

# Moderators and mediators of outcomes of parents with substance use problems: further evaluation of the Parents under Pressure programme

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## ABSTRACT

**Background and aims** Family-focused interventions can improve family functioning when parents have substance use problems. However, there has been little focus upon potential predictors of change and analysis of mechanisms of change. This study aims to identify mediators and moderators of change in a pragmatic, multi-site, randomized controlled trial of the Parents under Pressure (PuP) programme, a family-focused intervention for parents with substance use and other problems, and treatment-as-usual (TAU). **Design** Secondary analysis of data: multi-level modelling was used to investigate moderators of treatment outcome; mediation was tested with cross-lagged models. **Setting** Community-based family support services in the United Kingdom. **Participants** Parents ( $n = 100$ ) attending community-based addiction services with children aged 2.5 years or younger. **Measurements** Predictors of the primary outcome, child abuse potential, were: baseline child age and gender, composite family risk score, parental substance use and parental emotional dysregulation. Mediation was tested across three time-points with the observed variables parental emotion dysregulation and child abuse potential. **Findings** Increased child age [ $Z = 2.14$ , 95% confidence interval (CI) = 0.01, 0.33] at baseline was associated with greater reductions in child abuse potential for PuP programme participants compared with TAU. Poorer parental emotional regulation ( $Z = 2.48$ , 95% CI = -2.76, -0.32) was associated with greater reductions in child abuse potential for all participants. Parental substance use (either recent use or primary substance of concern) did not alter any treatment effects on child abuse potential. The mediation analysis showed that PuP produced greater improvements in emotional regulation at post-treatment ( $P < 0.001$ ) compared with TAU, which predicted lower child abuse potential at 6-month follow up ( $P < 0.05$ ). **Conclusions** For UK parents enrolled in a family-focused intervention, baseline measurements of higher child age appear to be associated with greater reductions in child abuse potential at 6-month follow-up in PuP participants compared with treatment as usual (TAU). Poorer parental emotional regulation and, potentially, higher family risk, appears to be associated with greater reductions in child abuse potential at 6-month follow-up in PuP and TAU. Emotional regulation appeared to act as a mediator as improvements in parental emotional regulation post-treatment appeared to be associated with greater reductions in child abuse potential at 6-month follow up. Notably, participation in the PuP programme led to better parental emotional regulation compared with TAU.

**Keywords** Addiction, child abuse, maltreatment, mediators, moderators, parenting.

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## INTRODUCTION

Parental substance use is associated with compromised child outcomes [1–4] and is frequently present in families engaged in the child protection system [5,6]. A growing literature indicates that improving family functioning and child outcomes in families with parental substance use is

possible [7,8]. However, there has been relatively little research exploring predictors of outcomes for families with parental substance use who engage with treatment, and limited investigation of underlying theoretical mechanisms that may be involved in bringing about change [9]. Extending intervention research beyond what works, to identify those who may respond differently to

the intervention (moderator analysis) and to investigate causal hypotheses underpinning the programme logic (mediator analyses) allows for the tailoring and prioritization of evidence-informed treatments [10,11].

The Parents under Pressure (PuP) programme was developed to support parents with problems that include exposure to childhood maltreatment and trauma, parental substance use and emotional dysregulation. The PuP programme has been evaluated in a series of studies with promising results (e.g. [12–14]). The present study extends the current literature by investigating predictors of outcome and mechanisms of change in a recent pragmatic randomized controlled trial (RCT) [12] to parents enrolled in community-based addiction services. There were significant reductions in the primary trial outcome, child abuse potential and improvements in emotional regulation in the intent-to-treat analysis, and in both these measures plus mood and borderline features in the per-protocol analysis [12]. While these results contribute to a growing evidence base for interventions for families with parental substance use, secondary analyses testing predictors of treatment outcome and putative mechanisms of change are now needed to help inform decision-making and the future development of targeted interventions.

#### **Predictors of outcome: testing moderation**

Identification of potential moderators of outcomes assists in identifying characteristics associated with improvement/deterioration [15]. The literature on the predictors of child maltreatment [16] and treatment outcomes informed our choice of potential predictors obtained at baseline. At the child level, younger children may be at increased risk of child maltreatment [17,18]. At the family level, factors that predict child abuse potential include single parenthood, poverty [19–21], domestic violence [22], low education and unemployment. Eight potential family risk factors were used to derive a cumulative risk score, as cumulative risk models are robust predictors of child developmental outcome generally [23], child maltreatment recidivism [24,25] and outcome in families with maternal substance use [25–27]. Parental characteristics highlight both psychopathology [28,29], conceptualized as the transdiagnostic construct of emotional regulation in the current study [30], and substance use [31] as potential predictors.

#### **Investigating mechanisms of change: mediator analysis**

Emotional regulation (ER) is a multi-dimensional construct involving the capacity to monitor, maintain and modulate the occurrence, duration and intensity of emotional experiences [32]. Contemporary models emphasize poor ER as a potential mechanism of change in treatment outcome studies among a range of psychological disorders [33],

leading to the proposal that ER can be viewed as a transdiagnostic construct [30,34,35].

A growing body of research underscores the relationship between parental ER, parenting practices and child outcomes. Parental emotional dysregulation and poor inhibitory control have been directly linked to parenting behaviour and the quality of parent–child interactions [36]. Further, modelling suggests that parental emotional dysregulation can contribute to poor child self-regulation [37], a key predictor of childhood behaviour problems [38,39]. Poor parental emotional regulation is also associated with harsh or inconsistent discipline [40] and with child maltreatment [41]. In a recent review [42], Rutherford and colleagues highlighted the importance of addressing ER as a transdiagnostic construct in parenting and drew attention to the potential roles of mindfulness and mentalization as avenues to enhance ER. There is also an established association between ER difficulties and substance use [30,43], particularly regarding impulse control, which is a core feature of many approaches in the treatment of addictive behaviours [44–46]. Thus, the link between ER and an environment in which there is elevated potential for child maltreatment supports the hypothesis being tested here that emotional regulation may act as a mechanism of change [47] in families with parental substance use.

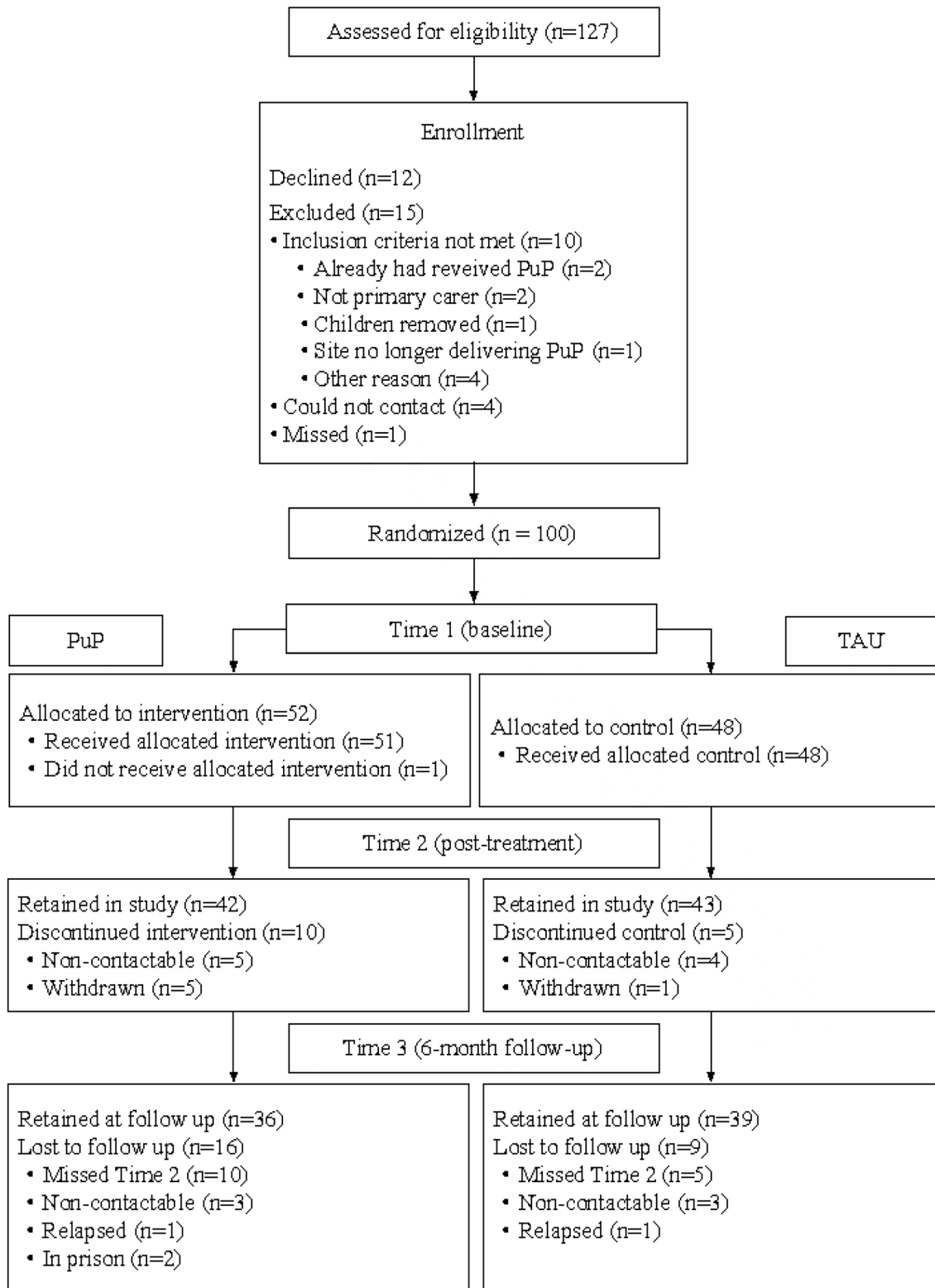
#### **Current study**

First, this study examined the impact of moderating factors that may be associated with child abuse potential risk. Secondly, the potential mediating role of parental emotional regulation on child abuse potential was examined by investigating the temporal precedence of change in emotional regulation across three time-points [48]. It was hypothesized that participation in a programme with mechanisms explicitly targeting emotional regulation (i.e. in this case the PuP programme) would lead to greater reductions in parental emotional dysregulation than treatment-as-usual (TAU) at time 2 (post-treatment) that, in turn, would predict a greater impact on reduction in child abuse potential at time 3 (6-month follow-up).

## **METHODS**

### **Participants**

The PuP trial recruited 100 families with parents engaged in community addiction services between October 2014 and December 2018. Of the 127 families referred to the trial, 52 were randomized to the PuP programme and 48 to TAU (see Fig. 1). As shown in Table 1, extensive family risk was evidenced by involvement in the criminal justice and child protection systems, single parenthood and reliance upon government benefits as the primary



**Figure 1** Consolidated Standards of Reporting Trials (CONSORT) study diagram

source of income. There was high engagement in the PuP programme; the mean number of sessions attended was 11.1 [standard deviation (SD) = 8.19], median 14 sessions.

#### Study design

Randomization was stratified by centre using minimization [49], and consenting parents were randomly allocated to

**Table 1** Baseline characteristics of parents and children ( $n = 100$ ).

	Mean (SD) or %
Parent characteristics	
Age (years)	30.8 (5.4)
Sex (% male)	4%
Marital status	
Married/cohabiting	38%
Single-parent household	52%
Other	10%
Education	
≤ 10 years education	48%
12 years education	9%
Tertiary	7%
Other	32%
Missing	4%
Primary source of income	
Paid employment	4%
Government benefits	96%
Family risk factor score	4.3 (1.4)
% 4 or more	57%
Criminal record ever	51%
Criminal record last 12 months	17%
Primary drug of concern	
Alcohol	28%
Non-prescribed opioids	3%
Prescribed opioids <sup>a</sup>	54%
Cocaine	4%
Cannabis	11%
Child characteristics	
Mean age (months)	9.2 (9.1)
Gender <sup>b</sup>	
Male	60%
Female	39%
Current involvement with child protection	82%

<sup>a</sup>Methadone and buprenorphine; <sup>b</sup>missing data  $n = 1$ . SD = standard deviation.

one of two arms using a computer-generated numbers table (using Stata version 7) by an independent statistician following baseline assessment. Data were collected at time 1 (baseline), time 2 (post-treatment) and time 3 (6-month follow-up) by a researcher who was blind to group allocation. The study was granted ethical approval from the University of Warwick Biomedical Research Ethics Committee (Reference no. 189-03-2012).

### Intervention

The PuP programme was developed for families facing multiple difficulties, including parental substance use. The key point of difference from other parenting programmes is that the PuP programme is underpinned by the integrated theoretical framework, a dynamic model of assessment and treatment planning drawing from attachment theory, behavioural parenting skills and adult psychopathology [12,50]. This provides a structure for

practitioners' assessment and development of an individualized therapeutic family support plan in collaboration with the family. Parents engage with the programme through a parent workbook, which provides a structure for the intervention, and can be completed by the parent when literacy levels allow or guide discussion between parent and practitioner. The parent workbook contains 12 modules, with a significant focus upon the development of emotional regulation skills. For parents of young children (as in this study) this entails helping parents directly with emotional regulation skills and the child/infant and indirectly by helping to enhance the care-giving relationship guided by principles of emotional availability [51].

The PuP programme was compared to TAU. These were services provided in children's centres which were established to give disadvantaged children 'the best start in life'. The centres provide a range of services at a single point of access including child-care, early education, health services, parenting classes and family support services. All parents were concurrently engaged in community addiction services that included opioid substitution therapy and counselling. As with other pragmatic effectiveness trials, no attempt was made to standardize TAU to allow for comparison of the PuP programme with real-world service configurations [14]. Fourteen practitioners in children's centres delivered the PuP programme, eight of whom were qualified social workers. All practitioners were accredited PuP therapists, having received a minimum of 40 hours of training and supervision in the PuP model. The mean number of supervision hours recorded was 55 (SD = 11.57).

## PROCEDURES

### Recruitment

Referrals were made to the trial by any practitioner working across a range of agencies, including midwives, drug treatment centre workers, staff at children's centres and staff working with charitable organizations within the field. Eligible families were provided with a brief information sheet inviting them to receive more details concerning the study and providing consent to be contacted by the research team. The researcher contacted the family and a visit was arranged. Participants who agreed to take part provided written informed consent.

### Measures

All measures were detailed and implemented as described in the protocol for the RCT [52]. The primary outcome was the risk abuse scale score from the Brief Child Abuse Potential Inventory [53], hereafter child abuse potential (CAP). This measure has good predictive and convergent validity for child maltreatment [53-55]. A threshold of

$\geq 12$  indicates risk of child abuse [54]. In addition to child age and gender, baseline moderators were assessed using measures of parental substance use (self-report primary substance of concern, timeline follow-back interview [56] and hair sample toxicology), parent ER (see below) and a family risk score informed by cumulative risk literature [57]. The score was constructed by summing eight risk factors as either present (1) or absent (0) to compute a total score. These were as follows: single-parent household, four or more children in the household, parent-reported history of a psychiatric problem that has been diagnosed by a mental health professional, parent-reported history of a substance use problem, scoring above the cut-off on a domestic violence checklist (HITS [58]) in the last 12 months, any conviction for a criminal offence, current involvement in child protection and main source of income government benefits (e.g. income support, disability allowance, unemployment benefit). The proposed mediator, parental emotional dysregulation, was assessed using the difficulties in emotional regulation scale (DERS) [59], which was highly correlated with the personality assessment inventory-borderline scale (PAI-BOR) [60,61] and depression, anxiety and stress scale (DASS) [62] assessed in the RCT.

### Data analysis

Multi-level modelling (MLM) in MLwiN (version 2.30) was used to investigate moderators of treatment outcome. MLM is suited to analysing longitudinal clustered data; in this case, assessment time-point nested within participants [63]. This allows for modelling of individual trajectories of change over time. MLM utilizes maximum likelihood estimation, which is optimal for handling missing data [64] and produces less biased estimates than other missing data approaches [65]. Full iterative generalized least-squares estimation, a type of maximum likelihood estimation, was employed for all outcome predictor models. MLM is not affected by sample size to the same degree as other approaches (e.g. generalized estimating equations) and typically produces comparable results [63,66]. Assumptions of linearity and normality were assessed by examination of residuals.

Baseline moderation models included a random intercept (constant,  $\beta_{0j}$ ), time (assessment occasion), treatment allocation (PuP or control) and the anticipated time  $\times$  treatment interaction. Separate moderator models were tested that added main effect and interaction terms for: (1) child factors; (2) family factors; (3) parental substance use; or (4) parental emotional dysregulation. Moderators were tested for significance using the Wald test [63]. Model predictors were grand mean-centred, except for treatment (TAU = 0, PuP = 1) and time (T1 = 0, T2 = 1, T3 = 2). As a result, the intercept can be

interpreted as the estimated mean CAP score for TAU at time 1. Model coefficients (unstandardized) represent change in CAP score for each 1-unit increase in the predictor.

Mediation was tested using cross-lagged models in AMOS 25 (see [67]). Three observed variables corresponding to the three-assessment time-points were included for parental emotional dysregulation and CAP. Times 2 and 3 parental emotional dysregulation was predicted by its score at the previous time-point (autoregressive paths) and previous time-point CAP (cross-lagged paths). Given the potential for shared variance between the DERS and CAP, the Heterotrait–Monotrait ratio (HTMT) using Smart partial least squares (PLS) [68] was calculated. The HTMT ratio is used to evaluate the discriminative validity of measures. The HTMT ratio for the BCAP and DERS was 0.83 at time 1, 0.77 at time 2 and 0.82 at time 3. These values are all below the conservative criteria of 0.85 [69] suggested for determining discriminative validity, indicating that the two measures were measuring related, but distinct constructs.

CAP was predicted by its score at the previous time-point and previous time-point parental emotional dysregulation. Residuals at each time-point were allowed to covary. The mediation model was fit using maximum-likelihood estimation. The comparative fit index (CFI) and root mean square error of approximation (RMSEA) were used to evaluate model fit with CFI  $\geq 0.95$  and RMSEA  $\leq 0.06$  indicative of ‘good fit’, and CFI  $\geq 0.90$  and RMSEA  $\leq 0.10$  indicative of ‘acceptable fit’ [70,71]. The  $\chi^2$  test of model fit ( $\alpha = 0.05$ ) is also reported, although it typically over-estimates poor fit in large samples [72].

The mediation hypothesis was tested using the joint significance procedure, which is less prone to Type II error [73] than the ‘causal steps’ procedure [74]. Support for mediation exists in the case of a significant direct effect from treatment allocation (PuP or TAU) to time 2 emotion dysregulation (path a) and a significant direct effect from time 2 emotion dysregulation to time 3 CAP (path b). The mediation effect was estimated using the product-of-coefficients method employed in RMediation to calculate 95% confidence intervals for the unstandardized indirect/mediation effect [75].

Primary trial analyses are described in the trial protocol [52]. The current analyses were not registered in the original trials protocol and thus are considered secondary analyses, and as such need to be viewed as exploratory.

## RESULTS

There was no statistically significant difference ( $P > 0.05$ ) at time 1 (baseline) between the participants who were retained at follow-up ( $n = 75$ ) and those who had dropped

out at time 2 (post-intervention;  $n = 15$ ) and time 3 (follow-up;  $n = 25$ ) on demographic characteristics (parents age or gender, marital status, educational level, ethnicity), proposed moderators (child age, child gender, family risk, primary drug of concern) or proposed mediators (child abuse potential, parental emotion dysregulation). Data were missing completely at random (MCAR) according to Little's MCAR test,  $\chi^2(81) = 76.50$ ,  $P = 0.62$ . Table 2 provides the descriptive statistics for CAP and parental emotion dysregulation over time for PuP, TAU and total sample.

### Moderation of treatment outcome

An 'empty' model containing only random intercepts revealed 44% of variance in CAP was due to differences between participants ( $VPC = 0.44$ ). A baseline model including time, treatment (PuP or TAU) and the time  $\times$  treatment interaction revealed differential change in CAP over time depending on treatment received. As shown in Table 3 ( $\beta_3$ ), families receiving PuP showed a significantly steeper reduction in CAP over time compared to TAU.

*Child factors.* The model testing moderation of treatment outcomes by child factors added child age (months) and child gender as predictors to the baseline model, together with their two- and three-way interactions with time and treatment. As shown in Table 3, there was a main effect showing greater baseline CAP was associated with children in the upper end of the age bracket of the study (up to 2.5 years). There was also a significant child age  $\times$  time  $\times$  treatment interaction ( $P = 0.03$ ). Families with children in the upper end of the age bracket of the study (up to 2.5 years) responded significantly better to PuP compared to TAU, showing a steeper reduction in CAP over time compared to younger children (see Fig. 2).

*Family risk composite.* Family risk was not associated with baseline CAP and did not predict changes over time in response to treatment (see Table 3).

*Parental substance use and emotional dysregulation.* The moderating role of parental substance use and parent emotion dysregulation on treatment outcomes was examined in separate models. The substance use model added primary substance of concern (PSOC) and number of days used in the past 30 days to the baseline model, together with their two- and three-way interactions with time and treatment. Primary substance of concern was operationalized using two dummy-coded variables: alcohol PSOC (0 = no, 1 = yes) and illicit drug PSOC, which included non-prescription opioid, cocaine and cannabis (0 = no, 1 = yes). Prescription opioid as PSOC (methadone, suboxone) served as the reference group. As shown in Table 3, parental substance use was not associated with baseline CAP and did not moderate response to treatment. There was a non-significant association between number of days used and higher baseline CAP that became statistically significant when it was analysed in a model that omitted PSOC to reduce the number of model parameters (see Supporting information).

Parental emotional dysregulation was associated with higher baseline CAP ( $P < 0.001$ ; see Table 3). Families with higher baseline parental emotional dysregulation also showed greater reductions in CAP across time with treatment, irrespective of whether they received PuP or TAU ( $P = 0.015$ ).

### Mediating mechanisms of change

The hypothesized cross-lagged model (Fig. 3) was found to provide a good fit to the data:  $\chi^2(8) = 15.65$ ,  $P = 0.05$ , CFI = 0.98, RMSEA = 0.10. As predicted, allocation to PuP led to greater reductions in time 2 parental emotional dysregulation than TAU, even after controlling for time 1 parental emotional dysregulation and CAP [unstandardized coefficient =  $-15.00$ , standard error (SE) = 4.44,  $P < 0.001$ ]. This supports path a of the hypothesized mediation effect (IV  $\rightarrow$  mediator). Supporting the hypothesized path b of mediation (mediator  $\rightarrow$  DV), lower time 2

**Table 2** Descriptive statistics for child abuse potential and parent emotion dysregulation over time by group and total sample.

Measure	Group	Baseline		
		Mean (SD), n	Time 2 Mean (SD), n	Time 3 Mean (SD), n
Child abuse potential	PuP	9.35 (5.55) 52	7.00 (5.67) 42	7.28 (5.79) 36
	TAU	8.83 (5.72) 48	8.79 (6.33) 43	9.80 (5.69) 39
	Total	9.10 (5.61) 100	7.91 (6.05) 85	8.59 (5.84) 75
Parent emotion dysregulation	PuP	86.46 (28.94) 52	74.89 (23.99) 43	78.77 (27.12) 36
	TAU	85.23 (27.48) 48	88.11 (24.89) 43	90.23 (22.29) 39
	Total	85.87 (28.11) 100	81.58 (25.20) 85	84.73 (25.22) 75

PuP = parents under pressure; TAU = treatment-as-usual; SD = standard deviation.

**Table 3** Moderation of treatment outcomes by child factors, family risk factors and parental psychopathology ( $n = 100$ ).

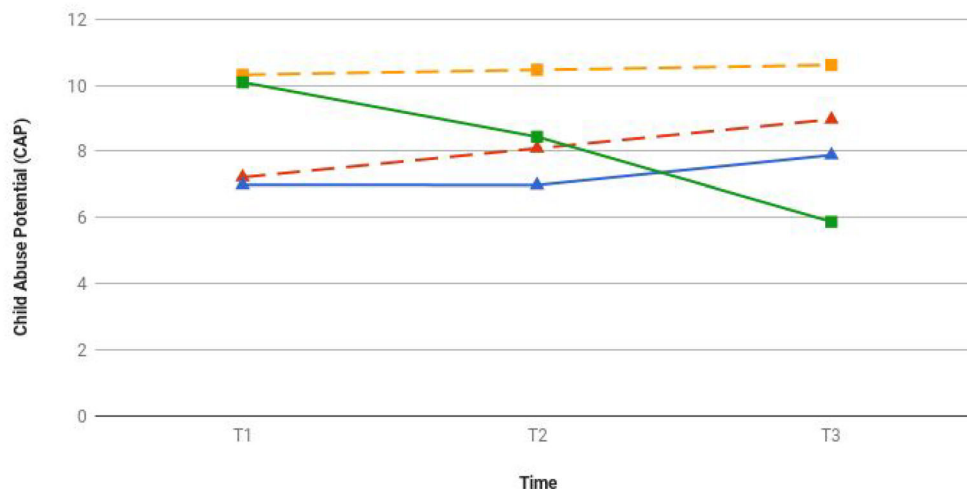
Parameter	Unstandardized coefficient	95% CI	Z	P
<b>Baseline model</b>				
Fixed effects				
Intercept, $\beta_{0j}$	8.67	7.12, 10.22	–	–
Time, $\beta_1$	0.53	–0.37, 1.43	1.15	0.25
PuP (Ref.: TAU), $\beta_2$	0.30	–1.86, 2.46	0.27	0.79
Time $\times$ PuP, $\beta_3$	–1.72	–3.01, –0.43	2.61	<b>&lt;0.01</b>
Random effects				
$\sigma_e^2$	17.84	13.96, 21.72		
$\sigma_{it0}^2$	14.90	8.59, 21.21		
Deviance ( $-2 \times \log$ likelihood)	1600.06			
<b>Child factors</b>				
Fixed effects				
Intercept, $\beta_{0j}$	8.77	7.26, 10.28	–	–
Time, $\beta_1$	0.51	–0.37, 1.39	0.01	0.90
PuP (Ref.: TAU), $\beta_2$	–0.23	–2.35, 1.89	0.21	0.83
Time $\times$ PuP, $\beta_3$	–1.34	–2.59, –0.09	2.09	<b>0.04</b>
Child age (months), $\beta_4$	0.17	0.01, 0.33	2.13	<b>0.03</b>
Child gender, $\beta_5$	–0.41	–3.49, 2.67	0.26	0.80
Time $\times$ child age (months), $\beta_6$	–0.04	–0.14, 0.06	0.80	0.42
Time $\times$ child gender, $\beta_7$	–0.68	–2.44, 1.08	0.76	0.45
PuP $\times$ child age (months), $\beta_8$	0.10	–0.14, 0.34	0.83	0.41
PuP $\times$ child gender, $\beta_9$	–0.55	–4.88, 3.78	0.25	0.80
Time $\times$ PuP $\times$ child age (months), $\beta_{10}$	–0.15	–0.29, –0.01	2.14	<b>0.03</b>
Time $\times$ PuP $\times$ child gender, $\beta_{11}$	0.88	–1.67, 3.43	0.68	0.50
Random effects				
$\sigma_e^2$	16.19	12.60, 19.78		
$\sigma_{it0}^2$	14.12	8.14, 20.10		
Deviance ( $-2 \times \log$ likelihood)	1535.14			
<b>Family factors</b>				
Fixed effects				
Intercept, $\beta_{0j}$	8.17	6.60, 9.74	–	–
Time, $\beta_1$	0.56	–0.34, 1.46	1.22	0.22
PuP (Ref.: TAU), $\beta_2$	1.10	–1.15, 3.35	0.96	0.34
Family risk composite, $\beta_3$	0.69	–0.39, 1.77	1.25	0.21
Time $\times$ PuP, $\beta_4$	–1.58	–2.93, –0.23	2.29	<b>0.02</b>
Time $\times$ family risk composite, $\beta_5$	–0.61	–1.26, 0.04	1.85	<b>0.06</b>
PuP $\times$ family risk composite, $\beta_6$	0.27	–1.44, 1.98	0.31	0.76
Time $\times$ PuP $\times$ family risk composite, $\beta_7$	–0.04	–1.10, 1.02	0.07	0.94
Random effects				
$\sigma_e^2$	16.54	12.66, 20.42		
$\sigma_{it0}^2$	13.31	7.12, 19.50		
Deviance ( $-2 \times \log$ likelihood)	1346.91			
<b>Parental substance use</b>				
Fixed effects				
Intercept, $\beta_{0j}$	8.74	7.15, 10.33	–	–
Time, $\beta_1$	0.49	–0.43, 1.41	1.04	0.30
PuP (Ref.: TAU), $\beta_2$	0.08	–2.02, 2.18	0.07	0.94
Alcohol PSOC, $\beta_3$	–1.70	–5.27, 1.87	0.93	0.35
Illicit substance PSOC, $\beta_4$	–2.55	–7.29, 2.19	1.05	0.29
Number of days used, $\beta_5$	0.21	–0.03, 0.45	1.75	0.08
Time $\times$ PuP, $\beta_6$	–1.66	–2.95, –0.37	2.52	<b>0.01</b>
Time $\times$ alcohol PSOC, $\beta_7$	–0.60	–2.60, 1.40	0.59	0.56
Time $\times$ illicit PSOC, $\beta_8$	–1.25	–4.05, 1.55	0.87	0.38
Time $\times$ number of days used, $\beta_9$	–0.04	–0.16, 0.08	0.67	0.50
PuP $\times$ alcohol PSOC, $\beta_{10}$	3.01	–1.87, 7.89	1.21	0.23

(Continues)

Table 3. (Continued)

Parameter	Unstandardized coefficient	95% CI	Z	P
PuP × illicit PSOC, $\beta_{11}$	0.39	-5.86, 6.64	0.12	0.90
PuP × number of days used, $\beta_{12}$	-0.20	-0.45, 0.05	1.54	0.12
Alcohol PSOC × number of days used, $\beta_{13}$	-0.10	-0.45, 0.25	0.56	0.58
Illicit PSOC × number of days used, $\beta_{14}$	0.11	-0.13, 0.35	0.92	0.36
Time × PuP × alcohol PSOC, $\beta_{15}$	-0.71	-3.67, 2.25	0.47	0.64
Time × PuP × illicit PSOC, $\beta_{16}$	2.33	-1.55, 6.21	1.18	0.24
Time × PuP × number of days used, $\beta_{17}$	-0.04	-0.20, 0.12	0.50	0.62
Random effects				
$\sigma_e^2$	17.22	13.48, 20.96		
$\sigma_{u0}^2$	12.64	7.01, 18.27		
Deviance ( $-2 \times \log$ likelihood)	1582.39			
Parental emotional dysregulation				
Fixed effects				
Intercept, $\beta_{0j}$	8.77	7.44, 10.10	-	-
Time, $\beta_1$	0.49	-0.35, 1.33	1.14	0.25
PuP (Ref.: TAU), $\beta_2$	0.10	-1.74, 1.94	0.11	0.91
Emotion dysregulation, $\beta_3$	0.15	0.09, 0.21	5.00	< 0.001
Time × PuP, $\beta_4$	-1.54	-2.76, -0.32	2.48	0.01
Time × emotion dysregulation, $\beta_5$	-0.04	-0.08, -0.0008	2.00	0.046
PuP × emotion dysregulation, $\beta_6$	-0.03	-0.09, 0.03	1.00	0.32
Time × PuP × emotion dysregulation, $\beta_7$	-0.02	-0.06, 0.02	1.00	0.32
Random effects				
$\sigma_e^2$	15.71	12.28, 19.14		
$\sigma_{u0}^2$	8.54	4.25, 12.83		
Deviance ( $-2 \times \log$ likelihood)	1540.35			

All predictors were grand mean-centred except time and PuP. Boldface *p*-values denote effects that are statistically significant ( $p < .05$ ) or approaching this cut-off. PuP = parents under pressure; PSOC = primary substance of concern; TAU = treatment-as-usual.

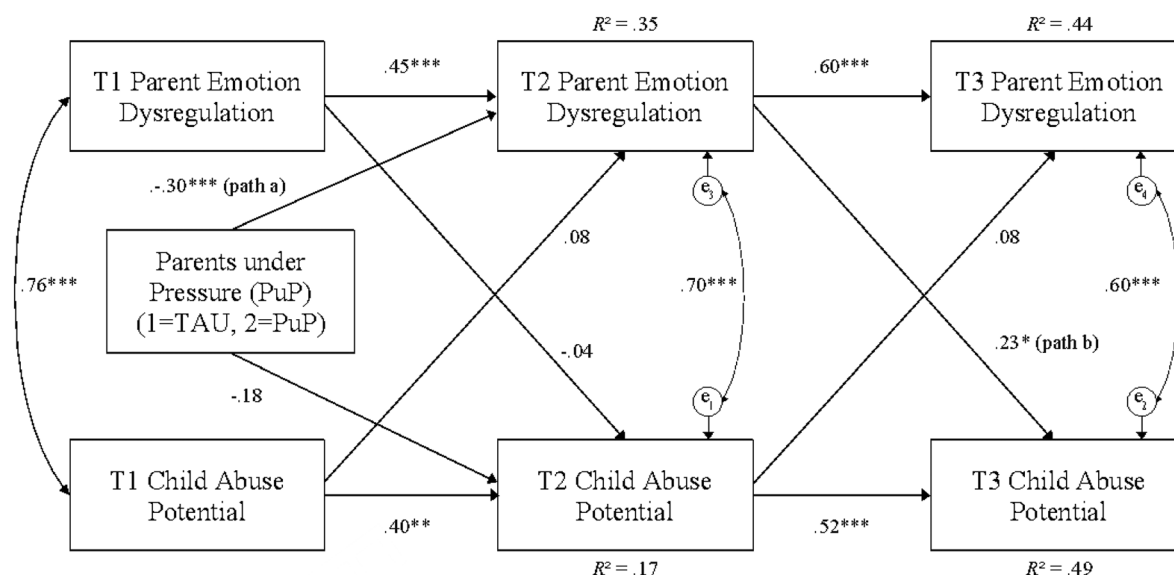


**Figure 2** Model estimates depicting significant time × parents under pressure (PuP) × child age (months) interaction. Control group is depicted with dashed lines; PuP is depicted with solid lines. Older child age [+ 1 standard deviation (SD)] is depicted with squares; younger child age [- 1 SD] with triangles [Colour figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

parental emotional dysregulation predicted significantly lower time 3 CAP, even after controlling for time 2 CAP and emotional dysregulation (unstandardized coefficient = 0.53, SE = 0.27,  $P < 0.05$ ). Together, these two

significant pathways provide support for mediation (IV → mediator → DV). The standardized indirect/mediated effect of PuP on time 3 CAP was estimated to be -0.16. The mediation effect was tested for significance using the





**Figure 3** Cross-lagged mediation model of treatment effect on parent emotion dysregulation and child abuse potential. Standardized parameter estimates are shown. 'Path a' and 'path b' denote parameters of interest for hypothesized mediation. \* $P < 0.05$ ; \*\* $P < 0.01$ ; \*\*\* $P < 0.001$

product-of-coefficients method in RMediation to calculate 95% confidence intervals, revealing an unstandardized indirect effect of  $-0.80$  (95% CI = 0.001,  $-1.88$ ). Notably, no other cross-paths were statistically significant. Specifically, PuP did not directly affect CAP (unstandardized coefficient =  $-2.21$ , SE = 1.21,  $P = 0.07$ ) and CAP did not predict changes in emotional dysregulation (time 2: unstandardized coefficient = 0.34, SE = 0.60,  $P = 0.57$  | time 3: unstandardized coefficient = 0.34, SE = 0.53,  $P = 0.52$ ).

To test whether this analysis was adequately powered for mediation, given the small sample size [72], an additional mediation model was run that included only autoregressive paths and covariances between CAP and emotion dysregulation at each time-point. That is, a model that specified no association between treatment group and outcomes of interest and no prospective associations between CAP and emotional dysregulation (and vice versa). This model provided a poor fit, according to the  $\chi^2$  test ( $\chi^2(14) = 33.44$ ,  $P = 0.002$ ) and RMSEA (0.12), and only 'acceptable' fit according to the CFI (0.94).

## DISCUSSION

The present study extends the research on family-focused interventions in parents engaged in substance misuse services by investigating potential predictors of change (moderator analyses) and testing an underlying programme logic model for the PuP programme (mediator analysis [71]).

Analysis of baseline characteristics associated with baseline CAP score, and predicted change in these scores, was undertaken across three domains: child factors, a

family risk score and parental characteristics. There was no moderating effect for child gender. However, there was a significant association between child age at baseline and CAP, with parents of children at the upper end of the age bracket of the study (2.5 years) having higher CAP scores, consistent with a broader literature that highlights risk in early infancy and the toddler years [17,18,76]. Notably, a significant three-way interaction indicated that parents of children at the upper end of the age bracket of the study (2.5 years) with greater risk at baseline benefited more from the PuP programme compared to TAU. Family risk was not statistically significant as a predictor ( $P = 0.06$ ).

The third domain consisted of parental substance use and psychopathology. Extensive literature links parental substance use to child maltreatment [77], engagement in child protection [78], lower rates of re-unification [79] and permanency planning for illicit substances [80]. The relative contribution of engagement in current treatment for substance abuse and child maltreatment has not been systematically investigated. The current findings provide evidence that, for parents engaged in community addiction services, the primary substance of concern is not associated with CAP at baseline nor across the study period. Notably, there was good compliance with opioid substitution therapy evidenced by hair toxicology, as reported in the original trial, and parents reported relatively little substance use in the 30 days prior to engagement in the current study. Thus, despite long histories of substance use problems, parents were successfully managing their substance use problem within the community. However, there were significant problems among measures related to parental emotional regulation in the original trial,

which decreased in those receiving the PuP programme. In the current study, we adopted a transdiagnostic approach [30,42] testing parent emotional dysregulation [34] as both a moderator and mediator. There is extensive evidence linking this construct with compromised parenting including poor cognitive control [81], reduced sensitivity [36] and harsh and abusive parenting [40]. Our findings add to this literature, with difficulty in emotional regulation strongly associated with baseline CAP [82]. Parents with higher emotion dysregulation at intake showed greater improvements in CAP with treatment. Notably, parents receiving PuP showed greater reductions in emotion dysregulation compared to TAU that, in turn, further reduced CAP.

The mediational analysis extends the literature on parental emotional regulation. The results of a cross-lagged model showing a temporal sequence consistent with mediation [48] suggests that better parental emotional regulation at time 2 (post-intervention) was associated with greater reductions in CAP at time 3 (6-month follow-up). Thus, our results support the hypothesis that emotion regulation was a mediator of change in CAP for those participating in the PuP programme, and is consistent with the proposition that improving parental emotional regulation may be one of the key mechanisms by which change can be achieved in substance-using parents. The PuP programme has a clear focus on supporting emotional regulation by providing explicit instruction on the use of mindfulness strategies [83], directly in the parenting role and more broadly as a way of managing stressful events in other contexts. The strategies have demonstrated efficacy across a range of treatments for adults [84,85] and extends this literature to parents with substance use problems.

These findings need to be considered in light of the study's strengths and limitations. A key strength of the original PuP RCT [52] was that it was a real-world assessment of effectiveness in which existing community services recruited and provided the intervention to families [12]. While adequately powered for mediation in the current study, the range of potential mediators was limited in both number and time. Future studies should ensure inclusion of other potential mediators, e.g. fathers as primary caregivers. Additional measures that are not reliant upon self-report such as administrative data would also strengthen confidence in these findings.

Notwithstanding these limitations, the current study indicates that primary substance of concern was not a predictor of outcome; parents of children at the upper end of the age bracket of the study (2.5 years) benefited more. Perhaps most importantly, improvement in parental emotional regulation across time was associated with greater reduction in child abuse potential. Future research is needed that is driven by a clear model of

programme logic and tested with larger samples across longer time-periods. This will allow for further refinement of programmes and approaches to supporting families with complex presentations.

#### Clinical trial registration

International Standard Randomized Controlled Trial Number Register: ISRCTN47282925; protocol published at: <https://www.ncbi.nlm.nih.gov/pubmed/23841920>.

#### Declaration of interests

P.H. and S.D. are the developers of the PuP programme. Findings from this study contribute to the evidence base for the PuP programme. The programme is owned and disseminated by Griffith University with a non-exclusive license granted to the University of Queensland. Proceeds from dissemination are distributed in accordance with Griffith University policy with 5% of training fees paid the University of Queensland. The remaining authors have no conflicts of interest to disclose.

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#### Author contributions

**Sharon Dawe:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization. **Paul Harnett:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization. **Matthew Gullo:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization. **Elizabeth Egginis:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization. **Jane Barlow:** Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization.

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### Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**Data S1** Supporting information.