Drug and Alcohol Dependence 194 (2019) 184–194

Contents lists available at ScienceDirect

Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep

Full length article

A randomized controlled trial and economic evaluation of the Parents Under Pressure program for parents in substance abuse treatment

Jane Barlow[a], Sukhdev Sembi[b], Helen Parsons[c], Sungwook Kim[d], Stavros Petrou[d], Paul Harnett[e], Sharon Dawe[f,*]

[a] Department of Social Policy and Intervention, University of Oxford, Oxford, UK
[b] Warwick Medical School, University of Warwick, Coventry, UK
[c] Warwick Clinical Trials Unit, University of Warwick, Coventry, UK
[d] Division of Health Sciences, University of Warwick Medical School, Coventry, UK
[e] School of Psychology, University of Queensland, Brisbane, Australia
[f] School of Applied Psychology, Griffith University, Brisbane, Australia

ARTICLE INFO

Keywords:
Parenting
Substance
Caregiving
Infants
Child abuse

ABSTRACT

Background: There is growing interest in the provision of parenting support to substance misusing parents.
Methods: This pragmatic, multi-center randomized controlled trial compared an intensive one-to-one parenting program (Parents under Pressure, PuP) with Treatment as Usual (TAU) in the UK. Parents were engaged in community-based substance misuse services and were primary caregivers of children less than 2.5 years of age. The primary outcome was child abuse potential, and secondary outcomes included measures of parental emotional regulation assessed at baseline, 6 and 12-months. A prospective economic evaluation was also conducted.
Results: Of 127 eligible parents, 115 met the inclusion criteria, and subsequently parents were randomly assigned to receive PuP (n = 48) or TAU (n = 52). Child abuse potential was significantly improved in those receiving the PuP program while those in TAU showed a deterioration across time in both intent-to-treat ($p < 0.03$) and per-protocol analyses ($p < 0.01$). There was also significant reliable change (recovery/improvement) in 30.6% of the PuP group compared with 10.3% of the TAU group ($p < 0.02$), and deterioration in 3% compared with 18% ($p < 0.02$). The probability that the program is cost-effective was approximately 51.8% if decision-makers are willing to pay £1000 for a unit improvement in the primary outcome, increasing to 98.0% at a £20,000 cost-effectiveness threshold for this measure.
Conclusions: Up to one-third of substance dependent parents of children under 3-years of age can be supported to improve their parenting, using a modular, one-to-one parenting program. Further research is needed.

1. Introduction

An increasing body of research suggests that adverse outcomes for children raised in families with parental substance-misuse emerge early in the child's life and are related to the quality of the parent-child relationship that significantly impacts on the child's developing neurological (Schore, 2010) and attachment (De Wolff and van Ijzendoorn, 1997) systems (see Hatzis et al., 2017 for a review). Importantly, the quality of the caregiving relationship is itself impacted by numerous chronic and inter-related problems that include co-occurring psychiatric disorders, particularly disorders of affect regulation (Taylor et al., 1997), depression (Dix et al., 2004), and borderline personality disorder (Petfield et al., 2015). Increasingly, families with multiple and complex needs, which include parental substance misuse, have become the primary client group of child protection systems across the world (Bromfield et al., 2012). Supporting such families requires early interventions that reduce the risk of child maltreatment by enhancing the quality of caregiving, provision of knowledge and skills around parenting and child development, and reducing maternal risk factors that include dysregulated affect.

1.1. Evidence supporting interventions for parents with substance abuse problems

A number of recent studies evaluating interventions for substance misusing parents have extended beyond a focus on parenting skills to address the factors that erode the capacity for sensitive parenting including parental emotional dysregulation. For example, Dakof et al.

* Corresponding author at: School of Applied Psychology, Griffith University, Brisbane 4111, Australia.
E-mail address: s.dawe@griffith.edu.au (S. Dawe).

https://doi.org/10.1016/j.drugalcdep.2018.08.044
Received 3 May 2018; Received in revised form 20 August 2018; Accepted 21 August 2018
Available online 03 November 2018

(2010) compared the Engaging Moms Program (EMP) with Intensive Case Management Services (ICMS) in a pilot study carried out in the context of the Family Drug Court. The authors reported large effect sizes on a range of outcome measures and suggested the intervention was promising despite the lack of statistical significance. Suchman and colleagues (Suchman et al., 2010, 2017) developed an attachment-based intervention (Mothering from the Inside Out, MIO) aimed at enhancing a mother's capacity to make sense of her own and her child's mental state. Two randomized controlled trials found improvements in maternal reflective functioning at three months (Suchman et al., 2010, 2017), with mothers who received MIO also showing significantly greater sensitivity and reciprocity on observational measures of mother-child interactions at 12-months. Two studies have evaluated interventions with parents in residential treatments that address trauma-related attachment patterns of parents with the goal of improving the parent-child relationship. In a small group of mothers (N = 21) Berlin et al. (2014) found their intervention increased sensitive parenting behavior. (Paris et al., 2015) found that mothers reported a decrease in psychological distress, with the greatest decrease reported by mothers initially displaying the highest level of psychological distress.

1.2. The Parents under Pressure (PuP) Program

The PuP program was specifically developed for complex families facing multiple adversities, including parental substance misuse and psychopathology, socioeconomic challenges and either potential or current involvement in the child protection system. While there are many challenges for such families, one key characteristic of people with substance abuse is dysregulated affect that underpins impulsive behavior (Dawe and Loxton, 2004). For parents, this results in an inability to manage emotions both within the context of parenting and in other areas of everyday living. Parents with poor emotional regulation show less attunement to their child, can be harsh and have little affective sensitivity, factors associated with compromised infant and child development (e.g., Martinez-Torteya et al., 2014), and child abuse potential (Smith et al., 2014). Helping parents enhance their capacity for emotional regulation is addressed in the PuP program through the use of mindfulness strategies to support mindful parenting. A randomized controlled trial in Australia of parents on methadone maintenance compared the PuP program with a brief behavioral parenting intervention and standard care (Dawe and Harnett, 2007) in children aged four years. Significant gains were found in self-reported child abuse potential, depression anxiety and stress, parenting stress and child behavior. A recent quasi-experimental study of a pre-birth risk assessment process compared a pre-birth risk assessment plus PuP to usual care in expectant mothers (Harnett et al., 2018). The pre-birth risk assessment process resulted in a greater number of removals at birth. Of those mothers who retained the care of their infants, 42% receiving the PuP program had improved child protection outcomes at 12-months compared to 14% of infants in routine care. The PuP program has also been evaluated in a series of single case studies of parents on methadone maintenance (Dawe et al., 2003), women leaving prison (Frye and Dawe, 2008) and families engaged in the child protection system (Harnett and Dawe, 2008).

1.3. Aims of the current study

The primary aim of the current study was to evaluate the PuP program with parents currently engaged in community-based substance abuse treatment. This study builds on the efficacy trial (Dawe and Harnett, 2007) to determine effectiveness and cost-effectiveness of the PuP program when delivered by front-line practitioners in community settings with a heterogeneous sample of parents engaged in substance abuse treatment services. Thus, this pragmatic, randomized controlled trial balanced the elements of an efficacy trial such as randomization and clearly defined treatment duration with elements of an effectiveness trial that included referral from a range of treatment agencies with the PuP program deliverd by existing practitioners (Marchand et al., 2011). This balance of internal and external validity is proposed to provide an optimal test of the intervention under real-world conditions.

2. Methods

2.1. Study design and randomization

This was a pragmatic, randomized controlled trial comparing the PuP program to Treatment as Usual (TAU) for parents who were currently engaged in substance misuse treatment services. A 1:1 computer-generated randomization sequence stratified by treatment site was implemented with minimization, using R (R Core Team, 2017). Participating parents were randomly assigned to either the PuP program or TAU by an independent researcher. Assessments were conducted at baseline, 6 and 12-months as the time to completion of the PuP program was approximately 6-months. Parents received a £20 gift voucher at each assessment point. The study was granted ethical approval from the Biomedical Research Ethics Committee at the University of Warwick (BREC reference number 189-03-2012).

2.2. Participants and procedure

Participants were parents who were receiving treatment for a drug or alcohol problem (opioid replacement treatment, relapse prevention, counseling) and were a primary carer of a child under the age of 2.5 years. If both parents had an alcohol or drug problem, the primary caregiver was assessed. Exclusion criteria were: (i) the infant was not currently residing with primary carer and there were no plans for re-unification, (ii) pregnant women (unless the baby was due within 4 weeks of the recruitment period) (iii) women who reported that being in a relationship in which there was active and ongoing domestic abuse, or (iv) were actively psychotic or expressing active suicidal ideation.

2.3. Study recruitment

Study recruitment took place between October 2014 and December 2016 at seven participating centers. Following consent from parents, the research team then contacted the parent, who completed the recruitment process including obtaining written consent, and baseline data. Data were collected by a researcher who was blind to study arm and randomization occurred post baseline interview (Fig. 1, Study flowchart).

2.4. Interventions: parents under Pressure

The PuP program was developed to address multiple domains of family functioning with the goal of reducing child abuse potential by enhancing parental emotional regulation (Dawe and Harnett, 2007; Harnett et al., 2018). The PuP program is underpinned by the Integrated Theoretical Framework (ITF) which is a dynamic model of assessment and treatment planning drawing from attachment theory, behavioral parenting skills, and adult psychopathology (see Barlow et al., 2016). The ITF provides a structure to assess the quality of caregiving relationship, parenting practices, values and expectations and the parent's capacity for emotional regulation with consideration given to the impact of the wider ecological context of the family. Specific targets for change are identified during the assessment, which then becomes the focus of treatment. There are twelve modules, and each comprises a theme that can continue throughout treatment. While each treatment plan is individualized, all cases include a focus on the quality of caregiving and parental emotional regulation. For example, Module 6, *Connecting with Your Baby or Child* provides structure and a series of activities whereby a parent is able to reflect on their own relational

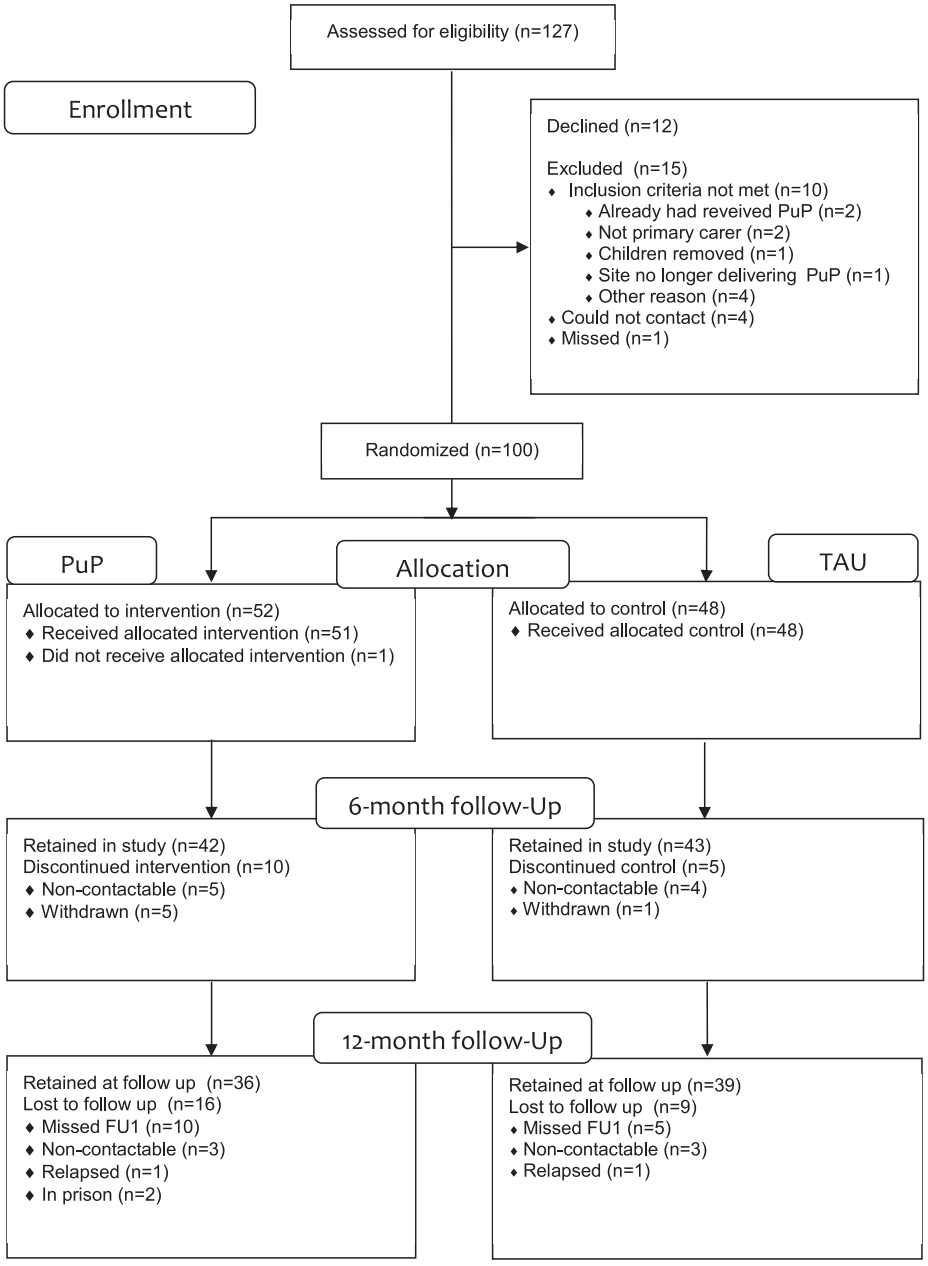

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) study diagram.

experience with their infant or child. 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 at special times. Module 4, *How to Manage Your Emotions Under Pressure: Increasing Mindful Awareness* provides opportunities for parents to reflect on their ability to manage mood and impulsive behaviors through the incorporation of mindfulness-based strategies. The use of the remaining modules depends on the identified needs and case formulation. For example, the *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 while the module on *Managing Substance Use Problems* focuses on both remaining abstinent and managing lapses. The PuP program was delivered in family homes with additional visits to support case management as appropriate.

Fourteen practitioners in family centers delivered the PuP program. Of these, eight held formal qualifications in social work; the remaining had previous experience in family support work. All practitioners were Accredited PuP therapists having received a minimum of 40 h of training and supervision in the PuP model and had completed accreditation requirements. Ongoing monthly clinical supervision was provided during the study period and six-monthly development days took place where workshops were provided in related topics led by either the PuP training team or outside experts (e.g., a workshop on mindfulness).

2.5. Interventions: treatment as usual

TAU provided the opportunity to compare the PuP program with established services across a range of sites. As in other studies of this population, (e.g., Donohue et al., 2014) no attempt was made to standardize TAU in keeping with the principles of pragmatic trials and thereby allowing for the comparison of outcomes to real-world service configurations. The referral agencies had a range of services available that included family support, family counseling, and parenting programs provided in a group format.

Table 1
Baseline characteristics of parents.

Parent Variable			PuP n = 52	TAU n = 48	t-test or χ^2	Total (n = 100)
Age in years (mean, sd)			30.6 (5.6)	31.0 (5.2)	$t = .76$	30.8 (5.4)
Sex (%)	Male		3 (5.8)	1 (2.1)	$\chi^2 = 0.8$	4
Marital status (%)	Married/Cohabiting		21 (40.4)	17 (35.4)	$\chi^2 = 1.1$	38
	Other		4 (7.7)	6 (12.5)		10
	Separated		1 (1.9)	1 (2.1)		2
	Single		26 (50.0)	24 (50.0)		50
Self-reported Ethnicity (%)	White British		42 (80.8)	44 (91.7)	$\chi^2 = 2.7$	86
	Other ethnicity*		7 (13.5)	2 (4.2)		9
	Missing/refused		3 (5.8)	2 (4.2)		5
Education level (%)	GCSE or below		23 (44.2)	25 (52.1)	$\chi^2 = 2.5$	48
	A-levels		6 (11.5)	3 (6.2)		9
	Higher Education		5 (9.6)	2 (4.2)		7
	Other		15 (28.9)	17 (35.4)		32
	Missing		3 (5.7)	1 (2.1)		4
Main income (%)	Paid employment		2 (3.8)	2 (4.2)	$\chi^2 = 1.8$	4
	Income Support/ Disability allowance		9 (17.3)	4 (8.3)		13
	Unemployment benefit/ Single parent allowance		41 (78.8)	42 (87.5)		83
Domestic violence† (%)	Positive risk (> 10 points)		6 (11.5)	8 (17.7)	$\chi^2 = 0.3$	14
	Negative risk (≤10 points)		37 (71.2)	36 (75.0)		73
	Missing**		9 (3.8)	4 (8.3)		13
Criminal record (%)	Yes, ever		26 (50.0)	25 (52.1)	$\chi^2 = < 0.1$	51
	Yes, within last 12 months		10 (19.2)	7 (14.6)	$\chi^2 = 1.5$	17
	Alcohol		12 (23.1)	16 (33.3)	$\chi^2 = 5.2$	28 (28.0)
	Non-prescribed opioid		3 (5.8)	0 (0)		3 (3.0)
	Prescribed opioid		30 (57.7)	24 (50.0)		54 (54.0)
	Cocaine		1 (1.9)	3 (6.3)		4 (4.0)
	Cannabis		6 (11.5)	5 (10.4)		11 (11.0)
Opioid Replacement dose	Methadone (n = 38)		47.5 (18.8	48.6 (24.4)	$t = -153$	48.05 (21.2)
SDS score	SDS current		6.91 (3.4)	7.16 (4.2)	$t = -0.3$	7.03 (3.8)
	% scoring > 4		78.3	70.5		74.6
Substance use in last 30 days (TLFB)						
Days of alcohol use (%)		0 use	63.5	79.2	$\chi^2 = 4.2$	71.0
		1 – 5 days	30.8	18.8		25.0
		6 – 15 days	1.9	2.1		2.0
		16 – 30 days	3.8	0.0		2.0
Days of non-prescribed opioid use (%)		0 use	82.7	89.6	$\chi^2 = 3.9$	86.0
		1 – 5 days	9.6	10.4		10.0
		6 – 15 days	5.8	0.0		3.0
		16 – 30 days	1.9	0.0		1.0
Days of cannabis use (%)		0 use	86.5	87.5	$\chi^2 = 1.4$	87.0
		1 – 5 days	1.9	2.1		2.0
		6 – 15 days	0.0	2.1		1.0
		16 – 30 days	11.5	8.3		10.0
Days cocaine use (%)		0 use	92.3	89.6	$\chi^2 = 0.3$	91.0
		1 – 5 days	5.8	8.3		7.0
		6 – 15 days	1.9	2.1		2.0
		16 – 30 days	0.0	0.0		0.0

*Other ethnicity includes responses not clearly White British, e.g., “Jamaican White”, “Scottish”.
†Scored using HITS - Fam Med 1998;30(7):508-12.
**At least one item not answered.

2.6. Treatment dose and adherence

Program dose and retention were monitored through the collection of information about session number and duration (weeks) of engagement in the PuP program. Supervision was provided and the number of supervision hours each practitioner received was recorded. Adherence to the PuP model was assisted by the provision of a Therapist Manual and Parent Workbook and further assessed by indepenent case file audits conducted by a senior practitioner not invovled in treatment delivery to ensure that practitioners were using key elements of the PuP program.

2.7. Measures

Baseline demographics included the history of substance use, current treatment and recent use in the last 30-days (Timeline Follow-Back Interview; Fals-Stewart et al., 2000). Concordance between TLFB and head hair (sample length 3 cm) was obtained from a random sample of 10 (10%) participants, and percentage concordance between hair sample and TLFB (baseline) for amphetamine, cannabis, cocaine, methadone, and other opioid was calculated (Sharma et al., 2016). Parents completed the Severity of Dependence Scale (Gossop et al., 1995) for the primary substance of use and the HITS (Sherin et al., 1998), to obtain parent report of involvement in domestic violence.

The primary outcome measure was the Risk Abuse Scale from the Brief Child Abuse Potential Inventory (BCAP; Ondersma et al., 2005) with a threshold of greater than or equal to 12 to indicate risk of child abuse. The BCAP has been validated across a range of populations, including mothers on opioid substitution therapy (Dawe et al., 2016). Secondary outcomes assessed parental emotional regulation, psychopathology and parenting stress using the following measures: Difficulties in Emotional Regulation Scale (DERS; Gratz and Roemer, 2004; Neumann et al., 2010), Personality Assessment Inventory-Borderline Scale (PAI-BOR; Gardner and Qualter, 2009; Morey, 1991; Trull et al.,

Table 2
Baseline characteristics of children.

Child Variable	PuP (n = 52)	TAU (n = 48)	t-test or χ^2	Total (n = 100)
Age in months (mean[1], sd)	9.8 (878)	8.6 (9.7)	$t=0.7$	9.2 (9.1)
Sex				
Female	21 (40.4)	18 (37.5)	$\chi^2=1.1$	39
Male	30 (57.7)	30 (62.5)		60
Missing	1 (1.9)	0 (0)		1
Child lives with:				
Mother	50 (96.2)	42 (87.5)	$\chi^2=2.5$	92
Not with Mother	2 (3.8)	6 (1254)		8
Has siblings - Yes (n, %)	43 (82.7)	36 (75.0)	$\chi^2=0.9$	79
Child currently involved in child protection - Yes (n, %)	40 (80.0)	42 (87.5)	$\chi^2=1.0$	82
Child previously involved in child protection - Yes (n, %)	13 (26.5)	12 (25.0)	$\chi^2=0.03$	25
Other children involved in child protection - Yes (n, %)	36 (72.0)	29 (61.7)	$\chi^2=1.2$	65

[1]One parent was still pregnant at baseline.

Table 3
BCAP scores by group at assessment; 6 months and 12 months.

Time point	Value	PuP	TAU
Baseline	Score (mean, sd)	9.3 (5.6)	8.8 (5.7)
	Positive for abuse (n, % valid)	19 (36.5)	17 (35.4)
	No. valid (n, % of group)	52 (100)	48 (100)
Post intervention	Score (mean, sd)	7.0 (5.7)	8.8 (6.4)
	Positive for abuse (n, % valid)	9 (21.4)	18 (41.9)
	No. valid (n, % of group)	42 (80.8)	43 (89.6)
Final follow up	Score (mean, sd)	7.3 (5.8)	9.8 (5.7)
	Positive for abuse (n, % valid)	8 (22.2)	16 (41.0)
	No. valid (n, % of group)	36 (69.2)	39 (81.8)

2006), the Depression, Anxiety and Stress Scale (DASS; Lovibond and Lovibond, 1995aa, 1995b), and the Parenting Stress Index short form (PSI-SF; Abidin, 1995). Infant outcomes were measured using the Brief Infant and Toddler Socio-emotional Adjustment Scale (BITSEA; Briggs-Gowan et al., 2004) for infants aged 12 – 36-months. Parent-infant/toddler interaction was assessed using the CARE-Index (Crittenden, 2006).

2.8. Statistical analyses and power calculation

Sample size was based on effect sizes obtained in Dawe and Harnett (2007) using the Child Abuse Potential Inventory (CAPI; Milner, 1986) where an effect size (ES) of 0.92 was obtained. As the current study was conducted as an effectiveness study, a smaller effect size was expected (Marchand et al., 2011). Hence, to detect an effect size (ES) of approximately 0.5 at 80% power and 5% significance, 54 parents would be required in each arm, and 57 in each arm allowing for dropout in the region of 5% (a total of 114 parents). Recruitment was slower than anticipated and was closed at 100 parents. With the smaller than anticipated sample and an observed loss to follow up of 10%, calculations estimated 70% power for an ES of 0.5 or 80% power at an ES of 0.55.

All analyses were undertaken using Statistical Package for the Social Sciences, SPSS version 22.0 and R. To adjust for loss to follow-up, data were multiply imputed (van Buuren and Groothuis-Oudshoorn, 2011) for the primary outcome measure (BCAP). Both intent-to-treat and per-protocol analyses were conducted given the smaller sample size and an attrition rate that exceeded 20% (Nich and Carroll, 2002; ICH Harmonised Tripartite Guidelines, 1998). The intent-to-treat analysis conducted on total scales used multi-level modeling (MLM; Bates et al., 2015) of outcomes for each participant with allocation group and follow-up point treated as fixed effects and a random effect added for each participant. P-values were calculated using the Satterthwaite approximation of the F-distribution. The per-protocol analyses were conducted on total scales using repeated measures Analysis of Variance on cases receiving three or more sessions and retained in the study to 12-months.

To establish if changes for the BCAP outcome were clinically meaningful, the Reliable Change Index (RCI; Jacobson and Truax, 1991) was calculated for each parent from baseline to 12-months. An individual score was determined to be clinically significant if the RCI index was greater than 1.96 and subsequently classified as improved/recovered, no change or deteriorated. Change in clinical risk status was also calculated with positive risk abuse set at greater than or equal to 12 (Ondersma et al., 2005).

2.9. Economic evaluation

A within-trial economic evaluation was conducted from the recommended UK NHS and personal social services perspective (National Institute for Health and Care Excellence, 2013). This involved the identification, measurement and valuation of costs and consequences in both trial arms over the trial time horizon to estimate the additional costs and benefits associated with the PuP program and synthesizing those estimates within cost-effectiveness ratios. Program costs were estimated primarily by PuP practitioners completing detailed weekly activity logs outlining the number, type and duration of contacts with families, and with professionals that provided supervision or support, and associated administrative activities, and the type and cost of consumables and other PuP-related expenses. Broader resource utilization 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 parent-child dyad. Information was also collected regarding the use of legal services and costs borne directly by parents. Unit costs (£, 2016 prices) were collected from national sources in accordance with guidelines and attached to resource inputs. The EuroQol EQ-5D-5l (Herdman et al., 2011) health-related quality of life questionnaire was completed by parents at baseline and at each follow-up point; responses were used to estimate quality-adjusted life year (QALY) profiles for each parent, calculated as area under the baseline-adjusted utility curve, assuming linear interpolation between utility measurements. 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 summarized using Rubin's rule (Rubin, 2004). Cost-effectiveness acceptability curves (CEACs) showing the probability that the PuP program 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 as follows: (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.

3. Results

3.1. Participant characteristics

There were no significant differences in baseline characteristics of parents allocated to the two groups. The majority of parents were mothers (96%), with a mean age of 30.8 years. Tables 1 and 2 present

Table 4
MLM of total scores over time by group with interaction.

Variable			Estimate	Lower 95% CI	Upper 95% CI	*p*-value
BCAP						
Allocation group (Reference = PuP)		TAU	−0.5	−2.7	1.8	0.13
Time Point		Post intervention	−2.5	−4.2	−0.7	
		Final follow up	−2.2	−4.2	−0.3	
Interaction effect		TAU × Post intervention	2.5	0.3	5.0	0.03*
		TAU × final follow up	3.3	0.7	5.9	
DERS						
Allocation group (Reference = PuP)	TAU		−1.3	−11.4	8.8	0.05
	Post intervention		−12.5	−19.7	−5.3	0.16
	Final follow up		−10.1	−17.7	−2.4	
Interaction effect	TAU × Post intervention		15.2	5.0	25.3	.005*
	TAU x final follow up		14.5	3.8	25.1	
DASS Total						
Allocation group (Reference = PuP)	TAU		1.2	−11.0	13.2	0.09
	Post intervention		−9.3	−18.1	−0.5	0.18
	Final follow up		−10.6	−19.0	−2.2	
Interaction effect	TAU × Post intervention		13.6	1.3	25.9	0.07
	TAU x final follow up		10.0	−1.8	21.8	
PSI Total						
Allocation group (Reference = PuP)	TAU		−2.3	−12.0	7.3	0.31
	Post intervention		3.5	−5.6	12.7	0.45
	Final follow up		4.7	−4.9	14.4	
Interaction effect	TAU × Post intervention		3.5	−5.6	12.7	0.68
	TAU x final follow up					
PAI BOR Total						
Allocation group (Reference = PuP)	TAU		0.3	−4.3	4.8	0.11
	Post intervention		−4.0	−7.4	−0.6	0.22
	Final follow up		−2.9	−6.5	0.6	
Interaction effect	TAU × Post intervention		3.9	−0.9	8.6	0.13
	TAU x final follow up		4.7	−0.3	9.7	

Table 5
Per protocol analysis of parents receiving PuP (n = 36) and TAU (n = 39).

Measure	Group	Baseline	Post	Follow-up	Group x Time interaction F value (η_p^2)[1]	Planned Contrasts paired t-test; *t* (cohen's d)[2]		
		Mean (SD)	Mean (SD)	Mean (SD)		Baseline vs 6 months	6 vs 12 months	Baseline vs 12 months
BACP	PUP	10.2 (5.6)	6.4 (5.5)	7.3 (5.8)	6.85** (0.09)	2.43* (0.69)	−1.21 (0.16)	2.54* (0.51)
	TAU	8.4 (5.6)	8.8 (6.5)	9.8 (5.7)		−0.09 (0.07)	−1.16 (0.16)	−1.57 (0.24)
DERS	PUP	91.5 (30.8)	74.3 (24.9)	78.5 (26.6)	6.77** (0.09)	3.50** (0.69)	−1.35 (0.16)	2.84* (0.45)
	TAU	86.1 (28.0)	87.8 (25.8)	90.2 (22.3)		−0.63 (0.06)	−0.68 (0.10)	−1.00 (0.16)
DASS-42	PUP	36.6 (33.2)	19.8 (25.1)	24.4 (29.9)	4.83* (0.06)	1.99 (p = .05) (0.57)	−1.37 (0.17)	2.18* (0.39)
	TAU	34.3 (32.2)	34.4 (32.3)	39.2 (31.4)		0.06 (0.00)	−1.27 (0.15)	−1.05 (0.15)
PSI_Total	PUP	74.4 (24.3)	61.9 (20.7)	61.6 (19.3)	2.84; p = .06 (0.04)	3.50 ** (0.55)	0.07 (0.02)	3.07** (0.58)
	TAU	70.9 (20.9)	68.4 (21.2)	68.3 (23.3)		0.98 (0.12)	−0.18 (0.00)	0.77 (0.12)
PAI-BOR	PUP	33.5 (15.7)	25.3 (12.3)	28.4 (14.9)	4.57* (0.06)	2.97** (0.58)	−1.64 (0.23)	2.31* (0.33)
	TAU	33.3 (13.2)	32.9 (12.9)	34.6 (11.3)		0.36 (0.03)	−0.92 (0.14)	−0.63 (0.11)

*p < .05; **p < .01; ***p < .001; η_p^2 = partial eta squared; BCAP = Brief Child Abuse Potential Inventory; PSI = Parenting Stress Index; DERS = Difficulties in Emotion Regulation Scale; PAI-BOR = Personality Assessment Inventory-Borderline; DASS = Depression, Anxiety and Stress Scale.
[1] Effect size (η_p^2) interpreted as: small - 0.01; medium - 0.06; large - 0.14.
[2] Effect size (cohen's d) interpreted as: small - 0.2; medium - 0.5; large - 0.8.

data on demographic and substance use measures. There was high concordance between hair sample toxicology and TLFB for amphetamines, benzodiazepines, cannabis, cocaine and non-prescribed opioids (100% – 70%). However, there was low concordance for methadone (50%) with a high rate of over-reporting by participants.

3.2. Program dose, retention and fidelity

The mean number of days of engagement in the PuP program from date of consent was 122 (SD = 122); the mean number of sessions delivered was 11.1 (SD = 8.19). Sixty-eight percent of parents completed six or more sessions. The mean number of supervision hours

Table 6
Clinically significant improvement and deterioration using Reliable Change Index from baseline to 12 months.

	RC +		RC-
	Recovered/Improved	Deteriorated	No change
PuP	11 (30.6%)	1 (2.8%)	24 (66.7%)
TAU	4 (10.3%)	7 (17.9%)	28 (71.8%)

TAU Treatment as usual; p < .02.

recorded for 14 practitioners was 55 (SD = 11.57) hours.

3.3. Statistical and clinical change on BCAP

As shown in Table 3, there was a decrease in BCAP scores for those receiving the PuP program from baseline to 12-month follow-up (9.3 to 7.3) with an increase in scores for those receiving TAU (8.8 to 9.8). Notably, 41% of those receiving TAU scored above the cut point for Abuse Risk compared to 22% in the PuP program at the 12-month follow-up. The intent-to-treat analysis found no significant impact on BCAP scores by group or time. However, there was a significant time by group interaction in which parents receiving PuP showed a decrease and parents in the TAU group showed an increase in BCAP scores ($p < .03$; Table 4). The per-protocol analysis found similar results with a significant time by group interaction and planned contrasts indicating a reduction in BCAP scores at 6 and 12-months for those receiving the PuP program (p < .01; medium effect size; Table 5). There was a clinically significant increase in the proportion of parents who had recovered/improved and fewer who deteriorated in the PuP group compared with those in TAU ($p < 0.02$; Table 6).

3.4. Analysis of change on secondary outcomes relating to parental emotion regulation, mood and parenting stress and child outcome

The intent-to-treat analysis found a significant interaction on emotional regulation with a significant improvement for those parents receiving the PuP program compared to those receiving TAU ($p < .005$). There was a trend towards a significant improvement in measures of depression, anxiety and stress ($p = .07$). There were no significant differences in the two groups on measures of borderline psychopathology or parenting stress (Table 5). A subsample of parents completed the BITSEA as many children were less than 12-months of age and thus not within the age range for this measure. The per-protocol analysis (Table 5) found significant improvements on four of the five secondary measures for those receiving the PuP program from baseline to post-treatment (i.e., 6-months) and from baseline to final follow-up (12-months). While there were changes in parenting stress, this interaction did not reach statistical significance ($p = .06$). There were no significant differences between the PuP group and TAU in children classified as at risk on either problem scores or competence of the BITSEA. The CARE-Index was coded on a subsample (PuP group = 21; TAU = 19) when children were present at the post-treatment interview. There were no differences between the groups (Supplementary Tables 1 and 2).

3.5. Economic evaluation

The mean (SE) total NHS and personal social service costs, inclusive of the cost of the PUP program, were £18,931 (£2443) for those receiving the PuP program compared to £16,451 (£2241) for those receiving TAU, in parents with complete data, generating a mean cost difference of £2480 (bootstrap 95% CI: -3906; £9156; $p = 0.457$). The incremental cost-effectiveness of the PUP program, following multiple imputation and bivariate seemingly unrelated regression of costs and outcomes, is shown in Table 7 and Tables 8. The mean incremental cost-effectiveness of the PUP program was estimated at £34,095 per QALY gained (Table 7) (If decision-makers are willing to pay £20,000 for an additional QALY, the probability that the program is cost-effective is approximately 26.7%, increasing to 34.6% at a £30,000 cost-effectiveness threshold, a result that remained robust to sensitivity analyses. When the BCAP measure was considered, the mean incremental cost-effectiveness of the PUP program was estimated at £1004 per unit improvement in the BCAP (Table 8). The probability that the program is cost-effective is approximately 51.8% if decision-makers are willing to pay £1000 for a unit improvement in the BCAP, increasing to 98.0% at a £20,000 cost-effectiveness threshold for this measure.

4. Discussion

The results of this pragmatic randomized controlled trial add to a growing literature evaluating the effectiveness and cost-effectiveness of parenting interventions in families who have a range of factors associated with child abuse and neglect. The findings from the present study provide converging evidence of improvements across primary and many secondary outcomes. Significant gains were found in child abuse potential in the PuP program while those receiving TAU showed deterioration at 12-months across both intent-to-treatment and per-protocol analyses. The RCI showed significant differences across the two groups: 30% of parents receiving the PuP program showed improvement compared to 10% receiving TAU; 3% of those receiving the PuP program showed significant deterioration compared to 18% in TAU. Comparison with the earlier trial of the PuP program (Dawe and Harnett, 2007) showed a marked similarity in findings: 31% of parents receiving the PuP program showed improvement compared to none receiving standard care; conversely there were no parents who showed deterioration in parents receiving the PuP program compared to 36% receiving standard care. The deterioration in the TAU group raises ongoing concerns about the future of the children in these families.

A range of measures was used to ascertain if differences in parental emotional regulation were found in parents who received the PuP program as this is proposed to be the key mechanism of change underpinning the PuP program (Barlow et al., 2013; Harnett and Dawe, 2012). Parents receiving the PuP program showed significant improvements in emotional regulation that measured constructs such as engagement in goal-directed behaviors, impulse control and emotional awareness for both the intent-to-treat analysis and the per-protocol analysis. There were also substantial and significant improvements on measures of mood and borderline psychopathology in the per-protocol analyses.

These results are consistent with accumulating evidence that parenting programs need to include an explict focus on the psychological well-being of the parent when there is comorbid psychopathology and parental substance misuse. The impact of the MIO program (Suchman et al., 2017) on the sensitivity and reciprocity of mothers towards their infants was attributed, in part, to the observation that the program, delivered concomitantly with addiction treatment, addressed parental emotion regulation challenges. Similarly, the Engaging Moms Program (Dakof et al., 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.

The results of the within-trial economic evaluation require careful interpretation. The estimated ICER of £34,095 per additional QALY translates into probabilities of cost-effectiveness for the PUP program of 26.7% and 34.6% at cost-effectiveness thresholds for an additional QALY of £20,000 and £30,000, respectively (National Institute for Health and Care Excellence, 2013). Although recommended for cost-effectiveness-based decision-making in the UK, our approach to QALY measurement focused on parental health-related quality of life outcomes and therefore is unlikely to have captured preferences for reductions in child abuse potential or improvements in infant social and emotional adjustment or parent-toddler interaction. When the BCAP

Table 7
Base case and sensitivity analysis for cost-effectiveness based on QALY outcome; Seemingly Unrelated Regression.

	PuP		TAU							
QALYs	Mean cost Mean (SE)	Mean effect Mean (SE)	Mean cost Mean (SE)	Mean effect Mean (SE)	Incremental cost (95% CI)	Incremental effect (95% CI)	ICER	Probability cost-effective[1]	Probability cost-effective[2]	Probability cost-effective[3]
1) Base case†*										
NHS & PSS perspective	12548.15 (1589.51)	0.887 (0.020)	10,161.51 (1655.34)	0.817 (0.020)	2386.64 (-1865.12, 6638.39)	0.07 (0.012, 0.128)	34094.86	0.22	0.268	0.346
Societal perspective	17747.99 (2060.5)	0.887 (0.020)	13,809.13 (2145.83)	0.817 (0.020)	3938.87 (-1547.4, 9425.13)	0.07 (0.012, 0.128)	56269.57	0.116	0.146	0.212
2) Completed case*										
NHS & PSS perspective	18997.57 (2180.77)	0.902 (0.017)	17,373.1 (2219.23)	0.813 (0.0171)	1624.47 (-4568.72, 7817.66)	0.09 (0.042, 0.137)	18049.67	0.449	0.502	0.609
Societal perspective	24669.26 (2642.67)	0.902 (0.017)	21,442.59 (2689.28)	0.813 (0.0171)	3226.672 (-4278.29, 10,731.63)	0.09 (0.042, 0.137)	35851.89	0.313	0.35	0.444
3) Highest PUP mean cost per session†*										
NHS & PSS perspective	13394.56 (1603.49)	0.887 (0.020)	10,156.28 (1669.89)	0.817 (0.020)	3238.28 (-1053.21, 7529.77)	0.07 (0.012, 0.128)	46261.14	0.134	0.176	0.262
Societal perspective	18594.4 (2075.212)	0.887 (0.020)	13,803.89 (2161.148)	0.817 (0.020)	4790.51 (-735.81, 10,316.82)	0.07 (0.012, 0.128)	68435.86	0.07	0.094	0.146
4) Lowest PUP mean cost per session†*										
NHS & PSS perspective	10940.05 (1568.17)	0.887 (0.020)	10,171.46 (1633.11)	0.817 (0.020)	768.59 (-3421.587, 4958.77)	0.07 (0.012, 0.128)	10979.86	0.432	0.458	0.562
Societal perspective	16139.89 (2036.53)	0.887 (0.020)	13,819.07 (2120.86)	0.817 (0.020)	2320.82 (-3100.09, 7741.73)	0.07 (0.012, 0.128)	33154.57	0.268	0.298	0.376

†Imputed costs.
*Covariates adjusted- Baseline costs, Parents age, Site, Substance, Child gender, Child age, and intervention dummy.
[1]Cost effective threshold of £15,000′; [2] Cost effective threshold of £20,000; [3]Cost effective threshold of £30,000.

Table 8
Base case and sensitivity analysis for cost-effectiveness based on BCAP outcome; Seemingly Unrelated Regression.

	PuP		TAU							
BCAP	Mean cost Mean(SE)	Mean effect[††] Mean (SE)	Mean cost Mean(SE)	Mean effect Mean (SE)	Incremental cost (95% CI)	Incremental effect (95% CI)	ICER	Probability cost-effective[1]	Probability cost-effective[2]	Probability cost-effective[3]
1) Base case[†]*										
NHS & PSS perspective	12548.15 (1589.51)	1.585 (0.838)	10,161.51 (1655.34)	−0.791 (0.805)	2386.64 (-1865.12, 6638.39)	2.376 (0.026, 4.726)	1004.48	0.288	0.518	0.98
Societal perspective	17747.99 (2060.5)	1.585 (0.838)	13,809.13 (2145.83)	−0.791 (0.805)	3938.87 (-1547.4, 9425.13)	2.376 (0.026, 4.726)	1657.77	0.164	0.334	0.974
2)Completed case*										
NHS & PSS perspective	18997.57 (2180.77)	1.567 (0.904)	17,373.1 (2219.23)	−0.599 (0.92)	1624.47 (-4568.72, 7817.66)	2.166 (-0.402, 4.734)	749.99	0.398	0.514	0.906
Societal perspective	24669.26 (2642.67)	1.567 (0.904)	21,442.59 (2689.28)	−0.599 (0.92)	3226.672 (-4278.29, 10,731.63)	2.166 (-0.402, 4.734)	1489.69	0.282	0.364	0.876
3) Highest mean cost per session[†]*										
NHS & PSS perspective	13394.56 (1603.49)	1.585 (0.838)	10,156.28 (1669.89)	−0.791 (0.805)	3238.28 (-1053.214 7529.77,)	2.376 (0.026, 4.726)	1362.91	0.192	0.394	0.978
Societal perspective	18594.4 (2075.212)	1.585 (0.838)	13,803.89 (2161.148)	−0.791 (0.805)	4790.51 (-1202.07, 10,783.09)	2.376 (0.026, 4.726)	2016.21	0.09	0.244	0.974
4) Lowest mean cost per session[†]*										
NHS & PSS perspective	10940.05(1568.17)	1.585(0.838)	10,171.46(1633.11)	−0.791 (0.805)	768.59 (-3759.82, 5297)	2.376 (0.026, 4.726)	323.48	0.522	0.726	0.988
Societal perspective	16139.89(2036.53)	1.585(0.838)	13,819.07(2120.86)	−0.791 (0.805)	2320.82 (-3560.05, 8201.69)	2.376 (0.026, 4.726)	976.78	0.33	0.532	0.978

[†]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 £20,000.

measure was selected as the primary measure of consequence, the economic evaluation generated probabilities of cost-effectiveness as high as 98.0% depending on the value of the cost-effectiveness threshold for a unit improvement in the BCAP. A recent stated preference study estimated a general US population willingness to pay of $175 for a 1 in 100,000 reduction in the risk of child maltreatment-related mortality (Corso et al., 2013). However, in the absence of empirical evidence from longitudinal studies exploring the relationship between unit changes in the BCAP and long-term risk of child maltreatment-related mortality, we are unable to use this or indeed any other external evidence to value societal preferences for the reduction in the BCAP score generated by the PUP program. Nonetheless, the probability that the program is cost-effective is approximately 51.8% if decision-makers are willing to pay £1000 for a unit improvement in the BCAP, increasing to 98.0% at a £20,000 cost-effectiveness threshold for this measure. This suggests that the PuP program is likely to be cost-effective with relatively little investment as the economic value associated with the reduction in child abuse potential is likely to outweigh the relatively small increase in economic cost.

This pragmatic trial compared TAU with the PuP program delivered by practitioners to families engaged in substance misuse treatment services. There are a number of limitations that need to be considered. The first relates to the delivery of the PuP program. Practitioners received supervision, the program was detailed in a Therapist Manual and accompanying Parent Workbook and independent clinical file audits were conducted. However, the actual quality of the delivery of the intervention was not measured. This is typically undertaken in treatment studies by recording sessions and having ratings of adherence to treatment protocols independently rated. While there are challenges associated with recording during home visits, particularly for populations with substance misuse problems, future research could revisit this issue. Second, there was a range of community-based addiction services supporting parents. There is likely to be variability in the quality and nature of the treatment provided which, in turn, may have influenced outcomes. Finally, the primary outcome measure was the parent report of child abuse potential. While there is considerable evidence supporting the validity of this measure (see Milner et al., 2017, for a review), administrative data from child protection records would have provided important additional information.

4.1. Concluding comments

Like many randomized controlled trials, recruitment was slower and resulting group sizes smaller than anticipated (McDonald et al., 2006). Despite a range of recruitment-promoting activities, including close liaison with key practitioners who served as gatekeepers, there were ongoing concerns raised by referral agencies about conducting an RCT in which a potentially effective treatment was being withheld to a vulnerable population (Borschmann et al., 2014). In contrast, once recruited, there was a high acceptance rate by study participants in both arms of the trial. While a per-protocol analysis potentially overestimates treatment effects (Nam and Toneatto, 2016), an intent-to-treat analysis has been criticized for being too cautious and thus more susceptible to type II error (Fergusson et al., 2002). Conducting both is recommended given power and attrition considerations (ICH Harmonised Tripartite Guidelines, 1998).

In conclusion, the current study was able to demonstrate both acceptability of the trial protocol to participants, high retention in a treatment protocol for those allocated to the PuP program and significant reduction in child abuse potential for those receiving the PuP program across a range of analytic strategies. Improvements in parental emotional regulation for those receiving the PuP program are also consistent with the proposed mechanism of change underlying the program logic.

Role of funding source

This study was funded by the National Society for the Prevention of Cruelty to Children (NSPCC; UK).

Contributors

JB designed the study, was PI of the grant that funded this study, was the primary author and wrote the first draft of this manuscript. SD and PH provided guidance and advice on measures and supported the role out of the PuP program by assisting in the training and accreditation process for practitioners subsequently involved in the delivery of the PuP program. Both contributed to writing and refining the manuscript. SS was the independent research assistant who initially contributed to the design of the study and subsequently collected data, assisted with preliminary data entry and screening and supported the statistical analysis. HP was the primary trial statistician who undertook initial power calculations, coordinated randomization processes through the Clinical Trials Unit, Warwick University, ran the primary analyses and constructed the tables for presentation of data and led the writing of the results around data interpretation. SP and SW designed the health economics analysis, undertook this analysis and wrote the key sections of the manuscript describing and interpreting these results. We confirm that the manuscript has been read and approved by all authors and that the order of authors has been approved by all of us.

Conflict of interest

PH and SD are the developers of the PuP program. Findings from this study contribute to the evidence base for the PuP program. The program 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 five per cent of training fees paid the University of Queensland. Surplus funds from training contracts are used to support research activities associated with the PuP program. The remaining authors have no conflicts of interest to disclose.

Clinical trial registration details: International Standard Randomized Controlled Trial Number Register: ISRCTN47282925; protocol published at: https://www.ncbi.nlm.nih.gov/pubmed/23841920.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.drugalcdep.2018.08.044.

References

Abidin, R.R., 1995. Parenting stress index. Professional Manual, third ed. Psychological Assessment Resources, Odessa, FL.

Barlow, J., Sembi, S., Gardner, F., Macdonald, G., Petrou, S., Parsons, H., Harnett, P.H., Dawe, S., 2013. An evaluation of the parents under pressure programme: a study protocol for an RCT into its clinical and cost effectiveness. Trials 14, 210.

Barlow, J., Dawe, S., Coe, C., Harnett, P., Newbold, C., 2016. OxPUP: An evidence-based, pre- birth assessment pathway for vulnerable, pregnant women. Br. J. Social Work 46 (4), 960–973. https://doi.org/10.1093/bjsw/bcu150.

Bates, D., Mächler, M., Bolker, B., Walker, S., 2015. Fitting linear mixed-effects models using lme4. J. Stat. Softw. 67, 1–48.

Berlin, L.J., Shanahan, M., Appleyard Carmody, K., 2014. Promoting supportive parenting in new mothers with substance-use problems: a pilot randomized trial of residential treatment plus an attachment-based parenting program. Infant Ment. Health J. 35, 81–85.

Borschmann, R., Patterson, S., Poovendran, D., Wilson, D., Weaver, T., 2014. Influences on recruitment to randomised controlled trials in mental health settings in England, a national cross-sectional survey of researchers working for the Mental Health Research Network. BMC Med. Res. Methodol. 14, 23.

Briggs-Gowan, M.J., Carter, A.S., Irwin, J.R., Wachtel, K., Cicchetti, D.V., 2004. The Brief Infant-Toddler Social and Emotional Assessment, screening for social-emotional

problems and delays in competence. J. Pediatr. Psychol. 29, 143–155.
Bromfield, L., Sutherland, K.J., Parker, R., 2012. Families with Multiple and Complex Needs: Best Interests Case Practice Model, Specialist Practice Resource. Victorian Government Department of Human Services, Melbourne, Australia. http://search.ror.unisa.edu.au/record/UNISA_ALMA11143248070001831/media/digital/open/9915909586101831/12143248060001831/13143247130001831/pdf.
Corso, P.S., Ingels, J.B., Roldos, M.I., 2013. A comparison of willingness to pay to prevent child maltreatment deaths in Ecuador and the United States. Int. J. Environ. Res. Public Health 10, 1342–1355.
Crittenden, P.M., 2006. CARE-Index Toddlers Coding Manual. Family Relations Institute, Miami, FL. https://www.iasa-dmm.org/pdf/assessment_pdf/2-CARE-Index-Toddlers-description.pdf.
Dakof, G.A., Cohen, J.B., Henderson, C.E., Duarte, E., Boustani, M., Blackburn, A., Venzer, E., Hawes, S., 2010. A randomised pilot study of the engaging Moms Program for family drug court. J. Subst. Abuse Treat. 38, 263–274.
Dawe, S., Loxton, N., 2004. The role of impulsivity in the development of substance use and eating disorders. Neurosci. Biobehav. Rev. 28, 343–351.
Dawe, S., Harnett, P.H., 2007. Reducing potential for child abuse among methadone-maintained parents: results from a randomized controlled trial. J. Subst. Abuse Treat. 32, 381–390.
Dawe, S., Harnett, P.H., Rendalls, V., Staiger, P., 2003. Improving family functioning and child outcome in methadone maintained families: the parents under pressure program. Drug Alcohol Rev. 22, 299–307.
Dawe, S., Taplin, S., Mattick, R.P., 2016. Psychometric investigation of the Brief Child Abuse Potential Inventory in mothers on opioid substitution therapy. J. Fam. Violence 32, 341–348.
De Wolff, M., van Ijzendoorn, M.H., 1997. Sensitivity and attachment: a meta-analysis on parental antecedents of infant attachment. Child Dev. 68, 571–591.
Dix, T., Gershoff, E.T., Meunier, L.N., Miller, P.C., 2004. The affective structure of supportive parenting, depressive symptoms, immediate emotions, and child-oriented motivation. Dev. Psychol. 40, 1212–1227.
Donohue, B., Azrin, N.H., Bradshaw, K., Van Hasselt, V.B., Cross, C.L., Urgelles, J., Romero, V., Hill, H.H., Allen, D.N., 2014. A controlled evaluation of family behavior therapy in concurrent child neglect and drug abuse. J. Consult. Clin. Psychol. 82, 706–720.
Fals-Stewart, W., O'Farrell, T.J., Freitas, T.T., McFarlin, S.K., Rutigliano, P., 2000. The Timeline Followback reports of psychoactive substance use by drug-abusing patients: psychometric properties. J. Consult. Clin. Psychol. 68, 134–144.
Fergusson, D., Aaron, S.D., Guyatt, G., Hébert, P., 2002. Postrandomisation exclusions: the intention to treat principle and excluding patients from analysis. BMJ 325, 652–654.
Frye, S., Dawe, S., 2008. Interventions for women prisoners and their children in the post-release period. Clin. Psychol. 12, 99–108.
Gardner, K., Qualter, P., 2009. Reliability and validity of three screening measures of borderline personality disorder in a nonclinical population. Pers. Individ. Dif. 46, 636–641.
Gossop, M., Darke, S., Griffiths, P., Hando, J., Powis, B., Hall, W., Strang, J., 1995. The Severity of Dependence Scale (SDS): psychometric properties of the SDS in English and Australian samples of heroin, cocaine and amphetamine users. Addiction 90, 607–614.
Gratz, K.L., Roemer, L., 2004. Multidimensional assessment of emotion regulation and dysregulation: development, factor structure, and initial validation of the difficulties in emotion regulation scale. J. Psychopathol. Behav. Assess. 26, 41–54.
Harnett, P.H., Barlow, J., Coe, C., Newbold, C., Dawe, S., 2018. Assessing capacity to change in high-risk pregnant women. Child Abuse Rev. 27, 72–84.
Harnett, P.H., Dawe, S., 2008. Reducing child abuse potential in families identified by social services: implications for assessment and treatment. Brief. Treat. Crisis. Interv. 8, 226–235.
Harnett, P.H., Dawe, S., 2012. The contribution of mindfulness-based therapies for children and families and proposed conceptual integration. Child Adolesc. Ment. Health 17, 195–208.
Hatzis, D., Dawe, S., Harnett, P.H., Barlow, J., 2017. Quality of caregiving in mothers with illicit substance use: a systematic review and meta-analysis. J. Subst. Abuse Treat. 11, 1–15.
Herdman, M., Gudex, C., Lloyd, A., Janssen, M., Kind, P., Parkin, D., Bonsel, G., Badia, X., 2011. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual. Life Res. 20, 1727–1736.
ICH Expert Working Group, 1998. Statistical Principles for Clinical Trials. Retrieved 2 May 2018. http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E9/Step4/E9_Guideline.pdf.
Jacobson, N., Truax, P., 1991. Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. J. Consult. Clin. Psychol. 59, 12–19.
Lovibond, P.F., Lovibond, S.H., 1995a. The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the beck depression and anxiety inventories. Behav. Res. Ther. 33, 335–343.
Lovibond, S.H., Lovibond, P.F., 1995b. Manual for the Depression Anxiety and Stress Scales, second ed. Psychology Foundation of Australia, Sydney, Australia.
Marchand, E., Stice, E., Rohde, P., Becker, C.B., 2011. Moving from efficacy to effectiveness trials in prevention research. Behav. Res. Ther. 49, 32–41.
Martinez-Torteya, C., Dayton, C.J., Beeghly, M., Seng, J.S., McGinnis, E., Broderick, A., Rosenblum, K., Muzik, M., 2014. Maternal parenting predicts infant biobehavioural regulation among women with a history of child maltreatment. Dev. Psychopathol. 26, 379–392.
McDonald, A.M., Knight, R.C., Campbell, M.K., Entwistle, V.A., Grant, A.M., Cook, J.A., Elbourne, D.R., Francis, D., Garcia, J., Roberts, I., Snowdon, C., 2006. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. Trials 7, 9.
Milner, J.S., 1986. The Child Abuse Potential Inventory, Second ed. Psytec Inc., Webster, NC.
Morey, L.C., 1991. Personality Assessment Inventory. Psychological Assessment Resources, Odessa, FL. https://www.parinc.com/Products/Pkey/287.
Nam, S., Toneatto, T., 2016. The influence of attrition in evaluating the efficacy and effectiveness of mindfulness-based interventions. Int. J. Ment. Health Addiction 14, 969–998.
National Institute for Health and Care Excellence, 2013. Guide to the Methods of Technology Appraisal. National Institute for Health and Care Excellence, London. https://www.nice.org.uk/process/pmg9/resources/guide-to-the-methods-of-technology-appraisal-2013-pdf-2007975843781.
Neumann, A., van Lier, P.A., Gratz, K.L., Koot, H.M., 2010. Multidimensional assessment of emotion regulation difficulties in adolescents using the Difficulties in Emotion Regulation Scale. Assessment 17, 138–149.
Nich, C., Carroll, K.M., 2002. Intention-to-treat meets missing data: implications of alternate strategies for analyzing clinical trials data. Drug Alcohol Depend. 68, 121–130.
Milner, J.S., Wagner, M.F., Crouch, J.L., 2017. Reducing child-related negative attitudes, attributions of hostile intent, anger, harsh parenting behaviors, and punishment through evaluative conditioning. Cognit. Ther. Res. 41, 43–61.
Ondersma, S.J., Chaffin, M.J., Mullins, S.M., LeBreton, J.M., 2005. A brief form of the child abuse potential inventory: development and validation. J. Clin. Child Adolesc. Psychol. 34, 301–311.
Paris, R., Herriott, A., Holt, M., Gould, K., 2015. Differential responsiveness to a parenting intervention for mothers in substance abuse treatment. Child Abuse Negl. 50, 206–217.
Petfield, L., Startup, H., Droscher, H., Cartwright-Hatton, S., 2015. Parenting in mothers with borderline personality disorder and impact on child outcomes. Evid. Ment. Health 18, 67–75.
R Core Team, 2017. R: a Language and Environment for Statistical Computing. https://www.R-project.org/.
Rubin, D.B., 2004. Multiple Imputation for Nonresponse in Surveys. John Wiley and Sons, New York.
Schore, A.N., 2010. Relational trauma and the developing right brain: the neurobiology of broken attachment bonds. In: Baradon, T. (Ed.), Relational Trauma in Infancy: Psychoanalytic, Attachment And Neuropsychological Contributions To Parent–Infant Psychotherapy. Routledge/Taylor and Francis Group, New York, NY, pp. 19–47.
Sharma, G., Oden, N., VanVeldhuisen, P.C., Bogenschutz, M.P., 2016. Hair analysis and its concordance with self-report for drug users presenting in emergency department. Drug Alcohol Depend. 167, 149–155.
Sherin, K.M., Sinacore, J.M., Li, X.-Q., Zitter, R.E., Shakil, A., 1998. HITS: a short domestic violence screening tool for use in a family practice setting. Fam. Med. 30, 508–512.
Smith, A.L., Cross, D., Winkler, J., Jovanovic, T., Bradley, B., 2014. Emotional dysregulation and negative affect mediate the relationship between maternal history of child maltreatment and maternal child abuse potential. Fam. Viol. Prev. Health Pract. 29, 483–494.
Suchman, N.E., DeCoste, C., Castiglioni, N., McMahon, T.J., Rounsaville, B., Mayes, L., 2010. The Mothers and Toddlers Program, an attachment-based parenting intervention for substance using women: post-treatment results from a randomised clinical pilot. Attach. Hum. Dev. 12, 483–504.
Suchman, N.E., DeCoste, C.L., McMahon, T.J., Dalton, R., Mayes, L.C., Borelli, J., 2017. Mothering from the Inside out: results of a second randomized clinical trial testing a mentalization-based intervention for mothers in addiction treatment. Dev. Psychopathol. 29, 617–636.
Taylor, G.J., 1997. Substance use disorders. In: Taylor, G.J., Bagby, R.M., Parker, J.D.A. (Eds.), Disorders of Affect Regulation: Alexithymia in Medical and Psychiatric Illness. Cambridge University Press, Cambridge, pp. 166–189.
Trull, T.J., Stepp, S.D., Solhan, M., 2006. Borderline personality disorder. In: Andrasik, F., Hersen, M., Thomas, J.C. (Eds.), Comprehensive Handbook of Personality and Psychopathology. Wiley, Hoboken, NJ, pp. 299–315.
van Buuren, S., Groothuis-Oudshoorn, K., 2011. MICE: Multivariate imputation by chained equations in R. J. Stat. Softw. 45, 1–67.