PARENTS UNDER PRESSURE: A PROGRAMME FOR FAMILIES WITH PARENTAL SUBSTANCE MISUSE

AN EVALUATION OF IMPACT, PROCESS AND COST-EFFECTIVENESS

Jane Barlow, Sukhdev Sembi, Stavros Petrou, Helen Parsons – University of Warwick
Sharon Dawe – Griffith University
Paul Harnett – University of Queensland

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Impact and Evidence series

This report is part of the NSPCC’s Impact and Evidence series, which presents the findings of the Society’s research into its services and interventions. Many of the reports are produced by the NSPCC’s Evaluation department, but some are written by other organisations commissioned by the Society to carry out research on its behalf. The aim of the series is to contribute to the evidence base of what works in preventing cruelty to children and in reducing the harm it causes when abuse does happen.

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The people featured are models.
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EXECUTIVE SUMMARY

Background

Many babies in the UK are born to substance-dependent parents, and dependence on psychoactive drugs during the postnatal period is associated with high rates of child maltreatment. Around a quarter of children subject to a child protection plan have families with parental substance misuse. Parents who are dependent on psychoactive drugs are at risk of a wide range of parenting problems, and studies have found reduced sensitivity and responsiveness to both the infant’s physical and emotional needs. The poor outcomes that are associated with such drug-dependence appear to be linked to the multiple difficulties experienced by such parents.

An increase in the understanding of the importance of early relationships for infant wellbeing has led to a focus on the development and delivery of services that are aimed at supporting parenting and parent–infant interaction. The Parents under Pressure (PuP) programme is aimed at supporting parents who face multiple adversities, including dependence on psychoactive drugs or alcohol, by providing them with methods of managing their emotional regulation, and of supporting their new baby’s development. An evaluation of the PuP programme in Australia with methadone-maintained parents of children aged 3–8 years found significant reductions in child abuse potential, rigid parenting attitudes (for example, measured using the Child Abuse Potential Inventory), parental psychological problems, child behaviour problems and prescribed methadone dose.

Methodology

The study comprised of a multicentre randomised controlled trial (RCT) using a mixed-methods approach to data collection and analysis in order to determine whether parents who received the PuP programme benefited more than parents who received treatment-as-usual (TAU), which varied across sites.

The study was conducted in seven family centres across the UK, and targeted substance dependent primary caregivers of children less than 2.5 years of age. Consenting parents were randomly allocated to either the PuP programme (n=52), conducted over 24 weeks, or to standard care (n=48).

The primary outcome was child abuse potential, and secondary outcomes included parental emotional regulation, parental psychological functioning, parenting stress, and infant/toddler social-emotional adjustment.
Strengths and limitations

The strengths of the design included:

• There have been relatively few studies specifically designed to improve outcomes in complex families characterised by parental substance dependence, comorbid psychopathology and environmental contexts that include social isolation, severe financial disadvantage, and housing problems. The PuP programme is one of several interventions that have a focus on addressing parental emotion regulation designed for this high-risk group. This randomised controlled trial is the first effectiveness study conducted in the field to date;

• Mixed-method design, including standardised measures, surveys and qualitative interviews;

• The inclusion of a group who received treatment-as-usual; and

• The range of perspectives included in the research, with views from parents, referrers and practitioners.

The limitations included:

• Interviews were not conducted involving parents who had dropped out of PuP;

• Follow-up only until six months.

Key findings

Parents who received the PuP programme showed reductions in scores reflecting child abuse risk using a standardised measure while those who received TAU showed an increase in these scores. Further, more PuP families showed a clinical improvement in abuse potential while more TAU parents showed a deterioration in terms of potential for risk abuse. There was a trend toward improvement in terms of the reduction in legal proceedings (including parenting assessment order through supervision order; special guardianship order; interim care order and care order) for the PuP group. We were not able to report the results for the parent–child interaction data in time for the publication of this report.

There were also statistically significant improvements in a number of measures relating to parents' capacity to manage their emotions, their overall psychological wellbeing and depression, although no differences on parenting stress. Parents also completed a measure of their child's social and emotional wellbeing, and there were no differences found between the PuP and TAU groups.
Parents, practitioners and service referral agencies took part in interviews. Overall, high levels of satisfaction were expressed regarding the PuP programme. Parents reported that they felt better able to manage their emotions and to use the mindfulness strategies as part of their parenting practice. Practitioners reported that their observations were consistent with these findings. In relation to training and clinical supervision, the practitioners were strongly supportive of the ongoing opportunity for clinical supervision as part of the implementation support process in PuP training.

The results of the economic analysis show that for the main study outcome measure, there was approximately 51.8 per cent probability of cost-effectiveness if decision-makers were willing to pay £1,000 for a unit improvement in the BCAP, increasing to 98.0 per cent at a £20,000 cost-effectiveness threshold for this measure.

Next steps

The findings of this study suggest that PuP is a potentially effective method of working with substance-dependent parents of young children. The findings of the current study are consistent with those of earlier studies, and support the further investment of funding in the delivery and evaluation of PuP in the UK.

The current study recruited high-risk parents who were currently engaged in substance dependence treatment services (for example, drug and alcohol). Future research is needed to evaluate whether the PuP programme would be effective for other groups of parents, such as high-risk parents involved with the child safety system in the UK who do not have a substance dependence problem. Importantly, the flexibility and underpinning theoretical framework that led to individualised treatment plans allows for investigation across other high-risk groups.

This research should aim to identify the system level factors that impact on the implementation of the PuP programme in different settings (for example, skill set of practitioners, feasibility of delivering a home-visiting programme) and programme-level factors (whether the content and dose of the programme fit the client group).

Further, the Implementation Science literature makes clear that modifications to programmes for different client groups, whether carefully planned or modifications that occur less systematically (as may be the case when practitioners deviate from a programme protocol they perceive to be a poor fit for their client group) can decrease the effectiveness of the programme when it is translated to different populations and settings.
The PuP programme was designed to minimise the need for modifications to the protocol by building flexibility into the protocol itself. That is, the PuP programme is underpinned by an integrated theoretical framework that leads to individualised case formulations and treatment plans. This component was identified by practitioners as a strength of the programme. Further research is recommended to document the specific content of case formulations and treatment plans, and the extent to which these case formulations and treatment plans vary for different populations of families. Such research would provide valuable information on the mechanisms of change, moving the focus from whether the programme works to a greater understanding of how it works.
1. Introduction

1.1 Background

The prevalence of child abuse

Despite extensive evidence concerning the importance of the first few years of life, recent estimates show that severely suboptimal parenting of infants is a major public health issue. Infants under one year old account for up to 13 per cent of child protection registrations in the UK, with neglect (55 per cent) and emotional abuse (17 per cent) accounting for nearly two-thirds of these (DCSF, 2009).

Infants also face four times the average risk of child homicide (Brookman & Maguire, 2003) – the risk being greatest in the first three months and the perpetrators being the parents in most cases (ibid). Furthermore, rates of abuse of very young children in the general population may be up to 25 per cent higher than indicated by official estimates (Sidebotham & ALSPAC team, 2000).

Concerns about possible abuse of infants have increased over the past few years, and recent estimates by the Association of Directors of Children’s Services of a large sample of local authorities found a 63.3 per cent increase in children under the age of one with a child protection plan (Brooks, 2010).

Child death review statistics suggest that one per cent of deaths in the 0–27 days age group were preventable; eight per cent were potentially preventable, and that in the 28–364 days age range, two per cent were preventable and 22 per cent were potentially preventable (NSPCC, 2011).

Impact of parental substance misuse

Drug and alcohol dependence has become a significant public health concern due to major human, social and economic consequences. While it is difficult to establish the actual number of children affected by, or living with, parental alcohol dependence, estimates suggest that parental alcohol dependence is more of a problem than parental drug dependence (NSPCC, 2011).

Statistics on drug dependence report that in 2009/10, 8.6 per cent of adults in the UK had used one or more illicit drugs within the last year, and 3.1 per cent of adults had used Class A drugs. These rose to 20 per cent and seven per cent, respectively, in the 16–24-year-old age group. During 2009/10, 206,889 people (those aged 18 and over) were in contact with structured drug treatment services (Health and Social Care Information Centre, 2011).
The evidence suggests that around one-third of drug dependent people in the UK are women, of which as many as 90 per cent are of childbearing age (Day & George, 2005). Estimates also show that around 2–3 per cent of children under 16 have a parent who is a problematic drug user and around one per cent of births are to drug users and a similar number to problem drinkers (Hidden Harm: Home Office, 2003).

Of children less than one year old, it has been estimated that 19,500 live with a parent who has used Class A drugs in the last year, and 93,500 live with a parent who is a problem drinker (Health and Social Care Information Centre, 2007).

**Impact on child development**

Many children in the UK are born to substance-dependent parents. While there has been extensive investigation of the effects of *in utero* exposure, disentangling the effects of substance use and lifestyle factors on children’s developmental outcomes is complicated. Thus, while some substances like alcohol have a clearly documented effect on development, the literature on other substances is less clear, with some studies finding less impact when children are raised in environments that foster emotional, social and cognitive development (see, for example, Harnett & Dawe [2013] for a review).

Parents with substance dependence problems also typically face a range of other adversities including their own histories of trauma and abuse; current comorbid psychopathology; domestic abuse and financial disadvantage. Children living in households where parents are substance-dependent are more likely to develop behavioural and emotional problems and tend to perform more poorly in school (Dawe et al, 2007). They are also more likely to be involved in the child protection system (Chaffin et al, 1996), with around 25 per cent of children subject to a child protection plan involving parental substance misuse (Advisory Council on the Misuse of Drugs, 2004).

Parents who are dependent on substances are at risk of a wide range of parenting deficits (Mays [1995] in Suchman et al, 2005). A recent systematic review and meta-analysis found that across a range of studies (*n*=23), mothers with substance misuse problems showed compromised sensitivity and responsivity to their infants (Hatzis et al, 2017).

There is also recognition that when a parent has a preoccupation with obtaining and/or using substances “parent–infant interaction is at risk of suffering from emotional unavailability, incongruent mirroring and dyadic dysregulation” (Soderstrom et al, 2009), all of which have been identified as being central to the child’s developing neurological system and their later capacity for affect regulation.
These findings are corroborated by research drawing on the perspectives of substance abusing parents, which suggests “a lack of understanding about basic child development issues, ambivalent feeling about having and keeping children, and lower capacities to reflect on their children’s emotional and cognitive experience” (Suchman et al, 2005).
2. Methods

2.1 Study objective

The objective of this study was to evaluate the effectiveness, cost-effectiveness, and user acceptability of the Parents under Pressure (PuP) programme for parents who were currently engaged in a substance dependence treatment service and had infants less than 2.5 years of age.

The objective of the qualitative data was to explore practitioner’s views and experiences of the acceptability and usefulness of the PuP training and programme and being part of an RCT; and to get an understanding of the participating families’ views about the programme.

2.2 Study design

This was a mixed-methods study using a sequential explanatory design in which it was intended that data from the quantitative strand of work would be used to select individuals for interview (ie individuals who showed changed and no change). However, in reality, identifying families who were willing to take part in an interview post-intervention was so difficult that we ended up interviewing everyone who agreed to take part. This undoubtedly resulted in biased samples favouring individuals who did well.

The quantitative component comprised a two-armed parallel RCT comparing the PuP intervention against the control group of TAU.

2.3 Hypotheses

The delivery of the PuP programme, a home visiting intervention developed for high-risk families delivered over 24-weeks to parents engaged with substance abuse treatment agencies, would reduce the potential for child abuse.

The programme would also improve parental emotional regulation and psychological wellbeing, including depression, anxiety and stress, parent–infant/toddler interaction, and infant/toddler social and emotional adjustment. This should also manifest in reduced substance use.
2.4 Study registration

This multicentre RCT was registered at the International Standard Randomised Controlled Trial, Number Register: ISRCTN47282925 and the protocol published at: www.ncbi.nlm.nih.gov/pubmed/23841920.

The study was granted ethical approval from the Biomedical Research Ethics Committee at the University of Warwick (BREC reference number 189-03-2012).

2.5 Parents and recruitment

Parents were engaged in substance dependence treatment, being mostly mothers, of children less than 2.5 years of age. They were eligible for the study if they were a primary caregiver with responsibility for a child under the age of 2.5 years and were receiving treatment for a drug or alcohol problem including opioid replacement treatment, relapse prevention or other treatment programme. If both parents had alcohol or drugs problem, only the mother was assessed if they were the primary caregiver.

We excluded parents whose child was not residing with them and did not have contact with them at the beginning of the intervention and where there was no plan for reunification. We also excluded pregnant women (unless the baby was due within four weeks of the recruitment period) who had no other child under 2.5 years residing with them, and women in a relationship in which there was active and ongoing domestic abuse, or who were actively psychotic or expressing active suicidal ideation.

Study recruitment took place between October 2014 and December 2016 at seven participating centres. Referrals were made by any worker who had contact with families who were in a drug or alcohol treatment programme, including midwives, drug treatment centre workers, staff at children’s centres and staff working with charitable organisations within the field.

Referrers provided eligible families with a brief information sheet inviting them to receive more information about the study and asking them to provide their consent to pass on their contact details to the research team. The research team then contacted the family, who completed the recruitment process, including securing written consent, obtaining baseline data and undertaking telephone randomisation.
2.6 Randomisation

A 1:1 computer-generated random allocation sequence stratified by centre of recruitment was generated using minimisation (Altman & Bland, 2005) using R (R Core Team, 2017) by the study statistician, independently from data collection. Participating families were randomly assigned to either the PuP group or to standard care, sequentially over the telephone by a researcher independent from the rest of the study team.

2.7 Intervention

Parents under Pressure Programme

The PuP Programme was developed as an intensive home-based intervention underpinned by an integrated framework of family functioning (Harnett & Dawe, 2012), which draws strongly on attachment theory with a focus on developing a safe and nurturing relationship (see Figure 1 below). The programme is underpinned by a recognition that the quality of the parent–child relationship is related to the parent’s capacity to provide sensitive, responsive and nurturing caregiving (Biringen & Easterbrooks, 2012), and that the quality of the parent–child relationship is compromised when the parent has faced past trauma or faces the stress of chronic adversity.

Figure 1: Integrated framework of family functioning

(Dawe & Harnett, 2007)
Parents are helped to recognise their own strengths and potential difficulties using video feedback, shared discussion with the practitioner and completion of exercises using the Parent’s Workbook. Additionally, difficulties in managing dysregulated affect and impulsive behaviour, both in relation to parenting and to substance abuse, are addressed through the use of mindfulness exercises and a focus on recognising and managing negative emotional states. In relation to the former, these include exercises that involve mindfulness meditations with the aim of helping a parent develop a greater awareness of being fully present in the moment with their infant during daily activities (for example, taking pleasure in watching an infant sleep, and during bath time and play).

In relation to the latter, the use of techniques like ‘urge surfing’, understanding cravings and learning to manage negative mood states without the use of substances, complement the care received from the standard drug and alcohol treatment services (Baer, 2003; Brown & Ryan, 2003). When parental resourcefulness is poor, therapeutic strategies are used aimed at increasing parental problem solving and engaging social support to help buffer the negative impact of the wider social ecology on the parent’s ability to be sensitive and responsive to their children.

The PuP programme contains 12 modules. The selection and delivery of the modules are determined by the assessment. The programme is embedded within a case-management framework, and day-to-day issues like housing and finance provide a therapeutic opportunity to put coping skills into practice in a mindful and emotionally contained manner. Sessions are conducted in the home and last between 1–2 hours with content drawn from the Parent’s Workbook. Additional case management occurs outside the treatment session, according to individual family needs (for example, housing, legal advice or school intervention).

The programme begins with a comprehensive assessment and individual case formulation conducted collaboratively with the family. Specific targets for change are identified during the assessment, which then become the focus of treatment. Each module comprises a theme that continues throughout treatment. For example, Module 6, *Connecting with Your Baby*, focuses on helping a parent connect with their child through a series of exercises that help the parent reflect on their own relational experience with their baby. There is an emphasis
on learning their baby’s language, and ‘mindful play’ in which a
parent is taught to use mindfulness constructs to observe, describe
and participate during play and special times. The use of the modules
depends on the personal situation of the parent. For example, the
\textit{Relationship} module includes a focus on improving communication in
intimate relationships. It also includes sections on defining the qualities
of a good and loving intimate relationship for couples with a troubled
relationship history.
3. Outcome measures

Assessments were made at baseline, immediately post-intervention and at a six-month follow-up. Data was collected by a researcher who was blind to the study arm, in the respondent’s home or at a drug treatment centre. Study parents were requested not to disclose their group allocation to the researcher, and loss of blinding was recorded and taken into account at the analysis stage. More details on the outcome measures, including their psychometric details, can be found in the study protocol, but a brief description of each outcome follows:

*Child abuse potential* was assessed using the 24-item Risk Abuse Scale from the Brief Child Abuse Potential Inventory (BCAP) (Ondersma et al, 2005), a self-report questionnaire developed to identify individuals at risk for physical child abuse. The BCAP has been validated across a range of populations including mothers on opioid substitution therapy (Dawe et al, 2016). The BCAP was considered the primary outcome measure for study design and analysis purposes.

*Emotional regulation* was measured using the Difficulties in Emotional Regulation Scale (DERS) (Gratz & Roemer, 2004), which is a 36-item self-report measure of difficulties with emotion regulation. Each item is rated on a five-point Likert-type scale that reflects the proportion of time for which an individual exhibits a particular aspect of emotion regulation; higher scores are indicative of greater difficulties with emotion regulation. Additionally, DERS has been shown to adequately predict behavioural outcomes believed to be associated with emotion dysregulation, such as intimate partner abuse, self-harm and aggression (Gratz & Roemer, 2004; Neumann et al, 2010).

*Severity of borderline personality* was assessed using the Personality Assessment Inventory – Borderline (PAI-BOR) (Morey, 1991). The full Personality Assessment Inventory (PAI) comprises 344 items covering constructs most relevant to a broad-based assessment of mental disorders. PAI-BOR focuses on borderline features and is a 24-item self-report questionnaire using a four-point Likert scale with four non-overlapping subscales that measure the essential features of borderline personality disorder: affect instability (BOR-A), identity problems (BOR-I), negative relationships (BOR-N) and self-harm (BOR-S). These four subscales were designed to measure the unique features given by DSM-IV.

*Parental psychological functioning* was assessed using the Depression, Anxiety and Stress Scale (DASS-21), which is a 21-item self-report instrument involving a four-point Likert scale designed to measure the three related negative emotional states of depression, anxiety and tension/stress (Lovibond & Lovibond, 1995a; Lovibond & Lovibond, 1995b).
Parenting stress was measured using the Parenting Stress Index short form (PSI-SF) (Abidin, 1995), which is a well-validated self-report measure comprising 36 items measured using a five-point Likert scale of perceived stress in the parenting role.

Parental drug/alcohol use was measured using Timeline Follow-back (TLFB), a widely used calendar-based method of assessment (Sobell & Sobell, 1992). Each interview is structured using a calendar in which recent events, such as payday or social events, are used as memory aids to assist in recall. The number of days of substance use (including amphetamines, cannabis, alcohol and heroin) in the 30 days prior to assessment was also recorded. This self-report was then validated using hair toxicology in a random sample of cases (10 per cent) (Darke, 1998).

Parent–toddler interaction was assessed using the infant and toddler (children over 2.5 years old) versions of the CARE-Index (Crittenden, 2006). The CARE-Index requires a three-minute video of the parent with their child. It measures three aspects of maternal behaviour (sensitivity, covert and overt hostility, and unresponsiveness) and four aspects of a toddler’s behaviour (cooperativeness, compulsive compliance, difficultness and passivity). Scores range from 0 to 14, with higher scores indicating better sensitivity and/or cooperation. The data for this measure is not yet coded.

Infant social and emotional adjustment was assessed using the Brief Infant and Toddler Socio-emotional Adjustment Scale (BITSEA) (Briggs-Gowan et al, 2004), which comprises a 42-item parent-report measure of infant and toddler (aged 1–3 years) social and emotional adjustment. It comprises two subscales – competence and problems measured using a three-point Likert scale. A higher score for the competence subscale and a lower score for the problems subscale indicate better adjustment.

3.1 Statistical analyses and power calculation

Dawe and Harnett (2007) found an effect size (ES) of 0.92 using the Child Abuse Potential Inventory (CAPI) scores, in an RCT of the PuP programme in Australia with parents of children aged 3–8 years. This is a large change and the current study, which is being conducted with a younger population of children (under 2.5 years), should therefore be powered to detect a much smaller change. Hence, to detect an effect size (ES) of approximately 0.5 with an ANCOVA at 80 per cent power and five per cent significance, 54 families were required in each arm. Allowing for dropout in the region of five per cent necessitated that approximately 114 families were recruited to the study (that is, 57 in each arm).
During recruitment, given a higher loss to follow up than initially anticipated (10 per cent observed, which inflated the sample size required to 120 families) combined with slow recruitment, it was decided jointly by the study team and the funders to close recruitment at 100 families. With the observed 10 per cent loss to follow up, this would result in an analysis of 70 per cent power at the initial ES of 0.5; or 80 per cent power at an ES of 0.55.

All analyses were undertaken using raw data and performed using Statistical Package for the Social Sciences, SPSS version 22.0 and R. To investigate the effects over time for the primary outcome, a multi-level model (MLM) was created, modelling the BCAP score of each participant as allocation group and follow-up point as fixed effects and adding a random effect for each participant. P values were calculated using the Satterthwaite approximation of the F-distribution. To adjust for loss to follow-up, data was multiply imputed for the BCAP outcome (Buuren & Groothuis-Oudshoorn, 2011).

To establish if changes for the primary outcome were clinically meaningful, the Reliable Change Index (RCI) was calculated for each person. The RCI calculates if the change is significantly larger than the error associated with the scale. Here, values of the RCI were classified as follows:

- If $\text{RCI} < -1.96$, the respondent was classed as improved. If the respondent moved from above to below the cut point for abuse, they were further classed as “recovered”.
- If $-1.96 \leq \text{RCI} \leq 1.96$, the respondent was classed as no change.
- If $\text{RCI} < 1.96$, the respondent was classed as deteriorated. If the respondent crossed from below to above the cut point for abused, they were further classed as “failed”.

To calculate the RCI, a conservative estimate of the internal reliability of 0.90 was used (Harnett & Dawe, 2008). Using a standard deviation of 5.8 points resulted in an RCI of 3.8 points, hence changes must be greater than 7.5 points to be considered a reliable change. The clinical cut point for abuse was set to scores greater than or equal to 12 points.

An intention-to-treat analysis was undertaken for all secondary measures. Descriptive statistical summaries, such as means and standard deviations or counts and percentages (subject to data type), are presented for the secondary outcome measures at each time-point.
3.2 Economic evaluation

A within-trial economic evaluation was conducted from the recommended UK NHS and personal social services perspective (NICE, 2013). The PuP programme was estimated using primary research methods, primarily through PuP practitioners prospectively completing detailed weekly activity logs outlining the number, type and duration of contacts with trial parents and supervisory staff, and associated administrative activities, and the type and cost of consumables and other PuP-related expenses.

Broader resource utilisation was captured through interviewer-administered questionnaires completed at baseline and at each follow-up point and provided profiles of hospital and community health and social services received by each trial participant–child dyad.

Information was also collected regarding use of legal services and costs borne directly by trial participants, over the relevant time horizons. Unit costs (£, 2016 prices) were collected from national sources in accordance with guidelines and attached to resource use.

The EuroQol EQ-5D-5L health-related quality of life questionnaire (Herdman et al, 2011) was administered at baseline and at each follow-up point; responses were used to estimate quality-adjusted life year (QALY) profiles for each woman, calculated as area under the baseline-adjusted utility curve, assuming linear interpolation between utility measurements.

Costs and QALYs were accrued within the first 12-months post-randomisation and therefore no discounting of values was required. Cost-effectiveness results are reported as incremental cost-effectiveness ratios (ICERs), calculated as the difference in mean costs divided by the difference in mean outcomes (QALYs or BCAP) between the trial comparators. Bootstrapped bivariate regression was used to model within-trial incremental changes in costs and QALYs, with multiple imputed models summarised using Rubin’s rule (2004).

Cost-effectiveness acceptability curves (CEACs) showing the probability that the PuP programme is cost-effective relative to TAU across a range of cost-effectiveness thresholds were also generated based on the proportion of bootstrap replicates with positive incremental net benefits.

Several sensitivity analyses were undertaken to assess the impact of uncertainty surrounding components of the economic evaluation. These included: (1) adopting a wider societal perspective; (2) restricting the analyses to complete cases; and (3) recalculating the average cost per PuP session by applying either: (i) the highest mean cost per session estimated across all sites; or (ii) the lowest mean cost per session estimated across all sites.
4. Results

4.1 Participant flow and baseline data

Figure 2 shows the study CONSORT diagram. Of the 127 parents assessed for eligibility, 100 (79 per cent) were randomised (PuP; n=52 and TAU; n=48), 12 (9 per cent) declined and 15 (12 per cent) did not meet the eligibility criteria.

Post-intervention in the intervention group data for 10 parents was not available (withdrawn or non-contactable) and five in the intervention group. At six-month follow-up, 16 parents were lost to follow-up in the PuP arm and nine in the control arm.

Parents were almost exclusively female (n=4 fathers). Both groups were similar ages, predominantly single, educated to GCSE level or below, and unemployed. Around half of parents had a criminal record, with nearly one-third (17 out of 51) of these occurring in the 12 months before recruitment. They were chiefly classed as substance dependent and were mostly likely to be having opiate replacement treatment.
Substance dependence was classed using the alcohol dependency threshold of a score on the SDS of 3 or more (Lawrinson et al, 2007). Substance dependence history was broadly similar between arms for many substances.

However, the PuP group were more likely to have ever used heroin, benzodiazepines and cannabis, and more likely to have recently used heroin, benzodiazepines and cannabis.

One third of parents had a partner who was also substance-dependent, but the intervention targeted the primary caregiver.

<table>
<thead>
<tr>
<th>Parent Variable</th>
<th>PuP (n=52)</th>
<th>TAU (n=48)</th>
<th>Total (n=100)</th>
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</thead>
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<td>31.0 (5.2)</td>
<td>30.8 (5.4)</td>
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<td>1 (2.1)</td>
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<td>47 (97.9)</td>
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<td>17 (35.4)</td>
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<td>24 (50.0)</td>
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<td>2 (4.2)</td>
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<td>3 (6.2)</td>
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<td>GCSE or below</td>
<td>23 (44.2)</td>
<td>25 (52.1)</td>
</tr>
<tr>
<td></td>
<td>Higher Education</td>
<td>5 (9.6)</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>14 (26.9)</td>
<td>17 (35.4)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>4 (7.7)</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Main income</td>
<td>Income Support/ Disability allowance</td>
<td>9 (17.3)</td>
<td>4 (8.3)</td>
</tr>
<tr>
<td></td>
<td>Paid employment</td>
<td>2 (3.8)</td>
<td>2 (4.2)</td>
</tr>
<tr>
<td></td>
<td>Unemployment benefit/ Single parent allowance</td>
<td>41 (78.8)</td>
<td>42 (87.5)</td>
</tr>
<tr>
<td>Domestic violence†</td>
<td>Positive risk (&gt;10 points)</td>
<td>6 (11.5)</td>
<td>8 (17.7)</td>
</tr>
<tr>
<td></td>
<td>Negative risk (≤10 points)</td>
<td>37 (71.2)</td>
<td>36 (75.0)</td>
</tr>
<tr>
<td></td>
<td>Missing**</td>
<td>9 (3.8)</td>
<td>4 (8.3)</td>
</tr>
<tr>
<td>Criminal record</td>
<td>Yes, ever</td>
<td>26 (50.0)</td>
<td>25 (52.1)</td>
</tr>
<tr>
<td></td>
<td>Yes, within last 12 months</td>
<td>10 (19.2)</td>
<td>7 (14.6)</td>
</tr>
</tbody>
</table>

* Other ethnicity includes responses not clearly White British, such as “Jamaican White”, “Scottish”
† Scored using HITS (Sherin et al, 1998)
** At least one item not answered

Table 2 shows the descriptive statistics of the children recruited into the study. There were similar numbers of males and females and most children were living with their mother. A large proportion of children in both groups were currently under a safeguarding order.
Table 2: Descriptive statistics of recruited children at baseline

<table>
<thead>
<tr>
<th>Child Variable</th>
<th>PuP</th>
<th>TAU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in months (mean*, sd)</td>
<td>9.6 (8.8)</td>
<td>7.6 (9.4)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>21 (40.4)</td>
<td>18 (37.5)</td>
</tr>
<tr>
<td>Male</td>
<td>30 (57.7)</td>
<td>30 (62.5)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (1.9)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Child lives with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>49 (94.2)</td>
<td>41 (85.4)</td>
</tr>
<tr>
<td>Not with Mother</td>
<td>2 (3.8)</td>
<td>6 (85.4)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (1.9)</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Has siblings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (n, %)</td>
<td>41 (78.8)</td>
<td>36 (75.0)</td>
</tr>
<tr>
<td>Child currently under safeguarding order: Yes (n, %)</td>
<td>38 (73.1)</td>
<td>42 (87.5)</td>
</tr>
<tr>
<td>Child previously under safeguarding order: Yes (n, %)</td>
<td>12 (23.1)</td>
<td>12 (25.0)</td>
</tr>
<tr>
<td>Other children subject to safeguarding order: Yes (n, %)</td>
<td>36 (69.2)</td>
<td>29 (60.4)</td>
</tr>
</tbody>
</table>

*One parent was still pregnant at baseline

4.2 Comparison of outcomes for PuP and control groups

BCAP scores greater than or equal to 12 points were used to indicate a clinical risk of child abuse. This cut point was chosen as it corresponds to the conservative CAP cut-off score of 215 (Ondersma et al, 2005). Table 3 presents the descriptive statistics for the BCAP at each time-point. This shows that at the six-month and twelve-month follow-up points there was a greater reduction in the BCAP scores in the PuP arm compared with the control group; however, these changes were not significant at the five per cent level.

Table 3: BCAP scores by intervention group at three data collection points

<table>
<thead>
<tr>
<th>Time-point</th>
<th>Value</th>
<th>PuP</th>
<th>TAU</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Score</td>
<td>(mean, sd)</td>
<td>(mean, sd)</td>
</tr>
<tr>
<td>Baseline</td>
<td>9.3 (5.6)</td>
<td>8.8 (5.7)</td>
<td></td>
</tr>
<tr>
<td>Positive for abuse (n, % valid)</td>
<td>19 (36.5)</td>
<td>17 (35.4)</td>
<td></td>
</tr>
<tr>
<td>No. valid (n, % of group)</td>
<td>52 (100)</td>
<td>48 (100)</td>
<td></td>
</tr>
<tr>
<td>Post-intervention</td>
<td>Score</td>
<td>7.0 (5.7)</td>
<td>8.8 (6.4)</td>
</tr>
<tr>
<td>Positive for abuse (n, % valid)</td>
<td>9 (21.4)</td>
<td>18 (41.9)</td>
<td></td>
</tr>
<tr>
<td>No. valid (n, % of group)</td>
<td>42 (80.8)</td>
<td>43 (89.6)</td>
<td></td>
</tr>
<tr>
<td>Final follow-up</td>
<td>Score</td>
<td>7.3 (5.8)</td>
<td>9.8 (5.7)</td>
</tr>
<tr>
<td>Positive for abuse (n, % valid)</td>
<td>8 (22.2)</td>
<td>16 (41.0)</td>
<td></td>
</tr>
<tr>
<td>No. valid (n, % of group)</td>
<td>36 (69.2)</td>
<td>39 (81.8)</td>
<td></td>
</tr>
</tbody>
</table>
Table 4 shows the results of the MLM for the BCAP score over time by group with interaction effect. This significant interaction indicates that those receiving the PuP program show an improvement across time, while those in TAU show a deterioration across time.

Table 4: MLM of BCAP score over time by group with interaction

<table>
<thead>
<tr>
<th>Variable</th>
<th>Estimate</th>
<th>Lower 95% CI</th>
<th>Upper 95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>9.3</td>
<td>7.73</td>
<td>10.83</td>
<td>-</td>
</tr>
<tr>
<td>Allocation group</td>
<td>TAU (Reference = PuP)</td>
<td>-0.5</td>
<td>-2.7</td>
<td>1.8</td>
</tr>
<tr>
<td>Time-point</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (Reference)</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>0.16625</td>
</tr>
<tr>
<td>Post-intervention</td>
<td>-2.5</td>
<td>-4.2</td>
<td>-0.7</td>
<td></td>
</tr>
<tr>
<td>Final follow-up</td>
<td>-2.2</td>
<td>-4.2</td>
<td>-0.3</td>
<td></td>
</tr>
<tr>
<td>Interaction effect</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAU × Post-intervention</td>
<td>2.5</td>
<td>0.3</td>
<td>5.0</td>
<td>0.03365*</td>
</tr>
<tr>
<td>TAU × final follow-up</td>
<td>3.3</td>
<td>0.7</td>
<td>5.9</td>
<td></td>
</tr>
</tbody>
</table>

Table 5 shows that there was a significantly greater proportion of parents who recovered/improved and fewer who deteriorated in the PuP group compared with the control group (p<0.02).

Table 5: Clinically significant improvement and deterioration using Reliable Change Index from baseline to follow-up

<table>
<thead>
<tr>
<th>RC + Recovered/Improved</th>
<th>RC - Deteriorated</th>
<th>RC - No change</th>
</tr>
</thead>
<tbody>
<tr>
<td>PuP</td>
<td>11 (30.6%)</td>
<td>1 (2.8%)</td>
</tr>
<tr>
<td>TAU</td>
<td>4 (10.3%)</td>
<td>7 (17.9%)</td>
</tr>
</tbody>
</table>

TAU Treatment as usual; p < .02

The safeguarding categories were reclassified as ‘low’ or ‘high’ involvement, with ‘high’ defined as any category involving legal proceedings. A chi square analyses found the percentage of families involved with legal proceedings in the PuP group at baseline (10.4 per cent) was similar to that in the TAU group (9.6 per cent); \( \chi^2 (1) = 0.02, p=.89 \).

At post-intervention, the percentage of families involved with legal proceedings in the TAU increased to 16.7 per cent but did not change in the PuP group (9.8 per cent).

Again, this difference was not statistically significant, \( c^2 (1) = 0.86, p=.35 \). At follow-up, there was a further increase in the TAU group (25.6 per cent) with no change in the PuP group (11.8 per cent).

While this difference was not statistically significant, there was a trend towards significance, \( c^2 (1) = 2.26, p = .13 \) (see Figure 3 below).
Table 6 shows the outcomes for emotional regulation, mood and parenting stress. Three of the six subdomains measuring emotion regulation showed significant change favouring PuP — reduced difficulty in engaging in goal-directed behaviours ($p<0.029$); reduced difficulties with impulse control ($p<0.003$); and improved emotional awareness ($p<0.02$), with the Total Score showing a trend ($p=0.059$). There were no differences for non-acceptance of emotional responses; limited access to emotion regulation strategies or lack of emotional clarity.

There were significant differences favouring PuP on the measures of Depression ($p<0.01$) and Total DASS score ($p<0.04$) and but not the Anxiety or Stress Scales; and significant improvements in affect instability ($p<0.049$) and identify problems ($p<0.048$) but no difference for negative relationships or self-harm. There were no differences between PuP and TAU in parenting stress.
## Table 6: Parental functioning at baseline, post-intervention and six-month follow-up

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Subscale</th>
<th>Baseline (mean, SD)</th>
<th>Post-intervention (mean, SD)</th>
<th>P value</th>
<th>Final follow-up (mean, SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PuP</td>
<td>Control</td>
<td>PuP</td>
<td>Control</td>
<td>PuP</td>
<td>Control</td>
</tr>
<tr>
<td>DERS</td>
<td>Total</td>
<td>86.31 (28.73)</td>
<td>85.01 (27.44)</td>
<td>87.87 (24.99)</td>
<td>0.022*</td>
<td>78.49 (26.55)</td>
</tr>
<tr>
<td></td>
<td>Non-accept</td>
<td>13.74 (5.99)</td>
<td>12.91 (5.41)</td>
<td>12.43 (6.37)</td>
<td>13.79 (5.14)</td>
<td>0.28</td>
</tr>
<tr>
<td></td>
<td>Goal</td>
<td>11.75 (4.14)</td>
<td>11.81 (4.31)</td>
<td>10.48 (3.49)</td>
<td>12.67 (4.11)</td>
<td>0.010*</td>
</tr>
<tr>
<td></td>
<td>Impulse</td>
<td>15.35 (4.89)</td>
<td>14.70 (5.42)</td>
<td>12.62 (4.53)</td>
<td>15.14 (4.69)</td>
<td>0.014*</td>
</tr>
<tr>
<td></td>
<td>Awareness</td>
<td>12.59 (5.22)</td>
<td>12.56 (4.73)</td>
<td>10.83 (4.47)</td>
<td>12.74 (4.69)</td>
<td>0.058</td>
</tr>
<tr>
<td></td>
<td>Strategies</td>
<td>21.47 (6.84)</td>
<td>21.85 (6.41)</td>
<td>19.19 (5.61)</td>
<td>22.30 (5.80)</td>
<td>0.014*</td>
</tr>
<tr>
<td></td>
<td>Clarity</td>
<td>11.40 (5.08)</td>
<td>11.17 (4.77)</td>
<td>9.76 (4.20)</td>
<td>11.22 (5.07)</td>
<td>0.15</td>
</tr>
<tr>
<td>PSI</td>
<td>Total</td>
<td>144.1 (22.5)</td>
<td>142.0 (24.0)</td>
<td>149.8 (28.4)</td>
<td>147.5 (20.0)</td>
<td>0.66</td>
</tr>
<tr>
<td></td>
<td>PD</td>
<td>41.6 (10.3)</td>
<td>42.2 (10.8)</td>
<td>46.6 (11.2)</td>
<td>43.3 (9.2)</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>DI</td>
<td>52.6 (7.5)</td>
<td>51.1 (9.8)</td>
<td>53.4 (9.9)</td>
<td>53.3 (6.3)</td>
<td>0.94</td>
</tr>
<tr>
<td></td>
<td>DC</td>
<td>49.8 (9.3)</td>
<td>48.7 (7.7)</td>
<td>49.8 (9.7)</td>
<td>50.8 (8.9)</td>
<td>0.61</td>
</tr>
<tr>
<td>PAI-BOR</td>
<td>Total</td>
<td>28.94 (10.49)</td>
<td>29.21 (13.34)</td>
<td>24.88 (12.32)</td>
<td>28.94 (10.30)</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>BOR-A</td>
<td>6.21 (4.50)</td>
<td>6.23 (4.48)</td>
<td>4.45 (3.79)</td>
<td>5.91 (3.80)</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>BOR-I</td>
<td>6.92 (3.68)</td>
<td>6.88 (4.26)</td>
<td>6.05 (4.04)</td>
<td>7.23 (3.12)</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>BOR-N</td>
<td>7.14 (3.59)</td>
<td>6.90 (4.37)</td>
<td>6.21 (3.97)</td>
<td>6.99 (4.38)</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>BOR-S</td>
<td>8.64 (2.62)</td>
<td>9.21 (2.90)</td>
<td>8.16 (3.30)</td>
<td>8.81 (2.60)</td>
<td>0.31</td>
</tr>
<tr>
<td>DASS-42</td>
<td>Total</td>
<td>34.3 (31.0)</td>
<td>35.4 (32.2)</td>
<td>24.1 (29.8)</td>
<td>34.5 (31.3)</td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>10.7 (11.9)</td>
<td>11.9 (12.4)</td>
<td>6.4 (9.6)</td>
<td>11.9 (11.4)</td>
<td>0.02*</td>
</tr>
<tr>
<td></td>
<td>Anxiety</td>
<td>14.4 (12.0)</td>
<td>14.6 (11.9)</td>
<td>10.3 (10.1)</td>
<td>13.4 (11.1)</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>Stress</td>
<td>9.3 (8.9)</td>
<td>9.0 (9.6)</td>
<td>7.4 (11.1)</td>
<td>9.2 (10.4)</td>
<td>0.42</td>
</tr>
</tbody>
</table>

Significant at the 0.05 level
Table 7 shows that there were no group differences in the number of children found to be at risk on the competence, problem or either socio-emotional subscale post-intervention or at follow-up.

Table 7: Child functioning by intervention group at three time-points

<table>
<thead>
<tr>
<th>BITSEA subscale</th>
<th>Baseline (N at risk, % valid)</th>
<th>Post-intervention (N at risk, % valid)</th>
<th>Final follow-up (N at risk, % valid)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PuP</td>
<td>TAU</td>
<td>PuP</td>
</tr>
<tr>
<td>Competence</td>
<td>5 (25.0)</td>
<td>2 (14.3)</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>Problems</td>
<td>2 (10.0)</td>
<td>3 (21.4)</td>
<td>6 (26.1)</td>
</tr>
<tr>
<td>Competence or problems</td>
<td>6 (30.0)</td>
<td>4 (28.6)</td>
<td>7 (30.4)</td>
</tr>
</tbody>
</table>
5. Economic evaluation

Over the entire follow-up period, the mean (SE) total NHS and personal social services costs, inclusive of the cost of the PuP programme, were £18,931 (£2,443) in the PuP arm compared with £16,451 (£2,241) in the TAU arm, in parents with complete data, generating a mean cost difference of £2,480 (bootstrap 95 per cent CI: -3906; £9,156; \( p = 0.457 \)). This cost difference was primarily driven by the cost of the PuP programme (average cost: £5,135).

The incremental cost-effectiveness of the PuP programme, following multiple imputation and bivariate seemingly unrelated regression of costs and outcomes, is shown in Table 8 for the QALY outcome measure and Table 9 for the BCAP outcome measure. The mean incremental cost-effectiveness of the PuP programme was estimated at £34,095 per QALY gained (Table 8).

If decision-makers are willing to pay £20,000 for an additional QALY, the probability that the programme is cost-effective is approximately 26.7 per cent, increasing to 34.6 per cent at a £30,000 cost-effectiveness threshold, a result that remained robust to sensitivity analyses.

In contrast, when the BCAP measure was considered, the mean incremental cost-effectiveness of the PuP programme was estimated at £1,004 per unit improvement in the BCAP (Table 9).
Table 8: Base case and sensitivity analysis for cost-effectiveness based on QALY outcome; Seemingly Unrelated Regression

<table>
<thead>
<tr>
<th>QALYs</th>
<th>Intervention Mean (SE)</th>
<th>Control Mean (SE)</th>
<th>Incremental cost (95% CI)</th>
<th>Incremental effect (95% CI)</th>
<th>ICER</th>
<th>Probability cost-effective¹</th>
<th>Probability cost-effective²</th>
<th>Probability cost-effective³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean cost Mean (SE)</td>
<td>Mean effect Mean (SE)</td>
<td>Mean cost Mean (SE)</td>
<td>Mean effect Mean (SE)</td>
<td>Mean cost Mean (SE)</td>
<td>Mean effect Mean (SE)</td>
<td>Incremental cost (95% CI)</td>
<td>Incremental effect (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Mean cost Mean (SE)</td>
<td>Mean effect Mean (SE)</td>
<td>Mean cost Mean (SE)</td>
<td>Mean effect Mean (SE)</td>
<td>Mean cost Mean (SE)</td>
<td>Mean effect Mean (SE)</td>
<td>Incremental cost (95% CI)</td>
<td>Incremental effect (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Mean cost Mean (SE)</td>
<td>Mean effect Mean (SE)</td>
<td>Mean cost Mean (SE)</td>
<td>Mean effect Mean (SE)</td>
<td>Mean cost Mean (SE)</td>
<td>Mean effect Mean (SE)</td>
<td>Incremental cost (95% CI)</td>
<td>Incremental effect (95% CI)</td>
</tr>
<tr>
<td>1) Base case†*</td>
<td>12548.15 (1589.51)</td>
<td>0.887 (0.020)</td>
<td>10164.51 (1655.34)</td>
<td>0.817 (0.020)</td>
<td>2386.64</td>
<td>0.07</td>
<td>34094.86</td>
<td>0.22</td>
</tr>
<tr>
<td>NHS &amp; PSS perspective</td>
<td>(-1865.12, 6636.39)</td>
<td>(0.012, 0.128)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Societal perspective</td>
<td>17747.99 (2060.5)</td>
<td>0.887 (0.020)</td>
<td>13809.13 (2145.83)</td>
<td>0.817 (0.020)</td>
<td>3938.87</td>
<td>0.07</td>
<td>56269.57</td>
<td>0.116</td>
</tr>
<tr>
<td></td>
<td>(-1547.4, 9425.13)</td>
<td>(0.012, 0.128)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Completed case*</td>
<td>18997.57 (2180.77)</td>
<td>0.902 (0.017)</td>
<td>17373.1 (2219.23)</td>
<td>0.813 (0.0171)</td>
<td>1624.47</td>
<td>0.09</td>
<td>18049.67</td>
<td>0.449</td>
</tr>
<tr>
<td>NHS &amp; PSS perspective</td>
<td>(-4568.72, 7817.66)</td>
<td>(0.042, 0.137)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Societal perspective</td>
<td>24669.26 (2642.67)</td>
<td>0.902 (0.017)</td>
<td>21442.59 (2689.28)</td>
<td>0.813 (0.0171)</td>
<td>3226.672</td>
<td>0.09</td>
<td>35851.89</td>
<td>0.313</td>
</tr>
<tr>
<td></td>
<td>(-4278.29, 10731.63)</td>
<td>(0.042, 0.137)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Highest PUP mean cost per session†*</td>
<td>13394.56 (1603.49)</td>
<td>0.887 (0.020)</td>
<td>10156.28 (1669.89)</td>
<td>0.817 (0.020)</td>
<td>3238.28</td>
<td>0.07</td>
<td>46261.14</td>
<td>0.134</td>
</tr>
<tr>
<td>NHS &amp; PSS perspective</td>
<td>(-1053.21, 7529.77)</td>
<td>(0.012, 0.128)</td>
<td></td>
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<tr>
<td>Societal perspective</td>
<td>18594.4 (2075.212)</td>
<td>0.887 (0.020)</td>
<td>13803.89 (2161.148)</td>
<td>0.817 (0.020)</td>
<td>4790.51</td>
<td>0.07</td>
<td>68435.86</td>
<td>0.07</td>
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<tr>
<td></td>
<td>(-735.81, 10316.82)</td>
<td>(0.012, 0.128)</td>
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<tr>
<td>4) Lowest PUP mean cost per session†*</td>
<td>10940.05 (1568.17)</td>
<td>0.887 (0.020)</td>
<td>10171.46 (1633.11)</td>
<td>0.817 (0.020)</td>
<td>768.59</td>
<td>0.07</td>
<td>10979.86</td>
<td>0.432</td>
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<td></td>
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</tr>
<tr>
<td>Societal perspective</td>
<td>16139.89 (2036.53)</td>
<td>0.887 (0.020)</td>
<td>13819.07 (2120.86)</td>
<td>0.817 (0.020)</td>
<td>2320.82</td>
<td>0.07</td>
<td>33154.57</td>
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<td></td>
<td>(-3100.09, 7741.73)</td>
<td>(0.012, 0.128)</td>
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</tbody>
</table>

¹ Imputed costs  * Covariates adjusted – Baseline costs, Parent’s age, Site, Substance, Child gender, Child age, and intervention dummy.
² Cost-effective threshold of £15,000; ³ Cost-effective threshold of £20,000; ⁴ Cost-effective threshold of £30,000
### Table 9: Base case and sensitivity analysis for cost-effectiveness based on BCAP outcome; Seemingly Unrelated Regression

<table>
<thead>
<tr>
<th>BCAP</th>
<th>Intervention</th>
<th>Control</th>
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<tbody>
<tr>
<td>Mean cost</td>
<td>Mean effect</td>
<td>Mean cost</td>
</tr>
<tr>
<td>Mean (SE)</td>
<td>Mean (SE)</td>
<td>Mean (SE)</td>
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<tr>
<td>*<em>1) Base case†</em></td>
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<td>Societal perspective</td>
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<tr>
<td>*<em>2) Completed case</em></td>
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</tr>
<tr>
<td>*<em>3) Highest mean cost per session†</em></td>
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<tr>
<td>NHS &amp; PSS perspective</td>
<td>13394.56 (1603.49)</td>
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<tr>
<td>Societal perspective</td>
<td>18594.4 (2075.212)</td>
<td>1.585 (0.838)</td>
</tr>
<tr>
<td>*<em>4) Lowest mean cost per session†</em></td>
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<td>NHS &amp; PSS perspective</td>
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<tr>
<td>Societal perspective</td>
<td>16139.89 (2036.53)</td>
<td>1.585 (0.838)</td>
</tr>
</tbody>
</table>

† Imputed costs †† The negative sign of BCAP score was inverted into positive to reflect the fact that a higher BCAP score indicates a worse outcome. *Covariates adjusted – Baseline costs, Parents age, Site, Substance, Child gender, Child age, and intervention dummy. ¹ Cost effective threshold of £500, ² Cost effective threshold of £1000, ³ Cost effective threshold of £20000
6. Qualitative results

6.1 Parents’ experiences

All interviews were fully transcribed, and the data coded and analysed thematically and independently by two researchers. This process enabled the identification and ordering of codes and themes, both anticipated and unanticipated. A narrative summary of these themes is provided alongside a range of quotations that are provided as examples.

6.2 Findings

NOTE: Data regarding views about taking part in the RCT are in Appendix A.

Expectations about the PuP intervention

There were mixed expectations about the intervention, with some parents claiming they had little expectation and were anxious of “being judged” while others hoped for some good support and, more specifically, help with being a parent:

I really expect what I got from it, I suppose you get from it what you put in and I put a lot in, if I was advised to do something I kind of took it on board and I did it. …but believe you me, she covered everything that I needed from her so if I said, ‘Why this and why this’ she’d stop and sort of answer my question, so my expectations were over met to be honest.

Overall impression of the service

The majority of participants were positive in their overall impression of the PuP programme; they noted the consistent, dependable support, which appeared to provide a foundation on which to build confidence and promote strategies for developing emotional intelligence:

Like I say, I think it’s all, very, worked out very well. She gave me the support I needed when I needed it. Helped me with my confidence and then helped me move on to when she was, like, having to step away. She helped me move on and helped me have a plan to move forward. So, no it’s brilliant.

Excellent, I had the same person every week, which is really good for me because it’s hard for me to build up trust so that same person every week at the same time was good for me because I like routine.
Duration and timing of PuP visits

The home visits varied in length depending on the client and their needs at any one time. Sessions took an average of 1.5 hours but participants stressed that they felt practitioners were flexible and that timings were driven by their own needs. A few parents felt that the intervention could have lasted longer but the majority stated that they felt the duration of the intervention was right. Parents appreciated the flexibility of the approach and the fact that they could contact the practitioner between visits if necessary:

Basically, it was, went with the flow of what we were talking about on that day and after we’d finished talking about what we were talking about, the session continued. She would be there as long as I wanted her to be there basically.

Working with a PuP practitioner

The quality of the relationship built with the PuP practitioner was key to a successful intervention and the reports from parents illuminate many positive practitioner qualities. The qualities particularly highlighted were those that focused on the PuP practitioners’ ability to work alongside parents, acting as a ‘critical friend’ in a supportive but helpful way, and most crucially, in a non-judgemental way. The PuP programme is flexible, and the assessment process ensures that families receive a support plan that reflects their current concerns. Parents’ narratives explain how they feel that the work undertaken, and the goals set were relevant for them:

She was on my side but if, the sort of thing I was saying she didn’t feel was right, she’d make sure I knew about it. So, she didn’t like just say, you know, yes X, no X, three bags full X. She did come across and explain her own views as well. So yes, which to me…that was good.

I think I trusted my PuP worker more than anything.

I think so because it was constant, regular contact and I got to know her, not as a friend but someone who I knew I could trust. If she said a time and a date, she would be there, there was no letting me down and I felt I could trust her. If I told her something, unless it was something serious, she wouldn’t pass it on, I knew when I told her something serious I’d got the confidence in her to pass it on in not a menacing way, if you get me?

The importance of a strengths-based approach

This sample of vulnerable parents are used to having their behaviour and actions examined closely and report feeling be watched and judged by others. They were therefore quite nervous of yet another agency appearing in their lives; however, the approach taken by PuP practitioners, working in a non-judgemental and strengths-based way, appeared to be successful and was received positively:
She was there to help me. The other professionals in my life at the time I felt were just trying to keep a beady eye on me, make sure I wasn’t doing anything wrong and they were being more negative. Whereas everything she did with me was very positive, she put a positive spin on everything.

Just to tell me that…like, reassuring me that I can do it. I can be what I want to be.

Challenges in the therapeutic relationship

There was one mother who was interviewed who did not like the intervention and this appears to have reflected their failure to establish a relationship with a PuP practitioner:

We never interacted, we never got the bond. It felt like they weren’t listening. It felt like they were judging us.

This participant had a series of practitioners within a very short space of time, due to bereavement and illness.

Sometimes the parents felt judged by their practitioner

It was really bad…when she came round, she told me about this stuff she was going to do and it was just things that wasn’t realistic. I wish I had asked if they could change my support worker because she just wasn’t upfront with me. She was saying things to other people, I just didn’t like it, and I don’t like people not being upfront.

Managing emotions and mindfulness

Many of the elements that PuP practitioners focused on with this particular client group were around developing strategies to manage emotions and impulsive behaviours. Parents reported that they were often reactive and that this played out in relation to child behaviours; learning to take the time to understand why an infant or child might be exhibiting a particular behaviour led to understanding and, in some cases, a change in behaviour:

Reacting before you speak. Obviously. Try and sit down and see what his triggers are instead of just jumping up and obviously going overboard. I mean just certain ways that I could talk to my son and, more calmer, and he’s much calmer.

Just to stay calmer obviously and to obviously think before I speak. And to observe a bit more. Not just dive up and just think they’re doing something naughty when they’re not. And just to, like, observe them and see what they’re doing.

Controlling the way I felt. My mood. How to relax myself, to remove myself if I got too friendly. Not just with, like, my youngest one, she helped me with all my kids.
As part of the PuP programme, a primary tool to use with clients in order to regulate and manage overwhelming emotions was ‘Mindfulness’. Mindfulness, used in the context of PuP, was designed to help parents shift their mental states so that they can focus on the present moment, letting go of distracting thoughts and negative mood states. This was a new concept for parents but one that they appeared to engage well with, with practice:

I’ve got an anxiety toolbox. So, when I am feeling low and anxious and I’m not dealing well, I’ve got my strategies in place to help me.

Interviewer: that sounds really good… [...] did you find that difficult at first?
I did at first, but when it was explained to me a lot more, and then we just did it step by step then it became a doddle… [...]And I’ve got my little book of mindfulness that I kept with me all the way.

Do you know, before I even started the course I’d like shout a lot. Now I don’t shout at all really. It’s the mindful thinking part of it. It’s useful.

I don’t get so anxious all the time. I can actually take, if something’s going on, I can take a step back, feel like I can breathe and then handle the situation.

Video feedback

Few of the mothers talked at length regarding the use of video feedback; however, one father found it to be a highlight of the intervention and talked at length of how powerful he had found it:

It helped [PuP intervention], especially the video side of things… [...] there’s things you notice when you are watching it that maybe at the time you don’t notice.

Impact on parenting

Many parents reported that PuP has had a big impact on their lives, from confidence to feeling more energised. Parents report one of the biggest gains from the PuP intervention was developing a self-awareness of their skills or weaknesses, particularly with themselves as a parent and in relation to their children. Some clearly felt that they had developed a much stronger sense of understanding their own actions and motivations. The following are examples of many comments that related to a self-awareness and demonstrated an increase in insight:

It’s made me probably look at me as a parent more. And it’s probably helped me a bit more with my thought system. Obviously just I get anxious and things seem bigger than they actually are. She helped me see that and you know, maybe I worry a bit more than I should. That affects me and I think she’s made me see that things aren’t as bad as they seem.
Confidence, or the lack of it, was frequently embodied in the narratives of the participants, with parents feeling guilty about their addiction; Just someone there to say that I wasn’t a bad mum.

This, in turn impacted on their confidence levels. Many report PuP as being confidence boosting throughout the course of the intervention:

I think just [pause] being a better person. [Pause.] I think that’s a lot better, like I say, I’ve got more confidence. I’m not frightened to go outside on my own with my child, and have people judge me. If they don’t like it, then that’s their problem, not mine.

I’m a lot more energetic. I don’t slob around feeling sorry for myself anymore. I just get up and do what I have to do. And it feels so much better.

Just basically with, especially myself as a parent and helping with my anxiety and stuff like that. Because I didn’t really notice I had these things until it was pointed out by her…Things are a lot better now than they were before I met her…[…] My drug worker introduced me to this programme and I was like, well I don’t mind the help. I’d enjoy it. So, and lucky for me I got into the programme and it helped a lot. It helped me stay off cannabis, because that had a lot to do with my anxiety. So yes.

The impact was also reported to sometimes extend beyond the immediate family and to relationships with others, such as the health visitor or GP; again, this was linked through a growing confidence:

Because I’m not scared now to go for help if I need it. If I need help then hopefully they’re not going to judge me because I’m actually, have, asking for help. Where before I wouldn’t. I’d just suffer in silence.

The gains made were hard to achieve

Yes, and I’ve cried a lot. But it was worth it.
7. Practitioner experiences

The aim of the interview was to enable practitioners to focus on their experience of delivering the intervention, and practitioners were encouraged to discuss both the gains from being involved in the current project as well as the challenges.

Data was collected from 29 PuP practitioners across 11 sites (RCT and evaluation sites); in some cases, the practitioners were joined by the PuP team manager. Overall, this was a very experienced group of practitioners. At the very least, two practitioners had two-years’ experience, one practitioner had 36-years’ experience, and the majority had an average of 18-years’ experience. All of the interviews lasted approximately two hours. The interviews were digitally recorded and transcribed, and thematically analysed.

7.1 Findings

Practitioner experiences of the initial two days of training

The PuP programme training process involves an initial two days in which the key concepts and underpinning theoretical model of the programme are provided. There is then ongoing implementation support in the programme with a focus on supporting practitioners to use the programme. Competency-based accreditation is provided to practitioners who demonstrate competency in:

(i) the use of standardised measures provided by a purpose designed database – the PuP Online Support Tool. Practitioners need to undertake assessment of three families.

(ii) Completion of a case study using a PuP proforma setting out assessment, goals and treatment for each of the PuP domains.

Most practitioners appeared to enjoy and appreciate the training, and also to understand the justification and need for such a programme:

I enjoyed the PuP training, I got quite a lot out of it to be honest.

Similarly, other practitioners pointed out that they found the training informative, effective, and enjoyable:

It was quite informative as well as being responsive to questions that were being asked as part of the training. And yes, I came away feeling quite confident as to implementing it.
The initial PuP training, I thought that it was very good. It seems a long time ago now, trying to remember. But yes, I thought it was very good and also a good opportunity to meet the other people with, who were going to be working on the same commission.

**Changes to practice**

Individual practitioners had to overcome personal challenges and change the way they worked with families in order to become an effective PuP practitioner:

I think the training made a lot of sense but from where I’d come from, I really struggled with it because I come from local authority and I found it very difficult not to be direct and instruct families what they need to do and how they need to improve. So, I think it was more of a personal challenge than the training not being there, but the training was very clear. It gave good examples of how to go about and challenges, so I thought the training was quite good really.

However, at least one practitioner felt that the training did not involve them in new learning:

It was interactive because we were invited to give our responses and to go off into groups and that, so from that perspective it was definitely interactive. It was engaging from the viewpoint that different practitioners were coming up with different theories and ways of looking at things, so it was engaging from that perspective. But it does come back to the fact, it wasn’t anything new really.

**Was two days of training sufficient?**

Overall, practitioners appear to feel that at the end of the initial two days of training, they were still lacking confidence and were not sure how to put the PuP programme into practice. They also reported that more information before the training would have been beneficial:

I think we had very little information about PuP prior to the training. So, a lot of time was spent on things that we probably should have known and then it was left to [Name] to talk to?. It was the accreditation. None of us knew that we were, we had to be accredited and what that meant and the way, you know the additional stuff. So, I think a lot of the time then that should have been kind of the training was used to deal with our, lots of stuff that really needed to have been done beforehand.

One practitioner felt that more of a discussion was required at the beginning to explore how they all felt about the PuP model and how it could be incorporated into their current work practices.

I think so and also a good discussion on the model in the context of that really. So how do people feel obviously about this as a model? In the context of your previous experience and your previous training in therapeutic work. Does it fit, does it not fit? What aspects of this are different, or what feels you know? And
also because obviously we put, there’s two parts of it really, there’s quite an element of it which is therapeutic and doing therapeutic work with people and then there’s quite an element of it which is a bit more family support based. And I think that would have been useful, because I think some staff as well initially might have seen it as being quite family support based, whereas I don’t think, again had there been more time to reflect and discuss and process that I think it’s a combination of those two. Which I think staff got to and understood but we just didn’t have time really to look at that I don’t think.

Lack of time to reflect

Practitioners felt that the initial two days of training did not provide them with the time needed to think through and integrate new learning:

I think from my point of view I would say there is parts of it because I did the training as well, so parts of it I think were helpful and there were some new ideas which I felt were good. I think it would have been again helpful like people have said to have had more time really to discuss I suppose what was a new model, in the context of our previous experiences of doing therapeutic work and our previous experiences of other programmes that we’ve been involved in. Whereas I would say it was very much sort of almost like, this is the training, this is the programme, get on with it. And staff didn’t really have time to think about that or process it or reflect on it. And I think if there was a bit more of that, that would have been helpful really.

Need for more training about the use of drugs and alcohol

Working with parents with a substance misuse problem was challenging even for the most experienced practitioners. There was a general feeling that in addition to the PuP training, some additional training about the specific issues of this client group, ie substance misuse, would have been beneficial. A background and familiarity with drugs and alcohol misuse – for example, the use of particular terms and levels of misuse – was missing, and its absence was noted:

I think that was something again which the staff I suppose felt a bit ill-prepared for. …staff having the skills and knowledge in relation to substance misuse to some degree but with it being a new area we were going into I think from quite early on staff were saying it would have been helpful to have had some proper training around substance misuse.

Giving practitioners basic knowledge about drug misuse would have provided insight into the implications of their use and how they could support the family on a practical level:

Yes, I mean in a way if there were even somebody to incorporate in the training that basic knowledge of drugs. About what are the implications on the family, how are things around how they could create poor parenting, how can we approach parents with that. It’s like putting a cart before the wheel because what’s, you know, we just go up and even [inaudible] to go on drugs
training. But for me if the core of this is built around supporting parents who are affected by drug misuse and alcohol, that should be the fundamental thing about understanding the issues around drugs misuse. How do they affect families and so on?

Individuals who are struggling with an addiction have a range of other comorbid psychological disorders. Some practitioners felt that more information and training on these comorbid conditions would have been beneficial to them:

I think as a base it’s grounding in the kind of rationale behind the programme, I felt that it was quite good. I feel that there could perhaps have been more input on mental health issues cos a lot of the staff would have social work backgrounds and a lot of childcare experience but wouldn’t know very much about adult mental health issues, and that seems to crop up a huge amount in work.

Understanding ‘mindfulness’ in the context of working with families with parental substance misuse

Mindfulness is an important part of the PuP programme and has been described as a process of developing a non-judgmental acceptance and awareness of moment-by-moment experience (Bishop et al, 2004; Kabat-Zinn, 2005). Used as a therapeutic tool, it can facilitate the awareness and recognition of positive experiences that otherwise may not be consciously acknowledged (Harnett et al, 2010). Mindfulness was a new concept to most practitioners and many felt that, even after the training, they did not fully understand enough about mindfulness – or being ‘mindful’ themselves – and its possible benefits:

Yes, I felt it was very good. I think as time’s gone on, there’s been areas that I think we needed more support with them. In particular, the mindfulness module. I think it’s not something you can just read about. It’s much more.

I think the two main things for me have been in relation to using the mindfulness aspect of the programme and also the use of the video recorder. If I had to rate those of which is the more difficult, it would be the mindfulness. I think I needed a bit more preparation in relation to that.

Practitioners also felt that they needed more resources or practical tools to use with families:

It is a new concept. I sort of look on it as it’s along the lines of meditation which I’ve done for years and years but to actually practice it with families, I felt that we didn’t really have the tools to be able to do that. We were given the information, we knew what it was and sort of how we could use that with families, but I would have liked more tools to share with families and I know I’ve trolled the internet, I think we all have haven’t we?
And also, things like equipment issues around burning DVDs and making CDs for service to do this mindfulness work with them, it’s still not resolved, we’ve got some antiquated software for burning DVDs, which is, you know, ridiculous and no way of burning CDs yet and we’re what, two or three years into the programme?

Implementation support and clinical supervision

The PuP training process emphasises the importance of ongoing implementation support to provide a bridge between initial training in the model and support for putting this into practice. In the current project, this involved group and individual supervision provided either face to face or by phone/Skype. In addition to this, development days were provided every six months and the topics selected were informed through consultation with practitioners. For example, the early development days focused on the underlying theoretical model of the PuP programme. As this became consolidated, the opportunity for learnings around constructs, such as mindfulness and the use of video, were given one-day workshops with external facilitators. Clinical supervision was a new concept for some, with the potential benefits not being fully appreciated initially. However, over time, practitioners began to recognise its value, noting it to be ‘consistent, reliable, and valuable,’ and providing reassurance and a boost to their confidence:

It is a privilege to have access to clinical supervision and to be able to talk through cases at that level and in an in-depth way.

I remember in the initial stages not really understanding clinical supervision, or its purpose/function. I’d never had clinical supervision, prior in social work it was case management supervision. So, I wasn’t really sure what it was all about or why it was necessary or appropriate, that’s the early stages. Now, my experience now…It really supports with going deeper into the case and what you can do to move families forward, that doesn’t happen in case management supervision…I feel that it has supported me to help move families forward and make changes for children – I’m quite sure of that.

Practitioners felt that the supervision was effective in helping what was going on for the family, providing a space for practitioners to reflect and reach the root causes of their substance misuse:

I think [name] has got the background on substance misuse. She can tap into what’s going on in a family with an objective hat on and, yes, it’s well worth the time every two weeks to actually meet with her face to face or on the phone to actually, it’s such valuable time. And it’s reflective time as well. I think we get wrapped up in. Well I get wrapped up in supervision, there’s so many this, that and the other to cover, you don’t really have so much time for reflection. Whereas [Name] brings that out. Well we bring, that’s, it’s our space to actually be able to talk unfettered as it were and discuss cases and yes, I think she’s very, very good. And I thoroughly appreciate it.
Importance of clinical supervision

Supervision is noted as being a valuable form of support from the practitioner in order to support families effectively:

I think that is a good point actually, one of the cases that I have got, it was negative, negative, negative. But when I had clinical supervision, we really drilled it down and there loads of positives. When I read the information, all I could really see was chaos and the negative things but actually there were a lot of positives and that helped me unpick the positives. I think that is a good point about PuP practitioner, being able to do that, whilst keeping safeguarding stuff in mind obviously. But I think a commitment to developing your own knowledge as well. That as a PuP practitioner you have got to be committed and have that thirst for knowledge and developing yourself. Because there are twelve modules, I know one is closure and one is assessment but there is so much knowledge that you need to know and so much research we have all done and looked into.

Over time, the practitioners found supervision to be a crucial element in their role supporting families with complex needs while still maintaining a professional boundary:

I think as the work progresses, the relationships are, I don't think you can do PuP well without being affected by the family and having an emotional link to them. So, I think the work and the clinical supervision is crucial because I think maintaining it very much depends on our capacity to stay strong even if the work doesn’t seem to be progressing in a positive direction. So, I think there’s an element of, with some clients, having to address say my own ambivalence or my own concerns about how the work is going. Whereas other clients, it’s a lot more straightforward and it’s easier to support them because the direction is clear, there are less hiccups. So, I think the maintenance is really supported by the clinical supervision.

The distinction between clinical and managerial supervision

Some practitioners compared clinical supervision with line management supervision and felt that although you need both, clinical supervision had a unique role:

I think that [supervisor's] approach I would say is like person centred whereas the line management is organisation centred. I think that’s the difference for me. You need both, I appreciate that, but I think we were very fortunate to have both because I don’t think all commissions have clinical supervisors. But I think it’s absolutely vital for our work and particularly as we’re so disparate, like ships that pass in the night. So, we don’t have a chance to give each other peer support very much. Although I always feel I could ask if I needed it for anything because we’re not actually in the same building very often. So therefore, clinical supervision is all the more important for the PuP service.
To me it feels there’s a bit of a disconnect, because I think the PuP clinical supervision...felt really good at getting to the bones and meat of what you’re doing. Whereas in management, supervision feels like you’re just telling them what you’re doing rather than exploring the issues.

**Expertise of supervisors**

Clinical supervision was seen to be more effective by some practitioners because it was delivered by a trained psychologist. Access to this area of expertise was seen to be helpful in identifying models and/or strategies to help the families they were supporting:

I really enjoyed the clinical supervision from [supervisor] and I think what helped there was that she was a therapist. She had the sort of the psychologist’s knowledge as well, but she was also a therapist and that was brilliant. And management here is very good in terms of the social work thing. PuP was developed by psychologists. I’m a social worker. I can get my social work support from my manager who is very, very good. But what I don’t know about is access to a psychologist.

Clinical supervision was deemed more helpful in grounding the practitioners in the work they carried out with families:

I don’t think it helps the family, but I think sometimes when you come back and say you’ve done a horrific session and be like ‘I don’t know what I have done this session, I have just done nothing, it was pointless, felt nothing’. I think it helps then because then we say like [name] said well we actually have done this or we have checked your kids or you have covered life skills. So, I think it helps the worker feel like they have accomplished more, rather than the family.

**Barriers to effective supervision**

Initially, supervision was provided by supervisors who were based in Australia. The PuP practitioners found that speaking over the telephone was not practical because they had to overcome technical issues as well as dealing with different accents:

I think another barrier was the fact that the distance. I mean [Name] was in Australia and supervising us here in the UK. And there was the barrier of the phone that we were using the spider phone so we could all listen in. The quality wasn’t great, the sound wasn’t great and of course accents as well both ways. Because sometimes, I can only talk about myself, sometimes I found it difficult to understand [Name] and because it was muffled as well, so it wasn’t just the accent, it was the sound system as well. Well conversely [Name] sometimes struggled with our accents as well so they were barriers too. It does impact on that interaction.
Supervision over the telephone was also felt to be more acceptable when face-to-face meetings were also set up:

I found the support really good… I like the way that it is structured, two weeks there’s an onsite visit and then the other two weeks there’s the telephone conference. And I think that’s a really nice way of doing it. You can always slot into one or both of those and get the right support. So, I would say it’s about right really for what we’re trying to do.

The journey of becoming a PuP therapist

Practitioners reflecting on the process of becoming accredited reported that a lot of learning came from their involvement in the training, clinical supervision and development days across the three years of the project:

For me, the way I learn, is by undertaking practical tasks. So, for me my learning really started when I started delivering PuP. Undergoing the training gave me a general overview of the programme and loosely how the programme worked. But for me I really started learning when I started the intervention into practice.

I mean I felt like (the initial training) gave an overview of the PuP programme but it’s the casework that it actually came to life. And it wasn’t really talking about things that I didn’t know already. So, until you actually get involved with parents it doesn’t really, yes it didn’t really prepare me as such.

With hindsight, two years later we have learnt as much from the experience as from the initial training, if not more, probably more.

So, I would probably suggest that the (initial two day) training didn’t adequately prepare for the delivery immediately, it took that combined with support from colleagues, starting a case and working through it.

While PuP itself involved working with families in a way that some practitioners were already used to, practitioners reflected that the theoretical framework underpinning the programme took some time to get used to:

So, trying to get the PuP framework in my head took some time I’d say but that’s not to do with the training, I think that is just about me trying to get my head around the actual framework and the delivery of it, the approach. So yes, I struggled initially but then I think working through a couple, so the first two or three cases that I had it started to embed a little bit and make more sense following the training that we’d had.

Practitioners also acknowledged that no amount of preparation would have adequately prepared them for every eventuality:
I think it’s because our families are so complex and the parents’ lifestyle can be very chaotic. I don’t think you can be adequately prepared. You have to be able to think on your feet. I think as preparedness goes, yes, I think we, I think as far as anyone could do it I think it was reasonable. I went out feeling reasonably confident that I had worked with parents with substance misuse issues before. So, it’s not a totally new area to me. I think, I don’t think adequately prepared, you know that’s just not, that’s a non-starter really because our parents are just, are very chaotic often by the very nature of the issues that they’ve got, etc. I think you’ve got to go in with an open mind and be able to react to what you find out and what happens in the, between sessions, not just the first time you go and see a client. Between sessions and each session, you never know what’s going to hit you. That’s the beauty of the programme, it’s so flexible.

**Learning new techniques**

The practitioners felt that they had learnt a great deal from the practical elements of PuP, such as mindfulness techniques:

Well I think for me the one thing that comes to, well the first thing that comes to my mind is that having learnt about mindfulness. So, it doesn’t work all the time, but I think that’s something that I’ve learnt is actually put mindfulness into practice. Because that way I get clarity of thought, I get ideas about how to work with parents in a different way if I need to. And then obviously you’re modelling for parents, for the parents you’re working with. If you, you’re modelling that for them in terms of keeping, helping them to actually be more mindful in their parenting, in their everyday lives, etc. I now meditate every day and continue to work on being mindful. And I think I’m definitely calmer. It’s identified for me areas where, don’t try to strive for things all the time, don’t try and control things I can’t control. So, I guess in a way it’s like I have a steadier core but a bit more flexible. Whereas before I think I probably had a more fixed view of things.

**Less judgemental**

Practitioners felt they were less judgemental in their approach to interactions in their own everyday lives, as well as the families they were supporting:

Because I think again it goes back to the mindfulness. I think I’m less judgmental. I am much more tolerant of social workers, inability to, I guess before I wanted people to get it right for the clients I was working with. And now I’m more accepting that we’re all flawed human beings and within the bounds of reasonability I will hold people to account but I won’t beat them up about things. I’ll try to be more understanding and tolerant. And that’s just not professionals. I think within my personal life I would say that I’m probably less judgmental and less controlling and less of the, some of the perhaps more negative aspects that I may have noticed.
Improved knowledge and understanding

The practitioners felt that they had a better understanding about drug misuse and the impact it had on the families, in addition to what issues they needed to focus on and prioritise:

I think because I’ve come from child protection background where I’d always be going in and you know my attitude would always be, well you have to prioritise your children over your drugs. And this is obviously, well we’re still saying that but at the same time accepting that that is a factor in their lives that we need to work with and actually we can make them good parents even if they are continuing to use. If that is possible. And if not, what can we do to support them. Which has been a bit of a learning curve for me. But it’s given me an opportunity to sort of accept the whole person a bit more than what I would have done in my previous job. Because where the drug use became so massive and that was the arguments we would have. Whereas now with the PuP programme you’re looking at them as a complete person and what’s led them to their using, which obviously you would look at in child protection but it’s from a different perspective. It’s quite an accepting programme I think. I think that’s what’s quite nice about it and you go in there from the offset of saying, ‘yes okay you’re doing this, what can we do to support you through that process? And bring you out the other side.’ So I think yes, it’s educated me and changed my perspective, the way that I look at people who take drugs as well actually.

They have also become more aware of what a positive outcome looks like in real life where substance misuse is an issue:

I think it’s been enriched by…I think it’s probably, my understanding was probably more simplistic prior to delivering the programme. I think it’s been enriched by delivering the programme and I think for me the biggest step has been actually looking at what constitutes success. I mean sometimes it might be about somebody becoming drug free and staying drug free, and sometimes it might be about children removed earlier rather than later when loads more damage has been done.

Recognising the positives

Some practitioners also realised that in some instances the parents may have issues with substance misuse, yet they are doing a 'good enough' job with their children.

I think there’s an assumption that all substance misusing and alcohol using parents have poor attachment with their children, and actually you’ve bought that home to me when you said, no they’ve got a really great relationship. And actually, that it’s not all negative. Because I think you can be led to believe that it’s all quite negative. But I think PuP promoted that it is positive.
The importance of setting relevant goals: The practitioners learnt the importance of working with the families to support them with their goals rather than setting families a list of impossible tasks to fight their way through:

I think that is what I’ve learnt – patience. I think it is a real skill to listen to parents and try and work out and then take that into a professional arena in a way in which both parents and professionals understand the importance of the child. Rather than just having a professional’s agenda, you have got to incorporate the parent’s agenda also. I think I learnt that from PuP, although sometimes you don’t feel that parents want the best for their child and you get frustrated because they are not following the professional plan. Actually, they are not following the professional plan because that is not their agenda, you have got to follow theirs and guide them to why these are important. I think that is a totally different way of working and teaching parents to slow down. I think a big learning curve is that a lot of adults don’t have an emotional regulator, although I knew that before, I didn’t know the academic terms and a way in which to put that that made sense. So, I had the knowledge that parents would fly off the handle but not be able to say, ‘well they can’t regulate their emotions’. If they can’t regulate their emotions, they are never going to teach their toddler to. As professionals you can sit here as much as you like and have a go at him, he can sit here and stomp off as much as he likes, we are not moving anywhere. I think I have learnt a lot about how to do the work and be more patient and don’t push my agenda onto theirs.

Satisfying work

The practitioners took some satisfaction when they were able to see an improvement in the parent–child interaction:

Well there’s lots of things. Seeing the parent/child interaction developing. The attachment and the play and the warming. That side of things is such a pleasure to witness and hopefully helps the parents to achieve. I suppose at the moment I just feel it’s just such an area of work that needs to be done. So I would be very disappointed if that didn’t continue. If it was just a research project. I think it’s just so vital and it has been acknowledged by other people, professionals and families but I feel it’s just vital work I’m doing and that’s what gets me up in the morning. And yes there are frustrations with the work and all sorts of things but it can be very, very rewarding.

I think I’ve, well I’ve been the happiest that I’ve been probably in my working career doing PuP. But I’ve also needed supervision more than I have in another job. And I don’t know whether that’s because you get to know people so well then when things don’t go right, then it’s, it kind of, it takes a while to recover from it. Yes. So it’s had, been the most impactful job.
Challenging work

Some practitioners highlighted how demoralising this work could also be with clients where it was difficult to establish a working relationship:

It can be very difficult as well to continue a piece of work when it’s stop/start, stop/start because it becomes very fragmented so what was the...and that person’s...priorities change within that as well because a lot can happen with our families within a couple of weeks when there is a lot of chaos so you might...I find that when services are disjointed, I’m kind of going in and starting again every time. So we’ll start something and we’ll have a focus and we’ll try and work towards that and then we’ll have a period where you don’t see them and so you’ll go back but then it’s a case of catching up on everything that’s happened and they’ve moved on and then there’s something else so you’re going to go away, you agree you’re going to focus on something else, come back and you’re back...it’s very stop/start so you come away just feeling I don’t actually know what we achieved within that in the sense of a tangible goal. With those clients it’s really demoralising and can get you down, and it undermines your confidence as a worker really quickly.

Valuing the opportunity to intervene sooner

The practitioners are keen to work with families as early as possible. They developed an in-depth understanding of early intervention and considered the opportunity to work with women in the antenatal period:

Connecting with your child shouldn’t be starting when your child is born, it should be starting when the child is in the parents’ womb; that is when we should be doing this connecting with your child work. I have had parents on PuP saying to me, I didn’t really connect until they were here and then there is all this overwhelming guilt, pre-RCT. ‘My child has got a disability and I didn’t connect with my child when they were born, I felt an overwhelming, what have I done?’ I think it is crucially important to get involved with pregnancy.

Yes, actually some of the cases I had in local authority, the damage had been done for quite a few years and I guess it’s that early intervention stuff. Early intervention with early babies is, you’re learning a lot more about the foundations of parenting young children. Which I think sometimes you’re only dealing with the end of it, in my previous role so it’s a good reminder of how getting the fundamentals right at the beginning can have a massive impact.

It really fits with where I feel that intervention should be coming in and you’re looking at early childhood development and you’re looking at supporting parents at the earliest opportunities. So, in terms of prevention and working with them at the optimum time for me that really fits well and gives me a good sense of job satisfaction.
Managerial support for practitioners

Each of the PuP sites had a designated PuP team manager. While managers may also have been involved in a variety of commissions, part of their role was to provide organisational support to practitioners delivering the PuP programme. Where the manager had been trained in PuP and had a good understanding of the programme, the supervision appeared to work well, and practitioner reports were positive:

My manager has been there to support me. So, we’d have regular teleconferences which has been good. So, I think from a management perspective there’s been a lot of support.

One practitioner felt that their manager did not have the requisite experience to support them:

The NSPCC has taken on work that in some cases people aren’t specialists in. So, you could have a manager who’s never worked with drug using parents for instance. So, if you’ve got experience in that field and you’re talking to your manager about that field and they don’t necessarily have any experience in that field, then that leads you to not feel as supported as you could be really.

However, managers said that they felt unclear about their responsibilities and areas of PuP that required more of their focus from the start:

I don’t think initially it was clear what was expected of us as line managers, managing PuP. In terms of things like compliance requirements and things like that, so obviously I would manage PuP pretty much in the way that I would manage all other casework. But that was difficult because it wasn’t spelt out to us at the beginning that these are the issues that you need to be paying attention to. When obviously we’d started to have the compliance meetings that started to become clearer, yes, and we said at that point well it might have been helpful to this at the beginning. So obviously further down the line we did become aware of that. And obviously then, yes, you can tighten up on issues.

Practitioners said that they felt confused as to what their priorities were, and felt anxious when they experienced competing deadlines to either meet their organisational requirements or the needs of the families whom they were supporting:

…So, fourteen hours a week doing the commission but you still have to fit all the commission meetings in to that time, so as a proportion of your time, the shorter your time on the commission, the more time, relatively, you spend on PuP meetings, training and clinical supervision and so on and so forth, and it’s quite difficult to work on and feel you’re a master of commission when you’re also on…and I’m only one other commission but I’ve met some people who are on, like, four or five different commissions, each of which has their own set of meetings and training and whatnot associated with it, so how on earth they’ve ever found any time to do any work in that is beyond me. They
continued to state: I think coming back to the support, whether you are on more than commission, sometimes you have more than one supervisor as well and that can be quite difficult in the sense that you’re being asked to do tasks for one commission and you’re being asked to do tasks for another commission and nobody is actually looking holistically at how that’s going to impact you in practice, your workload overall.

Also, where sites experienced managers with little knowledge of PuP or where there was rapid turnover of staff, practitioners were left feeling unsupported. The absence of a consistent manager also had a negative impact on the motivation and enthusiasm to promote PuP to referring agencies, as well as impacting on staff morale:

We started off with one manager who never managed to get PuP off the ground then they changed jobs, then somebody else stepped in and then we had somebody else, then we had a temporary manager…and now have a permanent manager so within two years, we have had five managers for PuP. The practitioner went on to say: Across the organisation they’ve found it hard to recruit managers because nobody from within the organisation feels that’s it’s a doable, worthwhile job and they recruit externally and people tend not to last very long because it’s a job that it needs looking at and changing because it’s just a…it’s an unrealistic job to do and I think people…there’s some teams across the country have had changes of manager every sort of few months. They come in from outside, realise they can’t do it and then leave again. So that’s something the organisation, if they’re serious about running commissions that have leadership and have that sort of sense of creating high levels of motivation among the staff, then the managers need to be supported by having their administrative burdens reduced so they can actually spend their time leading rather than sitting in front of a computer all day, which is what they’re currently doing.

The assessment process

Practitioners were asked the following question: Did the PuP assessment process help with initial engagement? Responses indicated that there was some confusion between the assessment process required as part of the PuP programme and an assessment process historically completed as part of the NSPCC procedures:

And I think it’s fair to say that there was some reflection about whether or not we were doing sufficient assessment with families that were considered high risk families…And if we went into therapeutic work without doing a full and proper assessment first, did that then leave us vulnerable if something happened in those cases?…Whereas with this I think there was a little bit of confusion about this, is…well are we doing a full assessment or are we doing a half-way house assessment, or what sort of assessment are we doing? And then that led to a little bit of confusion.
There was some concern about whether a two-week time frame for an assessment was long enough:

Two weeks far too narrow to really. If you wanted, like, quite a comprehensive assessment within that, you’ve got to complete the questionnaires etc. So two weeks, yes, that’s far too rushed.

I think it takes a lot longer than that to be fair, I think when you are doing all the questionnaires; you are trying to get all the information from them that they need. Sometimes they are not focused on giving that information and then you are having to then give them that feedback and then set the goals; it can be a lot longer process and actually you haven’t done anything with them.

The practitioners indicated that they knew they could revisit the assessment process at any time during the delivery of the intervention. Especially because they are aware that the parents may not always be as honest as they can be:

But on the other hand, I mean it’s not as though you can’t revisit it. I think for some people I think that there is a danger if you have too longer assessment period that people see an assessment as, like, social workers do and it’s a comprehensive assessment and need, it’s too wide. I think PuP just very much focuses your mind on what are we trying to achieve? We’re not trying to achieve a comprehensive assessment like social workers do. We’re trying to do an assessment of need according to what we can offer. And if you keep those kinds of boundaries around it then I think it’s achievable within two to three weeks. But I think one of the pressures of working on PuP within the NSPCC is that people often feel the need to do a more comprehensive assessment or indeed management kind of put that expectation on people that you’ll know about the older child who lives in that family.

Use of standardised measures

Practitioners felt that the standardised measures helped clients to articulate what they were thinking and feeling, and could therefore be shared with clients to track progress:

I had a woman who said…., she didn’t understand what she was feeling and then we did the DASS and I looked at the high levels of anxiety and she said, ‘now I’ve got a word for it, now I can say what it is I’m feeling’. Which was really helpful to her and allowed her to then access psychiatric services.

The way you get an assessment report and the graphs that you get with it is very good. The visual work we felt was very positive. To be able to use those with families and for them to be able to visually see the difference we felt was very good. The report told you where the areas for development were and where work needed to be focused. I think we were very pleased with that and positive about that.
Practitioners also noted that clients were not always as honest as they might be at the start and that later questionnaire scores sometimes appeared to be worse as trust was established, and clients became more truthful and honest:

And that’s the thing, you’re dependent on them answering the question honestly. And you know somebody who’s just had their children removed, if fighting to get them back, they are going to try and be as positive as possible. So, they’re not going to want to tell you their possible reality.

One practitioner expressed her passion regarding mindfulness and pointed out that while there was a measure of mindful parenting, it would have been helpful to have this included in the report chart:

The PuP database…it’s such a shame the mindful parenting doesn’t feature on that bar chart because the bar chart is meaningful to a lot of clients because a lot of words are about something visual.

The Parent Workbook

The Parent Workbook is part of the toolkit for the PuP program. It covers 12 modules, each of which contain suggested exercises that can be completed with parents, children or both together. The workbook is intended to complement the family treatment plan that is developed following the assessment process and, thus, it is not completed in a set order but rather is used as a flexible tool. There is no requirement that parents complete the written exercises and if a preference is expressed, the practitioner and parent can talk through the content. Practitioners generally found the Parent Workbook to be a useful tool, with practitioners valuing its flexibility, noting that this enabled them to work with the priorities of the client at a particular time. Initially, it was also useful as a reminder and a guide to the programme. They reported that the majority of clients enjoyed using the workbook, some going beyond the exercise they had been working on just because they were interested:

My experience of the workbook is mainly really positive, we’d dip into it and dip out of it and that’s the whole point of it, and sometimes we won’t even necessarily look at it but we’ll refer to it and, you know, when I’ve gone ‘I’ll just have a look at that’ or ‘do you remember when we did this’ so it is really useful.

I’ve had a couple of parents who have actually read through the whole book and gone through and written stuff. She was saying ‘Yes, I’ve written some stuff on that, I have got some ideas’ on each of the modules. So, in their own time, I didn’t ask them to go and read the whole book, but they have it.
Inevitably, some clients did not engage with the workbook and practitioners reported that they went on to use the workbook in a modified or a ‘more creative’ way to engage their clients. There were also comments from a few practitioners who felt that the workbook was not visual enough and was too ‘academic’:

I also think as a workbook itself it’s not very user friendly for our service users. If you were given that, again that could be a big turn off because actually the language… It’s assuming you can read, it’s not very, there’s not many visuals to look at, it’s not very stimulating. Or doesn’t to me go positive work, it just looks like an academic book that for many of our parents, they’re so far removed from that, that it just could be a turnoff.

PuP practitioners highlighted a number of ways in which they felt the programme had benefited families. There were comments regarding the way in which the programme enabled practitioners to build trust:

Well I suppose it was actually building up the relationship with the family and watch all that relationship develop in terms of them being able to trust me. I think the other bit was sort of being part of that family’s life so to speak and watching that and watching the baby or the child or the other children that were in the family, develop and grow.

Practitioners also reported that they believed it helped improve parent’s wellbeing as well as providing an opportunity for a reflective space as illustrated below:

I think it’s when you see people, usually their mood lifts, like there’s one woman that I worked with and she started having the lounge curtains open because her mood was lifting and because she would keep the curtains closed when she was depressed or anxious, and that was really nice. And finishing a piece of work with someone just after they’d moved home, they’d moved out of a really kind of quite grim situation where they were isolated from family and been rehoused in a town where they could actually get to see family easier. That was really nice. I think when people repeat back to you part of the PuP programme thinking or repeat back to you, for me it’s often about good emotional self-care stuff, like, so they’ll tell you, ‘I’ve been working really hard at not ruminating’ and you think yeah, there’s something there that’s going to be useful to you that you’ve learned from the delivery of the programme, and you hear people repeat things back to you, I always find that very rewarding.

In terms of change, just giving them, the parents, time to talk about their issues and have a voice. I think in my situation, a current case I’ve got, mum’s never felt any agency has listened to her and it’s only now that she’s had an opportunity to talk about these things, which is helping her work it through but also looking at her confidence. She’s suddenly discovered that she can do things. But I think she’s one of these people that needs to kind of, she needs reinforcement and talking it through and having that interaction has allowed her to go, okay it’s not just negative relationships that are part of her life. There are actually positive things going on and she can see that now, but it took, I think it
takes people who aren’t social services, you know all of that kind of have that, you must do X, Y and Z. It’s more, and she’s quite reflective, so a reflective space I suppose.

The parents were able to develop a sense of pride in their children and become less critical of themselves. Practitioners also believed that parents had greater confidence as a parent and were able to see how important their role as a parent was in their children’s lives:

Yeah, it was very good seeing people being proud of their children as well, that’s quite nice, you sometimes get that, you know. Because some service users that we work with actually have pretty good parenting skills and people forget that sometimes and when they become more able to take credit for that, that’s quite nice as well. I can think of a few people who begin to…you know, a lot of the service users that we work with have, I understand they’ve got some kind of parental figure on their shoulder that’s very critical of them, a lot of very demeaning thoughts about themselves and when actually you hear them say something positive about themselves as a parent, you kind of think well they’re fighting that kind of a consistorial curse that they’ve probably got from their own parents, so often somebody has mistreated them in the past. You get a lot of very self-critical thinking among PuP clients, very, very undermining of themselves; very, very…yeah, self-criticism in particular. You could do with a little section in the PuP manual just to work on that I think.

…around confidence, lots of parents saying they feel more confident around their child, which is really nice. Sort of about calmness, feeling that they’ve got more strategies to deal with calmness, feeling they’ve got more strategies to deal with anxiety. But generally, confidence I would say is the big thing.

The main thing would be about parents or a parent realising the level of influence that they have over their child and their child’s developments and outcomes really and their life chances. I think that’s the biggest thing that I’ve noticed. Once a parent actually realises that it’s not about the nursery that they go to or the school that they attend or – it’s getting in with that early relationship and looking at the influence that the parent has. That’s the biggest change really.

One of the other benefits that the PuP practitioners highlighted is that the families were committed to the programme and they noticed that families did not on the whole miss appointments or terminate their involvement:

I’ve got to say I think on the whole parents find it enjoyable, so if they want to cancel, they contact you to let you know. I’ve got to say this is the first place I’ve worked where I get parents asking me to rearrange appointments or letting me know they have got to cancel. I don’t just turn up very often and they are not in. I think on the whole parents find it enjoyable, I think as I say especially in the second half. I think that is the beauty of PuP really, that it is that comfortable that if they are not well they can just text, it is not the end of the world if they cancel an appointment. It is for you doing what you want to do and that is fine, we just rearrange.
I’ve had two PuP cases where the families have never missed, never missed an appointment or if they have, it’s been for very good reason and they’ve let you know in advance, and it’s been great, and you wouldn’t…you certainly wouldn’t expect that from service users across the board, you know, because life’s like that.

There were also life-changing decisions:

The PuP programme helped mothers to make life-changing decisions that would not only help them now but provide a better future for them and their children. I’ve worked with a parent who’s gone back into education. So, this was a mum who I believe was in her early thirties. So, she had left education quite young but obviously was fairly bright and when I picked that up with her through the work, her child was at an age where she could start to explore going back into further education. And she has actually got herself onto a course that starts in September. Which for her is going to potentially, it helps her change her identity.

One of my clients is, she’s managed to get off methadone completely and she’s been encouraged to become a peer mentor, or volunteer at the drug agency that she used to be involved with, or that she was coming to an end with. So that gives something back…

The person I’ve worked with was planning to move completely out of the area back to her parents to get away from what was an abusive partner. I think the strength to be able to do that. I think that was the most striking difference that I’ve seen in all the clients.

And parents were able to develop a hopeful and optimistic outlook. The PuP programme had provided the families with a unique type of support that helped them to be and believe that they could be ‘good enough parents’:

…sometimes you get a sense that they develop a slightly more hopeful and optimistic outlook, and that I think is at the essence of the PuP programme, but I think that reflects a change in their mental health. I think once you start to become more optimistic and hopeful I think you start behaving very differently, and I think the PuP programme has the potential to do that. The bit in the manual, ten things I’ve done well as a parent, I know there’s ten things to love about my baby, which is generally parents can do very easily but ten things I’ve done well as a parent, some of them are reasons why I’m a good parent, people do struggle with that so when people start actually believing that, they are, they’ve got lots of good qualities as a parent so that’s a lovely thing.

The practitioners found that the PuP programme used a strengths-based approach, helping the families to see the positives in their lives and interactions with their children and build on them. This is an important message that parents do not hear often but can be profoundly helpful for them to move forward:
I think because it is a strength model isn’t it, so it does build on family strength because obviously parents, where there’s been substance use, do have a negative view of themselves don’t they, as parents? And that comes from a variety of sources. So, it does help them have a sense of belief about themselves that they are a good parent. There’s lots that they do that is right and they’ve made those positive changes in their life.

But I wonder if that is because they get so much negative from everybody else, that actually we are going in and actually saying ‘you are doing really well here.’ So that is something they need, so once they get over that barrier and know what they are getting out of it, then actually they benefit from actually seeing that they are doing really well here.

I think it is just a rewarding program isn’t it, I think overall you are looking at the positives, so you are seeing the positives. I think even when a case goes wrong and the children aren’t able to remain there it is still positive because you know that that is the right thing for them children and you are confident in that decision and that is what needed to happen for them children.
8. Discussion

There have been relatively few studies specifically designed to improve outcomes in complex families characterised by parental substance dependence, comorbid psychopathology and environmental contexts that include social isolation, severe financial disadvantage, and housing problems. The PuP programme is one of several interventions that have a focus on addressing parental emotion regulation designed for this high-risk group. This randomised controlled trial is the first effectiveness study conducted in the field to date.

8.1 Quantitative findings

The findings from this trial suggest that the PuP programme has an impact on a range of outcomes that are associated with poor quality caregiving in high-risk families. The primary outcome focused on whether the PuP programme was associated with a reduction in child abuse risk using a well-validated measure of abuse potential. There was a significant interaction between the two groups; those receiving the PuP program showed a decrease in their BCAP scores from 9.3 at the commencement of the program to 7.3 12 months later. No change was found in those receiving TAU with a starting BCAP score of 8.8, increasing to 9.8 at 12 months. Notably, further analysis that looks at the proportion of parents who reported reliable change showed a similar pattern of improvement in the PuP group but not TAU (30 per cent and 10 per cent respectively), while there were marked differences in deterioration between the PuP group and TAU (3 per cent and 18 per cent respectively). There was a trend toward improvement in terms of the reduction in legal proceedings for the PuP group. We were not able to report the results for the parent–child interaction data in time for the publication of this report.

Comparison with the earlier trial of the PuP programme (Dawe & Harnett, 2007) indicates a marked similarity in findings. In the earlier study, conducted in Australia, exclusively with parents on methadone maintenance, 31 per cent of those receiving the PuP programme showed improvement compared with none receiving standard care; conversely, there were no parents who showed deterioration in the PuP group compared with 36 per cent receiving standard care. While numbers in both trials are small, it is reasonable to propose that in the UK, in the current study, treatment-as-usual was more efficacious than standard care in Australia at the time this study was conducted. Regardless, the deterioration in TAU raises ongoing concerns about the future of the children in these families.
There were a range of measures that were used to ascertain if differences in parental emotional regulation were found in parents who received the PuP programme because this is proposed to be the key mechanism of change underpinning the programme as there is extensive evidence that the capacity of parents to provide nurturing, sensitive, and responsive caregiving is fundamentally impacted by the emotional wellbeing of parents (Barlow et al., 2013; Harnett & Dawe, 2012).

Therefore, the PuP program places an emphasis on helping parents to develop emotional regulation skills that allow them to be fully present with their infant or child. There were encouraging findings relating to parental emotional regulation and emotion management. The parents receiving the PuP programme showed significant improvements in emotional regulation, including improvements in engaging in goal-directed behaviours, impulse control, and emotional awareness. There were also substantial and significant improvements on two key scales measuring features of borderline personality disorder: specifically, affect instability and negative relationships. Finally, there was a significant reduction in the PuP group on general psychological distress with significant reductions on the depression subscale and a trend for stress \( (p=0.07) \). Parental emotional regulation is addressed in the PuP programme as this is proposed to be a key factor underpinning a parent’s capacity to provide sensitive and responsive caregiving to young children.

The results of the economic analysis show that although there was a low probability that the programme is cost-effective using the QALY, for the main study outcome measure, there was approximately 51.8 per cent probably of cost-effectiveness if decision-makers were willing to pay £1,000 for a unit improvement in the BCAP, increasing to 98.0 per cent at a £20,000 cost-effectiveness threshold for this measure.

The present findings are consistent with the growing evidence showing that a focus on the psychological wellbeing of the parent is necessary for complex families with parental substance dependence. The impact of the MIO programme (Suchman et al., 2017) on the sensitivity and reciprocity of mothers towards their infants was attributed, in part, to the observation that the programme, delivered concomitantly with addiction treatment, addressed parental emotion regulation challenges. Similarly, the Engaging Moms Program that produced positive results (Dakof, 2010) included strategies to engage emotional and practical support from the mother’s family to assist the mother’s capacity to cope with environmental adversities.
These findings are promising but raise the question whether a flow-through effect is also present on infant and child outcomes. In the current analyses, there were no differences on the relatively small proportion of children who were within the age range for the BITSEA to be completed. This may be due to the small sample size. Conversely, it is possible that a longer period of time is required before changes in children’s social and emotional wellbeing are found on standardised measures.

Objective assessment of involvement in the child protection system, based on parent-report, was coded into one of three categories: an increase in surveillance, a reduction in surveillance and no change. There were no statistical differences in the classification of social care status across the two groups. Social care status was reported by parents rather than drawn from administrative data. While coding was undertaken by two coders, the accuracy of parent report on their social care status needs to be questioned and further studies should attempt to obtain data from government records.

8.2 Qualitative findings

The views of parents indicated that the key learning from their involvement with the PuP programme was around an increase in their capacity to manage their emotions. Comments were made about being calmer, an ability to control mood and reactivity, and to shout less. There were explicit comments made about the strategies taught, such as mindfulness, and the ways in which this impacted on both emotional regulation and anxiety.

Importantly, the parents were clear that the relationship with their practitioner was critical to their capacity to change. Comments were made relating to parents being able to develop a more trusting relationship that felt safe; having confidence that their practitioner was open, honest and non-judgemental.

In relation to the experience of the PuP practitioners, a number of key points stand out. First, training is of paramount importance, and the notion that an initial training is just the start of a learning process through to accreditation is important to flag up at the start of the process. Every effort should be made to ensure that practitioners receive the standard PuP training.

Clinical supervision was a new concept for many, and the process and advantages need to be fully explained during initial training.
Practitioners also reported that mindfulness and video feedback were important elements of the PuP programme, and that both need dedicated time and support in order to become competent in their use. Further support in both these areas could be advised. For example, practitioners could spend some time at their office videoing one another to become proficient and confident in videoing parent–child interaction.

Practitioners could be given some Mindfulness DVDs to listen to and practice with. Ensuring that PuP trained managers are in place has an impact on the programme in terms of recruitment, programme delivery, and wellbeing of staff.

Many of the frustrations, occurring from the reiterative approach to setting the RCT criteria, might have been dealt with through a planned pilot phase, during which time the referral criteria and definitions could be examined and modified as necessary.

Practitioners valued the PuP programme, which they felt was distinctive and offered a level of detail and flexibility not found in other parenting programmes.

8.3 Study strengths and limitations

The study experienced difficulties in recruitment due in part to the fact that referring agencies expressed initial reluctance to refer to a study in which there was a 50 per cent chance that the parents referred would not receiving the PuP program. A series of presentations to referring agencies explaining the rationale of a randomised controlled trial lead to an increased referral rate over the course of the study, but due to time constraints it was necessary to stop after 100 parents had been recruited. As such, the study was underpowered and may have not correctly estimated the effect sizes.

A major strength of the study was that it was an effectiveness trial, carried out under close to real-world conditions. Families recruited were a high-risk group of substance-dependent parents receiving treatment for a drug or alcohol problem. Families referred to the program were only excluded if the child was not residing with the parent and there was no contact or plan for reunification, or if there was active and ongoing domestic abuse or the parents were actively psychotic or expressing active suicidal ideation. All other parents were eligible, with nearly half having a criminal record, one-third of which was recent.
A large proportion of children were currently under a safeguarding order. This is representative of the type of families the service would routinely work with. The programme was delivered by existing staff of the agency (who varied in professional training and existing skills set), in their real-world clinical setting, and who had been provided with the standard training and implementation support offered to any agency adopting the programme. The comparison group was usual care, rather than no treatment as is common in efficacy trials.

A challenge for the successful implementation of programmes is to maintain a fit between the intervention and families under different conditions of implementation (for example, characteristics of the client group and service providers in different agencies). If the circumstances in which the programme is implemented are different to those originally evaluated, either the intervention may need to be adapted, or the context in which it is implemented needs to be altered (Peacock-Chambers et al., 2017). Adaptation of a programme is potentially problematic (Shelton et al., 2018). The potential problems associated with adaptation of programmes has led to the call for programme developers to anticipate the diversity of client groups and agency characteristics in which the programme may eventually be disseminated, and plan for adaptation (Peacock-Chambers et al., 2017).

The explicit intention during the development of the PuP programme was to design a flexible intervention based on a trans-theoretical framework that explicitly included the development of a case-formulation, and that would enable the content, dose and processes (for example, goal setting) of the programme to be individualised to the needs of a family, eliminating the need for adaptation. Thus, the treatment protocol did not need to be modified from the protocol that was evaluated in the previous efficacy study (Dawe & Harnett, 2007) because the programme was originally designed to flexibly respond to the needs of families. This avoided the need for modification to the program that can reduce the impact of a programme when moving from the ideal conditions of efficacy studies to the real-world conditions of an effectiveness study.

**8.4 Future research**

Future research is needed to evaluate whether the PuP programme would be effective for other groups of parents, as the flexibility and underpinning theoretical framework that led to individualised treatment plans allows for investigation across other high-risk groups. This research should aim to identify the system level factors that impact on the implementation of the PuP programme in different settings (for example, skill set of practitioners, feasibility of delivering a home-visiting programme) and programme level factors (whether the content and dose of the programme fit the client group).
Further, the Implementation Science literature makes clear that modifications to programmes for different client groups, whether carefully planned or modifications that occur less systematically (as may be the case when practitioners deviate from a programme protocol they perceive to be a poor fit for their client group) can decrease the effectiveness of the programme when it is translated to different populations and setting (Stirman et al, 2017).

The PuP programme was designed to minimise the need for modifications to the protocol by building flexibility into the protocol itself. That is, the PuP programme is underpinned by an integrated theoretical framework that leads to individualised case formulations and treatment plans. This component was identified by practitioners as a strength of the programme. Further research is recommended to document the specific content of case formulations and treatment plans, and the extent to which these case formulations and treatment plans vary for different populations of families. Such research would provide valuable information on the mechanisms of change, moving the focus from whether the programme works to a greater understanding of how it works.
9. Conclusions

A significant number of parents of young children have substance dependence problems (ie both illegal drugs and alcohol). There is a considerable body of literature pointing to the extensive associated problems that substance dependent parents face, which impacts on current psychological functioning. Further, a substantial body of literature points to compromised caregiving in young children of substance dependence mothers.

Despite this extensive literature, there is to date limited evidence of effective methods of working to improve the parenting of this high-risk group of parents. Promising approaches include programmes that target the parents’ capacity for mentalisation, and the findings of the current study suggest that programmes targeting parental affect regulation using mindfulness-based strategies also impact on parental functioning and child abuse risk.
References


NSPCC (2011) *All Babies Count.* Available on https://www.nspcc.org.uk/services-and-resources/research-and-resources/pre-2013/all-babies-count/


Appendix A – Parent and practitioner views about taking part in an RCT

Practitioners’ experiences

The study design adopted the Medical Research Council’s framework for the development and evaluation of complex interventions (Craig et al, 2008), which promotes a reiterative process. Sites initially provided PuP as a service until the final decisions were made regarding which of them would become RCT sites. This change appeared to create a sense of uncertainty within the teams. While practitioners understood why this process had to be undertaken, they reported feeling uncomfortable explaining all of the changes to external referring agencies.

There wasn’t enough clarity and it’s all waiting till you get to a compliance meeting to see what they want. Hindsight again is wonderful but again if it was more script and more what they wanted from us, then you would have had clearer guidelines. That’s the bit that was the confusion for me really. It wasn’t the case of the programme, that was self-explanatory in how you deliver and the modules within it, they were straightforward coming back to the family support. It was more about how they wanted you to do it.

I felt it was quite rushed in its planning. If it had been planned differently. So, for instance if you’d have started PuP as a research item rather than starting as a service and then a research. Then I’d have felt a lot more comfortable with it. Because to be honest, from the start what it was, what was expected. And be clear with other agencies. But I felt it wasn’t thought through enough. It was quite rushed, and it kept chopping and changing and then that created anxieties [from years of working when we told people?]. What do I say? That type of stuff. So, it could have been better planned for me. (S2:P2)

Further changes to the eligibility criteria were deemed necessary once the RCT was underway. For those sites delivering PuP prior to the RCT, practitioners imply that the referring agents had been keen to send in referrals, knowing the family would receive the programme. However, practitioners found numerous changes to the eligibility criteria difficult. Therefore, they found it difficult to promote the process to referring agencies who were already less than happy that their clients were not guaranteed a service from PuP.

Nevertheless, some practitioners valued the experience of being in an RCT.
I think the other thing for me I suppose is, for all of us this is the first time we’ve done an RCT, and they are really unusual within social work, so it’s a new experience for almost all of the agencies that we are working with, and within medical models obviously it’s much more familiar, so when we’ve worked with health workers, like health visitors and nurses, they’ve kind of had an easier understanding of it, but certainly within social work, it’s been much more of a challenge. And I think, for me, there was a gap for us as practitioners kind of really looking at that, and having some of the ethical debates around the RCT, and I think with hindsight, because that’s something we’ve then experienced, through trying to drum up referrals, and recognising that that’s one of the barriers, and we’ve had to have ethical conversations on loads of occasions, with everything from area managers down to social workers. I would have found it more helpful to kind of maybe be a wee bit clearer on some of that, both for myself, and then to be kind of able to have that debate, if you like, in meetings and stuff (S5:P1)

Oh, I liked that, yeah, I liked that. I think there’s so much of that that we’ve done in the past as an organisation that we’ve always felt somebody needs to write this up and to put something down on paper. So, it’s nice being part of a research project I think because unless you’re writing stuff down no-one will ever get to hear of it and unless people get to hear about it, they can’t repeat it…yeah, and I think for me one of the develops for the future that I could see would be for staff within the organisation to have the potential to design interventions which would then invite researchers like yourself to come in and evaluate for us. (S1:P1)

The constant modifications that were made caused some frustrations with many practitioners. The practitioners’ perceptions were that this reiterative approach felt disruptive and hindered the referral process. This was reflected in discussion, where many were concerned with the impact of these changes. A fragile faith in the process of the RCT was seemingly undermined by all the changes, resulting in a loss of confidence. In turn, this appeared to impact on the referral process:

…and getting the parameters shifted from, like, it was being dictated by the research more than it was by the practice. And so that was a real frustration. I think those priorities should have shifted right at the start. (S5:P2)

Whereas if we’d been allowed to get it up and running, it was established, we’d got referrals coming in and then we said, ‘right now we’re ready to go into the RCT and have some control over that’, then I think it would have been much more effective. Because what happened was, is we went in too early, it killed off any referrals we did have. (S2:P1)

Too narrow referral criteria. Because I think that’s acted as a big hindrance in terms of getting referrals through. We’ve often had occasions where partner agencies have wanted to refer but the child has been slightly older. So, they’ve not been accepted onto the criteria. So, I think the narrowness of the criteria has been a hindrance. (S11:P1)
Participating parents’ experiences

Parents reported feeling happy with being referred to the PuP programme, which they felt was something positive and could possibly be helpful – they reported not feeling unduly worried or anxious about the process. There was a strong sense of having been well prepared for their involvement in the RCT, as parents clearly demonstrated an understanding that they had an equal chance of being in either the control or intervention group. Most admitted to being unsure as to how they thought the PuP programme might help them but had confidence in the fact that their referrer felt positively about the intervention and that any additional help and support would be beneficial.

The following example illustrates some of the anxiety that emerged but was not at a level that precluded them from participating:

I did at first because I thought it was just going to be people spying on me to ring social services because I’ve not had a very good understanding with, not had a very good time with them anyway. But so I was a bit worried you know, at first. But then I thought well I’m not doing nowt wrong and I’m trying, so what can anybody say, I’m doing what I’m doing. (N)

That the nature and process of involvement in the RCT had been clearly explained to parents was reflected in their comments. They appeared to have a realistic expectation of the group allocation process and possible outcome. Clearly, and understandably, parents were ‘disappointed’ when they were told that they were not in the intervention group; however, it is interesting to note that there were no ‘drop outs’ solely due to group allocation:

No. I was actually quite looking forward to, you know, well I was hoping that I was going to get obviously the intervention part of it but obviously I didn’t, so I think I was a wee bit sad because I thought that I would probably would have benefited most from that part of it. But like I said I just wanted to help somebody else (G05)

Parents were asked if they had considered dropping out at this point and a number admitted that they had; however, they had invested time in the programme and appeared to understand the importance of collecting evidence for the RCT, as the following quote explains:

Interviewer: Did you consider dropping out at this point?
Respondent: Well yes, because there’s no point.
Interviewer: But you obviously didn’t, and we’re really pleased you didn’t…so what made you decide to stay in the research?
Well thought I might as well…, like, see it to the end.
In answer to the same question asking if the participant considered dropping out of the research, another respondent stated that she had considered dropping out but cited the qualities of the researcher as being the main reason that she did not. Her response emphasises the importance of a sensitive, non-judgemental researcher:

Because the lady that come and see me, she was quite nice to be fair. And when I was going through it at the beginning, she was somebody to talk to because I’m in a different city, on my own, I don’t know anybody […] And I talked to her, yes maybe the first time I got a bit emotional, but it was just somebody to talk to and that just helped at that time. Really helped. And I liked her. It really helped.

Completing the questionnaires

Parents were able to complete the questionnaires with help from the researcher and although this was a somewhat lengthy procedure they had been realistically prepared for the process and the time involved – some even professed to enjoy it, as this participant claimed:

Gives me an hour on me own and I found it quite pleasant.

Another described how the process of completing the questionnaire had made her think about her situation in a different way, which, for her, she found to be therapeutic:

No, sit down and actually think and then the questions, just something that doesn’t come in your head. But I got a positive thing out of that, even though it’s not, I was realising, maybe I’m suffering a bit of postnatal depression which I, instead brushing it under the carpet.