PROTOCOL

Study Title:

Improving outcomes for children and families affected by PATERNAL substance misuse: A feasibility study of the PARENTS UNDER PRESSURE (PuP) programme for fathers.

Short Title:

PuP4Dads

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Funder: National Institute for Health Research (NIHR) Public Health Research (PHR) programme: 15/82/01

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Introduction

Parents affected by drug misuse are a highly stigmatised and marginalised group of parents, who are often reluctant to engage with family support services and group-based parenting programmes [1]. Thus a targeted approach to supporting these families, with effective programmes specifically designed for high-risk parents [2], is required. This study involves opioid-dependent fathers in a parenting intervention – the *Parents under Pressure (PuP) programme* – which is specifically designed for high-risk parents. It aims to improve family functioning by addressing affect regulation as a key driver of parenting and couple-related behaviours in men. This fits with the most recent research and clinical recommendations by Panter-Brick et al [3], informed by their recent systematic review of the global evidence on father-inclusive parenting and co-parenting interventions. Importantly, this study will focus on vulnerable children (aged 0-8 years old) living with opioid-dependent fathers.

In the UK, an estimated 350,000 children are affected by parental drug misuse [4], with prevalence increasing [5]. Parental drug misuse severely compromises the caregiving environment in which children grow up [6] and is strongly associated with inequalities, the intergenerational transmission of harm [7] and child protection involvement, with rates of parental substance misuse listed as key concerns in 30-70% of all child protection cases [8].

Problem drug use is a chronic public health problem, with opioid and crack cocaine use considered the most harmful and costly [11, 12]. Prevalence of drug use, and the profile of drug users, has remained relatively stable over recent years [12], despite the rapid expansion of recovery-focused treatment. However, increasing numbers of drug users are now accessing treatment, the majority opioid users. For example, in England in 2012-2013, the prevalence of opioid and crack users was estimated to be nearly 300,000 with 71% in treatment in the same year [12], and of those in treatment, 79% were opioid users [12]. Notably, there are far more men than women in drug treatment (averaging >70%) most of whom are parents, or have some parenting role and responsibility. For example, in Scotland in 2012-2013, over 40% of new drug treatment attenders reported living with dependent children [11].

Supporting families with parental substance misuse requires an explicit focus on both parent's wellbeing, with parental affect regulation consistently highlighted across different programme models [13]. This, in turn, affects parenting behaviours that include the capacity to understand and reflect on the child or infant's state of mind and the quality of the caregiving relationship. Parenting skills

are taught in the context of helping parents to remain calm in the face of parenting challenges whilst ensuring that they have a repertoire of skills that they can draw upon. Additionally, interventions need to include a focus on the broader ecological context of families' lives and help families connect with a wider social environment, have safety, and some security around accommodation and financial issues [14, 15]. Although relatively few in number, there is growing evidence that promotes such approaches when delivered across community settings such as opioid substitution therapy settings [16, 17] and within the context of family drug courts [18]. Notably, these programmes address multiple domains in families' lives and incorporate a case management approach in order to address wider contextual factors.

Although fathers play a critical role in child development, family functioning, and maternal wellbeing [9], parenting interventions rarely target men, or make a dedicated effort to include them, especially fathers with complex needs [3]. Drug dependent fathers tend to be excluded from family support services [20] despite evidence that drug-using fathers have a parenting style that often involves physical and verbal aggression towards children and situational violence towards partners [21]. Further, there have been ongoing concerns about fathers' involvement in cases where there have been serious and catastrophic outcomes for children in families with paternal drug use [22]. Consequently, there is a compelling argument to involve fathers in programmes that reduce aggression towards children and partners and focus on emotional regulation within the context of family life. This research is highly relevant to the UK public health agenda, with implications for improving the quality of caregiving in complex families, reducing child abuse and situational family violence, improving children's developmental outcomes across all domains, and reducing inequalities in the trajectories of adults and families affected by drug dependence. As there is a large knowledge gap around the potential to include drug-dependent fathers in parenting programmes, this research will contribute knowledge around feasibility and acceptability to the large numbers of men, currently receiving opioid substitution therapy.

One promising parenting programme for drug-dependent parents, developed in Australia, is the *Parents under Pressure (PuP) programme*. PuP was found to be effective in a randomised controlled trial (RCT) [16] with parents in methadone maintenance treatment and is currently the subject of a multi-centre RCT in the UK [40]. However, these evaluations primarily focus on mothers. Evidence from our review of the literature suggests that there are many challenges to involving fathers, especially high risk fathers with complex needs, in both parenting programmes [41] and research studies [3]. Thus, we need to determine: a) the uptake, retention and acceptability of PUP among drug-dependent fathers (and partners when recruited together); b) acceptability among staff referring into and delivering the programme and; c) critical factors that would affect a future RCT including, gaining informed consent, uptake and participation rates, the feasibility of gathering outcome and cost data from fathers, mothers and staff, and possible sources of contamination.

Research objectives

Aim: To implement and test the feasibility and acceptability of the PARENTS UNDER PRESSURE (PuP) programme for opioid-dependent fathers and their families and to determine whether a future pilot RCT and full scale evaluation including an economic evaluation, could be conducted.

Objectives: By the end of the study (24 months), we will have:

1. Determined whether a pilot RCT and full evaluation, including an economic evaluation, could be undertaken on the Parents under Pressure (PuP) programme with drug-dependent fathers and their families.
2. Assessed the recruitment and retention of drug-dependent fathers, as well as feasibility, and acceptability of the intervention among fathers, mothers, practitioners, referrers and key services.
3. Assessed the fidelity and reach of intervention delivery by PuP practitioners, including barriers and facilitators to successful implementation.

4. Refined and tested the logic model and theoretical basis of the intervention.
5. Enhanced understanding of the parenting needs of drug-dependent fathers and what programme components work best with fathers.
6. Determined key trial design parameters for a possible future large-scale trial, including recruitment and retention rates and strategies, outcome measures, intra-cluster correlation and sample size.
7. Determined the key components of a future cost effectiveness analysis and test data collection methods.
8. Established whether pre-set progression criteria are met and a larger scale trial is warranted. If yes, designed the protocol, including identification of required structures, resources and partnerships.

Research design

In line with MRC guidelines on developing and evaluating complex interventions [42], this is a mixed methods, two part feasibility study.

The key research questions include:

For the intervention

1. How feasible is it to deliver PuP for opioid-dependent fathers in routine family-based local government and voluntary sector services?
2. How acceptable is PuP among staff and recipients and what are the barriers/facilitators to uptake and retention?
3. How acceptable and adequate is the training and supervision for staff?
4. To what extent can PuP be integrated into non-NHS settings across the UK?

For the study

5. What is the optimal level of recruitment, consent, and retention for a future trial?
6. What are the best methods of collecting outcome data from fathers and mothers at baseline (pre-intervention), 24 weeks (end of treatment), and at six months follow-up?
7. How feasible is it to collect attendance, medical and cost data on participating families?
8. How acceptable and appropriate are the assessment methods?
9. Is the profile of change in fathers, mothers and children clinically significant?
10. What is the nature and extent of routine family support services for fathers in drug treatment?
11. Which study design would best suit a future evaluation, including an economic evaluation?

PART ONE: Will answer research questions 1-4. Firstly, we will estimate the pool of potential fathers in Lothian who are on opioid substitution therapy (OST). Treating clinicians (in Lothian region) will invite eligible fathers to take part in the study, and we will enrol 24 fathers and their families in the PuP programme, thereby providing information on numbers eligible, approached and enrolled in the programme. The intervention will be delivered by twelve accredited PuP practitioners employed by four partner agencies: the City of Edinburgh Council Social Work Department 'PREPARE Team', and the Third Sector Scottish Family Support Service 'CIRCLE', Children 1st (Midlothian) and West Lothian Drug and Alcohol Service (WELDAS). PuP will be provided as an adjunct to 'treatment as usual' health and social care, including individual-based addiction treatment and child protection services. Expert PuP practitioner supervision will be provided by an accredited PuP supervisor, based in Oxford. Treatment fidelity will be monitored by asking parents to complete a bespoke PuP Treatment Experience Measure.

Qualitative interviews with enrolled fathers and mothers before starting PuP will investigate 'treatment as usual' service utilisation, including drug treatment and previous involvement with parenting and family support services. 'Usual care' for drug dependent fathers will also be explored in focus groups with referrers at the end of the implementation phase and with other key stakeholders in our 'expert event' (see below). Interviews with both parents when they complete the programme, or drop out, will explore acceptability of PuP and strategies for successful implementation. Interviews

with PuP practitioners conducted throughout the implementation phase, and focus groups with referring professionals, will explore operational issues and provide an iterative approach to feedback on programme delivery. All interviews and focus groups will be conducted by the Research Fellows and will take place in convenient locations (e.g. community 'recovery hubs' or within participants' homes).

PART TWO: Secondly, we will examine the main feasibility research questions (5-11 above) that will inform a future pilot RCT and full evaluation of PuP, in order to: test and verify methods of data collection with both parents, determine the rate at which fathers can be recruited to PuP and identify issues related to recruitment, assessment or delivery of PuP using ADePT [43] - a process which helps to systematically appraise problems and solutions encountered during a feasibility study. Our final report and recommendations will be based on the results of this process.

Qualitative interviews will ascertain acceptability of measures, including quality of caregiving based on video recording parent-child interactions and standardised measures relating to couple and family functioning, child development/wellbeing and parental substance use. Measures will be administered (by the Research Fellows) pre-treatment, end of treatment (around 24 weeks) and at six months post treatment, with completion rates examined and dose of treatment monitored. Interviews with father and mother participants will be conducted in the home where possible, or in a suitable community venue (e.g., recovery hub).

In addition, we will host an 'expert event', where key stakeholders will be invited to detail family support services for drug-dependent fathers nationwide. This data, along with qualitative data on routine service utilisation from parents enrolled in the study, will allow us to determine 'routine care pathways' for drug-dependent fathers beyond the locality of the study. This data will inform our decisions about a future study design.

Economic assessment: The feasibility of collecting suitable cost and outcome data will be investigated with a view towards a full cost-utility evaluation from a health and social service perspective as per NICE preferred reference case [44]. Parents will complete a self-report survey of NHS and criminal justice service resource use and EQ-5D-5L [45] at baseline, end-of-treatment and 6 month follow-up. NHS costs will include drug and alcohol service use, primary care consultations, secondary care consultations and community prescribing. Prescription medication will be limited to those associated with drug and alcohol treatment only in order to minimise patient burden.

Progression Criteria: The following criteria will be used to guide decisions concerning the progress of the study. The research group will review these criteria on a regular basis and report to the study Steering Committee (SSC) at each of its meetings. The SSC will also be informed of any immediate concerns as these arise. The funder will be informed of the SSC's view on any matter concerning the progress of the study.

Stopping rules / Progression criteria

Criteria	Indicator	Method of assessment
Successful recruitment of families to the PUP intervention and study.	Trained practitioners to recruit and deliver PUP to minimum of 1:5 families approached or average of 2 families per month. Total number = 24	Project monitoring data
Delivery of PUP	PUP delivered to required standard	Bespoke treatment fidelity measure

Acceptability of PUP to practitioners	Broad satisfaction of PUP among staff delivering the intervention	Qualitative interviews and regular feedback from practitioners to the research group
Engagement with PUP practitioners in research	90% (7/8) of those approached agree to participate in a qualitative interview	Qualitative interview data.
Engagement in research with staff from agencies referring to PUP	80% of those approached agree to participate in qualitative interview	Qualitative interview data.
Family engagement with PUP	66% of families recruited complete the PUP intervention. Total = 16.	Project monitoring data
Acceptability of PUP to families	Broad satisfaction of PUP among families receiving the intervention	Qualitative interviews with fathers and mothers
Family engagement with research component to inform the development of the logic model	Minimum of 10 fathers recruited to the research study complete the baseline and end-of-treatment quantitative interviews and at least one qualitative interview	Baseline and end-of-treatment questionnaire data and qualitative interview data
Adverse effects	Maintain a list of all adverse effects that might arise for each family comprising those that may be attributed to the intervention and those that may be attributed to the research study.	Discussion and decision regarding the adverse effects at monthly management meetings, study steering committee and DM[E]C meetings.

Study population

The target population for this study is 24 families, living in Lothian, with at least one child aged 0-8 years old, affected by paternal drug misuse - namely, families with fathers/male caregivers, diagnosed with opioid dependence (according to ICD-10 criteria), who are currently prescribed opioid substitution therapy (OST).

We anticipate that the majority of participants enrolled in this study will largely reflect the population of men normally enrolled in OST treatment programmes. That is, the majority will be aged between 18-55 years old, on a low income or unemployed and in receipt of welfare benefits, living in social housing in areas of deprivation, and have a history of poly-drug use and criminal justice involvement, including imprisonment. Many of the parents will have complex needs e.g. poor physical health/blood borne viruses, mental health issues (anxiety and depression), a history of trauma and/or childhood abuse and neglect themselves. Typically, these parents present with emotional dysregulation, poor problem solving and coping skills, low educational attainment, limited social skills, and problems with debts/budgeting, housing stability and employability.

Our recruitment strategy will aim to include a diverse range of fathers and families who broadly reflect the diversity of family constellations which are now common place amongst this population. Thus we will include:

- biological and non-biological ('social' or 'step') fathers
- resident and non-resident fathers, so long as the father plays an active role in the day-to-day care of the children
- concordant couples (where both the father and the mother are drug-dependent)
- discordant couples (where only one adult in the family – the father – is drug-dependent).

By adopting a 'real life' approach to fathering and fatherhood diversity, we aim to enhance the clinical relevance and ecological validity of the study findings. We propose to take a pragmatic approach and include any male partner who is a caregiver to one or more children and defines himself as a 'father', 'father figure' or 'male caregiver' to a preschool aged child. This is in keeping with Panter-Brick et al's [3] systematic review which defined the term 'father' as "all men who are socially significant to children or assume actual fatherly roles in taking care of children, whether or not the birth father, married to the mother, or co-resident with the child" pg1191.

It should be noted that PuP involves all children living in the family but the focus of this study will be on outcomes for one 'index' child (0-8 years old) in order to maintain a focus on the early years. In order to reduce bias in the selection of the index child, we will use a sampling frame to include different types of children: female/male, age range (lower, middle and upper), children with special needs (e.g. behavioural difficulties, ADHD) and those without. We will then measure this child's progress, using the measures outlined below. In addition, we expect that some families will have other adults (e.g. kinship carers and possibly other fathers) who are involved with the children and who may want to take part in PuP. Where this is appropriate (i.e. in the child's best interests) and relevant to the delivery of the programme (and individualised case plan/case conceptualisation) then wider family members will be encouraged to take part in the programme (i.e. with the agreement of the consenting mother and father and PuP practitioner).

We will recruit families into the study using the following inclusion and exclusion criteria:
Inclusion criteria:

1. Fathers who meet ICD-10 diagnostic criteria for opioid dependence who are prescribed opioid substitution therapy e.g. methadone, buprenorphine.
2. Fathers with opioid dependence who also use other types of psychoactive substances (e.g. benzodiazepine, cocaine, cannabis or alcohol) are eligible for inclusion in this study, in recognition that poly-drug use is the norm.
3. Mothers/partners of fathers recruited into the study are eligible to take part whether or not they have a diagnosis of substance dependence themselves.
4. Each family will have at least one 'index' child aged 0-8 years old, or will be expecting a child.
5. Target children included in the study can be biological or non-biological children of the included father.
6. Fathers must be involved in the day-to-day care of the index child.
7. Fathers must have been in a relationship with the mother/partner for at least 6 months.

Exclusion criteria:

1. Either parent has a serious mental illness (e.g. active psychosis) which prevents them from fully participating in the programme.
2. Families where domestic abuse or child abuse has resulted in the father being prohibited from contact with the target child or family.
3. Families where the father is facing an imminent prison sentence of longer than 6 months, or a criminal justice order of longer than 6 months which would prohibit their active involvement in the programme.
4. Either parent is under the age of 16 years and/or NOT officially resident in Lothian region.

The intervention

The *Parents Under Pressure (PuP) programme* (see http://www.pupprogram.net.au/) will be delivered to families where the father is currently on opioid substitution therapy (OST) and receiving community support from NHS Lothian addiction treatment services (delivered within specialist and primary care services).

Theory of Change: The PuP programme aims to enhance parents' capacity to provide a safe and nurturing environment and sensitive and responsive caregiving for children. However, in order to provide sensitive and responsive caregiving (including managing difficult behaviours and limit setting), it is essential that parents are able to understand and manage their own emotions. Impulsivity and poor affect regulation are key features of substance misuse and can be viewed both as a contributor to and a consequence of substance misuse [47]. Before parents, and in particular fathers/male caregivers who have engaged in hostile, reactive behaviour patterns in the context of family life [21], are able to respond sensitively to their children and partners, they need to be able to manage their own dysregulated affect.

Thus, the PuP programme extends beyond instruction in traditional behavioural parenting strategies such as managing non-compliance, better limit setting and rewarding good behaviour to a focus on helping develop a calmer, less reactive, family environment. This proposed mechanism of change is that the relationship between sensitive and responsive parenting (quality of caregiving) and parenting skills (knowing what to do) and child outcome is influenced by the parent's capacity to manage their emotions.

(1) Assessment and individualised support plan developed with family. Unlike many parenting programmes, PuP is individually tailored to each family. The assessment model allows for an individualised case plan to be developed that is guided by a model of case conceptualisation. Immediate priority areas and goals for change are identified by the practitioner and parent/caregiver and are worked towards collaboratively. The process of treatment planning is undertaken by drawing from a *Parent Workbook* consisting of 12 discrete modules. These are selected and ordered according to the needs of the family and the immediate presenting issues. This approach allows for flexibility, i.e., immediate problems may include potential homelessness, high risk of relapse to drug use, which need to be addressed in order to introduce both stability in the family environment and engage high-risk families. Integral to these processes is engagement of the parent(s) in the process of developing better coping skills and being able to identify and manage their emotions. This "thread" runs through all PuP sessions regardless of the task at hand, and extends to supporting parents to develop emotional regulation skills in their young children.

(2) Specific programme components that link to mechanisms of change. The quality of the parent-child relationship is intrinsically linked with the capacity of parents to provide nurturing, sensitive, and responsive caregiving [17]; and this capacity is fundamentally impacted by the capacity of parents to regulate their own emotional state in the face of parenting challenges [40, 48]. Therefore, many of the PuP treatment modules focus on improving parents' emotional state and fostering a positive parent-child relationship. For example, the *Mindful Child Management* and *Connecting with your Child* modules focus on helping parents develop a range of appropriate and non-punitive child management techniques, strategies for 'mindful play', skills for understanding their children's cognitive and emotional states, and mindfulness techniques to promote sensitive caregiving in stressful parenting contexts (e.g. tantrums or prolonged infant crying). Being in the "right state of mind" to manage difficult parenting situations, helping parents to develop coping skills and mindfulness strategies to reduce dysregulated affect [48]. This dual focus aims to reduce coercive hostile parenting behaviours, make caregiving more nurturing and child-focused and enable a reduction in situational aggression between partners. In regards to parental emotional regulation, the PuP *Parent Workbook* contains several treatment modules that aim to reduce dysregulation and psychopathology, by the use of mindfulness exercises (*Managing Under Pressure* module) and urge-surfing techniques for substance misuse issues (*Managing Substance Use Problems* module). In addition, this study will provide an opportunity for fathers and their partners to develop communication skills and to co-regulate by identification of high risk situations for situational verbal and physical aggression. This component of PuP will be undertaken initially with fathers alone and then extend to couples sessions. Whilst this needs to be undertaken with great sensitivity and awareness of safety issues for both, the work of Stover and colleagues [13] indicates that this

approach is acceptable for both partners. PuP includes a module on *Communication* in intimate relationships and this will be combined with modules on managing emotions to address interpersonal aggression between partners and potentially, towards the children.

Finally, self-regulatory skills are developed with children through combined sessions with the caregivers and child/children. These self-regulatory skills again draw from mindfulness constructs with a growing body of evidence supporting the relationship between mindfulness and adaptive emotional regulation [49] particularly for young children with difficulties with emotional regulation. These skills are appropriate for children aged 3-8 years. As parents become more emotionally regulated, they are able to provide more sensitive caregiving. This in turn, is associated with the development of emotional regulation in young children [50]. Thus, the *Parent Workbook* supports the parent by allowing for a documentation of his or her own personal journey through the programme.

Delivery of the intervention: PuP is a 20-24 week programme designed to be delivered in families' homes although, where there are concerns regarding practitioner safety, it can be delivered equally well in community-based clinical settings. For this study, PuP will be delivered by four organisations: PrePare, CIRCLE, Children 1st and WLDAS. Between them, they have 12 full-time trained practitioners (six located in CIRCLE, two in PrePare, two in Children 1st and two in WLDAS), trained by the developers of PuP (Professor Dawe and Dr Harnett), who will deliver the programme to fathers and families enrolled in this study.

CIRCLE is a Scottish National Charity for Vulnerable Children and Families which provides a community-based early years' and family support service to over 600 families per year, targeting the most disadvantaged families, especially those affected by parental substance misuse. It has purpose built facilities for working with parents, children and families but also provides a home visiting service for difficult-to-engage families. Circle is an established and highly regarded service, commissioned to provide family support services in Edinburgh, East, Mid and West Lothian by the Alcohol and Drug Partnerships, and is therefore an ideal organisation to deliver the intervention.

PREPARE is a City of Edinburgh Council led organisation which provides a comprehensive care service to over 100 substance-dependent pregnant women each year via a multidisciplinary team which comprises a senior social worker/manager, early years workers, addiction nurses, midwives and a health visitor. PrePare is located in a deprived area in South West Edinburgh - Westerhailes Healthy Living Centre, with a satellite service in East and Midlothian. PrePare provides a home-visiting service but can also see families in the centre. It works with pregnant women who are alcohol or drug dependent and they engage with the whole family, including fathers, from the antenatal period through to six months postnatal. The Early Years' workers in the service take a lead role in providing parenting support.

Children 1st is a Scottish National Charity for vulnerable children and families, established in 1884. In Midlothian, the Children 1st DASS (Direct Support Advice Support Service) works with families affected by parental substance use, and provides a home visiting 'whole family' strengths-based approach, so the PuP model fits well with their role and remit. Qualified practitioners provide emotional and practical support to around 50 families per year to prevent neglect and abuse and to help families and communities keep children safe. DASS includes four full-time practitioners and one team manager and is funded by the Cora Foundation and Mid and East Lothian Drug Partnership.

West Lothian Drug and Alcohol Service (WLDAS) is an independent registered 3rd sector charity established in 1985, with an office base in Craigshill Livingston. The service has a multi-skilled staff team of 17 who deliver addiction treatment and care in the community and 'whole family' work to approx. 25 families per year. WLDAS has a part-time 'resident' clinical psychologist and senior practitioner who will deliver the PuP programme in West Lothian as part of their family service.

Note: Both CIRCLE and PREPARE have dedicated 'father's workers' who will be part of the PuP practitioner team for this project.

NHS Lothian addiction services: NHS Lothian Substance Misuse Directorate (SMD)/Integrated Health and Social Care Teams and Primary Care Teams will provide organisational support for this project. This will include: a) recruitment of drug dependent patients into the study; b) retrieval of prescribing data on parents enrolled in the study (with the parent's permission) and; c) staff involvement in focus groups to discuss the research questions on acceptability and delivery of PuP and 'usual care'.

NHS Lothian Substance Misuse Directorate (SMD)/Integrated Health and Social Care Teams in Lothian offer a wide range of evidence-based alcohol and drug treatment approaches, delivered in partnership with Primary Care, Social Services and Third Sector Organisations. The SMD plays a key role in supporting high risk parents to stabilise on opioid substitution therapy (OST) and, in line with Government drug policy, priorities those whose children are at risk of abuse and neglect. The Lead Consultant Clinical Psychologist (Littlewood) is a co-investigator on this study.

Primary Care Teams in Lothian include 93 GP practices who provide drug treatment under the National Enhanced Services (NES) contract for drug misuse in Scotland. Lothian's NES involves over 3500 drug-dependent patients, 2300 of whom are prescribed methadone by their GP (65.8% male, 34.2% female). Approximately 40% are estimated to be living with dependent children (based on SMR data reported to ISD and Primary Care contract return data). Professor Robertson, GP and co-investigator on this study, will advise on the involvement of Primary Care. SPCRN will also assist with recruitment of patients from GP practices where needed.

Note: The delivery of PuP will involve liaison between PuP practitioners and the families' direct care team (e.g. GP, Health Visitor, Addiction worker, allocated Social Worker etc) as would normally be the case when patients/families are involved with PrePare and Circle.

Procedure/Methods

Recruitment: Participants will be recruited into this study (approximately two families per month) via the following services: NHS Lothian Substance Misuse Directorate/Integrated health and social care teams in Lothian, Primary Care Teams in Lothian, CIRCLE, PrePare, Children 1st and WLDAS. A study invitation letter will be prepared and sent out to all recruitment sites. This will include information on the study, participant eligibility criteria, participant information sheets, and clear instructions on how to refer into the study. Meetings with staff teams will be offered to answer any questions about the study and the intervention. Staff will be asked to identify eligible fathers (prescribed opioid substitution therapy) and their families when they attend for routine appointments and, if they show an interest in the study, with their permissions, pass their contact details onto the research team. Treating clinicians will be advised to log in the patient's notes that they have agreed to be contacted. The research team will contact (via study mobile phone) potential participants (fathers and mothers separately) to discuss the study and PuP programme in more detail and will obtain informed written consent if they both wish to take part.

The consent process will involve: agreement regarding confidentiality (including the limits of confidentiality in respect of child and adult protection and legal issues), permissions regarding data collection (including audio and video recording and follow-up), data protection and data management, anonymity, GP notification, payment of all expenses, and freedom to withdraw from the study. Children in the family, who are deemed to have the capacity to consent, who wish to participate in the intervention will also be consented into the study, after their parents agree to the child being approached by the research team. Likewise, kinship carers or other family members who wish to take part in the programme will be asked to provide consent to take part, after agreement

with the parents and allocated PuP practitioner. Please note: If any young person or significant other does not wish to take part in the study, the PuP programme will be delivered with only those whom consent has been obtained.

Drop-outs: Additional measures will be taken to ensure retention of fathers and to maximise follow-up of drop-outs. When we enrol participants we will seek permission to:

1) Document and use mobile phone numbers of both the father, mother and significant others (e.g. siblings and kinship carers) who may know the whereabouts of the family.
2) Write to family members with contact verification cards (using reply paid envelopes).
3) Use text messaging to send appointment reminders (using study mobile phones).
4) Trace the whereabouts of the father/family through professionals involved in the care of the family (e.g. prescribers/GPs, addiction staff, social workers) – we will include a parent consent form to enable this kind of contact tracing.

In addition, we will:

1) Provide the Research Fellows with a study mobile phone so that participants can telephone or text the researchers direct.
2) Send birthday cards to all the family members, Christmas cards and 'father's day'/'mother's day' cards. This strategy has been found to retain families in longitudinal studies.
3) Ensure research interviews are arranged at a convenient place and time for participants.
4) Repeat offers for follow-up interviews if participants fail to attend research interview appointments.
5) Offer each mother and father a gift voucher and expenses for taking part in the research interviews to cover child care costs, travel, subsistence and any other out-of-pocket expenses.
6) Escalate payment schedule so that follow-up data is worth more (£15 baseline, £20 end-of-treatment, £25 follow-up).

Outcome measures

As this is a feasibility study, the main study outcome is whether the study meets pre-set progression criteria (see page 4-5). However, the study will also test a range of outcome measures for acceptability and sensitivity to change (see Table below) for use in a subsequent trial.

As the goal of the PuP programme is to improve child outcome and reduce child abuse potential in high risk families, the primary outcome measures will be measures of child outcome, parental report of child abuse potential and safeguarding information on children's involvement in child protection services. Secondary outcome measures will assess the domains of parental functioning that measure the proposed mechanisms of change in the PuP programme that have a direct impact on child outcome. These consist of quality of caregiving relationship, parenting skills and knowledge, and measures that are conceptually related to parental affect regulation including levels of spousal aggression and substance use/misuse.

Table 1.

Domain of Focus	Description of measure & suitability
Child behaviour outcomes	
Strengths & Difficulties Questionnaire (SDQ)	25 items, subscales: attention & concentration, conduct problems, emotional problems in children 2-16 years. Widely used across diverse groups, showed sensitivity to change in PuP RCT [16]. Completed by mothers and fathers.

Brief Infant Toddler Social and Emotional Assessment (BITSEA)	42 items. Widely used, sensitive to change, used for infant 12-36 months.
Child protection outcomes	
Brief Child Abuse Potential Inventory (B-CAPI)	33 items, subscales include Abuse Risk plus Lie Scale and Random Responding. Sensitive to presence of abuse, validated for use in mothers on OST and used in PuP RCT [16].
Child Protection data on child involvement	At-risk CP registrations and de-registrations and out-of-home placements - obtained from Social Work Scotland records (with participants' permission).
Parenting knowledge, skills and competence	
The Parenting Sense of Competence Scale (PSCS)	17-item self-report scale used to measure satisfaction / comfort with being a parent; parental self-efficacy (i.e. perception of knowledge and skills); and interest in parenting. Widely used in parenting literature and sensitive to change.
Quality of caregiving	
Emotional Availability Scales (EAS)	10 minute video recording of parent and child; age appropriate game or activity. Scale draws from attachment theory and emotional availability constructs; has good convergent validity with attachment style as assessed by the *Strange Situation* procedure. Suitable from infancy to late childhood.
Maternal Antenatal Attachment Scale (MAAS)	19-item self-report scale used to measure antenatal maternal attachment and is widely used. Suitable for first-time parents or those without current child care responsibilities during antenatal period. Conducted once at baseline and before EDD.
Paternal Antenatal Attachment Scale (PAAS)	The PAAS is the corresponding measure to the MAAS. 16-item self-report scale used to measure paternal antenatal attachment. It is an accurate predictor of post-birth father-child attachment. Conducted at baseline and before EDD.
Parental affect regulation	
The Difficulties in Emotion Regulation Scale (DERS)	36-item scale measuring six dimensions; e.g., lack of awareness of emotional responses, limited access to emotion regulation strategies, difficulties controlling impulses when experiencing negative emotions. Well validated psychometrically and widely used in intervention studies that focus on mindfulness.
Couple Relationship	
The Revised Conflict Tactics Scale (CTS2)	39-item scale used to assess the presence and severity of Intimate Partner Violence, sensitive to change. Used by Stover et al. [13] - the only existing study of IPV prevention in substance-abusing men.
Substance use	

Treatment Outcome Profile (TOP)	20 items. Measures substance use, including illicit use in last 28 days, injecting risk behaviour, crime, health and quality of life. Widely used in clinical practice in the UK to measure change and progress in drug treatment.
Prescribed OST drugs & daily dose	Objective data to show changes in OST drug type and dosage. Obtained from prescriber (with permission from participants).
Health Economics	
Service Use questionnaire	Bespoke weekly parent-report questionnaire that measures health, social care, and criminal justice service utilisation.
EQ-5D-5L	5-item health related quality of life survey, used in the generation of quality adjusted life years (QALYs)
Treatment Fidelity	
PuP Fidelity Measure	20-item parent completed measure at end of treatment to assess which components of the PuP programme were covered.

OST = opioid substitution therapy

Note: all measures to be completed independently by both fathers and mothers in the study.

Observational measure: Improving the quality of the caregiving relationship is a key focus of the PuP programme. The use of video recorded interactions is considered the gold standard for obtaining the best measures of quality of caregiving. In this study we will video record approximately 10 minutes of father (caregiver)-child and mother-child interaction. The parents are simply asked to "be with their child as they usually would". This will be done in the home using a digital recording device. The footage (recorded on encrypted NHS video-recording equipment) is downloaded onto a NHS computer secure drive and is then coded/scored. This method is widely used in family intervention research including the RCT of PuP in the UK [40]. There is no undue participant burden on families over and above self-report measures. The importance of obtaining independent observational data to support self-reported measures of change is key in this project. Mixed methods evaluations where there is convergence between self-report and observational measures provide greater confidence in outcomes. Permission to use and analyse video-recorded data for this study will be obtained from each parent as well as NHS Lothian R&D Office.

***Randomisation**:* Because randomisation will not be evaluated directly in this study, we will assess acceptability of randomisation in a future PuP trial by exploring the concept in qualitative interviews with parents and services. We will ask parents (hypothetically) whether they'd be willing to be randomised in a research evaluation of this intervention. This question will be accompanied by a brief description of what the randomised comparison would be – e.g., randomisation to early vs delayed receipt of the PuP intervention; or randomisation to PuP vs standard care. To explore the feasibility of cluster-randomisation, we will ask a range of service managers whether they'd be willing, in principle, for their service to be randomised to implementing PuP or standard care.

Assessment and follow up

Assessment of families will be conducted at baseline (prior to starting PuP), end-of-treatment (at completion of PuP or at drop-out), and at six months follow-up. In addition, parents recruited into the study during the antenatal period, who are expecting their first child, or who have no current child care responsibilities because their children are not living with them, will complete MAAS & PAAS close to the expected date of delivery (36-40 weeks gestation).

Because assessment of effectiveness is not a study aim, our feasibility assessment is described below.

Assessment of efficacy/effectiveness

Assessing training, the delivery, uptake and engagement with PuP: (Research questions 1-4 are addressed in this section). Between October 2017 and April 2018 qualitative work will be undertaken to better understand the factors that shape the implementation and uptake of PuP. This includes semi-structured interviews with PuP practitioners and recipients of the programme and focus groups with staff from referral agencies. Interviews with PuP practitioners will take place after they have completed the programme with two families. This will offer them greater opportunity to reflect on their experience. Fathers and mothers will be interviewed after they complete, or drop out of the programme. Referrers (e.g., GPs and Addiction treatment staff) will take part in a focus group at the end of the implementation phase to enable them to reflect upon the process of referral, acceptability and delivery of the programme. The interviews and focus groups will be conducted by the Research Fellows in convenient venues for staff. Recruitment data will be recorded by the Research Fellows. Attendance and completion data on each family will be recorded by the PuP practitioners using a specially designed recording sheet.

Analysis: Qualitative data will be analysed iteratively to capture emerging themes and to elicit perspectives on the underlying theory of change which underpins PuP, for example, fathers' ability to improve emotional regulation and the relationship they have with their children. We will also explore barriers and facilitators that affect the implementation and uptake of PuP. For fathers, this includes pragmatic and other events that might prevent/enable engagement with PuP such as time commitments, acceptability or changes to their health, social, criminal justice or family circumstances. For the PuP practitioners we are interested in their perception of the training programme and supervision (including acceptability) and the extent to which PuP becomes embodied within their professional role. We will also examine the extent to which it is embedded in the host organisations (PrePare, CIRCLE, Children 1st, WLDAS) and in the referral pathways from the perspective of staff working in services who refer fathers and families to PuP (e.g. Primary Care and specialist addiction services). The Research Fellows will report on the feasibility of interviewing fathers who drop out of PuP including the practical and ethical issues that need to be addressed and overcome when undertaking this work. Recruitment and attendance data will be analysed to provide uptake and flow rates through the programme.

Assessing recruitment, gathering research data, assessing impact, and a future study: (Research questions 5 – 11 are addressed in this section). Routine data collected by the Research Fellows between May 2017 and October 2018 will provide: detailed quantitative data on participant flow through the study comprising recruitment rates, numbers providing informed consent and numbers completing the outcome measures at baseline, end-or-intervention and at six months follow up. Researcher field notes will provide the reasons for these rates and the best methods of recruiting and retaining participants in the study. We anticipate that we will need to be flexible and dynamic to maximise retention of families, particularly at six months follow-up. All difficulties and solutions (e.g. change of address/mobile phone numbers, use of text messaging and reminders), will be recorded in the final report. At each research interview we will ask families to provide their views on the acceptability and appropriateness of all the measures, including the economic measures, for example, time taken to complete and level of intrusiveness. In addition, we will explore the parent's willingness to provide consent in the future for their routinely collected data to be used in future studies that link data sets to answer questions about long term outcomes.

Although our predominant focus is on questions of feasibility, we will provide an indication of the possible impact of PuP. Analysis of change will include a calculation of the clinical significance of change using the *reliable change index [51]*. The focus will be on measures of parental emotion regulation; emotional availability/antenatal attachment and child abuse potential. Data will be synthesised in the final report and recommendations made as to whether a pilot trial should be conducted and if so, what features should be considered including an economic evaluation. We will use the ADePT process to guide our recommendations [43].

Sample size justification

Our main justification for the sample size of 24 families with a father/male caregiver who is on opioid substitution therapy (OST) is related to the qualitative data collection and analysis requirements, namely:

1. This number is large enough to include a purposive sample of families with differing characteristics to reflect diversity within the larger population of families who would likely take part in a larger trial - for example: families with concordant parents (where the mother is also drug-dependent) as well as discordant couples; younger and older fathers; first-time and experienced fathers (with more than one child), resident and non-resident fathers; biological and non-biological fathers. We will develop a sampling matrix to guide recruitment to ensure our study sample reflects the wider population of families seen in routine clinical practice. We will also document a socio-demographic profile of the sample to demonstrate the results of our sampling approach.
2. This sample size is also small enough to enable an in-depth analysis of the qualitative data (within the time constraints of the study) to inform our research questions around acceptability, barriers and facilitators to implementation and 'usual care' for fathers. We will conduct in-depth interviews with all parents involved in the study, as well as interviews with the PuP practitioners and focus groups with referring clinicians. We anticipate that this qualitative data will result in lengthy transcripts which will provide rich accounts of involvement in the PuP programme and study. A sample size, limited to a maximum of 24 families, will allow the research team to undertake a more detailed and critical comparative analysis of the whole data set.
3. This sample size also allows for an attrition rate of approx. 1/3 of families (n=8) without jeopardising the validity and rigour of the study - for example, some may withdraw from the study, or drop out of the intervention or fail to complete follow-up measures. In clinical practice, many of these families stop attending services for a variety of reasons (for example, the children are taken into care, the family moves out of the catchment area, imprisonment, illness/hospitalisation etc) and attendance rates are often poor when compared to other families who have less complex needs. Thus, we calculated a desirable number of families (n=16) to complete the PuP programme and 6 month follow-up measures and then added a hypothetical but realistic attrition rate of 1/3rd to arrive at a sample size of 24 families.

Statistical analysis

Quantitative data analysis: Descriptive statistics of routinely collected data, including standard deviation values to inform the sample size calculation of the future trial, will provide a profile of the participants and an estimate of study throughput. This will include: number of eligible fathers approached, number who decline to join the study, enrol, complete and drop-out of PuP. Flow of participants through the screening, intervention and follow-up stages of the study will be summarised in a similar manner to the CONSORT guidance for clinical trial reporting.

Quantitative feasibility outcomes (willingness of participants to be randomised; outcome measure completion rates; up-take, retention and follow-up rates) will be summarised by the number and percentage of participants. Descriptive statistics (number and percentage; or mean, standard deviation, median, lower quartile and upper quartile) will be used to summarise pre-treatment, end-of-treatment and follow-up (6 months after treatment completion for: child behaviour (SDQ, BITSEA), paternal and maternal parenting confidence (PSCS), maternal and paternal antenatal attachment (MAAS/PAAS), couple relationship functioning (CTS2), substance use substance related problems (TOP), prescription data, child protection data, sociodemographic data, child and family health, relationship history and paternity. In addition, changes from pre-treatment to each of the subsequent time points will be reported descriptively.

Clinically significant change measure: We will determine the extent to which individual families made clinically significant change using the Reliable Change Index [51]. This will determine whether there has been a reliable improvement in each of the key domains for both fathers/caregivers and mothers on: parental emotion regulation (DERS); emotional availability (EAS); antenatal attachment (MAAS/PAAS); and child abuse potential (B-CAPI). This measure of individual change is able to provide data on the proportion of fathers and mothers who were able to show a clinically significant improvement, those who showed no change and those who deteriorated.

Health economic assessment: The acceptability of the measures used, in particular the potentially sensitive issues around criminal justice and child protection will be assessed qualitatively. It will also be important to identify if health utility measurement using EQ-5D-5L is felt to be appropriate by this patient group in this context. A dry run conversion of resource use data to generate cost data will be performed by applying standard UK price weights and quality adjusted [45]. A full cost-effectiveness analysis will not be attempted as this would be inappropriate with this sample size. Analysis will instead focus on completeness of returned data, barriers to data collection, acceptability of data collection process and limitations in costing exercise with only summary statistics reported for outcomes.

Qualitative data analysis: Interviews and focus groups will be audio-recorded using an encrypted digital voice recorder, transcribed verbatim, anonymised and entered into NVivo v10 for content coding and thematic analysis. The Research Fellows will anonymise the data and complete the initial content coding, referring to the interview schedules and focus group topic guide for *a priori* issues, but also highlighting emergent topics. Transcripts will be second coded by research team members and initial analytic summaries will focus on participant views, experiences and meanings [53] as well as barriers/facilitators and contextual issues related to the implementation and acceptability of PuP. A constant comparison method [54] and framework analysis [55] will be used to build a matrix of the 'theme' and 'case' analysis, so that they can be mapped onto the logic model and discussed in research team meetings. This will provide a more nuanced and explanatory analysis for discussions on the implications of the findings. A narrative report of the qualitative data results, illustrated with participant quotes and focus group excerpts, will be written up for the final report.

Data Management Plan

All data pertaining to this study will be managed in accordance with The University of Stirling IT security and data protection policies and NHS Lothian IT security and data protection policies in order to ensure that participants' personal identifiable data and anonymised data are fully protected.

This study does not involve storage of any personal identifiable data on University computers nor does it involve the electronic transfer of personal identifiable data from the NHS to the University. Recruitment of participants into the study will involve transfer of patients' names and contact details - this will be done either via telephone or via Dr Whittaker's secure nhs.net email account.

The Research Fellow will record personal identifiable details of participants (e.g. consent forms, personal details sheet) on paper only and these paper records will be kept in a locked cupboard, in a locked room, in a University campus building. The Research Fellow will use a password protected and encrypted University laptop (for use in community treatment sites) to record participant responses to the questionnaires used in this study. All questionnaires will have identifying information (e.g. names, D.O.B) removed and will include only participant unique identifier codes (allocated on enrolment into the study), with the laptop stored in a locked cupboard and locked room in the NMAHP Research Unit, University of Stirling. Access to study data held in the University will be restricted to Dr Whittaker and the appointed Research Fellows.

Audio-recordings of qualitative research interviews/focus groups with patients and staff will be conducted using an encrypted digital voice recorder. Audio files will be downloaded by the Research

Fellows (who conduct the interviews) onto the secure server site at The University of Stirling, transcribed, anonymised and then entered onto NVivo v10, a software package to aid qualitative data analysis. Audio-recordings will be deleted from the voice recorder machine as soon as the file has been downloaded to the secure server. Only fully anonymised transcripts (anonymised by the Research Fellows and checked by Dr Whittaker) will be made available to the wider research team. Any publications/presentations from this study will include only anonymised excerpts from interviews to ensure participants cannot be identified.

Video recording of parent-child interaction for the observational measure (Emotional Availability Scale - EAS) will be recorded using an encrypted NHS video recording device and downloaded onto a secure NHS shared server site within the Clinical Directorate, accessible only to Dr Whittaker and Dr Littlewood (Lead Consultant Clinical Psychologist). Dr Whittaker will arrange on-site access to the video recordings for the purpose of coding the data (over a two day period at the end of the data collection period) by trained EAS data coders who will obtain a 'letter of access' agreement via NHS Lothian R&D Office. Professor Dawe/Dr Harnett will approve the nominated EAS data coder and will also code a random 25% sample of the EAS scores.

All personal identifiable data for this study (e.g. consent forms, participant details sheet, audio-files, video files) will be destroyed by Dr Whittaker within 12 months of the study ending. All non-identifiable data (e.g. questionnaire data, anonymised transcripts) will be held for a maximum of 5 years after the study has ended. Dr Whittaker will ensure that all data for this study is securely stored/archived and destroyed as described above.

Dissemination

This project is a collaboration between clinicians and researchers to help improve the lives of children and families affected by parental drug misuse. The evaluation places families centre stage and utilises their views and experiences to guide implementation. We will ensure findings are disseminated widely and discussed with key stakeholders including: families involved in the study, Service User Forums, the Study Steering Committee, service providers and managers, commissioners, policymakers, and Alcohol and Drug Partnerships. To this end we will host an expert event for stakeholders, ensuring both adult and child health audiences are included. We will offer further meetings should these be required, for example to help disseminate the intervention into routine practice. In addition to the final report and lay summary we will publish our findings in peer-reviewed journals and present at an international conference.

The research team

The research team includes a range of experts who are ideally suited to conduct this study. Dr. Whittaker (Chief Investigator) is an experienced mental health and addictions nurse, researcher and project manager. She conducted an extensive literature review which led to the identification of PuP as a prime candidate intervention. She will lead the study, provide support and supervision for the Research Fellows, advise on recruitment of fathers and families, advise on qualitative research design and analysis and liaise closely with the Clinical Directorate, PrePare, CIRCLE, Children 1st and WLDAS. Professor Dawe and Dr Harnett are the Australian developers of the PuP programme and will advise on all aspects of the delivery, implementation and evaluation of the intervention, including staff training/competency/supervision and fidelity testing. Professor Elliott has a substantial track record in public health research, including addictions, spanning 25 years and will support all aspects of the study. Professor Taylor has extensive experience of conducting research in parenting and child welfare and is a Professor in Child Protection. She will advise on child welfare and protection issues and ethics. Professor Robertson (GP and Professor of Addiction Medicine) will provide advice and guidance on recruitment of NHS drug dependent patients from Primary Care services. Dr Littlewood, Lead Consultant Clinical Psychologist, will provide advice on recruitment of patients from the Clinical Directorate. Andrew Stoddart is an experienced health economist,

particularly in the assessment of community-based health interventions. He will provide expert advice and support on economic outcome measures and analysis.

Research Governance

The nominated **SPONSOR** for this research is Dr Susan Alexander, Research Development Manager, Research & Innovation Services, University of Stirling, Tele: +44 (0)1786 466444, Email: susan.alexander@stir.ac.uk

The Chief Investigator (Whittaker) will have overall responsibility for the conduct of the study and day-to-day management. Day-to-day coordination of the project will be supported by Co-applicant (Elliott). Experienced mixed methods Research Fellows (RFs) will assist with recruitment, enrolment, data collection and analysis, and will be closely monitored, mentored and supervised by the Chief Investigator (Whittaker) and Co-investigator (Elliott). An administrator from the University of Stirling will support Dr Whittaker with procurement of study materials and the financial management of the project.

Study Steering Committee (SSC): A Study Steering Committee, nominated by the research group and appointed by NIHR will comprise an Independent Chair and other clinical and academic members and two service users. A SSC charter (approved by NIHR) will detail the role and remit of the committee, and terms of reference. The Chief Investigator (Whittaker) will attend SSC meetings as a non-voting member, as well as co-applicants and the RFs as required. The SSC will include the operational leads from PrePare (Michelle Kirkpatrick) and CIRCLE (Rhona Hunter) who will also provide routine reports on intervention implementation in the two PuP delivery sites and will liaise closely with the Chief Investigator (Whittaker), appointed Research Fellows and PuP practitioners within their respective services. The SSC will also include an experience statistician, Professor Christopher Weir (University of Edinburgh), and an international expert on research involving drug dependent fathers, Professor Thomas McMahon, from Yale University School of Medicine (USA). The SSG will be involved in the final decision on whether progression criteria for the development of a pilot RCT have been met.

Data Monitoring and Ethics Committee (DM[E]C): A data monitoring and ethics committee, nominated by the research group and appointed by NIHR will comprise an Independent Chair and at least two other clinical and academic members. A DM[E]C charter (approved by NIHR) will agree the role and remit of the committee, and terms of references.

Study timetable

See 'Project Management Plan 28.11.16 v1.0' which details the timetable and milestones for the study.

Key ethical considerations in this study

Risks, potential harms and benefits

Risks: Systematic reviews of parenting programmes [26-28], integrated family support programmes targeting substance-misusing parents [15, 29, 30], and previous studies of the intervention that is the subject of this study – the Parents under Pressure (PuP) programme [31] - report no adverse effects on children and families. This suggests that the risk of unintended negative consequences is minimal. However, there are potential risks which we will take into account from recruitment right through to completion.

Involving fathers/partners in child and family-focused programmes can be a sensitive issue [20], especially where there is a history of parental conflict and/or domestic abuse. Women can feel challenged or even undermined in their role as mothers and can act as 'gatekeepers' to fathers' involvement in the programme, or vice versa. In recognition of this, we plan to involve mothers and

fathers (in their own right as caregivers) in all aspects of the research process, and will meet with them independently to seek their informed consent to take part in the study. We will also collect study data from mothers and fathers separately, and ensure that the impact of the programme on both mothers and fathers is investigated in qualitative interviews with PuP practitioners, referrers and the parent's themselves. The research team has previous experience of involving fathers in research studies and will pay particular attention to relationship dynamics and the welfare of the family as a whole, especially in relation to domestic abuse.

Another potential risk is the likelihood that parental involvement in PuP may uncover previously unidentified child protection concerns or harms to children, whether or not the family are already involved with child protection services [32]. This would be expected with any increased scrutiny of high risk families. Previous studies manage this potential problem by ensuring that parents clearly understand through informed consent processes, that concerns regarding potential harm to self or others will require action from the practitioner and/or researcher that may include reporting to child protection services. PuP is designed to be delivered as an adjunct to 'usual care', and is a strengths-based programme, so PuP practitioners work closely with other professionals who are normally involved in the care of the family (e.g. GP, Health Visitor, Social Worker, Addiction worker). Therefore, any child protection issues can be identified and communicated early, so that appropriate action can be taken, and additional support offered to the family. If the child/children are removed from the family, ongoing support in the PuP programme will be offered as long as there is a plan for family reunification. In addition, the research team will make all attempts to stay in contact with parents and will ensure additional support is offered after taking part in research interviews, for example, by arranging an appointment with a suitable support agency.

Lastly, we anticipate that disruption to NHS clinical services during recruitment and data collection will be minimal. The research team will work with NHS Lothian Substance Misuse Directorate and GP Practices in Edinburgh to identify the least disruptive way of identifying potential participants for the study and to inform healthcare practitioners about the parenting programme and allay any concerns (via information sheets, meetings with practice teams if necessary, and by maintaining open lines of communication). Dr Littlewood will advise about any operational issues within the Substance Misuse Directorate and Professor Robertson and the Scottish Primary Care Research Network will support the involvement of Primary Care. We anticipate that baseline, end-of-treatment and follow-up data collection will be conducted in the participant's family home or within local community-based healthcare settings, whichever is the most suitable venue for the family, and an environment that will ensure both privacy and safety (including that of the researchers). Routine clinical practice risks assessments on participants who take part in this study will inform decisions about recruitment of eligible families and the arrangements for research interviews. In addition, we will employ mixed methods' Research Fellows with previous experience of research with challenging patients and vulnerable children and families within the NHS.

Harms: The potential harm to researchers and practitioners relate to safety concerns associated with lone working and home visiting**.** The research team has previous experience of conducting research with this population of parents and have developed a robust set of strategies to both minimise potential harms and respond to harms when they do arise. The NHS and the agencies involved with the study have robust safety protocols in place for lone working and have extensive experience in assessing potential safety concerns around home visiting. In the first instance, the researcher and practitioner will conduct a joint visit to the family's home. Thereafter, visits for research interviews will involve the researcher providing his/her line manager (Whittaker) with information about location and time of visit and notification by text message/telephone when they have left the family home and again when they have safely returned to base. This process has received full ethical approval in previous studies.

There are no potential harms to families associated with this protocol. The length of assessment measures and literacy required to complete them has been carefully assessed across previous studies and is not considered onerous. The potential problem of poor literacy can be overcome by sensitively reading out part or all of the measures; in practice this rarely occurs and for those with poor literacy the most typical request is simply clarification of the meaning of a word or sentence. As stated previously, it is possible that child or adult protection concerns will be identified in the course of the study. It is most likely that these would be identified by the PuP practitioners in the course of their contact with the family rather than by the researcher. However, in the event that the researcher has concerns regarding child or adult protection, she/he will immediately contact Dr Whittaker, for advice on the appropriate course of action to take. Furthermore, our Research Fellows will obtain a research passport from NHS Lothian R&D Department to conduct this study. This will include abiding by NHS Lothian's policies on patient confidentiality, data protection, lone working, child and adult protection. A protocol for dealing with serious child and adult protection issues will be put in place and the Chief Investigator (Whittaker) and Professor Elliott will be available by mobile phone during the study to enable any issues to be resolved quickly. All risks or incidents will be recorded and a report will document how they were resolved.

Procedure for dealing with adverse events: Any adverse events that occur in research studies must be reported. In the University, adverse events must be reported to the Faculty *Research Ethics Committee* (REC). The Faculty REC reports to the University REC who have oversight of any research undertaken within the each faculty and have the power to suspend any study and investigate any adverse events which arise or which were not foreseen.

We will therefore follow agreed procedures for managing adverse events by systematically recording, investigating, monitoring, reporting and responding to adverse events as they occur. For example, we will intervene where necessary to protect the welfare of women and children involved in the study where there is suspected or reported cases of child abuse or domestic abuse on the part of the father. We will maintain a list of all adverse effects for each family comprising those that may be attributed to the intervention and those that may be attributed to the research study. Discussion and decisions regarding adverse events will be considered at monthly management meetings and meetings of the study steering group. Please see 'Stopping rules/Progression Criteria'.

Benefits: There are major potential public health benefits for children, families and wider society. Evidence from other intensive parenting and family support programmes for substance-misusing parents [15, 29, 30, 33], and previous PuP studies [31], suggest that these interventions can result in positive changes in parenting and the overall caregiving environment, leading to positive effects on the health and wellbeing of children. Drug dependent men have been shown to engage well with targeted family-orientated interventions, and when combined with structured drug treatment programmes, can have positive effects on couple relationship functioning, substance use outcomes and the psychosocial adjustment of other family members, including children, even if they do not participate in the treatment [for a review see 1]. These benefits, in turn, can lead to reduced demand on child health services (e.g. health visiting) and child protection involvement (e.g. health, police and social services). In addition, interventions that have a positive impact in the early years are known to have downstream benefits for example, improved school readiness and educational attainment [34]. Involvement in the intervention may also create opportunities for parents to consider other pressing health and social needs (e.g. hepatitis C treatment), employment and training opportunities, re-housing and new social support networks, drug detoxification and rehabilitation programmes. Thus we anticipate that the programme will lead to longer term benefits for the parents who take part in this study. We expect that participating NHS and social care services will also benefit from the intensive support offered to families and the augmentation of care which will contribute to the parent's overall recovery care plan. Any reduction in child maltreatment for children involved in this study may result in longer term benefits across the life course [35].

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