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Pilot Evaluation Summary	
Intervention Developer	Manchester City Council
Delivery Organisations	Manchester City Council, Barnardo's and the 'Big Manchester' Partnership
Evaluator	The Institute of Public Care at Oxford Brookes University
Principal Investigator	Katy Burch
Protocol Author(s)	Katy Burch
Pilot Intervention Recipients	Approximately 60 unborn or newborn infants and their parents
Pilot Evaluation Participants	Up to 60 parents of unborn or newborn children Approximately 10 core staff and managers (of the Thriving Babies: Confident Parents Project Core Team) Approximately 15 Home Start volunteers working with Thriving Babies: Confident Parents Approximately 10 broader stakeholders and service leaders
Number of Pilot Sites	1 site: Manchester City Council
Protocol Date	3 June 2021
Version	1

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Summary

This document outlines the pilot evaluation of Thriving Babies: Confident Parents (Thriving Babies: CP) in Manchester.

Thriving Babies: CP aims to intervene and provide support at an early stage for potentially vulnerable (prospective) parents of babies and infants pre- and post-birth. It recognises that parent vulnerability and therefore risks to the baby or infant may arise because of a range of factors including:

- Parent exposure to adverse childhood experiences (ACEs) including abuse or neglect.
- Lack of adult (including parenting) role models.
- Domestic abuse.
- Substance misuse.
- Mental health problems.
- Learning disability or difficulty.
- Vulnerability to exploitation in the community.

This project aims to work proactively with parents to build on their strengths, develop an understanding about and attunement to the needs of babies and children, develop their parenting skills, reduce the risks, and develop family resilience as well as the parent's own wellbeing. This work will be directed by a named 'key worker' for the family who will come alongside the parent(s) to develop a trusting relationship which will be the core enabler of a positive engagement with the overall project.

The project also aims to 'wrap' other support around the parent and family, for example to help with their mental health needs. This will be achieved in 2 ways: (1) through strong links with the voluntary sector, generated through the 'Big Manchester' Programme and facilitated by Barnardo's; and (2) through deployment of a 'Think Family Coordinator' for individual families. It is anticipated that these two mechanisms will help to 'fast track' holistic support for these families when and where it is needed most.

The evaluation to be undertaken by the Institute of Public Care at Oxford Brookes University between May 2021 and June 2022 is a form of pilot evaluation. It will be:

- **Exploring the key elements** of 'Thriving Babies: CP', its feasibility, and evidence of promise with reference to the key aims of the project.
- **Mixed method** (we will want to draw on some quantitative as well as qualitative data generated by the site(s) and ourselves).
- **Realist(ic)** – exploring not only whether the model seems to work but in what circumstances, for whom, why, to what extent. Also, any barriers to participation.
- **Collaborative** – working with sites to generate the best learning about what works.
- **Applying the following key methods:**
 - Whole cohort data analysis
 - Standardised measures' analysis
 - Case file sampling
 - Interviews with parents
 - Practitioner, volunteer and stakeholder interviews
 - Costs / unit costs analysis

Background and Problem Statement

The first year of a child's life, indeed the first 1,001 days, are extremely significant in terms of laying the foundations for their cognitive, emotional and physical development (Early Years Healthy Development Review, 2020).

As the number of infants becoming looked after has continued to grow in recent years (Broadhurst et al, 2018; Neil et al, 2019), local authorities and national policy makers are concerned to better understand and to reduce the growth. A specific concern is that support for many of these children and their often very vulnerable parents is insufficient, or insufficiently holistic, and/or that it starts insufficiently early to enable parents to demonstrate their capacity to parent adequately or to stop or reduce potentially harmful behaviours such as abuse of drugs or alcohol, or intimate partner violence or intense arguing (Burch et al, 2020). Parental learning difficulty or disability can sometimes be hidden from the view of professionals involved in safeguarding the child until a late stage, with the result that supports are not sufficiently well-tailored (Burch et al, 2019).

Many of the parents who are referred to social care services in relation to safeguarding issues and whose children are at significantly increased risk of being removed into care have themselves experienced abuse and neglect (and are therefore looked after, care leavers or social care experienced young people). They are more likely than peers to become pregnant early and to continue with the pregnancy, even when it is not planned (Haydon, 2003; Dixon et al, 2006; Wade, 2008; Maxwell and Chase, 2008; Mendes, 2009; Dworsky and Courtney 2010; Matta Oshima et al, 2013; Botchway et al., 2014; Craine et al, 2014). Knight et al (2006b) emphasize the emotional consequences of being in care and how this influences decisions around pregnancy and parenthood. This research team has characterized pregnant young care leavers as highly vulnerable emotionally, experiencing feelings of rejection (by birth families and/or the care system), loneliness, stigma, insecurity, social exclusion, and marginalization.

Some care experienced young people who become pregnant report experiencing pressure from services to end a pregnancy but limited pregnancy or parenting-specific support during it (Chase et al, 2006, Dixon et al, 2006). When the child is born, some have reported feeling like they are 'under the microscope' to a greater extent than others, even other young parents (Chase et al, 2006). Beyond the 'trusted individual', not much is yet known about how best to support care experienced young people once they do become pregnant (Knight et al, 2006a, Fallon et al, 2015, Hyde and Jones, 2018), either pre or post birth.

This is particularly striking because existing research suggests that babies and children of care experienced parents are at significantly increased risk of coming into care, continuing what has been described as an 'intergenerational cycle' of abuse and care (Jackson and Smith, 2005 and Broadhurst et al, 2015). These same parents are highly likely to experience 'recurrent' care proceedings in due course in relation to any subsequent offspring (Broadhurst et al, 2014 and 2017). Substantial investment has recently been steered towards programmes designed to reduce the occurrence of recurrent pregnancies or care proceedings once a first child has been taken into care, for example 'Pause' (McCracken et al, 2017).

However, alongside this investment, Broadhurst et al (2018 and 2020) have also cast a spotlight on a growing trend of local authorities to issue care proceedings at or soon after the birth of a child to care leaver or other vulnerable young parent(s), raising concerns about what has been described as a 'typically short window for pre-birth assessment' which means that prospective parents who are known to be vulnerable do not have enough opportunity to work purposefully on their parenting skills before the child is removed from their care.

Experiences of vulnerable young parents who are not care experienced but who have nonetheless been the subject of at least one statutory (Child in Need or Child Protection) plan as a child are not as well explored in the research to date, although these two cohorts are likely to have had similar experiences including abuse or neglect and significant trauma (Broadhurst and Mason, 2014) and the recent evaluation of a similar project in Calderdale (Burch et al, 2020) suggests that they are at least as vulnerable as their care experienced peers.

These vulnerabilities and risk factors may make parenting for some young parents very challenging. However, evidence and lessons from several local studies, reports and national policies in the UK show that poor outcomes are not inevitable if early, coordinated, and sustained support is put in place (Public Health England, 2016).

A recent study conducted by Burch et al (2020) suggests that there needs to be more consistent pre-birth as well as post-birth support including assertive outreach, warm, engagement and sessional 'educative' work with parents (fathers as well as mothers where possible) including:

- Exploration of the significance of baby or child attachment and support for bonding.
- Work on domestic abuse including the impact of domestic abuse or arguing in front of babies and children, and broader work on couple and family relationships.
- Support for specific parent 'issues', most commonly substance misuse and/or emotional health and wellbeing but also personal hygiene and smoking cessation.
- Understanding risk to parents themselves, for example of (sexual) exploitation, and support to address this risk.
- Educational support and practical modelling of basic baby routines and meeting baby needs including feeding, weaning, modelling, and supporting play time.
- Support for parents 'through' social services processes including emotional support but also ongoing explanations of statutory processes.
- Support for contact arrangements with other parents or family members.
- Practical support including in relation to finances, budgeting, and money management; to access appropriate housing; with home conditions (including to understand the impact of poor home conditions); and to access nurseries.
- Support for parents to gain self-esteem not only through emotional support but also achievements such as being able to organise effective contraception, or to access college or other educational or employment opportunities.
- Support for parents to reduce social isolation and access broader community (baby) groups.

Intervention and Theory of Change

'Thriving Babies: CP' Manchester will incorporate:

- A pilot project in Manchester's North and Central localities.
- For approximately 60 families over a period of 12 months
- Delivered in family homes and children's centres.
- An early response to babies both pre- and post-birth and their (prospective) parents who have complex vulnerabilities including learning disability; mental ill-health; domestic abuse; substance misuse, or who have had a child previously removed – including care and social care experienced young people.
- A **Lead Practitioner** (mostly the child's social worker but also early help practitioners) including to ensure assessment is strength and evidence based.
- **Workers in a co-located core, gender diverse, multi-disciplinary team** including statutory and voluntary sector services will provide:
- A **'Key' Family Practitioner** (Early Help, Barnardo's or other practitioner) to build trust and provide the core evidence-based parenting and therapeutic support to individual families.
- **Peer support** for parents (including from approx. 20 Home Start volunteers).
- A **'Think Family Coordinator'** to provide connectivity with adult-focused services e.g. substance misuse, mental health.
- Close work with partner agencies to provide a **'team around the family' approach**.
- A **Resource Panel** will support identification of lead (key) worker and whether multi-service provision is concurrent or sequential.

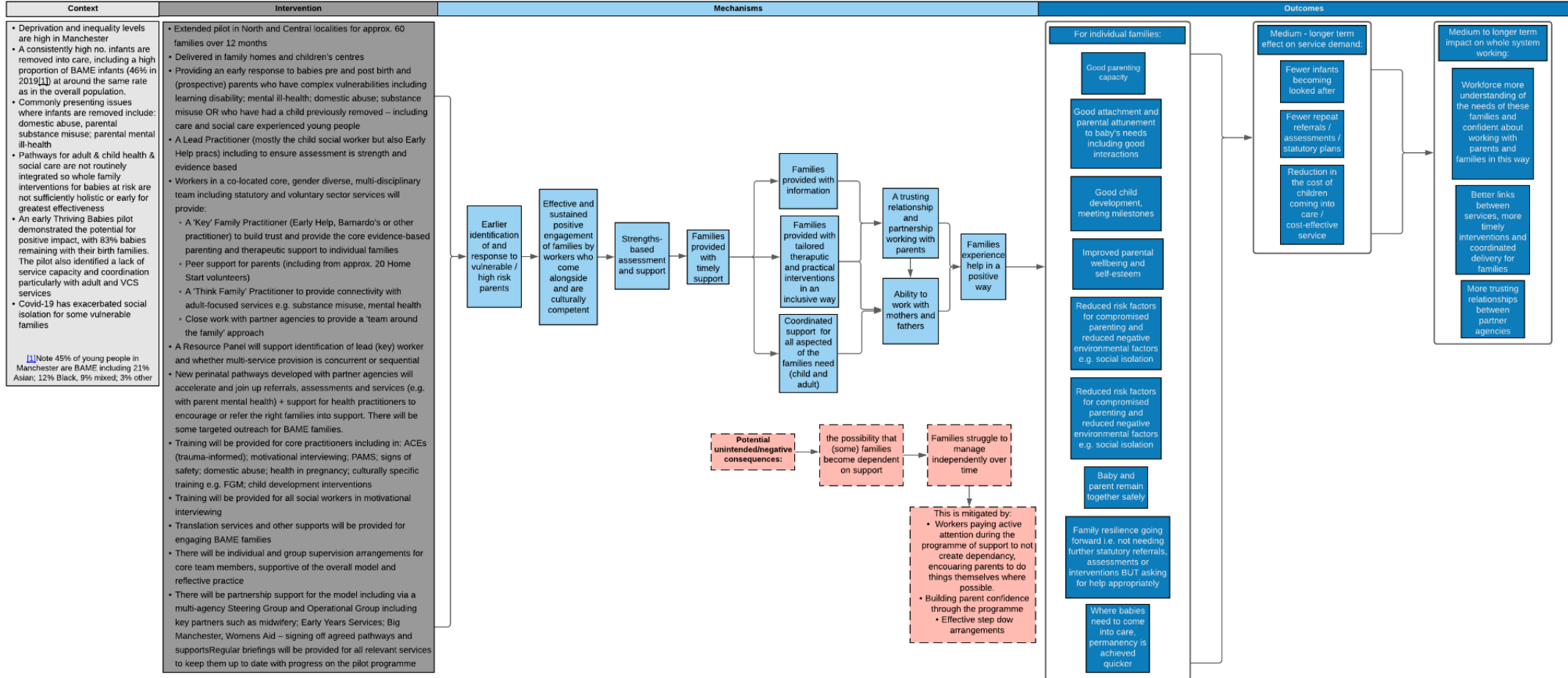
- New **perinatal pathways developed with partner agencies** will accelerate and join up referrals, assessments and services (e.g. with parent mental health) and support health practitioners to encourage or refer the right families into support. There will be some targeted outreach for BAME families.
- Training will be provided for core practitioners including in: ACEs (trauma-informed); motivational interviewing; PAMS; signs of safety; domestic abuse; health in pregnancy; culturally specific training e.g. FGM; child development interventions.
- Training will be provided for all social workers in motivational interviewing.
- Translation services and other supports will be provided to support the engagement of BAME families.
- There will be individual and group supervision arrangements for core team members, supportive of the overall model and reflective practice.
- There will be partnership support for the model including via a multi-agency Steering Group and Operational Group including key partners such as midwifery; Early Years Services; Big Manchester, Womens Aid – signing off agreed pathways and supports.

Regular briefings will be provided for all relevant services to keep them up to date with progress on the pilot programme.

A logic model for the project provides the basis for the research questions outlined below:

Logic Model

Thriving Babies: Logic Model



Research questions

The pilot aims to address the following key research questions:

1. Evidence of Feasibility: **How feasible is it to deliver this service?**
 - How has the intervention been developed and what are its key elements?
 - How are families referred into the intervention and to what extent do these referral channels 'work'?
 - To what extent has the intervention been delivered as intended? What has become adapted?
 - What variation is there, if any, in delivery across teams and localities?
 - What are the (unit) costs of delivery?
 - What are considered to be the key supports for delivery e.g. training; supervision; leadership; multi-agency working?

2. Evidence of Promise: **To what extent, how, for whom, in what circumstances:**
 - (a) **does it show promise** in identifying and engaging high-risk babies / families; and providing better coordinated, culturally attuned services (including to meet adult as well as child needs) + assessments?
 - (b) **does it / do aspects of it** (including e.g. key worker core work with the parent(s); cultural attunement / involvement of volunteers & the vol sector; multi-agency aspects) **show promise from the perspective of families, Thriving Babies: CP staff and other professional stakeholders in relation to promoting the following outcomes:**
 - ✓ Sustained positive engagement of vulnerable parents in a programme of development.
 - ✓ Secure child + key parent attachments.
 - ✓ Confident parenting (mothers and fathers).
 - ✓ Parenting capacity including parent attunement to their baby's / infant's needs.
 - ✓ More infants are able to remain safely at home in a sustainable way.
 - ✓ Increased early permanency for vulnerable infants.
 - ✓ Parent wellbeing and confidence about the future.
 - ✓ Reduced risk factors (for compromised parenting) and increased resilience factors including parents feeling able to ask for help before reaching a crisis.
 - (c) **are there any unintended consequences or negative effects** of the project?

Outcomes

Research question	Indicator	Method
1. Evidence of feasibility	The project is delivered as anticipated or in different ways, including as it progresses? E.g. have staff, volunteers and interpreters been recruited and utilised as intended; what training did they receive; how have partners engaged strategically and operationally; what in fact has been provided for families including the	<ul style="list-style-type: none"> - Co-production of a logic model - Analysis of project reports and materials + administrative data - Researcher presence at (some) steering group and team meetings - Interviews with service leads and team members - Service user interviews

	amount, frequency and from whom?	
	Consistency or variation across localities	
	Supports for delivery e.g. training, supervision, leadership, multi-agency working, interpreter services perceived to be effective by those receiving and providing them	
	An understanding of key enablers and barriers to delivery and uptake reported by staff and service users	
	(Unit) Costs of delivery	- Administrative data including financial information
	How acceptable did families find the support, including with reference to cultural acceptability, and what proportions in fact participated (of those referred)	- Administrative data (cohort number participating and declining participation or dropping out) - Interviews with service users - Case file sampling
2. Evidence of promise	To what extent are services perceived to be well-coordinated and culturally attuned to support minority ethnic groups in Manchester including through the effective use of interpreters and translation and effective, culturally attuned practice?	- Case file sampling - Interviews with service users - Interviews with staff and stakeholders
	The project effectively identifies and 'engages' the intended cohort, i.e. very vulnerable including high risk (prospective) parents into the project including a proportion pre-birth as well as post-birth, by ethnicity and whether care experienced / social care experienced	- Administrative Data collected by sites including regarding overall level of risk and in relation to key indicators - Stakeholder interviews - Service user interviews - Case file sampling
	There is sustained positive engagement of parents in the programme beyond an initial engagement stage, completing key aspects of the programme	- Administrative data regarding the whole cohort (including drop out rates) - Case file sampling - Service user interviews

	Participating children (with parents) are reported to have secure attachments at mid to end intervention and, particularly for families participating post birth, improving attachment	<ul style="list-style-type: none"> - Using the Maternal Antenatal Attachment Scale (MAAS) (Condon, J. (2015)), Maternal Postnatal Attachment Scale (MPAS) (Condon, J. (2015)) and the Paternal Postnatal Attachment Scale (PPAS) (Condon, J. (2015)) – before, during and end of intervention scores. These questionnaires are relatively short (19 ‘items’ or questions) - Service user and staff interviews
	(Key) parents are or become confident in their parenting by the end of an intervention	<ul style="list-style-type: none"> - The Karitane Parenting Confidence Scale (Crncec, R. (2008)) – start, during and end of intervention scores (Postnatally only). This questionnaire is relatively short (15 items) - Service user and staff interviews
	(Key) parents have good or improved parenting capacity including attunement to their child’s needs by the end of an intervention	<ul style="list-style-type: none"> - Administrative data regarding the whole cohort (for example relating to the need for statutory plans) - Case file sampling - Service user and staff interviews
	More infants able to remain safely at home in a sustainable way including low numbers of children needing to become looked after	<ul style="list-style-type: none"> - Administrative data regarding the whole sample (e.g. number and % of children in the cohort remaining at home at the end of the intervention, 6 months on, number of re-referrals and new statutory plans) - Whole LA data regarding the number and rate of infants becoming looked after over time - Case file sampling
	Where children are not able to remain living with birth parent(s), they experience early(ier) permanency	<ul style="list-style-type: none"> - Administrative data regarding the whole cohort including compared with rates of early permanency in previous years’ cohorts - Case file sampling - Stakeholder interviews (particularly lead professionals)
	Parents have good wellbeing and confidence about the future by the end of an intervention	<ul style="list-style-type: none"> - Service user interviews

	There are reduced risk factors for compromised parenting and increased resilience factors by the end of the intervention, including parents feeling able to ask for help before a crisis once discharged from the service	<ul style="list-style-type: none"> - Administrative data relating to the cohort (gathered by the key worker over the time of the intervention) - Case file sampling - Service user interviews - Staff and stakeholder interviews
	What are the unintended including any negative consequences of the project on families, professionals and services?	<ul style="list-style-type: none"> - Service user interviews - Staff and stakeholder interviews

Methods

Sample selection and recruitment

The main sample to be included in the evaluation is effectively the whole cohort of parents and families who become involved in the Thriving Babies: CP Project over a period of approximately 12 months – n. 60 approx.

The sample characteristics include:

- Parents who are likely to be young(er) and much more vulnerable than many other parents in Manchester.
- Parents who are likely to have experienced trauma, adverse childhood experiences including abuse and neglect as a child.
- Parents who may still be looked after or a care leaver.
- Parents who may have a learning difficulty or disability.
- Parents who have previously had a child removed from their care.
- Parents who are not white British and who speak English as a second language.

Administrative data will be collected by the Thriving Babies: CP project in relation to the whole cohort. Researchers will have access to an anonymised set of this data.

For the more in-depth evaluation activities (case file sampling, interviews), all parents will be asked for their informed consent to participate with reference to accessible information about the study and their rights which they will have the opportunity to discuss with a trusted worker as well as with the researchers themselves. All documentation and discussions will be accessible including to parents with a learning difficulty / disability or for whom English is not their first language. More information about this is provided in the section below on ethics.

Based on previous similar evaluations, the research team estimates that the majority of parents are likely to consent to participate in this way, at least in terms of the case file sampling element (approximately 50-55). Approximately 15-20 are likely to consent to participate in an interview.

Staff and stakeholder interviewees will be recruited using an information sheet that will be sent to all potential participants and followed up by researchers using email.

Data Collection

The research team will collect data via the following methods:

1. From the anonymised administrative data collected by the site in relation to the whole cohort of families involved with the project, for example: child and participant demographic data; key parent history and risk indicators; start and end intervention dates; outcome measure recordings. The outcome measure recordings will be generated as follows (with guidance provided for the key workers who are supporting their capture and recording):
 - a. For parents joining the programme antenatally, their key worker will in one of the first three visits, ask mothers to complete a Maternal Antenatal Attachment Questionnaire and this questionnaire will be completed again with the mother after three months or towards the end of the antenatal period, whichever is soonest. Soon after the birth, the mother will be asked to complete a Maternal Post-natal Attachment Questionnaire and Karitane Parenting Confidence Scale. If involved, fathers will be asked to complete a Paternal Post-natal Attachment Questionnaire. Both parents, if involved, will also be asked to complete these questionnaires plus the Karitane at three months later and at the end of the intervention.
 - b. For parents joining the programme postnatally, their key worker will in one of the first three visits, ask mothers to complete a Maternal Post-natal Attachment Questionnaire and Karitane Parenting Confidence Scale. Fathers will be asked around the same time to complete a Paternal Postnatal Attachment Questionnaire. These questionnaires will be repeated after three months and again three months later or at the end of the intervention, whichever comes first.

Parents will be able to complete the questionnaires by hand themselves or to be asked to answer the questions posed by their key worker and for the key worker to record their responses. As many as possible of parents participating in the programme will be asked to complete these questionnaires, which we anticipate will also be useful in the intervention itself. The data will be uploaded by the key worker into a prepared spreadsheet that references the parent's unique case number and no other personally identifying information about them, to enable anonymous sharing of the data with evaluators. All of the measures proposed have good psychometric qualities for the total scores, including well-reported validity and reliability.

2. From broader data relating to all infants requiring a social worker-led intervention or to become looked after across a number of years in Manchester. This data is always anonymised and published or publishable.
3. Case file sampling – in approximately 50 cases (depending on parent consent). The data from case file sampling will include a more detailed history of the child and parent(s), information from (risk) assessments and reviews; and key worker case recordings.
4. Interviews with service users (approximately 15-20 parents) – one to one interviews will be undertaken, with the parents' informed consent, in a way and at a time that suits them e.g. by Zoom, telephone or (if safe to do so) in person. These will be recorded, with the consent of the parent(s) concerned. Otherwise, hand-written transcripts will be generated. The interviews will be conducted by trained researchers with several years' experience, also in working with children and families (most are social workers). They will be tailored to participants' learning needs e.g., we will develop an accessible semi-structured interview schedule for use with parents with learning difficulty or disability, will facilitate a 'supporter', and can deploy learning disability-experienced interviewers. The interviews will also be tailored to participants' cultural background and linguistic preferences¹. We cannot promise exact cultural and linguistic 'matches', but we will do our best to achieve culturally attuned interviewee/interviewer pairings and will also deploy an interpreter, as necessary.

¹ We note that approximately 1/3 of the cohort are likely to be of BAME ethnicity including: South Asian, African, Caribbean, Kuwaiti, Romanian

5. Interviews with staff including volunteers (approximately 25) – 1 focus group meeting with the core team members (approx. 15 including managers, key workers and practice manager) to start with; followed by one-to-one interviews towards the end of the study period undertaken with staff members' and volunteers' informed consent. Most of these interviews will be undertaken by Zoom or telephone. These will be recorded, with the consent of the staff member concerned.
6. Interviews with professional stakeholders (approximately 10 including referring social workers, health visitors and midwives, providers of domestic abuse or substance misuse support, voluntary sector). One-to-one interviews will be undertaken with stakeholders with their informed consent towards the end of the study period. Most of these interviews will be undertaken by Zoom or telephone. These will be recorded, with the consent of the stakeholder concerned.
7. Data regarding the costs and unit costs of delivery will be collected from the site in a pre-prepared template with reference to:
 - a. The additional core staffing type and number by agency incurred by providing the intervention in the 12 month pilot period, with reference to the logic model.
 - b. The additional costs from the perspective of the local authority and key partners of each core element of the service e.g. senior and team management; core staff (key workers); volunteer support by % time required for the project over the 12 month period. These costs will be fully inclusive of salary, national insurance, pensions, benefits.
 - c. Non-core (additional) training costs i.e. those not included in the overheads
 - d. Overheads linked with the service + what these are e.g. buildings, administration, recruitment costs
 - e. Ancillary costs (approximate) for key voluntary sector or statutory supports that are regularly drawn into supporting Thriving Babies: CP families
 - f. The number of family units 'worked' over a 12-month period and approximate caseload numbers for each key worker

In summary, pilot data will be captured through:

Data Collection Method	Sample Size	Collection Timeline
Administrative data	Approximately 60	June 2021 – June 2022
Case file sampling	Approximately 55	June 2022
Service user (parent) interviews	Approximately 15-20	As parents and families complete interventions during the period June 2021 – June 2022
Staff and stakeholder interviews	Approximately 35	Mostly towards the end of the study period

Data Analysis

The research team will undertake analyses of the quantitative data, including standardised measures data, using SPSS. The qualitative data from interviews will be transcribed from recorded interviews and analysed thematically, with the support of NVivo using a defined coding list. The data from case file sampling collected by evaluators will have been collected

in a tailored spreadsheet including some 'drop down list' elements (prescribed responses) and some free text entries in relation to more subjective elements. This data will be analysed using SPSS (with reference to the quantitative elements) to produce descriptive statistics, and thematically with reference to the free text entries. We will also undertake pre-post intervention analyses with reference to the standardised measures, also using SPSS or 'R'.

Overall and unit costs for the intervention (per family unit) will be calculated with reference to the cost-related data collected, as above. Specifically, we will calculate the overall costs of providing the service in the first 12 months of delivery, and then divide that by the number of fully participating families across the same 12-month period. We will identify unit costs in relation to a 'first year of delivery' as well as delivery over time, with reference to the fact that there may be some start-up costs that do not repeat year on year. If appropriate, we will also identify unit costs of families starting the programme pre- as opposed to post-birth, with reference to broader quantitative and qualitative data regarding intervention duration and session intensity by group.

The quantitative data sets are relatively small and will be carefully checked and cleansed for potential errors in uploading etc. before any analyses are undertaken.

The qualitative data will be interpreted with reference to the key research questions and will consider the full range of potential responses rather than seeking to provide a measure of central tendency.

Ethics

What Works for Children's Social Care is providing an oversight of the ethical issues relating to this study and has granted approval to proceed.

The key ethical issues and mitigation are listed in the table below:

Ethical Consideration	Mitigation
Ensuring parents are not pressured into participating – give informed consent	Parent participants will be recruited into the study through early (early in their involvement with the project or control service) conversations with their key worker about the evaluation (with the support of an accessible, easy read 'information sheet' and privacy notice outlining in more depth what we are proposing to do with the data we collect from them, how we will store it and for how long etc. The information sheets and other materials will be translated into some of the key languages that are thought to be spoken by parents locally so that they can have information in their preferred language. Parents will additionally be able to contact the principal researcher for more information if they wish before giving an informed consent. This will be an initial informed consent (covering the case file sampling element plus permission to contact them about an interview as they are completing or have just completed an intervention). It will be taken on our behalf by key workers in the Thriving Babies: CP Programme. When researchers wish to approach parents about an interview (towards the end of their period with the programme), the site(s) will provide details of those who are 'ready' to be contacted and researchers will then contact the parents again (by text initially and then by telephone) to check that they understand all about what is being asked and why and that

	<p>participation in the interview is completely voluntary. They will be given that information and asked again at the start of any actual interview which will likely be undertaken by telephone or 'Zoom'.</p> <p>The procedure for gaining informed consent from prospective parent participants will be exceptionally 'held' and staged including with specific reference to the need to address the likely power imbalance in the relationship between key worker and parent or researcher and parent.</p> <p>This procedure will be undertaken on a rolling basis (as parents come into and exit the programme). At all times, parents will be encouraged to ask questions and to seek more information if they wish before agreeing to participate and/or reassured that saying no will not affect their rights in any way.</p> <p>Consent will be:</p> <ul style="list-style-type: none"> ● Brokered by the key workers at an initial stage (using the information sheet and consent forms – see attached). The key workers will work to a 'script' that emphasises the voluntary nature of participation and encourages parents to take time to think about it or seek more information if they wish. ● Checked at around the time the parent finishes an intervention –initially by their key worker. Only if they would like to proceed with an interview will their contact (telephone) details will be sent securely to researchers to make contact with them. Once again, the parent will be reassured that participation is completely voluntary. ● Checked again (with reference to the information in the information sheet and privacy notice) when a researcher makes contact with the parent to make arrangements for an interview. ● Checked finally (with reference to the information sheet and privacy notice) at the start of any pre-arranged interview. As the interviews are likely all to be undertaken remotely, i.e. by telephone or 'zoom', informed consent will be recorded by the interviewer on behalf of the parent(s).
<p>Ensuring that staff and stakeholders give informed consent to participate</p>	<p>Professional participants (including Thriving Babies: CP Managers and Staff, volunteers, and key stakeholders) will be recruited into participating in the study using a different 'information sheet' which they will be sent when being approached (mostly by email) for an interview. Their informed consent to participate will be checked at least once before an interview is conducted.</p>
<p>Protecting participants from harm</p>	<p>The key risks to parent participants from the research are emotional in nature i.e. the risk that they experience intense, perhaps negative, feelings when asked questions in interview. Whilst all efforts will be made to ensure participants feel comfortable and questions are handled sensitively, given the nature of the project it is anticipated that an interview has the potential to trigger underlying trauma resulting either from the (failed) intervention or from earlier or ongoing experiences.</p>

	<p>All interviewers have received The Institute of Public Care’s training in undertaking interviews with very vulnerable participants, including specific reference to the potential for re-trauma through interviews. They are supervised directly by the Principal Investigator (or deputy when the PI is on leave) with whom they can be in direct contact very readily. They will be alive in their questioning to the potential for distress and re-trauma. They will also be alive to the need for significant care to be taken with interviewees many of whom are likely to have vulnerabilities and experiences that may be difficult to discuss. For example, significant attention is paid in setting up the interview to finding a time and ‘space’ (online or telephone) that suits the parent. They will be encouraged to take the interview at their own pace and to take breaks when necessary, also reminded that they do not have to answer a question if they do not wish to do so.</p> <p>All interviewers will also be highly familiar with the tailored ‘distress protocol’ co-produced with the site(s) to include standard, effective processes enhanced by local information / services into which participants can be directed.</p> <p>Another risk is that parents share information with researchers that suggest someone (including them or their child) is at risk of harm. In the event that this happens, it is clear (and shared up front with participants) that researchers will have to share the information with someone – for example the Police (in an emergency) or their key worker / the service or children’s social care services in Manchester. Within the distress protocol, there is guidance for interviewers about what to do in this eventuality (i.e. contact the police and/or children’s social care services), with these instructions backed up on a regular basis through training and supervision of all interviewers.</p> <p>Finally, it is anticipated that the power balance between some parents (mothers and fathers) may be skewed or that one parent may feel pressure from the other to say or do things. The research team will be alert to this scenario and will work actively to provide non-confrontational ways for parents to contribute individually rather than as a pair.</p>
Protecting researchers from harm	<p>There is a small risk of harm to researchers through their involvement in the interviews including:</p> <ul style="list-style-type: none"> - A small risk of physical harm in the event that they are undertaken face to face (which is unlikely as a result of Covid). In the event that face to face interviews do take place, IPC has a standard process for protecting researchers undertaking family interviews, particularly those undertaken in family homes. For example, we undertake checks with the Service being evaluated regarding any known hazards or reasons that might indicate a risk for any interview prior to contacting any family regarding undertaking these. It is also a requirement that researchers inform an ‘in situ’ member of staff of the interview schedule in advance and on the day of interviews and to ‘report in’

	<p>after each interview and at the end of the day. All of our interviewers carry mobile phones which must be kept charged including for emergency use.</p> <ul style="list-style-type: none"> - A small risk of psychological harm as a result of an interview (for example one where a parent displays significant emotional distress that is difficult for the researcher to resolve). We will mitigate this risk by providing pro-active supervision of interviewers and encouragement to 'check in' with senior members of the team in the event that they are concerned about or affected by any of the interviews.
<p>Protecting parent confidentiality</p>	<p>The key measures that will be taken to ensure participant confidentiality and privacy during and beyond the end of the project include the following:</p> <ul style="list-style-type: none"> ● Ensuring that we only collect the data that is required for the evaluation. ● Not collecting any personal (identifier) data from the case file sampling activity or through the administrative data in relation to which we will undertake secondary analysis. ● Minimising the number of researchers involved in the project and ensuring that all researchers who are involved have a recent DBS check and recent training about how to collect and process personal data in the context of an interview. ● Ensuring that all our interviewers have received training on and are practiced in securely uploading recorded online interviews and transcriptions to our secure database (and immediately deleting any other versions and copies on their own computer system). ● Interpreters will be asked to sign a confidentiality agreement to ensure that parent confidentiality is assured. <p>The main limitation in relation to the otherwise complete nature of confidentiality in the context of interviews are those outlined in the information sheets for participants, namely that if they reveal something that suggests a person is at risk, researchers may have to share the information with someone else (for example the Police, Social Care Services, other). In the event of such an event, the distress protocol for researchers outlines what we will do to share information with or without the consent of the participant and in what timescales including in an emergency.</p> <p>The research team will guard against not only directly (through naming) or indirectly identifying the identity of research participants in reporting – including in main text and case studies and through written and oral reporting processes. Additionally, the anticipated parent and stakeholder sample sizes are relatively small, so the research team will be aware of and guard against the indirect identification of research participants in reporting, for example by providing unnecessary amounts of information about their personal circumstances or agency.</p>

Data Protection

The WWCS internal data protection ID reference for this project is #2124.

The data generated by field work specifically for the evaluation will be stored securely on our server and/or in a locked cupboard (used for confidential hard copy information) for the duration of the project and will be destroyed safely 10 years after its completion.

A data sharing agreement between Manchester City Council and the Institute of Public Care will be signed, setting out the basis upon which personal data will be shared in a confidential, safe manner for the purposes of: case file analysis and interviews with parents and staff. For the purpose of data protection legislation, What Works for Children's Social Care and IPC are joint data controllers with Manchester City Council as an independent controller, as they will be helping the evaluation team to access the data.

Access to the data (files) will be by named researchers only from the Institute of Public Care only on a 'need to know' basis. Access will be strictly managed by the Project Manager, Katy Burch, who has many years' experience of managing research and evaluation projects of this nature. Our standard processes also ensure that:

- Case file sampling 'findings' harvested by researchers undertaking this activity is uploaded directly (usually in spreadsheet form) onto our secure server – not onto individual laptops. We never record names (only reference numbers) or addresses or any other personal data that could subsequently reveal someone's identity. We record case reference numbers so that, in the event we identify something in the case file analysis that is of a safeguarding concern, we can contact the relevant social work team in the local authority area to alert them.
- Where personal data (such as addresses) need to be carried physically with researchers, we take care to ensure that it is not linked with any other personal data and is destroyed safely as soon as possible thereafter. We take care to record (for example on completed interview schedules) client reference numbers only (no names in the actual interview schedules either, rather initials e.g. 'C').
- Lists of participants (including their contact details) are always transferred securely including with a range of measures such as password protection, secure transfer using systems required by the site. When requesting such lists, we always remind clients of the need to send them securely.
- The Institute of Public Care uses a software package 'Panopto' to initially transcribe interviews recorded using Zoom and has guidance for staff on how to ensure that original recordings and transcriptions are uploaded as soon as possible after an interview and that all residual recordings or transcriptions are immediately deleted from their individual computer.

IPC currently holds and processes information about a wide range of data subjects for academic, administrative and commercial purposes. When handling such information, IPC, and all staff or others who process or use any personal information, comply with the Data Protection Principles which are set out in the General Data Protection Regulation (GDPR) 2016/679 and Data Protection Act 1998. In summary, these state that personal data shall:

1. Be processed fairly and lawfully.
2. Be obtained for a specified and lawful purpose and shall not be processed in any manner incompatible with the purpose.
3. Be adequate, relevant and not excessive for the purpose.

4. Be accurate and up-to-date.
5. Not be kept for longer than necessary for the purpose.
6. Be processed in accordance with the data subject's rights.
7. Be kept safe from unauthorised processing, and accidental loss, damage or destruction.
8. Not be transferred to a country outside the European Economic Area, unless that country has equivalent levels of protection for personal data, except in specified circumstances.

IPC benefits from Oxford Brookes University's systems and IT security. More information can be found using this link - <https://www.brookes.ac.uk/it/information-management/policies-procedures-legislation/>. In particular:

- We have appropriate firewalls in place to prevent unauthorised access to or from private networks.
- Secure configuration - all our systems are password protected which are held by the relevant person.
- Access control - all our systems have restricted access ensuring only an appropriate person can view relevant folders/documents.
- Malware protection - our systems are protected by Sophos.
- Patch management - Windows software is regularly patched.
- Any personal data that is carried or captured on lap top computers whilst away from the office will be subject to full encryption and restricted access.
- Any information collected in hard copy, including hand written form, will be stored securely by the researchers and transferred, as soon as practicable, to a secure unit in IPC's Bath office with only the appropriate senior researchers having access as well as officers from Oxford Brookes University and regulatory authorities for audit and monitoring processes.
- IPC has ISO 27001 'Cyber Essentials' accreditation.

IPC has a destruction policy for all confidential material, both online and hard copy materials. The key is safe destruction – to protect personally identifiable information in particular.

Ethical practices within research require informed consent to be gathered for the data subject's participation in the evaluation of the effectiveness of the Intervention and for research to be conducted using their personal data. Not granting consent does not preclude any data subject from participation in the Intervention programme.

For the avoidance of doubt, informed ethical consent shall be regarded as a sufficient safeguard for the processing of personal data including the capture and storage of personal data up to the point analysis of the data is being conducted. Once analysis is being conducted, depending on the dataset in use, a data subject is unable to withdraw consent inasmuch as this would detrimentally affect the analysis process intrinsic to the research being conducted.

Where ethical consent has been withdrawn by a data subject, where possible and dependent on the stage of the research process, each organisation agrees to discontinue the processing of the data subject's personal data and either fully delete, partially delete, pseudonymise or anonymise all identifiers associated to the data.

The point at which analysis for the purposes of research has begun the lawful basis for processing shall be in accordance with GDPR Article 6.1(e), and GDPR Article 9.2(j) and DPA18 Schedule 1 Part 1.4(a),(b)&(c) for special category data including data considered to be a protected characteristic under the UK Equality Act 2010.

Throughout the entirety of the project there are different lawful bases for processing personal data inclusive of GDPR Article 6.1(e), for the alleviation of doubt these are outlined below and shall be shared with data subjects (participants) as part of the Data Privacy Notice that will be shared with them:

Purpose	Lawful Basis for Processing
To allow Manchester City Council to identify your administrative data combined with that of others participating in the Programme to be shared with IPC for the purposes of the evaluation.	Processing is necessary for the performance of a task carried out in the public interest (“public task”).
For Manchester City Council to contact you and other parents to ask whether you would like to participate in an interview as part of the evaluation.	Participation in the programme evaluation is voluntary and you can cease to participate at any time.
To gain access to and review your child(ren)’s data within the child and family case file(s) for the purposes of conducting analysis to further inform and facilitate the development of an outcome report (all children’s data will be anonymised for the purpose of the outcome report and deleted when the data is no longer required for processing).	
To gain access to and review your data within the child and family case file(s) for the purposes of conducting analysis to further inform and facilitate the development of an outcome report (this will only happen if you have agreed to take part).	
To gather your and other parents’ insights regarding the effectiveness of the project within an interview where you have agreed to participate.	
To help build data evidence of the effectiveness of the Thriving Babies: Confident Parents programme.	
To conduct the programme evaluation and analysis based on the data collected from Manchester City Council and parents who agree to being interviewed.	
To request and capture consent (“ethical consent”) from you for agreement to participate in the programme evaluation based on ethics guidelines for ethical practices in research developed from the Nuremberg Code 1974 and the Helsinki Declaration 1964 as referenced in UK Government guidelines.	
To transcribe the audio captured from any recorded interviews we have with you and other parents.	
To identify your data, which will be deleted where possible, if you no longer agree to have data processed for the purpose of conducting the evaluation.	

Personnel

Katy Burch, Assistant Director IPC. Katy will be the Principal Investigator. With over 25 years’ experience as an evaluator, she has recently led other evaluations of similar projects

(for example of Calderdale’s ‘Positive Choices’ with very vulnerable first-time parents), of the impact of culturally attuned family support; edge of care interventions; work with young people who have experienced sexual exploitation; support for parents with learning disability and others. Katy has also led many evaluations involving Barnardo’s or other 3rd sector organisations including: of the experiences of asylum seeking, BAME, and other vulnerable young people; of innovative support for children affected by domestic abuse; and therapies.

Professor Jane Appleton, Principal Investigator at OBU. Jane is a qualified health visitor and researcher specialising in safeguarding within the context of community health services for children and families. She will work with Katy to develop the key quantitative measures, case sampling tools and interview schedules for the evaluation; submit first-class proposals for delivering a highly ethical evaluation. As a journal editor, Jane will also lead on the dissemination aspects of the study.

Vivien Taylor, Visiting Research Fellow at OBU. Vivien is a qualified social worker with over 30 years’ experience of front-line practice with children and families and research. She will deliver the case file sampling and practitioner interview fieldwork. Viv has worked in the research team for over 10 years, providing this type of fieldwork for evaluations of children’s social care innovations including edge of care, parents with LD, young people at risk of sexual exploitation; culturally attuned practice.

Dr Sue Wise, Associate Researcher at OBU. Sue has over 30 years’ experience working with very vulnerable young people and families, incorporating 10 years within the research team providing and advising on high quality interviews with children, young people, and vulnerable parents for the purposes of research and evaluation.

Roomana Ali, OBU Researcher. Roomana has 10 years’ experience of clinical practice and research in primary and tertiary health settings including in ‘family medicine’ in Pakistan, and speaks fluent Urdu, Hindi, Gujarati, and English. She will provide qualitative interviews with programme participants for the evaluation.

Dr Mamdooh Alzyood, OBU Researcher. Mamdooh is a qualified nurse and experienced researcher specialising in group and individual patient / service user interviews. He speaks Arabic and English fluently. Mamdooh will provide qualitative parent interviews and will support Katy Burch with the rapid research review and qualitative data analysis.

Dr Haggi Ansera. Qualified nurse and specialist in the experiences of Eritrean refugee families in the UK. Fluent in English, Tigrinya, Tigre (Eritrean), will provide qualitative interviews with the rest of the team.

Lindsey Coombes, OBU Associate Researcher. Lindsey is a highly experienced quantitative researcher, including of standardised measures for the purposes of evaluations of innovation in children’s services. Lindsey will lead on the quantitative including standardised measures’ analysis for this project.

Risks

The anticipated risks to the successful completion of this project that may arise and the steps that will be taken to mitigate against these are as follows:

Risk	Mitigation
(High likelihood and impact) There is not enough time in the proposed duration for	<ul style="list-style-type: none"> Continue to monitor with colleagues at What Works For Children’s Social Care

<p>this study to identify enough about its operation (for the process element) or the impact on families. The service is only just starting up in June 2021. Unexpected events, e.g. Ofsted Inspection, Pandemic may cause disruption or delays to the delivery of the programme or collection of evaluation data</p>	<p>and in Manchester what should be the timescales for this study</p> <ul style="list-style-type: none"> Collecting follow-up data as late as possible within the existing agreed timescales
<p>(Medium likelihood, high impact) Practitioners do not collect the standardised measure data from parent participants sufficiently consistently</p>	<ul style="list-style-type: none"> The production of clear guidance for practitioners about how to use these tools 'Selling' the use of these tools to practitioners including with reference to how they can assist with the intervention itself Ongoing support and encouragement to staff to use the tools including through workshops, check ins etc.
<p>(Low likelihood, high impact) Insufficient numbers of parents consent to participate in the study</p>	<ul style="list-style-type: none"> Good quality, accessible information about the study to be shared with parents Including in a language they can understand Staff adequately briefed about the importance of sharing this information with parents and to answering basic questions Direct link to the research lead for parents who are unsure or who have questions

Timeline

Phase	Timing	Lead
Refine evaluation design and logic model	May 2021	Katy Burch
Ethics application	May 2021	Katy Burch
Fieldwork starts	June 2021	
Support for Teams to collect standardised measures	June – July 2021 with regular follow ups	Katy Burch
Fieldwork Ends	May 2022	
Data Analysis	June – July 2022	Katy Burch
Pilot report	August 2022	Katy Burch

Appendices

1. [Information Sheet for Parents](#)
2. [Privacy Notice for Parents](#)
3. [Information Sheet for Professionals](#)
4. [Participation Form for Parents](#)