The Parents under Pressure parenting programme for families with fathers receiving treatment for opioid dependence: the PuP4Dads feasibility study

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Scientific summary

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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 (RCT) comparing PuP with usual care, significantly lower rates of parental child abuse potential were reported (Barlow J, Sembi S, Parsons H, Kim S, Petrou S, Harnett P, *et al.* A randomized controlled trial and economic evaluation of the Parents Under Pressure program for parents in substance abuse treatment. *Drug Alcohol Depend* 2019;**194**:184–94.). However, the 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:

- How feasible is it to deliver PuP for opioid-dependent fathers in routine family-based local government and voluntary sector services?
- How acceptable is PuP among staff and recipients and what are the barriers to and facilitators of uptake and retention?
- How acceptable and adequate is the training and supervision for staff?
- To what extent can PuP be integrated into non-NHS settings across the UK?
- What is the optimal level of recruitment, consent and retention for a future trial?
- What are the best methods of collecting outcome data from fathers and mothers at baseline (pre-intervention), follow-up 1 (FU1) (end of treatment) and follow-up 2 (FU2) (post treatment)?
- How feasible is it to collect attendance, medical and cost data on participating families?
- How acceptable and appropriate are the assessment methods?
- Is the profile of change in fathers, mothers and children clinically significant?
- What is the nature and extent of routine family support services for fathers in drug treatment?
- Which study design would best suit a future evaluation, including an economic evaluation?

Protocol changes and project extension

The eligibility criteria for the study were changed to include expectant fathers and fathers with children aged 0–8 years. Service managers in the implementation sites were invited to take part in a qualitative interview. Data collection for parent measures was changed to fixed time points of baseline, 6 and 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. Ethics approval for the study was granted (Integrated Research Application System reference 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), FU1 (end of treatment) and FU2 (post treatment); sociodemographic, 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

The programme was based at two community-based non-NHS services for children and families affected by parental substance use in Lothian, Scotland.

Intervention

The PuP programme is a manualised home-visiting parenting programme that is delivered flexibly and is individually tailored to the needs of each family. The PuP programme 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) who have been diagnosed with opioid dependence, prescribed OST and are caring for at least one 'index' child aged 0–8 years.
- Mothers/partners with/without drug dependence who have been in a relationship with the father for at least 6 months.

Exclusion criteria

- Parents aged < 16 years.
- Parents not resident in Lothian.
- Parents with a 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 of > 6 months.

Fathers were referred via the 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.

Parents under Pressure 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 the barriers to and facilitators of recruitment, and acceptability and implementation of PuP. Owing to COVID-19, some final interviews were conducted by telephone.

Data sources

The researcher administered validated questionnaires and collected sociodemographic data. OST prescription data were obtained from the NHS, child protection data were obtained from Social Work Scotland (Edinburgh, UK) records and PuP session attendance data were obtained from practitioners. Fidelity was assessed using a bespoke (parent-reported) measure at the end of treatment.

Qualitative data collection included interviews with fathers and mothers at baseline and at the 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.

Primary outcome measures

- Brief Child Abuse Potential Inventory (BCAPI).
- Brief Infant Toddler Social Emotional Assessment or Strengths and Difficulties Questionnaire (depending on the age of the 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 Antenatal Attachment Scale/Maternal Antenatal Attachment Scale (for expectant parents caring for no other children).
- Treatment Outcomes Profile (illicit drug use).
- OST (drug/daily dose) from prescription records.

Economic measures included the EuroQol-5 Dimensions, five-level version, and parent-reported health, social care and criminal justice service use.

Both quantitative and qualitative data were used to assess prespecified progression criteria that included achieving the recruitment target ($n = 24$), broad acceptability of PuP to families and practitioners, father engagement in the intervention and study (including a minimum of 66% of fathers recruited into the study and a minimum of 10 fathers completing baseline and post-treatment interviews), participant engagement in qualitative interviews (including a minimum of 10 fathers and 90% practitioner uptake and 80% manager uptake) and focus groups (with a minimum of 80% referrer uptake), adequate fidelity of intervention delivery and adverse events associated with the intervention and/or study.

Data analysis

Quantitative data were entered into SPSS® version 25 (IBM SPSS Statistics, Armonk, NY, USA). All instruments were scored as per authors' instruction. Participants' sociodemographic data, PuP session attendance and retention in the study were summarised using descriptive statistics. Data were not normally distributed and so medians and interquartile ranges are reported.

The Reliable Change Index (RCI) was used to analyse change over time for the candidate primary outcome measures of parental child abuse potential and 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) were pseudonymised, anonymised and then entered onto NVivo v12 (QSR International, Warrington, UK) 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 policy-makers, 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 (A process for Decision-making after Pilot and Feasibility Trials) framework, a process that helps to systematically appraise problems and solutions encountered during a feasibility study.

Results

Description of father and family participants

Forty-four fathers who were in receipt of OST were referred to the study, of whom 38 (86%) were eligible. Twenty-five fathers consented to participate in the study. Most fathers had a current (female) partner ($n = 19$), of whom 17 enrolled.

Twenty-three fathers completed baseline interviews and provided sociodemographic data. Fathers were aged between 27 and 52 years. Most fathers were unemployed and in receipt of welfare benefits, had a history of incarceration and 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 was divorced and two were living apart from their child's mother, but were co-parenting.

Seventeen mothers provided sociodemographic data (one was withdrawn from the study after consenting). Mothers were aged between 22 and 41 years. Fourteen mothers were in receipt of OST, two were non-drug users and, in one case, drug-using status was unkown. The majority of mothers were unemployed and in receipt of welfare benefits. Some mothers reported current criminal justice issues and a history of incarceration.

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 0–16 years). Eight fathers had between one and three children living at home. Fifteen were non-resident fathers and eight were expectant fathers (including three first-time fathers). The remaining 47 children (biological and non-biological) were in kinship care ($n = 38$), in foster care ($n = 4$), in residential care ($n = 3$) and adopted ($n = 2$). All fathers had regular contact with at least one 'index child' aged 0–8 years.

Progression criteria results

- Twenty-five of 38 fathers (66%) and 17 of 19 mothers were recruited into the study.
- Twenty fathers (80%) and 14 mothers (82%) started PuP. One father withdrew following baseline interviews and four became ineligible after enrolment or baseline.
- The acceptability of the programme was rated highly by fathers and mothers, with the majority stating that they would recommend PuP to other drug-using parents.
- Fourteen of 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%). The median length of engagement for fathers was 26 weeks and for mothers it was 30 weeks. One father was incarcerated and could not complete the programme.
- Twenty-three (92%) fathers completed the baseline and first qualitative interview. Sixteen (64%) fathers completed the FU1 and second qualitative interview. Thirteen (52%) fathers completed the FU2 measures (all research interviews).

- Fidelity was high (median of 15/20 core components received, according to fathers and mothers).
- The majority of practitioners, supervisors and managers rated acceptability, suitability and deliverability of PuP highly.
- All PuP practitioners ($n = 8$), supervisors ($n = 2$) and service managers ($n = 7$) that were approached completed a qualitative interview. Four of five 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 with 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 CIRCLE (Edinburgh, UK), a third-sector family support service, and PREPARE (Edinburgh, UK), a local authority-led specialist multidisciplinary pregnancy support service] 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 and flexible programme length), therapeutic approach (e.g. strengths based, collaborative goal-setting, focus on emotion regulation and therapeutic alliance) and programme model (e.g. 'whole-family' approach, therapeutic focus on fathers, structured but flexibly delivered modules and use of measures to assess and report progress).

Profile of change

The sample size was too small to draw conclusions about the impact of the intervention on outcomes. Individual change was measured using the RCI. There was evidence of reduced child abuse potential scores for 4 out of 14 fathers at FU1, which was maintained at FU2. In addition, there was improvement in emotion regulation for 7 of 15 fathers at FU1 and 4 of 11 fathers at FU2. Days abstinent from illicit drug use and alcohol in past 28 days reported by fathers also improved from baseline (median 18 days) to FU1 (median 24 days) and FU2 (median 26 days).

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 the completeness of researcher-administered measures resulted in few missing data. Some measures were not suitable for all families (e.g. because of the age of child, out-of-home placements or no couple relationship). The video observational measure was not feasible to collect for primarily logistical reasons rather than because of 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 were 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 by 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 the clinical effectiveness and cost-effectiveness and implementation at scale. We explored extensive possibilities for RCT designs and ruled them out as 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 BCAPI score. The feasibility study estimated a clinically significant difference of 9 points for the change in BCAPI score from baseline to follow-up, with a standard deviation of 4.7, indicating that a minimum sample size of 116 participants 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 participants.

Conclusion

The results of this study indicate that a larger evaluation of the 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.

Trial registration

This trial is registered as ISRCTN43209618.

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