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**‘Life after Mellow’- An exploration of the feasibility and  
acceptability of long-term follow-up methods for the Mellow  
Babies intervention**

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*In loving memory of my Dad*

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## **Chapter 1: Systematic Review**

# **The Feasibility of conducting long-term follow-up research on group-based parenting interventions targeted at children under the age of three years: A Systematic Review**

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## **Abstract**

### ***Introduction***

Maladaptive parenting is associated with substance misuse, mental health difficulties and chronic health conditions and interventions that focus on improving parental skills are associated with short-term improvements in parent and child outcomes. Long-term effectiveness remains poorly evidenced. Therefore, an exploration of the current available evidence with a focus on the feasibility of conducting long-term research on parenting interventions is needed. This review will also synthesise research findings, appraise the quality of the evidence and make recommendations for future follow-up studies.

### ***Methods***

Systematic searches were conducted on Medline, EMBASE CINAHL, PsycINFO, Psychology & Behavioural Sciences and Child Development & Adolescent Studies, and the reference lists of related reviews were examined. The Cochrane Risk of Bias tool was used to assess bias in relation to the true intervention effect in the studies. Data were synthesised and the feasibility of conducting follow-up research within this population was discussed.

### ***Results***

This review identified 9 papers describing 8 relevant studies. Two studies outlined participant retention strategies such as monetary incentives and the importance of building relationships with referrers. The review found mixed results for parent, child and parent-child interaction outcomes

across all included studies. There were many areas of high and unclear risk within the studies.

### ***Conclusions***

This review highlights that it is feasible to conduct long-term research on the treatment effects of parenting interventions. However, due to heterogeneity in the interventions, low statistical power and small sample size the data available on specific parenting interventions is limited.

Further research into the long-term impact of parenting interventions is necessary with a focus on discussing the methods and infrastructure necessary to conduct these complex studies.



## **Introduction**

Over the last several decades service providers have recognised that parenting is one of the most important public health issues facing our society (Hoghughi, 1998). There is a large and growing body of research into the impact of parenting on a child's neurophysiological, physical and psychological development (Parkes, Sweeting, & Wight, 2016; NICE, 2014), with children exposed to maladaptive parenting, before the age of three, showing disturbances in socio-emotional development, language acquisition and academic attainment (World Health Organization, 2004). Disturbances in these developmental areas are linked to major public health concerns such as criminality, substance misuse, mental health difficulties and relationship difficulties throughout an individual's life (Rees, 2007), which can lead to a cycle of social deprivation and intergenerational parenting difficulties (Hoghughi, 1998). There is also evidence for a strong graded relationship between exposure to maltreatment in childhood and multiple risk factors for several of the leading causes of death in adults (Felitti et al., 2019). This evidence suggests that parenting may be one of the most important modifiable influences on child development.

Although the first three years of life are an important window for the development of attachment security, there is strong evidence to suggest that internal working models of attachment are subject to change in later childhood and adolescence, due to changes in the caregiving environment such as parental divorce; the biological, cognitive, emotional, and social changes that occur in adolescence which can lead to increased abstract thinking and re-evaluation of past experience; and heritable traits that influence how adolescents perceive, feel about and respond to, family interactions and relationships (Groh et al, 2014; Piquart, Feußner, & Ahnert, 2013; Fearon, Shmueli-

Goetz, Viding, Fonagy, & Plomin, 2014). Furthermore, research on Romanian orphans found that many of those who were adopted into an environment with few stressors went on to develop secure attachments with their adoptive parents (Chisholm, 1998).

Although attachment styles can change over time, this has been shown to be dependent on conducive environmental factors. It can be argued that it may be less complex to intervene in the early years in order to promote positive attachments from the outset rather than to influence a wider range of environmental factors later in the child's life. Due to this, it is not surprising that the UK government are treating parenting as a high priority area for investment in order to bridge the gap that can be caused by parental difficulties (All Party Parliamentary Group on Parents and Families & All Party Parliamentary Group on Social Mobility, 2015). There are many individual and group-based early intervention parenting programmes routinely delivered across the UK such as Mellow Parenting (Puckering et al, 1999), The Incredible Years (Webster-Stratton, 2005), The Family Nurse Partnership (Olds, 1996), and Triple P Positive Parenting Program (Sanders, 2008). Although there is evidence for the benefits of both forms of delivery, group-based interventions are considered efficient and cost effective methods of intervention as they provide a single localised system of support to a number of individuals (Wittkowski, Dowling, & Smith, 2016). There are a lack of systematic reviews which focus on group-based parenting interventions that target children during the crucial window of opportunity in their first three years of life. A Cochrane review focusing on this area found evidence of short-term improvements in child emotional and behavioural problems (Barlow, Bergman, Kornør, Wei, & Bennett, 2016). A meta-analysis of interventions targeted at parents of children under the age of 12-months found short-term medium positive effects on maternal sensitivity and the quality of the parent-child relationship and a small positive effect on child behaviour

(Rayce, Rasmussen, Klest, Patras, & Pontoppidan, 2017). Both studies found mixed results on child behavioural or parent-child interaction outcomes at follow-up with insufficient evidence to make recommendations. Rayce et al. (2017) could only perform a meta-analysis on the long-term data available from three studies on child behavioural outcomes and found no significant long-term effect. Both studies highlighted lack of funding, high attrition rates or lack of outcomes for the comparison groups, as barriers to follow-up data collection. Both reviews stress that further exploration of the long-term impact of parenting interventions are necessary with Barlow et al. (2016) highlighting parent-child interaction and child social and emotional development outcomes as an area of priority.

### ***Rationale for the current systematic review***

There are currently no published systematic reviews that focus on the feasibility of conducting long-term research on parenting interventions aimed at children under the age of three years where a range of parental and child outcomes are included. Owing to this, the current review has employed broader inclusion criteria than previous reviews in order to capture research on both parent and child outcomes for interventions that are both universally delivered or targeted at 'at-risk' groups.

The timing of the Rayce et al (2017) and Barlow et al (2016) systematic searches are now three to four years old and as this is an area of growing research it is important to explore recent evidence.

This review focused on the feasibility of conducting long-term research into parenting interventions as there is currently a paucity of information published on the practicalities and processes involved in such research i.e. optimising participant retention. Owing to this, the current study aims to review the available information on

the feasibility of conducting long-term research and make recommendations for future studies.

### **Review Aims**

- Focus on the feasibility of conducting long-term research in this area and make recommendations for future research.
- Review the literature in order to explore any long-term effects of group parenting interventions, targeted at parents with children under the age of three years, on parent and/or child outcomes.
- Appraise the quality of this research, highlighting methodological strengths and limitations.

### **Review Methods**

This review was conducted and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P) guidelines (Moher et al., 2015).

### ***Search Strategy***

The researcher conducted scoping searches on key databases to review the literature available on the feasibility of conducting long-term research on parenting interventions aimed at parents with children under the age of three. This highlighted that there is currently a paucity of research available in this area. A search of the literature on key databases, and on the PROSPERO and Cochrane archives, revealed that there are no listed systematic reviews (published or planned) which focus on the above area.

Systematic searches were undertaken on the 25<sup>th</sup> and 26<sup>th</sup> May 2019 on the electronic databases: Medline, Embase, CINAHL, PsycINFO, Psychology & Behavioural Sciences and Child Development & Adolescent Studies. The Cochrane Handbook for Systematic Reviews of Interventions guidelines (Higgins and Green, 2011), were followed in order to use sensitive and specific search terms for Randomised Controlled Trials (RCT). Details of the Medline search has been documented to provide a replicable record of the review process (see Appendix 2).

A search was also undertaken on Google Scholar using the terms: parent\* intervention AND long-term. The first 100 results from this search were screened and this did not identify any additional studies.

The reference lists of two related systematic reviews (Rayce et al., 2017; Barlow et al., 2016) were reviewed in order to identify further relevant research and to serve as a 'quality check' in terms of the coverage of the database searches. One additional study was identified this way.

### ***Inclusion criteria***

The inclusion criteria were as follows:

- (1) Published in English in a peer reviewed journal.
- (2) RCT's or quasi RCT's of group-based parenting interventions, including those delivered in the antenatal period, offered to both male and female parents with children under three years old.
- (3) All services or comparison interventions received or provided to the control group were included.
- (4) Parent and/or child outcomes and parent- child interaction outcomes reported, including:

- Parental emotional, behavioural and language outcomes
- Child emotional, behavioural and language outcomes
- Parent-child interaction outcomes

(5) Long-term outcomes: data collected from 6 months post-intervention onwards.

Review papers, qualitative studies and studies with a principal focus on medical outcomes (e.g. obesity and diabetes) were excluded from this review.

### *Types of interventions*

Studies evaluating the effectiveness of group-based parenting interventions from a range of theoretical perspectives were included. The review also included parenting interventions that were delivered universally or targeted at 'at-risk' parents.

Studies that focused on interventions tailored to specific populations e.g. parents with learning disabilities or children with neurodevelopmental conditions were not included as they were outwith the scope of the current review.

### *Feasibility*

This review provides a synthesis of study findings at long-term follow-up compared to other time-points. It explored attrition rates within each study and reviewed methods used to retain participants between time-points. Recommendations were provided for future research based on findings from methodological research.

### *Eligibility and study selection*

An overview of the screening process is provided in Figure 1 (overleaf). As shown, a total of 3918 articles were retrieved from the database searches. After removal of duplicates, the titles and abstracts of 1836 papers were screened in accordance with the

inclusion and exclusion criteria. The full text of 37 studies were assessed for eligibility and 9 papers describing 8 studies were identified as meeting the criteria for the review and were subject to data extraction and quality appraisal. Each study was screened by the Trainee Clinical Psychologist and uncertainties regarding eligibility were discussed with the Research Supervisor.

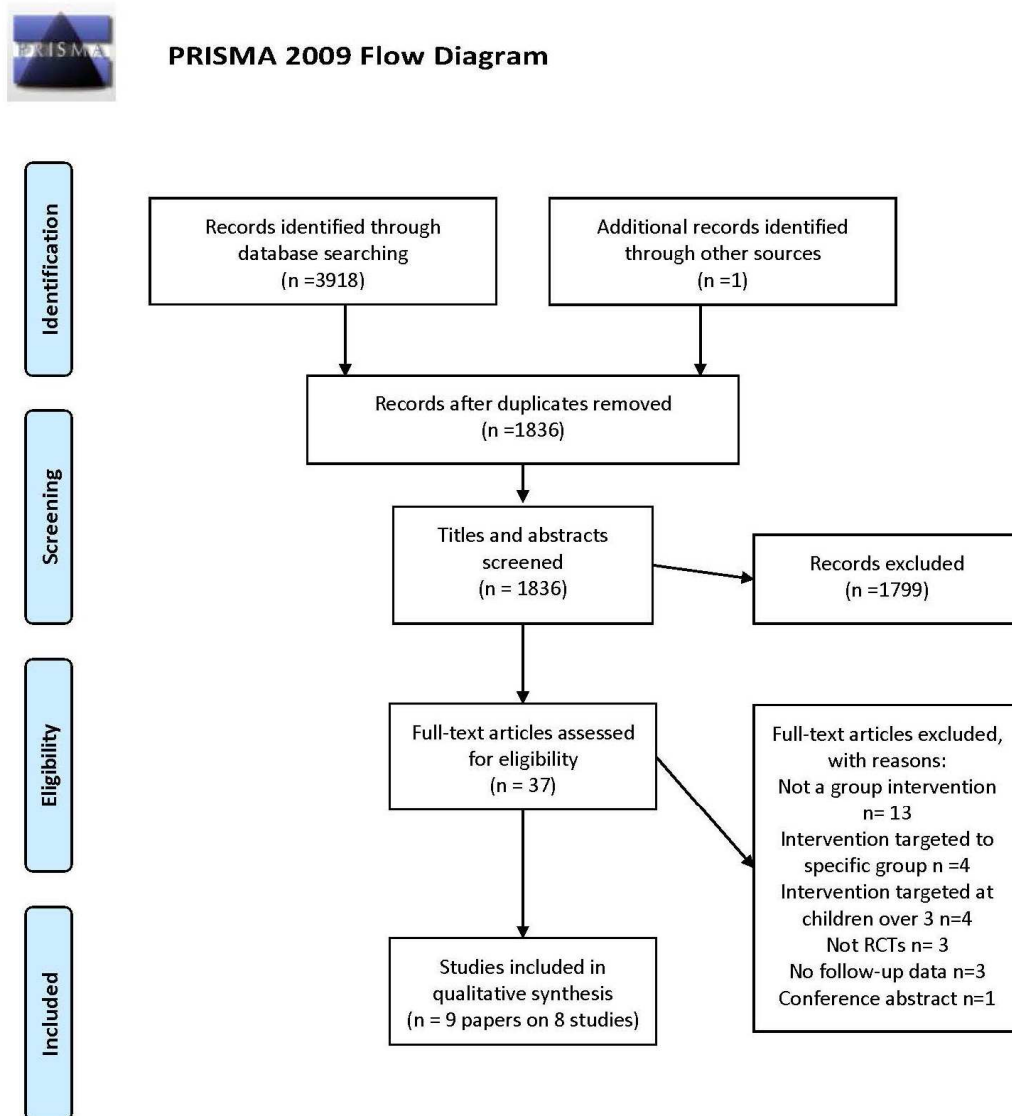


Figure 1. PRISMA Flow Diagram

### ***Quality appraisal***

In accordance with best practice guidelines (Moher et al., 2015; Higgins and Green, 2011) the Cochrane Risk of Bias tool (Higgins and Green, 2011) was used to determine the risk of bias in the methodology and reporting of included studies. The tool requires the researcher to assess bias in studies across seven areas; random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. Each area is categorised as low risk, high risk or unclear risk, with evidence to support each judgement.

All included studies were reviewed by the Trainee Clinical Psychologist. Inter-rater reliability was carried out by another Trainee Clinical Psychologist on four of the nine papers. Disagreements were resolved through discussion until 100% agreement was reached.

### ***Data Extraction***

A data extraction table was compiled for the eight included studies (see Table 1 in Results), which provides a full but concise description of each study in terms of authorship, year of publication and country, design, method of analysis, inclusion criteria, sample characteristics, outcome measures and follow-up assessment.



## Results

Table 1. Baseline characteristics of studies included in the review

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
Gridley, Hutchings, & Baker-Henningham, (2015), UK	<p><b>Design:</b> RCT</p> <p><b>Unit of randomisation:</b> Individual participant</p> <p><b>Analysis:</b> Intention to treat</p> <p><b>Inclusion criteria:</b> Parents who (1) lived in the Flying Start catchment area, (2) had a child aged between 12 and 36 months, (3) who had not attended an incredible years programme in the last two years.</p>	<p><b>Participants:</b> 89 parent-child dyads</p> <p><b>Mean age of parents:</b> 28.9 years (SD = 6.72, range = 16 to 48 years)</p> <p><b>Mean age of child age:</b> 21.57 months (SD = 6.71, range = 11 to 34 months)</p> <p><b>Ethnicity:</b> not reported</p> <p><b>Number randomised:</b> 60: parenting programme 29: wait-list control group</p> <p><b>Setting:</b> Community-based early intervention services</p>	<p><b>Two conditions:</b> Parenting intervention Waiting list control group</p> <p><b>Duration of intervention:</b> 12 weekly 2 hour sessions.</p> <p><b>Details of intervention:</b> The Incredible Years Parent–Toddler Programme is a behavioural intervention based on social learning theory that teaches positive relationship and behavioural management skills.</p>	<p><b>Parental language:</b> Frequency of parental utterances and child initiations across the five domains of: Quantity and variety of language, encouraging language, critical language, child-led language and parent-led language interaction.</p> <p><b>Timing of outcomes:</b> Pre-intervention Post-intervention</p>	<p><b>Timing of follow-up:</b> 6 months</p> <p><b>Attrition rate:</b> 27% (16 out of 60) of the intervention group 20% (6 out of 29) of the control group</p>

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
Gross et al., (2003) USA	<p><b>Design:</b> Cluster-RCT</p> <p><b>Unit of randomisation:</b> Day care centres</p> <p><b>Analysis:</b> Not specified</p> <p><b>Inclusion criteria:</b> Parents who (1) were the legal guardian of a 2- or 3-year-old child enrolled in the participating day care centre and (2) completed all baseline assessments. If the parent had more than one child in the centre within the target age range</p>	<p><b>Participants:</b> 208 Parents and 77 teachers of child enrolled in a participating day care centre in low socioeconomic areas</p> <p><b>Mean age of parents:</b> 27.9 (SD 6.8) reported at baseline for all parents.</p> <p><b>Age of child:</b> 2 or 3 years (mean, SD: NR)</p> <p><b>Ethnicity:</b> 57.2% African American; 29.3% Latino; 3.4% White; 4.3% Multi-ethnic; 5.8% other</p> <p><b>Number randomised:</b> 264 Intervention one: 78 Intervention two: 75</p>	<p><b>Four conditions:</b> Incredible Years BASIC with parents and teachers; Incredible Years BASIC with parents only; Incredible Years BASIC with teachers only; Waiting-list control</p> <p><b>Duration of intervention:</b> 12 (2 hours) sessions over 12 weeks</p> <p><b>Details of intervention:</b> Incredible Years BASIC aims to support parents and teachers to encourage child language, social, and emotional development, and to use positive discipline to manage misbehaviour.</p>	<p><b>Parenting self-efficacy:</b> The Toddler Care Questionnaire.</p> <p><b>Parent discipline strategies:</b> The Parenting Scale</p> <p><b>Parent behaviour:</b> The Dyadic Parent-Child Interactive coding system-Revised</p> <p><b>Parental depression:</b> The Center for Epidemiological Studies Depression Scale</p> <p><b>Parental everyday stress:</b> The Everyday Stress Index</p> <p><b>Parental neighbourhood stress:</b> The Neighbourhood Problem Scale</p> <p><b>Child behaviour problems:</b> Parent and</p>	<p><b>Timing of follow-up:</b> 6 months 12 months</p> <p><b>Attrition rate:</b> 21% of parents and 31% of teachers dropped out over the course of the study</p> <p>Of the parents 73% (41) dropped out between baseline and post-intervention. Among teachers, 29% (8) of The drop-out occurred between Baseline and post intervention.</p>

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
	then the younger child was selected for inclusion.	Intervention three: 52 control: 59 <b>Setting:</b> Multi-site; recruited from preschools in community		teacher report and an observational rating of a 15min parent-child play session <b>Parent- reported child behaviour problems:</b> The Eyberg Child Behaviour Inventory and The Problem Scale <b>Teacher-reported child behavioural problems:</b> The Kohn's Problem Checklist, as completed by teachers <b>Observer rated child behaviour problems:</b> Measured adapted from the Dyadic Parent-Child Interactive coding system-Revised	

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
				<p><b>Consumer satisfaction:</b> Consumer satisfaction questionnaire</p> <p><b>Timing of outcomes:</b> Outcomes reported for post-intervention</p>	
<p><b>Hackworth et al., (2017)</b> <b>Australia</b></p>	<p><b>Design:</b> two parallel cluster-RCT</p> <p><b>Unit of randomisation:</b></p> <p><b>The infant trial:</b> Maternal and child health centre</p> <p><b>The toddler trial:</b> Facilitated playgroup services</p> <p><b>Analysis:</b> Intention to treat</p> <p><b>Inclusion criteria:</b> Parents who (1) lived</p>	<p><b>Participants:</b> 2186 Mothers</p> <p><b>Mean age of parents:</b> Parent ages, means and range not report. % of parents under 25y/o reported in each group</p> <p><b>Infant trial:</b> 19.2% control group 18.3% smalltalk group only 19.3% smalltalk plus group</p> <p><b>Toddler trial:</b> 21.7% control group 22.4% smalltalk group only</p>	<p><b>Three conditions for both trials:</b> smalltalk- group-only smalltalk plus- Enhanced intervention with home coaching and ‘standard’ practice controls</p> <p><b>Duration of intervention:</b> The infant trial: 6 weekly 2 hour sessions. The toddler trial: 10 weekly 2 hour playgroup sessions.</p>	<p><b>Parent–child interactions:</b> The Indicator of Parent–Child Interaction</p> <p><b>Parent verbal responsivity:</b> Measured by the Parental Verbal Responsivity subscale of the StimQ-T</p> <p><b>Parental warmth:</b> measured by a 6-item scale from the Longitudinal Study of Australian Children</p>	<p><b>Timing of follow-up:</b> 32 weeks</p> <p><b>Attrition rate %:</b> <b>The infant trial:</b> 40% (160 out of 403) in the control group 41% (160 out of 393) in the smalltalk group only 38% (171 out of 455) in the smalltalk plus group</p> <p><b>The toddler trial:</b></p>

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
	<p>within the boundaries of the trial location, (2) with a child aged either 6-12 months for the infant trial or 12-36 months for the toddler trial, (3) with at least one indicator of social disadvantage e.g. low family income, (4) aged over 18 years old, (5) had sufficient English to take part, (6) did not receive intensive support or child protection services.</p>	<p>22.8% smalltalk plus group</p> <p><b>Age of child:</b> Means in months and SD reported per group in each trial.</p> <p><b>Infant trial:</b> 7.9 (2.4) control group 8.1 (2.2) smalltalk group only 8.0 (2.2) small talk plus</p> <p><b>Toddler trial:</b> 21.7 (7.5) control group 22.4 (7.2) smalltalk group only 22.8 (7.1) smalltalk plus</p> <p><b>Ethnicity:</b> Indigenous Australian Australian</p> <p><b>Number randomised:</b></p>	<p><b>Details of intervention:</b> smalltalk: Content targeted behaviours to enhance child language, communication, socioemotional development, increase the frequency of responsive parenting behaviours and strategies for providing a stimulating home learning environment.</p>	<p><b>Parental irritability:</b> The 5-item scale from LSAC.</p> <p><b>Home learning activities:</b> The 5-item LSAC modification of the Early Childhood Longitudinal Study, Kindergarten Cohort measure</p> <p><b>Home literacy environment:</b> 6 domains from the 15-item Home Literacy Environment Index</p> <p><b>Household chaos:</b> The 6-item short-form of the Confusion, Hubbub, and Order Scale (CHAOS) 20–30 minute computer-assisted telephone interview (CATI)</p>	<p>41% (189 out of 462) in the control group</p> <p>37% (193 out of 518) in the smalltalk group only</p> <p>41% (245 out of 576) in the smalltalk plus group</p>

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
		<p><b>The infant trial:</b> 51 locations randomised; 986 parents 312: control group 312: smalltalk group-only 362: smalltalk plus</p> <p><b>The toddler trial:</b> 58 locations randomised; 1200 parents 350: control group 410: smalltalk group only 440: smalltalk plus</p> <p><b>Setting:</b> Multi-site; Community settings</p>		<p><b>Timing of outcomes:</b> Baseline 12 weeks</p>	
<p><b>Hiscock et al, (2008)</b> <b>Australia</b></p>	<p><b>Design:</b> cluster-RCT</p> <p><b>Unit of randomisation:</b></p>	<p><b>Participants:</b> 733 mothers</p> <p><b>Mean age of parents:</b> Intervention 33.0 (SD 4.8) years; control 33.3 (SD</p>	<p><b>Two conditions:</b> Group-based intervention (Toddlers Without Tears); Control group: usual primary care</p>	<p><b>Externalising problems:</b> The Child Behaviour Checklist 1.5 to 5 years as reported by the mother</p>	<p><b>Timing of follow-up:</b> 12 months 18 months 24 months 3 years old</p>

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
<b>Three year follow-up:</b> <b>Bayer, Hiscock, Ukoumunne, Scalzo, &amp; Wake, (2010)</b> <b>Australia</b>	Maternal and child health centre <b>Analysis:</b> Intention to treat <b>Inclusion criteria:</b> All mothers of 6-7 month old babies in 31 local government areas with sufficient English to take part.	4.7) Age range: NR <b>Age of child:</b> 8 months <b>Ethnicity:</b> Not reported <b>Number randomised:</b> 733 Intervention: 329 Control: 404 <b>Setting:</b> multi-site Recruited from community settings	<b>Duration of intervention:</b> 7 months <b>Details of intervention:</b> Universal intervention consisting of three structured sessions delivered when the child was aged between 8 and 15 months. The intervention targeted parental risk factors for children's externalising behaviour problems.	<b>Internalising problems:</b> Child Behaviour Checklist 1.5 to 5 years – as reported by the mother. <b>Parenting style:</b> Parent Behaviour checklist <b>Maternal Mental health:</b> Depression Anxiety stress scale <b>Child temperament:</b> Parent rated global temperament item <b>Timing of outcomes:</b> Baseline	<b>Attrition rate:</b> 9% (31 out of 329): intervention group at 18months 7% (30 out of 404): control group at 18 months 11% (37 out of 329): Intervention group at 24 months 10% (40 out of 404): Control group at 24 months 21% (70 out of 329): Intervention group at 3 year 18% (74 out of 404): Control group at 3 years

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
<b>Perrin, Sheldrick, McMenemy, Henson, &amp; Carter, (2014) USA</b>	<p><b>Design:</b> RCT</p> <p><b>Unit of randomisation:</b> Individual parents</p> <p><b>Analysis:</b> Intention to treat</p> <p><b>Inclusion criteria:</b> Parents of ‘at risk’ children aged 2-4 years who (1) reported disruptive behaviours on a 20-item checklist , (2) had sufficient English/Spanish to participate, (3) their child did not have a diagnosis of developmental</p>	<p><b>Participants:</b> 262 mothers, 11 fathers</p> <p><b>Mean age of parents:</b> &lt; 27 years old: n= 68 28 to 33 years: n= 68 34 to 37 years: n= 68 &gt; 38 years old: n= 68</p> <p><b>Mean age of child age:</b> 2-4 years (mean: 2.8 SD: 0.61)</p> <p><b>Ethnicity:</b> 18% Hispanic, 82% not Hispanic</p> <p><b>Number randomised:</b> 150 89: Parenting training group (PTG) 61: Waiting list control 123: Non randomised- Parent Training Group (NR-PTG)</p>	<p><b>Three conditions:</b> PTG NR-PTG Waiting list control</p> <p><b>Duration of intervention:</b> 10 weekly 2 hour sessions</p> <p><b>Intervention details:</b> Incredible Years abbreviated. Made up of four module (play, praise and rewards, effective limit setting, and handling misbehavior).The programme uses videotaped modeling to encourage positive parenting and discourage harsh approaches.</p>	<p><b>Parent-report outcomes:</b> The Parenting Scale, The Early Childhood Behaviour Inventory</p> <p><b>Independent observer outcomes:</b> Coder Impression Inventory (CII)</p> <p><b>Timing of outcomes:</b> Baseline Post-intervention</p>	<p><b>Timing of follow-up:</b> 6 months 12 months</p> <p><b>Attrition rate:</b> 19%: PTG 18%: Waiting list control 41%: NR-PTG</p> <p>It is not specified if this was at 6 months or 12 months.</p>



Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
	disorder or global developmental delay	<b>Setting:</b> multi-site; recruited from health centres in the community			
<b>Muñoz et al, (2007) USA</b>	<p><b>Design:</b> RCT</p> <p><b>Unit of randomisation:</b> Individual participant</p> <p><b>Analysis:</b> Not specified. Results suggest intention to treat was used.</p> <p><b>Inclusion criteria:</b> Mothers who (1) were fluent in English/ Spanish, (2) at high risk of a major depressive episode (based on DSM-5 criteria), (3)</p>	<p><b>Participants:</b> 41 pregnant women</p> <p><b>Mean age of parents:</b> Intervention group: 24.8 y/o (SD:4.18) Control group: 25.0 y/o (SD: 4.7)</p> <p><b>Mean age of child age:</b> Not reported</p> <p><b>Ethnicity:</b> <u>Intervention group</u> Mexican: M=15, SD= 71.4 Other Latin American: M=2, SD= 9.6 USA: M= 4, SD= 19</p> <p><u>Control group</u></p>	<p><b>Two conditions:</b></p> <p>Intervention condition: Mothers and Babies course Control group: Treatment as usual</p> <p><b>Duration of intervention:</b> 12 weeks and 4 booster sessions at 1,3,6 and 12 months post-partum</p> <p><b>Details of intervention:</b> The Mamás y Bebés/Mothers and Babies Course is developed in Spanish and English and uses a cognitive-behavioural mood</p>	<p><b>Maternal depression</b></p> <p>The Center for Epidemiologic Studies Depression scale, The Edinburgh Postnatal Depression Scale</p> <p><b>Timing of outcomes:</b> Pre-and post-intervention time-points during pregnancy 1 month post-partum 3 months post-partum</p>	<p><b>Timing of follow-up:</b> 6 months 12 months</p> <p><b>Attrition rate:</b> 9% at 12 months</p>

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
	were over 18 years, (4) were between 12-32 weeks pregnant, (5) had no major mental health or substance misuse problems.	Mexican: M= 8, SD=40 Other Latin American: M= 6, SD= 30 USA: M= 4, SD=20 Other: M=2, SD= 10 <b>Number randomised:</b> 21: Intervention 20: Control group <b>Setting: Community;</b> public sector women's clinic	management framework. It incorporates social learning concepts, attachment theory, and socio-cultural issues.		
<b>Niccols, (2008)</b> <b>Canada</b>	<b>Design:</b> Parallel RCT <b>Unit of randomisation:</b> Individual participant <b>Analysis:</b> Intention to treat <b>Inclusion criteria:</b> Mothers of 'at risk' infants who (1) had	<b>Participants:</b> 76 mothers <b>Mean age of parents:</b> 28.8 (SD 6.2, range 18 to 40) <b>Mean age of child age:</b> 8.4 months (SD5.4, range 1 to 24 months) <b>Ethnicity:</b> Not reported	<b>Two conditions:</b> Group-based parent training (Right from the Start) Control group: usual Primary-Care (home visit) <b>Duration of intervention:</b> 8 weekly, 2 hour sessions <b>Details of intervention:</b>	<b>Infant attachment security:</b> Attachment Q-set reported by Mother. <b>Maternal sensitivity:</b> Maternal Behaviour Q-sort Infant/Toddler Home Observation for Measurement of the Environment	<b>Timing of follow-up:</b> 6 months <b>Attrition rate:</b> 16% (64 out of 76): % for each group not specified.

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
	sufficient English to complete questionnaires and (2) had not taken part in the intervention previously.	<b>Number randomised:</b> 76 Intervention: 48 Control: 28 <b>Setting:</b> single-site; community	<b>Right From the Start</b> Based on the Coping Modeling Problem Solving Approach. Aims to enhance carer skills in reading infant cues and responding sensitively.	Responsivity Scale <b>Timing of outcomes:</b> pre-intervention, post-intervention	
<b>Tucker, Gross, Fogg, Delaney, &amp; Lapporte, (1998)</b> <b>USA</b>  <b>Supplementary research to Gross, Fogg and Tucker, (1995)</b>	<b>Design:</b> RCT <b>Unit of randomisation:</b> Individual family <b>Methods of analysis:</b> intention-to-treat <b>Inclusion criteria:</b> Parents of children who were (1) aged between 24 -36 months, (2) who meet criteria for mild behavioural	<b>Participants:</b> 23 families (23 mothers and 23 fathers) <b>Mean age of parents:</b> Mothers 33 (SD 4.6) years, fathers 35 (SD 4.5) years <b>Child age:</b> 24 -36 months <b>Ethnicity:</b> Mother were 78% Caucasian and 22% African American <b>Number randomised:</b> 23 families: 11 : Intervention group although Gross et al,	<b>Two conditions:</b> Group-based parent training No intervention <b>Duration of intervention:</b> 10 (2 hours) sessions over 10 weeks <b>Details of intervention:</b> Behavioural Parent training program that includes information on how to play with your child, how to help	<b>Parenting self-efficacy:</b> Toddler Care Questionnaire <b>Parental stress:</b> Parent Domain of the Parenting Stress Index. <b>Child behaviour:</b> Eyberg Child Behavioural Inventory, Toddler Temperament Scale <b>Observed parent-child interactions:</b> Dyadic Parent-Child Interaction Coding System	<b>Timing of follow-up:</b> 1 year <b>Attrition rate:</b> 0%- all participants retained

Author, year and country	Study methods	Participants	Interventions	Outcome measures	Long-term Follow-up
	difficulties based on parent ratings on the Eyberg Child Behaviour Inventory. (3) Both parents must be living with the child.	(1995) reports 10 families in intervention group <b>Setting:</b> single-site; urban medical centre and community	your child learn, effective use of praise and rewards, strategies for setting limits effectively, and managing misbehaviour.	<b>Timing of outcomes:</b> post-intervention and 3 months post intervention reported in Gross et al, 1995.	

### *Long-term follow-up*

The follow-up assessment time-points ranged from six-months post-recruitment (Gridley et al., 2015) to three-years post-intervention (Bayer et al., 2010). It is important to note that although reported as a six-month follow-up, Gridley et al. (2015) counted from baseline, which resulted in the follow-up taking place at three-month post-intervention. Additionally, Muñoz et al. (2007) offered four booster sessions, two of which coincided with data collection windows, which is likely to have impacted on the outcome evaluation.

Attrition rates varied widely with a range of 0% attrition at one year post-intervention (Tucker et al., 1998) to 41% attrition at 32 weeks post-intervention (Hackworth et al., 2017). Tucker et al. (1998) reported paying participants to complete the one-year follow-up, however they do not specify the amount. Hackworth et al. (2017), who reported the highest attrition rates highlighted parental competing demands as the reason for drop out, however this appears to be speculation and not participant reported. Gross et al. (2003) found attrition was unrelated to baseline demographic factors or parental stress, however they did note that those who dropped out were less likely to use overactive discipline. Hiscock et al. (2008) and Bayer et al. (2010) reported that participants were assumed lost to follow-up if they did not return postal questionnaires. However, they did not document any procedures to encourage return of questionnaires. They reported similar baseline characteristics between those who dropped out and those who remained. Three other studies (Gridley et al., 2015; Perrin et al., 2014; Niccols, 2008) also reported no statistical differences between those who dropped out and those who remained however, they did not provide any further information on follow-up recruitment procedures. Muñoz et al. (2007) did not provide any information on the participants who dropped out of the study.

### ***Key findings***

This review found mixed results across all parent, child and parent-child interaction outcomes at long-term follow-up. A study evaluating ‘Toddlers without Tears’ reported no difference in child behavioural outcomes at all three time-points (Bayer et al., 2010; Hiscock et al., 2008). Whereas, a study on ‘Behavioural Parent Training’ (Tucker et al., 1998), and another study on ‘Incredible Years’ (Perrin et al., 2014), reported improvements in child behavioural outcomes in those who received the intervention at both post-intervention and follow-up time-points. In Tucker et al. (1998) mothers and fathers of the same children differed in their self-report of behavioural difficulties, which highlights the bias that can appear when using such measures.

The ‘Toddlers without Tears’ study reported no differences between the intervention and the comparison group on maternal stress, anxiety and depression at all time-points (Bayer et al., 2010; Hiscock et al., 2008). Whereas the ‘Behavioural Parent Training’ study (Tucker et al., 1998), and the ‘Mother and Babies’ study (Muñoz et al., 2007), observed positive impacts on parental well-being with parents in the intervention groups reporting lower rates of depression and stress and higher parental self-confidence.

There was no difference found between the ‘Toddlers without Tears’ group and the comparison group at 18-month follow-up, however at 24-month follow-up parents who received the intervention used less mean and harsh parenting and displayed fewer unreasonable development expectations. The latter was maintained at three-year follow-up suggesting the possibility of a “sleeper” effect (Bayer et al., 2010). One ‘Incredible Years’ study (Perrin et al., 2014) observed decreases in negative parenting and increases in the quality of the parent-child interaction at six and 12-months. While the ‘Behavioural Parent training’ study (Tucker et al., 1998) observed an increase in

parental use of praise and a decrease in negative physical behaviours at follow-up. However, the decrease in parental critical statements observed at post-intervention was not maintained at follow-up. The ‘Right from the Start’ study (Niccols, 2008) found no differences in attachment security or maternal sensitivity between the intervention and control groups at any time-point with both groups showing small improvements. A study evaluating ‘The Incredible Years Parent–Toddler Programme’ (Gridley et al., 2015) found that the intervention group showed significantly more child-led language interactions than the control group at follow-up. Greater use of encouraging language was also observed in the intervention group when a per-protocol analysis was conducted. The ‘smalltalk’ infant trial (Hackworth et al., 2017) found no differences in verbal responsivity and home learning activities between the control and intervention groups at 32-week follow-up. However, the toddler trial found that those in the smalltalk group showed significantly greater verbal responsivity and use of home learning activities than controls.

The findings from the included studies suggest that positive changes found at the post-intervention time-point were maintained at the follow-up time-points in the majority of studies and that there is evidence to suggest a positive impact from parenting interventions on child and parent outcomes over time.

### ***Risk of bias***

The risk of bias assigned to each domain of the Cochrane Risk of Bias tool for all included studies can be seen in Figure 2 below. Appendix 3 contains explanations of these judgments along with a synthesis of risk across domains.

Gridley et al (2015)	+	+	-	+	+	+	+	+
Gross et al (2003)	?	?	-	-	?	+	+	-
Hackworth et al (2017)	+	+	-	-	+	+	+	?
Hiscock et al (2008)	+	+	-	-	+	+	+	+
Muñoz et al (2007)	?	?	-	-	?	+	+	?
Niccols (2008)	+	+	-	+	?	+	+	+
Perrin et al (2003)	?	+	-	-	+	+	+	+
Tucker et al (1998)	?	?	-	-	?	+	+	+
			Blinding of participants and personnel (performance bias)					
			Blinding of outcome assessment (detection bias)					
			Incomplete outcome data (attrition bias)					
			Selective reporting (reporting bias)					
			Other bias					

Figure 2. Risk of bias summary

**Summary of Risk of bias in included studies**

Four of the eight studies were deemed as unclear risk in terms of randomisation due to reasons such as insufficient reporting of the randomisation process (Gross et al., 2003; Tucker et al., 1998) or the addition of a non-randomised control group in order to account for participant drop-out (Tucker et al., 1998; Perrin et al., 2014). The latter highlights the difficulties studies can face in retaining participants in the intervention group however, a robust randomisation procedure is preferable, whenever possible.

All of the included studies were deemed as high risk for blinding of participants and study personnel and six were deemed as high risk for the use of self-report measures as the primary outcome. It is not always possible to blind participants to these areas in psychological research and therefore assignments of high risk should not be judged harshly. That said, readers should remain mindful of the suggested influence that lack of blinding in these areas can have on results.



Four of the studies were deemed as unclear risk for attrition bias. This was due to reasons such as insufficient reporting of participant drop-out (Perrin et al., 2014; Muñoz et al, 2007), small sample size for primary outcome analysis (Niccols, 2008), baseline differences between drop-outs and those who remained (Gross et al., 2003) and unexplained increased numbers in the intervention group at follow-up (Tucker et al., 1998). These issues highlight the need for transparent reporting of participant drop-out as well as the need to sufficiently power studies for exploration of the primary outcome.

One of the studies included self-referring volunteers (Niccols, 2008) which can introduce bias and reduce the ability to generalise results as volunteers are often motivated to change; while another only included parents who lived together with their child (Gross et al., 2003), which is problematic because it is not common for vulnerable families to live together in one unit. It was unclear if the Muñoz et al. (2007) study targeting Latino mothers had sufficient Spanish-speaking research staff, which could negatively affect recruitment and participant engagement in the intervention. These issues could lead to inflated intervention outcomes in comparison to what might be seen in the general population.

## **Discussion**

This review aimed to explore the current evidence on the long-term effects of parenting interventions aimed at parents with children under the age of three years with a primary focus on the feasibility of conducting long-term follow-up assessment.

The main issues that led to high risk of bias within included studies were lack of blinding of participants, study personnel and lack of blinding to the outcome assessment. It is not always possible to blind participants to these areas and therefore assignments of high risk are not overly problematic in the context of this review, and as

primary care-giver report is recognised as the most useful measure of child behaviour (Glascoe, 2005), it is important to continue to use these measures. While methodologically preferable, measures of direct observation may not be feasible when scaling-up to large numbers of participants, especially in population-based research. (Bayer et al., 2010; Heinrichs, Bertram, Kuschel, Hahlweg, 2005). Direct observation measures are more expensive, and as evidenced in two papers, can also come with practical issues that can impact on analysis such as poor video quality or lack of funding to analysis all study data (Hackworth et al., 2017; Perrin et al., 2014). Self-report measures are also important for capturing mental health outcomes for participants. Given the nature of the research, it is not always possible to conceal parents to intervention allocation unless another intervention is offered as a comparator. However, this would incur significant costs for trials and demand greater numbers of participants to be allocated to another intervention group.

The heterogeneity in the sample of studies highlights that there is currently very little long-term data available on specific parenting interventions. The ‘Incredible Years’ programme was included in three of the studies (Gridley et al., 2015; Gross et al., 2003; Perrin et al., 2014), however each study focused on a different intervention package and different parent and child outcomes.

### ***Feasibility of long-term follow-up***

This review suggests that it is feasible to conduct follow-up research on the effects of parenting interventions targeted at children under the age of three years, however there is currently a paucity of long-term research available on a range of interventions. Very little information was provided on participant retention procedures across the eight included studies. Only two studies provided information on attempts to encourage

recruitment and retention which included assigning a researcher to each recruitment site in order to build relationships with study referrers (Gross et al., 2003), and paying participants to complete data collection time-points (Tucker et al., 1998). Specification of this amount may have helped to explain the studies uncharacteristically low 0% attrition rate at one-year follow-up. All of the other studies were affected by participant drop-out with two studies creating non-randomised control groups as a way of addressing this issue (Perrin et al., 2014; Tucker et al., 1998). Although an attempt to improve the success of the studies, it reduced the strength of the statistical analysis.

The timing of the follow-up assessment did not appear to influence attrition rates with varied rates seen across all time-points. The use of waiting-list controlled trials could result in limited opportunity for assessing further long-term outcomes in the included studies. A longitudinal study, employing a stepped-wedge design, could address this issue however it would incur significant costs and resources.

Research into the long-term effects of parenting interventions appears to be affected by a Catch 22 situation where there is currently a paucity of high quality research, but those that target vulnerable population are prone to high drop-out rates (Brown, Goslin, & Feinberg, 2012). This means that many studies do not meet recruitment targets needed to provide scientifically robust evaluation of outcomes. This was evidenced in two of the included studies (Perrin et al., 2014; Tucker et al., 1998).

It is evident from one of the included studies that differences in participant characteristics may be predictive of loss to follow-up (Gross et al., 2003). An understanding of the characteristics of parents who are not retained in intervention studies could provide important information for developing participant retention strategies. A study that focused on reasons for attrition in a parenting intervention for at-risk mothers found that those who did not engage with perinatal care were more likely

to drop out and those who misused substances were more likely to decline participation (Katz et al., 2001). This highlights a population of parents who are not engaging with health and support services and it is important that they are supported to participate in interventions. Previous parenting research and methodological studies highlight the importance of involving service users in the study design so that it is appropriate to the target population, the use of taxis to transport participants to and from groups if needed, multiple contact sources for locating participants, gift incentives for completing milestones in the study and seeking consent to maintain contact with primary healthcare providers and schools (if appropriate) to enhance participant tracking (Katz et al., 2001; Hill, Woodward, Woelfel, Hawkins, & Green, 2017).

The implementation of a process evaluation and economic evaluation as recommended by the complex intervention guidelines (Craig et al., 2013) would add value to future research within this area and result in more robust evaluation of the long-term efficacy of parenting interventions. This could add important information on the challenges and successes of the implementation, refinement and optimisation of processes and assessment of implementation quality and fidelity. Recruitment and retention strategies should be an area of focus within this evaluation in order to help to overcome the high attrition rates within this population. It is also recommended that future research includes qualitative interviews with participants and group facilitators in order to capture valuable information on barriers to participation and experience of study participation. This could help to inform attrition estimations when powering studies from the outset as well as effective costing-models at the time of grant application to ensure all data collected can be appropriately analysed (Trewick et al., 2015). An economic evaluation to develop more precise cost-effectiveness and health economic analysis would provide valuable information to decision makers on the return

on investment on parenting interventions and the appropriate allocation of resources within this area (Craig et al., 2013).

### *Limitations*

This review used a broad inclusion criteria which led to heterogeneity within the findings as it included a wide variety of primary and secondary outcomes. The inclusion of only RCTs led to the exclusion of non-randomised studies and qualitative studies which could have provided valuable information on the feasibility of conducting long-term research in this area.

Low statistical power and small sample sizes in the included research means it is not possible to make inferences from study findings. Due to the small research base on parenting interventions, four of the studies included in this review have been included in two previous Cochrane reviews (Barlow et al., 2016; Barlow, Coren, & Stewart-Brown, 2010). However, due to its different focus, the current review includes important research not included in either reviews as well as a long-term update of a key study with-in the area (Bayer et al., 2010).

This study focused on interventions that were delivered in the first three years of life. This period has often been recognised as a crucial window of intervention in order to protect against a range of difficulties throughout life for example poor mental health and physical health outcomes. However, there is a large body of evidence to suggest that positive changes can occur outwith this timeframe. This is particularly evident in attachment research where, within a low stress environment, attachment security can be achieved after three years of age (Chisholm, 1998). Modifications in attachment can also occur in later childhood and adolescence due to the range of biological, cognitive and social changes that occur during these periods of development (Groh et al, 2014).

Additionally, a meta-analysis of over twenty-one thousand attachment relationships found that the medium-sized stability of attachment security found in the first five years of life declined as the child aged no significant stability was found in intervals larger than 15 years (Pinquart, Feußner, & Ahnert, 2013).

Many of the included studies look at the quality of the parent-child relationship as a predictor for later developmental and behavioural outcomes. However, there is evidence to suggest that exposure to cumulative risk factors between the ages of one and 36 months may be a more reliable predictor of poor outcomes for children at three years (Belsky & Fearon, 2002). A more recent longitudinal study found that both avoidant attachment, independent of social risk factors, and a combination of disorganised attachment and social risk factors were significantly associated with behavioural difficulties in school ages children (Fearon & Belsky, 2011). These findings suggest that it is important to consider the role of social risk factors in the development of child behaviour problems.

#### *Implications for future research*

The search strategy was wide and inclusive, however only nine papers describing eight follow-up studies were found. This suggests that further research within the area should be treated as a priority. Future research should include a process evaluation in order to optimise research procedures and provide transparent reporting on methods and infrastructure for retaining participants across time-points. The practical strategies for participant retention outlined in methodological research should be observed in order to encourage participants to feel like valuable contributors to society rather than research subjects.

The findings are important for practice as they suggest parenting interventions that are widely implemented in the UK, such as 'The Incredible Years', may have long-term benefits for parents and their children. Early intervention in this way could have lifelong benefits for children and their families and could reduce the need for expensive public health services at later stages in life.

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## **Chapter 2: ‘Life after Mellow’- An exploration of the feasibility and acceptability of long-term follow-up methods for the Mellow Babies intervention**

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## **Plain English Summary**

**‘Life after Mellow’ - a study into the practicality of conducting an 18-month follow-up assessment with parents who took part in Mellow Babies.**

### ***Introduction***

The quality of the relationship between a parent and their child plays an important role in the child’s physical and emotional development. Parent training groups, such as Mellow Babies, which focus on strengthening this relationship have short-term improvements for parents and their children. However, at the moment there is very little research into the benefits that these groups have over time on parents and their children and it is important that we research this area further.

### ***Aims***

This project explored whether or not it was possible to recruit parents to a follow-up study of Mellow Babies 18 months after they took part in it. The main aim of the study was to recruit 45 of 60 (75%) potential participants. It also aimed to see if there were any changes in their mental health, life satisfaction or the quality of their relationship with their child and to provide information for a future larger research study.

### ***Methods***

The researcher invited parents to complete questionnaires on their well-being. The researcher also video recorded the parents interacting with their child in order to rate the quality of their relationship. The questionnaires and videos were compared to how they were before and after the parenting group using statistical analysis.

### ***Results***

The project successfully recruited 22 participants (37%) out of a possible 60. Eighteen (30%) could not be contacted by the referrer, 3 (5%) declined participation, 15 (28%) did not respond to the referrer or the researcher. Five of the seven parents of older

children who took part in the AIM Project took part in this follow-up study. Parents who were successfully recruited to follow-up were more likely to be older than those who did not engage. There were small positive changes in participants' scores on the psychological well-being, anxiety and quality of life questionnaires at the follow-up time-point. However, as this study did not have a large number of participants these results may not be due to the intervention and should be interpreted with caution.

### ***Conclusions***

This study shows that it is possible to conduct a long-term follow-up study of Mellow Babies. It recommends that future research should consider developing detailed plans from the outset in order to encourage participants to remain in the research. This could include involving service users in the development phase, creating systems to track participants contact details over time, informing participants of the progress of the research and keeping in touch with participants between time-points (e.g. sending birthday cards or tokens of appreciation) in order to recognise their valuable contribution to society.



## **Abstract**

### ***Background***

The quality of the early parent-child relationship is linked to a child's neurophysiological, physical and psychological development with relationship difficulties being linked to emotional and physical difficulties throughout the child's life. Parenting interventions, such as Mellow Babies, which focus on the quality of the parent-child relationship, have been found to improve parent and child outcomes. There is currently very little research into the long-term effects of parenting interventions on parents and their children, feasibility studies are necessary in order to guide implementation of larger scale research in the area.

### ***Aims***

This study aims to explore the feasibility of conducting follow-up research with parents 18 months after taking part in a Mellow Babies intervention in order to inform future larger scale research in the area. The study estimated a 25% attrition rate and aimed to recruit 45 of 60 (75%) potential participants.

### ***Methods***

Sixty parents who took part in the Mellow Babies intervention as part of the AIM Project were invited to complete questionnaires on their psychological well-being and quality of life. They were also video recorded interacting with their baby to provide information on the quality of the interaction. Parents' scores on all outcomes measures at follow-up

were compared to pre- and post-intervention outcomes from the AIM Project.

### ***Results***

22 out of a possible 60 (37%) parents were successfully recruited to the study. 18 (30%) could not be contacted by the referrer, 3 (5%) declined participation, 15 (28%) did not respond to the referrer or the researcher.

Five of the seven parents of older children who took part in the AIM Project engaged in the long-term follow-up. Those who were successfully recruited to follow-up were more likely to be older than those who did not engage.

Small positive effect sizes were observed on measures of global psychological severity, anxiety and quality of life at T3 when compared to T1. However, these results should be interpreted with caution due to the small sample size of the study.

### ***Conclusion***

It is feasible to recruit parents to follow-up research, however changes in service provision in the region led to difficulties and delays in recruitment.

Due to the small sample size assumptions cannot be made from the findings of the outcome evaluation and follow-up research is necessary in order to continue to explore the impact of Mellow Babies on parent and child outcomes.

## **Introduction**

From the moment a baby is born they are motivated to seek relationships with their primary caregiver. They have an intrinsic ability to seek out human faces, voice and touch and recognise and reciprocate emotional states in others which in turn influences the behaviour of their caregivers and increases their chance of survival (Tarabulsky, Tessier & Kappas, 1996; Trevarthen & Aitken, 2001). According to attachment theory, children use their early relationships to form internal working models of their concept of self, others and the world around them, which becomes a template for future relationships and experiences (Bowlby, 1969). Early positive relationships where primary caregivers are sensitive and responsive to childrens' needs are linked to the healthy development of neurophysiological, physical, psychological and socio-emotional processes, as well as language acquisition and academic competence (Parkes, Sweeting, & Wight, 2016; World Health Organization, 2004; NICE, 2014). In contrast, persistently negative early relationships have been found to have a detrimental effect on all of the above domains and can impact the individual from childhood through to adulthood (World Health Organization, 2004; Thompson & Calkins, 2009; Shonkoff and Phillips, 2000). Poor parent-child relationships are replicated in intergenerational parenting problems and can predispose children to substance abuse, homelessness, early pregnancy, and criminality (Puckering, McIntosh, Hickey & Longford, 2010; Rees, 2007). There is also evidence for a strong graded relationship between exposure to maltreatment in childhood and multiple risk factors for several of the leading causes of adult death (Felitti et al., 2019). These findings have significant financial and public health implications as they require ongoing support from public services such as social work, education and the National Health Service (NICE, 2014). It is therefore important

to understand and attempt to address the processes underlying the development of poor parent-child relationships.

Vulnerability factors for the development of poor parent-child relationships include socio-economic deprivation, childhood neglect and abuse, lack of knowledge about child development, parental state of mind with regards to attachment, lack of social support and poor parental psychological well-being (Zeanah, Berlin & Borris, 2011; Rees, 2007; Puckering et al., 2010). The first three years of life is an important window of opportunity for intervening in parent-child relational difficulties (Barlow, Bergman, Kornør, Wei, & Bennett, 2016). There are many parenting interventions which have been developed to target the early years including; The Incredible Years (Webster-Stratton, 2005), Family Nurse Partnership (Olds, 2006), Triple P Positive Parenting Program (Sanders, 2008) and Mellow Parenting (Puckering et al., 1999).

A Cochrane review (Barlow et al., 2016) and a meta-analysis (Rayce et al., 2017) of parenting interventions targeted at parents of infants highlighted that although there is well-established evidence regarding the short-term effects of parenting interventions very few randomised controlled trials have assessed the effects these interventions have over time. Findings from both reviews showed mixed results for the long-term maintenance of child and care-giver outcomes reported at the post intervention time-point, such as improvements in parent-child relationship, reductions in parental stress and reduction in child emotional and behavioural difficulties. In many cases, long-term data was only available for parents who received the parenting intervention. Both reviews along with other previous research into parenting interventions (Bayer et al., 2010; Bennett, Barlow, Huband, & Roloff, 2013; Niccols, 2008) have repeatedly stressed the need for further long-term exploration of the effects of parenting interventions on child and parental outcomes, particularly, interventions

aimed at parents of children under the age of three years. As long-term research would incur significant costs and resources, research exploring the feasibility of conducting such studies is warranted in order to avoid unnecessary expenditure of public funds.

### ***Mellow Parenting***

Mellow Parenting interventions deliver attachment-based interventions to parents who are at high risk of adverse outcomes due to parental difficulties. All interventions meet the NICE best practice guidelines for antenatal and postnatal mental health (NICE, 2014). Interventions are manualised, group based and promote parental sensitivity and attunement. A systematic review and meta-analysis of Mellow Parenting interventions found medium treatment effect sizes on maternal mental health and child behavioural problems, although it noted limitations such as heterogeneity within the participants and a failure to blind raters to treatment allocation. It highlighted the need for further quantitative research and recommended the exploration of outcomes beyond end of intervention (Macbeth et al., 2015).

The current study focused on Mellow Babies, a 14 week early intervention developed by Mellow Parenting which uses an attachment model to enhance parent-child attunement (Puckering, 2005). It is a group based early intervention which targets parental difficulties in order to reduce the legacy of disadvantage that can result from maladaptive parenting. As the most widely adopted of all Mellow Parenting interventions, research on its long-term benefits is likely to provide the best return on investment. There is evidence from a small waiting list controlled trial to show associations with improvements in maternal mood and the quality of the mother-child relationship (Puckering et al., 2010). However, as described by Macbeth et al. (2015) further research into the long-term effects of the programme is needed.

### ***Study context***

The current study explored the feasibility of conducting a long-term follow-up on participants who took part in the AIM Project (named after its funder the AIM Foundation; ISRCTN17621046). The AIM project, led by Mellow Parenting, was a UK multi-site non-randomised study that explored the impact of Mellow Babies on parental psychological well-being and quality of life, child behavioural outcomes and the quality of the parent-child relationship. The AIM Project included the completion of pre- and post-intervention outcome measures. Health, education and social care staff who were independent from Mellow Parenting, were trained to deliver the intervention.

Due to resource limitations the present study focused on a single site within the AIM Project. Fife was chosen for largely pragmatic reasons: at baseline all of the participants agreed to be contacted for further research; allowing the researcher to access the most participants while focusing on a single locality. The current researcher engaged with the participants at 18-months post-baseline assessment.

### ***Aims***

The current study aimed to explore the feasibility and acceptability of obtaining long-term outcomes for parents and babies who took part in the Mellow Babies intervention as part of the AIM Project.

### ***Research questions***

1. Did participants who took part in the AIM Project consent to this follow-up study and engage in long-term data collection 18-months post commencement of Mellow Babies?

The following research questions will be addressed depending on the number of participants who consent to the follow-up and engage in long-term data collection.

2. Was there a change in parental psychological well-being and quality of life when compared to AIM Project pre- and post-intervention outcomes on the Brief Symptom Inventory-18?
3. Was there a change in the quality of the parent-child relationship when compared to the AIM Project pre- and post-intervention outcomes on video observation analysis?
4. What is the likely long-term clinical effect of the intervention, as measured by scores on all outcomes, when compared to the AIM Project pre- and post-intervention outcomes?
5. How many participants would be needed for a sufficiently powered future study into the long-term outcomes of Mellow Babies?
6. What proportion of participants would be willing, in principle, to be contacted for a qualitative interview at a later date?

### ***Ethical Approval***

Ethical approval for the current study was obtained via the University of Glasgow Medical, Veterinary and Life Sciences ethics panel (Reference number 200170179: Approval date: 30/08/2018 (Appendix 4).)

### **Methods**

#### ***Design***

A within-group observational study design was conducted in order to explore the feasibility and acceptability of conducting follow-up research within a population of parents who have completed Mellow Babies as part of previous research on pre- and post-intervention outcomes.

Although the current study was an exploratory feasibility study the CONSORT guidance for feasibility trials was used and adhered to wherever possible (Eldridge et al., 2016).

### ***Inclusion and exclusion criteria***

Parents who consented to participate in the AIM Project, whether or not they completed Mellow Babies, and who consented to be contacted for involvement in future research were included. This included males and females over 18 years old who met the AIM Project inclusion criteria at time of recruitment. All participants were reviewed by the Aim Project group facilitators to ensure that contact was appropriate and not likely to result in additional distress.

Mellow Babies is targeted at parents of children in their first 18 months of life, however real world implementation of the intervention requires facilitators to include parents of older children in order to run groups of sufficient numbers. Due to this, parents of children 19 months and older will be included in the current study in order to assess their engagement with follow-up research.

The AIM Project did not include parents who were experiencing a psychotic episode or who were known to be actively misusing substances. Parents who did not have sufficient English language and communication abilities to provide informed written consent and take part in data collection were excluded. These criterion were reassessed by group facilitators before parents were approached for the current study. Parents of children who had died or were taken into care by social services post participating in the Aim Project were also excluded.



### ***Recruitment Procedures***

Fife AIM Project participants who met the study inclusion criteria and were deemed appropriate to be contacted for research purposes were approached by group facilitators and asked if their contact details could be passed on to a researcher. The researcher contacted parents by telephone to discuss the study and arranged home visits with all parents who assented to take part in order to take informed written consent and conduct data collection. The researcher emphasised that participation was voluntary and would not affect their relationship with Mellow Babies. Participants completed two self-report measures of psychological well-being and quality of life. Finally, they were video recorded while completing a care task with their child (e.g., mealtime). This process took approximately 45 minutes. Participants received a £10 Superdrug shopping voucher as compensation for any costs incurred from taking part. As this was a feasibility study, there was no minimum requirement on data collection. The researcher contacted facilitators weekly by phone or email to enquire about new referrals.

Data collection was completed in two phases to coincide with 18-months post-baseline for each of the AIM Project's groups. Phase 1 recruitment was planned across a 12 week period between August and October 2018 and Phase 2 recruitment was planned across a 12 week period between February and April 2019.

### ***The Intervention***

All participants included in the study received the Mellow Babies intervention. The intervention was delivered in the community one day a week for 14 weeks by appropriately trained group facilitators from social work, education and the community sector.

## *Measures*

The researcher replicated a portion of the AIM Project outcome measures completed at baseline and post-intervention time-points.

### *Quality of parent-child interaction*

Video recordings of the parent and child interacting were used to assess the quality of the parent-child relationship. Videos were coded using the Child and Adult Relationship Observation, (CARO), (Thompson, King, & Wilson, 2018) where proportions of positive and negative interaction behaviours are noted. A trained and reliable analyst within Mellow Parenting who was blind to the pre- and post-intervention outcome status of the participant conducted the CARO analysis.

### *Parental psychological well-being and Quality of life*

The Brief Symptom Inventory 18 (BSI-18) was used to assess parent psychological well-being. It is an 18 item self-report screening tool for identifying psychological distress in the form of depression, anxiety, and somatization. It is designed for use with medical and community populations (Derogatis, 2000).

The Quality of Life Enjoyment and Satisfaction Questionnaire (Short Form) (Q-LES-Q-SF) was used to assess parental quality of life. It is a 16 item self-report questionnaire that measures quality of life by assessing physical health, subjective feelings, leisure activities, social relationships, general activities, satisfaction with medications and life-satisfaction domains (Endicott et al., 1993).

### *Justification of Sample Size*

The current study utilised an existing sample of research participants who agreed to be contacted for further research at the AIM Project baseline assessment, which resulted in a fixed number of 60 participants. As this was a feasibility project which aimed to establish the proportion of participants who successfully engaged in follow-up data collection it was not possible to provide an a priori power calculation. Previous community based research on interventions for vulnerable populations have resulted in a 15-17% attrition rate at 1 year follow-up (Gilliss et al., 2001; Gustavson et al., 2012). Due to this, a conservative 25% attrition rate was estimated for the current study and the researcher aimed to recruit 45 participants.

### *Data Analysis*

Descriptive statistics will be used to explore the proportion of parents who consent to the follow-up study and engage in data collection. Depending on the number of participants to consent to follow-up and take part in data collection the following outcomes will be analysed.

In order to explore parental well-being and quality of life, participant mean scores on the BSI-18 and the Q-LES-Q-SF will be compared to AIM Project pre- and post-intervention time-points using paired sample t-tests. Effect sizes and confidence intervals will be estimated.

In order to explore the quality of the parent-child relationship, participants' data from the CARO will be compared to AIM Project pre- and post-intervention time-points using paired sample t-tests. Effect sizes and confidence intervals will be estimated.

If meaningful data are gathered on the effect sizes of the intervention, a power calculation will be carried out using the online calculator G\*Power (Faul, Erdfelder,

Lang, & Buchner, 2007) in order to inform future research. Descriptive statistics will be used to report the proportion of participants who are willing, in principle, to be contacted for a qualitative interview.

## **Results**

This feasibility study recruited and completed follow-up data collection for 22 out of a possible 60 (37%) potential participants who agreed to be contacted for further research at baseline, resulting in a 63% attrition rate from the AIM Project pre-intervention time-point (T1). Figure 1 shows the flow of participants through the study including reasons for exclusion and lack of engagement.

The AIM Project recruited and assessed 60 participants at T1. These included 53 parents who met the specific criteria for Mellow Babies and seven parents of children ages over 18 months. Approximately four months later, at the post-intervention time-point (T2), 57 were retained and assessed, resulting in a 5% attrition rate between the two time-points.

Of the 29 parents who had consented to follow-up (T3) research in Phase 1, 11 took part in data collection and 18 were excluded from the study. Of these 18 parents, the group facilitator did not have up-to-date contact details for seven parents, one was deemed inappropriate for further contact, four did not respond to the group facilitator, two declined to participate, two did not respond to the researcher, one moved away with no forwarding contact information and one removed their data from the study.

Of the 31 parents from Phase 2 who consented to be contacted for future research, 11 took part in data collection and 20 were excluded from the study. Of these 20 parents, the facilitator did not have up-to-date contact details for one parent, two were deemed inappropriate to be contacted, eight did not respond to the facilitator, three

did not respond to the researcher, one declined to participate, four moved away with no forwarding contact information and one removed their data from the study.

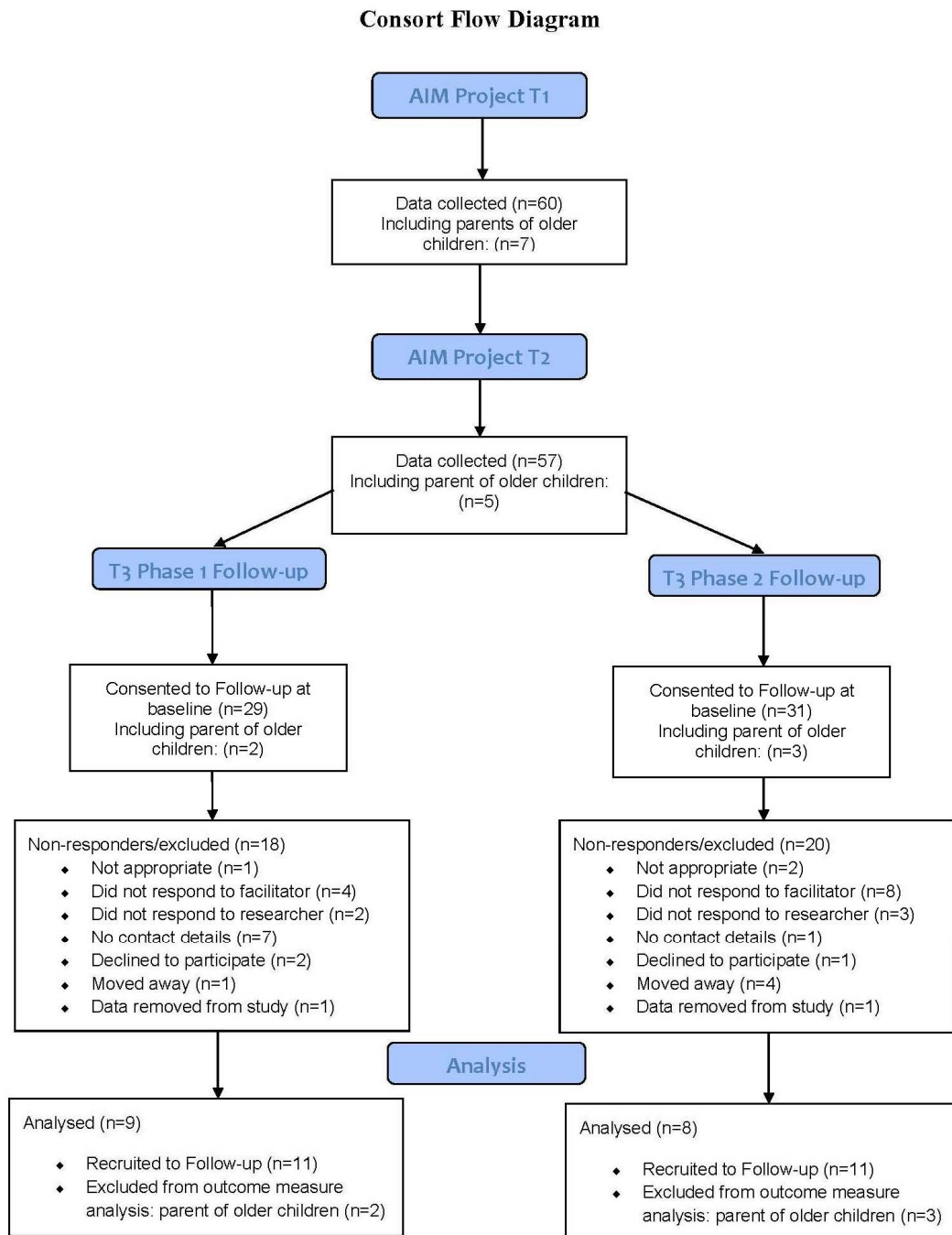


Figure 1: Consort Diagram of participant flow through the study including reasons for non-responders/ those excluded.

For Phase 1 all participants were assessed between 75 weeks (17 months) and 87 weeks (20 months) post-baseline. For Phase 2, all participants were assessed between 74 weeks (17 months) and 87 weeks (20 months) post baseline.

The baseline characteristics recorded at T1 of the 22 participants who were recruited to the follow-up study and the 36 non-responders that data was available for are described in Table 1. Demographic data was not reassessed at the T3 time-point.

Table 1. Baseline (T1) characteristics of participants who took part in the follow-up analysis and those who did not

<b>Baseline Characteristics</b>	<b>Recruited to Follow-up (n= 22)</b>	<b>Did not engage in follow-up (n=36)</b>	<b>P-Value</b>
<b>Gender</b>			
Female <i>n</i> (%)	13 (32)	28 (68)	.149
Male <i>n</i> (%)	9 (53)	8 (47)	
<b>Ethnicity</b>			
White Scottish <i>n</i> (%)	20 (38.5)	32 (61.5)	.589
Other <i>n</i> (%)	2 (33)	4 (67)	
<b>Age (years)</b>			
Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	27.5 (23.8, 35)	22 (19.3, 28)	<b>.011</b>
<b>Baby Age (months)</b>			
Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	11 (5.8, 21)	8 (6, 13.8)	.138
<b>Baby gender</b>			
Female <i>n</i> (%)	10 (34.5)	19 (65.5)	.787
Male <i>n</i> (%)	12 (41)	17 (59)	
<b>Other children</b>			

<b>Baseline Characteristics</b>	<b>Recruited to Follow-up (n= 22)</b>	<b>Did not engage in follow-up (n=36)</b>	<b>P-Value</b>
No other children <i>n</i> (%)	9 (29)	22 (71)	.178
Other children <i>n</i> (%)	13 (48)	14 (52)	
<b>Employment status</b>			
Full-time employment <i>n</i> (%)	1 (14)	6 (86)	.292
Part-time employment <i>n</i> (%)	3 (60)	2 (40)	
Unemployed <i>n</i> (%)	18 (40)	27 (60)	
Missing data <i>n</i>	0	1	
<b>Education</b>			
Up to GCSE/ Standard Grade level <i>n</i> (%)	10 (29)	25 (71)	.098
College/other higher level education <i>n</i> (%)	12 (52)	11 (48)	
<b>Relationship status</b>			
Single <i>n</i> (%)	6 (30)	14 (70)	.549
In a relationship, co-habiting <i>n</i> (%)	11 (39)	17 (61)	
In a relationship, not co-habiting <i>n</i> (%)	5 (50)	5 (50)	
<b>Psychological well-being and quality of life</b>			
BSI-18 GSI T score Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	58.5 (47, 66)	55.5 (47, 61.8)	.441
BSI-18 Somatisation T score Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	45 (41, 61.5)	52.5 (41.3, 65)	.337
BSI-18 Depression T score	61.5 (45, 66.3)	50 (45, 62)	.335



<b>Baseline Characteristics</b>	<b>Recruited to Follow-up (n= 22)</b>	<b>Did not engage in follow-up (n=36)</b>	<b>P-Value</b>
Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)			
BSI-18 Anxiety T score Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	55.5 (45, 66.5)	54 (45.8, 61.8)	.647
Q-LES-Q-SF T score Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	55 (50, 68)	63.5 (49, 71)	.451
Q-LES-Q-SF overall satisfaction Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	3 (0, 4)	2 (0, 4)	.694
Q-LES-Q-SF medication satisfaction Median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	3 (3, 4)	4 (3, 4)	.080

Significant p values ( $p < .05$ ) are highlighted in bold

Participants who were followed up were older than those who did not engage in the follow-up study ( $p = .01$ ). As can be seen from Table 1, there were no other statistically significant differences found in the baseline characteristics of those who took part in the follow-up study and those who did not. As can be seen in Figure 1, five out of seven (71%) of the parents with older children at the T1 time-point engaged in the follow-up study compared to 17 out of 52 (32%) of the parents who met the Mellow Babies criteria at T1. Baseline data were not available for the proportion of positive and negative interactions, as measured by CARO, as these data had not been coded by the AIM Project at time of analysis.

Twenty one of the 22 participants (95%) were willing, in principle, to be contacted for a qualitative interview at a later date about their experiences since Mellow Babies.

Five participants were not appropriate to be included in the outcome measure analysis as their children were over 19 months at the time of the intervention. This resulted in a sample of 17 participants in the T1 to T3 outcome measure analysis and a sample of 16 participants in the T1 to T2 and T2 to T3 outcome measure analysis as one participant did not complete T2 data collection.

Five of the participants did not have complete datasets for the video data, which resulted in a sample of 12 participants in the analysis on the quality of the parent-child interaction. There were attendance records for 13 of the 17 participants included in the analysis. Seven had 100% attendance at the group, three had 93% attendance, one had 64% attendance, one had 71% attendance and one had 14% attendance. This study used an intention to treat analysis and included all participants whether or not they completed Mellow Babies. Participants who completed the follow-up assessment at T3 had similar baseline characteristics to the AIM Project participants at T1 and no statistical differences were observed between the two groups.

Table 2 gives an overview of participants' scores across all of the outcomes measures at each time-point. Number of participants, mean and standard deviation are reported for participants' scores on each outcome measure. The p-value, Cohen's d effect size and corresponding confidence intervals are also included for each measure. Paired sample t-tests were used to explore any significant changes between the three time-points.

Table 2. Scores of participants included in the outcome analysis on all standardised measures at T1, T2 and T3

Measure	T1		T2		T3		T1-T2		T1-T3		T2-T3	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	P-value	Effect size (CI lower, CI upper)	P-value	Effect size (CI lower, CI upper)	P-value	Effect size (CI lower, CI upper)
CARO: Proportion of positive interactions	12	0.71 (0.30)	12	0.75 (0.19)	13	0.63 (0.22)	.512	-0.2 (-0.9, 0.5)	.340	0.3 (-0.3, 0.9)	.098	0.5 (-0.1, 1.2)
CARO: proportion of negative interactions	12	0.07 (0.14)	12	0.08 (0.09)	13	0.12 (0.14)	.702	-0.1 -0.8, 0.6	.325	-0.3 -0.9, 0.3	.371	-0.3 -0.9, 0.4
BSI-18 GSI T Score	17	57.9 (11.5)	16	55.8 (11.9)	17	56.9 (13.2)	.223	0.3 -0.2, 0.9	.710	0.1 -0.4, 0.6	.106	-0.4 -1.0, 0.1
BSI-18 Somatisation T Score	17	50 (10.7)	16	51.4 (11.9)	17	54.5 (12)	.543	-0.2 -0.7, 0.4	.050	-0.5 -1.0, 0.0	.061	-0.5 -1.0, 0.0
BSI-18 Anxiety T Score	17	58.7 (11.4)	16	56.9 (12.2)	17	56.1 (13.5)	.369	0.2 -0.3, 0.8	.374	0.2 -0.3, 0.7	.900	0.0 -0.6, 0.5
BSI-18 Depression T Score	17	59.2 (10.9)	16	55.3 (10.8)	17	59.1 (10.9)	.078	0.5 -0.1, 1.0	.678	0.1 -0.4, 0.6	.067	-0.5 -1.0, 0.0
Q-LES-Q-SF T score	17	59.4 (12.3)	16	57.8 (17.2)	17	58.4 (17.6)	.814	0.1 -0.5, 0.6	.699	0.1 -0.4, 0.6	.965	0.0 -0.5, 0.5

Measure	T1		T2		T3		T1-T2		T1-T3		T2-T3	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	P-value	Effect size (CI lower, CI upper)	P-value	Effect size (CI lower, CI upper)	P-value	Effect size (CI lower, CI upper)
Q-LES-Q-SF (medication)	17	2.2 (2.0)	16	2.5 (1.9)	17	2.5 (1.4)	.423	-0.2 -0.7, 0.3	.599	-0.1 -0.6, 0.4	.839	-0.1 -0.6, 0.5
Q-LES-Q-SF (overall satisfaction)	17	3.2 (0.7)	16	3.3 (1.1)	17	3.5 (0.8)	.718	0.1 -0.6, 0.4	.083	-0.4 -1.0, 0.1	.173	-0.4 -0.9, 0.2

### *Statistical Analysis*

Participants' mean proportion of positive interactions was lower at T3 than at T1 and T2. Due to the decrease in the proportions of positive interactions a small positive effect size was found between T1 and T3 ( $d=0.3$ ) and a medium positive effect was found between T2 and T3 ( $d=0.5$ ). The mean proportion of participants' negative interactions increased across the three time-points with medium negative effects observed between T1 and T3 and T2 and T3 ( $d=-0.3$ ).

Participants' mean scores on the BSI-18 Global Severity index decreased between T1 and T2 and increased between T2 and T3. A medium negative effect observed between T2 and T3 ( $d=-0.4$ ). However, the T3 mean score was lower than T1 and a small positive effect size was observed between the time-points ( $d=0.1$ ).

Participants mean scores on the BSI Somatisation increased over time with a medium negative effect observed between T1 and T3 and T2 and T3 ( $d=-0.5$ ). There was a statistically significant change between T1 and T3 ( $p=.05$ ). Participants mean scores on the BSI Anxiety subscale decreased over time with a small positive effect observed between T1 and T3 ( $d=-0.2$ ). T3 scores were similar to T2, therefore no effect size was observed. Participants' mean scores on the GSI Depression subscale decreased between T1 and T2 and increased between T2 and T3. A medium negative effect was found between T2 and T3 ( $d=-0.5$ ). However, at T3 scores were similar to T1.

The mean T scores for the Q-LES-Q-SF measure decreased between T1 and T2 and increased between T2 and T3. However, the T3 mean score remained lower than the T1 time-point and a small positive effect size was present ( $d=0.1$ ). Participants mean scores on the overall quality of life measure and the medication satisfaction measure increased over time. These increases lead to moderate negative effects between T1 and T3 and T2

and T3 ( $d = -0.4$ ) on overall life satisfaction. Small negative effect sizes were observed between all time-points on the medication satisfaction measure.

An additional analysis was conducted on all 22 participants including those whose children were outwith the age range of Mellow Babies. The results of this analysis can be seen in Appendix 5.

### ***Power calculation***

Due to the small sample size and lack of meaningful effects at the follow-up time-point, this study reflects the need to be cautious in designing sufficiently powered future large scale studies. Also, the attrition rates in this study may not be representative of research within this area (see Discussion).

The current study will consider the effect sizes for Mellow Parenting interventions that were observed in a systematic review and meta-analysis (Macbeth et al., 2015). Moderate positive effect sizes were found for maternal mental health and child behavioural difficulties at post-intervention. Attrition rates for long-term follow-up assessment vary considerably across previous research and few studies have assessed past 12-months post-intervention (Rayce et al., 2017). Due to this, the current study will retain its pre-specified attrition rate of 25%. This study provides useful information about the number of participants with children over 19 months old who are included in Mellow Babies. At the AIM Project baseline time-point 11% (7 out of 66) of the participants did not meet Mellow Babies criteria due to having a child over 19 months old.

An a priori power analysis was conducted on G\*Power 3.1.9.4 (Faul et al, 2007) using the above information and assuming 80% power and a significance level of .05. It is estimated that a future randomised controlled trial comparing an intervention and

control group across measures of parental mental health or child behavioural difficulties would need to recruit a total of 144 (72 intervention, 72 control) participants at baseline.

## **Discussion**

The current study aimed to assess the feasibility of conducting long-term follow-up research with participants who had previously taken part in the AIM Project. The study successfully conducted an 18-month follow-up assessment on 22 out of a possible 60 (37%) participants who consented to take part in follow-up research at T1 and did not meet the aim of 45 participants. Although attrition rates with vulnerable parents is usually high (Brown et al., 2012), this rate is higher than previous research with similar populations (Gustavson et al., 2012). However, the majority of participants who were approached agreed to take part in the study. The study found that older parents were more likely to engage in the follow-up research and the majority of the parents of older children (71%) took part. The biggest barrier to recruitment appeared to be a lack of up to date contact details for participants. Additionally, a follow-up assessment had not been funded at the time of intervention which meant that the facilitators and participants had not expected to be contacted again. This led to delays and difficulties engaging some of the facilitators and some did not have the capacity to contact participants on more than one occasion.

Contextual factors within the site locality may have impacted on the follow-up recruitment rates. In the months preceding the implementation of this study, significant changes were made to the provision of parenting and children's services in the region. Due to increased demand for one-to-one interventions, family support workers experienced a change in job role and responsibilities, which led to significant increased demands and less capacity to engage in the research.

Of the 13 group facilitators, two were on long-term sick leave, two had moved out of locality and two did not engage with the researcher (i.e., did not respond to email/phone messages). The remaining facilitators made first contact with participants, which led to varied engagement. It was the impression of the research team that facilitator-participant relationship was the biggest predictor of follow-up recruitment. Those who were referred into the AIM Project by a facilitator were more likely to continue a relationship with them; either through remaining on their caseload (e.g., support work) or through continued ad hoc support. Although this relationship might not be replicable in future studies, it highlights the importance of relationships in promoting participant retention in long-term research.

Participants who are at high risk of problem behaviours such as drug use or anti-social behaviour are more difficult to retain in long-term studies (Cotter, Burke, Stouthamer-Loeber, & Loeber, 2005). As these participants are commonly found in parenting intervention research, an understanding of the characteristics of individuals who drop out of long-term research can help future studies to develop a robust participant retention strategy from the outset which could include; service-user involvement in the design phase; adequate compensation for participant time and efforts; consistency of research staff across all time-points; creation of a study identity through the use of a memorable name and logo; regular research meetings to monitor and problem solve barriers to retention; and enhancement of participants' role as a collaborating contributor to society through the use of thoughtful gestures such as birthday cards and non-monetary incentives. (Abshire et al., 2017; Hill et al, 2017).

In the current study, facilitators did not have contact details for 17% of participants and 29% of those contacted did not respond to the facilitator. Therefore, it is crucial that a future trial develops strategies to monitor participant movement over



time. Hill et al. (2017) recommends using up to three reliable “locator contacts” such as a parent, sibling or close friend and anticipating additional funding to travel to participants who have moved out of the area or for purchasing mobile phones that can accommodate appropriate media platforms for communicating with participants.

The main outcome of this study was to explore the number of AIM Project participants who engaged in follow-up data collection. Therefore, it was important to include all AIM Project participants, including those whose children were outwith the specified age range. It is common practice in real world implementation of parenting interventions to include parents who don't meet the specific criteria (Niccols, 2008). Mellow Babies often requires facilitators to include parents with children over 19 months in order to be able to run a group economically and offer support to the target parents. These parents can access the peer support within the group and partake in group discussions, and the programme has adapted to allow facilitators to tailor group content according to the parents' needs. However, there is currently no research into whether or not this is of benefit to these parents. It is likely that future research into the Mellow Babies intervention, if adopting a real-world approach, would include parents of children over 19 months and it may be beneficial to explore whether or not participation has any benefits for these parents.

The researcher had planned to attend the Mellow Babies reunion lunch, which is arranged as part of Mellow Parenting practice, a few months post group. However, this did not coincide with the timeline of the study. This might have removed some of the burden of engaging parents from group facilitators as they could have approached multiple participants at one time. Future researchers could arrange to attend these lunches as part of their recruitment strategy. Additional lunches could also be used to

promote participant retention by breaking up the gap between data collection time-points.

This study included two participants who were seen outwith both 12 week recruitment periods in the analysis. This was due to a delay in ethical approval and difficulty scheduling an appointment with one participant. The recruitment windows were set as flexible guides in order to inform appropriate data collection windows for future research. A 12-week time frame is recommended for a future large scale trial as it captured the majority of the participants.

The time-frame of the 18-month follow-up was chosen in order to capture the majority of the participants when their children were approximately 2-3 years old. As the AIM Project was already underway when the opportunity to conduct this follow-up study arose it was not possible to incorporate follow-up prior to 18 months. However, assessment at this timeframe can capture important social-emotional, cognitive and language milestones and this period has been used in previous research (Fearon & Belsky, 2011; Hiscock et al, 2010). Long-term follow-up at six and 12 months is also common (Gross et al, 2003; Perrin et al, 2014; Muñoz et al, 2007). This allows for close monitoring of post-intervention outcomes as well as maintaining contact with participants which may encourage study retention. In light of this, the current study suggests possible benefits of completing follow-up at six months, 12 months and 18 months post intervention. It may also be beneficial to access routine data collected at the 27-30 month Child health surveillance visit (conducted by health visitors in Scotland) in order to further assess children's socio-emotional and language development.

The present study would have been strengthened by the inclusion of qualitative interviews. The MRC guidelines for complex interventions recommends that feasibility studies should include both quantitative and qualitative methods in order to understand

barriers to recruitment and estimate response rates (Craig et al., 2013). As the current study experienced challenges to recruitment, an understanding of the participants' or facilitators' personal experiences of taking part in the study and their journey from post intervention to long-term follow-up would have been beneficial. As the majority of the participants (95%) would be willing in principle to take part in a future interview on their experiences of participation in Mellow Babies, it is recommended that future feasibility studies ensure that adequate resource is included to allow a robust qualitative component.

The AIM Project was not designed for a long-term follow-up and was not powered to assess the long-term efficacy of the intervention. The aim to explore the impact of the intervention on outcomes for parents and their children was dependent on the number of participants who engaged in the long-term follow-up. The current study also had a low sample size that may not be representative of Mellow Babies target population. Therefore, inferences should not be made on the findings from the outcome measure analysis. A moderate negative effect size was found on participants' depression scores at T3 when compared to T2. However, participant scores at both time-points were below the cut-off (score of 63 or above) in the BSI-18 measure (Derogatis, 2000) and were not considered a clinical risk for depression. It is important to note that the proportion of negative interactions increase across the three time-points and proportions of positive interactions are lower at T3 than at T1. These changes are not considered to be clinically significant and are normal changes that are commonly observed in parent-child interactions as the child increases in age. Similar patterns have been observed in previous research (Gross et al., 2003; Tucker et al., 1998). This analysis would benefit from a control group, who did not receive the intervention, in order to show differences between the two groups at the follow-up time-point. There were small positive effect

sizes observed at the T3 time-point when compared to T1 on measures of global psychological severity and anxiety. Participants' scores on the depression measure return to baseline at the T3 time-point after a reduction at T2. Although there was a reduction in global psychological severity at T3, participants' scores on the somatisation subscale increased overtime and medium negative effects were observed between all time-points. Small positive effect sizes were observed between T1 and T3 on participants' quality of life scores. However, due to the limitations mentioned previously, it is not possible to make inferences based on these changes and a larger sample of participants is necessary in order to undertake an adequately powered analysis into whether or not these changes are due to a treatment effect.

An additional exploratory analysis was conducted including parents of children over 19 months old as there is currently no known research on the benefits of Mellow Babies for this group. As observed in the main analysis, negative interactions increased over time and positive interactions were lower at T3 than at T1. Minimal positive changes in scores can be seen at T3 when compared to T1 on measures of global psychological severity, anxiety and quality of life. Participants' also reported increased overall quality of life at T3 when compared to T1. Again, inferences cannot be made on these findings due to the small sample size, lack of control group and lack of power for follow-up analysis.

### ***Missing Data***

There were missing data in the main outcome analysis at each time-point of the study. There were only 12 complete data sets for the analysis of the video data. This was due to some participants declining the video or to a lack of opportunity to complete the

video within the target time-frame. One participant did not complete T2 data collection, which resulted in 16 complete data-sets for the participant-reported outcome measures.

### ***Limitations***

This feasibility study has several limitations. The attrition rates for this study may not be an accurate representation of participant dropout rate at follow-up for Mellow Babies due to the changes in service provision that coincided with data collection. Although, chosen for pragmatic reasons the single study site greatly reduced the number of potential parents available for recruitment. An AIM Project follow-up component was not planned in advance, which impacted on group facilitator engagement and meant the study was not formally powered to assess the long-term treatment effects of Mellow Babies. It had a small sample size, which may not have been representative of Mellow Babies target population. Also, the AIM Project did not include a control group which meant that long-term follow-up data could only be provided for parents who received Mellow Babies.

Another limitation of this study is that video recordings were conducted by group facilitators at T1 and T2 and by the researcher at T3. Participants had no prior relationship with the researcher, which may have affected the quality of the video data. For consistency, facilitators could record all videos in future studies. However, this may not be possible due to staff leave and turnover.

### ***Future directions***

The current study makes an important contribution to the research into parenting interventions with vulnerable populations. As there is a paucity of long-term data on parenting interventions, it aimed to assess the feasibility and acceptability of conducting

a long-term follow-up of Mellow Babies. The study successfully conducted follow-up data collection with the majority of participants who were contacted by facilitators, however it did not meet its recruitment target of 45 participants. If possible, future studies should extend recruitment to multiple sites in order to increase chances of recruitment. Future studies that have the funding and capacity to conduct follow-up data collection should set this expectation from the beginning and employ the pragmatic retention strategies outlined previously, where possible.

Findings from the outcome measure analysis of this study must be interpreted with caution due to the aforementioned limitations. Further long-term research is necessary in order to continue to explore the impact of Mellow Babies on child and parental outcomes. It is recommended that a future large trial should incorporate an internal pilot/feasibility phase in keeping with complex intervention guidelines (Craig et al., 2013)

This study highlights the complexity of conducting research within real-world settings where uncontrollable factors can lead to delays and disruptions to study procedures. It also highlights the practical difficulties that arise when conducting a long-term follow-up with a vulnerable population and makes recommendations to overcome these where possible. With the appropriate funding and resources, long-term research within this area could reap positive rewards and improve early intervention services for parents and their children.

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*Updated 27-03-2019*

## Appendix 2: Medline search strategy

Table 1. Medline search strategy

Line	Searches
1	exp Infant/
2	(baby or babies or child\$ or toddler\$ OR infant\$ or preschool\$ or pre-school\$).tw.
3	Child, Preschool/
4	Child/
5	1 OR 2 OR 3 OR 4
6	(parent\$ adj1 component\$).tw.
7	(parent\$ adj1 course\$).tw.
8	(parent\$ adj1 education\$).tw.
9	(parent\$ adj1 intervention\$).tw.
10	(parent\$ adj1 group\$).tw.
11	(parent\$ adj1 positive).tw.
12	(parent\$ adj1 program\$).tw.
13	(parent\$ adj1 promotion).tw.
14	(parent\$ adj1 training).tw.
15	(parent\$ adj1 training).tw.
16	(parent\$ adj1 support\$).tw.
17	prevent\$ intervention\$.tw.
18	Group-based parent training program\$.tw.
19	parent-child relations/
20	father-child relations/
21	mother-child relations/
22	parenting/
23	6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22
24	randomi?ed controlled trial.pt.
25	controlled clinical trial.pt.
26	randomi?ed.ab.
27	clinical trials as topic.sh.
28	randomly.ab.
29	trial.ti.
30	24 OR 25 OR 26 OR 27 OR 28 OR 29
31	exp animals/ not humans.sh.

32	30 not 31
33	(long term or long-term or follow-up or follow up or longitudinal).tw.
34	Follow-up Studies/
35	Treatment Outcome/
36	33 OR 34 OR 35
37	5 AND 23 AND 32 AND 36

### Appendix 3: Cochrane Risk of Bias tables and synthesis of risk across domains

Table 1: Gridley et al, 2015

Bias	Judgement	Support for Judgement
Random sequence generation (selection bias)	Low risk	An independent statistician using computer-generated randomisation conducted group assignment.
Allocation concealment (selection bias)	Low risk	Researchers were blind to participant assignment throughout the trial. Parents were asked not to inform researchers of their allocation throughout data collection.
Blinding of participants and personnel (performance bias)	High risk	It was not possible to blind participants from their allocation as they would have been aware of the group they were assigned to due to their active participation. Personnel who delivered the interventions were also aware of participant allocation.
Blinding of outcome assessment (detection bias) (patient-reported outcomes)	Low risk	This study did not include patient reported outcomes.
Blinding of outcome assessment (detection bias)	Low risk	Researchers, who were blind to the participants'

(independent observer-reported outcomes)		<p>group allocation, rated the video data.</p> <p>Inter-rater reliability was conducted on 28 of the videos at the pre and post time-point. Inter-rater reliability was reported as good.</p> <p>Due to time and financial constraints only 15minutes of each 30 minute video was transcribed. However, it is stated that the transcriptions give a detailed and accurate record of the interaction.</p>
Incomplete outcome data addressed (attrition bias)	Low risk	<p>27% (16 out of 60) of the intervention group did not complete the 6 month follow-up</p> <p>20% (6 out of 29) of the control group did not complete the 6 month follow-up.</p> <p>The two fathers included in the study were assigned to the intervention group and declined to participate. Apart from this there were no statistically significant differences between those lost to attrition and those retained.</p>

Selective reporting (reporting bias)	Low risk	Results were reported for all measures that were outlined in the paper.
Other bias	Low risk	No other risk of bias identified.

Table 2: Gross et al, 2003

Bias	Judgement	Support for Judgement
Random sequence generation (selection bias)	Unclear risk	The paper reports that participants were randomly assigned to an intervention group and a control group. However, no information reported on how random assignment of participants was conducted.
Allocation concealment (selection bias)	Unclear risk	No information reported on concealment of allocation.
Blinding of participants and personnel (performance bias)	High risk	It was not possible to blind participants from their allocation as they would have been aware of the group they were assigned to due to their active participation. Personnel who delivered the interventions were also aware of participant allocation.
Blinding of outcome assessment (detection)	High risk	Parents and teachers participated in the intervention and then



bias) (patient-reported outcomes)		completed self-reports which may have resulted in bias.
Blinding of outcome assessment (detection bias) (independent rater - reported outcomes)	Low risk	The observational outcome was coded by trained assessors who were blind to study hypotheses and participant's group assignment
Incomplete outcome data addressed (attrition bias)	Unclear risk	The study reported no significant differences between the teachers who dropped out of the study and those who remained. Parents who dropped out of the study had significantly lower overactive discipline scores than those who remained, which suggested that dropouts were less likely to use harsh and coercive discipline strategies. Parents who dropped out and remained were similar across all other measures.
Selective reporting (reporting bias)	Low risk	Results were reported for all measures that were outlined in the paper.
Other risk	High risk	As a cluster randomised controlled trial this paper should have reported

		<p>intraclass correlation coefficient (ICC) in order to describe how strongly units in the same group resembled each other.</p> <p>Also, it is not clear if this study used an intention to treat analysis or not.</p> <p>The paper reported that parents who remained in the study were more likely to be Latino.</p>
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Table 3: Hackworth et al, 2017

Bias	Judgement	Support for Judgement
Random sequence generation (selection bias)	Low risk	The paper states that allocation of locations was stratified by local government area using block randomisation.
Allocation concealment (selection bias)	Low risk	In order to conceal allocation a researcher who was unaware of the location identities conducted the block randomisation. This researcher was not involved in recruitment. Locations were allocated in the order that they

		<p>were consented, in batches using fixed block sizes of a multiple of 3.</p> <p>Inter-rater reliability on 20% of the videos was 87.4%.</p>
Blinding of participants and personnel (performance bias)	High risk	<p>It was not possible to blind participants from their allocation as they would have been aware of the group they were assigned to due to their active participation. Personnel who delivered the interventions were also aware of participant allocation.</p>
Blinding of outcome assessment (detection bias) (patient-reported outcomes)	High risk	<p>Parents completed self-report measures. They may have known if they were taking part in an intervention as the control group received no intervention.</p>
Blinding of outcome assessment (detection bias) (independent-reported outcomes)	Low risk	<p>The CATI interviews were conducted by independent staff who were blind to participants' group allocation.</p> <p>Videos were recorded by study researchers.</p> <p>However the paper states that</p>

		<p>“coding using a standardised protocol was undertaken by two independent, accredited, post-graduate research assistants at the University of Kansas under the supervision of the research scientist who developed the method”</p>
Incomplete outcome data addressed (attrition bias)	Low risk	<p>Attrition rates and missing data was described and reported for all groups in each trial.</p> <p>Missing data was minimal and appeared to be balances across the assessment time-points.</p>
Selective reporting (reporting bias)	Low risk	<p>Results were reported for all measures that were outlined in the paper.</p>
Other bias	Unclear risk	<p>20% of observational data was randomly selected to be coded due to financial constraints. Some of this sample could not be coded due to poor video quality or non-English words spoken. Final sample size for video data is not reported.</p>

		Also, parent age ranges were not reported. The paper reported percentages of parents under the age of 25 years old but no other ranges.
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Table 4: Hiscock et al, 2008, Bayer et al, 2009

Bias	Judgement	Support for Judgement
Random sequence generation (selection bias)	Low risk	Cluster randomisation performed by independent statistician using a computer generated allocation sequence.
Allocation concealment (selection bias)	Low risk	An independent statistician performed randomisation.
Blinding of participants and personnel (performance bias)	High risk	Group allocation was concealed from participants and researchers until after allocation was complete. However, there is no further information given on participants. It does not seem possible that parents could remain blinded as they received either the intervention or usual care. Personnel delivering the groups would have been aware of the participants' group allocation.

Blinding of outcome assessment (detection bias) (patient-reported outcomes)	High risk	Mothers completed all outcomes. Mothers may have known if they were taking part in the target intervention as the control group received no intervention.
Blinding of outcome assessment (detection bias) (independent observer-reported outcomes)	Low risk	No independent observer reported outcomes.
Incomplete outcome data addressed (attrition bias)	Low risk	<p>9% of the intervention group and 7% of the control group were lost to follow-up at the 18-month assessment.</p> <p>11% of the intervention group and 10% of the control group were lost to follow-up at the 24-month assessment.</p> <p>21% of the intervention group and 18% of the control group were lost to follow-up at the 3-year assessment.</p> <p>All parents lost to follow-up failed to return questionnaires. No further information given on reasons for this.</p>

Selective reporting (reporting bias)	Low risk	Results were reported for all measures that were outlined in the paper. Child temperament was measured at the 18-month and 24-month follow-up but not at the 3 year follow-up. There is no justification given for this.
Other bias	Low risk	No other risk of bias identified.

Table 5: Muñoz et al, 2007

Bias	Judgement	Support for Judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation was conducted using a blocked randomization procedure. There was no other information given on randomisation so a clear judgement could not be made. It was stated that women in the intervention and control conditions did not differ statistically on baseline characteristics.
Allocation concealment (selection bias)	Unclear risk	The paper states that “Neither participant nor interviewer knew the result of the random assignment until a sealed envelope was opened”. There is

		insufficient information to make a definite judgement or risk as it was not reported if envelopes were sequentially numbered, opaque and sealed.
Blinding of participants and personnel (performance bias)	High risk	It was not possible to blind participants from their allocation, as they would have been aware of the group they were assigned to due to their active participation. Personnel who delivered the interventions were also aware of participant allocation.
Blinding of outcome assessment (detection bias) (patient-reported outcomes)	High risk	Mothers completed self-report questionnaires. Mothers were aware of their group allocation.
Blinding of outcome assessment (detection bias) (independent observer-reported outcomes)	Low risk	There were no independent-rater reported outcomes
Incomplete outcome data addressed (attrition bias)	Unclear risk	There was a 9% attrition rate reported in this study at 1-year follow-up. It is not clear if they were in the intervention group or the control, however it appears to be from the intervention group.



		<p>6-month attrition rate was not reported.</p> <p>Missing data not addressed.</p>
Selective reporting (reporting bias)	Low risk	Results were reported for all measures that were outlined in the paper.
Other bias	Unclear risk	<p>The paper states that 70% of the population were Spanish speaking and that the study recruited bilingual researchers “to the degree possible”. A lack of bilingual researchers may have biased recruitment to the study. This is unclear. Not specified if it is per protocol or intention to treat analysis.</p> <p>Participants completed on average 7 out of the 12 sessions. “To address this limitation, if a participant was not able to attend a class session, one of the instructors would review the materials with her over the phone”. It is unclear if this is programme protocol or not.</p>

Table 6: Niccols, 2008

Bias	Judgement	Support for Judgement
Random sequence generation (selection bias)	Low risk	The random number table was used for random assignment. Those with numbers 0,1,2,3,4,5 were assigned to the intervention and those with 6,7,8,9 were assigned to home visiting.
Allocation concealment (selection bias)	Low risk	The research assistants who conducted the outcome measures at all time-points were blind to the group assignment and method of randomisation.
Blinding of participants and personnel (performance bias)	High risk	It was not possible to blind participants from their allocation as they would have been aware of the group they were assigned to due to their active participation. Personnel who delivered the interventions were also aware of participant allocation.
Blinding of outcome assessment (detection bias) Independent observer reported outcomes	Low risk	Research assistants completed all outcome measures. They were blind to group allocation during data collection at all time-

		points. However, there is no information provided on procedures if an assistant becomes unblinded to group allocation.
Blinding of outcome assessment (detection bias) (patient-reported outcomes)	Low risk	No patient reported outcomes
Incomplete outcome data addressed (attrition bias)	unclear risk	<p>For the primary outcome (Attachment security) only participants with a child over 9 months could be included. This meant only 28 out of 76 (37%) participants were included.</p> <p>Of the 76 mothers randomised 73 (96%) completed the post-intervention assessment. 64 out of 76 (84%) completed the 6 month follow-up assessment. Those who withdrew from the study prior to follow-up did not differ from the participants included in the assessment in terms of demographics.</p> <p>3 out of 28 (11%) mothers randomly assigned to the</p>

		<p>home visiting group and 20 out of 48 (42%) of the mothers assigned to the intervention group did not attend.</p> <p>All non-attenders were included in the intention to treat analysis.</p>
Selective reporting (reporting bias)	Low risk	Results were reported for all measures that were outlined in the paper.
Other risk	Low risk	No other risk of bias identified

Table 7: Perrin et al, 2014

Bias	Judgement	Support for Judgement
Random sequence generation (selection bias)	Unclear risk	<p>Randomisation was conducted using a random number generator.</p> <p>However, due to participant drop out a third non-randomised intervention group was created in order to increase the number of parents receiving the intervention.</p> <p>The paper states that “families from practices in the NR-PTG condition were more likely to report minority race/</p>

		ethnicity, lower levels of education and family income, and being a single parent”
Allocation concealment (selection bias)	Low risk	This is not outlined in the paper. However, further information obtained from the authors by Barlow et al (2016) states that the group assignment was communicated directly to clinicians, who then informed parents.
Blinding of participants and personnel (performance bias)	High risk	It was not possible to blind participants from their allocation as they would have been aware of the group they were assigned to due to their active participation. Personnel who delivered the interventions were also aware of participant allocation.
Blinding of outcome assessment (detection bias) (patient-reported outcomes)	High risk	Parents completed self-report measures. Parents were not blind to their group assignment.
Blinding of outcome assessment (detection bias) (Independent observer reported outcomes)	Low risk	Observers that were blind to participant group assignment completed the

		Dyadic Parent-Child Interaction Coding System.
Incomplete outcome data addressed (attrition bias)	Low risk	19% of the Intervention group were lost To follow-up. 18% of the control group Were lost to follow-up 41% of the non-randomised Intervention group were lost To follow-up. It is not specified if this was at 6 months or 12 months. The authors reported that data were missing “at random” across the study with several baseline variables missing.
Selective reporting (reporting bias)	Low risk	Results were reported for all measures that were outlined in the paper.
Other bias	Low risk	No other risks of bias were identified

Table 8: Tucker et al, 1998

Bias	Judgement	Support for Judgement
Random sequence generation (selection bias)	Unclear risk	The paper reports that participants were randomly assigned to an intervention group and a control group. However, no information is given on how

		<p>randomisation was carried out.</p> <p>A third comparison group of intervention ‘drop-outs’ were combined with the control group as there were minimal pre-intervention differences found between the groups.</p>
Allocation concealment (selection bias)	Unclear risk	There was no sufficient information reported to make a clear judgement on this.
Blinding of participants and personnel (performance bias)	High risk	It was not possible to blind participants from their allocation as they would have been aware of the group they were assigned to due to their active participation. Personnel who delivered the interventions were also aware of participant allocation.
Blinding of outcome assessment (detection bias) (patient-reported outcomes)	High risk	Parents completed the Eyberg Child Behavioural Inventory and the Toddler Temperament Scale. Parents were not blind to their group assignment.
Blinding of outcome assessment (detection bias)	Low risk	Observers that were blind to participant group assignment completed the

(independent observer-reported outcomes)		Dyadic Parent-Child Interaction Coding System.
Incomplete outcome data addressed (attrition bias)	Unclear risk	There were data reported for 12 children from the intervention group in this paper. However, the original paper Gross et al (1995) reported data for 11 children from the intervention group. It is unclear why there is a difference in this numbers between the two studies.
Selective reporting (reporting bias)	Low risk	Results were reported for all measures that were outlined in the paper.
Other bias	Low risk	No other risks of bias were identified.

### *Risk within studies*

A synthesis of risk domains is outlined below.

#### *Random sequence generation*

Three out of the eight studies were assigned unclear risk of bias for this domain (Gross et al., 2003; Muñoz et al., 2007; Tucker et al., 1998). This was due to insufficient information provided on the generation of the randomisation. The rest of the studies were deemed low risk as sufficient information was provided to make a clear judgement.

#### *Allocation concealment*

Three out of the eight studies were assigned unclear risk of bias for this domain (Gross et al., 2003; Muñoz et al., 2007; Tucker et al., 1998). This was due to little or no



information being provided on this domain. All other studies provided adequate evidence to be judged as low risk.

#### *Blinding of participants and personal*

All of the studies were assigned as high risk for this domain. However, the Cochrane manual (Higgins and Green, 2011) recognises that many studies cannot blind participants to their group allocation and that not all that do can be described as low quality. With parenting interventions, it is very difficult to blind participants to their allocation due to their active participation in the group. Studies who used another intervention as a comparison group did not specify if participants were blind to the target intervention.

#### *Blinding of outcome assessment- patient report*

Two out of the eight studies did not use parent-report measures and were deemed low risk in this domain (Gridley et al., 2015; Niccols, 2008). All other papers used parent, or in one case teacher, report measures and were deemed as having a high risk of bias within this domain. Patient report measures are commonly used in healthcare and psychological research however they can lead to response bias due to a lack of understanding of the measurement, ‘social-desirability bias’, where the participant wants to look good even in anonymous questionnaires and ‘response-shift bias’ where the participant recalibrates their understanding of the measure between assessment time-points (L. G. Hill, 2014).

#### *Blinding of outcome assessment- independent-rater reported*

Two out of the eight studies did not include independent-observer rated outcome measures (Bayer et al., 2010; Hiscock et al., 2008; Muñoz et al., 2007). All other studies were deemed as low risk within this domain as they included outcome measures rated by independent observers who were blind to the participants’ group allocation.

#### *Incomplete outcomes data*

Four out of the eight studies were deemed as unclear risk within this area. One follow-up study reported different participant numbers in the intervention group to the original study and did not explain the rationale for this (Bayer et al., 2010). Another study could only provide outcome data on an attachment measure for infants over nine months old (Niccols, 2008). Attrition rates were not adequately reported for another paper which

made it difficult to assign a judgement of bias (Muñoz et al., 2007). In another study, participants who dropped out of the study had significantly different lower scores on Active Discipline which may have caused bias in the overall study results (Gross et al., 2003).

#### *Selective reporting*

All studies were deemed as low risk in this domain as they included all pre-specified outcomes.

#### *Other bias*

One study was deemed as high risk in this area (Gross et al., 2003) as it did not report intraclass correlation coefficients (ICC) which would give an indication of how strongly individuals within the same group resemble each other. All other cluster randomised controlled trials reported ICC. Two studies were deemed as unclear risk within this domain. One study contacted participants who did not attend sessions for catch-up phone calls which was not specified as part of the intervention (Muñoz et al., 2007). This study provided ambiguous information around appropriateness of researchers for recruiting Spanish speaking parents. The paper did not specify if the analysis was per protocol or intention to treat. Another study did not provide a clear description of the analysis of video data (Hackworth et al., 2017). A final sample size for this outcome was not reported. This study provided unclear information about the age ranges of participants, only reporting the percentages of mothers who were under 25 years old.

**Appendix 4: University of Glasgow Medical and Veterinary and Life  
Sciences letter of ethical approval**



**30/08/2018**

**MVLS College Ethics Committee**

***Project Title: 'Life after Mellow'- An exploration of the feasibility and acceptability of long-term follow-up methods for the Mellow Babies intervention***

***Project No: 200170179***

Dear Dr Thompson,

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project.

- Project end date: End July 2019
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research:  
([http://www.gla.ac.uk/media/media\\_227599\\_en.pdf](http://www.gla.ac.uk/media/media_227599_en.pdf))
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely,

Jesse Dawson

MD, BSc (Hons), FRCP, FESO  
Professor of Stroke Medicine  
Consultant Physician  
Clinical Lead Scottish Stroke Research Network / NRS Stroke Research Champion  
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## Appendix 5: Analysis of all study participants who consented to follow-up

Table.1: Scores of all participants who consented to the follow-up study on all standardised measures at T1, T2 and T3

Measure	T1		T2		T3		T1-T2		T1-T3		T2-T3	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	P-value	Effect size (CI lower, CI upper)	P-value	Effect size (CI lower, CI upper)	P-value	Effect size (CI lower, CI upper)
CARO: Proportion of positive interactions	14	0.70 (0.29)	14	0.76 (0.19)	15	0.65 (0.23)	.337	-0.3 -0.9, 0.3	.486	0.2 -0.4, 0.8	.124	0.4 -0.1, 1.0
CARO: Proportion of negative interactions	14	0.06 (0.13)	14	0.07 (0.09)	15	0.11 (0.14)	.763	-0.1 -0.7, 0.5	.266	-0.3 -0.9, 0.3	.267	-0.3 -0.9, 0.3
BSI-18 GSI T Score	22	57.1 (10.1)	21	53.9 (11.2)	22	55.3 (12.5)	.069	0.4 0.0, 0.9	.492	0.1 -0.3, 0.6	.199	-0.3 -0.7, 0.2
BSI-18 Somatisation T Score	22	50.9 (11.5)	21	51.4 (11.5)	21	53 (11.6)	.949	0.0 -0.5, 0.4	.131	-0.3 -0.8, 0.1	.176	-0.3 -0.8, 0.2
BSI-18 Anxiety T Score	22	56.4 (12.4)	21	53.7 (12.5)	22	54 (13.6)	.241	0.3 -0.2, 0.7	.287	0.2 -0.2, 0.7	.669	-0.1 -0.5, 0.4
BSI-18 Depression T Score	22	57.2 (11.2)	21	53.5 (10.4)	22	57.7 (11.1)	.05	0.4 0.0, 0.9	.838	0.0 -0.5, 0.4	.014	-0.6 -1.0, -0.1

Measure	T1		T2		T3		T1-T2		T1-T3		T2-T3	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	P-value	Effect size (CI lower, CI upper)	P-value	Effect size (CI lower, CI upper)	P-value	Effect size (CI lower, CI upper)
Q-LES-Q-SF T score	22	59.6 (11.3)	21	59.5 (15.5)	22	60 (15.8)	.732	-0.1 -0.5, 0.4	.843	0.0 -0.5, 0.4	1.00	0.0 -0.5, 0.5
Q-LES-Q-SF (medication)	22	2 (2)	21	2.2 (1.9)	22	1.9 (1.6)	.419	-0.2 -0.6, 0.3	.853	0.0 -0.4, 0.5	.649	0.1 -0.4, 0.6
Q-LES-Q-SF (overall satisfaction)	21	3.2 (0.7)	21	3.4 (1)	22	3.6 (0.8)	.214	-0.3 -0.8, 0.2	.02	-0.5 -1.0, -0.1	.329	-0.2 -0.7, 0.2

### *Statistical Analysis*

This analysis found similar results to the main outcome analysis. Participants mean proportion of positive interactions are lower at T3 than at T1 with a small positive effect size observed ( $d = 0.2$ ). Participants mean proportion of negative interactions increase across the three time-points with a small negative effect size observed between T1 and T3 and T2 and T3 ( $d = -0.3$ ).

Participants' mean scores on the Global Severity Index reduced between T1 and T2 but increased between T2 and T3. A small negative effect size was observed between T2 and T3 ( $d = -0.3$ ). Participants' scores on Anxiety subscale were lower at T3 when compared to T1 with a small positive effect size observed between the two time-points ( $d = 0.2$ ). As in the main analysis participants' scores on the Somatisation subscale increased across the three time-points with a small negative effect size observed between both T2 and T3 and T1 and T3 ( $d = -0.3$ ).

Participants' scores on the BSI-18 Depression subscale returned to T1 levels at T3. This result was also found in the main analysis. A medium negative effect size was found between T2 and T3 ( $d = -0.6$ ). This increase in scores was statistically significant ( $p = .01$ ).

Participants' scores on the quality of life measure remained stable across the three time-points. Participants' overall satisfaction increased across the three time-points. This increase resulted in a small negative effect size between T2 and T3 ( $d = -0.2$ ) and a moderate negative effect size between T1 and T3 ( $d = -0.5$ ). The increase in scores between T1 and T3 was statistically significant ( $p = .02$ ). Participants mean medication satisfaction scores increased between T1 and T3 but returned to T1 level at T3.

## Appendix 6: Participant Information Sheet



### PARTICIPANT INFORMATION SHEET

#### Study title

‘Life after Mellow’- An exploration of the feasibility and acceptability of long-term follow-up methods for the Mellow Babies intervention

#### Invitation

You are being invited to take part in a research study. Before you decide, please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. If you decide to take part in this study, you will be given a copy of this Participant Information Sheet and a signed consent form to keep.

#### What is the purpose of the study?

This study is being undertaken by a student in Clinical Psychology at the University of Glasgow as part of their doctorate qualification. The purpose of this study is to find out if parents who have taken part in the Mellow Babies group as part of the AIM project would be interested in taking part in more research to see if there are any long-term benefits for them and their babies.

At the moment there is no research that we are aware of on the benefits that parenting groups have over time on parents and their children. We aim to find out if it is possible to carry out a research project with parents 18 months after they started the Mellow Babies group.

We will look at parents’ mental health, their quality of life and their relationship with their baby and compare this to how they were before and after taking part in Mellow Babies.

#### Why have I been invited to participate?



You have been invited to take part in this study because you took part in the AIM Project and you agreed to be contacted for any future research on Mellow Babies.

### **Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you do decide to take part, you are free to change your mind at any time and without giving a reason. If you decide not to take part this will not change your relationship with the Mellow Babies group facilitators.

### **What will happen if I take part?**

If you decide to take part a researcher will arrange to meet with you in your home or a place of your choice. The place should be somewhere where you feel comfortable and are used to being with your baby. The researcher will chat to you about the study and ask you to sign a consent form if you agree to take part. She will then ask you to complete the same questionnaires and video recording that you completed during the AIM Project. This includes three things:

1. A questionnaire on your mental health and well-being.
2. A questionnaire on your quality of life.
3. A video recording of you interacting with your baby in order to look at the quality of the relationship between you and your baby.

Total time: approximately 35 minutes

You do not have to agree to do all three things. It is ok to do one or two of these things and still take part in the study. Once we are finished, you will be given a £10 Superdrug voucher to cover any travel expenses and as a thank you for your time and effort. We will not ask you for any more information and we will not visit you again.

### **What are the possible risks of taking part?**

You might find it uncomfortable to talk about your mental health and quality of life and to be videoed interacting with your baby. The researcher will make sure that you feel comfortable and they will not ask you to do anything that you do not want to do. If you become upset or distressed the researcher will stop collecting information. We will also make sure you have someone to talk to afterwards if you need to. This could be your Mellow Babies group facilitator or a health professional. We will arrange for everyone to

have the chance to talk to their Mellow Babies group facilitator afterwards if they want to.

**What are the possible benefits of taking part?**

There may be no direct benefit to you from taking part in this study. If you have any concerns about any issues raised during the research, the researcher will be able to advise you on the best person to contact for support. Taking part may have wider benefits to society because it will give us an understanding of any benefits of Mellow Babies to parents and their children over time.

**Will my taking part in this study be kept confidential?**

Yes, All information collected about you during the study will be kept strictly confidential. You will be identified by an ID number, and any information about you will have your name and address removed from it. As the videos will show images of you and your baby they will be stored safely throughout the study and destroyed confidentially once the videos have been analysed. The researchers have a duty of confidentiality to you and they will not discuss your details with anyone who isn't involved in the study. There are some times when we might need to break confidentiality and contact relevant support agencies. We would only do this if we believed that you or someone else were at serious risk of harm. We would always discuss this with you first and encourage you to take the first steps to sharing this information.

**What will happen to my data?**

All individuals involved in this study will collect, store and process all your personal information in line with the General Data Protection Regulation (2018).

All questionnaires will be stored in locked cabinets in rooms with restricted access at the University of Glasgow. All video data will be stored on secure password-protected computers with restricted access. No one outside of the research team or research governance staff will be able to find out your name, or any other information which could identify you.

The data will be stored in line with The University of Glasgow policies for up to 10 years. After this time, your data will be securely destroyed confidentially.

Your data will be used to write a student dissertation. The study may also be published in an academic journal or presented at conferences or talks. Your name will not appear in any publication. The researcher will send you a summary of the results of the study if you would like to receive this. The researcher will also request to keep your anonymous data for future research by the study team. This data will be stored in line with The University of Glasgow data management policy.

**Who is organising and funding the research?**

The study has been organised and funded by the Clinical Psychology doctorate programme at The University of Glasgow. It has also been funded by the Mellow Parenting Research and Development Fund and the Children, Young People and Families Early Intervention Fund.

**Who has reviewed the study?**

The study has been reviewed by the College of Medical, Veterinary & Life Sciences Ethics Committee.

**Contact for Further Information**

Name: Caoimhe Clarke

Position: Study Researcher

Phone number: 07785984358

Email: [c.clarke.2@research.gla.ac.uk](mailto:c.clarke.2@research.gla.ac.uk)

*Thank you for taking the time to read this information sheet*

## Appendix 7: Participant Information leaflet

### What is the purpose of the study?

This study is being undertaken by a doctoral student in Clinical Psychology at the University of Glasgow.

We want to find out if parents who have taken part in the Mellow Babies group as part of the AIM project would be interested in taking part in more research to see if there are any long-term benefits for them and their babies.

At the moment there is no research that we know of on the long-term benefits that parenting groups have on parents and their children.

### Our Aim

To find out if it is possible to carry out a research project with parents 18 months after they started the Mellow Babies group.

To find out if there are any changes to parents' mental health, quality of life and quality of their relationship with their baby 18 months after starting the group.

**Thank you for reading the information sheet.**

**Please get in touch if you have any questions**

Phone: +44 (0)7785 984358

Email: [c.clarke.2@research.gla.ac.uk](mailto:c.clarke.2@research.gla.ac.uk)

If you have a complaint about this research or would like to speak to an independent person please contact:

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## Mellow Babies Research Project

'Life after Mellow'- An exploration of the feasibility and acceptability of long-term follow-up methods for the Mellow Babies intervention



**Information about the study**

## Appendix 7: Participant Information leaflet cont

### Why am I being asked to take part?

You have been invited to take part in this study because when you took part in the AIM Project you agreed to be contacted for any future research on Mellow Babies.

### What will happen if I take part?

A researcher will arrange to meet with you at home. If you consent to take part in the study the researcher will ask you to sign a consent form. She will then ask you to:



Fill out a questionnaire about your mental well-being



Fill out a questionnaire about your quality of life



Be video recorded interacting with your baby for 5 minutes

You only need to do each thing once and on one occasion.

**Total time:** approximately 35minutes



As a thank you for taking part and to cover your travel expenses, the researcher will give you a £10 Superdrug voucher.

### What else do I need to know?



#### What are the risks?

You might find it uncomfortable to take about your mental health. The researcher will stop if you become upset and will not ask you to do anything you don't want to. We will arrange for everyone to have the chance to talk to their group facilitator afterwards if they want to.

#### What are the benefits?

Understanding the impact Mellow Babies has on you and your baby will be very helpful for parents all over the world. We aim to anonymously share this information with other researchers and practitioners.



#### Will be information be confidential?

All information about you will be kept strictly confidential.

Your personal details will be removed from all data. No one outside of the research team or research governance staff will be able to find out your name, or any other information which could identify you. If we believe that you or someone else is at risk you might need to break confidentiality in order to protect your safety.

### What will happen to my data?



All individuals involved in this study will collect, store and

process all personal information in line with the General Data Protection Regulation (2018). All of your information will be kept confidential in locked filing cabinets and will be destroyed after 10 years. The videos will be destroyed as soon as they are analysed. Anonymised data will be used to write research papers.

You do not have to take part in this Research and your relationship with Mellow Babies will not be affected. We will ask if we can keep the data that we have already collected about you.

#### Who has reviewed the study?

The College of Medical, Veterinary & Life Sciences Ethics Committee.

#### Who is organising and funding the research?

- ⇒ The Clinical Psychology doctorate programme at The University of Glasgow
- ⇒ Mellow Parenting Research and Development Fund
- ⇒ The Children, Young People and Families Early Intervention Fund.

## **Appendix 8: Major Research Project Proposal**

### **Major Research Project Proposal**

'Life after Mellow'- An exploration of the feasibility and acceptability of long-term follow-up methods for the Mellow Babies intervention

**Matriculation Number:** 1005336

**Submission Date:** 29/01/18

**Maximum Word Count:** 3000

**Word Count:** 3627

## **Abstract**

### ***Background***

The quality of the early parent-child attachment plays a fundamental role in individuals' social, emotional and physical development. Parenting interventions which focus on the quality of the mother-child attachment lead to improved outcomes for parents and children. One such intervention, Mellow Babies, has shown positive associations with maternal well-being and the quality of the parent-child relationship. However, further research is necessary particularly into its long-term benefits. There is currently no published research on the long-term benefits of parenting interventions aimed at children under three years old. Therefore, research in this area would be valuable.

### ***Aims***

- To explore the feasibility of measuring long-term outcomes for parents and babies who have participated in Mellow Babies.
- To explore parent and child outcomes at 18 months post commencement of Mellow Babies.
- To explore effect sizes of secondary outcomes and provide power calculations to inform future research.

### ***Method***

Parents who have taken part in Mellow Babies will be asked to complete questionnaires and be video recorded interacting with their child.

### ***Applications***

To provide information on the feasibility of conducting a long-term follow-up of Mellow Babies participants. To provide preliminary information on long-term outcomes of Mellow Babies as well as providing information on effect size and sample size to inform future research.

**Word count: 207**

## **Introduction**

The quality of the early parent-child attachment plays a fundamental role in individuals' social, emotional and physical development. The parent-child attachment refers to the emotional closeness and attunement between a child and their primary caregiver which prepares them for independence and functioning within society (Bowlby, 1969). There is a large amount of evidence to support the connection between the parent-child attachment and the development of adaptive emotional regulation and socioemotional competence (Teicher & Samson, 2016; NICE, 2014; Thompson & Calkins, 1996; Rees, 2007), as well as positive neurological, physical and behavioural development (Rees, 2007; Schore, 1994). However, the quality of the parent-child relationship is also linked to developmental disorders such as Autism, Reactive Attachment Disorder and failure to thrive (Rees, 2007; Minnis, 2013). There is evidence for a strong graded relationship between exposure to maltreatment in childhood and multiple risk factors for several of the leading causes of death in adults (Felitti et al, 2009). All of these issues lead to significant financial burden on society and public services. As the parent-child relationship impacts on a range of child outcomes and has significant public health implications it seems logical that attachment theory and research should be incorporated into parenting interventions provided by clinical services.

Research on the effectiveness of parenting interventions found that those which focused on parental sensitivity and the mother-child relationship led to a reduction in maternal depression, enhanced attachment security and improved outcomes for children (Wright & Edginton, 2016; Bakermans-Kranenburg, van, & Juffer, 2003). Although these interventions are recommended in best practice guidelines (NICE, 2014) the evidence base is subject to methodological weaknesses, such as small homogeneous samples, with the majority of the research being conducted in the United States (Wright & Edginton, 2016).

Mellow Parenting interventions are recommended as part of best practice guidelines in Scotland (NICE, 2014). They deliver attachment based interventions targeted at parents of children from pre-birth to five years old who are at high risk of adverse outcomes because of parental difficulties. All interventions are group based and promote parental sensitivity and attunement. The programme is manualised and offers on-going



supervision to practitioners. Parents who participated in interventions reported a reduction in anxiety and increased attunement with their child (Bruestedt & Puckering, 2003; Puckering et al, 1996). A systematic review and meta-analysis of the interventions found medium treatment effect sizes on maternal well-being and child behavioural problems although it noted that there was heterogeneity within the participants and a failure to blind raters. It highlighted that much of the research was derived from qualitative studies and small samples and recommended the exploration of outcomes beyond end of intervention (MacBeth et al, 2015). The Mellow Babies programme, developed by Mellow Parenting, is a 14 week programme which uses an attachment model to enhance parent-child attunement (Puckering, 2005). A small scale waiting list controlled trial of Mellow Babies found that the intervention was associated with improvements in maternal mood and the mother-child relationship (Puckering et al, 2010).

Whilst research into parenting interventions for children over the age of three is well established, there is currently no research published to date on the long-term benefits of parenting interventions for children under three years old (Barlow et al, 2012). As long-term research would incur significant costs and resources, feasibility work on programmes such as Mellow Babies is warranted in order to avoid unnecessary expenditure of public funds.

### ***MRP context***

The current MRP will explore the feasibility of conducting long-term follow-up on participants who have consented to take part in the AIM project. The AIM project, led by Raquib Ibrahim of Mellow Parenting, is a UK multi-site research project which aims to explore the impact of Mellow Babies on parental psychological well-being, quality of life and the parent-child relationship. The AIM project has completed pre and post intervention outcome measures. The Fife implementation team, which includes health, education and social care staff independent from Mellow Parenting, were trained to deliver the 14 week Mellow Babies intervention.

A total of 74 AIM participants agreed to be contacted for further research, with 46 based in Fife. The researcher aims to engage with the Fife AIM participants at 18 months post commencement of intervention. Fife was chosen for pragmatic reasons as it gives the

researcher access to the most participants while focusing on a single health board. Approval was granted by the University of Glasgow and University of Edinburgh doctorate programmes to undertake research within this health board.

### ***Study Aim and Research questions***

The current study aims to explore the feasibility and acceptability of obtaining long-term outcomes for parents and babies who have taken part in the Mellow Babies intervention as part of the AIM project.

### ***Research questions***

7. Will participants who have taken part in the AIM project consent to the MRP research and engage in long-term data collection 18 months post commencement of Mellow Babies?
8. Will there be a change in parental psychological well-being when compared to AIM project pre and post intervention outcomes on the Brief Symptom Inventory-18?
9. Will there be a change in the quality of the parent-child relationship at 18 months post commencement of Mellow Babies compared to the AIM project pre and post intervention outcomes on video observation analysis?
10. What is the likely long-term clinical effect of the intervention, as measured by scores on all outcomes, when compared to the AIM project pre and post intervention outcomes?
11. How many participants would be needed for a sufficiently powered future study into the long-term outcomes of Mellow Babies?
12. What proportion of participants who would be willing, in principle, to be contacted for a qualitative interview at a later date?

## **Plan of Investigation**

### ***Design***

A within participants observational study design will be conducted in order to explore the feasibility and acceptability of conducting follow-up research within a population of parents who have completed Mellow Babies as part of previous research on pre and post intervention outcomes.

### ***Inclusion criteria***

- Parents who have consented to participate in the AIM project, whether or not they completed Mellow Babies, and have consented to be contacted by the Fife implementation team for involvement in future research. This includes males and females over the age of 18 years old who are experiencing parental difficulties.
- Parent has sufficient English language and communication abilities to understand the research process, provide informed written consent and take part in data collection.
- Participants must be reviewed by the Fife implementation team to ensure that contact is appropriate and not likely to result in additional distress.

### ***Exclusion criteria***

- Parents who are experiencing a current psychotic episode or are active chaotic drug users as they are ineligible for Mellow Parenting interventions.
- Parents who do not have sufficient English language and communication abilities to understand the research process, provide informed written consent and take part in data collection.
- Parents of children who have died or been taken into care since participating in Mellow Babies.

### ***Recruitment Procedures***

Fife AIM project participants who have consented to be contacted for further research and who meet all inclusion criteria will be approached by the implementation team and asked if their contact details can be passed on to the researcher. As they hold clinical responsibility, the researcher will respect the implementation team's judgement of whether or not a parent is appropriate to approach. The researcher will also request an up to date risk assessment from them. The researcher will telephone assenting parents to discuss the research. She will post an information sheet to the participant and arrange a call back to discuss any queries. If the participant agrees to take part in the project the researcher will arrange a home visit. In addition, the researcher will attend the Mellow Babies reunion lunch organised, as part of usual practice, by the implementation team. In order to avoid coercion/bias the researcher will not approach participants unless they have agreed to this and she will make it clear that participation is voluntary and declining will not affect their relationship with the implementation team. The researcher will then discuss the project with them and provide an information sheet. The information sheet

and the researcher will emphasise that participation is voluntary and that they may choose to withdraw at any time. The researcher will make an appointment to go to parents' homes or a safe and private location, e.g. family centre, to discuss the study further. If the parent agrees to take part in the study, the researcher will ask for written consent before commencing data collection. Participants will be asked to complete two self-report measures of parental well-being and quality of life with a total estimated completion time of 20 minutes. Finally, they will be asked to be video recorded while completing a care task with their child. This procedure will take approximately 15mins. The participant will be given a £10 shopping voucher for Superdrug as a thank you for taking part in the research and to cover any expenses incurred whether or not they withdraw consent from the study. As this is a feasibility study there is no minimum requirement on data collection. The researcher will schedule 2-3 data collection visits per day in order to minimise travel time and costs.

### ***Measures***

The researcher will replicate AIM project outcome measures completed at baseline and post intervention time points. The measures are outlined below.

#### ***Quality of parent-child interaction***

Video recordings of the parent and child interacting will be used to assess the quality of the parent-child relationship. The rates per minute of positive and negative interaction behaviours will be analysed by a trained and reliable analyst within Mellow Parenting who is blind to the pre and post intervention outcome status of the participant, using the Child and Adult Relationship Observation (CARO) (Thompson, King, & Wilson, 2018). Analysis will take approximately 15 minutes per video.

#### ***Parental psychological well-being and Quality of life***

Brief Symptom Inventory 18 (BSI-18) – An 18 item self-report questionnaire. BSI-18 is a screening tool for identifying psychological distress in the form of depression, anxiety, and somatization. It is designed for use with medical and community populations (Derogatis, 2000).

Quality of Life Enjoyment and Satisfaction Questionnaire (Short Form) (Q-LES-Q-SF) – A 16 item self-report questionnaire. It measures quality of life by assessing physical health, subjective feelings, leisure activities, social relationships, general activities, satisfaction with medications and life-satisfaction domains (Endicott et al, 1993).

### ***Data Analysis***

- Descriptive statistics will be used to explore the proportion of potential participants who consented to the MRP project and engaged in data collection.
- In order to explore parental well-being and quality of life, participant mean scores on the BSI-18 and the Q-LES-Q-SF will be compared to AIM project pre and post intervention time-points using a statistical analysis appropriate for parametric or non-parametric repeated measures. Effect sizes will be estimated for the impact of Mellow Babies on parental well-being and quality of life.
- In order to explore the quality of the parent-child relationship, participants' data from the CARO will be compared to AIM project pre and post intervention time-points using a statistical analysis appropriate for parametric or non-parametric repeated measures. Effect sizes will be estimated for the impact of Mellow Babies on parent-child positive and negative interactions.
- A power calculation will be carried out using an online calculator such as G\*Power based on recruitment and retention rates at the AIM project baseline and post intervention time-point as well as the MRP follow-up time-point in order to inform future research.
- Descriptive statistics will be used to report the proportion of participants who would be willing, in principle, to be contacted for a qualitative interview.

### ***Justification of Sample Size***

The current MRP is utilising an existing sample of research participants which means that there is a fixed number of 46 participants available for recruitment. As this is a feasibility project which aims to establish the proportion of participants who successfully engage in follow-up data collection it is not possible to provide a power calculation of participants. Previous community based research on interventions for vulnerable populations have resulted in a 15-17% attrition rate at 1 year follow-up (Gilliss et al, 2001; Gustavson et al, 2012). Due to this, a conservative 25% attrition rate will be estimated for the current study. Taking this into account the researcher aims to recruit 35 participants. The data

from the current study will inform estimates of power for future studies by enabling an informed approach to modelling attrition over time.

### ***Settings and Equipment***

Data will be collected at participants' homes or a safe and private location of their choice. The chosen location would need to be somewhere that the parent and child commonly interact together in order to provide a naturalistic setting and the most accurate data for the parent-child interaction.

### ***Equipment and financial costs***

- Paper questionnaires and cost of printing
- Cost of postage of information packs
- Video camera- provided by Mellow Parenting
- SD card for storing video data- cost requested from University
- Pre-paid mobile phone for contacting participants. The current MRP supervisors advised that, based on their experience, text messaging is the most effective way of contacting this population- Cost requested from University
- Travel expenses and incentive for participants (£10 Superdrug voucher)- funding secured from the Mellow Parenting Research and Development fund.
- Trainee travel expenses- funding secured from the *Children, Young People and Families Early Intervention Fund* student and volunteer expenses fund.

### **Health and Safety Issues**

#### ***Researcher safety issues***

The researcher will follow The University of Glasgow and Mellow Parenting home visit policy during data collection. A risk assessment will be sought from the Fife implementation team before conducting home visits and a check in-check out procedure will be put in place. The researcher will not work alone if a serious risk has been identified. The home visit policy is outlined in Appendix 1: Health and Safety for Researchers.

### ***Participant safety issues***

Testing procedures should not pose any health or safety risk to the participant. Participants have the right to decline involvement in any aspect of the study without affecting their relationship with the implementation team. The researcher is a Trainee Clinical Psychologist who is skilled at undertaking outcome measures in a sensitive way. However, should concerns be raised about a participant or a child the implementation team and the participants' GP will be informed. Participants will be advised to contact their GP or to attend Accident and Emergency services if necessary. If there is risk to a child, the researcher will discuss this with the implementation team and activate referral to child protection services if this is warranted. The researcher will offer all participants the option to have a follow-up call with the implementation team for the chance to debrief. They will also offer the opportunity to speak with someone not affiliated with the project (details in appendix 1). The researcher will inform the referrer of any previously unidentified risk highlighted during her appointment with the participant in line with The University of Glasgow confidentiality procedures. This will be communicated in advance to potential participants.

### ***Ethical Issues***

Approval will be sought from the University of Glasgow college of Medical, Veterinary and Life Sciences ethics committee. Participants will be given information about the research process a minimum of 24 hours prior being asked to provide informed consent or opt out if they prefer. Contact details for the researcher will be available should people wish to seek further information.

AIM project participant identifier codes will be retained in order to store current data and to compare data to pre and post intervention outcomes. Personal identifiers will be separated from data and kept in locked filing cabinets. Encrypted laptops will be used to analyse data. Participants' will be informed that they can request to have their data destroyed at any point without adverse effect to themselves. Participants will be informed of details for individuals/services they can contact in the Participant Information Sheet. The trial report and submissions will contain anonymous summaries of data. This will include a submission to the University of Glasgow in accordance with the Doctorate in Clinical Psychology course requirements and submission to a national journal.

**Timetable**

Submit draft proposal on the 4<sup>th</sup> December 2017

Meeting with supervisors on January 15<sup>th</sup> 2018

Submit final proposal on 29th January

Meeting with supervisors on 26<sup>th</sup> February

Apply for ethical approval: April/May

Meeting with supervisors on April 16<sup>th</sup>

Final proposal submission May

Receive ethical approval: June/July

Data collection: August 2018- March 2019

Data analysis and write up: March- June 2019

Submit final theses in July 2019

**Practical Applications**

This MRP will explore the feasibility of collecting follow-up data 18 months post commencement of Mellow Babies. It will provide valuable information about the engagement of parents and their children in research and data collection. This research may serve to provide preliminary information on long-term outcomes of Mellow Babies on parental wellbeing and quality of life as well as the quality of the parent-child relationship. The study also aims to provide information on the effect size of all outcomes as well as provide a power calculation in order to inform future research. This study would be beneficial to service providers as there is currently no published to date long-term outcome data on the Mellow Babies intervention.



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## Appendices

### Appendix 1: Health and Safety for Researchers

#### WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW

#### DOCTORATE IN CLINICAL PSYCHOLOGY

#### HEALTH AND SAFETY FOR RESEARCHERS

1. Title of Project	'Life after Mellow'- An exploration of the feasibility and acceptability of long-term follow-up methods for the Mellow Babies intervention
2. Trainee	
3. University Supervisor	
4. Other Supervisor(s)	
5. Local Lead Clinician	
6. Participants: (age, group or sub-group, pre- or post-treatment, etc)	Approximately 35 male and female parents aged over 18 years. All parents have completed the Mellow Babies intervention as part of the AIM project: a research study, led by Raquib Ibrahim of Mellow Parenting, which aims to explore the impact of the Mellow Babies intervention on parental mental well-being and quality of life as well as the quality of the parent-child relationship.
7. Procedures to be applied (eg, questionnaire, interview, etc)	<b>Measures</b> The researcher will replicate measures that were completed at the AIM project baseline and post intervention data collection time points. The measures are outlined below.  <b>Quality of parent-child interaction</b> Video recordings of the parent and child interacting will be used to assess the quality of

	<p>the parent-child relationship. This data will be analysed by a trained rater within Mellow Parenting, who is blind to participant pre and post outcome data, using the Child and Adult Relationship Observation (CARO).</p> <p><b>Parental well-being and Quality of life</b></p> <p>Brief Symptom Inventory 18 (BSI-18) – An 18 item self-report questionnaire. BSI-18 is a screening tool for identifying psychological distress in the form of depression, anxiety, and somatization. It is designed for use with medical and community populations.</p> <p>Quality of Life Enjoyment and Satisfaction Questionnaire (Short Form) (Q-LES-Q-SF) – A 16 item self-report questionnaire. It measures quality of life by assessing physical health, subjective feelings, leisure activities, social relationships, general activities, satisfaction with medications and life-satisfaction domains.</p>
<p>8. Setting (where will procedures be carried out?)</p> <p>i) Details of all settings</p>	<p>Data will be collected at participants’ home or a safe location of their choice. The chosen location would need to be somewhere that the parent and child commonly interact together in order to provide a naturalistic setting and the most accurate data for the parent-child interaction.</p>
<p>ii) Are home visits involved</p>	<p>Yes</p>

**WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW**

**DOCTORATE IN CLINICAL PSYCHOLOGY**

**HEALTH AND SAFETY FOR RESEARCHERS**

<p>9. Potential Risk Factors Considered (for researcher and participant safety):</p> <ul style="list-style-type: none"><li>i) Participants</li><li>ii) Procedures</li><li>iii) Settings</li></ul>	<p>Participants: This is a vulnerable population who are often deemed as high risk due to issues such as mental health problems/domestic violence.</p> <p>Procedures: The testing procedure should not pose any health or safety risk to the participant. However, they may become distressing during the data collection process as these will include sensitive questions about their relationship with their child and their mental well-being.</p> <p>Setting: The research setting will be the participants' home or a safe location of their choice. As this is an uncontrolled environment there may be risks to the researcher during data collection.</p> <p>It is important that data collection is carried out in participants' homes or a familiar location in order to provide a naturalistic environment for the parent-child interaction. Recordings out-with their familiar environment would not provide accurate data.</p>
<p>10. Actions to minimise risk (refer to 9)</p> <ul style="list-style-type: none"><li>iv) Participants</li><li>v) Procedures</li></ul>	<p>Participants: A full risk assessment will be conducted by a team member of the Fife Implementation Team. This will include all risk information known about the participant.</p>

<p>vi) Settings</p>	<p>The researcher will not include participants if significant risks have been highlighted.</p> <p>Procedures: Testing procedures should not pose any health or safety risk to the participant. Participants have the right to decline involvement in any aspect of the study without affecting their relationship with the implementation team. The researcher is a Trainee Clinical Psychologist who is skilled at undertaking outcome measures in a sensitive way. However, should concerns be raised about a participant or a child the implementation team and the participants' GP will be informed. Participants will be advised to contact their GP or to attend Accident and Emergency services if necessary. If there is risk to a child, the researcher will discuss this with the implementation team and activate referral to child protection services if this is warranted. The researcher will offer all participants the option to have a follow-up call with the implementation team for the chance to debrief. They will also offer the opportunity to speak with someone not affiliated with the project (details in appendix 1). The researcher will inform the referrer of any previously unidentified risk highlighted during her appointment with the participant in line with University of Glasgow confidentiality procedures. This will be communicated in advance to potential participants.</p> <p><u>Non affiliated contact</u></p>
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Settings: Participants must have been seen recently by a member of the clinical team involved in their care and a risk assessment must be carried out. If the participant has had no recent involvement with a clinical team then a home visit will not be carried out.

The researcher will apprise themselves of the risk assessment in all cases prior to the visit.

The researcher will discuss potential for risk with a member of the clinical team who has seen the patient recently.

If there is doubt the researcher will discuss with their University supervisor and/or a senior member of the clinical team that have responsibility for management of the patient.



	<p>The overall appraisal of risk must take into account what is known about the participant, a risk assessment of their living environment by the clinical team and consideration of the geographical siting of the visit. This will include assessment of any risk associated with travelling to and from the participant's home.</p> <p>Home visits must be in normal working hours.</p> <p>The lone worker policy for Mellow Parenting will be adhered to at all times during home visits. In addition to the points outlined above, the Mellow Parenting policy requires all researchers to check in and out with a member of Mellow Parenting before and after every home visit. The researcher will have a designated person to contact if they have concerns about their own safety during a home visit.</p>
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Trainee signature: ..... Date: .....

University supervisor  
signature: ..... Date: .....

**Appendix 2: Research equipment, consumables and expenses**

**RESEARCH EQUIPMENT, CONSUMABLES AND EXPENSES**

**Trainee** .. .. .

**Year of Course** ...2<sup>nd</sup> Year..... **Intake**

**Year**...2016.....

Please refer to latest stationary costs list (available from student support team)

<b>Item</b>	<b>Details and Amount Required</b>	<b>Cost or Specify if to Request to Borrow from Department</b>
Stationary	Envelopes (A4) 1 box of 250 (35 needed but can only order in batch of 250)	£9.01  Subtotal: £9.01
Postage	2 <sup>nd</sup> class postage of 35 A4 envelopes @ 56p per envelope	£19.60  Subtotal: £19.60
Photocopying and Laser Printing	Photocopying of 350 sheets. ( approximately 10 pages per 35 information and consent packs)	£17.50  Subtotal: £17.50
Equipment and Software	Use of university laptop to analyse data	Borrow from University department

	<p>Video camera for recording parent-child interaction</p> <p>SD card for storing data</p> <p>Pre-paid mobile phone with free sim card</p> <p>Phone credit for texting participants. Estimate for 4 texts per participant at 15p per text.</p>	<p>Provided by Mellow Parenting</p> <p>£10</p> <p>£9.99</p> <p>£20</p> <p>Subtotal: £39.99</p>
Measures	<p>Brief Symptom Inventory-18</p> <p>Quality of Life Enjoyment and Satisfaction Questionnaire (Short Form)</p>	<p>Approximately £80 Cost covered by the <i>Children, Young People and Families Early Intervention Fund</i></p> <p>Free to use for research</p> <p>Subtotal: £0</p>
Miscellaneous	<p>Researcher travel expenses</p>	<p>Approximately £250-300</p>

	Participant incentive: individual £10 voucher	Funding secured from the <i>Children, Young People</i> and Families Early Intervention <i>Fund</i> to cover the first £250 with the option to review if extra funding needed.  Approximately £350 Funding secured from the Mellow Parenting research and development fund  Subtotal: £0
<b>Total</b>		£86.01

**For any request over £200 please provide further justification for all items that contribute to a high total cost estimate. Please also provide justification if costing for an honorarium:**

Trainee Signature..... Date.....

Supervisor's Signature ..... Date .....

### **Appendix 3: Plain English Summary**

‘Life after Mellow’- An exploration of the feasibility and acceptability of long-term follow-up methods for the Mellow Babies intervention

#### Plain English summary

The quality of the relationship between a parent and their child plays an important role in how the child learns to manage their emotions and feelings and cope with difficult situations in life. It also affects how the child’s brain develops which can lead to changes in how they learn and develop language. Children who have a negative relationship with their care-giver are more likely to have difficulties in all of these areas and a poorer quality of their life.

Parenting interventions which focus on improving the relationship between the mother and child can help them to form a positive relationship together which can improve the mother’s mental health and lead to many improvements for the child such as better language abilities and the ability to cope with stressful situations. The child learns to see the parent as a safe place from which they can explore the world which encourages them to grow in a healthy and positive way.

Mellow Parenting is a charity which delivers parenting groups to parents who are more likely to have difficulties forming a positive relationship with their child due to reasons such as drug use or poor mental health. Research shows that Mellow Parenting groups can improve the relationship between a mother and her child which can lead to better mental health for mothers and reduce behavioural problems in children.

At the moment there is no research on the benefits that parenting groups have over time on parents and their children. It is important that we research this area to find out if the benefits of parenting interventions continue over time.

This project hopes to explore whether or not it is possible to carry out research on parents who took part in a study on the benefits of parenting groups (The AIM Project) 18 months ago. The researcher will ask parents who took part in the AIM project in Fife if they would like to take part in more research so that we can find out if there are any benefits from the groups that have lasted over time. It will look at the parents’ mental health and also the quality of their relationship with their child and compare this to how they were before and after the parenting group. It will do this by asking the parents to complete short questionnaires on their mental health and their feelings about the quality of their life. The

researcher will also video record the parent while they interact act with their baby so that they can look at their relationship. This will take around 5 minutes.

As this project is looking at the possibility of doing this type of research it will provide information for a bigger study in the future. It will also let us know if the benefits to mothers and their children last over time which could help service providers.

**Appendix 4: Confirmation of approval of funding from the *Children, Young People and Families Early Intervention Fund***



28.03.2018

Caoimhe Clarke,  
Doctorate in Clinical Psychology Programme  
Department of Psychological Medicine,  
Institute of Health and Wellbeing  
University of Glasgow

Dear Ms Clarke,

***Funding for research follow up of mothers who attended a Mellow Parenting Programme in Fife***

As discussed and agreed Mellow Parenting is happy to offer you £250 as a contribution towards any travelling expenses occurred when visiting the mothers. This funding is available via our Scottish Government CYPFEIF project (Grant Number: SG-16/215).

Mellow Parenting will also provide 50 BSI-18 hand-scoring sheets for you to use at the point of follow up with each parent.

**Appendix 5: Confirmation of approval of funding from the *Mellow Parenting Research and Development Fund***



14.03.2018

Caoimhe Clarke,  
Doctorate in Clinical Psychology Programme  
Department of Psychological Medicine,  
Institute of Health and Wellbeing  
University of Glasgow

Dear Ms Clarke,

***Funding for research follow up of mothers who have attended a Mellow Parenting Programme in Fife***

I am pleased to inform you that at the board of Mellow Parenting of November 2017 it was agreed to award up to £500 for expenses for the follow up of mothers and children who attended the

Dr Christine Puckering  
Programme Director

Ms Senga Rocke  
Finance Officer

Mellow Parenting is a Company Ltd by Guarantee (349127) and a Charity Registered in Scotland Number SC037384  
Unit 4 - Six Harmony Row, Glasgow G51 3BA Phone/Fax: 0141 445 6120/6066



