

Mellow Parenting: systematic review and meta-analysis of an intervention to promote sensitive parenting

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ABBREVIATIONS

AACPD	American Academy for Cerebral Palsy and Developmental Medicine
PRISMA	Preferred Reporting Items of Systematic reviews and Meta-Analyses
RCT	Randomized controlled trials

AIM To review and meta-analyse Mellow Parenting interventions for parent–child dyads at high risk of adverse developmental outcomes.

METHOD Using Preferred Reporting Items of Systematic reviews and Meta-Analyses (PRISMA) guidelines, we extracted all published evaluations of Mellow Parenting and Mellow Babies programmes. We identified published studies with randomized controlled trials, quasi-experimental or within-subject pre–post designs. We incorporated ‘grey literature’ for unpublished publicly available evaluations. Effect sizes were calculated for impact of Mellow Parenting on parental mental health and child behaviour. Data were extracted on demographics, age of participants, country, and potential sources of bias.

RESULTS We identified eight papers, representing nine data sets, from five of which we calculated effect sizes. There was evidence of a medium treatment effect of Mellow Parenting compared with comparison groups on maternal well-being and child problems. Drop-out from treatment was variable. However, data were heterogeneous and there was evidence of methodological bias.

INTERPRETATION Our data give some support to claims for effectiveness of Mellow Parenting as a group intervention for families with multiple indices of developmental adversity. Given the methodological weaknesses of literature in the area, novel approaches are needed in future trials of low-budget complex interventions in non-commercial settings.

Social adversity and poor parental mental health confer vulnerability to long-term negative effects on children’s psychological, social, educational, and economic outcomes.^{1–4} Exposure to early stress has deleterious effects on the development of regulation systems of infant stress,⁵ leading to increased problematic behaviour with corresponding long-term implications for vulnerabilities in neurological and physical health.⁶ Parental risk factors include exposure to relational violence, parental mental ill health or problem drug use, adolescent parenthood, and multiple indices of social deprivation, sometimes leading to social work involvement or child protection measures.^{7–10} The combination of maternal mental health, optimal parent–child attachment, and parental sensitivity with contingent, developmentally appropriate parental responses to infant signals of distress or the need for stimulation have been shown to be important for the development of infant attachment security and optimal childhood psychological development.^{11–13} Furthermore, the use of parenting interventions in vulnerable groups^{14,15} has mixed effectiveness in reducing children’s psychosocial problems.

Parenting programmes have achieved broad support as preventative interventions that may positively affect childhood well-being. However, current intervention packages with a substantial evidence base such as Incredible Years¹⁶ and the Triple P Programme¹⁷ tend to focus on parental management of children’s behaviour or are primarily targeted at families with children of 2 years and over. Attachment relationships and parental sensitivity – key psychological mechanisms for the transmission of resilience – are not the primary focus of these programmes.¹² Although there is broad agreement that attachment-informed parenting programmes confer benefits for developmental outcomes and parental sensitivity in vulnerable families with young children,¹⁸ such interventions tend to focus on parent–infant interaction without a corresponding emphasis on maternal mental health.¹⁹ Such an approach is likely to be limited in effectiveness because uptake of parenting interventions is lowest among parents with mental health problems.²⁰ The Nurse–Family Partnership adopts a different model,¹ giving support to adolescent mothers through a programme of home visitation spanning the antenatal

period and the first 2 years of a child's life. It appears to have long-term effectiveness¹ but is costly and has a target group restricted to adolescent first-time mothers attending for antenatal care before the third trimester.

The Mellow Parenting intervention has been developed as an alternative, attachment-informed suite of interventions specifically targeted at parents of children from 0 to 8 years of age at high risk of adverse outcomes because of parental difficulties. It includes an emphasis on developing parental sensitivity and attunement recommended by previous meta-analyses of attachment-related interventions,¹² but also incorporates components emphasizing both parental mental health (cognitive behavioural strategies for ameliorating parental depression and anxiety) and the parent-child relationship. It is group-based, includes provision for strategies to enhance engagement (transport and crèche provision), and can be delivered by non-specialists (albeit with experience of work with young children and their families) with minimal training. Ongoing supervision is provided to practitioners and is essential for accreditation as a practitioner. Use of video feedback and interactive tasks are key to programme delivery, consistent with best practice in evidence-based parenting.¹² Mellow Parenting was initially developed for use with children under age 5 years (Mellow Parenting), but has subsequently, without deviating from the core intervention format, been adapted for use with infants (Mellow Babies), antenatally (Mellow Bumps), and with fathers (Mellow Dads). Mellow Parenting and Mellow Babies have rapidly gained support with early years practitioners and have been recommended in UK national guidelines for evidence-based parenting interventions and the California Evidence-Based Clearinghouse for Child Welfare (<http://www.cebc4cw.org/program/mellow-babies/>); however, much of this evidence is derived from small case studies²¹ and qualitative studies.^{22,23} There is therefore a disjunction between positive representations of Mellow Parenting in practitioner reports and policy guidance compared with the relative lack of outcome-driven, clinically informed research, such as adequately powered randomized trials.

More broadly there are also general difficulties in moving plausible non-pharmaceutical interventions towards evaluation in definitive randomized controlled trials. Calculations of trial sample sizes conventionally require one or more exploratory randomized trials of adequate size and it is difficult to gain external research funding for them: few non-commercial developers of interventions for children have the resources to obtain the results they need.

To address both the limitations of the evidence base for Mellow Parenting and its variations and the broader issue of developing evaluation mechanisms for non-commercial complex interventions, we present a synthesis of data from several small randomized controlled trials (RCTs), and quasi-experimental and within-subject evaluations, to generate an estimate of an expected effect size for Mellow Parenting.

The primary aim of the current review was to review and meta-analyse maternal and child outcomes for the

What this paper adds

- Mellow Parenting has medium effect sizes on parent/child outcomes.
- Data were subject to methodological limitations of small sample size.
- Synthesizing evidence across methodologies may facilitate trials of non-commercial complex interventions.

Mellow Parenting programme, with a view to generating estimates of effect size for these outcomes. A secondary aim was to assess systematically, and where possible statistically, methodological limitations of the current evidence base for Mellow Parenting. We were aware that a sizeable proportion of available data on Mellow Parenting are contained within 'grey literature'.

We hypothesized that participation in a Mellow Parenting group would be associated with (1) improved parental mental health and (2) a reduction in child problem behaviour at post-group evaluation, compared with baseline. In addition, we hypothesized that the effect size for improvements in parental mental health and child outcomes would be greater than the corresponding effect for comparison groups (where available).

METHOD

Protocol and registration

We did not register a protocol for the meta-analysis.

Eligibility criteria and information sources

Our eligibility criteria for the meta-analysis were as follows: (1) projects evaluated outcomes for the Mellow Parenting programme; (2) outcomes were described for a defined variable (e.g. maternal depression) using a validated outcome measure (e.g. Adult Wellbeing Scale). Articles published or available online between 1990 and 2014 were eligible for inclusion.

Search strategy and information sources

A search was performed on 7 July 2014. The search used conjunctions of the following search terms: Mellow AND toddler* OR bab* OR parent* OR dad* OR mum*. The following online databases were systematically searched to identify relevant studies: Web of Science, CINAHL, PsycINFO, MEDLINE. In addition, we searched the 'grey literature' using the following approaches. First, we used the reference lists of published papers. Second, a search of Google Scholar was made for published reports available in the public domain. This included data available in the form of reports or other unpublished data where reference to the data could be obtained through a standard Google search. Finally, where necessary, authors were contacted for additional information on the data set.

Study selection and data collection

The first author performed the initial search and extraction of 'grey literature'. Queries about eligibility were resolved by discussion between two of the authors (PW, AM). For eligible studies, data were collected, with permission, onto a form adapted from that used by the Scottish Intercollegiate

Guideline Network.²⁴ One of the authors (PW) has used this procedure in a review of the Triple P parenting programmes.¹⁷ Two authors (AM, IM) performed independent data extraction. If the authors disagreed, a third author adjudicated. The study selection process is displayed in Figure 1.

Data items

The following variables were assessed: (1) numbers of patients or families included in the study; (2) location of study; (3) main characteristics of the patient population (including case mix); (4) nature of the intervention being investigated; (5) which outcomes were compared across groups/between time points; (6) nature of the control or comparison group (where applicable); (7) length of follow-up (if any); (8) nature of child-based outcome measure(s) used in the study; (9) parental mental health outcomes; (10) study design (RCT/wait-list control/pre-post comparison); (11) if treatment comparison, use of a waiting list

design; (12) whether the assignment of participants to treatment groups was randomized; (13) whether reporters of the child-based outcomes were blind to treatment allocation; (14) drop-out rates for participants recruited into each arm of the study; (15) mean and standard deviation of post-intervention child-based outcome measures (for meta-analysis); (16) mean and standard deviation of post-intervention outcome measures of parental mental health (for meta-analysis); (17) whether a statement of study funding was included; (18) whether a conflict of interest statement was included; (19) we also classified studies according to American Academy for Cerebral Palsy and Developmental Medicine (AACPDM) levels of evidence.²⁵

Analyses

The effect size for each study included in the meta-analysis was estimated using the standardized mean difference, with post-intervention mean and pooled standard deviation.

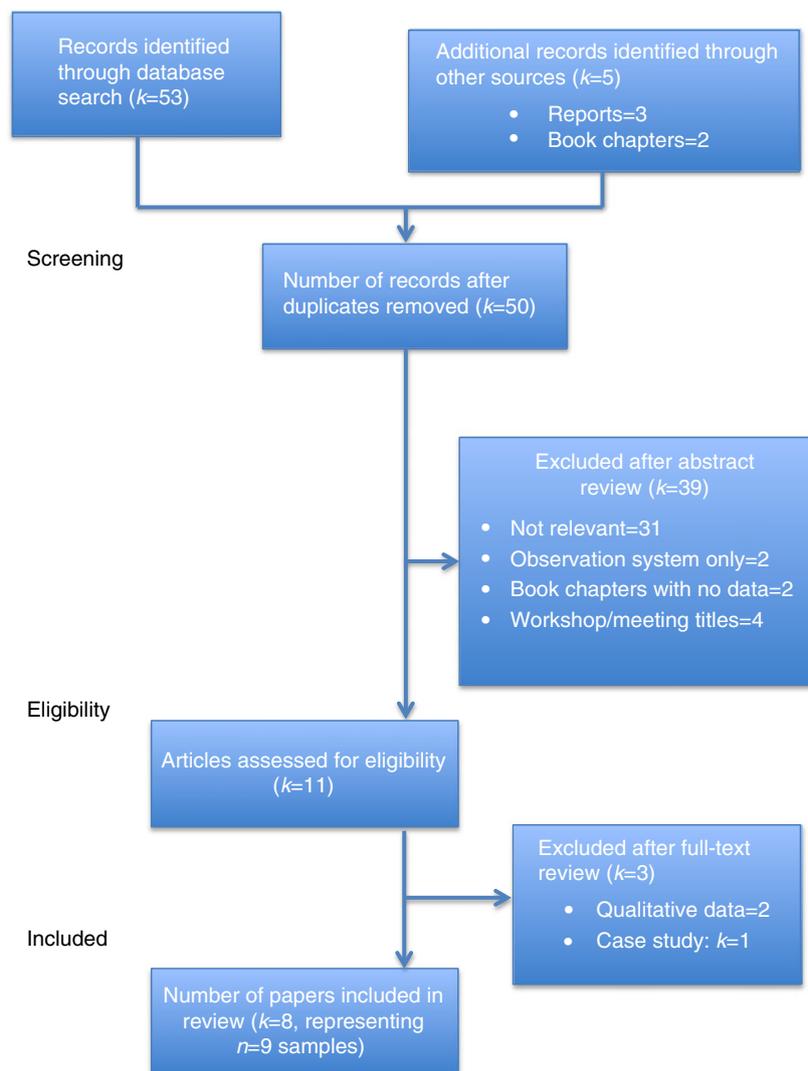


Figure 1: Preferred Reporting Items of Systematic reviews and Meta-Analyses (PRISMA) diagram of study identification.

Table 1: Main characteristics of included studies

Location	Study type	Level of evidence ^a	Sample <i>n</i> (comparison <i>n</i>)	Patient characteristics	Cases mean age of child in mo (SD)	Cases mean age of mothers in y (SD)	Controls mean age of child in mo (SD)	Controls mean age of mothers in y (SD)	Intervention (MP/MB)	Group comparison	Comparison group	Parental mental health outcome measure	Child-based outcome measure	Interaction measure
Forth Valley, Scotland ^{27,31}	Case-control	III	45 (23)	Families with child under 5y with child protection concerns, persistent violence, relationship difficulties, mental disorder, child behavioural/emotional disorder	39 (12)	27 (6)	36 (12)	26 (5)	MP	Pre- vs post-treatment	N/A	AWS	PHS	MPOS
West of Scotland ²²	Within subjects	IV	12	Existing cohort of children in study of RAD; consecutive groups	6-9y	N/R	N/A	N/A	MP	Pre- vs post-treatment	N/A	HADS	SDQ PHS	MPOS
St Petersburg, Russia ²⁸	Case-control	IV	16 (15)	Socially disadvantaged mothers	N/R	N/R	N/R	N/R	MP	Pre- vs post-treatment	Waiting list control	EPDS	RBC	-
Dungannon, Northern Ireland ³⁵	Within subjects	IV	7	Mothers with more than one risk: domestic violence, child protection concerns, difficulties in relationship with child; history of mental health or substance misuse issues	N/R	N/R	N/A	N/A	MP	Pre- vs post-treatment	N/A	WEMWBS	N/A	-
Craigavon, Northern Ireland ³⁵	Within subjects	IV	8	Mothers with more than one risk: domestic violence, child protection concerns, difficulties in relationship with child; history of mental health or substance misuse issues	N/R	N/R	N/A	N/A	MP	Pre- vs post-treatment	N/A	WEMWBS	N/A	-

Table 1: Continued

Location	Study type	Level of evidence ^a	Sample n (comparison n)	Patient characteristics	Cases mean age of child in mo (SD)	Cases mean age of mothers in y (SD)	Controls mean age of child in mo (SD)	Controls mean age of mothers in y (SD)	Intervention (MP/MB)	Group comparison	Comparison group	Parental mental health measure	Child-based outcome measure	Interaction measure
Newry, Northern Ireland ³³	Within subjects	IV	13	Mothers with more than one risk: domestic violence, child protection concerns, difficulties in relationship with child; history of mental health or substance misuse issues	N/R	N/R	N/A	N/A	MP	Pre- vs post-treatment	N/A	WEMWBS	N/A	-
Aotearoa, New Zealand ^{32,34}	Stepped-wedge design	IV	39	Maori mothers experiencing relationship and child behaviour difficulties	N/R	28.6 (8.2)	N/R	N/R	MP	Pre- vs post-treatment	Data unavailable on controls	N/A	SDQ	-
Lanarkshire, Scotland ³⁰	Case-control	III	19 (8)	Mothers scoring above cut-off on EPDS at 12-16wks post-partum	N/R	N/R	N/R	N/R	MB	Pre- vs post-treatment	Waiting list control	EPDS	N/A	MPOS
St Petersburg, Russia ²⁹	Case-control	IV	14 (12)	Socially disadvantaged mothers	N/R	N/R	N/R	N/R	MB	Pre- vs post-treatment	N/A	EPDS	N/A	-

^aLevel of evidence applied using the American Academy for Cerebral Palsy and Developmental Medicine guidelines for quality in group studies. MP, Mellow Parenting; MB, Mellow Babies; N/A, not applicable; AWS, Adult Wellbeing Scale; MPOS, Mellow Parenting Observation Scale; RAD, reactive attachment disorder; N/R, not reported; HADS, Hospital Anxiety and Depression Scale; SDQ, Strengths and Difficulties Questionnaire; PHS, Parental Hassles Scale; EPDS, Edinburgh Postnatal Depression Scale; RBC, Richman Behaviour Checklist; WEMWBS, Warwick-Edinburgh Mental Well-Being Scale.

Table II: Studies included in meta-analysis

Study	Parental mental health outcome measure						Child-based outcome measure					
	Pre-intervention			Post-intervention			Pre-intervention			Post-intervention		
	<i>n</i>	Mean	SD	<i>n</i>	Mean	SD	<i>n</i>	Mean	SD	<i>n</i>	Mean	SD
Intervention												
Puckering et al. ³¹	42	19.3	7.8	42	12.0	8.5	44	24.7	11.3	44	21.7	5.3
Puckering et al. ²²	12	18.3	6.3	12	14.3	7.6	12	21.2	6.8	12	19.4	4.5
Borjeson et al. ²⁸	16	8.9	5.4	16	6.4	4.2	15	4.0	3.2	15	2.9	3.3
Southern Health and Social Care Trust ³³	4	47.5	6.8	4	54.3	6.8	–	–	–	–	–	–
Southern Health and Social Care Trust ³³	6	27.2	24.6	6	51.8	24.6	–	–	–	–	–	–
Southern Health and Social Care Trust ³³	10	39.7	10.3	10	50	10.3	–	–	–	–	–	–
Penehira and Doherty ³²	39	12.0	1.7	39	3.4	0.9	26	15.8	6.2	26	12.0	5.1
Puckering et al. ³⁰	11	18.8	4.7	11	11.2	5.9	–	–	–	–	–	–
Morozova et al. ²⁹	14	7.1	3.6	14	7.71	3.2	5	2.4	2.3	5	1.2	0.8
Controls												
Puckering et al. ³¹	23	13.1	7.3	23	8.8	4.9	28	18.9	4.9	28	20.0	4.4
Borjeson et al. ²⁸	15	6.1	4.8	15	6.5	4.0	15	2.7	2.2	15	1.9	1.6
Puckering et al. ³⁰	5	17.8	4.8	5	19.6	4.0	–	–	–	–	–	–
Morozova et al. ²⁹	12	7.9	5.8	12	8.5	5.1	11	2.4	1.7	11	1.9	2.1

Hedges' *g*, under a random effects modelling approach, was used to obtain unbiased estimates of effect sizes. Owing to the small number of studies and assumption of between-study heterogeneity, random effects modelling was applied. Variation in standardized mean differences attributable to heterogeneity was assessed with the I^2 statistic (the percentage of between-study heterogeneity attributable to variability in the true treatment effect, rather than sampling variation). Risk of bias was assessed descriptively using the above checklist items.

RESULTS

Study characteristics

After extraction of papers, three studies were excluded as only presenting qualitative or case study data,^{21,23,26,27} consistent with level V of AACPD guidelines. All studies presented in Table I met levels III or IV of AACPD levels of evidence. The studies in our final data set included four waiting-list controlled trials,^{28–31} one study that proposed a stepped-wedge design but for which only treatment group data were available,³² and four within-subject studies evaluating Mellow Parenting for reactive attachment disorder²² and evaluating Mellow Parenting in routine care.³³ Data were reported for studies from Scotland, Northern Ireland, Russia, and New Zealand. For the Russian, New Zealand, and Northern Irish data sets^{28,29,32,33} we requested additional data from the authors because of insufficient detail in the source material. Owing to insufficient data we were unable to include the Northern Irish data sets in the meta-analysis but retain them in the review.

The total sample consisted of outcome data on 95 parent-child dyads and 55 comparison dyads. Most data sets reported outcomes for Mellow Parenting although two samples evaluated Mellow Babies.^{29,30} The parental data identified in the systematic review related exclusively to maternal outcomes: no outcome data for fathers were available. Child outcome data were available from three of the

studies.^{22,28,31} Measures were mainly taken at baseline before intervention start and at intervention end. Two studies provided follow-up data at 3 months,³⁴ and 1 year post-group,³¹ but owing to the paucity of data we did not incorporate follow-up into the meta-analysis.

Measures

All studies' papers included in the meta-analysis had a measure of maternal mental well-being pre- and post-treatment. There was some variability in the measures used (Table I); however, all maternal health measures reported depression as either scale or subscale scores. For child psychological functioning, four studies reported a measure of childhood difficulties using a parent-reported checklist. Again, all these measures incorporated a score for childhood problems as either a scale or a subscale of the total score. Therefore we were able to derive standardized scores both for maternal health and for child outcomes. We note that three studies used a parent-child interaction measure, but reporting of the data was too heterogeneous to allow analysis of outcome.^{22,30,31}

Risk of bias within studies

Risk-of-bias characteristics are summarized in Table SI (online supporting information). To our knowledge, no studies in the review were registered with a national or international trials registry. No conflict of interest declarations were found. The data from two studies^{28,29} were reported within a book chapter and the evaluations from the Northern Irish Southern Health and Social Care Trust³³ were routine data.

For methodology, individual randomization to treatment was reported in one study;³⁰ the remainder of studies were explicitly reported as quasi-experimental or within-subject evaluations. Outcome measures were either collected by facilitators^{33,34} or not clearly reported. Consequently, there is a risk of bias in reporting. With regard to negative

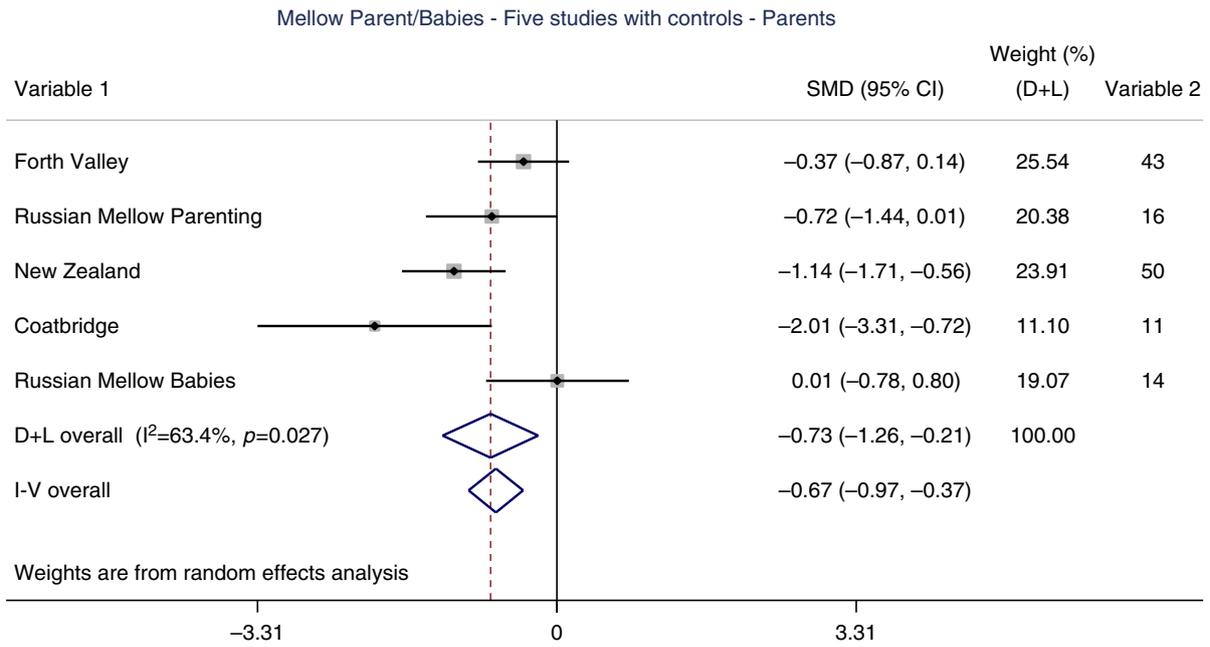


Figure 2: Meta-analysis for effect of Mellow Parenting on parental well-being. I^2 , heterogeneity statistic; I-V, Using Fixed Effects model; D+L, Using DerSimonian-Laird random effects model; SMD, Standardised Mean Difference.

findings, Puckering et al.²² reported that in its current delivery model Mellow Parenting was unlikely to benefit children presenting with reactive attachment disorder. Drop-out rates are recorded in Table II. Drop-out rate from start to conclusion of treatment for Mellow Parenting/Mellow Babies ranged from 0% to 29%, whereas the drop-out rate for comparison groups (where recorded) ranged from 4% to 34%. We note that drop-out rates both for treatment and for comparison groups were not recorded in the Russian samples.^{28,29}

No intention-to-treat analyses were reported, and the data sets contained insufficient numbers for sub-group analyses.

Results of individual studies

Mean scores and standard deviations for the studies included in the meta-analysis are reported in Table II. Data are therefore reported only for those who completed treatment. With regard to the quasi-experimental studies, Puckering et al.³¹ used a comparison group of families attending family centres not offering Mellow Parenting; for the Russian studies,^{28,29} comparison groups were other families attending family centres but on the waiting list for Mellow Parenting/Mellow Babies. Finally, the comparison group for the Mellow Babies study by Puckering et al.³⁰ received treatment as usual, whereas mothers in the treatment group received treatment as usual plus Mellow Babies.

Synthesis of results

Results for maternal mental health and childhood outcomes are presented in Figures 2 and 3. Owing to small

sample sizes, results for Mellow Parenting and Mellow Babies are combined. The weighted mean effect size for change in parental mental health for cases versus controls was $d=-0.67$ (95% CI -1.26 to -0.21), indicative of a medium effect size for improvement in maternal mental health. For child outcomes the weighted mean effect size for change in child problems for cases versus controls was $d=-0.40$ (95% CI -0.77 to -0.02), indicative of a medium effect size for reduced childhood problems. There was evidence for medium levels of heterogeneity in the parental data ($\chi^2=10.93$, $df=4$, $p=0.027$; $I^2=63.4\%$). There was no evidence of heterogeneity for child data ($\chi^2=0.38$, $df=2$, $p=0.827$; $I^2=0\%$). However, sample size was small. We repeated the analyses incorporating the pre-post treatment evaluations into the effect size estimate with no change in the pattern of results.

Analyses using Egger's test, funnel plots, and trim-and-fill procedures indicated the absence of publication bias, small study effects, or undue influence of individual studies.

DISCUSSION

Our meta-analysis presents the first quantitative synthesis of results for the Mellow Parenting programme of parenting interventions. These associations were of medium effect size, suggesting that participation in a Mellow Parenting programme was associated with improvements in maternal well-being and a reduction in child behaviour problems, albeit with a small and heterogeneous sample of studies. Retention rates were favourable for participants who received the intervention. We note that the statistical

Mellow Parent/Babies - Three studies with controls - Child

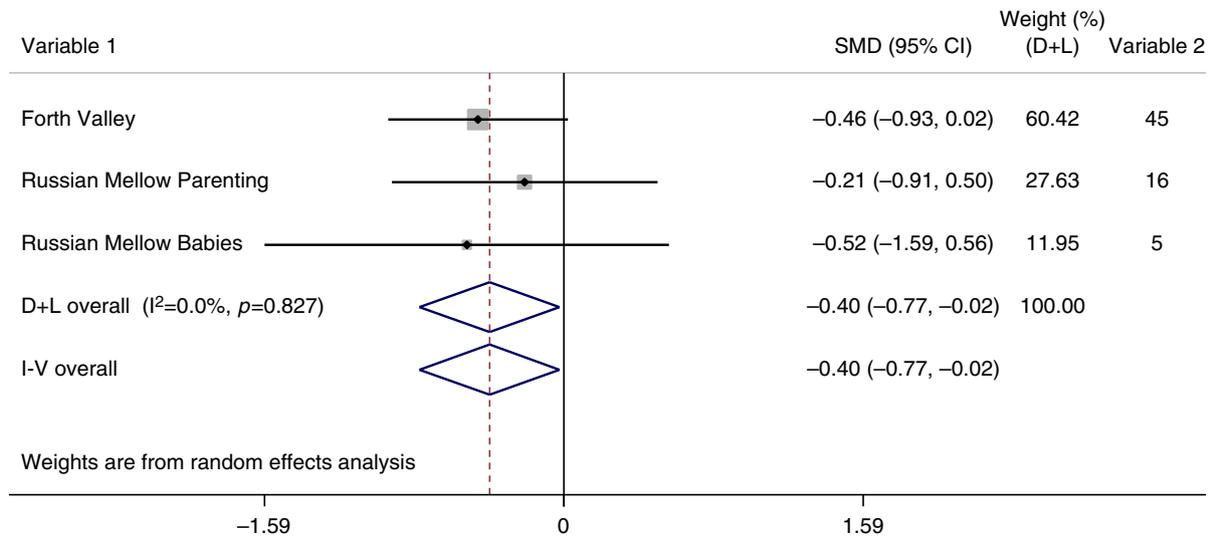


Figure 3: Meta-analysis for effect of Mellow Parenting on child outcomes. I^2 , heterogeneity statistic; I-V, Using Fixed Effects model; D+L, Using DerSimonian-Laird random effects model; SMD, Standardised Mean Difference.

analyses indicated no evidence of publication bias or small study effects. However, owing to the heterogeneous nature of the included studies and the small sample sizes, we urge caution in interpreting this finding.³⁵ Additionally, there remains the possibility of unpublished negative findings. However, we suggest that this pattern of results has important implications for building the evidence base for Mellow Parenting, for implementing Mellow Parenting in practice, and for developing evaluation mechanisms for non-commercial complex interventions.³⁶ Given the lack of high-quality RCTs, we suggest these data identify the need for one or more adequately powered RCTs of Mellow Parenting.

We note that the meta-analysis has several limitations, some of which we suggest are instructive in improving evaluation frameworks for complex interventions. The studies retrieved were small in number, and within-studies the sample sizes were small. Study quality corresponded to level III or IV levels of evidence, suggestive of the need for further high-quality research in this area. This is also possibly a reflection of the complexity in conducting research in families considered to be at developmental ‘high-risk’. We are aware of two further studies for which outcomes are not yet published: one completed pilot trial of the Mellow Bumps antenatal intervention (clinicaltrials.gov NCT01590212) and an ongoing trial comparing antenatal Mellow Parenting with Triple P (ISRCTN21656568).

Data were heterogeneous, reflected in the I^2 values for change in maternal mental health. There were also gaps in the data for sample characterization and outcome data. We note that recording of drop-out rates, both before intervention and within intervention, was rather variable. Consequently, we were unable to conduct any adequate

drop-out analyses, nor can we exclude the possibility of a biased drop-out profile. We were unable to retrieve data for dropout rates before intervention, but this suggests that there could be improvements in the pathway by which families who might benefit from Mellow Parenting are identified and engaged in services. A further statistical limitation was the lack of intention-to-treat analyses in these studies, adding a further note of caution to our findings.

The small number of studies prevented analysis of the different variants on the Mellow Parenting base programme (e.g. Mellow Babies, Mellow Bumps). Similarly, small sample size limited the data on long-term follow-up beyond end of intervention. Therefore, our data are silent on whether Mellow Parenting confers long-term developmental benefits to children: this deficit is equally evident in relation to all postnatal parenting interventions with children under 3 years (Barlow et al.¹⁸). There were also limited data on mother–infant interaction, and no reporting of standardized parenting measures. Finally, we note that there were multiple indicators of potential bias within studies, such as failure to blind raters, some developer involvement, and lack of declaration of conflicts of interests. To an extent this can be explained by the lack of RCTs in the synthesis and consequently, lower standards of methodological rigour.

Turning to the implications of our meta-analysis, we suggest that our findings support the evidence from single case and narrative reviews of Mellow Parenting that a group-based, attachment-informed intervention can be effectively targeted towards parent–child dyads at risk of serious adverse outcomes resulting from parental difficulties. The baseline samples for all studies included in the meta-analysis had multiple indicators for developmental risk (including

social adversity, exposure to interpersonal violence, parental substance misuse, parental mental illness, or previous statutory social-service involvement). Importantly, the results suggest the evidence of benefit from Mellow Parenting may be shared across both parents and offspring, consistent with findings from other attachment-informed programmes such as Incredible Years¹⁶ and the Nurse–Family Partnership.¹ The review suggests that Mellow Parenting occupies a unique place with attachment-informed parenting programmes in its explicit focus on families with substantial difficulties, time-limited nature, group-based approach, and flexibility in age range.

The results give tentative support to the existing position in the UK where Mellow Parenting is recommended in national guidelines as an early years intervention. The meta-analysis improves the evidence base by applying a degree of methodological rigour to it. We suggest that this has important implications for developing Mellow Parenting in routine practice. Mellow Parenting and other programmes involving parents and young children would benefit from a clear, standardized set of outcome measures focussed on tracking pre–post change in maternal (parental) mental health, indicators of child social, emotional, and linguistic development,^{37–40} and perhaps parent–infant interaction.¹¹ As Mellow Parenting training is delivered through an international network of trainers, there is scope for developing a routine framework for this intervention. A parallel example from clinical interventions in adult mental health is the increasing use of standardized outcomes in mentalization-based therapy.⁴¹

Our results demonstrate the challenges and opportunities for developing evaluations of complex interventions. This analysis identified a substantial ‘grey literature’ reporting Mellow Parenting outcomes, in terms of commissioned reports, small-scale studies, and conference presentations. Despite substantial efforts, we were unable to use much of the data because of ethical barriers to using unpublished data for which research ethical consent may not have been sought. Mellow Parenting is therefore in the uncomfortable position where there is dissemination of the intervention in routine practice, with some collection of routine evaluation data, but without peer-reviewed or publicly available access to these data. We suggest that this requires a change in how we approach the use of routine data. Mellow Parenting is an example of an intervention that targets hard-to-engage families, and sometimes the gathering of explicit consent for anonymized data collection may be unduly burdensome. One consequence of this is that families with substantial parenting difficulties may remain under-represented in the

research literature.¹⁸ It may in some circumstances be appropriate to approach informed consent for (non-randomized) evaluation of these interventions from a community rather than an individual perspective, as has been recommended for health services research more generally;³⁶ in these circumstances, review of independent research ethics should be sought. In tandem, this requires the following: transparency from practitioners that routine anonymized data may be used to develop the knowledge base supporting the intervention; the use of outcome measures that are not burdensome; and robust systems for ensuring anonymization of data. Similar ethical considerations have been applied to the use of family practice data for pharmaceutical post-marketing surveillance. As we move to increasing stratification of interventions to target subsets of a population likely to derive greatest benefit from a given treatment,³⁶ this may be an effective approach to the provision of an exploratory evidence base for complex interventions in the non-commercial sector.

CONCLUSION

Our meta-analysis of Mellow Parenting suggests the intervention confers medium-level treatment effects to mothers and children presenting with multiple indices of environmental adversity threatening good developmental outcomes, albeit with some methodological weaknesses. We suggest that further research in this area should focus on better specification of the child development factors most likely to be improved (e.g. language acquisition⁴²) and on delineation of the effectiveness of specific parenting programmes. To achieve this, we suggest increased reliance on routine data evaluation will be required.

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SUPPORTING INFORMATION

The following additional material may be found online:

Table SI: Risk of bias in individual studies

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