Big Lottery Fund's investment?
- V. Is the programme investment worthwhile?
- VI. How much does it cost to run the programme, including the initial set-up, and over time?
- VII. How cost-effective are different approaches in terms of the outcomes achieved?

### 4.2 Overall ABS hypotheses

The study has been designed to address the following hypotheses:

1. A Better Start will have an impact on children's socio-emotional functioning, their nutritional status, and their language development at 3 and 7 years of age;
2. The impact of the programme will be mediated by change in parental functioning including their mental health and parenting practices;
3. A range of process factors including the level of service provision and the integrity with which such services are delivered will mediate the success of the programme.

## 5. Design and Methodology of the implementation evaluation

### 5.1 Introduction

The overall aim of the implementation/process evaluation is to provide data that will enable identification of the factors in terms of the key practice and systems lessons that are necessary for wider replication and taking to scale. As such, the evaluation will enable the theory (or theories) of change that are shaping ABS to be examined. In practice, this means using the implementation data alongside the impact/outcome data to get a better picture of: which particular service configurations were associated with better outcomes for families, and; which family service trajectories were associated with better outcomes. Thus, while the impact evaluation will tell us ‘what’ has happened in terms of whether ABS was effective, the implementation evaluation will enable us to show ‘how’ this happened.

**In essence, the work will involve two key components:**

- a) Phase 1 - Profiling of the structure and services being provided in the 5 ABS sites focusing in particular on issues such as ‘connectivity’ between services, and ‘pathways’ at baseline (i.e. the stage of early implementation by sites October/November 2016); and the way in which this provision changes over the course of the next five years, using conversations with key members of staff and both data and documentary analysis;
- b) Phase 2 - The collection of core process data from the sites regarding the participating families, and the services that they receive, using: i) routinely collected data from the sites; ii) researcher telephone interviews with key stakeholders.

These are described in further detail below. In brief, this implementation evaluation data (described below) will be used as follows (see table 1 below for further description):

- i) Baseline data about the number and type of services provided (component 1) and routine data collected by the sites regarding attendance and dropout etc.) will be used to create an ‘index’ regarding the quality and quantity of services in each of the sites; this will then be used as part of the impact evaluation to understand better the results in terms of the outcomes for children. For example, we would expect sites whose index is lower to have poorer child outcomes, and sites whose index is higher to have better child outcomes.
- ii) The implementation data will be used alongside the impact data regarding risk and outcomes to create some CMO (context; mechanism; outcome) profiles. This will involve us creating maps in which align the following data: baseline risk score for families (based on the presence of factors that pose risk for children – depression; domestic abuse; substance use etc. to create an index of low, medium or high risk); index score for the services – high quality; medium quality and low quality); and outcomes for the family (e.g. Significant change; some change; no change). This will enable us to identify some typical family trajectories – for example, what does this map tell us about women who are at most risk? What level and

quality of service did they need to bring about change; or was it the case that for this group no change was identified irrespective of the level and quality of services.

## 5.2 Implementation study research questions

1. Which ABS service configurations are associated with better outcomes for children?
2. What CMO (context; mechanism; outcome) trajectories were identifiable across the ABS sites? (See Appendix 1 for an example)
3. How feasible and acceptable were the services that were provided?

## 5.3 Implementation Study Research Objectives

The above questions will be addressed by the following **objectives**:

### Phase 1

- What system change has been implemented in each of the 5 ABS sites? This will include both changes in the *total* system in each site (e.g. reconfiguration of services, and the ways in which services interact, including LA, Health and VCS) and changes in configurations and practices within services, including commissioned services. Examples include the workforce, both directly employed and commissioned; co-production with communities; shared accountability for outcomes; data collection, storage, analysis, reporting systems including models of communication and sharing; increased use of evidence (research and local data) to shape practice.
  - This will involve assessing the change that has taken place in terms of services, organizational structures and monitoring systems that were in place prior to the introduction of the ABS funding, and the ways in which these have changed up until the current time point and continue to change over the next 5 years.
  - It will also involve examining the connections between services and different organisational structure, and the pathways that have been established across services for parents.
  - This data will enable us to establish a) what services were in place at baseline; b) the ways in which these services were modified over time in response to the need, demand and outcomes in the local population.
  - This data will contribute to answering research questions 1 and 2.
  - Timeline: Sept 2016 to March 2017 for baseline review; annual review thereafter in March 2018; 2019; 2020; 2021
  - Deliverable: Report summarising findings; annual updates
- What processes were implemented in order to a) set up and; b) maintain the programme of services in each site?
  - This will involve identifying 'how' the above system change was achieved in terms of both meta (e.g. new regulations and working practices) and micro (e.g. new staff; training etc.) level practices.
  - This data will enable us to provide the necessary information for future replication and roll out of ABS services.

- This data will contribute to answering research question 1.
- Timeline: As above
- Deliverable: As above
- Is the system change identified above associated with improved outcomes for children and parents:
  - This will involve using the data collected here and in Phase 2 (below) to create an 'index' regarding the nature, quantity and quality of services provided, and using that alongside the impact outcome data to assess whether 'what' is provided influences outcomes for children.
  - This data will contribute to answering research question 1 and 2.
  - Timeline: Co-ordinated with impact data outcome points
  - Deliverable: Additional analysis to main impact outcome report

### **Phase 2**

- What is the quality and quantity of services being provided by ABS sites?
  - Routine service data will be provided by the sites at regular time-points (e.g. monthly) as shaped by current work by Big Lottery Fund (the Fund) with sites on common data dashboard.
  - This will be used in addition to the data from phase 1 about the service profiles to develop an 'index' for each site in terms of the nature, quality and quantity of services being provided by the ABS sites;
  - We will use this data as part of the impact evaluation to assess whether factors such as 'amount' or 'quality' of services were associated with evidence of improvements in outcomes for children.
  - Timeline: Monthly data summary from Jan 2017;
  - Deliverables: a) Data analytics summary for each site; b) Additional analysis to main impact outcome report as above
- What are the context, mechanisms and outcome profiles for families in each of the ABS sites? (This analysis can only be undertaken if identifiable data is provided by the sites to enable us to match service data with impact data).
  - The impact data will be used to produce a context profile for each family (high risk; medium risk; low risk); the service data will be used to create an overall service profile for the families (high input; medium input; low input); and an outcome profile (improved; same; not improved). The latter may also be seen as better than expected; same; less than expected in terms of impact data at baseline as predictors of likely development;
  - These CMO maps will enable us to assess the type and level of service that needs to be provided to different groups of parents to achieve a change in outcome;
  - This data will be used to answer research question 2;
  - Timeline: Analysis conducted at each main data analysis point.
  - Deliverables: CMO maps for each of the sites at each main data analysis point.

- How acceptable and feasible are the ABS services?
  - Impact data will be used to identify parents who show change and those who show no change, who will be invited to take part in an interview focusing on what they liked and didn't like;
  - A range of service providers will be identified based on the index score for each site to take part in interviews to assess their views about the feasibility of providing the services and any difficulties they encountered;
  - This data will contribute to answering research question 3;
  - Timeline: Interview to be conducted in 2018 and 2019;
  - Deliverables: Report summarising the findings of the stakeholder data in 2019

<b>Data type</b>	<b>Type of data</b>	<b>What research question will the data address</b>	<b>Link with impact data</b>
Baseline and annual profile of services	Description of key ABS services; date started; frequency of provision; staff numbers	What is the nature of the services being provided; How were the services established/maintained?	Creation of an index score for each site that can be used as part of the impact evaluation
Routine <u>de-identifiable</u> data from sites	Number of families reached overall broken down by service For each service: family recruitment; throughput; %attendance; dropout;	What is the quality and quantity of the services being provided?	This data will be used as part of the index score for each site, and integrated in the impact analysis
Routine <u>identifiable</u> data from sites	Family name Services received For each service – frequency and duration of attendance	What are the different CMO patterns across the difference sites	Will be combined with: demographic and outcome impact data to create CMO maps context (demographics); mechanisms (service data); outcomes (child improvement)
Stakeholder interviews Parents Service providers Service managers	Themes from interviews with quotations	How acceptable and helpful were the services being provided to participating families? What problems were associated with their delivery?	Impact data will be used to identify families who showed change and those who didn't

**Note. If identifiable data are not available a revised approach will be necessary, e.g. using aggregated family data**

## 5.4. Component One: Profiling of Structure and Services

### 5.4.1 Aim

The profiling of ABS site structures and services will be undertaken immediately and updated at regular time points (i.e. yearly) throughout the remainder of the study, and the primary aim is to establish a clear picture of a) what ABS comprises in each of the sites in terms not only of core provision but the ways in which services are connected and the use of pathways to deliver enhanced services to families; and b) the ways in which this has been achieved. The data from the annual updates will be used as part of the creation of an index that can be used as described above. For example, if major changes to the baseline service provision have taken place it may be necessary to revise the index score based on later service profiles.

We will also seek to obtain data regarding the services being provided in the comparison areas (see below for further information). This data will enable us to better understand the results that are obtained. For example, if the comparison sites have outcomes that are comparable to ABS sites, this may be explained by the level of service provision in that site taking into account potential confounding factors including population movement, socioeconomic changes (e.g. poverty, unemployment).

### 5.4.2 Objectives

Specific objectives will be agreed with each area via the existing stakeholder group which includes representatives from the Fund, each site, the implementations leads and researchers and which will include the process of implementation that has taken place to date:

#### *Inputs*

- Identification and mapping of *current* services, interventions, delivery mechanisms, data monitoring, and reporting to create baseline scenarios, to include e.g. Needs analysis; Infrastructure including staff, IT systems, management systems etc.
- Determination and agreement of *policies and procedures for A Better Start* (e.g. examination of evidence for possible interventions and decision-making regarding the selection):

#### *Activities*

- Process implementation – this will involve an examination of how the agreed policies and procedures were implemented e.g.: Staff recruitment; Training; supervision; data collection and management; methods of joined up working; financial linking.

#### *Outputs*

- Performance implementation – this will involve an examination of the success or otherwise of the inputs and activities in terms of service delivery and operation.

### 5.4.3 Methods

The primary methods to be used will be agreed with the stakeholder group and may involve recorded conversations with key individuals at the 5 ABS sites and documentary analysis. For the purpose of the annual updates we will use a simple proforma, which will list all of the services being provided, by the site at the last time point, with space to identify services that have been discontinued and new services that have been introduced.



For the purpose of comparison sites we will use publically available documents to assess the type and amount of services being provided. This will in all likelihood involve telephone conversations with at least one person locally to ascertain the best place to secure access to such documents.

#### **5.4.4 Data analysis**

The analysis stage will involve compiling the data that has been obtained using the agreed methods in order to present a clear picture of what the ABS sites are providing in terms of services and the processes and structures that underpin these.

#### **5.4.5 Site involvement**

The sites will be involved as follows:

1. Shaping the objectives and resulting research activities as part of the stakeholder group meeting;
2. Advising the research team about the relevant staff with whom the research team should liaise to collect data;
3. Providing relevant documents to the research team.

### **5.5 Component Two: Core Process Data**

#### **5.5.1 Aim**

This part of the work will be undertaken once the cohort study has begun<sup>1</sup> and the primary aim is to identify the way in which services have been delivered across the 3-5 sites in terms of throughput data (e.g. reach; dosage; dropout etc.), and to obtain a picture of the type of service trajectories experienced by individual families.

#### **5.5.2 Methods**

##### *5.5.2.1 Design*

A mixed-methods approach will be used that involves the separate but concurrent collection of qualitative and quantitative data.

The data collection will focus on program monitoring, which refers to the process of assessing the manner in which a service has been implemented. This will be undertaken using a) routine data collected by the sites i.e. indicating the way in which the service was actually provided (e.g. number of sessions; provider; training and support etc.); and the support systems in place to optimize fidelity (e.g. supervision, further training); and b) researcher collected data using brief telephone interviews with key stakeholders (see next section).

This part of the work will require a) a data sharing agreement; and b) work with the sites to develop the data collection mechanisms that will provide us with the routine process data that is needed. Ideally we would be able to collect identifiable data (i.e. in which we can relate the participant with the programmes; however, de-identified data will be used if necessary.

---

<sup>1</sup>Preparation in terms of the data collection at the sites will be set in place immediately

This work will begin immediately (i.e. October 2016). The data will be collated at routine intervals from the 5 sites.

#### 5.5.2.2 Data Collection

The following methods of data collection will be used:

1. **Routine data collected by the sites** regarding the following:

*Family profiles* – Number and nature of services accessed by each participating family; demographic data; service outcome data etc.

*Service profiles* – For each service we will collect the following:

- Number of staff, roles, background/qualifications, and costs delivering each programme;
- Number of families to whom the service has been delivered; frequency; numbers attending; dropout etc.
- Service output data (to be discussed)
- Satisfaction measures

Common data and a common coding system will be necessary and the data should be identifiable. Other less rigorous approaches are possible depending on the data characteristics

2. **Researcher collected data** will include the following:

*Semi-structured telephone interviews* will be used to explore the views of key stakeholders (i.e. primarily service providers and recipients) regarding service delivery. The quantitative impact data will be used to identify service recipients who have both benefited or not benefited from an intervention, to take part in a telephone interview. Interviews will be selectively transcribed.

#### 5.5.2.3 Data Analysis

The data analysis will involve two types of analysis:

- a) The standard data analysis techniques that are routinely used for analyzing both quantitative and qualitative process data:
  - *Quantitative analysis* of the process data will involve the use of simple descriptive statistics (e.g. means, spread, etc.) that will enable us to identify how well services have been delivered; in order to measure change, inferential statistics will be used, depending on the nature of the data available
  - *Qualitative data analysis* will involve the full transcription of all data into NVivo followed by a) thematic analysis to identify common patterns that are present across the data; b) case profiling which will be undertaken as part of the CMO profiling described next. This 'rich data' may be supplemented in some cases by more focused data which may be analysed statistically as well as qualitatively
- b) *CMO Profiling* will be undertaken using the process data that has been collected above. This part of the analysis is aimed at enabling us to track the mechanisms that support ordinary behaviour (regularities), in addition to those that may be triggered within certain contexts to produce change (Pawson and Tilley 1997).

This part of the analysis will involve constructing profiles for both individuals and also services. Quantitative outcome data will be used to identify which individuals and projects are profiled using this technique, and will involve the selection of both successful and unsuccessful cases. We will then develop profiles for each of these using the data about contextual factors (e.g. demographics etc.) alongside mechanisms (e.g. logic model) to identify why the outcomes produced occurred. This will enable us to identify the critical success factors' in terms of the key practice and systems lessons that are necessary for wider replication and taking to scale. *Individual profiling*: will involve us using quantitative outcome data from each site to identify families who appear to have had a) significant change; b) moderate change; c) little or no change, in terms of our key outcomes (n.b. we will do this for each of the three types of outcome because some families may, for example, have improved on nutritional outcomes but not educational outcomes). We will then build maps for each of these groups of families that consist of 2 further additional pieces of information i) the baseline contextual factors for these families in terms of age; ethnicity; level of risk; readiness to change; level of toxic stress etc., alongside ii) the program mechanisms to which they were exposed (e.g. amount and nature of services received). This will enable us to build maps to identify *what worked, for whom and why*.

*Project profiling*: will involve similar strategy described above but will be undertaken at the level of the projects and possibly even wards or sites. Again, we will identify projects for whom there was good change, moderate change and no change, and then we will build up maps by adding in contextual and mechanism data to identify why the above outcomes occurred. These maps will be translated into simple messages for the sites and that can be used more widely.

#### 5.5.2.4 Site Involvement

1. Work with the research team and BIG and the Fund's contractor developing the common data dashboard to develop and finalise the Common Data Set;
2. Development of a data-sharing agreement;
3. Involvement in stakeholder group to shape the objectives and resulting research activities.
4. Provision of data from the Common dataset in an agreed format and at agreed specified time points;
5. Identification of processes and stakeholders for the purpose of telephone interviews.

#### 5.5.2.5 Deliverables

Deliverable 1: Report summarising the profiles of the sites + annual updates.

Deliverable 2: a) Data analytics summary for each site; b) Additional analysis to main impact outcome report.

Deliverable 3: CMO map/analysis for each of the sites at each main data reporting point.

#### Timeline

August/September 2016 – Agree revised implementation protocol with the Fund and with stakeholder group; finalise revised costs;

September/October 2016 – Appoint new researchers; circulate revised IE protocol to sites;

October/December 2016 – Commence profiling of structures and services (Component One of revised IE); establish group to set up data collection processes in sites (Component Two of revised IE).

December to March 2017 – develop and test local data collection processes (Component Two)

August 2017 – Commence Core Process Data Collection (Component Two).  
Continue over 2017 to 2021.

## Appendix 1 – CMO example

### A Realist Evaluation of the Processes and Outcomes of Infant Massage Programs

Underdown, A., Norwood, R. and Barlow, J. (2013). A realist evaluation of the processes and outcomes of infant massage programs. *Infant Mental Health Journal* 34: 483–495.

#### ABSTRACT

##### Background

The sensitivity of early interactions conveyed through eye contact, voice tone, facial expression and gentle touch, plays a crucial role in healthy development. Recognition of the importance of parent-infant interaction for later attachment has underpinned the search for innovative ways of promoting sensitive parent-infant interaction. However, a recent review of its effectiveness in population samples found no evidence of effectiveness. This points to the need to identify which parent-infant dyads are potentially able to benefit from such intervention.

##### Aim

This study aimed to identify the contextual factors and program mechanisms that were associated with different outcomes for a group of mother-infant dyads who attended an infant massage program.

##### Methods

A realist mixed-methods research design was used to identify the context, mechanism and outcome (CMO) patterns across a sample of 39 mother-infant dyads attending infant massage programs. A range of quantitative measures (Working Model of the Child Interview - WMCI; Edinburgh Postnatal Depression Scale - EPDS; and video-recordings of mother-infant interaction (CARE-Index) were administered pre and post-intervention, alongside the conduct of qualitative observations and interviews with a range of stakeholders.

##### Results

Three key CMO patterns were identified. Women categorized as 'low' risk on the whole showed no change in parent-infant interaction (i.e. because they were already in the adequate range), and limited change in levels of depression, irrespective of the quality of the program attended. Mothers who were categorised as being at 'moderate' risk (i.e. they had 1-2 risk factors over and above their demographic risk), appeared to require 'good' quality programs (7 or more program mechanisms) in order for change to occur. Mothers categorized as being at 'high risk' showed no benefits irrespective of the quality of the program, and there was evidence of unresponsive mothers becoming more intrusive.

##### Conclusions

These findings suggest that infant massage programs should be targeted at parents experiencing moderate problems in terms of parent-infant interaction, and that primary care professionals working in a range of settings need the skills to identify such compromised

parenting in order to do this. High-risk mothers appear unlikely to benefit from infant massage alone. Rigorous RCT evidence is needed to test the hypotheses raised by this study.

**Context, mechanism, outcome (CMO) patterns for infant massage programmes**

<b>CONTEXT (Risk Level)</b>	<b>MECHANISMS (Program quality)</b>	<b>OUTCOME (Change)</b>
<b>1a. Low risk (n=14)</b> Balanced WMCI Sensitive interactions EPDS below or close to threshold	Good Program (n=4) Fair Program (n=7) 'Poor' Program (n=3)	No change No change No change
<b>2a. Moderate Risk (n=11)</b> Disengaged WMCI Adequate Interactions EPDS above threshold	Good Program (n=2) Fair Program (n=2) Poor Program (n=6)	Some change Some change No change
<b>3a. High risk (n=8)</b> Disengaged or distorted WMCI Inept or at-risk interactions Elevated EPDS	Good Program (n=2) Fair Program (n=3) Poor Program (n=4)	Possible adverse change No change No Change

'Poor' >=4 or fewer mechanisms; 'Fair' >= 5-9 mechanisms; 'Good' >=10 mechanisms

## References

Glover V., O'Connor TG., O'Donnell K. Prenatal stress and the programming of the HPA axis. *Neuroscience and Biobehavioral Reviews*. 2010 Sep;35(1):17-22.

Harris F., Law J., Roy P. The third implementation of the Sure Start Language Measure. Research Report, DfES. 2005. Available at: [http://www.surestart.gov.uk/\\_doc/P0001802.pdf](http://www.surestart.gov.uk/_doc/P0001802.pdf)

Hompes T., Izzi B., Gellens E., Morreels M., Fieuws S., Pexsters A., Schops G., Dom M., Van Bree R., Freson K., Verhaeghe J., Spitz B, Demyttenaere K., Glover V., Van den Bergh B., Allegaert K., Claes S. Investigating the influence of maternal cortisol and emotional state during pregnancy on the DNA methylation status of the glucocorticoid receptor gene (NR3C1) promoter region in cord blood. *Journal of Psychiatric Research*. 2013;47(7), 880-891.

Kochanska G., Kim S., Barry RA., Philibert RA. Children's genotypes interact with maternal responsive care in predicting children's competence: diathesis-stress or differential susceptibility? *Developmental Psychobiology*. 2011 May;23(2):605-16.

Marmot M., Friel S., Bell R., Houweling TA., Taylor S. Closing the gap in a generation: health equity through action on the social determinants of health. *Lancet*. 2008 Nov 8;372(9650):1661-9.

McGowan PO., Sasaki A., D'Alessio AC., Dymov S., Labonté B., Szyf M., Turecki G., Meaney MJ. Epigenetic regulation of the glucocorticoid receptor in human brain associates with childhood abuse. *Nature Neuroscience*. 2009 Mar;12(3):342-8.

National Institute for Health and Care Excellence (NICE). Guide to the Methods of Technology Appraisal. London. 2008

Olds DL., Kitzman H., Cole R., Robinson J., Sidora K., Luckey DW., Henderson CR Jr., Hanks C., Bondy J., Holmberg J. Enduring effects of nurse home visiting on maternal life-course and child development: Age-six follow-up of a randomized trial. *Pediatrics*. 2004 Dec;114(6):1550-9.

Olds DL. Preventing child maltreatment and crime with prenatal and infancy support of parents: the Nurse-Family Partnership. *Journal of Scandinavian Studies in Criminology and Crime Prevention*. 2008 Dec 1;9(S1):2-24.

Radtke KM., Ruf M., Gunter HM., Dohrmann K., Schauer M., Meyer A., Elbert T. Transgenerational impact of intimate partner violence on methylation in the promoter of the glucocorticoid receptor. *Translational Psychiatry*. 2011 Jul 19;1:e21.

Robinson J., Hérot C., Haynes P., Mantz-Simmons, L. Children's story stem responses: a measure of program impact on developmental risks associated with dysfunctional parenting. *The International Journal of Child Abuse Neglect*. 2000 Jan;24(1):99-110.

Sammons, P., Sylva K., Melhuish EC., Siraj I., Taggart B., Smees R., Dobson A., Jeavons M., Lewis K., Morahan M., Sadler S. The Effective Provision of Pre-School Education (EPPE) Project: Technical Paper 2 – Characteristics of the EPPE Project sample at entry to the study. London: DfE/Institute of Education, University of London. 1999.

Shonkoff JP., Boyce WT., McEwen BS. Neuroscience, molecular biology, and the childhood roots of health disparities: building a new framework for health promotion and disease prevention. *The Journal of the American Medical Association*. 2009 Jun 3;301(21):2252-9.

Sroufe LA. Attachment and development: a prospective, longitudinal study from birth to adulthood. *Attachment and Human Development*. 2005 Dec;7(4):349-67.

Sylva K., Melhuish E., Sammons P., Siraj-Blatchford I., Taggart B. Effective pre-school, primary and secondary education 3-14 project (EPPSE 3-14). Final report from the key stage 3 influences on students' development from age 11-14. Research Report DfE-RR202. London. 2010.

Underdown, A., Norwood, R. and Barlow, J. (2013). A realist evaluation of the processes and outcomes of infant massage programs. *Infant Mental Health Journal* 34: 483–495.