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A feasibility study of the Parents under Pressure programme for improving outcomes for children and families affected by opioid-dependent fathers

Submission date
29/11/2016

Recruitment status
No longer recruiting

Registration date
19/12/2016

Overall study status
Completed

Last Edited
28/06/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Around 350,000 children in the UK are living with a parent who has a serious drug problem. Research shows that these children often suffer abuse and neglect. Health and social care services have a responsibility to help children at risk of abuse and provide additional support to parents who need help to look after their children. Strategies include engaging families in parenting services and helping parents access drug treatment. To date, parenting services have focused almost entirely on drug-using mothers. However, children in the UK are as likely to be living with a drug-using father as a drug-using mother. Studies also show that drug-using fathers can pose a serious risk to children and mothers. Parenting research on fathers, especially fathers with a drug addiction, is very limited. One promising programme, called 'Parents under Pressure (PuP)' http://www.pupprogram.net.au/, has been specially designed for drug-using parents, and has been shown to improve parenting and child welfare and reduce drug use, but studies so far have not focused on fathers and coparenting. The aim of this study is to find out if PuP is acceptable and helpful to drug-addicted fathers and their families, whether it can be established properly within social work and charitable sector services and if fathers can complete the correct tests, and in enough numbers, for a future evaluation.

Who can participate?
Families where the father/male caregiver has a diagnosis of opioid dependence (drug addiction), is currently in drug treatment, and is receiving opioid substitution therapy (e.g. prescribed methadone as a substitute for heroin). Both parents must be 18 years of age or older and there must be at least one preschool age child (aged 0-5 years).

What does the study involve?
The study involves testing how well Parents under Pressure can be delivered to 24 families with a drug-using father, in addition to the usual care that these families receive, including drug treatment. Parents under Pressure is a manual-based home-visiting programme which includes 12 'modules', delivered over a period of about 6 months by specially trained PuP practitioners.

The programme starts with a detailed assessment of the family, including the needs of each family member, and then a joint agreement on a family care plan that aims to improve family life. The programme includes a parent workbook to help each parent document their progress through each module. Examples of the modules include: 'Connecting with your child', 'Mindful child management', 'Managing substance use', 'Managing under pressure' and 'Communication'. Depending on the needs of each family, the 12 modules are delivered flexibly according to their most pressing needs and the PuP practitioner works with the family every week until the 12 modules have been successfully completed. During the programme, the PuP practitioners chart the progress of the parents and children, and tailor the programme according to how well each family is doing.

What are the possible benefits and risks of participating?

There are major potential benefits for children, families and wider society. Parenting and family support programmes can result in positive changes in parenting and the overall caregiving environment, leading to positive effects on the health and wellbeing of the children. Drug-using men have been shown to engage well with targeted family-orientated programmes, and when combined with structured drug treatment programmes, this can have positive effects on relationships, substance use and the wellbeing of other family members, including children, even if they do not participate in the treatment (e.g. couples therapy). These benefits, in turn, can reduce the demand on child health services (e.g. health visiting) and child protection services (e. g. police, social services and health). In addition, programmes that have a positive impact when children are very young (e.g. preschool age) are known to have later benefits (e.g. school performance). Involvement in the intervention may also create opportunities for parents to consider other pressing health and social needs (e.g. hepatitis C treatment, employment, re-housing, new friendship networks, and drug recovery programmes). Thus the programme could lead to longer term benefits for the parents as well as the children. Any reduction in child maltreatment for children involved in this study may also result in longer term benefits into adulthood.

Previous PuP studies report no negative effects on children and families. However, there are potential risks which need to be taken into account. Involving fathers/partners in family support programmes can be a sensitive issue, especially where there is a history of parental conflict or domestic abuse. Women can feel undermined in their role as mothers and can act as 'gatekeepers' to fathers' involvement in the programme, or vice versa. In recognition of this, mothers and fathers (in their own right as caregivers) will be involved in all aspects of the research, and the trialists will meet with them independently to seek their informed consent to take part in the study. Study data will also be collected from mothers and fathers separately, and 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 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 harms to children, whether or not the family are already involved with child protection services. This would be expected with high-risk families. Previous studies manage this by ensuring that parents clearly understand that concerns regarding potential harm to self or others will require action from the practitioner and/or researcher, including reporting to child protection services. PuP is a programme which focuses on the strengths of families, 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 discussed 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 the family to be reunited. In addition, the research team will maintain contact with parents and will arrange additional support if required with other suitable

support agencies. There are no potential harms to families associated with this study. Nevertheless, a procedure for dealing with serious child and adult protection issues will be put in place and members of the study team will be available by mobile phone to enable any issues to be resolved quickly. In addition, any risks, incidents or adverse events will be recorded and responded to in accordance with existing policies and procedures. For example, the study team 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.

Where is the study run from?
PuP will be delivered via two organisations, PrePare and Circle, based in Edinburgh, UK

When is the study starting and how long is it expected to run for?
February 2017 to December 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Improving outcomes for children and families affected by paternal substance misuse: a feasibility study of the Parents under Pressure (PuP) programme for fathers

Acronym
PuP4Dads

Study objectives
The aim of this study is to implement and test the feasibility and acceptability of the Parents under Pressure (PuP) parenting programme for drug-dependent fathers and their families and to determine whether a future large scale evaluation, including an economic evaluation, could be conducted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/03/2017, NHS South East Scotland REC 02 (2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 465 5674; Joyce.Clearie@nhslothian.scot.nhs.uk), REC ref: 17/SS/0023

Study design
Mixed methods single-centre non-randomised single-group feasibility study

Primary study design
Interventional

Secondary study design
Feasibility study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Parental substance misuse and its effects on children and families

Interventions
The Parents under Pressure (PuP) programme is an intensive manual-based home-visiting parenting intervention, delivered over a 24-week period by accredited PuP practitioners. In this study, PuP will be delivered to 24 families via two organisations: PrePare, a social work led team

which provides a comprehensive care service to substance-dependent pregnant women and their partners and; Circle, a 3rd sector community-based early years' and family support service designed for the most disadvantaged families, especially those affected by parental substance misuse. Measures will be administered at baseline (pre-intervention), end-of-treatment (post-intervention) and at 6 months follow-up.

The PuP programme aims to enhance parents' capacity to provide a safe and nurturing environment and sensitive and responsive caregiving for children. 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. Before parents, and in particular fathers /male caregivers who have engaged in hostile, reactive behaviour patterns in the context of family life 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.

Unlike many parenting programmes, PuP is individually tailored to each family. The assessment model allows for an individualised care 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. 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. 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. 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.

In addition, 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, particularly for young children with difficulties with emotional regulation. These skills are appropriate for children aged 3-5 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. Thus, the Parent Workbook supports the parent by allowing for a documentation of his or her own personal journey through the programme.

Intervention Type
Behavioural

Primary outcome measure
As this is a feasibility study, the main study outcome is whether the study meets pre-set progression criteria. However, the study will also test a range of outcome measures for acceptability and sensitivity to change for use in a subsequent trial.

Feasibility outcomes:
1. Recruitment rate, recorded as the number of eligible families who consent to participate in the study by 12 months
2. Retention rates, recorded as the number of eligible families who complete the parenting programme and the number of families that remain in the study until the follow-up at 6 months
3. Acceptability of the intervention, assessed by parent (on completion or drop out of the programme), practitioner and referrer feedback (over the 12 month implementation phase), including analysis of barriers/facilitators to recruitment and retention
4. Successful implementation of the intervention in non-NHS settings, measured by the number of PuP practitioners trained to accreditation level who are retained in each delivery site, and continuing provision of the intervention in both delivery sites by the end of the study
5. Fidelity of intervention delivery, measured by a parent-reported bespoke PuP fidelity measure (on completion or drop out of the programme)
6. Acceptability and appropriateness of all outcome measures, measured by questionnaire completion rates and rates of missing data per questionnaire (at baseline, end-of-treatment, and 6 month follow-up)

Secondary outcome measures
Outcome measures for the family are assessed at baseline (pre-intervention), end-of-treatment (post-intervention) and at 6 months follow-up:
1. Child behaviour, measured by father and mother reported SDQ and BITSEA
2. Child protection outcomes, measured by father and mother reported B-CAPI and child protection 'at-risk' registrations, de-registrations and out-of-home placements (retrospective continuous data obtained from Social Work Scotland records at 6 month follow-up)
3. Quality of caregiving, measured by the Emotional Availability Scales (EAS)
4. Parenting knowledge, skills and competence, measured by the Parenting Sense of Competence Scale (PSCS)
5. Parental affect regulation, measured by the Difficulties in Emotion Regulation Scale (DERS)
6. Couple relationship functioning, measured by the Revised Conflict Tactics Scale (CTS2)
7. Substance use, measured by the Treatment Outcome Profile (TOP) and prescribed opioid

substitution therapy (OST) daily dose (retrospective continuous data obtained from prescribing records at 6 month follow-up)
8. Health utility, measured by the EQ-5D-5L
9. Acceptability of health economics measures, assessed by father and mother feedback (via qualitative data at end-of treatment interview) and completion rates of service use questionnaires
10. Clinically significant change in outcomes for individual families, measured using the Reliable Change Index. This will determine whether there has been a reliable improvement in each of the key domains for both fathers and mothers on: DERS, EAS and B-CAPI (from baseline to end-of-treatment and 6 month follow-up)

Overall study start date
01/02/2017

Completion date
31/12/2020

Eligibility

Key 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 0-5 years old
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

Participant type(s)
Other

Age group
All

Sex
Both

Target number of participants
24 families (including fathers, mothers, infants, children, young people in family and kinship carers/significant others), if we assume a minimum or average of two individuals per family then the total would be 48 individuals

Total final enrolment
25

Key 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

Date of first enrolment
01/04/2017

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Circle
Head Office
18 West Pilton Park
Edinburgh
United Kingdom
EH4 4EJ

Study participating centre
PrePare
City of Edinburgh Council Social Work Department
C/o Westerhailes Healthy Living Centre
30 Harvesters Way
Edinburgh
United Kingdom
EH14 3JF

Sponsor information

Organisation

University of Stirling

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Sponsor type
University/education

Website
http://www.stir.ac.uk/

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

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. Findings will be 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 an expert event will be hosted for stakeholders, ensuring both adult and child health audiences are included. Further meetings will be offered should these be required, for example to help disseminate the intervention into routine practice. In addition to the final report and lay summary the findings will be published in peer-reviewed journals and presented at an international conference.

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Anne Whittaker (A.Whittaker@napier.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		13/09/2021	13/12/2021	Yes	No
Protocol (other)		16/12/2020	13/12/2021	No	No
Funder report results		01/01/2022	28/06/2022	Yes	No
HRA research summary			26/07/2023	No	No