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Feasibility study of a family-focused intervention to improve outcomes for children with FASD

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ABSTRACT

Background: Growing evidence shows that children with fetal alcohol spectrum disorder (FASD) can benefit from interventions, and specifically interventions focused on improving self-regulation. However, novel ways of improving outcomes for children with FASD need further investigation so that programs target not only the individual child but also the family context, which includes the parent–child relationship.

Aims: The current study aimed to evaluate the feasibility of an adapted version of the Parents under Pressure (PuP) program that addresses self-regulatory processes, through improving the parent–child relationship and the use of mindfulness-based strategies for both children and parents.

Methods: This was a mixed methods study. Feasibility was examined by evaluating recruitment, data collection/outcome measures, and intervention procedures. The study used a phenomenological approach to obtain qualitative information from caregivers and a single-case experimental design to evaluate the preliminary participant responses to the intervention.

Results: Two out of three families completed treatment. The recruitment and intervention procedures were found to be suitable for and acceptable to the families involved. Some concerns were identified regarding the outcome measures that would need to be addressed in future research. Quantitative and qualitative outcomes were positive.

Conclusions and implications: The results provide preliminary support for the feasibility of an adapted version of the PuP program. Thus, offering a potential multi-component option, that aims to improve self-regulatory skills for children with FASD, through focusing on improving the parent-child relationship and incorporating mindfulness-based techniques for both parents and children.

What this paper adds?

The current study provides preliminary evidence of an adaptation of a multi-component family-based intervention for children with FASD. The Parents under Pressure (PuP) program is a comprehensively evaluated program that focuses on improving self-regulation for children and parents, through the inclusion of mindfulness-based strategies and by improving the quality of the parent-

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child relationship in families with complex needs. The current study assessed the feasibility of providing the PuP program for children with FASD. Both families that completed treatment reported that recruitment and intervention procedures were suitable and acceptable. Further, both families reported quantitative improvements in their child's level of psychosocial distress and qualitative improvements in the parent-child relationship.

1. Introduction

Fetal alcohol spectrum disorder (FASD) refers to the physical, cognitive, behavioural and/or learning disabilities that can be associated with prenatal alcohol exposure (Cook et al., 2016). While there is large variability in prevalence estimates (Roozen et al., 2016), evidence suggests that at least 2.4–4.8% of children in the United States have FASD (May et al., 2014). With substantially higher estimates for children in out-of-home care (e.g., Lange, Shield, Rehm, & Popova, 2013) and communities with high -levels of alcohol exposure (e.g., Fitzpatrick et al., 2015). The costs to society and individuals and their families are considerable. Thus, ongoing efforts to both prevent the occurrence of FASD and to ameliorate difficulties for those with FASD are essential.

Importantly, growing evidence suggests that children with FASD are able to benefit from interventions aimed at enhancing self-regulatory capacity (Reid et al., 2015). For example, benefits have been reported on the use of the ALERT program (Williams & Shellenberger, 1996), a 12-week manualised program that teaches children to recognise and change their arousal levels using sensory strategies, based on their current environmental needs. Three studies reported improvements in aspects of self-regulation, such as emotional problem-solving (Wells, Chasnoff, Schmidt, Telford, & Schwartz, 2012); inhibitory control and social cognition (Nash et al., 2015); parent-reported executive functioning skills in everyday life (Nash et al., 2015; Wells et al., 2012); and increases in cortical gray matter in regions underlying self-regulatory processes (Soh et al., 2015).

More recently, Kable, Taddeo, Strickland, and Coles (2016) conducted a pilot study that implemented Phase 1 of the GOFAR program. The broad goals of the program are to improve self-regulation skills using a computer program to teach problem-solving and adaptive life skills. In the GOFAR program, children are taught metacognitive learning strategies (e.g., Focus and Plan, Act and Reflect) to solve problems. Parents are provided with information about the metacognitive learning strategies and taught skills to manage children's heightened arousal states, in addition to behavioural management techniques. Children showed an improvement in their ability to sustain attention, with the effect more pronounced when parents received the same information as the children during the training and when they reported higher levels of engagement in the therapeutic process.

Consequently, previous interventions have focused on teaching children and parents mind-body awareness and sensory coping strategies (Nash et al., 2015; Soh et al., 2015; Wells et al., 2012) and/or metacognitive control strategies (Kable et al., 2016) to improve children's self-regulatory capacity. An additional approach to the enhancement of self-regulatory capacities is drawn from the growing literature on the incorporation of mindfulness-based strategies into psychological therapies for both adults (e.g., Khoury et al., 2013) and children (Harnett & Dawe, 2012; Kallapiran, Koo, Kirubakaran, & Hancock, 2015). Mindfulness training has been proposed as a method to improve self-regulation through improving top-down executive processes associated with frontal lobe structures, such as sustained attention and cognitive flexibility. At the same time, diminishing bottom-up influences associated with the limbic areas of the brain involved in the regulation of emotional arousal, such as stress or physiological dysregulation (Shapiro, Carlson, Astin, & Freedman, 2006; Zelazo & Lyons, 2012). Thus, we propose that a strong case can be made for the potential of mindfulness-based approaches to enhance self-regulatory capacities in children with FASD.

Furthermore, one of the proposed benefits of mindfulness meditation is that it produces a physiologically calmer state. (e.g., Burg, Wolf, & Michalak, 2012; Tang et al., 2009). This has been measured using respiratory sinus arrhythmia (RSA), a physiological measure of self-regulation. RSA refers to the observation that the intervals between successive heart beats (inter-beat intervals) are shorter during inspiration than during expiration (Beauchaine, 2015). Previous research with adults and our own research with children with FASD (Reid et al., under review) has found that RSA increased either during or following mindfulness practice (e.g., Burg et al., 2012; Tang et al., 2009). Higher values of RSA reflect greater variability in inter-beat intervals, which in turn has been found to be associated with more effective vagal control of emotional states in the face of environmental challenges (Beauchaine, 2015). Consequently, increasing RSA would be viewed as a positive outcome of therapy.

However, this would not necessarily be the case for children who continue to live in stressful home environments. As emerging research has demonstrated, higher RSA can actually be associated with more behavioural difficulties for children who are living in poverty and/or experiencing inconsistent caregiving (e.g., Conradt, Measelle, & Ablow, 2013). This may be due to children allocating additional attentional resources to monitor their unpredictable environment. Also, in the absence of a caregiver to promote self-regulatory skills, these children may develop maladaptive physiological mechanisms to regulate their emotional state, leading to emotional, behavioural, and physical health problems later in childhood (Conradt et al., 2016 Hostinar & Gunnar, 2013). Consequently, mindfulness training for children with FASD needs to be provided in conjunction with an intervention that aims to improve the quality of family functioning more generally. This is particularly important for children with FASD as they often live in families facing a range of psychosocial risk factors (Chamberlain, Reid, Warner, Shelton, & Dawe, 2017; Yumoto, Jacobson, & Jacobson, 2008).

Therefore, we are proposing an adaptation of the Parents under Pressure (PuP) program. The PuP program was developed as a home-based program for high-risk, vulnerable families. The program targets multiple domains of family functioning including: (i) the quality of the caregiving relationship; (ii) the parents' capacity to manage emotions and (iii) the broader ecological context in which the child is living. Consequently, the PuP program differs from previous interventions targeting self-regulation (i.e., Nash et al., 2015; Wells et al., 2012

The PuP program has a growing evidence base (e.g., Frye & Dawe, 2008; Harnett and Dawe, 2008 Harnett & Dawe, 2008), and has

been identified by a range of reviews as an evidence-based program for high-risk vulnerable families with children from pre-birth mothers to families with children in middle childhood (Commissioner for Children and Young People, 2014). A randomised control trial conducted with parents on methadone maintenance found significant reductions in child abuse potential, parenting stress, and related constructs in those who received PuP compared to standard care and a brief intervention group (Dawe & Harnett, 2007). A quasi-experimental study of high-risk pregnant mothers found greater improvement in child protection outcomes for those mothers who took part in a pre-birth pathway that included the PuP program compared to routine care (Harnett, Barlow, Dawe, Coe, & Newbold, In Press). Finally, the PuP program is currently subject of a randomised controlled trial based in the UK (Barlow et al., 2013).

Importantly, many parents experience multiple difficulties that extend beyond parenting knowledge and skills and this is also the case for many families parenting a child with FASD. The treatment foci of PuP are aligned with many of the challenges facing families with a child with FASD. For example, the capacity to manage emotions in the context of parenting a child with self-regulatory difficulties has been identified as a significant difficulty (Chamberlain et al., 2017). Helping children develop self-regulatory skills is also a key treatment focus of the PuP program and a key area of deficit for children with FASD and adapting both the home and educational settings to support children with FASD has been widely acknowledged as a key target of interventions (Reid et al., 2015).

Consequently, in the current study we have adapted the PuP program for children with FASD who had previously attended a diagnostic service. Reid, Shelton, Warner, O'Callaghan, and Dawe (2017) recently conducted a retrospective chart review of the diagnostic service, which found that while the majority of children were not found to display growth deficiency or facial features, 58% of children still had significant central nervous system dysfunction and 90% had significant behavioural difficulties.

The aims of the current study were to assess key elements of feasibility (Orsmond & Cohn, 2015) as follows: (1) recruitment, (2) data collection procedures and outcome measures, (3) suitability of the intervention protocol, (4) resources and management of the study, and (5) the preliminary evaluation of participant responses to the intervention.

2. Methods

2.1. Design

This is a mixed methods feasibility study that utilised a phenomenological approach (Carpenter, 2007) to obtain qualitative information from caregivers, and a single-case experimental design with a minimum of three baselines as recommended by Beeson and Robey (2006) to assess the preliminary quantitative treatment effects.

2.2. Participants

Three families were recruited from an FASD diagnostic service. The only inclusion criteria were that the children received an FASD diagnosis and lived locally. All children had received a 4-Digit Diagnostic Code (Astley, 2004) diagnosis of Neurobehavioural Disorder. See Tables 1 and 2 for a description of the participant characteristics.

2.3. Measures

2.3.1. Feasibility questionnaire

After treatment follow-up, the researchers completed a survey to assess program feasibility, based on Orsmond and Cohn (2015) guiding questions for feasibility. The survey required the researchers to reflect on five key objectives: (1) recruitment, (2) data collection, (3) acceptability of intervention procedures, (4) resources and management, and (5) participant responses to the intervention. See Supplementary Table 1 for the questionnaire details.

2.3.2. Parent interviews

Semi-structured interviews were conducted by the first author (NR) with the parents (each couple together) at the completion of treatment and then again at three months post-treatment. The initial interview focused on the parents' experiences of treatment;

Table 1
Child Characteristics.

Characteristics	Child 1	Child 2	Child 3
Age	9	12	11
Gender	Female	Female	Female
Siblings	0	3	0
Time since diagnosis	12 months	4 months	12 months
FSIQ (WISC-IV)	Low Average Range	Average Range	Average Range
Adaptive behaviour (ABAS-II)	Extremely Low	Extremely Low	Extremely Low
Child Behaviour (CBCL)	Clinical Range	Clinical Range	Clinical Range

Note. Assessment results from initial FASD diagnostic assessment. FSIQ = Full Scale Intelligence Quotient; ABAS-II = Adaptive Behaviour Assessment System, 2nd Edition; CBCL = Child Behaviour Checklist.

Table 2
Parent Characteristics.

Characteristics	F1, P1	F1, P2	F2, P1	F2, P2	F3, P1	F3, P2
Age	53	52	57	51	43	47
Level of education	High school	University	High school	High school	High school	High school
Caregiver type	Kinship	Kinship	Adoptive	Adoptive	Biological	Biological
Existing mental health diagnosis	Depression	–	–	PTSD	Depression	Panic Disorder

Note. F = Family; P = Parent; PTSD = Post-traumatic stress disorder.

specifically, which aspects of treatment they found helpful or unhelpful. The subsequent interview focused on what the parents' experiences had been in the months following the intervention. Specifically, this consisted of any changes that they had observed or areas that they thought had remained the same following treatment; also, if there had been any specific barriers encountered by their family during that three month period; and their outlook for the future.

2.3.3. Parent–report measures

The 86-item *Behaviour Rating Inventory of Executive Function* (BRIEF; Gioia, Isquith, Guy, & Kenworthy, 2000) was used to evaluate children's executive functioning abilities in their daily activities. The BRIEF provides eight non-overlapping clinical scales. These form two indexes: The Behavioural Regulation Index (BRI; three scales: Inhibit, Shift, Emotional Control); and the Metacognition Index (MI; five scales: Initiate, Working Memory, Plan/Organise, Organisation of Materials and Monitor). Also, an overall Global Executive Composite (GEC) score is provided. The BRIEF has been used with a variety of clinical populations including those with FASD (e.g.,Nash et al., 2015), and internal consistency and test-retest reliability of the parent report is high (Gioia et al., 2000). The BRIEF was completed by both parents in each family at three time points (pre, post and three-month follow-up).

The 64-item *Youth Outcome Questionnaire – parent report* (Y-OQ-PR; Burlingame et al., 2001) was used as a repeated measure to evaluate the children's psychosocial distress. Items are rated on a 5-point Likert-type scale and summative scoring produces six subscales (Intrapersonal Distress, Somatic, Interpersonal Relations, Social Problems, Behavioural Dysfunction and Critical Items). The total score was reported in the current study. The Y-OQ Total score has a test-retest reliability of .83, an internal consistency of .95 for an outpatient population, and concurrent reliability has been reported with a range of other child behaviour measures (Burlingame et al., 2001). The Y-OQ-PR was completed by both parents in each family.

2.3.4. Child measures

Children's *Respiratory Sinus Arrhythmia* was used as a repeated measure, at the same time-points the Y-OQ parent report was administered. At each time-point, a baseline measure (i.e., sitting watching a 5-min video) and a mindfulness measure (i.e., sitting listening to a 5-min mindfulness exercise) was taken and a simple change score was calculated between each condition. Children's cardiac activity was collected with an eMotion Faros 180° heart rate monitor cable set (Mega Electronics Ltd., Kuopio, Finland) with two electrodes affixed to the child's chest. The ECG data was imported into the Biopac AcqKnowledge 4.1 software package (Biopac Systems Inc., USA) and corrected for artifacts. The tachogram data was then imported into CardioEdit and CardioBatch Software (Brain-Body Centre, University of Illinois at Chicago, 2007). RSA was calculated by summing the variances of heart rate activity across the band of frequencies associated with spontaneous breathing of both children and young adults (i.e., .12–1.00 Hz). RSA was calculated as the natural logarithm of the extracted variance for each successive 30-s epoch.

The *NEPSY, Second Edition* (NEPSY-II; Korkman, Kirk, & Kemp, 2007) is a standardised neuropsychological battery for children aged 3–16 years. The NEPSY-II has been used with a variety of clinical populations including children with FASD (e.g., Nash et al., 2015). For the current study, one subtest (Inhibition) from the Attention and Executive Functioning domain was administered. This subtest was designed to assess the ability to inhibit automatic responses in favour of novel responses and the ability to switch between response types. Three conditions were used: (1) Naming, where the child simply names the shape or direction of the arrow; (2) Inhibition, where the child must provide the opposite response (e.g., "say circle when you see a square"); and (3) Switching, where the child switches between providing the correct response and the opposite response depending on the colour of the shape or arrow. The time taken to complete each task and the number of self-corrected and uncorrected errors were recorded. The NEPSY was completed at three time points (i.e., pre, post and three-month follow-up).

The 64-item *Youth Outcome Questionnaire – Self Report* (Y-OQ SR; Burlingame et al., 2001) is the parallel form of the Y-OQ for adolescents aged 12–18 years. The internal consistency of the Total score is reported as .95, a re-test reliability of .89, and it has moderate to good concurrent validity with other child self-report measures of behaviour (Ridge, Warren, Burlingame, Wells, & Tumblin, 2009). The Y-0Q SR was completed at three time points (i.e., pre, post and three-month follow-up).

2.4. Procedure

The current study was approved by the relevant university and hospital research ethics committees. Families were referred to the study by their treating clinician at the FASD diagnostic service. The therapist met with each family to provide further information about the study and to obtain informed consent to participate in the research. Families were given the choice of whether treatment would take place at the university clinic or in their home. The assessments and PuP therapy was delivered by NR, a Registered

Psychologist and who had undergone specialist training in the assessment and diagnosis of FASD and in the PuP program. The initial training for PuP therapists is approximately 30 h and ongoing supervision was provided on a fortnightly basis by one of the program developers (SD). This also ensured that there was fidelity to the model.

2.5. Treatment: adaptation of the PuP program

The PuP program is a home-based intervention underpinned by two key constructs: (1) that child wellbeing is dependent on the parent's capacity to provide a sensitive, responsive, and nurturing caregiving environment; and (2) that in order for this to occur, a parent needs to be able to understand and manage their own emotional state, which includes the resources to manage stressors present in the wider social ecological context of the family (Dawe & Harnett, 2013).

Importantly, the PuP program assessment allows for an individualised case plan to be developed. Immediate priority areas and goals for change are identified by the practitioner in collaboration with the caregivers and a treatment plan is developed. This approach allows flexibility and provides a tailored approach to supporting families (see Table 3). For families in the current study, the PuP program was adapted by including psychoeducation regarding the neurobehavioural impacts of FASD and strategies aimed at enhancing self-regulatory skills of the children. School consultation is often undertaken in PuP; however, given the significant difficulties children with FASD have at school, this was considered a core-element of the current intervention.

Sessions took place weekly or fortnightly and lasted between 1 to 2 h, depending on the families' needs. Sessions began with a review of the events of the week (e.g., any difficulties at home or school) and moved onto a discussion of the way in which strategies around self-regulation had been implemented. Problems were identified and discussion followed to help caregivers plan for more effective use of the strategies. Activities from the PuP Parent Workbook were completed to complement the focus of the session and, where appropriate, the therapist provided specific guidance based on each child's individual neurobehavioural needs, which had been identified at their diagnostic assessment. Both parents and the child participated in each of the sessions. Typically, there would be individual child time at the start of the session, then time spent together as a family, and finally a discussion with parents on their own. Sometimes additional family members would also participate (e.g., siblings or grandparents) depending on the focus of the session.

There was consistent child involvement during the program that included teaching age-appropriate mindfulness exercises, augmented with games and tablet application-based mindfulness training. Time was also spent in sessions to help resolve communication difficulties that had arisen in the family by teaching effective skills in the context of improving self-regulation of all family members. Potential resources in the public domain that reflected the key therapy goals of improving self-regulation were identified and piloted prior to the study. For example, the children's book Mindful Monkey, Happy Panda (Alderfer & Maclean, 2011) was provided to each family. This allowed a metaphor of being in a "monkey mind" or "panda mind" to be used by the children and their parents and was complemented with a small monkey finger puppet.

2.6. Data analysis

2.6.1. Qualitative methods

Parent interviews were audio-recorded and transcribed verbatim, with all identifying information removed. Parent interviews were compared sequentially to identify continuities and changes in their accounts over time. Additionally, the interview transcripts were cross-compared to identify any similarities or differences between the families' experiences of treatment and follow-up. Thematic analysis using QSR International's qualitative software package (Nvivo 10) was undertaken. The analysis was guided by the Braun and Clarke (2006) six phase approach to coding: (1) data familiarisation; (2) initial code generation, which involves detailed examination of the transcripts by two researchers. Initial codes are then discussed and agreed upon; (3) theme searching; (4) reviewing themes; (5) defining and naming themes (stages 3–5 also involves discussion and agreement between two researchers); and (6) producing the report.

2.6.2. Quantitative methods

Analysis of the repeated measure Y-OQ-PR was conducted using a combination of visual inspection and a *Tau-U* online calculation tool (singlecaseresearch.org; Parker, Vannest, & Davis, 2011). *Tau-U* is a method for measuring data non-overlap between two conditions (i.e., baseline and intervention) and examination of trends both within and between conditions. *Tau-U* analysis provides a more accurate evaluation of non-overlap of one condition compared to mean or median differences. This type of analysis has strengths in controlling for baseline trend and variability, ceiling and floor effects, and has sensitivity to condition change irrespective of baseline length (Parker et al., 2011). *Tau-U* scores can be interpreted using the following criteria: 65% or lower: weak or small effect; 66% to 92%: medium to high effect; and 93% to 100%: large or strong effect (Parker, Vannest, & Brown, 2009). Analysis of the pre-post and follow-up BRIEF parent reports was conducted using clinically significant and reliable change index (RCI) calculations. See Supplementary Table 2 for the Jacobson and Truax (1991) criteria that were used for these calculations.

3. Results

All families completed three baseline assessments. Families 1 and 2 completed treatment (they remained in contact for 27 weeks) with a total of 17 and 21 treatment sessions respectively and then 3 post-assessments. Subsequently, both families completed a 3-month follow-up assessment. Family 3 completed four sessions (3 baselines and 1 treatment) over seven weeks and then withdrew

Table 3
Overview of Treatment Process and Content.

Family 1: Activities, relevant PUP modules & resources	Family 2: Activities, relevant PUP modules & resources
● Information gathering, case conceptualisation, assessment feedback, and goal setting (PUP modules 1 & 2) ● Psychoeducation regarding the impact of FASD on behaviour and establishment of realistic behavioural expectations (resources: results of the neurocognitive assessment; 3D brain app on iPad; Forgetful Frankie children's book). ● Helping parents and children manage emotions under pressure: Increasing mindful awareness (PUP module 4) ○ Initial focus on parents helping their child to recognise and label emotions (resources: Inside out figurines, games based on the movie characters) ● Introduction to mindfulness (resources: Sitting Still Like a Frog book; Mindful Monkey, Happy Panda book; belly breathing with favourite stuffed toy) ● Managing emotional outburst ● View of self as parent e.g., challenging the notion of a perfect parent, developing understanding of parenting beliefs and strengths (PUP module 3) ● Focus on improving the parent child relationship (PUP module 6) (resources: applicable chapters from Universal Language of Love book; feedback from video of free play interaction with each parent individually and their child; structured activities in session that parents and child engage in together to foster positive interactions) ● Facilitating communication between child and parents to promote understanding of difficulties ● Structured activities in session that parents and child engage in together to foster positive interactions ● Parents paying attention to their child and spending small amounts of quality time with child engaging in positive interactions and building up to longer periods. ● Parents as good role models ● Helping parents understand individual parenting styles and work together with each other's strengths and weaknesses (resources: feedback from the parent-child interaction videos) ● Continued focus on helping parents and children manage emotions under pressure: Increasing mindfulness awareness (PUP module 4) ● Managing emotions in tricky situations at home and at school (resources: Breathe, Think Do iPad app, worksheet based on the app & worksheet based on the Mindful Monkey Happy Panda book to help child use "panda" mind vs "monkey" mind) ● Generalising to school setting ● Activities based on difficulties encountered at school; parents debriefing with child and problem solving difficulties that were occurring; social story about friendship; school meeting to share strategies that were being implemented at home to encourage communication and consistency across the home and school settings. ● Continued focus on helping parents and children manage emotions under pressure: Increasing mindful awareness (PUP module 3) ● Reviewing strategies for managing anger outbursts ● Encouraging informal and formal mindfulness practice – parents and children together and separately (resources: information about mindfulness in everyday life for parents & Smiling Mind app and stop, breathe & think app) ● Closure e.g., assisting parents to make action plans for what they are going to continue to focus on (PUP module 12)	● Information gathering, case conceptualisation, assessment feedback, and goal setting (PUP modules 1 & 2) ● View of self as parent e.g., challenging the notion of a perfect parent, developing understanding of parenting beliefs and strengths (PUP module 3) ● Helping parents and children manage emotions under pressure: Increasing mindful awareness (PUP module 4) ○ Managing anger outburst ● Significant initial focus on reducing level of conflict in the house and fostering a calm home environment ● Psychoeducation regarding the impact of FASD on behaviour and establishment of realistic behavioural expectations (resources: results of neurocognitive assessment, 3D brain app on iPad). ● Extending social support networks e.g., snapshot of social supports; breaking down barriers to asking for help and support (PUP module 9) ● Helping parents understand individual parenting styles and work together with each other's strengths and weaknesses. ● Focus on improving the parent child relationship (PUP module 6) ● Facilitating communication between child and parents to promote understanding of difficulties ● Structured activities in session that parents and child engage in together to foster positive interactions ● Parents paying attention to their child and spending small amounts of quality time with child engaging in positive interactions and building up to longer periods. ● Parents as good role models ● Focus on improving child's sleep quality (resources: sleep hygiene for teenagers, mindfulness audio on iPod, cognitive strategies to assist with managing worry, melatonin from family doctor) ● Continued focus on helping parents and children manage emotions under pressure: Increasing mindful awareness (PUP module 4) ● Reviewing strategies for managing anger outbursts at home ● Managing emotions in social situations with peers and classroom difficulties with teachers ● Continued focus on helping parents and children manage emotions under pressure: Increasing mindful awareness (PUP module 4) ● Encouraging informal and formal mindfulness practice (resources: info. about mindfulness in everyday life for parents, Smiling Mind and stop, breathe & think app) ● Generalising to school setting ○ Discussion and debriefing with child regarding challenging situations at school; collaborative problem solving; facilitating communication with parents regarding difficulties that were occurring at school ● School meeting to share strategies that were being implemented at home to encourage communication and consistency across the home and school settings. ● Closure e.g., assisting parents to make action plans for what they are going to continue to focus on (PUP module 12)

due to significant health concerns of a caregiver. All sessions, except for school meetings, were held in the families' homes.

3.1. Feasibility questionnaire

The current study was able to recruit appropriate participants through the FASD diagnostic service and all three families who were offered treatment agreed to participate. The data collection procedures for the parent-report measures were found to be acceptable. However, there were some difficulties with the child measures. Specifically, the YOQ-self report measure took longer than expected for the child to complete and was consequently used as a pre-post and follow-up assessment, rather than a repeated

measure. There were also difficulties with the measurement of RSA (data presented below). Since the sessions took place after school to fit in with the families' schedules, it is possible that this measure was affected by how stressful the child's day at school had been. Overall, the intervention procedures were evaluated as acceptable to participants, with two out of three families completing treatment and one family withdrawing due to poor health unrelated to the intervention procedures. There were no difficulties encountered with management of the study by the research team and, as will be discussed in further detail, the preliminary evaluation of the participant responses was positive and promising. Refer to Supplementary Table 1 for the full details of the feasibility questionnaire.

3.2. Parent interviews

The qualitative data suggests that the PuP intervention provided parents with an increased understanding of their child and also provided them with emotional support and practical guidance. Over time, parents described feeling more confident in their own abilities to respond to their child in a helpful way and manage their child's emotions and behaviour. Overall, following completion of the intervention, parents reported a sense of improvement in functioning for the whole family, which fostered feelings of hope for the future. Thematic analysis yielded five major themes: (1) An increased understanding of self and child; (2) Feeling supported; (3) Improved functioning; (4) Aspects of the intervention that were helpful and unhelpful; and (5) Areas to continue to focus on. Table 4 provides a summary of these major themes, as well as subthemes and example quotations. Additional themes were also identified that related to the many difficulties families had experienced with the education and health systems. These topics were beyond the scope of the current study; however, these experiences had resulted in significant distress for both families, and therefore have been included in Supplementary Table 3.

3.3. Parent report measures

Y-OQ parent-report data is displayed in Fig. 1.Visual analysis suggests that the intervention was associated with improvements in parent-reported child psychosocial distress. To determine the magnitude of the effect, Tau-U effect sizes were calculated for each parent who completed treatment and for the combined weighted average. Although the visual inspection of Family 1 Parent 1 suggested a baseline trend was present, the statistical analysis found no significant trends in the baseline phases for any participants. As displayed in Table 5, a significant difference was found between the baseline and treatment phases for two of the parents (p $.05 < .05$); one parent demonstrated a large treatment effect, two parents a medium to high effect, and one parent a small treatment effect. The overall combined weighted average *Tau-U* effect size was $-.75$, $p = .00$ (95% CI $= -1.14$ to $-.36$). This result indicates that 75% of the data showed improvement between the baseline and intervention phases. Table 6 displays the BRIEF parent report results. Family 1 reported improvements on the BRIEF, whereas Family 2 did not report any changes.

3.4. Child measures

Table 7 displays the NEPSY results for each child. Both children who completed treatment demonstrated a decrease in the number of errors they were making for each task; however, the time they were taking to complete the tasks tended to increase from pre- to follow-up. Table 8 provides a summary of the RSA during baseline and mindfulness tasks at pre-assessment, post-assessment and the three-month follow-up. Although at some assessment time points both children displayed changes in RSA from baseline to mindfulness, these changes were not consistently found during or following the intervention. Further, no overall increases were noted in RSA at baseline or mindfulness assessments following the intervention. Additionally, Child 2 completed the YOQ self-report measure at the first session and scored 70, which was in the clinical range, and then at the post-assessment they scored 45, which was in the non-clinical range. Subsequently, at the three month follow-up, Child 2 scored 12. According to Jacobson and Truax's (1991) criteria, this outcome is classified as Recovered.

4. Discussion

The present study assessed the feasibility of an adaptation of the PuP program for children with FASD and their families. A number of key findings were identified from the feasibility questionnaire and the qualitative and quantitative results. We briefly review the findings that are specific to feasibility studies, and discuss how these findings could be incorporated into future trials.

The first component of a feasibility study is an evaluation of the recruitment and intervention procedures. Importantly, these were found to be feasible and acceptable to participants. All three of the families accepted treatment and two families completed treatment and were retained at the three-month follow-up. The second component addresses the data collection procedures and the utility of the outcome measures used. The parent-report measures of child functioning (i.e., the BRIEF & Y-OQ-PR) were easily completed by all parents. Some important findings in relation to the feasibility of the child measures were identified. The Y-OQ-SR is designed as a repeated measure to track the progress of treatment (Burlingame et al., 2001). However, the participant burden for the older child who completed the Y-OQ-SR would have been too great if she was required to complete this measure weekly. Nonetheless, it proved to be a sensitive measure of change and provided important feedback from the child's perspective on the three occasions which it was completed. Further, RSA was used as an index of potential improvement in self-regulatory processes. However, the data were less reliable than anticipated and we hypothesised that this could partially be attributed to the timing of the physiological assessments. Thus, the use of RSA in future studies may need to have greater standardisation around the time of measurement.

Table 4
Themes Identified from Parent Interviews.

Themes & subthemes	Example quotations
Major theme 1: An increased understanding of self and child	
Increased understanding of FASD and child's behaviour and emotions	"I think for both of us, it has normalised what's the behaviour and we have understood this is why it happens; that is the biggest thing"(F2,P1). "I think I am cutting [child's name] more and more slack" (F2,P2). "We are not overreacting to [child's name] as much as we used to, which is a good thing cause we understand what she is going through" (F1,P1).
Increased awareness of personal responses to child	"I do think it is better if I have got my shit together; then it is a lot better to deal with [child's name]" (F2,P2). "I can generally calm down and think about it and then go back to [child's name] about it···So it has changed my focus" (F1,P2).
Major theme 2: Feeling supported	
Value of therapeutic relationship	"It made us feel like somebody understood and that somebody was going to help us get through this." (F1,P1). "It was good that [child's name] felt that she could have a talk to [therapist's name] and tell her things that, you know, maybe she couldn't talk to us about" (F1,P2).
Increased support within the parent relationship	"I think things are better with us [between the parents]" (F2,P2). "We are supporting each other now" (F1,P1). "It [the intervention] has been a real help because I think before we were fighting each other as much as we were fighting her disability" (F1,P2).
Major theme 3: Improved functioning	
Improved family communication	"The communication seems to be better" (F2,P1). "You taught us how to put it in her language and how to show her that this is the appropriate behaviour; not just telling her, 'Don't do that' (F1,P2).
Improved child behaviour	"A lot of her skills have now improved. Like, she is now cooking. She wasn't capable of some of these things prior···I think it has probably given her confidence that she can do some things. Before, she didn't have the confidence to try things" (F1,P2).
Positive relationships	"Overall I think it [the parent–child relationship] is improving" (F1,P1). "I think it has been better than when we started, yeah definitely" (F2,P2). "I have noticed now when she gets in trouble at school she wants to get home to tell mum about it straight away" (F1,P1). "That has changed because she used to not tell me and try to hide it because I would go off" (F1,P2).
A sense of hope	"There is light at the end of the tunnel" (F2,P1). "It has actually been only in the past couple of months that I have actually felt like, you know what, she probably will get a job. That used to worry me. Her future used to terrify me … Now I feel like, you know what, I think she is going to find her little niche … I feel a lot more confident that we can put her on the right track and she will be able to contribute to society in a good way" (F1,P2).
Major theme 4: Aspects of the intervention that were helpful or unhelpful	
Therapist knowledge of FASD	"That [therapist name] knows what the condition is means that [therapist name] starts to understand the difficulties it presents for the child straight away" (P F2,P1). "As a parent you need to know that these things are real" (F2,P1) "Yes that your kid is not just 'acting out'" (F2,P2).
Intervention strategies were concrete and they worked	"I have noticed that I have definitely changed my modelling with her … I stop and think; now, 'how can I explain this?' I won't go off. Ok [child's name], why has this happened? Let's talk about it." (F1,P2) "[Child's name] likes the Frankie and Panda books, and she really likes to read those and that has helped. It has given her coping strategies" (F1,P2). "Ok, this is a concrete thing that we know has worked that we go back to doing" (F1,P1).
Benefits of the intervention taking place in the family home	"I don't think it would work as well in a clinic situation. The kids are always going to be on their best behaviour out of home" (F2,P2). "You pick up more cues about what is really happening in the family home … people tend to feel more comfortable, relaxed in their own environment" (F2,P1).
Flexibility of the intervention	"I think the format of the program has been really helpful as through the process [therapist's name] has had a bit of flexibility … the flexibility has been a key thing because there are peaks and troughs and you've got to adjust the process to suit where people are" (F2,P1).
The therapist meeting with school staff	"As parents you go to the school and you will tell them this is happening, but having [therapist's name] involved… authenticated it; that it was a real problem" (F2,P1). "That was fantastic, and I think that is something that needs to happen in more places" (F1,P1).
Recommended a more structured approach to post-intervention follow-up	"Maybe a phone call or monthly check in or email or something, just so you feel that lifeline is still there." (F1,P1). "I think sometimes you doubt yourself … How do I handle this? What did [therapist's name] say? And sometimes you find it a bit hard to think back and you get so caught up in what's happening that you can't calm down sometimes to think through" (F1,P2).
Major theme 5: Areas to continue to focus on	
Child's social skills and teenage relationships	"I think the next big one as they become a teenager and get into relationships is helping with that. That is going to be a big one for [child's name]" (F2,P2). "We are still working on those [social skills], but they are getting better" (F1,P2).
Communicating instructions to their children	"I need to obviously break that down, or say it better or communicate differently. That is something I am going to have to work on" (F2,P2). "And I have to really try my hardest

(continued on next page)

Table 4 *(continued)*

Themes & subthemes	Example quotations
	not to assume that she has understood something" (F2,P2).
Parental emotion regulation	"It does worry me that those little stresses in life can just get on top of me" (F2,P2). "Sometimes when I am angry I don't always remember" (F1,P2). "We can't always get it right, but we are trying" (F1,P1).
Acknowledged that when things are going well it is easy to forget to use the intervention strategies	"When things are going well you think, 'Oh well, you can stop'. You sort of relax off on doing some of the things … Because when you put strategies in place and they work so well you tend to think it is a cure, it's fixed" (F1,P2). "But then we hit a road bump and we are like, 'Oh, we forgot to do this or we forgot to do that (F1,P1). "Yeah, when it is going really well, you do tend to just sort of let things slide" (F1,P2).

Note. F = Family; P = Parent.

In relation to the acceptability and suitability of the intervention, parents identified several aspects of the intervention that they found particularly helpful. For example, both families spoke about the importance of the relationship with the therapist. This is an important aspect of the PuP program, because the therapeutic alliance that the PuP therapist develops with a family is considered to be critical to treatment effectiveness. Further, this is an empirically supported notion as many "relationship factors" have been found to be robust predictors of outcome, including the alliance, therapist genuineness, positive regard, and empathy (Norcross, 2011).

Parents also identified that the flexibility of the intervention as helpful. This is also an important aspect of the PuP program, because the modules are designed to be administered in varying orders depending on the families' needs. Further, therapists need to be responsive to the emerging therapy context. For instance, they may need to deviate from session plans to provide support in an unexpected family crisis. This individualised approach to treatment planning draws from models of case conceptualisation (e.g., Kuyken, Padesky & Dudley, 2008) and avoids what has been referred to as the rigid "cookbook"-style approaches of many manualised therapies (Beutler & Howard, 1998), which tend to focus on the outcome rather than the processes of therapy (Barlow, 1996).

Preliminary examination of quantitative and qualitative outcomes suggested that the PuP program has promise as an intervention for children with FASD. Both families reported qualitative improvements in their parent–child relationship; specifically, parents could spend increasing amounts of time in positive interactions with their children. The positive outcomes in this domain are particularly noteworthy, because previous evidence indicates that the quality of the parent-child relationship has an important influence on the development of self-regulation (Calkins, 2007; Fox & Calkins, 2003).

Both families also reported quantitative improvements in their children's psychosocial distress. The Y-OQ-PR results were discussed with the parents after each assessment was completed. Previous research has shown that providing this feedback can significantly increase clients' progress and treatment effectiveness (Lambert, Jasper, & White, 2005). The results from the Y-OQ-PR were also supported in the interviews from both families where they verbally reported improvements in their children's behaviour and interpersonal functioning.

All parents communicated in their follow-up interviews that their increased understanding of the neurological basis for some of their children's challenging behaviours may have contributed to the positive changes in this domain. This is consistent with previous intervention research that also found that providing caregivers with information about the child's neurodevelopmental deficits is a critical component of interventions for children with FASD (e.g., Kable et al., 2016). This finding was also consistent with Petrenko, Pandolfino, and Roddenbery (2016), who found that when caregivers attributed their child's misbehaviour to underlying neurodevelopmental disabilities they felt more confident in managing their behaviour and were more likely to use antecedent rather than consequence-based behaviour strategies. It was also encouraging that the older child who completed the Y-OQ-SR felt that she had personally experienced significant improvements in her psychosocial functioning following the intervention.

Both children who completed treatment showed fewer errors when completing the inhibition tasks; however, as a result of being more careful, the completion time generally increased. Consequently, in real life situations (e.g., completing school or homework), although their ability to inhibit their behaviour may have improved, they may require extra time to complete tasks or activities. However, it should also be considered that Child 2 was performing at a reasonably high level on this task at the pre-assessments, with many of her scores already at an Expected Level or Above an Expected Level for her age. It is interesting to consider Child 2′s relatively high level of performance on this task, compared to the parent reports of her EF abilities in everyday life (i.e., the BRIEF). It is possible that objective measures of EFs fail to capture daily EF abilities. That is, Child 2 may have adequate EF abilities under ideal conditions (i.e., in a controlled distraction-free environment); however, she may not be able to employ these skills in the more complex situations that she faces in her everyday life.

Alternatively, the difference between the scores on these two measures may also reflect a third parental variable, such as parental frustration or stress, which could be influencing the scores on the parent report measure in this domain (Gross, Deling, Wozniak, & Boys, 2015). This may also be relevant regarding previous interventions targeting self-regulation (e.g., Nash et al., 2015; Wells et al., 2012) who found statistically significant change on the BRIEF; however, the mean scores remained in the elevated range post-intervention. This highlights the importance of including family-focused interventions relating to parent self-regulation to improve parent-child relationships and to assist children in generalising their self-regulatory skills.

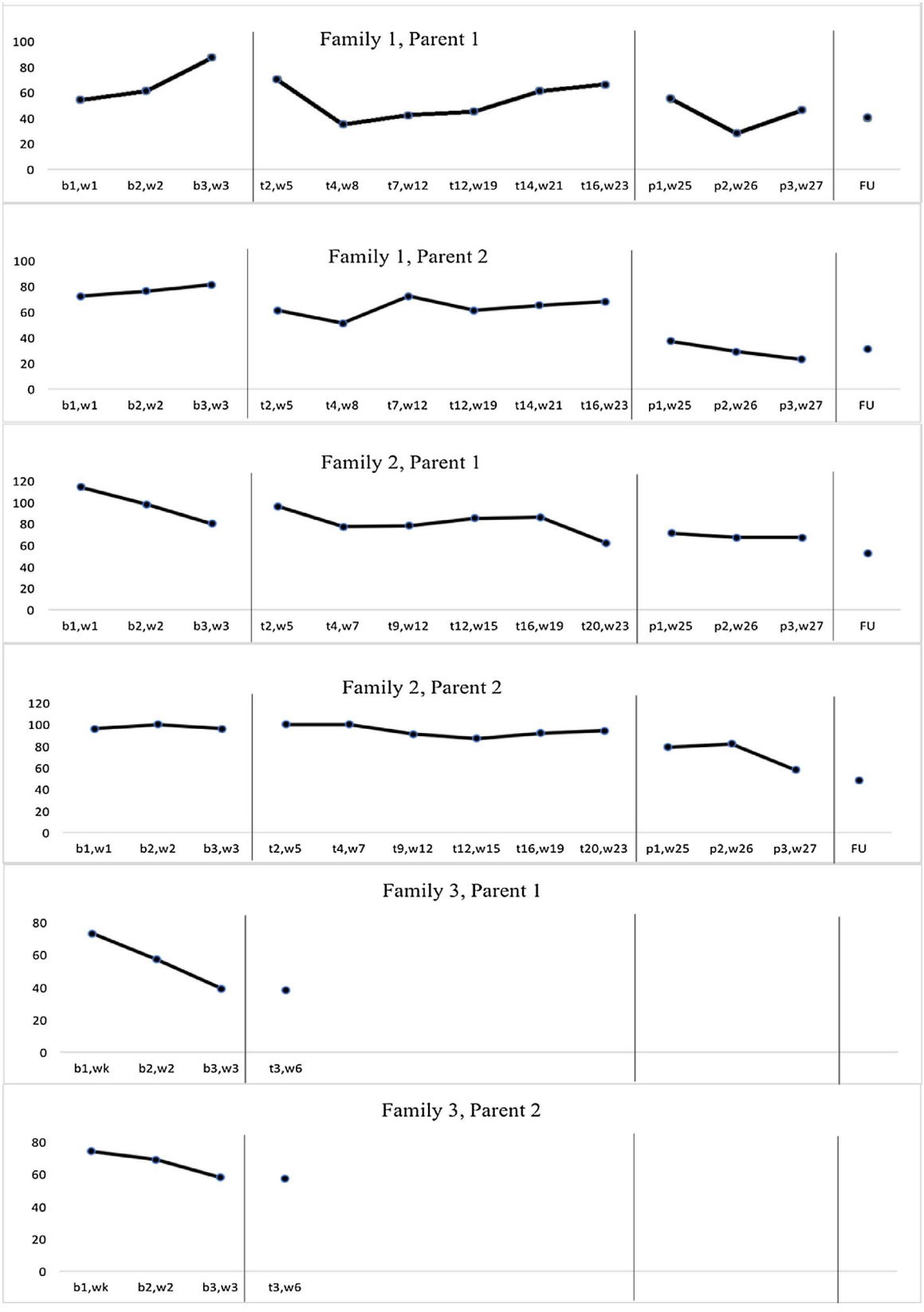

Fig. 1. Youth-Outcome Questionnaire Parent Report Results. *Note* b = baseline; t = treatment; w = week; p = post; FU = Follow-up at 3 months.

Table 5
Individual Baseline Trends and Phase Comparisons.

	Baseline Trend		Baseline vs intervention phase comparison	
Participant	*Tau-U*	*p*-value	*Tau-U*	*p*-value
Family 1 Parent 1	1	0.12	−0.57	0.15
Family 1 Parent 2	1	0.12	−0.97	0.01
Family 2 Parent 1	−1	0.12	−0.80	0.04
Family 2 Parent 2	0	1	−0.67	0.09

Table 6
Summary of BRIEF Results.

	Measure	Pre-score	Post-score	3-month FU	RCI
Family 1	BRIEF – BRI	62	57	57	Unchanged
Parent 1	BRIEF – MI	68	66	58	Recovered
	BRIEF – GEC	67	64	58	Recovered
Family 1	BRIEF – BRI	64	52	51	Recovered
Parent 2	BRIEF – MI	78	66	69	Improved
	BRIEF – GEC	74	62	62	Improved
Family 2	BRIEF – BRI	73	74	67	Unchanged
Parent 1	BRIEF – MI	65	61	94	Unchanged
	BRIEF – GEC	69	67	63	Unchanged
Family 2	BRIEF – BRI	74	81	79	Unchanged
Parent 2	BRIEF – MI	69	70	68	Unchanged
	BRIEF – GEC	76	75	73	Unchanged
Family 3	BRIEF – BRI	72			
Parent 1	BRIEF – MI	76			
	BRIEF – GEC	76			
Family 3	BRIEF – BRI	74			
Parent 2	BRIEF – MI	76			
	BRIEF – GEC	80			

Note: t-scores are provided; BRI = Behavioural Regulation Index; MI = Metacognition Index; GEC = Global Executive Composite; RCI = Reliable Change Index.

Table 7
Summary of Individual Child NEPSY Scores.

		Pre–score	Post-score	Follow-up Score
Child 1	Naming Total Errors	2[a]	2[a]	0[aa]
	Naming Total Time	61[b]	70[b]	78[w]
	Inhibition Total Errors	12[w]	9[bb]	3[a]
	Inhibition Total Time	101[b]	134[w]	139[w]
	Switching Total Errors	16[bb]	16[bb]	7[a]
	Switching Total Time	151[b]	170[bb]	183[w]
Child 2	Naming Total Errors	1[b]	0[a]	0[a]
	Naming Total Time	50[b]	44[a]	46[b]
	Inhibition Total Errors	2[a]	0[aa]	0[aa]
	Inhibition Total Time	67[a]	67 [b]	77[bb]
	Switching Total Errors	3[a]	1[aa]	0[aa]
	Switching Total Time	76[aa]	74[aa]	84[a]
Child 3	Naming Total Errors	7[w]		
	Naming Total Time	49[a]		
	Inhibition Total Errors	4[a]		
	Inhibition Total Time	69[a]		
	Switching Total Errors	9[a]		
	Switching Total Time	123[a]		

Note. aa = above expected level; a = at expected level; b = borderline; bb = below expected level; w = well below expected level.

Table 8
RSA at Pre-intervention Compared to Post-intervention and 3-month Follow-up.

	Child 1	Child 2	Child 3
Initial baseline	6.57	6.03	6.42
Initial mindfulness	7.82	6.03	7.65
RSA Δ baseline to mindfulness	1.25	0	1.23
Post baseline	6.37	6.14	–
Post mindfulness	6.70	6.99	–
RSA Δ baseline to mindfulness	0.33	0.85	–
3-month follow-up baseline	6.93	5.59	–
3-month follow-up mindfulness	7.32	5.68	–
RSA Δ baseline to mindfulness	0.39	0.09	–

Note. RSA = Respiratory sinus arrhythmia.

4.1. Limitations

There are several limitations of the current study that can be addressed in future research. A systematic assessment of the risk of bias should be conducted for future studies, that includes independence of the assessment and follow-up measures from the delivery of treatment and ensuring that the assessments are conducted by a researcher who is blind to the treatment condition. Second, future research should consider the use of additional self-report measures for young children and the inclusion of quantitative measures to assess parent and family functioning. Finally, the current study utilized a minimum of three baseline measurements as recommended by Beeson and Robey (2006); however, stability was not established for all parents. Future research using single-case methodology could consider extending the baseline period.

4.2. Conclusions

There is growing interest regarding interventions that can improve self-regulatory outcomes for children with FASD, as these foundational skills in self-regulation are proposed to underpin future adaptive functioning. The current study was one of the first to implement a multifaceted intervention that aimed to improve self-regulatory skills in children with FASD through focusing on improving the parent-child relationship and incorporating mindfulness-based techniques for both parents and children. The results provide preliminary support for the feasibility of an adapted version of the PuP program to support the needs of children with FASD and their families.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ridd.2017.06.004.

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