Title

PuP4Dads: A feasibility study of the Parents under Pressure parenting programme for families with fathers who have an opioid-related disorder.

Keywords

Parents; Parenting; Fathers; Father-Child Relations; Mothers; Mother-Child Relations; Interpersonal Relations; Emotion Regulation; Affect dysregulation; Family Conflict; Domestic Violence; Infant; Child; Child, Preschool; Child Development; Child Abuse; Opioid substitution therapy; Opiate substitution treatment; Medication-assisted treatment; Opioid replacement therapy; Methadone maintenance treatment; Analgesics, Opioid; Narcotics; Methadone; Buprenorphine; Substance-related disorders; Opioid-related disorders; Feasibility Studies; Evidence-Based Practice.

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Potential Conflict of Interest

Anne Whittaker: Competing interests: None declared.

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the PuP programme. No payments for training or implementation support was received from participating agencies during the course of this study.

Paul Harnett: Competing interests: Paul Harnett is the co-developer of the Parents under Pressure (PuP) programme. The PuP programme is owned and disseminated by Griffith University. The university receives payment for training and implementation support. Proceeds from dissemination are distributed in accordance with Griffith University policy. Surplus funds from training contracts are used to support research activities associated with the PuP programme. No payments for training or implementation support was received from participating agencies during the course of this study.

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Scientific Summary

Background

The Parents under Pressure (PuP) parenting programme was specifically developed for substance-using parents. In a UK randomised controlled trial comparing PuP with usual care, significantly lower rates of parental child abuse potential were reported. However, that trial involved mostly mothers. This study takes the next step in parenting research with this population by examining the feasibility and acceptability of implementing PuP, delivered to families with fathers prescribed opioid substitution therapy (OST) in community-based services.

Objectives

This study aimed to answer the following research questions:

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?
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), follow-up one (end-of-treatment), and follow-up two (post-treatment)?
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?

Protocol changes and project extension: The eligibility criteria for the study was changed to include expectant fathers and fathers with children aged 0-8 years old. Service managers in the implementation sites were invited to take part in a qualitative interview. Data collection for parent measures were changed to fixed time points: 0, 6 & 12 months. The original project timetable was extended by 21 months to accommodate prolonged intervention delivery times, an extended recruitment period and research fellow absence. Ethical approval for the study was granted (IRAS: 17/SS/0023).

Methods

This mixed-methods feasibility study involved: staff training in PuP; intervention delivery; quantitative outcome measures from parents at baseline (pre-treatment), follow-up one (end-of-treatment), and follow-up two (post-treatment); socio-demographic, attendance, and project monitoring data; qualitative interviews with fathers, mothers, PuP practitioners, PuP supervisors and service managers, and focus groups with referrers. Preliminary results were discussed at an expert event with key stakeholders.

Setting: Two community-based non-NHS services for children and families affected by parental substance use in Lothian, Scotland.

Intervention: PuP is a manualised home-visiting parenting programme delivered flexibly and individually tailored to the needs of each family. PuP aims to enhance parents' capacity to provide a safe and nurturing environment, and sensitive and responsive caregiving for children by increasing parents' capacity to regulate their own emotional state in the face of parenting challenges.

In this study, PuP was delivered by eight experienced family support workers who were trained and accredited PuP practitioners.

Study Selection

Inclusion criteria for families:

- Fathers (biological/non-biological, resident/non-resident, and expectant fathers), diagnosed with opioid dependence, prescribed OST, caring for at least one 'index' child aged 0-8 years.
- Mothers/partners with/without drug dependence, in a relationship with the father for at least six months.

Exclusion criteria:

- Parents under the age of 16 years, not resident in Lothian, and those with serious mental illness (e.g., active psychosis).
- Fathers with a court order/child protection order prohibiting contact with the index child, and those with a criminal justice order or impending prison sentence longer than 6 months.

Fathers were referred via NHS and Third Sector addiction services, General Practitioners, Health Visitors, and the two PuP implementation site services. The researcher then consented them into the study, along with their partner/mother if they wished.

PuP practitioners delivering the intervention were invited to a qualitative interview to explore their views and experiences of training, supervision, and delivering PuP. Managers and PuP supervisors were interviewed to explore their views and experiences of adopting and embedding PuP within their service/team. Referrers were invited to focus groups to explore barriers and facilitators to recruitment, acceptability and implementation of PuP. Due to COVID-19, some final interviews were conducted by telephone.

Data Sources: The researcher administered validated questionnaires and collected socio-demographic data. OST prescription data was obtained from the NHS, child protection data from Social Work Scotland records, PuP session attendance data from practitioners, and fidelity was assessed using a bespoke measure (parent-reported at end-of-treatment).

Qualitative data collection included: interviews with fathers and mothers at baseline and end-of-treatment; interviews with practitioners, supervisors and service managers in implementation sites; and focus groups with referrers.

Potential primary and secondary outcome measures for a main study were tested for acceptability, suitability and completeness of data. Measures included:

- *Primary Outcome Measures:* Brief Child Abuse Potential Inventory (BCAP); Brief Infant Toddler Social Emotional Assessment or Strengths and Difficulties Questionnaire (dependent on age of child); Social Work data on child protection registrations/de-registrations and out-of-home placements.
- *Secondary Outcome Measures:* Difficulties in Emotion Regulation Scale; Parenting Sense of Competence Scale; Revised Conflict Tactics Scale; Emotional Availability Scale (video observational measure); Paternal/Maternal Antenatal Attachment Scale (for expectant parents caring for no other children); Treatment Outcomes Profile (illicit drug use); Opioid Substitution Therapy (drug/daily dose) from prescription records.

Economic measures included: EQ-5D-5L and parent-reported health, social care and criminal justice service use.

Both quantitative and qualitative data was used to assess pre-specified progression criteria: achieving the recruitment target (n=24); broad acceptability of PUP to families and practitioners; father engagement in the intervention and study (66% complete intervention; minimum 10 fathers complete baseline and follow-up two measures); participant engagement in qualitative interviews (fathers n=10 minimum; PUP practitioners 90% uptake; service managers 80% uptake) and focus groups (referrers 80% uptake); adequate fidelity of intervention delivery; and adverse events associated with the intervention and/or study.

Data analysis: Quantitative data was entered into SPSS version 25. All instruments were scored as per authors' instruction. Participants' socio-demographic data, PuP session attendance and retention in the study were summarised using descriptive statistics. Data were not normally distributed and so medians and IQRs are reported.

Reliable Change Index (RCI) was used to analyse change over time for the candidate primary outcome measures: parental child abuse potential; parental emotion regulation.

Intervention fidelity was assessed using a five-point rating of PuP components delivered. This was converted to a binary variable (agree/disagree component delivered) and summarised.

Attendance, prescription and child protection data were summarised. COVID-19 travel restrictions prevented coding and analysis of the observational measure (video data).

Qualitative data (transcribed verbatim) was pseudonymised and anonymised, then entered onto NVIVO v12 for coding. Framework matrices on NVivo and framework analysis were used to analyse and compare data sets (parents and professionals).

An online public engagement 'expert event' was convened in October 2020 with policymakers, commissioners, senior managers and service users (n=39). Findings informed scalability and the main study design.

Overall feasibility for a main study was assessed using the ADePT framework, a process which helps to systematically appraise problems and solutions encountered during a feasibility study.

Results

Description of father and family participants

There were 44 fathers prescribed OST referred into the study, of which 38 (86%) were eligible. Twenty five fathers consented to participate in the study. Most had a current (female) partner (n=19), of whom 17 enrolled.

Twenty three fathers completed baseline interviews and provided socio-demographic data. Fathers were aged between 27-52 years. Most were unemployed and in receipt of welfare benefits, had a history of incarceration, were living in social/rented housing in areas of deprivation, or were homeless/living in temporary accommodation. Seventeen fathers were either cohabiting or married, three were single, one divorced, two living apart but co-parenting.

Seventeen partners/mothers provided socio-demographic data (one was withdrawn from study after consenting). Mothers were aged between 22-41 years; 14 were prescribed opioid substitution therapy, two were non-drug users, one unconfirmed. The majority were unemployed and in receipt of welfare benefits. Some reported current criminal justice issues and a prison history.

The majority of parents reported complex needs including co-occurring physical and mental health problems, domestic abuse, and a history of childhood trauma/being in care as a child themselves.

Children: At baseline, fathers reported a total of 51 children (aged 0-16yrs). Eight fathers had between one and three children living at home; 15 were non-resident fathers; and eight were expectant fathers (3 first-time dads). The whereabouts of the remaining 47 children (biological and non-biological) included: kinship care (n=38), foster care (n=4), residential care (n=3) and adopted (n=2). All fathers had regular contact with at least one 'index child' aged 0-8 years old.

Progression criteria results:

- 25/38 fathers (66%) and 17/19 mothers were recruited into the study.
- Allocation to PuP: 20 fathers (80%) and 14 mothers (82%) started PuP: 1 father withdrew following baseline; 4 became ineligible after enrolment or baseline.
- Acceptability of the programme was rated highly by fathers and mothers, with the majority stating they would recommend PuP to other drug-using parents.
- 14/20 (70%) fathers completed six or more sessions. Practitioners delivered 248 sessions including: 140 couple, 52 father only, and 56 mother only sessions. Attendance rates did not differ between fathers and mothers (mean:71%). Length of

engagement: fathers (median:26 weeks), mothers (median:30 weeks). One father was incarcerated and could not complete the programme.

- Retention in study: 23 (92%) fathers completed baseline and first qualitative interview; 16 (64%) completed follow-up one and second qualitative interview; and 13 (52%) completed follow-up two measures (all research interviews).
- Fidelity was rated highly (median:15/20 core components received, according to fathers and mothers).
- Majority of practitioners, supervisors and managers rated acceptability, suitability and deliverability of PuP highly.
- 100% of PuP practitioners (n=8), supervisors (n=2) and service managers (n=7) approached completed a qualitative interview; 4/5 focus groups (80%) were convened with referrers (n=28).
- There were no adverse events.

Deliverability: The programme was successfully adopted and integrated within the two non-NHS agencies. Agency managers reported that PuP was a good fit with their service 'ethos' as well as the policy agenda and national child welfare practice framework. Delivery in both agencies was sustained beyond the intervention phase.

Staff training and supervision: Eight accredited practitioners delivered the intervention. Practitioner training was considered adequate by professionals, although greater implementation support in the adoption phase could have helped to embed the programme earlier. Two practitioners (from PREPARE and CIRCLE) became accredited PuP supervisors which enhanced implementation.

Acceptability: The programme was rated highly in terms of acceptability and suitability by parents and professionals. Participants valued the mode of delivery (e.g., home visiting, flexible programme length); therapeutic approach (e.g., strengths-based, collaborative goal-setting, focus on emotion regulation, therapeutic alliance); and programme model (e.g., 'whole family' approach, therapeutic focus on fathers; structured but flexibly delivered modules, use of measures to assess and report progress).

Profile of change*:* The *s*ample size was too small to draw conclusions about the impact of the intervention on outcomes. Individual change was measured using the reliable change

index. There was evidence of reduced child abuse potential scores for 4/14 fathers at FU1 that was maintained at FU2, and improvement in emotion regulation for 7/15 fathers at FU1 and 4/11 at FU2. Days abstinent from illicit drug use and alcohol in past 28 days reported by fathers also improved from baseline (median:18) to FU1 (median:24) and FU2 (median:26).

Usual care for fathers: The majority of fathers reported little or no previous engagement in parenting and family support services. Both fathers and mothers talked about mother-focused services and negative previous experiences of children's services.

Measures: Despite the high burden and the level of sensitivity and intrusiveness, most measures were considered acceptable to the parents and completeness of researcher administered measures resulted in little missing data. Some measures were not suitable for all families (e.g. because of age of child, out-of-home placements, no couple relationship). The video observational measure was not feasible to collect for primarily logistical reasons, not parent refusal.

Attendance, prescription, child protection and cost data: Practitioners provided a complete set of attendance data. All parents except two couples consented to NHS prescription data access. All parents except one couple consented to child protection data access from Social Work Scotland records. Parent self-completed service use data for the economic component was not feasible to collect. Only one couple returned completed forms.

Optimal recruitment and retention: Referrals were highest from drug treatment services, primary care prescribers and the two implementation sites. Recruitment was enhanced when there was an organisational culture that supported 'father-inclusive' practice and 'whole family' approaches. Joint researcher and practitioner home visits also worked well. Child protection and early years' children's centres would be a logical source of referrals in a main study.

Retention was enhanced with frequent researcher-family contact, flexible and repeat home visits for data collection, using 'contact tracing' to locate parents who could not be reached and vouchers for each interview.

Most suitable study design for a main study: The findings of this study suggest that a pragmatic evaluation, focusing on real world implementation of PuP with fathers who are opioid-dependent would be the most feasible and clinically informative study design to evaluate effectiveness and implementation at scale. We explored extensive possibilities for randomised controlled trial designs and ruled them out as either unsuitable, unethical, too lengthy and costly, or not feasible.

A mixed-methods quasi-experimental (pre- and post-test) design would be feasible. The design should include an outcome and process evaluation, incorporating a structural equation modelling approach to minimise bias, adjust for covariates and explore mediators, along with a realist evaluation to examine what works, for whom, why, and under what circumstances. Parental child abuse risk would be a candidate primary outcome, measured using the BCAP score. The feasibility study estimated a clinically significant difference of 9 points for the change in BCAP score from baseline to follow-up with a standard deviation of 4.7, indicating a minimum sample size of 116 would be required to provide 90% power for a study with our proposed analytical framework. Allowing for an anticipated 70% retention rate gives a total sample size required of 165.

Conclusion

The results of this study indicate that a larger evaluation of the Parents under Pressure (PuP) programme for families with a father who is opioid-dependent is feasible, assuming adequate resources for recruitment, retention and data collection of this hard-to-engage population. Implementation support for services to embed the PuP model in practice and at scale would enhance deliverability and fidelity.

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