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"Partnership for Change": Co-production and feasibility randomised controlled trial of an intervention to improve the mental health of children with a social worker

Intervention Developer	University of Glasgow and NSPCC
Delivery Organisations	NSPCC
Principal Investigator	Professor Helen Minnis and Mr Matt Forde
Protocol Author(s)	Helen Minnis, Judith Fisher, Matt Forde, Carol Atkinson, Karen Crawford, Janet McCullough, Fiona Turner, Kathleen Boyd, Sharon Graham, Alex McConnachie, Kapil Sayal, Dennis Ougrin
Type of Trial	Coproduction and Feasibility Randomised Controlled Trial
Age or Status of Participants	Phase 1, adults (stakeholders), Phase 2, infants and children aged 0-5 and their parents
Number of Participating Local Authorities	2: Glasgow City Council and the London Borough of Bromley

Number of Children and Families	30 families with children under 5 who have a Social Worker
Primary Outcome(s)	Recruitment and retention rates
Secondary Outcome(s)	>Improvement in the organisation, access, and quality of services, for children with a social worker and mental health issues. >Examination of putative primary and secondary outcomes for a future definitive RCT of IPS (see below) >Development of a parent-supported outcome measure and a parent-supported experience measure for use in a future definitive RCT >Whether it is possible to expand into new sites to conduct a successful Phase III trial.
Contextual Factors	Process evaluation will describe the many contextual factors.

Summary

Questions addressed	Can we coproduce, with parent collaborators, a new service, Infant Parent Support (IPS), to improve the mental health of children with a social worker? Can we test the feasibility of an RCT of IPS compared with services as usual?
Considered for entry	Parents of children aged 0-5 who have mental health concerns, social workers, and a multi-agency support plan.
Inclusion criteria	Any family in the Glasgow or Bromley trial sites with a child aged 0-5 years with mental health concerns, a social worker, and a multi-agency support plan.

Exclusion criteria	At the outset of the Trial there were no exclusion criteria. Over the course of Phase 1, the following exclusion criteria have emerged: - If the child has a Child Protection Plan or is on the Child Protection Register - If the family are in the process of 'stepping down' from a CPP or CPR - If the child is currently engaged in therapeutic work.
Intervention	Infant Parent Support (a multidisciplinary infant mental health team aiming to improve the mental health of children aged 0-5 with a social worker). Primary, Phase 1: Coproduction, with parents of children who have a social worker, of the IPS intervention. Secondary, Phase 1: preliminary mapping of service context. Primary, Phase 2: Recruitment and retention (at 3 and 6 months) to a feasibility RCT.
Outcomes	Secondary: >Improvement in the organisation, access, and quality of services, for children with a social worker and mental health issues. >Examination of putative primary and secondary outcomes for a future definitive RCT of IPS (see below) >Development of a parent-supported outcome measure and a parent-supported experience measure for use in a future definitive RCT >Whether it is possible to expand into new sites to conduct a successful Phase III trial.
Co-ordination	**Local:** by University of Glasgow trial office **Central**: by University of Glasgow trial office

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Background and Problem Statement

Background

In 2019/20, UK referrals to child mental health services rose by 35%, yet access to treatment only rose by 4% (Lennon, 2021) . Children with psychiatric diagnoses incur more than four times the health and social care costs than their peers (Waldmann et al., 2021) If placed in care, these costs multiply (Holmes & McDermid, 2012; Ward, Holmes, & Soper, 2008). Providing support sooner is right for the child, family, and society (Campbell, 2011). In many families where the children have a social worker, the parents have experienced challenges in their own childhoods or have neurodevelopmental conditions like ADHD or Autism. These families inevitably experience stress, often exacerbated by money or housing problems, and the stigma of living in poverty. This strains relationships and can lead to child maltreatment

and children's mental health problems that, in turn, burden families, services and society (Hefti et al., 2020). Our literature review found no trial evidence for programmes aiming to prevent child maltreatment. However, relationship-focussed interventions show promise, especially if involving child protection services (Self-Brown et al., 2017). Health and social care organisations, and governments, believe organisations should work together to support families before children are taken into care (Campbell, 2011; Gov, 2022; C. Review, 2020). A study of an intervention incorporating these elements is timely in this encouraging current policy landscape (H. Government, 2021; C. Review, 2020).

Timeline

- Phase 1 (April 2022 – February 2022): Intervention coproduction of IPS and contextual mapping
- Phase 2: (March 2023 – November 2023) Feasibility RCT-IPS v local authority (LA) run services-as-usual.

Aims

- Co-produce a new service called Infant Parent Support (IPS), developed from an existing NSPCC service called Infant and Family Teams, with parents who themselves have had children involved with social work. We will address three gaps in current service provision:
    - A relationship-focussed approach
    - Mental health and neurodiversity awareness
    - Poverty-aware practice, respectfully addressing money/housing problems
- Map and improve the current services landscape for struggling families
- Test the feasibility of a definitive Randomised Controlled Trial (RCT) of IPS.

A service like IPS, which addresses these gaps while developing and strengthening multi-agency partnerships, has never previously been tested.

Overall Research Question: Can we coproduce IPS and test the feasibility of conducting an RCT of IPS?

Methods

Phase 1 (months 0-10) Two groups of Parent Collaborators whose children have a social worker will work with professionals, from health and social care services and the judiciary to co-produce IPS.

Phase 2 (months 11-21) We will conduct a feasibility RCT of IPS to examine the potential for a future definitive RCT. Thirty families in which children have a social worker will be recruited and, after baseline assessments, randomly allocated to either IPS or services-as-usual. Quantitative outcomes will be recruitment and retention rates (three- and six-months post randomisation). A qualitative process evaluation with participating families and stakeholders will examine views of IPS and research processes.

Dissemination and impact: Throughout this study, we will produce bespoke accessible communications and develop partnerships to ensure the studies' learning is acted upon by families, multi-agency colleagues and policy makers. In a future definitive RCT, we aim to test the clinical and cost effectiveness of IPS to fill a key evidence gap and provide much needed services for this group of children and families.

Rationale for the trial

This proposal has been developed by a partnership between parents whose children have a social worker, charities, scientists, and health and social care professionals. It builds on our ongoing NIHR-funded Best Services Trial (BeST? PHR: 12/211/54), by adapting our existing Infant and Family Team (IFTs) (the Glasgow Infant and Family Team; GIFT, and the London Infant and Family Team; LIFT) to form IPS teams, to address the problem of poor mental health in children who have a social worker and reduce the risk of children coming into care.

In BeST?, those families randomised to IFT intervention receive an intensive multidisciplinary attachment-based assessment, then a tailored intervention using evidence-based therapies that focus on the parent-child relationship (NSPCC, 2022). Although BeST? will not report its quantitative findings until 2024, both IFTs have maintained stable staff groups over several years and are perceived as bringing greater influence to decision-making due to their depth of focus, provision of a trial of treatment for the family, and objectivity (Turner-Halliday et al., 2017). This builds on promising research findings from New Orleans, US, where the model on which IFTs are based originated, which suggested improvements in safety of subsequent children (Zeanah et al., 2001) and in the child's mental health in the longer term (Robinson

et al., 2012). However, it has been challenging to deliver the IFT model within the highly structured parameters of the legal system (Turner-Halliday et al., 2017). We have frequently been asked why we are not delivering IFT much earlier in the family's development – well before care proceedings, or even before child protection proceedings, are required. Intervening to support parents in building family resilience before a crisis precipitates a child coming into care – with an emphasis on understanding, respect, reducing stressors and improving resilience - gives families a much greater opportunity for change (Harvard, 2022). Focusing on families at this earlier stage chimes well with current social care (Gov, 2022; C. Review, 2020) and judicial (Judiciary, 2021) policy nationally. The English Care Review Case for Change states that "too often we are allowing situations to escalate and then being forced to intervene too late, severing children's relationships and setting them on a worse trajectory"(page 10) (I. Review, 2021) The Scottish Care Review concluded that "where children are safe in their families and feel loved they must stay – and families must be given the support together to nurture that love can overcome the difficulties which get in the way"(page 9) (H. Government, 2021).

All UK children in need of mental health services face challenges accessing them in the wake of a recent massive rise in referrals (Lennon, 2021), but children from ethnic minorities or those with a disability wait the longest (page 50) (Lennon, 2021). Parents of children with neurodevelopmental conditions (NDCs), such as Attention Deficit Hyperactivity Disorder (ADHD), Autism Spectrum Disorder (ASD) and Intellectual Disability (ID), often experience a high level of stress (Crum & Moreland, 2017). NDCs are not mental health problems - they can confer strengths as well as emotional and social challenges (Crum & Moreland, 2017) – but, if stressed, family relationships can deteriorate, and both parents and children are more likely to experience a deterioration in their mental health (Theule, Wiener, Tannock, & Jenkins, 2013). A lack of support for parents with a child who has a disability can further increase parental stress (Hsiao, 2018), increasing the risk of the parent developing entrenched psychiatric disorder and/or substance misuse (Skinner et al., 2021). Often, when families have asked for help, the response has been a child protection investigation rather than referral for treatment or support (Lennon, 2021), and judgements about parenting capacity are usually not based on validated assessments (Davies & Ward, 2012).

Parents whose children have a social worker have typically also experienced multiple adversities in their own childhoods (Broadhurst & Mason, 2017). Socioeconomic factors, such as low household income and parental unemployment, undoubtedly increase parental stress and are associated with poorer child mental health (Reiss et al., 2019). There is often a failure to address major challenges in material circumstances (Bywaters & Team, 2020), such as inadequate housing (Cross, Bywaters, Brown, & Featherstone, 2022), and little

therapeutic support is offered to improve family wellbeing (Morriss, 2018). Extreme parental stress is a key risk factor for child abuse and neglect (Hefti et al., 2020) which is likely to worsen any child mental health/behavioural problems (Dinkler et al., 2017). A vicious cycle can ensue in which the child is eventually taken into care, and this can sometimes become an entrenched multigenerational pattern (page 51) (I. Review, 2021) that indicates a “spiral of failure” on the part of services (Bilson & Bywaters, 2020).

Yet recent research suggests that, in many cases, this kind of vicious cycle could have been prevented if intervention had been provided for the family much earlier in this process (Barlow et al., 2019). Short, focussed interventions can greatly improve parental sensitivity if offered soon enough in a child’s life (Juffer, BAKERMANS-KRANENBURG, & Van Ijzendoorn, 2018). Children whose parents were supported enough to be able to provide the most sensitive care in the early years incur less than a thirteenth of the lifetime costs (including family expenditure and costs of health, education and social care and justice services) compared to children whose parents provided the least sensitive care (Bachmann, Beecham, O’Connor, Briskman, & Scott, 2022).

Maltreatment (i.e., child abuse and neglect) and subsequent care placement is profoundly costly for the children involved (Waldmann et al., 2021) and for their families (Holmes & McDermid, 2012). It is also profoundly costly for society (Soper, Ward, Holmes, & Olsen, 2008): children with psychiatric diagnoses incur more than four times the health and social care costs compared to children who do not have a psychiatric diagnosis (Waldmann et al., 2021) and, if children are placed in care, these costs multiply(Holmes & McDermid, 2012; Ward et al., 2008) - yet there are wide cost variations across the UK (Ward et al., 2008). “It costs more to place a child in the care of a local authority than it does to send a child to a top boarding school” (Ward et al., 2008).

For over a decade, the number of children on child protection plans or in care in England has grown year-on-year (Bilson & Bywaters, 2020). It is highest in local authorities where there are high levels of social deprivation and where local authorities have been rated as inadequate or needing improvement (Bywaters & Team, 2020). In Scotland, there has been a year-on-year reduction in the number of children coming into care (S. Government, 2018), so upward trends are not inevitable.

New multi-agency systems to build resilience in struggling families are urgently required. Previous attempts to develop effective interventions to reduce maltreatment in high-risk families have largely failed (Euser, Alink, Stoltenborgh, Bakermans-Kranenburg, & van IJzendoorn, 2015). We therefore propose to develop and test a new service called Infant

Parent Support (IPS), addressing three important missing components of previous interventions:

- A relationship-focussed approach to comprehensive understanding of family functioning: The IPS intervention will use the relationship-focussed infant mental health approach, already used in our IFTs, to create a comprehensive understanding of the child's developmental status and needs, the nature of the key caregiving relationships and the strengths and needs of the parents. The IFT comprehensive attachment-focused assessment provides a foundation for relationship-focused treatment. The only example of such an infant mental health approach in the UK within the context of children's social care is IFT (Hogg, 2019), which, until now, has focused on children in foster care. It uniquely incorporates a focus on the parent's own needs and, through intervention, tackles the unresolved legacy of their childhood experiences that impedes attuned parenting. It aims to interrupt the cycle of intergenerational transmission of problems, enabling parents to make a change that might improve the safety of subsequent children (Zeanah et al., 2001) and the child's mental health in the longer term (Robinson et al., 2012)
- Mental health and neurodevelopmental awareness: People who have experienced maltreatment are at increased risk of having neurodevelopmental conditions (NDCs) (e.g., ADHD, ID, and ASD). Maltreatment does not appear to cause these conditions (Dinkler et al., 2017): NDCs are highly heritable (Pettersson, Anckarsäter, Gillberg, & Lichtenstein, 2013). In our trial of a parenting intervention for parents of children with ADHD, more than 40% of parents also had symptoms of ADHD (Chief, 2017). Symptoms of children's NDCs (e.g., hyperactivity, impulsiveness in ADHD, insistence on routines, sensory sensitivities in ASD) and associated temper tantrums can make parenting very challenging – more so if the parent has similar difficulties. Additional child and parental mental health problems, such as anxiety and depression, can result (Green et al., 2021; Peasgood et al., 2021). Yet the presence of childhood adversity delays diagnosis of NDCs – probably because the child's behaviour problems are regarded as being caused by "social" (Minnis, 2021) issues rather than warranting an assessment by a mental health team. Identifying NDCs is crucial: treatment of ADHD is associated with reduced risk of poor outcomes such as crime and substance misuse (Mohr-Jensen, Bisgaard, Boldsen, & Steinhausen, 2019), and autism-friendly approaches can help people with ASD to thrive (Fernell, Eriksson, & Gillberg, 2013)
- Poverty awareness: Poverty interacts with psychological and social factors, acting directly through material hardship and structural inequalities (Cuevas et al., 2020), and indirectly through parental stress, health, and poor environments (Bywaters et

al., 2016). Yet assessments in child protection do not routinely address this (Bywaters et al., 2018; Bywaters, Featherstone, & Morris, 2019). Recent reviews suggest that reduction in inequalities must underpin future child welfare provision (Hood, Goldacre, Grant, & Jones, 2016; Webb et al., 2020) and that improving material circumstances can improve children's mental health (Zimmerman et al., 2021). A poverty-aware approach recognises hardships and insecurity faced, including structural inequalities such as classism and racism, their impact, and works with families to improve their circumstances as a key factor in their attempt to be the best parents that they can be (Krumer-Nevo, 2016). Professionals' own values and beliefs about poverty can compound stigma and exclusion, and reinforce shame felt by families (Gupta, Featherstone, & White, 2016). Shame, in turn, reduces trust in others and is associated with problems achieving closeness in relationships (van Schie, Jarman, Reis, & Grenyer, 2021). By enabling professionals to treat families with empathy and respect (Saar-Heiman & Gupta, 2020), a poverty aware approach is therefore likely to counter feelings of shame and set the foundation for effective relationship-based interventions (Krumer-Nevo, 2016). We will provide whole team training to the IPS team members in poverty awareness, using a programme developed by the NSPCC and the Joseph Rowntree Foundation, which incorporates language and tools developed by the JRF designed to counteract stigma and shame (Barrett, 2021).

Health and social care organisations, and the governments who fund them, believe agencies should work together to support families before children are taken into care (C. Review, 2020; I. Review, 2021). In response, we plan to co-produce (with parents whose children have a social worker) the IPS intervention, and to improve the organisation, access, and quality of services, for children with a social worker and mental health issues. Our future intention is to conduct an RCT to test the effectiveness and cost effectiveness of IPS.

Review of existing and current evidence: In 2015, Euser and colleagues published a systematic review and meta-analysis entitled "gloomy picture: a meta-analysis of randomized controlled trials reveals disappointing effectiveness of programs aiming at preventing child maltreatment" (Euser et al., 2015). In May 2021, we updated the Euser systematic review (Euser et al., 2015). We are currently updating and broadening this by including reviews and protocols of ongoing studies and including studies that measured indicators or increased risks of child maltreatment as well as actual maltreatment (completion planned for November 2021). We searched for forward citations of the Euser paper and the databases PubMed, Cochrane Library, PsychINFO, Social Care Online and NHS Evidence, using the search terms: "Randomised controlled trial (RCT)" [Keywords]

AND "Child abuse" [Keywords] AND "Preventive action" [Keywords] OR "Provision of services" [Keywords] OR "Preventive work" [Keywords] OR "Intervention" [Keywords] OR "Evaluation" [Keywords] AND 2012...2021 [Year]. We found five additional relevant published randomised controlled trials (RCTs) (Calheiros, Patrício, Graça, & Magalhães, 2018; Ondersma et al., 2017; Self-Brown et al., 2017; Shenderovich, 2018; van der Asdonk et al., 2020) and three protocols of relevant ongoing trials (Kliem et al., 2018; Mattheß et al., 2020; Nekkanti et al., 2020). Only one ongoing study addresses parental mental health (and is restricted to postpartum mental disorder) (Mattheß et al., 2020). Similar to Euser's original findings, none of the trials provide evidence of lasting differences between treatment and control groups - although there are suggestions of improvements in parenting behaviours (Whitcombe-Dobbs & Tarren-Sweeney, 2019) and rates of maltreatment when relationship-focussed interventions were used, especially if involving child protection services (Self-Brown et al., 2017). A study incorporating these elements would therefore be timely, especially in the encouraging current policy landscape (H. Government, 2021; C. Review, 2020).

A new approach should therefore:

- use an infant mental health approach to offer struggling families a thorough relationship-focussed assessment
- identify any NDCs and/or mental health problems that parents and child(ren) might have
- identify any material challenges families are facing – and use this information to respectfully offer timely, poverty-aware, relationship-focused interventions.

A service like IPS, that uses a relationship-focussed approach to child and parent mental health, neurodevelopmental and money/housing problems, has never been tested before.

Both the current state of the evidence and a uniquely favourable UK policy landscape makes this research timely. English and Scottish Governments have expressed urgency about the need to make real change in children's social care services:

The Case for the English Care Review states simply 'We need to do more to help families (I. Review, 2021) (page 10). It identifies the multiple adversities that many parents face and calls for action to address inequalities. The Scottish Review drew similar conclusions, stating that "it is impossible to review Scotland's 'care system' without properly considering the pervasive impact of poverty" and that we must ensure that "providing support… is non-stigmatising for families and is critical to building relationships with trusted professionals which can ameliorate the impact of poverty" (C. Review, 2020).

Research has suggested various ways that practitioners might try to prevent children coming into care. These include programmes aiming to reduce recurrence of abuse (Vlahovicova, Melendez-Torres, Leijten, Knerr, & Gardner, 2017), strengths-based, safety-oriented approaches to child protection (Sheehan et al., 2022), and intensive approaches for use when a family is in crisis (Al et al., 2012; Bezeczky et al., 2020). Yet the strength of evidence for these approaches is weak to moderate and/or studies have been conducted in areas such as the USA, with very different social care contexts compared to the UK (Care, 2022).

Recent research syntheses (Bywaters & Team, 2020; Cross et al., 2022) have suggested new ways in which elements of previous interventions might be combined to provide a holistic poverty-aware approach (Saar-Heiman & Gupta, 2020) to supporting struggling families.

Intervention and Theory of Change

Partnership for Change is an Intervention development and feasibility study undertaken in two stages.

Phase 1 – Intervention Coproduction

We will form Parent Collaborators groups (two groups of 4-5 parents with experience of child and family social work, one group in Glasgow, one in London) led by our co-investigator with lived experience and Patient/Public Involvement (PPI) lead. Parent Collaborators (PCs) will play a PPI role. A group of around twenty multi-agency professionals including social workers, social work managers, members of the existing IFTs, primary care (e.g., health visitors), early years education, mental health clinicians working in Infant Mental Health and Adult Mental Health teams will also contribute their views to the coproduction. Groups will draw on wider expertise from various stakeholders where necessary.

The coproduction work will be to refine what has gone before to assess its fit within this new context and optimise its usefulness for families in which the child has a social worker. This is an interative process, so this could refer to any aspect of that process e.g. draft job descriptions for the IPS team could be revised based on feedback from clinicians and parent collaborators and then revised again once power dynamics are further discussed; decisions

about the balance of consumables spent of professional and parent collaborator travel could be revised once a development day has been held and certain aspects were found to be less than ideal etc. The first task will be for intervention team members (Infant Parent Support team) to become familiar with our draft Logic Model and to work with the project team to challenge and refine it.

The Logic Model is explicit about:

- the problem that the intervention seeks to address, including contextual factors (Logic Model part A) and the mechanisms through which these problems arose (part B)
- the mechanisms through which IPS aims to achieve change - including the assessment and treatment components of the intervention (part C)
- the intended outputs and outcomes of the intervention (parts D and E).

At subsequent sessions, the PCs and professionals' groups will work together through each of these aspects in turn to consider how best to optimise them for IPS. To achieve this, the Parent Collaborator groups will host small workshops, likely fortnightly, inviting the relevant members of the wider Intervention Coproduction Team to explore and discuss each aspect of the intervention in turn. These workshops will use tried and tested techniques, agreed in advance with Parent Collaborators, to ensure power dynamics are managed to ensure everyone's voice is heard. One such technique is the "golden silence" method in which a topic is briefly described on paper or video at the start of the meeting and, instead of discussing directly, ideas are first submitted anonymously (e.g., using post-it notes or via a web package e.g. https://www.mentimeter.com). Learning from sessions will be captured in minutes or, if deemed appropriate, through focus groups.

Topics for workshops will include (but will not be limited to):

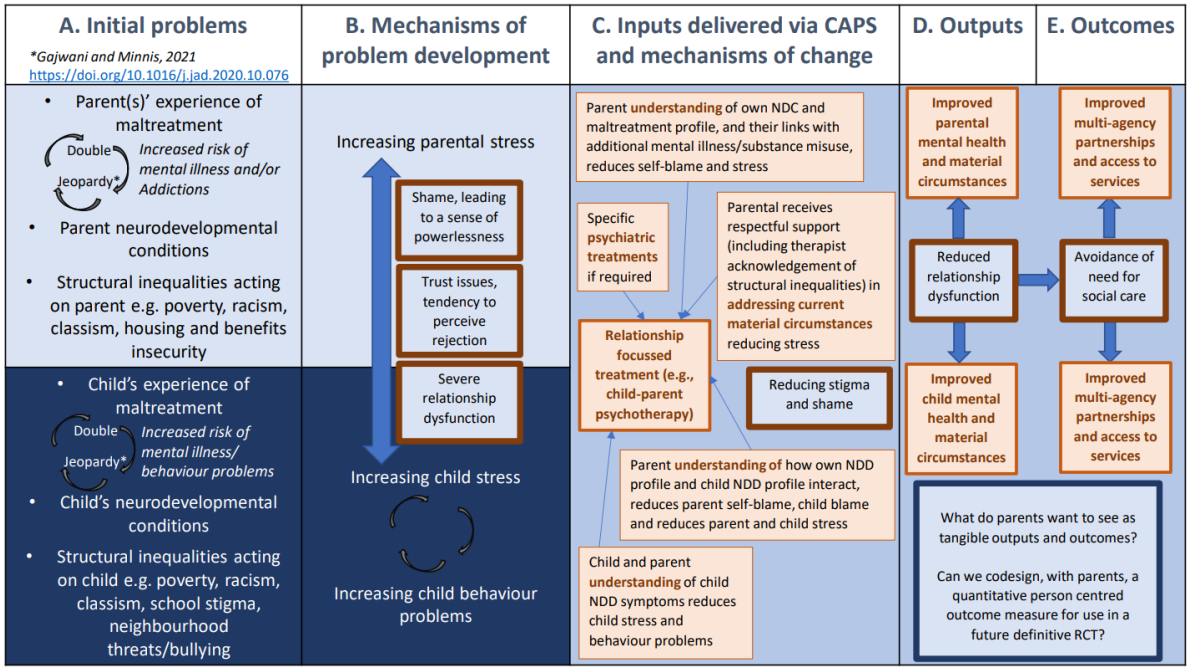
- Establishing and maintaining approaches to codesigning the IPS intervention such as: establishing principles for working together; appropriate language and communication styles; ways of working collaboratively with service users to ensure shared objectives
- Exploring the mode of delivery of each components of IPS
- Putting forward views, based on experience of receiving/ delivering services in the past, on optimal ways for IPS staff to work effectively together and with families
- Challenging entrenched approaches to service delivery - why do services/ practitioners deliver things the way they do? What are the barriers to service users being able to effectively engage and get the maximum benefit?
- Discussing optimal duration, intensity of support from IPS

These topics will be revisited iteratively until all are satisfied that each aspect of IPS delivery has been considered. The intervention will then be ready for feasibility delivery. As participating families engage with IPS in Phase 2, we may learn of additional barriers and issues, even before we have conducted any qualitative/quantitative research. Close communication between Parent Collaborators and delivery professionals will allow tweaks to engagement processes, aspects of delivery etc. to be achieved quickly. Parent-collaborators will therefore be invaluable in facilitating agile improvement of IPS throughout.

Phase 2 - Feasibility RCT

For our feasibility RCT, we aim to recruit 30 families living in Glasgow or London, who are likely to benefit from IPS: families with problems severe enough that IPS will offer tangible benefits yet whose problems are not so entrenched that change is impossible, with an inclusive approach to social class, ethnicity, gender, sexuality, and disability. We wish to target families whose children are 'in need' (or the Scottish equivalent), do not yet have a child protection plan (are not yet on the child protection register), but are at risk of formal child protection proceedings. Just over three in every 100 English children are described as being 'in need', i.e., 'a child who is unlikely to reach or maintain a satisfactory level of health or development, or their health or development will be significantly impaired without the provision of children's social care services' and 13% of these children (~4 in every 1,000 English children) have a child protection plan (Gov, 2021). The signal for children likely to transition from "in need" to "child protection" is often a need for multi-agency support. Our preliminary plan for defining our target population is, therefore, children in need (or Scottish equivalent) who also have at least one additional service involved e.g., child and adolescent mental health services, paediatrics, or educational psychology and where a parent and/or child has a mental health problem or neurodevelopmental condition identified at initial trial screening. Further refining the definition of our target population will be a task of the qualitative process evaluation in Phase 1 of the research, and continued refinement might also be necessary during Phase 2.

Theory of Change



Impact Evaluation

Research questions

The pilot aims to address the following overarching research questions:

- Can we coproduce, with parent collaborators, a new service, Infant Parent Support (IPS), aiming to improve the mental health of children with a social worker?
- Can we test the feasibility of an RCT of IPS compared with services as usual?

Evidence of feasibility

- Can sufficient numbers of families be recruited and retained such that a full-scale RCT is likely to be feasible?
- Can the project expand to include new partners?
- What is the profile of services-as-usual (SAU) (including infant/adult mental health; social care statutory processes) at each site and can care pathways be improved?

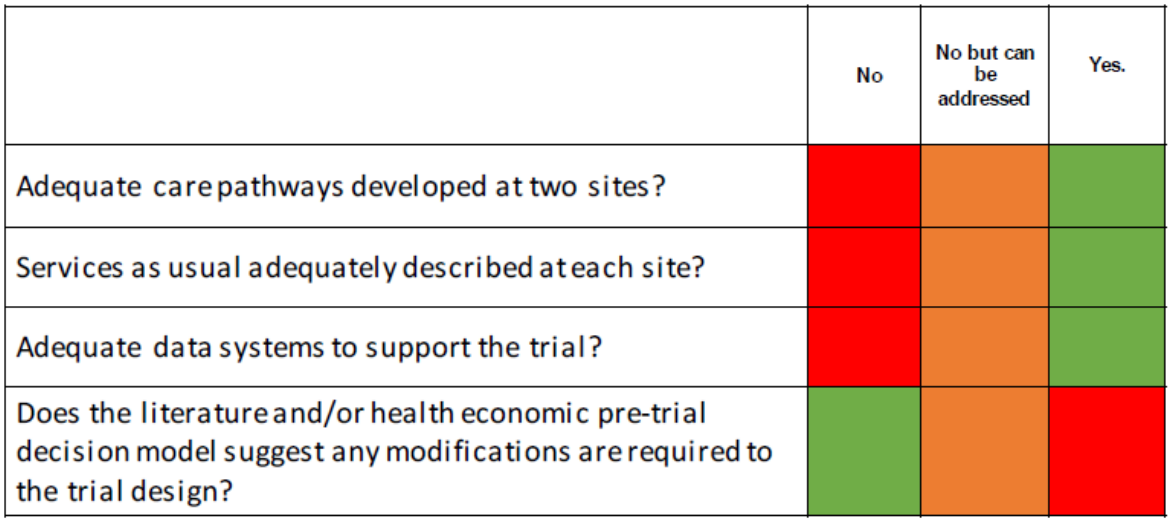
Evidence of promise

- What outputs and outcomes would families like to see from IPS (see Logic Model sections D and E) and can we use this information to develop a "parent-reported outcome measure" (PROM) and a "parent-reported experience measure" (PREM)?
- How acceptable are trial assessments and interventions to parents and professionals?
- What are struggling families' experiences of, and barriers/access to, mental health services?

Readiness for trial

Before moving on the Phase 2, we will check that the stop: go criteria for moving on to a feasibility RCT have been met. These include: Are care pathways between child and adult health and social services adequate to ensure safe delivery of IPS (i.e., sufficient multi-agency communication and planning to ensure child safety) in the contrasting legal/social care contexts of Glasgow and London? Have we sufficiently described services-as-usual in each of the trial sites (Glasgow and Bromley) to be confident about the care pathways and to recruit to the trial? Have we developed or accessed adequate data systems to allow the trial to proceed? Is there any new literature that has emerged since our feasibility RCT was originally designed that suggests we should do things differently than we had originally intended?

Figure – stop:go criteria for moving on to the feasibility RCT



Cost Evaluation

- What are the likely resource requirements (number of sites, duration) to conduct an adequately powered randomised trial?

Outcomes

Research Question	Indicator	Method
Can we coproduce, with parent collaborators, a new service, Infant Parent Support (IPS) aiming to improve the mental health of children with a social worker?	Continued involvement of parent collaborators and successful ongoing collaboration with clinicians and other stakeholders.	Phase 1 coproduction as described above.
Can we test the feasibility of an RCT of IPS compared with services as usual?	Are 30 eligible families able to be identified and randomised across Glasgow and Bromley?	Employment of recruitment coordinators in Glasgow and London who will liaise with social care colleagues to identify eligible families (see further detail under Methods, below).
Are the putative measures for a future Phase 3 RCT acceptable to families?	Employment of recruitment coordinators in Glasgow and London who will liaise with social care colleagues to identify eligible	Qualitative research

	families (see further detail under Methods, below).	
		Co-production of referral pathways
How acceptable are trial assessments and interventions to parents and professionals?	Parents provide feedback on their experience of research assessments. Rates of engagement with IPS and follow-up retention rates.	Qualitative interviews with parents and professionals carried out 3-6 months after randomisation. Recruitment and retention rates will be measured at recruitment and 3-6 months post-randomisation.
What are struggling families' experiences of, and barriers/access to, mental health services?	Families share their experiences of barriers and access to mental health services	Qualitative interviews carried out in Phases 1 and 2 of the study.
Are there adequate data systems to support the trial?	A robust DPIA is in place	DPIA developed by the research team and reviewed by WWCSC and the University of Glasgow Data Protection team
Does the literature and/or health economic pre-trial decision model suggest any modifications are needed to the trial design?	No new relevant studies emerging in the literature.	Systematic literature review carried out by NSPCC and supervised by Helen Minnis – currently being written up for publication.

Methods

Sampling

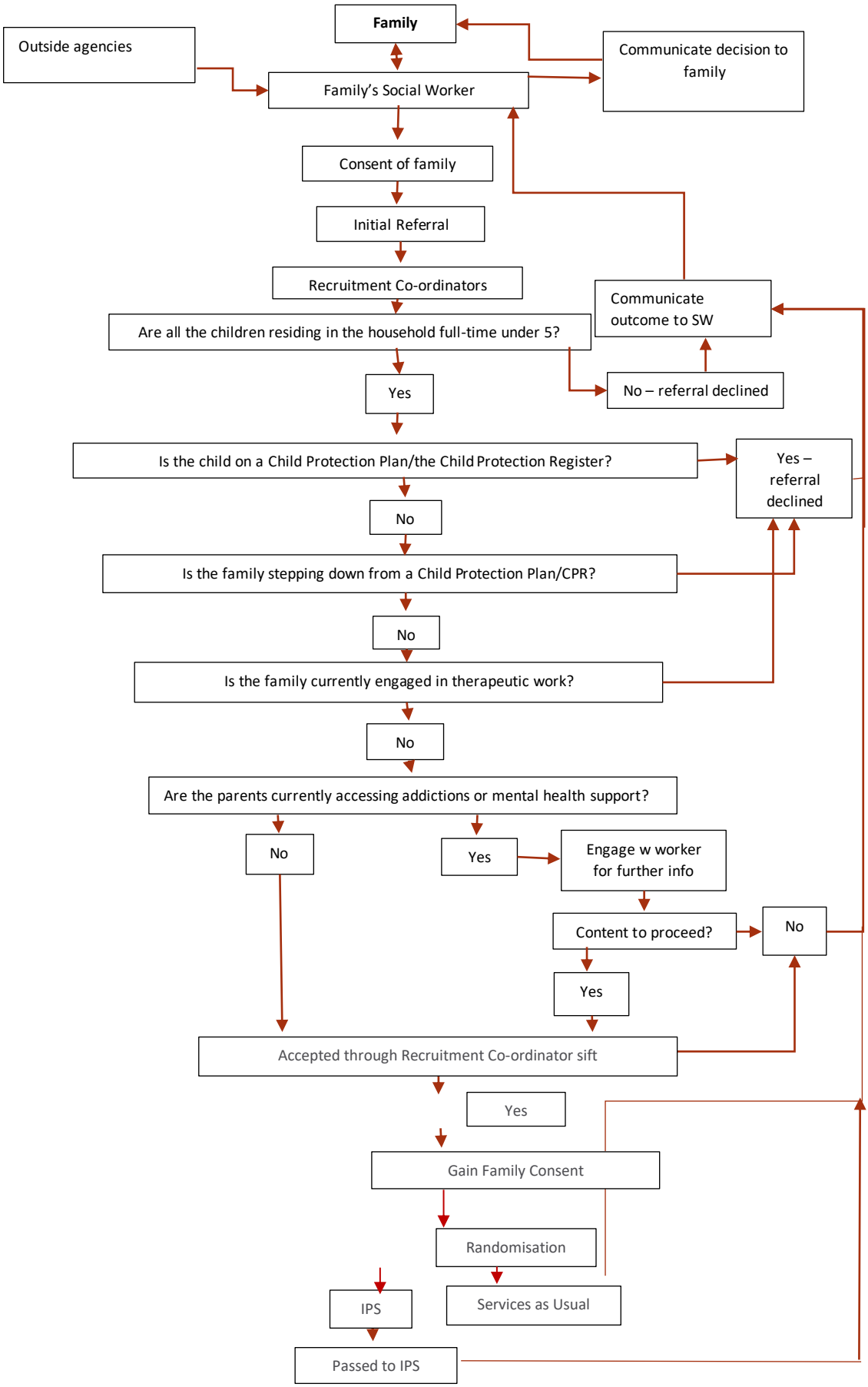
We intend to recruit a sample of 30 families in Phase 2, 15 families will be randomly allocated to each group. This number will be ideal for allowing us to investigate participant experiences and trial processes in detail. Since the purpose of the feasiblity RCT is not to examine quantitative outcomes other than recruitment and retention rates, the information that we gather about the putative outcome measures for a definitive RCT, from this and other studies, will inform the sample size calculation for a future definitive RCT. Therefore, formal power calculations are not appropriate for this largely qualitative study. In our ongoing BeST? trial, that compares IFTs with services-as-usual, we have been successful in recruiting more than 50% of all families with children under age five coming into an episode of foster care, and we have not found any systematic biases in our recruitment compared to the base population. We have managed to retain 72% of these families over 2.5 years. This has been achieved through our partnership approach (Turner-Halliday et al., 2018): i. utilising the expertise of a senior social work manager co-investigator (in this current proposal - JMcC), and ii. employing experienced social workers as Recruitment Coordinators (RCs). These RCs have limited access to local authority data systems (so can target the eligible population), are experienced in assessing capacity and ensuring families are fully informed before deciding whether or not to consent, and their seniority and networks encourage other social workers to engage in the research. We would use similar successful strategies in this proposed study.

During Phase 1, we will work with the social work representatives from each of the two participating local authorities, Glasgow, and Bromley, to establish how our RCs will establish our target population. The parents of any child in these local authorities who meets our criteria and is aged 0-60 months will be approached by our RCs to discuss the study. If they consent, families will be invited for baseline research assessments (usually remote but face-to-face assessment if preferred). Thereafter the family will be randomised to IPS or services-as-usual and followed up at six months post randomisation. Participants will receive a voucher for taking part in research interviews. Parent Collaborators will help us develop ways of supporting all participants including any who withdraw. We will also draw on existing assets such as NSPCC helpline and Local Authority partners for any safeguarding concerns. Further purposive sampling from this group of 30 families will allow us to explore specific questions arising in our qualitative process evaluation.

Trial Recruitment

- Trial population
- Families in the Glasgow or London (Bromley) trial sites where all children in the household are aged 0-5 years and the family has an allocated social worker plus a multi-agency support plan.

- Inclusion and exclusion criteria
- Inclusion criteria: Families in the Glasgow or London trial sites where all children in the household are aged 0-5 years and the family has an allocated social worker plus a multi-agency support plan.
- Exclusion criteria:
    - If the child has a Child Protection Plan or is on the Child Protection Register
    - If the family are in the process of ‘stepping down’ from a CPP or CPR
    - If the child is currently engaged in therapeutic work
- Identifying and approaching participants
    - Pathways into trial have been defined collaboratively with Parent Collaborators, local authority partners in Glasgow and Bromley and the IPS teams and are illustrated on the following page.


Family
Outside agencies
Communicate decision to family
Family's Social Worker
Consent of family
Initial Referral
Recruitment Co-ordinators
Communicate outcome to SW
Are all the children residing in the household full-time under 5?
Yes
No – referral declined
Is the child on a Child Protection Plan/the Child Protection Register?
Yes – referral declined
No
Is the family stepping down from a Child Protection Plan/CPR?
No
Is the family currently engaged in therapeutic work?
No
Are the parents currently accessing addictions or mental health support?
No
Yes
Engage w worker for further info
Content to proceed?
No
Yes
Accepted through Recruitment Co-ordinator sift
Yes
Gain Family Consent
Randomisation
IPS
Services as Usual
Passed to IPS

Potential participants may be identified by social workers or other support services, with the referral needing to be submitted by the family's social worker. Consent will be required from the family for their referral to be submitted. Recruitment Coordinators will work with organisations to identify the target population, screen for eligibility and facilitate referrals to the study. Potential participants will then receive a participant information sheet and consent form by mail, and a follow-up telephone call from the trial office to review the information sheet and respond to any comments or questions.

Screening for eligibility

Referring Social Workers & Research Coordinators will screen potential participants for eligibility using a list of eligibility criteria provided by the trial office. To ensure inclusion/exclusion criteria are met, the researcher will also confirm potential participants' eligibility during the first phone call (see below).

Informed consent

Potential participants identified by the referring Social Worker will receive a participant information sheet (PIS), Privacy Notice and consent form and will be asked to give their consent before a referral is passed to the study. Following randomisation, potential participants who have been selected for inclusion in the trial will receive an information sheet, Privacy Notice, and a consent form for participation in the trial. A follow-up telephone call from the trial office will take place within one week of receipt of PIS. Having reviewed the information sheet during this phone call, consenting participants will be asked to return the freepost consent form and an appointment will be made to collect baseline data by the UoG research team. Should the consent form not be returned by post, this will be completed during baseline data collection. The participant will have an opportunity to ask as many questions as needed and will be invited to contact the researcher (using info on the PIS) with any further queries. It will be made clear to participants that their involvement is entirely voluntary, and they can opt out or withdraw at any time.

Randomisation and allocation

Once baseline data is collected, participants will be randomised. A central randomisation facility will randomise patients (1:1) to IPS or SAU. The randomisation list will be created by a computer program written by a statistician who will have no involvement with the final analysis. The randomisation list, the program that generated it and the random seed used will be stored in a secure network location.

Administration arrangements post recruitment

The University of Glasgow trial office, and researchers at Queen Mary University London, will be responsible for the following:

- Arranging an appointment with the participants at a mutually convenient time and place (e.g., community health centre/participant's home or online) to collect baseline data
- Providing the randomisation facility with participant details
- Informing the participant and any referring organisation of the outcome of randomisation
- Informing the appropriate contact person from IPS of the outcome of randomisation
- Contacting parents to remind them of follow -up assessment
- Arranging an appointment with the participant to collect follow-up data

Post randomisation, arrangements for support will then be taken forward by respective services, and the trial team will not be involved.

Data Collection

Baseline

Measuring outcomes (putative outcome measures for a future definitive RCT - expected sample size for each measure ~30). As these are putative measures for a future definitive RCT, none of these measures are included in the study to measure any of our outcomes but simply to see if they are appropriate and acceptable for a future definitive RCT. We will be looking at basic aspects of the data from these measures, such as missingness of data, mean scores and standard deviations (to support sample size calculations for a future definitive RCT), and - qualitatively - at whether parents perceive the questions asked to be measuring the right kinds of things and are happy with the burden and have any other comments about acceptability.

Target	*Measure*	*Source*
Child mental health	RADA, SDQ, PIRGAS and Quality of life measure (PEDs-QL)	• Parent self-report questionnaires •Health routine data
Child material circumstances	Service use data	• Routine data

		• Parent interviews – including demographics, benefits etc • Social worker interviews
Parental mental health	GHQ and Quality of life measure (EQ-5D)	• Parent self-report questionnaires • Health routine data
Parental material circumstances	Service use data Parent-Reported Outcome Measure	• Routine data • Parent interviews including demographics, benefits, housing, employment etc • Social worker interviews • Co-created with parents to explore how service-focussed goals have been met
Parental experience of respect/stigma	Parent-reported Experience Measure	• Co-created with parents to explore how their goals have been met

After consent, we will arrange a baseline data collection appointment at a mutually convenient time, place and method. This may be conducted remotely if the participant prefers. This will involve the parent answering a semi structured interview (the RADA), and a number of multiple-choice questionnaires (as per table above) about their child and themselves. We will also ask them to record a ten-minute video of them interacting with their child. This session will last between 1-1.5 hours. We will be guided by the participant as to whether it makes sense to break this into more than one session or visit.

Qualitative interviews

Semi-structured interviews will be conducted in a separate session at a mutually convenient time and place by virtual or face to face methods. The entire sample will be asked to participate in interviews, but these will be optional and consented separately and will last up to an hour. It is possible that interviews may

explore some difficult experiences and participants could become upset. The researcher will be skilled and experienced in interviewing vulnerable people about potentially sensitive topics and will stop the interview if necessary, and only resume if the participant is happy to. The researcher will provide information on local support services if the participant is not receiving relevant help.

Video

Video collection will depend largely on the format of the baseline data collection visit. If the visit is in person, the researcher will seek to collect a video then and there. If the visit is being conducted remotely, we will seek to record the interaction via the method used (MS Teams) or, if that is not possible, we will ask the participant to record a video and send it to the research team via secure file transfer. Over the course of the Trial, we will establish which approach is most acceptable to participants.

Follow-up

Follow up data collection will mirror that of the baseline (Table 6.1) and will include the qualitative component. Follow up will take place 3-6 months after baseline and will allow us to track likely retention rates in a bigger trial.

End of Study

Participants will be contacted when the results of the study are published and will be provided with a summary of the results and publication details. We will work with Parent Collaborators to ensure accessibility of the summary findings.

Analysis

Qualitative analysis

The Process Evaluation forms a key part of this feasibility trial. It will explore and capture data on the process of coproduction of IPS, map out the context within which IPS will sit, and will capture issues around the implementation and effectiveness of IPS, capturing learning that will be essential for a future Phase III trial.

Co-production work throughout the study will be underpinned by the theory of partnership and the associated methodology that we have developed in previous studies (Turner-Halliday et al., 2018). Qualitative interviews and focus groups are a powerful way of developing new (and strengthening existing) relationships across groups and agencies. Qualitative interviews are particularly useful for parents or others who may need to discuss sensitive or personal topics, and focus groups are particularly useful for professional or other groups used to sharing experiences, allowing the group dynamic to facilitate the safe emergence of different perspectives. A carefully orchestrated iterative process of interviews and focus groups can give participants the space to consider and articulate their own views, then share them with other participants in a way that helps all involved to see where their common ground lies and, together, develop solutions to challenges (Turner-Halliday et al., 2018).

The co-production values of equality, diversity, access, and reciprocity (Needham, 2009) are key to the success of this process to ensure that those who have been previously silenced by structural inequalities are able to have a voice and an equal role in shaping the IPS teams.

In Phase 1, intensive mapping and modelling will be achieved through carrying out six- to eight focus groups and one to one interview per site with professional stakeholders who have knowledge and experience of working with families who are struggling and at risk of child removal from the parental home. Potential parent and child pathways will be identified and explored through interviews with GPS, health visitors, social workers, third sector organisations, etc.

Six-eight interviews with parents whose children are at risk of SW involvement (in total across Glasgow and London) to explore their experiences and needs of services.
Preliminary findings will be fed back to PC and intervention development stakeholder groups to identify any potential learning that could support intervention development.

A key component of the process evaluation in Phase 1 will be to capture the process of intervention co-development itself. The data for this will be captured as the co-development work progresses. Any data collected such as notes, will be used. In addition, we will conduct qualitative research towards the end of Phase 1 with parent collaborators to capture their views on how the process has worked for them.

Documenting coproduction/codesign processes will also provide additional data which could be useful for the Process Evaluation.

Qualitative data will be collected to explore the following topics:

- Are research procedures and measures acceptable to participating families (including experience of randomisation, level of communication from trial office, experience of consent)?
- What are parental expectations and experiences of the interventions (and to what extent were they met in later phase interviews)
- Are research procedures acceptable to referring and intervention practitioners?

Qualitative work in Phase 2 will be informed by the findings of Phase 1 and will include two-four focus groups with professionals and 16-20 interviews with IPS/services-as-usual participants to allow for greater focus on participants' experiences of services.

Through this iterative process, topics or areas of interest or debate not previously included in interview/focus group questions will be followed up on and explored further as the project progresses. This will allow for both pre-defined, and participant-led data to be gathered in a balanced way throughout the study.

Interview and focus group data will be transcribed verbatim and thematically analysed, according to the methodology of Braun and Clarke (Braun & Clarke, 2006), to identify themes including any recurrent and shared patterns of participant perceptions.

Qualitative work in phase 2 will follow MRC guidance (Moore et al., 2015) and aims to keep abreast of issues and themes uncovered in Phase 1, to explore drivers and barriers to safe/optimal IPS/SAU delivery at all trial sites. comprehensive information on the acceptability and feasibility of research procedures Data will be managed using NVivo qualitative data software and analysed thematically following Braun and Clarke's steps which include independent reading of transcripts to develop a coding frame, review and naming of codes, and development and reporting of key themes (Braun & Clarke, 2006). Findings will be fed back to PC and professional stakeholder groups (possibly using Delphi method or group feedback) in order to identify whether barriers and facilitators to services can be refined and developed into codesign responses.

Quantitative Data analysis

Quantitative analyses are not required: recruitment and retention rates will be simple percentages (Braun & Clarke, 2006).

Cost Evaluation (if appropriate)

Economic evaluation

Preliminary data will be collected to understand the costs of delivering each arm of trial including group facilitator time and grade, training costs, staff, or participant transport costs. In addition, health, personal social services, and broader educational and societal resources both within IPS and SAU will be considered, to develop an approach to build a mean cost per participant, using a bespoke 'Use of Services Questionnaire'. This will be designed specifically to examine service use relevant to this patient group from our first qualitative interviews with service users. To test data collection methods, service use diaries will be given to parents for self-completion and brought to each research assessment to support more accurate face-to-face completion of the Use of Services Questionnaire which will measure multi-sector costs. We will also ask participants detailed questions about the impact of their family's circumstances on parental employment, leisure time and about any other personal costs. We will not be constructing an economic model within this pilot trial but, instead, exploring and setting up systems to do so in future. In a future definitive study, we would explore the potential for validation of participant-report health, education and social care service use using routine health, education and social care data. In this current study, we simply intend to seek consent for this, so that routine data from this current study could potentially be pooled with data from a future definitive study (trial advisors will ensure that this process is completed in line with recent GDPR legislation).

Ethics

The University of Glasgow is the sponsor for the trial.

Ethics and regulatory approvals

A Research Ethics Committee (REC) at the University of Glasgow will review this trial. The trial is conducted according to the principles of GCP provided by Research Governance Guidelines. Annual

progress reports, end of Trial declaration, and a final report are submitted to the Sponsor and the REC within the timelines defined in the regulations.

Protocol compliance and amendment

The Investigators will conduct the trial in compliance with the Protocol given favourable opinion by the Ethics Committee. Any amendment to the project is approved by the Sponsor and funder before application to REC and R&D, unless in the case of immediate safety measures when the Sponsor is notified as soon as possible. Any deviations from the Protocol will be fully documented using a breach report form.

Ethical Consideration	Mitigation
Participant Distress	Participants may experience some upset or discomfort completing the questionnaire but, since all participants are being referred have mental health concerns, a social worker, and a multi-agency support then our information sheets will direct participants to discuss any concerns with their NHS clinician or multi agency support group.
Consent	All parents will be asked to provide informed consent for themselves and their young child before joining. Information about the study will be provided through verbal and written information. Participation in the project will be completely voluntary. Along with the consent form this information will be sent with participant's letter. Families who have agreed to participate will be asked to complete and return a consent form for their details to be shared with the research team and stating their willingness to being considered for the study and a second consent to participate in the study prior to randomisation.
Confidentiality	Patient identifiable data will be available to the participant's direct Social Work team, the local centre research team, and the Trial Office staff. The randomisation service at the Institute of Health and Wellbeing, University of Glasgow, will require only a date of birth, gender and minimisation criteria and is held on a secure online server and only accessible to those people working directly on the trial. Case Report Forms (CRFs) will be used to capture all data, but this data will be anonymised, and each participant will be allocated a unique Study Identity Number to remove the need for any other identifiable data.

Data Protection

A Data Protection Impact Assessment has been completed and submitted to the University of Glasgow as part of the Ethical Approval process.

Patient identifiable data will be available to the participant's direct Social Work team, the local centre research team and the Trial Office staff. The randomisation service at the Institute of Health and Wellbeing, University of Glasgow, will require only a date of birth and gender and is held on a secure online server and only accessible to those people working directly on the trial.

Case Report Forms (CRFs) will be used to capture all data, but this data will be pseudonymised and each participant will be allocated a unique Study Identity Number to remove the need for any other identifiable data.

The Data Management system for data collection and analysis will be held at the trial office in password protected files and computers and any hard copies in locked cabinets all kept in locked offices. Participant's contact details will only be used to facilitate the delivery of follow up questionnaires and any other trial information. Paper logs will not contain any information linking a trial number to any identifiable participant information. Publication of data in reports or journals will also not contain any identifiable information.

Personal data will be regarded as strictly confidential and will only be accessed by delegated members of the participants' social participants social work, clinical and research team.

To preserve pseudonymity, all trial paperwork will identify participants by their unique study Identity Number only. The trial will comply with the Data Protection Act 1998. All trial records and Site Participant confidentiality will be maintained at all times in accordance with GCP Investigator Files will be kept by the Social Worker either online or held securely in secure in a locked in locked office with restricted access. and the Social Work/NHS code of confidentiality.

Participants names and CHI/NHS numbers may be required to maintain trial records and prevent re-approaching patients who have already participated. Any paper records with patient details will be stored in a locked filing cabinet in the Social Work department. Any electronic versions (for screening logs) will be password protected and held on the secure University server (will not be held on any portable laptop devices etc).

Data collected during the course of the research is kept strictly confidential and accessed only by members of the trial team and may be looked at by individuals from the Sponsor organisation, regulatory authorities or sites where it is relevant to the participant taking part in this trial. Participants are allocated an individual trial number. Participant's details are stored on a secure database under the guidelines of the Data Protection Act. Personal data is not kept for longer than is required for the purpose for which it has been acquired. The study is compliant with GDPR and will achieve this by ensuring that all data management procedures comply with GCP and are entirely transparent to study participants.

The researchers who will be responsible for all aspects of recruiting and follow up of the participants will have access to participants' personal data. Any other member of staff will be appropriately trained and delegated this responsibility on the delegation log.

The data will be uploaded, stored, and analysed by statisticians at the University. No identifiable data will be linked to the CRF and outcome databases. 10% of all data will be screened for errors, and data will be locked before unblinding of group allocation.

Access to Social Care records by those outside the direct social care team will be required and will be accessed, with the consent of the participant, through a Data Sharing Agreement with the participating Local Authorities.

Patient identifiable data will be available to the participant's direct Social Work team, the research team and the Trial Office staff.

The trial will comply with the Data Protection Act 1998. All trial records and Site Participant confidentiality will be maintained at all times in accordance with GCP Investigator Files will be kept by the Social Worker, either online or held in a secure locked office with restricted access.

The data will be archived as per University Research governance. Anonymity will be maintained by the CI or designated individual. Data will be collected and retained in accordance with the Caldicott Principles, UK Data Protection Act 2018, and General Data Protection Regulation (GDPR). For this trial, research data will be kept for at least 10 years. Personal data (e.g., name and address, or any data from which a participant might be identified) will not be kept for longer than is required for the purpose for which it has been acquired. Documents will be reviewed by the CI before being destroyed.

In addition to working with their parents, this study will involve working with children aged 0-5, with the consent of their parents. As the purpose of the study is to improve the mental health of this group, working with them is a necessity. All IPS team members require up to date PVG scheme membership. Members of the research team who have contact with children or vulnerable families are also required to have an up-to-date membership of the PVG scheme.

Data recording and processing

UoG trial office staff will enter locally collected data into the trial database. All staff will work to ensure the data are as complete and accurate as possible. Randomisation data will be transferred to RCB using a secure file transfer protocol (SFTP), and standard data validation checks will be performed by the study statistician. Any queries will be resolved with the CI prior to database lock.

Participants have a unique participant identification number that allows identification of all data reported for each participant. Research staff can access records for all participants. All Investigators and study site staff involved with this study must comply with the requirements of the General Data Protection Regulation (or subsequent legislation), with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Computers used to collate the data will have measures to limit access via username and passwords.

Qualitative data management

Interviews will be recorded on [encrypted] digital recorders or on MS Teams - anonymously - and transcribed verbatim by a member of the study team. Transcripts will be anonymised, and quality assured before recordings are deleted. The non-identifiable research data will be saved on university computers, on the secure server. The analysis will be conducted by the study qualitative researcher supported by the wider research team. Qualitative Analysis will follow Braun and Clarke's (2021) Thematic Analysis methodology and qualitative data will be managed on a password protected computer using NVivo Qualitative Data Analysis Software.

As part of the process of obtaining informed consent, participants will be issued with a Privacy Notice, a copy of which is included in the appendices.

Personnel

Qualifications and Experience of Applicants

Lead Applicant Professor Helen Minnis

Qualifications

1985 University of Glasgow, B.Sc. Biochemistry

1988 University of Glasgow, MB.ChB

1996 London School of Hygiene and Tropical Medicine, MSc. Epidemiology

1999 University of London, PhD. Child Psychiatry

1995 Membership of the Royal College of Psychiatrists

2011 Fellowship of the Royal College of Psychiatrists

2022 Fellowship of the Academy of Medical Sciences

Organisation

University of Glasgow, Glasgow, G12 8QQ

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LEAD APPLICANT RESEARCH BACKGROUND

Publication record (selected publications)

Cummins T, English O, Minnis H, Stahl D, O'Connor RC, Bannister K, McMahon SB, Ougrin D (2021). Assessment of Somatosensory Function and Self-harm in Adolescents. JAMA Network Open, 4(7), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781925

Rooksby M, Di Folco S, Tayarani M, Dong-bach V, Huan R, Vinciarelli A, Brewster S, Minnis H (2021). The School Attachment Monitor – A novel computational tool for assessment in middle childhood. PLOS ONE, 16(7), https://doi.org/10.1371/journal.pone.0240277

Wilson P, Wilson N, Turner F, Minnis H (2021). 'Escaping the Inescapable': Risk of Mental Health Disorder, Psychosomatic Complaints and Resilience in Palestinian Refugee Children. Transcultural Psychiatry, 58 (2), 307-320. https://doi.org/10.1177/1363461520987070

Gajwani R, Dinkler L, Lundstrom S, Lichtenstein P, Gillberg C, Minnis H (2020). Mania symptoms in a Swedish longitudinal population study: the roles of childhood trauma and neurodevelopmental disorders. Journal of Affective Disorders, 280, 450-456, https://doi.org/10.1016/j.jad.2020.10.076

Lehmann S, Breivik K, Monette S, Minnis H (2020). Potentially traumatic events in foster youth, and

association with DSM-5 trauma- and stressor related symptoms. Child Abuse and Neglect 101, 104374. https://doi.org/10.1016/j.chiabu.2020.104374
Dinkler L, Lundstrom S, Gajwani R, Lichtenstein P, Gillberg C, Minnis H. Maltreatment-associated neurodevelopmental disorders: a co-twin control analysis. Journal of Child Psychology and Psychiatry, 58(6):691-701 httpp://onlinelibrary.wiley.com/doi/10.1111/jcpp.12682/epdf

Experience
Experienced trialist with a research focus on the mental health of abused and neglected children and their families.

Co-Applicants

Mr Matt Forde
Post Partnerships & Development Director
Qualifications
Diploma in Social Work 1993
Open University: BA (Hons) Psychology 1994
Employer NSPCC
Work Address 42 Curtain Rd,
London
Greater London
Post Code EC2A 3NH
Matt.Forde@NSPCC.org.uk

Experience
Joint Principal Investigator with expertise in developing and scaling up integrated health and social care models. Matt joined the NSPCC in 2010 as first National Head for Scotland. Previously, worked in statutory children's services, researching childhood experiences of offenders led him to develop evidence-based prevention services. Matt is a registered social worker who is active in policy, practice development, and research projects. In 2014, completed a Winston Churchill fellowship travelling in the USA and Europe to explore insights in preventing child abuse and upholding children's rights.

Judge Carol Atkinson
Post Lead Judge
Qualifications LLB Hons – Law, 1984
Employer East London Family Court
Work Address 11 Westferry Circus
London

Post Code E14 4HD
hhj.carol.atkinson@ejudiciary.net
Experience
Expert on judicial processes around children involved in social care

Ms Janet McCullough
Post Head of Children's Services South Glasgow
Qualifications
First degree in English Literature and Philosophy (Glasgow Uni, 1993)
Post grad Diploma in Social Work in 1997 at Glasgow Uni.
MSc to distinction from Edinburgh Uni in 2003
Professional Advanced Award in Social Work practice
MSc is in Criminal Justice Studies
Employer Glasgow Health and Social Care Partnership
Work Address Glasgow Health and Social Care Partnership, Pavilion One
5 Ardlaw Street, Glasgow
Glasgow
Post Code G51 3RR
Telephone 0141 451 7110
Janet.McCullough@glasgow.gov.uk

Experience
Expert on Family Group Conferencing and poverty-aware social work

Ms Karen Crawford
Post Research Associate and Senior Trial Manager
Qualifications
MA (Hons) in Politics and Social Policy, University of Glasgow
PGDip in Local Economic Development, University of Glasgow
Employer University of Glasgow
Work Address ACE Centre, Institute of Health and Wellbeing
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Experience

Expert in RCT management, including recruiting and retaining families involved in social care

Dr Fiona Turner
Post Research Associate
Qualifications
PhD
Professional Doctorate in Health Psychology (2013)
MSc Health Psychology with Distinction (2003)
BSc (Hons) Psychology with Sociology & Social Policy - 2:1 (2002)
Employer University of Glasgow
Work Address ACE Centre, Institute of Health and Wellbeing
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fiona.turner@glasgow.ac.uk

Experience
Expert in qualitative aspects of process evaluation, especially re families involved in social care

Dr Kathleen Boyd
Post Reader (Health Economics)
Qualifications BA (Hons), MSc, PgCAP, PhD
Employer University of Glasgow
Work Address Health Economics and Health Technology Assessment (HETA) Institute of Health and Wellbeing
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Kathleen.Boyd@glasgow.ac.uk

Experience
Expert in Health Economics of complex interventions, including at social care/health interface

Professor Alex McConnachie
Post Reader
Qualifications
BSc Mathematics 1991

1992-1993: MSc Medical Statistics 1993
1993-1997: PhD Statistics 2004
Employer University of Glasgow
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Telephone 0141 330 4744
Alex.McConnachie@glasgow.ac.uk

Experience
Expert in statistical analysis of social care/health complex trials

Professor Kapil Sayal
Post Professor of Child and Adolescent Psychiatry
Qualifications
PhD - Psychiatry University of London - 31/08/2004
Other - CCST in Child & Adolescent Psychiatry Specialist Training Authority - 13/03/2003
MSc - Psychiatry University of London - 31/03/2000
MRCPsych - Psychiatry Royal College of Psychiatrists - 13/12/1996
BM - Medicine University of Southampton - 30/06/1992
BSc (Hons) - Psychology University of Southampton - 01/07/1991
Employer The University of Nottingham
Work Address Faculty of Medicine & Health Sciences
Division of Psychiatry & Applied Psychology, Institute of Mental Health,
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Experience
Expert in Clinical Trials of complex interventions and ADHD

Prof Dennis Ougrin
Post Professor of Child and Adolescent Psychiatry
Qualifications
MBBS, MRCPsych, PGDip Cognitive Therapy (Oxon), CCT Child and Adolescent Psychiatry,
PGCAPHE, PhD

Employer East London NHS Foundation Trust
Work Address Queen Mary University of London King's College
London
Post Code EC1M 6BQ
d.ougrin@qmul.ac.uk

Experience
Expert in Child and Adolescent Psychiatry in high-risk populations

Ms Sharon Graham
Post Research Assistant (lived experience)
Qualifications COSCA Counselling, NLP and Life Coaching. Reiki 1 and 2. Learning to Advise. SVQ 3 Advice and Guidance.
Employer University of Glasgow
Work Address Academic CAMHS, 4th Floor
WGACH, Dalnair St
Glasgow
Post Code G3 8SJ
Telephone +441412019239
sharon.graham@glasgow.ac.uk

Experience
PPI lead with lived experience of social care intervention and significant experience of supporting health and social care research, and social work service users. Sharon has experience of the care system and professional experience of supporting parents and families who access social care. Sharon works in person centred and trauma informed way and will work in partnership with two groups of parent collaborators from Glasgow and Bromley to shape the development of the intervention and research.

Ms Judith Fisher
Post Project Manager
Qualifications BSc (Soc Sci) Psychology 1999, Edinburgh University
MSc (Play Therapy) (Distinction) 2019, Queen Margaret University
Employer University of Glasgow
Work Address Academic CAMHS, 4th Floor
WGACH, Dalnair St
Post Code G3 8SJ
Telephone +441412019239
judith.fisher@glasgow.ac.uk

Experience

Judith brings the experience of two decades of combining research and policy work with direct work with children. Judith previously worked at the University of Strathclyde and as a freelance research and education consultant.

Ms Lindsay Dalgarno
Post Research Assistant
Qualifications
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Experience

An experienced researcher on all aspects of social and health focused mixed methods studies. and expertise in qualitative research and analysis. Lindsay has worked on feasibility and pilot studies to multisite randomised controlled trials including formal process evaluations.

Dr Jaycee Pownall
Post: Research Associate
Qualifications
BSc., PhD., CPsychol
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Experience

Research experience across the areas of intellectual disabilities and health psychology. Research interests include exploring sex and relationship issues for young people with intellectual disabilities and their families. Recent research projects have explored the impact of social exclusion upon the health knowledge and behaviour of young people with intellectual and physical disabilities.

Tricia Hart
Post Trainee Clinical Psychologist

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Experience
Tricia is a second year trainee Clinical Psychologist. She will be working with the research team to develop the Parent-Reported measures.

Risk Management

Risk	Mitigation
Unable to get LA partners to work within timeframe	Secure engagement and commitment through planned series of meetings and engagement events
Low recruitment of participants/ low engagement: Insufficient numbers of families consenting to the take part in the project	There is a lot of welcomed positivity around this trial with local authorities, stakeholders and parents wanting to engage in its delivery. There has been a lot of engagement since conception and with good relationship maintenance we should be able to recruit to target. We have additionally kept a low number of recruitments as this is a feasibility trial.
Delays in drawing up Data Sharing Agreements with Local Authorities	A No-Cost Extension to the project timeline has been submitted to account for this contingency.
Potential safeguarding concerns	NSPCC is providing safeguarding training to all staff involved in the project. They have NSPCC safeguarding policies in place and working to their guidelines. Additionally for Safety measures, they have process in place for reporting any Serious Adverse Events relating to the project and will report this to both WWCSC and the University of Glasgow if they occur.
Ethical approval isn't received by project start date	Ethical approval secured from the University of Glasgow after the gathering of a bespoke panel. NSPCC ethics application prepared with intention to submit to January panel.
Voices of Parent Collaborators won’t be given equal weight.	Parent Collaborators will lead development sessions and this type of risk (including power dynamics and status quo) will be addressed from the beginning of the development sessions in Phase 1. It will also be written into the terms of reference. The research team will aim to reduce any power imbalances in these environments and support parent collaborators, including inviting a coproduction expert to address sharing of power within the coproduction team.

Timeline

Milestone Number	Dates	Activity	Staff responsible/ leading
1	31/03/22	Project set-up actions, pre-official project start date: ● Incorporated learning from parent-led Aberlour Trust-funded qualitative study ● Secured ethical and governance research approval from UoG, NSPCC and LAs ● Recruited research staff (delivery staff are already in place) ● Recruited parent collaborators ● Attend WWCSC facilitated kick-off meeting ● Trial protocol draft submitted to WWCSC for comment	Helen Minnis
2	31/05/22	• Host UoG/NSPCC stakeholder engagement workshop with CAMHS, AMHS and social care	Helen Minnis/Matt Forde
3	31/12/22	● Completed 6-8 focus groups with practitioners/parents/stakeholders to inform point below ● Completed coproduction of IPS intervention, understanding of services as usual context, and research processes (including finalising research measures for a definitive RCT) ● We will produce an outline model of IPS and a Theory of Change, describing the various elements of assessment and intervention and the tools, measures and professional roles involved in IPS. This will be disseminated through the NSPCC website ● Draft Trial Protocol to be submitted in WWCSC template, including incorporation of WWCSC feedback	Helen Minnis/Matt Forde
4	31/01/23	● Consolidate discussions with potential sites for a definitive RCT	Helen Minnis/Matt Forde

		● Concluded preparation for Phase 2 (participant recruitment pathways and IPS delivery readiness) ● Shared bi-annual report with WWCSC ● Final Trial protocol submitted to WWCSC with all required comments and feedback incorporated, ready for publishing ● Protocol published on the Open Science Framework (OSF), ● Completed IPS team poverty awareness training	
5	28/02/23	● Submitted paper on service context for publishing	Helen Minnis
6	31/03/23	● Secure ratification to proceed to Phase 2 based on progression criteria review by Trial Steering Committee	Helen Minnis/Matt Forde
7	31/05/23	● Completed recruitment and randomisation of 30 participants for feasibility study ● Completed 30 baseline qualitative and quantitative assessments ● Shared bi-annual report with WWCSC	Helen Minnis/Matt Forde
8	31/07/23	● Hosted UoG/NSPCC conference for policy makers and practitioners	Helen Minnis/Matt Forde
9	30/11/23	● Conducted 30 follow-up qualitative and quantitative assessments ● Delivered IPS to 15 families ● Submitted feasibility study for publication by peer reviewed journals ● Published feasibility evaluation report on NSPCC Learning ● Disseminated learning animation ● Disseminated end-of-study knowledge outputs ● Developed application to NIHR for full stage RCT ● Final Report submitted to WWCSC	Helen Minnis/Matt Forde

Outcome measures

- Clearly define the primary and secondary outcomes and how they will be measured, including source instruments or datasets.
- There should ideally be only one primary outcome. However, more than one can be used if there is a sound rationale in the theory of change of the intervention to support this decision.
- For trials with more than one follow-up point (e.g., delayed post-test), specify which time point constitutes the primary outcome.
- If using multiple primary outcomes, specify the approach to addressing multiple testing/ family-wise error rates.
- Details of any plans to ensure tests are administered and marked blinded to treatment allocation, if applicable.
- Consider and identify any harms that are likely or possible consequence of the intervention and consider whether and how they can be measured. As two interventions which each avoid harming people may be interpreted as equivalent, and their choice a matter for expert or professional judgement, harms analysis will be considered separately for multiple comparisons purposes.

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Appendices

1. Interview Participant Consent Form
2. Interview Participant Sheet
3. Initial Referral with Consent Form
4. Participant Consent Form
5. Participant Information Sheet
6. Participant Privacy Notice
7. Phase 1 Stakeholder Interview Topic Guide
8. Phase 2 Stakeholder Interview Topic Guide

Interview participant consent form

Please read the following statements and **initial** in the box:

I confirm that I have read and understood the information sheet and have had the chance to ask questions about the project and my participation.	
I voluntarily agree to participate in the study.	
I understand that I do not have to take part in the research and I am free to withdraw at any time without giving any reason, and without my medical or legal rights being affected.	
The procedures regarding confidentiality have been clearly explained (e.g. use of names, pseudonyms, anonymisation of data, etc.) to me.	
Interviews may be recorded and transcribed. Following transcription the original recording will be destroyed and all personal data removed from the transcription. I agree to my interviews being recorded and transcribed for this study. Any quotes taken from transcriptions will be anonymised.	
I would like to receive a copy of the research findings.	
I confirm that I can be contacted in the future by a member of the Partnership for Change Project Team to discuss possible participation in further research arising from this study. I understand that this will not commit me in any way to taking part in further research.	

If you have any further questions about the study please contact:
Prof Helen Minnis: 0141 201 9239

I consent to take part in the Partnership for Change Project:

Name (Printed): ……. Name (Signed): …….

Date: Date:

To be completed by the local team member taking consent. I confirm that I have explained to the person named above, the nature and purpose of the study and the procedures involved.

Researcher's Signature: …….

Researcher’s Name (Printed): …….. Date:

Interview participant information sheet

Invitation to take part

We would like to invite you to take part in the ***Partnership for Change*** project. This is a research study about support services for families with young children (aged 0-5) with a social worker. We are gathering views from a range of perspectives to help inform the development of a new support service, Infant Parent Support (IPS). Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the research about?

We want to find out how best to support families with young children who have a social worker. We are particularly interested in exploring the effectiveness of a new service, Infant Parent Support (IPS), which we are codeveloping and codesigning with parents and practitioner stakeholders. We are gathering the views and experiences of a range of stakeholders to inform the development of this new support service.

Why have I been asked to take part?

You have been asked to take part because you are either a parent with lived experience of Social Work intervention or a professional with experience in this area.

Do I have to take part?

No, you do not have to take part in the research, and it will not affect any social work, medical/psychological services or treatment that you are receiving. You are free to withdraw from the study at any time. You can also refuse to answer any questions that you do not feel comfortable with.

What will I be asked to do?

If you are interested to find out more, one of researchers will be in touch to discuss the project with you. You will have the chance to ask questions. If you would like to take part, you will be asked to sign a consent form.

You will then take part in either a 1 to 1 interview or a focus group with a small number of other stakeholders. These will take place either in person or online via Microsoft Teams or Zoom, whichever suits you best. This will enable us to gather your views.

What will happen with the interview information?

These interviews will be audio recorded, to allow your insights to be captured properly and then typed verbatim by a member of the research team, so that the content can be used to inform the research. All interviews will be anonymised so that participants will not be identifiable in any reports which will be produced as a result of the research.

Who will know I am taking part in the study?

Only certain members of the research team will have access to your information to phone you or to arrange to meet with you. It is a requirement that your records in this study are made available if requested by monitors from the Sponsor, the University of Glasgow. The Regulatory Authorities, whose roles it is to check this research is properly conducted and the interests of those taking part in this study are protected, may also need to look at your records.

Will my information be protected?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Any comments you make will be anonymised in any outputs.

All information which is collected about you during the research, including identifiable data, will be kept strictly confidential and will be held securely for 10 years after the study has ended in accordance with the latest Data Protection legislation.

The University of Glasgow is the Sponsor and Data Controller for this study and are responsible for looking after your information and using it properly.

The research team, including researchers from the University of Glasgow, will have access to your information. They will use your name and contact details to contact you about the study, to make sure that relevant information about the study is recorded, and to oversee the quality of the study.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

Other researchers may wish to access data from this study in the future. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth. The sponsor will ensure that other researchers comply with legal, data protection and ethical guidelines and have ethics approval for their research.

What are the benefits of taking part?

There may be no direct benefit to you. The main benefit of your participation in the study is to help us understand how effective certain types of services and treatments are for families in need of support. You may be helping to find better ways for families to get the best kind of help in the future. If you decide not to take part, you will still receive the support you would normally receive from social work and any other services you receive.

Is there a downside to taking part?

We do not expect that taking part will cause you any problems. If you find taking part in the research distressing, you can discuss this with us and you are free to stop at any time. We have also provided information at the end of this leaflet on where you could access confidential support if you feel you need it.

If you share information that makes the research team concerned for your safety or the safety of other people we have a duty of care to tell others who are involved in working with you. We will always notify you beforehand if we are going to do this and explain why.

If at any point during the research process there is a question about your capacity to continue with the research, we would terminate the session immediately and consult with your direct care team. We will of course discuss this with you fully before talking with anyone. If this occasion were to arise and your capacity is restored, we would require confirmation with your direct care team before continuing with any assessment.

What will happen to the results of the study?

The results will be published in a health science journal and the research team will make sure that the general public know about our results. Your name will not be used in any report.

Can I speak to someone who is not involved in the study?

Yes, for independent advice about this study please contact…

Dr Lynda Russell

Mental Health and Wellbeing

Academic Centre

Gartnavel Royal Hospital

Glasgow, G12 0XH

Tel: 0141 211 3912

Email: lynda.russell@glasgow.ac.uk

Who is organising and funding the research?

The University of Glasgow is the organiser of the research as well as the
Chief Investigator Professor Helen Minnis (contact details are provided at the end of this information sheet).

The What Works for Children's Social Care (WWCSC) is providing the funding for this research.

What if I have any further questions about the study?

If you would like to talk about the study further or have any questions about your participation, please contact Prof Helen Minnis (Chief Investigator) or Judith Fisher (Project Manager). Their contact details are listed at the end of this information sheet.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the researcher who will do their best to answer your questions.

If you remain unhappy and wish to complain formally you can do this through the University of Glasgow complaints procedure here: https://www.gla.ac.uk/connect/complaints/howtomakeacomplaint/

If taking part in this study harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have ground for legal action but you may have to pay your legal costs.

Who has reviewed the study?

The study was reviewed and approved by the University of Glasgow Research Ethics Committee.

Thank you for taking the time to read this information sheet.

Researcher Contact Details:

Prof Helen Minnis
University of Glasgow
General Practice and Primary Care
House 1 (Academic CAMHS),
1 Horselethill Road
Glasgow
Tel: 0141 201 9239
E-mail: helen.minnis@glasgow.ac.uk

Judith Fisher
University of Glasgow

Level 4, West Glasgow Ambulatory Care Hospital,
(Academic CAMHS)
Dalnair St, Glasgow
Tel: 0141 201 9239
E-mail: judith.fisher@glasgow.ac.uk

To be completed for all new referrals

Referral and consent form

Partnership for Change Trial
Eligibility Assessment and Study Referral Form

Date Family Referred:

Glasgow ☐ Bromley ☐

Referrer's Name:

Referrer's email address:

Name of child's Social Worker:

Email address for child's Social Worker:

Eligibility Assessment

1. Is the child aged between 0 and 5 years old Yes ☐ No ☐
2. Does the child have an allocated Social Worker Yes ☐ No ☐
3. Is the child living with birth parent Yes ☐ No ☐
4. Is the child on the Child Protection Register Yes ☐ No ☐

If **yes to 1, 2 and 3 and no to 4**, give parent a copy of the information sheet and seek permission to pass on details to the research team.

Information sheet provided to parent Yes ☐

Contact Details

RECORD DETAILS ONLY IF PERMISSION IS GIVEN

Child/ren's name:

Parent Name:

Address:

Postcode:

Landline telephone number:

Mobile telephone number:

Parent Email address:

I (parent)_____ give my permission to be referred to be assessed for inclusion in the Partnership for Change trial. I have received the information sheet on the trial and understand that I can withdraw my permission at any time.

Signed (parent)_____ Date_____

Signed (Referrer)_____Date_____

Participant consent form

Please read the following statements and **initial** in the box:

1. I confirm that I have read and understood the information sheet and have had the chance to ask questions about the project and my participation.	
2. I confirm that I can be contacted in the future by a member of the Partnership for Change Project Team to discuss possible participation in further research arising from this study. I understand that this will not commit me in any way to taking part in further research.	
3. I understand that I do not have to take part in the research and I am free to withdraw at any time without giving any reason, and without my medical or legal rights being affected.	
4. The procedures regarding confidentiality have been clearly explained (e.g. use of names, pseudonyms, anonymisation of data, etc.) to me.	
5. I agree for my GP to be informed about my participation in the study.	
6. I agree to the study team accessing routinely collected health and social care data about me and my child	
7. Interviews may be recorded and transcribed by a member of the research team. Following transcription the original recording will be destroyed and all personal data removed from the transcription. I agree to my interviews being recorded and transcribed for this study. Any quotes taken from transcriptions will be anonymised.	
8. (i)I would like to receive a copy of the research findings (please delete as necessary) (ii)My preferred method for receiving the results is via (please delete as necessary)	Yes/No Email/Post
9. I understand that data collected during the study may be looked at by individuals from the University of Glasgow (study sponsor) or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	

10. I consent to members of the research team obtaining routinely collected health data including from my medical notes	
11. I voluntarily agree to participate in the study.	

If you have any further questions about the study please contact:
Prof Helen Minnis: 0141 201 9239

I consent to take part in the Partnership for Change Project:

Name (Printed): ……. Name (Signed): …….

Date: Date:

Researcher's Signature: …….

Researcher's Name (Printed): …….. Date:

Participant information sheet

Partnership for Change Information Sheet
Developing new family support services

Invitation to take part

We would like to invite you to take part in the ***Partnership for Change*** project. This is a research study about support services for families with young children with a social worker. The project is inviting thirty families with children aged 0-5, who currently have a social worker, to take part in this research. Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the research about?

We want to find out how best to support families with young children who have a social worker. We are particularly interested in exploring the effectiveness of Infant Parent Support (IPS), a new service which we are developing in partnership with parents and other stakeholders. We do not know which approach is better and want to be as fair as possible so some families in the study will work with IPS while others will continue to work solely with established services. We will compare IPS with the existing health and social care services which would be received by families with a social worker.

Why have I been asked to take part?

You have been asked to take part because you have a child or children aged 0-5 with a social worker.

Do I have to take part?

No, you do not have to take part in the research, and it will not affect any social work, medical/psychological services or treatment that you or your child(ren) are receiving. You are free to withdraw from the study at any time. You can also refuse to answer any questions that you do not feel comfortable with.

What will I be asked to do?

If you are interested to find out more, one of researchers will be in touch to discuss the project with you. You will have the chance to ask questions. If you would like to take part, you will be asked to sign a consent form.

You will then take part in a ***baseline research assessment.*** The research assessment will take place as an online/ virtual meeting on Microsoft teams, or in person. During this meeting, one of our researchers will go through some questionnaires and brief interviews about you and your child. We will also ask you to record a short video of you playing with your child. The baseline research measures will take 2-3 hours. You may also be asked to take part in an ***optional interview*** where our researcher will ask some more in-depth questions.

After the baseline research assessment, your family will be assigned to **either** IPS, which you will receive along with any other services you are currently receiving **OR** you will continue to work with social work and any other teams around you. This will be ***randomly assigned***.

You will then have follow-up assessments at 12 - 24 weeks after your initial research assessment. The follow up assessments will repeat the same questionnaires as at baseline.

What Services are Available?

Social work and health services are available to all families with a social worker. Services are tailored to specific needs. In Glasgow and Bromley, a new service is also available: Infant Parent Support (IPS), which is offered by NSPCC's team of mental health and social

work staff. Families receiving IPS will also receive any other statutory or health services input required.

Will my information be protected?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information which is collected about you during the research, including identifiable data, will be kept strictly confidential and will be held securely for 10 years after the study has ended in accordance with the latest Data Protection legislation.
The University of Glasgow is the sponsor and data controllers for this study and is responsible for looking after your information and using it properly.

The research team, including researchers from the University of Glasgow, will have access to your information. They will use your name and contact details to contact you about the study, to make sure that relevant information about the study is recorded, and to oversee the quality of the study.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.
Other researchers may wish to access data from this study in the future. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth. The sponsor will ensure that other researchers comply with legal, data protection and ethical guidelines and have ethics approval for their research.

What are the benefits of taking part?

There may be no direct benefit to you. The main benefit of your participation in the study is to help us understand how effective certain types of services and treatments are for families in need of support. You may be helping to find better ways for families to get the best kind of help in the future. If you decide not to take part, you will still receive the support you would normally receive from social work and any other services you receive.
We would also like to give you a £35 voucher each time we do a research meeting with you, to thank you for your time.

Is there a downside to taking part?

We do not expect that taking part will cause you any problems. If you or your child find taking part in the research or in IPS distressing, you can discuss this with us and you are free to stop at any time.

If you share information that makes the research team concerned for your safety or the safety of other people we have a duty of care to tell others who are involved in working with you. With your consent, we would like to inform your GP that you are taking part in this study. If we identify that you may benefit from any additional support relating to symptoms other than those explored during the IPS intervention, we will feed this back to your GP or team involved with you or you child (for example Adult Mental Health Services, Addiction Services). We will always notify you beforehand if we are going to do this and explain why.

If at any point during the research process there is a question about your ability to consent to continue with the research, we would terminate the assessment/session immediately and consult with your direct care team. We will of course discuss this with you fully before talking with anyone. If this occasion were to arise and your ability to consent is restored, we would require confirmation with your direct care team before continuing with any assessment.

What will happen at the end of the study?

During your time in the study, whether you are randomised to the IPS intervention or not, your child's social worker will continue to have a case management role and any social work processes will continue as normal. You may be referred to other services during your involvement in IPS. These services will be independent of IPS and the research and will continue as long as needed after your involvement in the study ends.

What will happen to the results of the study?

The results will be published in a health science journal and the research team will make sure that the general public know about our results. Your name will not be used in any report.

Can I speak to someone who is not involved in the study?

Yes, for independent advice about this study please contact…

Dr Lynda Russell

Mental Health and Wellbeing

Academic Centre

Gartnavel Royal Hospital

Glasgow, G12 0XH
Tel: 0141 211 3912
Email: lynda.russell@glasgow.ac.uk

Who is organising and funding the research?

The University of Glasgow is the organiser of the research. The Chief Investigator is Professor Helen Minnis (contact details are provided at the end of this information sheet). What Works for Children's Social Care (WWCSC) is providing the funding for this research.

What if I have any further questions about the study?

If you would like to talk about the study further or have any questions about your participation, please contact Prof Helen Minnis (Chief Investigator) or Judith Fisher (Project Manager). Their contact details are listed at the end of this information sheet.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the researcher who will do their best to answer your questions.
If you remain unhappy and wish to complain formally you can do this through the University of Glasgow complaints procedure, which is outlined here: https://www.gla.ac.uk/connect/complaints/howtomakeacomplaint/

If taking part in this study harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have ground for legal action but you may have to pay your legal costs.

If you have private medical insurance, you may wish to check with your company before agreeing to take part in the study to ensure participation will not affect your insurance cover.

Who has reviewed the study?

The study was reviewed and approved by the University of Glasgow, Medicine and Veterinary Life Sciences Research Ethics Committee.

Thank you for taking the time to read this information sheet.

Researcher Contact Details:

Prof Helen Minnis
University of Glasgow
General Practice and Primary Care
House 1 (Academic CAMHS),
1 Horselethill Road
Glasgow
Tel: 0141 201 9239
E-mail: helen.minnis@glasgow.ac.uk

Judith Fisher
University of Glasgow
Level 4, West Glasgow Ambulatory Care Hospital, (Academic CAMHS)
Dalnair St
Glasgow
Tel: 0141 201 9239
E-mail: judith.fisher@glasgow.ac.uk

Privacy Notice for the Partnership for Change Study

Your Personal Data

The University of Glasgow will be what's known as the 'Data Controller' of your personal data processed in relation to your participation in the Partnership for Change Study. This privacy notice will explain how The University of Glasgow will process your personal data.

Why we need it

We are collecting your basic personal data such as name, email address/contact details to contact you about the study, to make sure that relevant information about the study is recorded, and to oversee the quality of the study. Where relevant, we will also collect limited special categories data (such as disability, ethnicity, other health data) in order to help us get a better understanding of how things are working or not for you with the services you already work with. We will only collect data that we need for this study.

Legal basis for processing your data

We must have a legal basis for processing all personal data. In this instance, the legal basis is

- Task in the public interest

Who will know I am taking part in the study?

Only certain members of the research team will have access to your information to phone you or visit you to complete questionnaires. The study team would like to access various records, with your permission to help us get a better understanding of how things are working or not for you with the services you already work with. With your consent, we would like to inform your GP that you are taking part in this study. It is a requirement that your records in this study are made available, if requested, by monitors from the Sponsor (University of Glasgow, College of Medical, Veterinary and Life Sciences Research Ethics Committee). This would be for the purposes of ensuring that this research is properly conducted and the interests of those taking part in this study are protected. This would take place if a complaint had been made about the research, or a concern had been raised by the Trial Steering Committee, who oversee the study, or as part of a routine audit. If you would like more details about this process, please contact Mr Neil Allan, MVLS Ethics, on 0141 330 5206 or mvls-ethics-admin@glasgow.ac.uk .

What we do with it and who we share it with

Only certain members of the research team will have access to your information to phone you or visit you to complete questionnaires. The study team would like to access various records, with your permission to help us get a better understanding of how things are working or not for you with the services you already work with. It is a requirement that your records in this study are made available, if requested, by monitors from the Sponsor (University of Glasgow, College of Medical, Veterinary and Life Sciences Research Ethics Committee). This would be for the purposes of ensuring that this research is properly conducted and the interests of those taking part in this study are protected. This would take place if a complaint had been made about the research, or a concern had been raised by the Trial Steering Committee, who oversee the study or as part of a routine audit. If you would like more details about this process, please contact Mr Neil Allan, MVLS Ethics, on 0141 330 5206 or mvls-ethics-admin@glasgow.ac.uk .

Will my information be protected?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information which is collected about you during the research, including identifiable data, will be kept strictly confidential and will be held securely for 10 years after the study has ended in accordance with the latest Data Protection legislation.

The University of Glasgow is the sponsor and data controllers for this study and is responsible for looking after your information and using it properly.

The research team, including researchers from the University of Glasgow, will have access to your information. They will use your name and contact details to contact you about the study, to make sure that relevant information about the study is recorded, and to oversee the quality of the study.

Other researchers may wish to access the findings from this study in the future as part of a larger-scale study to further test this intervention. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth and

will be presented as aggregate data. The sponsor will ensure that other researchers comply with legal, data protection and ethical guidelines and have ethics approval for their research.

How long do we keep it for

Your data will be retained by the University for 10 years after the end of the Study. After this time, data will be securely deleted.

What are your rights?*

Individuals have certain rights: to request access to, copies of and rectification or erasure of personal data and to object to processing. In addition, to restrict the processing of the personal data and to data portability.

Whilst you can request access to the information we process about you at any time, your rights to access, change or move your information will be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

If at any point you believe that the information we process relating to you is incorrect, you can request to see this information and may in some instances request to have it restricted, corrected or, erased. You may also have the right to object to the processing of data and the right to data portability.

Where we have relied upon your consent to process your data, you also have the right to withdraw your consent at any time.

If you wish to exercise any of these rights, please submit your request via the webform (https://www.gla.ac.uk/myglasgow/dpfoioffice/gdpr/gdprrequests/) or contact dp@gla.ac.uk.

*Please note that the ability to exercise these rights will vary and depend on the legal basis on which the processing is being carried out.

Complaints

If you wish to raise a complaint on how we have handled your personal data, you can contact the University Data Protection Officer who will investigate the matter.

Our Data Protection Officer can be contacted at dataprotectionofficer@glasgow.ac.uk

If you are not satisfied with our response or believe we are not processing your personal data in accordance with the law, you can complain to the Information Commissioner's Office (ICO) https://ico.org.uk/

□ I consent to the University processing my personal data for the purposes detailed above.

□ I consent to the University processing my sensitive personal data for the purposes detailed above.

I have read and understand how my personal data will be used.

Signed: ……

Date: ……

Partnership for Change Trial

Phase 1 Topic Guides

Topic Guide Questions:

Focus Group/one to one professional interview questions:

[send this question out in advance – request written responses?] With 'at risk' and 'in need' children in mind can you describe the legal and service landscape in your local area (SAU and specific provision)?

1. What are the differing pathways into services for families and who would usually be involved (and at which points)? (Prompt: can you think of other routes or examples?)
2. Do you feel that children are appropriately referred for assessments in terms of 1) safety and 2) need (for example: medical, neurodevelopmental, physical, over-all development, etc.)?
3. What facilitates parent and child journeys into and out of services?
4. What barriers are you aware of to parent and child journeys into and out of services? (Prompt) What professional and personal barriers are there to families progressing through support services are you aware of?
5. What sort of professional understanding/service developments do you now feel are necessary to support at risk families better? (Prompt: any thoughts around intersectional issues, safeguarding, trauma-informed and poverty-aware approaches?) (Any thoughts around training needs and requirements for people engaging with families 'at risk'?)
6. In future service developments what are your thoughts around working alongside workers with lived experience?

One to one parent interview questions:

(n=6-8 across 2 sites): 8 would be preferred number minimum if one to one interviews are the preferred method)

1. Can you tell us about your journey into services as a parent?
2. What is your families experience of services since then?
3. What if anything, has been helpful to your family?
4. What if anything, has been less helpful?
5. Do you feel your needs have been met? (If yes, how? If no, why not?)
6. What if anything would you like to see change?
7. What sort of service developments would improve parent and child journeys?

Parent collaborator FG questions:

1. What motivated you to become involved in the Partnership for Change Study?
2. Overall, how have you found the experience of being a parent collaborator? (prompt: perceptions of role)
3. How has the process of developing the CAPS Programme worked in practice? (Should identify pros and cons)
4. For you, what ways of working have been helpful in terms of coproducing CAPS with other stakeholder groups?
5. Is there anything about that process that you would improve, and if so how?

Parent Collaborator Parent-Reported Measures Development Focus Group

1. What was the most important or significant issue, that you wish services paid more attention to when your family was involved with social work? *(What was really important to you at that time?)*

2. What were the most important changes you would have liked to have seen in your lives at that time?
3. Is there anything that you can think of that the Infant and Parent Support team could do to offer more support to families going through similar experiences?
4. From the first few questions, is anything that you think could help the research team capture this type of information? What would this have looked like?
5. How could we collect data on these? (Use stimulus material to prompt, for example illustrations of Likert scales)
6. How did you feel when you were receiving support from services previously?
    a. How were you treated? How did you feel?
    b. Was there anything in particular that was helpful or not helpful? (Prompts: Respect, stigma, ashamed, helpful, equality, level playing field, supported).

7. Thinking about how your family experienced accessing social work, mental health services, and/or other supports, what are ways that this experience could be improved in IPS?
8. What information could we collect to measure this?
9. Just before the break, we discussed how we can measure and collect data on outcomes. Now we would like to know how you think we should measure experience?
10. Is there anything that you would like to add?

Partnership for Change

Phase 2 Topic Guides

First of all, can you tell me how your referral into services came about?

1. Can you tell me about your journey through the referral process?

2. Can you tell me how you felt about the possibility of being referred and accepted into either services included in the study?

Now, thinking now about the research part of your involvement in the PfC Study:

3. How do you feel about how your involvement in the research has been explained to you (time commitment, questionnaire completion, interviews, methods used, RCT group allocation)? How did what was actually involved compare with your expectations?

4. Supplementary probing question if necessary: what do you understand about your involvement in the research?

5. How did you feel about the consent you gave and the points you agreed to? Did the information provided make sense to you? (Readability, accessing wider records, sharing information, researcher interviews, etc.)

6. How did you feel about the assessments used? (probe – potential burden, e.g. length of time it took and whether they liked the assessment method etc)

7. How did you feel about where and how assessments were completed? (venue, setting, comfort levels, engaging with staff, etc.)

8. How did you feel about the types of questions included in the questionnaires used as part of the assessment? Was there anything in particular that you would like to comment on? (relating to personal questions without leading participants)

9. Are there any questions not included that would have been helpful to cover that would help us understand your situation better? (Relating to income (money coming in and out of your family), access to travel to get places, access to services, cultural needs, etc.)

10. Are there any practical issues for you that the research team should be aware of? (travel, language, support, childcare?)

11. Up to now have there been any particular ways that you have been contacted that you have found particularly helpful/unhelpful? (Probes: text/phone/time of day/etc.)

12. Any other comments?

Professional Key Stakeholder Interviews for Phase 2

Feasibility of Methods

1. Can you tell us your thoughts on referral routes into the trial and into the new intervention if randomised that way?
2. If randomised to SAU, how did it work identifying and providing support for the family (if applicable)? (Prompt: enquire about each type of service if families received more than one)
3. What was your knowledge of the new intervention? Knew anything about/ had any links/ what they thought about the new intervention's content and delivery, duration etc. (Probe specifically for different aspects of intervention)
4. How did it fit with other services being delivered to families – eg overlap, filling a gap, replacing/ negating the need for other services (if so which)
5. Referrals into other services from and around the new intervention – can they tell us anything about that worked from their perspective.
6. What went well/ is good about the new intervention?
7. Do you have any suggestions for improvements to the research and to the intervention?

Parent Collaborator FG questions:

Explores RQ1, RQ3 & RQ5

6. What motivated you to become involved in the Partnership for Change Study?
7. How would you describe your role as a Parent Collaborator?
8. Overall, how have you found the experience of being a Parent Collaborator?
9. How has the process of developing the intervention worked in practice? (Should identify pros and cons)
10. For you, what ways of working have been helpful in terms of coproducing the new intervention with other stakeholder groups?
11. What has been less helpful?
12. What are the challenges, or potential challenges with the new intervention?
13. Is there anything about that process that you would improve, and if so how?