

NIHR135460: PHIRST Fusion Evaluation of the Nottinghamshire Healthy Families Programme Parent/Infant relationship initiative

Study Title	PHIRST Fusion Evaluation of the Nottinghamshire Healthy Families Programme Parent/Infant Relationship initiative
Study Period	April 2023 - April 2024 (12 months)
Study Design	Mixed methods
Research Aim	The overall aim of the evaluation is to explore the feasibility, acceptability and effectiveness of the Nottinghamshire Healthy Families Programme Parent/Infant relationship initiative (PIRi). It will look at whether the PIRi is perceived as an acceptable and beneficial approach from the perspectives of service users and practitioners, and to what extent the PIRi support is effective for improving reported parent-infant relationship outcomes for service users.
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Funder	This project is funded by the National Institute for Health and Care Research (NIHR) [Public Health Research Programme (NIHR131566)].
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Abstract

This protocol outlines the approach and methods that will be used in the PHIRST Fusion evaluation of the Nottinghamshire Healthy Families Programme Parent/Infant Relationship initiative (PIRi). The PIRi offers a short one-to-one intervention with families identified as being in need of support around developing interaction and connection in parent-infant relationships.

The evaluation consists of a mixed methods approach. Primary qualitative data exploring perspectives and experiences of the PIRi will be collected through interviews with key professionals (e.g., service staff involved in the referral of service users, delivery of work, and the management and commissioning of the service) and service users. Existing and routinely collected quantitative data will be used to explore pre- and post-intervention outcome measures.

The findings of the evaluation will provide Nottinghamshire Healthy Families Team with evidence which will help them understand the feasibility, acceptability and effectiveness of the PIRi. The findings will help shape current and future service delivery and help influence future commissioning intent, as well as having the potential to inform service delivery in other areas.

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1.0 Background, contextual information, and overview of the intervention to be evaluated

1.1 Background to the PHIRST scheme

The study is funded by the National Institute for Health and Care Research (NIHR) and will be undertaken by the Public Health Intervention Responsive Studies Team (PHIRST) Fusion team. The PHIRST Fusion team's approach to evaluation follows a 5-step process: brokerage, work allocation, research, reporting and knowledge mobilisation, and continuous improvement, which includes evaluability assessment methodology and embedded research with local government practitioners.

This protocol outlines the approach and methods that will be used in the PHIRST Fusion evaluation of the Nottinghamshire Healthy Families Programme Parent/Infant Relationship initiative (PIRi).

1.2 The Evaluability Assessment process

We have used evaluability assessment (EA) methods to co-develop the evaluation design. EA is a rapid, systematic, and collaborative way of deciding whether and how a programme can be evaluated, and at what potential cost. An EA was facilitated by PHIRST Fusion from October 2022 to December 2022. We undertook three workshops with key stakeholders involved with the PIRi service and wider Healthy Families Programme to explore their understanding how the PIRi works, and to map out its process and theory of change (see appendix 1).

Each workshop lasted 1.5-2 hours. During the workshops we explored:

- The underpinning aims, assumptions and context of the PIRi
- Stakeholder thoughts and perspectives around delivery outcomes (primary and secondary)
- Potential evaluation design options
- What information is needed to inform future service development and commissioning

A feasibility evaluation study was agreed as the aim of the PHIRST Fusion evaluation, with interim feedback being provided at a mid-way point (September 2023) to enable initial findings to feed into a service report for the potential re-commissioning of the PIRi programme.

1.3 Overview of the intervention to be evaluated and contextual information

It is widely recognised that the first 1001 days of a child's life, from conception to two, are a critical period of development. Parents who are aware of, and able to respond to their baby's needs sensitively in an appropriate and timely way, support early development. In recent years there has been an increased understanding of the wider and long-term impacts of parenting support interventions aimed at improving the health and wellbeing of young children. Indeed, supporting family relationships has become increasingly prominent in national policy in recent years (Pote et al., 2019).

In the aftermath of COVID-19 policies and restrictions, and the adverse impact this had on child wellbeing and development, Nottinghamshire County Council identified an opportunity to increase

capacity and expertise to support the parent-infant relationship, through the introduction of a bespoke parent/infant interaction team, housed within the existing integrated 0-19 Healthy Families Programme. The Healthy Families Programme is the delivery mechanism for the nationally mandated Healthy Child Programme which all local Authorities are responsible for commissioning.

The aim of the Nottinghamshire Healthy Families Programme Parent/Infant relationship initiative (PIRi) is to support parents with identified need to strengthen their relationship with their baby. The initiative is usually delivered to parents with babies under 16 weeks old, but the PIRi team work with parents with babies up to 12 months old. The PIRi involves the identification of families in need of support, following the completion of a Brazelton Newborn Behavioural Observation (N-BO) assessment, at either the mandatory new birth visit or 6-8 week development review, by health visitors. N-BO results and professional clinical judgement are used to make a referral to the parent infant relationship practitioners. Parents are invited to opt-in to the initiative. The initiative provides up to 6 support sessions over a range of areas around infant development, responsive parenting, parents' emotional health and wellbeing, parent-infant relationship, depending upon the specific needs of the family.

The EA sessions identified two key areas of interest:

- Qualitative exploration of key stakeholders' (staff and service users) perspectives of the PIRi programme, particularly around perspective of engagement and acceptability.
- Quantitative exploration of intervention routinely collected outcome data (pre- and post-intervention self-reported data on parent-infant relationships).

Thus, the focus of this project will be on evaluating the feasibility, acceptability and effectiveness of the Nottinghamshire Healthy Families Programme Parent/Infant relationship initiative. Using primary qualitative data, we have the ability to examine the perceived impacts of the PIRi from service users and staff, and ability to explore barriers and facilitators around service engagement. Using routinely collected service outcome data we can explore the effectiveness of the PIRi on recorded parent-infant relationships outcomes.

Based on the EA process, the evaluation will take a formative rather than summative approach, with two-way engagement between the evaluation and service teams. The findings of the research will help inform the future delivery and commissioning of the service. Further, Healthy Families Programme teams more generally will benefit from the translational knowledge produced.

2.0 Review of existing evidence

There are well-established bodies of work which show that the quality of parent-infant relationships are a salient influence upon children's health outcomes, educational attainment, and life chances (Harold et al., 2016; Cramphorn, 2020; Bywater et al., 2022; NICE, 2012). Poor parent-infant relationships are associated with various negative short- and long-term health outcomes for children, including behavioural and mental health outcomes (Harold et al., 2016; Cramphorn, 2020; Doubell et al., 2017), and there is evidence that children can be adversely affected across all ages including infancy (Harold et al., 2016). Worryingly, families living in socioeconomic disadvantage are at a greater risk of experiencing relationship difficulties (Harold et al., 2016). Thus, the importance of early intervention, and support directed to those with greatest need, is clear.

There is an established international, and growing UK-specific evidence base that parenting support interventions help improve parenting practices and outcomes for children (Gonzalez et al., 2018; Barlow and Coren, 2018; Welsh Government, 2017; Kane et al., 2007; Mytton et al., 2014), and that parenting interventions show the potential of being good value for money (Sampaio et al., 2022; Barlow and Coren, 2018). Further, parenting support interventions have been noted as producing beneficial outcomes for families from disadvantaged neighbourhoods and minority ethnic backgrounds, and are acceptable if delivered sensitively (Welsh Government, 2017; Scott et al., 2006). However, it is evident that there are numerous barriers to engaging parents in parenting support, typically around the accessibility (locations of support, and time/costs to participate), and acceptability (perceived stigma, guilt or connotations of inadequate parenting around engagement with support services) of interventions (Pote et al., 2019; Cramphorn, 2020; Mytton et al., 2014; Doubell et al., 2017). Some groups are noted as 'underserved' (e.g., the most disadvantaged, minority ethnic groups), with an acknowledged gap between parents who are in need of support, and who actually access support (Gonzalez et al., 2018; Hackworth et al., 2018; Doubell et al., 2017). It is understood that more disadvantaged groups experience multiple and intersecting barriers to service engagement, and a silent challenge of intervention delivery is identifying, and ensuring the attendance and engagement of 'at-risk' families (Moran et al., 2004; Raouna et al., 2021). Recent work has advocated for services to strengthen recruitment strategies, but also strengthen retention barriers, as the most disadvantaged groups have been noted as having high drop-off rates after initial engagement (Pote et al., 2019).

Despite growing evidence that overall parenting interventions can be effective, there is less information about what makes specific parenting interventions effective, meaningful/helpful to parents, and the features of support that contribute to acceptability and engagement (Kane et al., 2007; Mytton et al., 2014). There is a suggestion that the type of parenting support and intervention that meets parents' needs will vary (Welsh Government, 2017; Hackworth et al., 2018), and thus it may be important to work with families to develop and deliver a flexible approach which provides support and information to meet specific needs. Features of parenting interventions which have been noted to encourage engagement include the development of trusting relationships, accessible support (i.e., fits around people's lives), the ability to learn new skills presented in a non-judgmental way, ensuring sensitivity to individual practical and socio-cultural needs when accessing support (Mytton et al., 2014; Vseteckova et al., 2021; Pote et al., 2019; Doubell et al., 2017).

It has been noted as important to continue to explore the views of service users and service providers when looking at facilitators and barriers to engagement across different intervention contexts (Mytton et al., 2014; Doubell et al., 2017). This may enable a greater understanding of the specific features of an intervention which promotes its acceptability and fidelity.

3.0 Evaluation Aim and Objectives

The aim and objectives were informed by the EA process with the Nottinghamshire Healthy Families team, and the rapid literature review undertaken for the EA report.

The overall aim of the evaluation is to explore the feasibility, acceptability and effectiveness of the Nottinghamshire Healthy Families Programme Parent/Infant relationship initiative (PIRi).

The evaluation will take a formative approach, with a mid-point review being used to feedback emerging findings to help inform the future commissioning decision of the intervention.

The evaluation will explore the following research questions and associated objectives:

Qualitative

- RQ1 How acceptable and effective is the PIRi perceived to be in supporting the parent-infant relationship?
 - What is the perceived impact of the PIRi upon parent-infant relationship (e.g., upon supporting parent-infant interaction and connection)
 - What aspects of the PIRi are valued most by service providers/service users, and why?
 - What are the experiences and perspectives of service users around the support and delivery of support in the PIRi?
 - What are the perceptions of how the PIRi meets the needs of different clients/different priority groups?
 - For service staff, what are the perceived cost/workload of the PIRi?

- RQ2 What factors make it easier for service users to engage or maintain engagement with the PIRi?
 - How is the service presented/provided/offered to service users?
 - How do service providers and users understand the PIRi?
 - What do service providers and users hope for/expect from the programme?
 - What are the facilitators and barriers to delivering the PIRi service and engaging service users?
 - What are the facilitators and barriers to participating in the PIRi?
 - What factors would make the PIRi service more acceptable/engaging?
 - Where does the PIRi programme fit alongside other support services?

Quantitative

- RQ3 To what extent is the PIRi support effective for improving reported parent-infant relationship outcomes for service users?
 - What is the impact of the initiative on short-term primary outcomes for participants?
 - To what extent do parents and practitioners report parents being better able to interact with their infants?

- To what extent do parents report feeling /practitioners report observing parents being better connected to their infants?
- What are the engagement and treatment completion rates for the PIRi?
 - To what extent are parents' additional needs identified and referred?
 - Where and how do parents move to the next destination?

Objectives

- To conduct interviews with service staff and key service stakeholders
- To conduct interviews with service users
- To produce descriptive statistics that describe the key outcome measures around parent-infant relationships for those participating in the PIRi
- Create an interim/final report summarising key findings and learning about the initiative for improvement

4.0 Methods

This study involves a mixed methods approach. We will collect primary qualitative data from interviews with service staff delivering the PIRi and other key stakeholders (including service providers, managers, commissioners, Parent-Infant Relationship Practitioners, Health Visitors, associated health care service staff), and interviews with service users who have received the PIRi programme. These interviews will explore perspectives and experiences of the PIRi service (RQ1, RQ2). We will use routinely collected PIRi service data to undertake descriptive data analysis of service outputs and outcomes. Descriptive statistics will be produced to explore the extent involvement in the PIRi programme has had on reported parent-infant relationship outcomes for service users (RQ3). The qualitative and quantitative data will be brought together to help draw out learning points (overarching aim).

4.1 Qualitative data

4.1.1 Service staff interviews (n=10)

The perceived feasibility, acceptability and effectiveness of the PIRi to delivery staff will be examined through qualitative Interviews. Up to 5 service staff delivering the PIRi programme (e.g., Parent-Infant Relationship Practitioners, Health Visitors, associated health care service staff), and up to 5 professional stakeholders involved in the development and running of the PIRi programme (e.g., PIRi service managers and service commissioners, linked/partnering services), will be purposively recruited to participate in one-to-one interviews exploring their perspectives of the PIRi programme.

Recruitment will be supported by our Nottinghamshire County Council and Nottinghamshire Healthcare NHS Foundation Trust project partners who will facilitate recruitment and dissemination of study information and information sheets to potential participants. Participation will be voluntary; those who have expressed interest in taking part and who have read the information sheet and completed a consent form will be eligible to participate.

Interviews will take place either over the phone or online via a video call, depending on the preference of the participant. The interviews will be conducted by members of the research team. The interviews will last around 60 minutes.

The recruitment materials and topic guides will be developed with our Nottinghamshire County Council project partners and reviewed through PIE input. We anticipate the topic guide will explore:

- Introduction and explanation of the programme to service users
- The facilitators and barriers to delivering the PIRi programme
- Experiences and perspectives regarding recruitment and engagement of service users
- Perceptions of how the service is/can meet the needs of different service users
- Perceived outcomes of the intervention, including perceived effectiveness in improving parent-infant relationships
- Unintended consequences
- What works well/what could be improved
- Where does the PIRi programme sit in relation to other provision (including onward referral pathways)

We will complete the service staff interviews and analysis before undertaking the service user interviews. This will allow this initial analysis to inform the interview questions and topic guide for the service user interviews.

4.1.2 Service user interviews (n=15)

Up to 15 service users will be recruited. Due to the small-scale nature of the PIRi programme, we do not expect large sample sizes for service staff or service users. Due to this reason, we do not intend to attempt to recruit or stratify the sample by participant characteristics, and instead will adopt a convenience sample to ensure sufficient sample numbers.

Potential participants will be recruited through our Nottinghamshire Healthcare NHS Foundation Trust project partners. Parent-Infant Relationship Practitioners will help to recruit service users to participate in interviews; they will speak to the PIRi service users during their sessions and ask them if they are interested in taking part in an interview with the research team regarding their thoughts and experiences of the PIRi programme. Parent-Infant Relationship Practitioners will be provided with information by the research team to verbally describe the research to service users, as well as an information flyer. Those interested will be given an information and consent form by the Parent-Infant Relationship Practitioners who will also collect service user consent to share their contact details with the research team. This will be done via the sharing of an encrypted document. Potential participant contact information will be recorded on a password protected spreadsheet on the University of Sheffield secure drive. The research team will then contact the potential participants seven days after the sharing of the information sheet, via phone/email to discuss participation. This will provide potential participants time to study the information sheet and contact relevant parties to ask questions about the research/participating. The research team will again discuss the research with the potential participants, and will arrange an interview time to suit the participant. The participants will be asked to complete a consent form before participation in an interview.

This process will continue until we have an adequate number of participants. Participation will be voluntary; all service users involved in, or those who have previously received the PIRi programme, and who have expressed interest in taking part and who have read the information sheet and completed a consent form will be eligible to participate.

Interviews will take place either over the phone or online via a video call. The interviews will be organised around what is most suitable and preferred by the participant. Participants will be able to use their own personal devices to participate in the interview. A safeguarding protocol developed in collaboration with our Nottinghamshire County Council and Nottinghamshire Healthcare NHS Foundation Trust project partners will be in place for data collection. Interviews will last around 60 minutes.

The recruitment materials and topic guides will be developed with our Nottinghamshire County Council project partners and PIE group. We will also use the initial service staff data to help shape the topic guides. We anticipate the topic guide will explore:

- Understanding of the PIRi programme / Introduction to and explanation of the programme
- The facilitators and barriers to engagement and receiving the PIRi programme

- Experienced and perceived impacts regarding delivery and outcomes of the PIRi programme
- What are the most valued aspects of the programme
- Unintended consequences of the programme
- What works well/what could be improved

We appreciate that topics around parenting may be sensitive, due to perceived stigma around requiring service support. We will work with our project partners who are experienced practitioners in this field, and with our PIE group to help guide our approaches, our information sheets, and our topic guide to help approach such topics in the most appropriate way possible. Ethical protections around informed consent, confidentiality, participation rights and withdrawal from the research will be highlighted to all participants.

Service users who take part in the interviews will be offered a £30 voucher as a thank you for their time.

4.1.3. Analysis

The interviews, with the participants' consent, will be audio recorded, and transcribed verbatim. An inductive thematic analysis will be conducted, informed by Braun and Clarke's (2006) six stage thematic analysis approach. This involves: Step 1: Become familiar with the data, Step 2: Generate initial codes, Step 3: Search for themes, Step 4: Reviewing themes, Step 5: Defining themes, Step 6: Write-up. The research team will read a small selection of transcripts, and meet to review and discuss initial codes, from this we will produce a conceptual coding framework of key themes and sub-themes. The transcripts will be coded using NVivo software. The research team will meet regularly to discuss coding and to amend the coding framework as appropriate.

The data will be explored to look at the perceived feasibility, acceptability and effectiveness of the PIRi programme, and to draw out key learnings for service development and improvement.

4.2 Quantitative data

Quantitative data analysis will be supported by a staff member within the service provider organisation Nottinghamshire Healthcare NHS Foundation Trust.

The PIRi service collects the following outcome data from service users and service providers:

- a self-reported pre- and post-outcome tool
- a practitioner moderated outcome tool recorded post-intervention
- service user satisfaction survey
- infant social and emotional development measure (ASQ-SE)
- the Edinburgh Postnatal Depression Scale (EPDS).

The self-reported pre- and post-outcome tool, the practitioner moderated outcome tool recorded post-intervention, and the service user satisfaction survey, are all bespoke questionnaire-style outcome measures. These have been developed by the PIRi service staff to capture relevant feedback. Due to the specific focus and novelty of the PIRi, no existing validated tool was deemed appropriate

to capture relevant outcomes. The infant social and emotional development measure (ASQ-SE) and the Edinburgh Postnatal Depression Scale (EPDS), are both validated measures.

The collected data are stored in SystmOne and on Excel spreadsheets, this is held by Nottinghamshire Healthcare NHS Foundation Trust. Data are available from the start of the service in March 2022.

Through discussions with the PIRi service team, the following data items were identified as essential for the evaluation (Table 1).

Table 1. Data items for the evaluation.

Item	Description
<p>Number of clients accessing the service</p>	<p>Key descriptors:</p> <ul style="list-style-type: none"> • The number of individuals referred to the service + Outcome of referral <ul style="list-style-type: none"> ○ Number of accepted referrals ○ Number declined w/ reason why • Outcome of assessment <ul style="list-style-type: none"> ○ Number of accepted referrals ○ Number declined w/ reason why • Number discharged: <ul style="list-style-type: none"> ○ On completion of 6 session intervention ○ Disengaged or DNA (did not attend) • Average number of sessions received • Onward referral information <p>The number of individuals who subsequently access the service/are offered support.</p>
<p>Intervention outcome from pre/post intervention tool</p>	<p>A bespoke self-reported pre and post intervention tool developed by the PIRi team which measures across six outcomes around:</p> <ul style="list-style-type: none"> • mental and emotional wellbeing • physical health • Relationship

	<ul style="list-style-type: none"> • support network • looking after your baby • connecting with your baby <p>The post intervention tool is also moderated by practitioners, with this being recorded separately.</p>
Service user satisfaction survey	A bespoke brief survey developed by the PIRi team and completed by service users looking at perceived satisfaction with, and suggested changes to, service provision. The survey is completed anonymously.
Infant social and emotional development measure (ASQ-SE)	<p>A validated screening tool for social-emotional development completed by parents, which measures: self-regulation, compliance, social-communication, adaptive functioning, autonomy, affect, and interaction with people.</p> <p>ASQ-SE is completed at the start of the PIRi support sessions. It can then be used to compare scores when the ASQ-SE is completed by Health Visitors at a child's 1 year review.</p>
The Edinburgh Postnatal Depression Scale (EPDS).	<p>A validated screening tool for identifying postpartum depression in mothers.</p> <p>This is completed pre referral and post intervention, only where there are concerns about depression and / or anxiety.</p>

These data will help examine the impact on the PIRi programme on parent-infant relationships.

Costs / cost-effectiveness analysis were not discussed as a priority for our project partners during the Evaluability Assessment process. The PIRi is a relatively small and recently developed intervention, and our Nottinghamshire County Council and Nottinghamshire Healthcare NHS Foundation Trust project partners were more interested in a formative evaluation to help shape the delivery of the PIRi during the evaluation process. Due to this, there is a focus on the evaluation to exploring the perceived feasibility, acceptability and effectiveness of the PIRi. Cost-effectiveness analysis could be something which is considered and explored at a different stage in the evaluation of the PIRi.

4.2.2 Analysis

The quantitative data will be descriptive in nature, and will involve simple quantitative analysis.

Descriptive summary statistics will be produced that show:

- The number of service users referred and accessing the PIRi programme
- Pre- and post-intervention measures from the PIRi service outcome tool (numbers and percentage change)
- Service user satisfaction survey scores (numbers and percentage)
- Scores from the Infant social and emotional development measure (ASQ-SE), compared to scores from child's 1 year review (numbers and percentage), where available.
- Pre- and post-intervention measures from the Edinburgh Postnatal Depression Scale (EPDS) (numbers and percentage), where available.

4.3 Mid-point review

The qualitative and quantitative data will be separately analysed throughout the data collection period, before being brought together at a mid-point review. This mid-point review will generate recommendations based on the emerging data. The interim findings will be presented to our project partners to help inform service design and future commissioning intentions (see Gantt chart below). Data collection will continue following the mid-point review.

4.3 Co-production and knowledge mobilisation

Building on the EA process, our work and joint decision-making with our project partners will continue to shape our protocol, research design and knowledge mobilisation. Our collaborative approach relates to NIHR School for Public Health Research knowledge-sharing principles (School for Public Health Research, 2018).

Principle 1: clarify purpose and knowledge-sharing goals

During the evaluation, we will aim to share knowledge by working co-productively to provide evidence and insight for a range of stakeholders. The evaluation will support work by those in Nottinghamshire County Council coordinating and commissioning their PIRi programme. We are working to achieve our knowledge-sharing aim in a number of ways.

Principle 2: identify knowledge users

The most direct organisational knowledge users are the PIRi delivery team and commissioners of the programme. In addition, linked local authority teams, including data analysts, and Councillors with responsibility for policy areas that include the PIRi programme will be knowledge users within the Council. Wider knowledge users will include regional and national Health Family Programme Teams. Members of the public who benefit from the PIRi programme will be both informants in the evaluation, and knowledge users of the evaluation's findings. The evaluation will also be of interest to the academic community.

Principle 3: design the research to incorporate the expertise of knowledge users

The EA process, and ongoing discussions with members of the PIRi team, have influenced the research design. Our approach has been agreed with local stakeholders responsible for the PIRi programme,

based on what information, and in what formats, they would find helpful. Our approach will hopefully help to upskill team members, to enable them to conduct and repeat aspects of the evaluation once the project has come to a close, due to close involvement in the methodology. The formative evaluation design incorporates a formal mid-point check-in by the research team with key knowledge users, the format and scope of which will be agreed during the first part of the evaluation.

Principle 4: agree expectations

We will continue discussions with local knowledge users about options for increasing the usefulness and accessibility of knowledge from the evaluation, and to support the implementation of findings in the design and delivery of services. The outcome of these discussions will be reflected in a knowledge mobilisation plan, initial elements of which are outlined in the outputs section below.

Principles 5 and 6: monitor, reflect, be responsive

We are developing a framework to evaluate knowledge mobilisation activities, in line with SPHR knowledge-sharing principle 5, 'monitor, reflect, be responsive' (School for Public Health Research 2018). This might involve a contribution analysis methodology. These initial ideas will be worked through with local stakeholders in the PIRi programme. The aim will be to assess how far knowledge mobilisation activities contribute to the uptake, use and impact of the evaluation research, and to provide a legacy (SPHR knowledge-sharing principle 6) in Nottinghamshire, evidence of which will be generated in a post-evaluation review.

4.4 PIE (Public Involvement and Engagement)

We will ask our Nottinghamshire County Council project partners to set up small PIE groups of:

- relevant professional stakeholders (e.g., from linked-services such as Child Health services)
- service users from separate but relevant Healthy Families Programme projects (e.g., those working with Health Visitors, but not the PIRi service)

These groups will be used to help advise on the project information sheets, consent forms and topic guides. Their involvement could be especially important for understanding how to best approach and engage individuals around potentially sensitive topics of parenting support (how to approach etc.). Recruitment will be undertaken by our Nottinghamshire County Council project partners. We envisage the groups to support in a one-off capacity where they advise on the readability, accessibility and suitability of the project documents, but, depending on their availability and willingness to participate, we may work with them further to critically discuss emerging findings, advise on lay summaries and implication of findings, and on dissemination, ensuring it is appropriate.

5.0 Data management plan

5.1 Qualitative data

The University of Sheffield and Nottingham Healthcare NHS Foundation Trust will act as the data controllers for the qualitative data.

The project will generate qualitative data in the form of interview transcripts. All interviews (phone, online) will be audio recorded only using an encrypted digital dictaphone. Audio files from interviews will be uploaded to a secure, access-restricted folder on the University of Sheffield server, as soon as is reasonably possible. Once uploaded, they will be deleted from recorders. Transcription of interviews will be undertaken by the University of Sheffield School of Health and Related Research (ScHARR) transcription group. The rest of the project team, including those who may become part of the team in the future, will also have access to the study's data and will be able to comment on data at the analysis stage. Access to data will be restricted to these individuals. To enable anonymity, transcripts will have a unique identifier embedded in the filename.

Personal information will be collected as part of the qualitative research via consent forms and when arranging the interviews.

- For consent forms: participants' names will be recorded on consent forms. Consent forms will be scanned onto and stored securely in a restricted folder on the University of Sheffield's secure drive. Consent forms will be securely stored for 10 years and then deleted.
- When arranging interviews: The names of participants, contact details and times/dates of the data collection sessions will be recorded in a password protected spreadsheet on the University of Sheffield's secure drive. This information will be recorded for organising the data collection. This information will not be used in analysis or dissemination, and will only be used for project management purposes. Participant names and contact information will be deleted as soon as possible from this spreadsheet following participation of each participant.

General project documents will be stored either in a team google drive, or in a secure folder on the University of Sheffield secure Unidrive. Any personal information will be stored in password protected folders/documents on the secure drive. This includes contact information for participants, consent forms, audio recordings and transcripts.

In accordance with Research Councils UK guidance, all consent forms will be stored securely in electronic form for a period of 10 years. After 10 years, electronic documentation, and data will be destroyed via deletion from devices/servers.

Anonymised data will not be destroyed following completion of the study but kept available for future research in ORDA the University of Sheffield's Research Data Repository.

5.2 Quantitative data

Nottingham Healthcare NHS Foundation Trust will act as the data controller for the quantitative data.

As the quantitative data analysis will be undertaken by a service staff member within Nottingham Healthcare NHS Foundation Trust, there will be no transfer of data of identifiable service user data to the research team. Data will be managed internally following Nottingham Healthcare NHS Foundation Trust management policies.

Data will be anonymised before analysis. All data will only be stored on secure and restricted networks and accessed via password-protected computers and laptops, and will be accessible only to authorised individuals. No personal data will be stored on personal computers/networks.

6.0 Ethics

Ethical approval will be sought from the University of Sheffield School of Health and Related Research. Approval will also be sought from Research and Evidence Department at Nottingham Healthcare NHS Foundation Trust.

The research team will ensure that, where appropriate, issues of consent, confidentiality, safeguarding and data management are appropriately addressed across all aspects of the research process including recruitment, data collection, analysis and dissemination.

Qualitative data

Informed consent

- All participants will be provided with a verbal description of the research, as well as an information sheet detailing the project. All participants will be provided time to read the information sheet and consider participation, as well as time and research contact details to ask any questions they may have about the study/participating.
- All participants will be required to sign a consent form before participating.
- All participants will be informed of their rights to withdraw from participation.

Confidentiality

- Participants' confidentiality will be maintained throughout the project (with the limits of confidentiality being explained to all participants e.g., the need to break confidentiality if a safeguarding issue arises).
- Participants will be anonymised in all outputs. Participants will not be linked to any direct quotes.

Safeguarding protocol

- We appreciate the potentially sensitive nature of the topic. A safeguarding protocol has been developed in collaboration with our PIRi project partners. This includes having a PIRi/Nottingham Healthcare NHS Foundation Trust safeguarding contact available during all data collection times so any issues can be escalated to them. The research is looking at perspectives and experiences of the PIRi service, and will not be discussing service users parenting practices, only their thoughts on the service. The interview topic guides will be co-designed with our Nottinghamshire County Council, with input from our PIE groups around approach such topics appropriately and sensitively.
- Participation will remain confidential, but if there is a suggestion of safeguarding issues (i.e., someone is at harm), confidentiality will be broken, and Nottinghamshire County Council and the University of Sheffield safeguarding policies will be adhered to.

Data protection

- All data will be securely stored and processed in line with data protection requirements.

- All project data will be stored on the University of Sheffield secure drive, and only accessible to those within the research team members who require this.
- Any personal data will be stored in a password protected folder in the secure drive (e.g., contact information for arranging interviews, audio recordings, transcripts).

Quantitative data

Informed consent

- We follow the NHS national data opt-out policies, and will only use data from participants that have not opt-ed out. The national data opt-out is a service that allows patients to opt out of their confidential patient information being used for research and planning.

Confidentiality

- All existing routinely collected data will be anonymised before analysis.
- The quantitative findings are intended to be used internally to help our project partners processes explore service improvements and future commissioning intent. The quantitative data will therefore not be used beyond this.

Data protection

- All data will be securely stored and processed in line with data protection requirements.
- All project data will be stored on secure drives, and only accessible to those within the evaluation team who require this.

8.0 Outputs

Outputs will be informed by discussion and consultation with our project partners at the Nottinghamshire Healthy Families team.

Proposed outputs include:

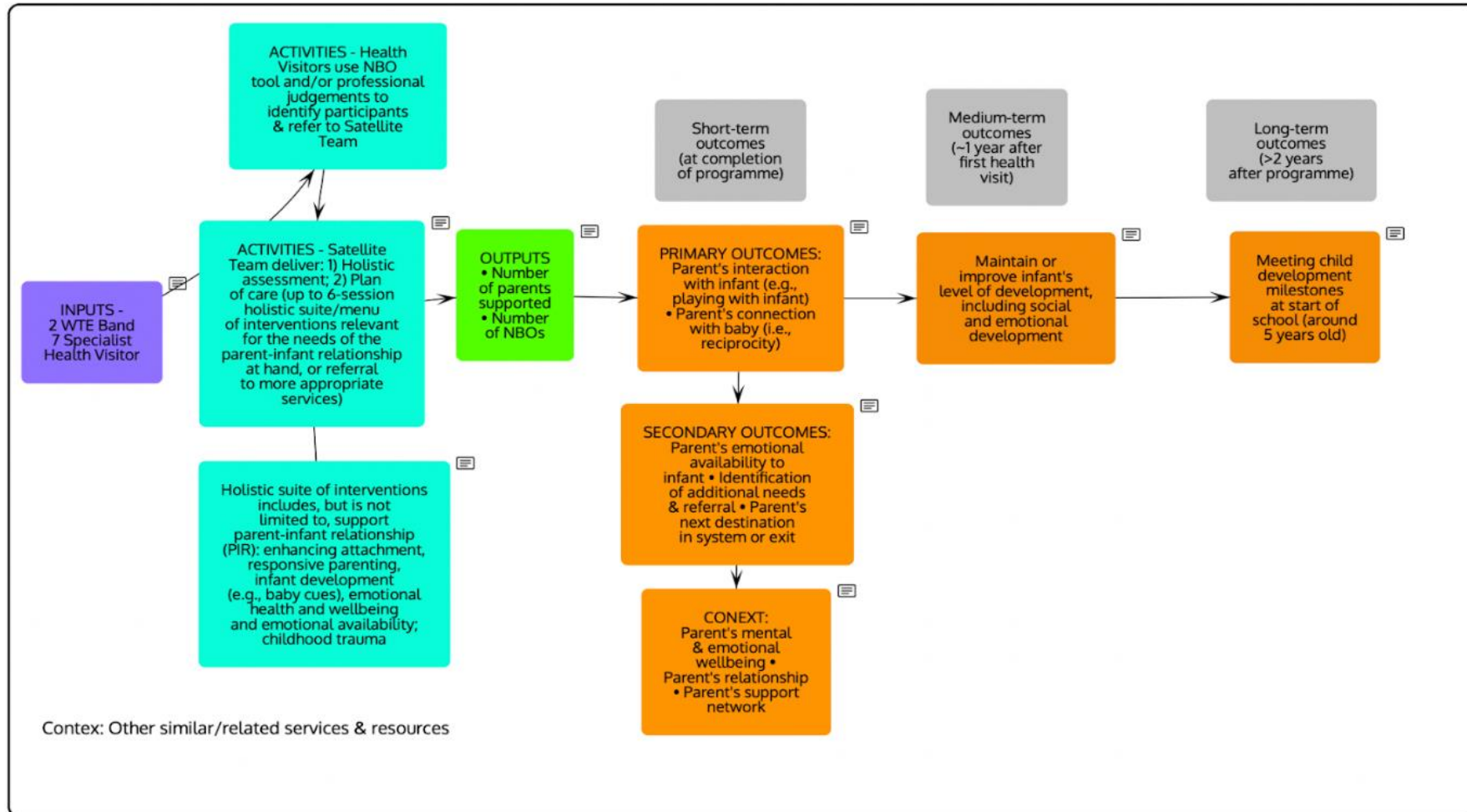
- an interim report for the Nottinghamshire Healthy Families team where we feedback emerging findings and initial learning to help shape continued development of the service, and feed into the commissioning process (and potential re-commissioning) of the PIRi programme.
- a final research project report with a brief executive summary/ short policy/research briefing paper for our project partners and for NIHR.
- public friendly summary of research and findings (potentially in the form of an infographic or animation).
- A reconvening of stakeholders from the EA process to discuss findings/implications.

We also aim to produce an academic paper, which will explore:

- Qualitative perspectives and experiences of service staff and service users regarding the PIRi initiative, and the barriers and facilitators around service engagement.

9.0 Appendix

Appendix 1 - Theory of change



10. References

Barlow, J. and Coren, E., 2018. The effectiveness of parenting programs: a review of Campbell reviews. *Research on Social Work Practice*, 28(1), pp.99-102.

Braun, V. and Clarke, V., 2006. Using thematic analysis in psychology. *Qualitative research in psychology*, 3(2), pp.77-101.

Bywater, T., Berry, V., Blower, S.L., Cohen, J., Gridley, N., Kiernan, K., Mandefield, L., Mason-Jones, A., McGilloway, S., McKendrick, K. and Pickett, K., 2018. Enhancing Social-Emotional Health and Wellbeing in the Early Years (E-SEE): a study protocol of a community-based randomised controlled trial with process and economic evaluations of the incredible years infant and toddler parenting programmes, delivered in a proportionate universal model. *BMJ open*, 8(12), p.e026906.

Cramphorn, K. 2020. Engaging parents in community-based support to develop co-parental relationships that positively impact on their children: a voluntary sector perspective, *Voluntary Sector Review*, vol 11, no 3, 373–381, DOI: 10.1332/204080520X15859270670333

Doubell L, Stock L, Acquah D, McBride EB. 2017. Inter-parental relationship support services available in the UK: Rapid review of evidence. London: Early Intervention Foundation.
<https://www.eif.org.uk/report/interparental-relationship-support-services-available-in-the-uk-rapid-review-of-evidence>

Gonzalez, C., Morawska, A. and Haslam, D.M., 2018. Enhancing initial parental engagement in interventions for parents of young children: A systematic review of experimental studies. *Clinical Child and Family Psychology Review*, 21(3), pp.415-432.

Hackworth, N.J., Matthews, J., Westrupp, E.M., Nguyen, C., Phan, T., Scicluna, A., Cann, W., Bethelsen, D., Bennetts, S.K. and Nicholson, J.M., 2018. What influences parental engagement in early intervention? Parent, program and community predictors of enrolment, retention and involvement. *Prevention Science*, 19(7), pp.880-893.

Harold, G. Acquah, D., Sellers, R. & Chowdry, H. 2016. What works to enhance inter-parental relationships and improve outcomes for children. <https://www.eif.org.uk/report/what-works-to-enhance-interparental-relationships-and-improve-outcomes-for-children>

Kane, G.A., Wood, V.A. and Barlow, J., 2007. Parenting programmes: a systematic review and synthesis of qualitative research. *Child: care, health and development*, 33(6), pp.784-793.

Moran P, Ghate D, Van Der Merwe A, 2004 What works in parenting support?: A review of the international evidence. Policy Research Bureau. London: DfES.
<https://dera.ioe.ac.uk/5024/1/RR574.pdf>

Mytton, J., Ingram, J., Manns, S. and Thomas, J., 2014. Facilitators and barriers to engagement in parenting programs: A qualitative systematic review. *Health Education & Behavior*, 41(2), pp.127-137.

NICE. 2012. Social and emotional wellbeing: early years.

<https://www.nice.org.uk/guidance/ph40/resources/social-and-emotional-wellbeing-early-years-pdf-1996351221445>

Pote, I. Doubell, L. Brims, L. Larbie, J. Stock, L. Lewing, B. 2019. Engaging disadvantaged and vulnerable parents: An evidence review. Early Intervention Foundation.

<https://www.eif.org.uk/report/engaging-disadvantaged-and-vulnerable-parents-an-evidence-review>

Raouna, A., Malcolm, R., Ibrahim, R. and MacBeth, A., 2021. Promoting sensitive parenting in 'at-risk' mothers and fathers: A UK outcome study of Mellow Babies, a group-based early intervention program for parents and their babies. Plos one, 16(2), p.e0245226.

Sampaio, F., Nystrand, C., Feldman, I. and Mihalopoulos, C., 2022. Evidence for investing in parenting interventions aiming to improve child health: a systematic review of economic evaluations. European Child & Adolescent Psychiatry, pp.1-33.

School for Public Health Research, 2018. The 6 SPHR Knowledge Sharing Principles.

https://sphr.nihr.ac.uk/wp-content/uploads/2018/10/Appendix-2_Knowledge-sharing-principles.pdf.

Scott, S., O'Connor, T. and Futh, A., 2006. What makes parenting programmes work in disadvantaged areas. The PALS trial. York: Joseph Rowntree Foundation. [https://www.jrf.org.uk/report/what-makes-parenting-programmes-work-disadvantaged-](https://www.jrf.org.uk/report/what-makes-parenting-programmes-work-disadvantaged-areas#:~:text=The%20PALS%20study%20aimed%20to,was%20a%20key%20outcome%20measure.)

[areas#:~:text=The%20PALS%20study%20aimed%20to,was%20a%20key%20outcome%20measure.](https://www.jrf.org.uk/report/what-makes-parenting-programmes-work-disadvantaged-areas#:~:text=The%20PALS%20study%20aimed%20to,was%20a%20key%20outcome%20measure.)

Vseteckova, J., Boyle, S. and Higgins, M., 2022. A systematic review of parenting interventions used by social workers to support vulnerable children. Journal of Social Work, 22(4), pp.992-1030.

Welsh Government. 2017. Parenting in Wales: Guidance on engagement and support.

www.gov.wales/docs/dsjlg/publications/cyp/140910-parenting-in-wales-guidance-en.pdf