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Regulatory problems and disorders in early childhood: aetiology, contextual factors, developmental outcomes and pathways, and treatment options

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Regulatory problems and disorders in early childhood: aetiology, contextual factors, developmental outcomes and pathways, and treatment options

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Editorial: Regulatory problems and disorders in early childhood: aetiology, contextual factors, developmental outcomes and pathways, and treatment options

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early regulatory problems, early regulatory disorders, parent-infant interaction, parenting interventions, developmental trajectories, parenting stress

Editorial on the Research Topic
Regulatory problems and disorders in early childhood: aetiology, contextual factors, developmental outcomes and pathways, and treatment options

We are delighted to present a diverse selection of current research on early regulatory problems (RPs; i.e., excessive crying, sleeping, or feeding problems) and parent-child interactions. The articles in this special topic range from primary data studies of heterogeneous and diverse populations from Denmark, the USA, and Germany (both longitudinal, cross-sectional, and interventions), to meta-analytic approaches, and an expert opinion. After the last few decades empirically established a clear association of early RPs with risks for later childhood mental health (1, 2), we can now focus on the clinical and societal importance of this topic and underlying mechanisms.

What risks do early regulatory problems pose to the child's later mental health?

Several studies explore the question of whether and under which conditions early RPs place a child at risk for later mental health problems. The meta-analysis by Galling et al., provides a summary of studies conducted in clinical and community settings with follow-up ages ranging from 2 to 14 years. Pooled results show that children with RFs are 4 times more likely to develop overall behavioural problems than controls. Interestingly, children with multiple RPs are not at a higher risk than those with single RPs. Using different samples from Denmark, Ammitzboll et al. show that infants with RPs (as assessed by community mental health nurses) are at a higher risk of clinical diagnoses at 1.5 years. Similarly, Weber-Pant et al. show that the concerns of community mental health

nurses about combined sleeping and feeding problems are associated with any neurodevelopmental disorder and autism spectrum disorder diagnoses at 1–8 years. Furthermore, Keller et al. investigate the impact of the COVID-19 pandemic on RPs and child mental health in a clinical sample. While parents do not report increased RPs during lockdown phases and the severity of pandemic restrictions have no impact, parental symptoms of depression are related to increased child behavioural problems in all age groups.

These studies support existing empirical evidence that RPs might reflect one of the earliest signs of an ongoing pattern of mental health problems that develop over time. In addition to the already mentioned robust evidence regarding the impact on later mental health problems, there are several arguments supporting this claim. First, the prevalence of RPs in infancy (approximately 20%) is similar to the overall prevalence of mental health problems in childhood. Second, consistency of the association between early RPs and mental health symptoms in childhood is demonstrated with evidence from a range of countries (e.g., Denmark, Germany, Finland, UK, Australia, Brazil) (3–9). Third, there is emerging evidence that RPs are associated with individual variations in the brain (i.e., default mode network) and physiological systems (i.e., the dysregulation of the HPA axis) that might account for the long-term negative impact on child mental health (10, 11).

Parent-child interactions as a contextual driver of long-term consequences

Long-term effects of RPs are now well documented and underscore the need to better assist affected families. However, little is known about the potential underlying mechanisms explaining long-term consequences on mental health. In this regard, examining parent-child interactions in affected families may help understand the complex and dynamic interplay of biological and environmental mechanisms over time (12). This may require, as shown in this article selection, developing and adapting new parameters to address the specific characteristics of these interactions. For example, Licata-Dandel et al. demonstrate that mothers of children with RPs use more appropriate mind-related comments as well as non-attuned mind-related comments when interacting with their children than mothers in a control group. The results suggest that RPs are related to modified interactional processes of maternal-infant attachment. Accordingly, Jaekel et al. show that more persistent RPs in infancy are associated with lower quality of dyadic autonomic emotional co-regulation using the universal Welch Emotional Connection Screen (uWECS) coding system in a linguistically diverse sample. Together with the findings from Hane et al., these promising pilot study results facilitate a window into evolutionary-based parent-child co-regulatory processes that are not only related to RPs but also have an inherent function for our species and potentially contribute to long-term mental health outcomes. We encourage future research to build on these results and further explore the underlying biopsychosocial mechanisms, particularly in the context of stressful parent-child interactions and their explanatory power in terms of child developmental and mental health outcomes.

How can we advance our understanding about regulatory problems?

Based on the identification of specific parameters of parent-child interactions and related mechanisms, we can finetune evidence-based intervention approaches (13). We already look back on effective treatment forms developed during the last decades (14, 15), but in some cases effect sizes are small and therefore unsatisfactory. In this topic selection, St James-Roberts and Llewellyn provide an expert opinion on the importance of providing support to parents of infants with RPs. Furthermore, two randomized control trials show that family-based interventions can have a range of benefits for developmental outcomes of preschool children with RPs (Welch et al.).

In addition to a clear need for large-scale assessments of evidence-based interventions and replication across different populations, another priority for future research includes the diagnostic specification of regulatory disorders, as there is currently no standardized approach. A unification of definitions and diagnostic methods would facilitate more comparable research as well as applied screening and prevention efforts. Finally, studies should systematically examine the implementation of interventions for early RPs to identify possible target-group specific barriers and facilitators to offer feasible and effective treatment options to affected families. We are enthusiastic that the selection of articles included in this special topic will contribute to progress in these areas and stimulate further research.

Author contributions

AG: Conceptualization, Writing – original draft, Writing – review & editing. JJ: Conceptualization, Writing – review & editing. AB: Conceptualization, Writing – original draft, Writing – review & editing.

Conflict of interest

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The impact of crying, sleeping, and eating problems in infants on childhood behavioral outcomes: A meta-analysis

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Background: There is increasing evidence that regulatory problems (RPs), such as excessive crying, sleeping or feeding problems in infancy, could be associated with the development of behavioral problems in childhood. In this meta-analysis we aimed to investigate the strength and characteristics of this association.
Methods: A systematic literature search (PubMed/PsycInfo, until 15/08/2021) for longitudinal prospective studies of infants with RPs and at least one follow-up assessment reporting incidence and/or severity of behavioral problems was conducted. The primary outcomes were (i) the cumulative incidence of behavioral problems in children (2–14 years) with previous RPs and (ii) the difference between children with/without previous RPs with regard to the incidence and severity of externalizing, internalizing and/or attention-deficit/hyperactivity disorder (ADHD) symptoms. Additionally, we analyzed behavioral problems of children with previous single, multiple or no RPs and with respect to age at follow-up. Subgroup and meta-regression analyses were added.
Results: 30 meta-analyzed studies reported on 34,582 participants (n_{RP} = 5091, $n_{control}$ = 29,491; age: baseline = 6.5 ± 4.5 months, follow-up = 5.5 ± 2.8 years) with excessive crying (studies = 13, n = 1577), sleeping problems (studies = 9, n = 2014), eating problems (studies = 3, n = 105), any single (studies = 2, n = 201) or multiple RPs (studies = 9, n = 1194). The cumulative incidence for behavioral problems during childhood was 23.3% in children with RPs. Behavioral problems were significantly more pronounced in infants with RPs compared to healthy controls (SMD = 0.381, 95% CI = 0.296–0.466, p < .001), particularly with multiple RPs (SMD = 0.291, p = 0.018).
Conclusions: Findings suggest that RPs in infancy are associated with overall behavioral problems (externalizing or internalizing behavior and ADHD symptoms) in childhood. Our data cannot explain linked developmental trajectories and underlying factors. However, detection of affected infants may help to adapt supportive measures to the individual familial needs to promote the parent-child-relationship and prevent the development of child behavioral problems from early on.

KEYWORDS

regulatory problems, early infancy, excessive crying, sleeping problems, eating problems, child behavior, ADHD

Abbreviation
regulatory problems (RPs).

Introduction

During the first years of life, the ability to self-regulate is one of the most important developmental tasks as it is closely related to the infant's general adaptability to its environment and ultimately its survival (1). Self-regulation entails the infant's ability to control behavior, including physiological, sensory, motoric, attentional, and emotional processes, such as self-soothing, ingesting food, developing a sleep-wake regulation as well as attaining an alert state that enables social interaction (2). Besides maturation processes, the development of self-regulation is enabled by the primary caregivers, mostly the parents, embedded in a dyadic interaction. This reciprocal relationship includes infant self and parent-infant co-regulatory processes (3, 4). Thus, an infants's regulatory capacities can be seen as fundamental aspects of childhood development (5). However, some infants display dysregulation in these processes which are defined as difficulties in adjusting to the environment, the regulation of behavior, arousal, and self-soothing. These are labelled as regulatory problems (RPs), which are excessive crying, sleeping, or feeding difficulties (6).

According to the diagnostic classification of mental health and developmental disorders of infancy and early childhood (DC: 0–5), infants are diagnosed with primary "sleep, eating and crying disorders", if the functioning of the infant, parent, or both is persistently impaired, and other diagnoses such as a sensory processing disorder are ruled out (7). RPs can either manifest themselves as a single problem (e.g., excessive crying only) or co-occur as multiple RPs (8, 9). Numerous studies have shown that an infant's capacity to regulate their own behavior in terms of crying, eating, and sleeping problems are strong predictors of developmental, cognitive, behavioral, and emotional difficulties throughout childhood, including aggression, attention problems, anxiety, or depression (10–13). While most RPs are temporary and disappear during infant development, some RPs can persist or even exacerbate and lead to long-term consequences (13–15).

There is increasing evidence that RPs such as excessive crying, sleeping, or feeding problems in infancy could be associated with the development of behavioral problems in childhood. A previous meta-analysis by Hemmi et al. (16) on this association found small effect sizes for internalizing behavior and ADHD and medium effect sizes for externalizing behavior.

Primary study data suggest that single RPs such as excessive crying (17), eating (18) or sleeping problems (19) are associated with a higher risk of behavioral problems in infancy. Combinations of RPs show similar relationships: Persistent crying problems co-occurring with sleeping or eating problems at 3–6 months were found to be associated with externalizing problems at age 8 to 10 (13), and multiple RPs at 6 months were found to be associated with internalizing, externalizing, and general behavior problems at age 5 and 14 (20). Moreover, one study found crying and sleeping difficulties to be linked with disorganized attachment (21). Research also found infants with RPs to be at an increased risk of developing deficits in social skills (9) and cognitive development (22) at preschool age.

Risk factors for RPs include parent-related factors, such as emotional or professional distress (23–26) or lack of parental intuitive skills (7). On the other hand, pregnancy (27–29), birth (14, 26, 30) and more infant-related factors (6, 23) also play a crucial role. Consequences of RPs include high level of distress for the family and are associated with psychosocial problems such as family disruption, parental insecurity, depression and anxiety, or lack of self-efficacy (31, 32). These can result in parents seeking professional help more frequently and considerably higher health care costs (33, 34), but may also lead to emotional and/or physical maltreatment of infants (35), such as the shaken baby syndrome (36).

A better understanding of the association of infant RPs and the risk of behavioral problems during childhood is of great importance to improve early detection and intervention. This is particularly true, since lasting behavioral problems during childhood have been linked to a higher risk for impairments in academic achievement (37) and subsequent mental illness (38).

Since several longitudinal studies have been published since 2,011 and provided additional evidence, we aimed to update and complement the findings of a previous meta-analysis (16). Particularly, we added the cumulative incidence as primary outcome and adjusted some analyses in view of methodological considerations. For example, we aimed to ensure a more distinct classification of outcomes by merging available data as accurately as possible. That is, we chose one outcome per study with *à priori* specified outcome definitions in contrast to the previous meta-analysis that combined ≥ one study outcome in the same meta-analysis. Moreover, we added several subgroup analyses and metaregression analyses. We compared for example behavioral outcomes of those with multiple vs. single RPs to find out whether behavioral problems are more likely in children with previous multiple RPs compared to those with single RPs. Also we analyzed the effect of the follow-up age to look for vulnerable time points for the development of behavioral problems (for details see methods).

Overall, our analysis aimed to allow for a better understanding of the strength and the characteristics of the association of RPs in infancy with the development of behavioral problems in childhood.

Methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standard (39, 40).

Literature search

Two independent authors (PS, HB) searched PubMed/MEDLINE and PsycInfo through 15/08/2021 without language restrictions, supplemented by a manual review of reference lists from eligible publications and relevant reviews and meta-analyses. The search terms used were: ("infant crying" OR "crying problem*" OR "excessive crying" OR "persistent crying" OR "feeding problem*" OR "feeding disorder" OR "refusal to eat" OR "picky" OR "choosy" OR "infant sleep" OR "sleeping disorder*" OR "regulation disorder*" OR "regulatory problem*" OR "regulatory disorder*") and ("attention-deficit" OR "attention deficit" OR hyperactivity OR ADHD OR ADD OR hyperkinetic OR "behavioral problems" OR "behavioral outcome" OR "emotional problem" OR "internalizing" OR "externalizing" OR "dysregulated behavior" OR dysregulation OR anxiety OR fear OR psychopathology OR "clinical symptoms" OR preschool OR

"growing up" OR follow-up OR "follow up" OR longitudinal OR prospective OR "mental health" OR "epidemiology"). Authors were contacted for additional information.

Inclusion criteria

Inclusion criteria were: (i) prospective study, (ii) reporting on ≥20 children with (iii) RPs regarding crying, sleeping, and/or eating problems (study-defined, see **Table 1**) (iv) during infancy (≤18 months of age (41)), and (v) more than one follow-up assessment during childhood (2–14 years of age) (vi) reporting on behavioral problems such as externalizing, internalizing, and/or ADHD symptoms. We did not include studies that only reported RPs as outcome at follow-up.

If studies with a community sample only reported continuous measures of RPs of the complete sample at baseline and did not distinguish between RPs and healthy controls (HCs), they were not included. We also excluded studies restricted to children with any kind of disability, pervasive developmental or autism spectrum disorder or those investigating other clinical outcomes only (e.g., eating disorder, obesity, developmental disorder, neurological outcomes). If studies reported on HCs, these data were used irrespective of whether they were assessed prospectively or retrospectively.

Outcomes and outcome measures

Primary outcomes were (i) the cumulative incidence of overall behavioral problems of infants with any RPs (single and multiple) during infancy and (ii) the overall behavioral problems of infants with any RPs (single and multiple) compared to HCs. The outcome of overall behavioral problems summarized the amount and severity of symptoms for the primary and secondary outcomes using the total behavioral problem scores (such as CBCL total score). If those measures were not available, measures of externalizing (preferred), internalizing, and/or ADHD symptoms were supplemented. Both continuous and categorical outcomes were included (42, 43).

Secondary outcomes included (iii) overall behavioral problems of infants with single RPs compared to HCs, (iv) overall behavioral problems of infants with multiple RPs compared to healthy controls, and (v) overall behavioral problems of infants with multiple RPs compared to those with single RPs.

Other outcomes included the cumulative incidence of overall behavioral problems in infants with any RPs and HCs as well as overall behavioral problems and in-between group differences (as described above) of (vi) externalizing problems, (vii) internalizing problems, and (viii) ADHD symptoms separately. If a study reported multiple measures for one outcome, we chose the scale used most often in the overall study sample to ensure homogeneity (for details see **Table 1** and Online Resource 1 **Supplementary Table S1**).

Data extraction

Data of each study were independently identified and extracted by more than 2 authors (HB; PS); inconsistencies were resolved involving a third reviewer (BG). Unadjusted outcome data were preferred. When more than 2 samples with different symptom severity of the same RPs were studied, we extracted data from the sample with the most severely reported symptoms. If continuous and categorical data were reported, continuous data were preferred. Whenever data were missing, authors were contacted for more information.

In the case of overlapping samples, we included the most suitable data (largest sample size and/or matching inclusion criteria). In this context, we decided in one case (18) to extract outcomes from a limited study sample that better matched the predefined follow-up age (9.5 years instead of 4 years). All outcomes were extracted separately for the following groups: (a) any RPs, (b) single RPs, (c) multiple RPs, and (d) HCs. In the group of any RPs, outcomes of infants with single or multiple RPs were pooled, and the incidences/severity scores were merged.

If multiple follow-up assessments were available, we preferred those at age 5–11 years for the main analysis, as most children were assessed at that age. In case of multiple follow-up assessments between age 5–11 years, the later time point was preferred. Additionally, all other follow-up time points were extracted for a separate analysis of age groups. For the studies with multiple follow-up time points, we extracted and used multiple data from different time points. For the category "definition of RP" a studies definition was considered strict, if the assignment to the RP group was based on a structured interview or questionnaire, and it was considered lenient if it was based on a one-item parent report.

Assessment of study quality

Study quality was evaluated *via* the Newcastle-Ottawa Scale (NOS), which is a scale used for assessing the quality of nonrandomized studies in meta-analyses in the three categories 1) selection of study groups, 2) comparability of the groups and 3) ascertainment of outcome of interest. Data regarding the study quality of each study were independently identified and extracted by ≥2 authors (HB; PS). The overall result is indicated by the NOS score, where a score of ≥7 out of 9 indicates high study quality (44).

Data analysis

The cumulative incidence was computed as the number of children with mental or behavioral problems at follow-up divided by the total number of individuals in the population at risk.

Between-group differences were described for each outcome where more than 2 studies were available using the standardized mean difference (SMD). The SMD was either extracted directly or calculated from means, standard deviations (SDs) and sample sizes, odds ratios, F-statistics, or correlation coefficients (45). The SMD was adjusted using the small sample size bias correction (Hedges' g) (42). SMDs were considered small if between 0.2–0.49, medium if between 0.50–0.79, and large if ≥0.80 (46). Data were analyzed using R (R Core Team, 2019) and Comprehensive Meta-Analysis Version 3 (Borenstein, 2013). All analyses used a random effects model (47), were two-sided, with alpha = 0.05, and were presented as point estimates and corresponding 95%

TABLE 1 Study and sample characteristics.

Study	Study quality (NOS)	N (baseline)		Age (mean)		Sample		Analyzed follow-up outcomes
		RPs	HC	Baseline (months)	Follow-up (years)	Clinical vs. community	RP assessment criteria	Outcomes (Categorization)
Crying								
Bell 2018 (Australia)	7	99	182	1.7	2	Clinical	Wessel criteria	CBCL (EXT, INT)
Canivet 2000 (United States)	7	52	102	3	4	Community	Wessel criteria	RCBQ (EXT, INT)
DeSantis 2004 (United States)	4	165	–	2	5.6	Clinical	N hours crying/fussing	CBCL (overall BP, EXT, INT, ADHD)
Elliott 1997 (Canada)	6	10	72	1.8	3	Community	Wessel criteria	CBCL (overall BP)
Neu 2003 (United States)	5	20	20	2.5	7	Clinical	Crying for ≥2.8 h/d, ≥ 3 days	CBCL, DICA-R (EXT, INT, ADHD)
Papousek 2001 (Germany)	6	83	57	4.1	2.5	Clinical	Wessel criteria	CBCL (EXT, INT)
Rao 2004 (Norway)	7	63	264	9	5	Community	Daily uncontrolled crying, ≥ 2 weeks	PIC (ADHD)
Rautava 1995 (Finland)	6	338	866	3	3	Community	Questionnaire-based colic d/o	Parent-Report (EXT)
Santos 2015 (Brazil)	7	437	3237	3	4	Community	> avg. crying at same age	CBCL (overall BP, EXT, INT)
Savino 2005 (Italy)	7	52	51	2	10	Clinical	Crying avg. 4 h/d, > 4 d/week	Clinical evaluation (EXT)
Smarius 2017 (Netherlands)	7	102	3287	3	5	Community	Crying avg. ≥3 h/d/week	SDQ (overall BP, EXT, INT)
Wake 2006 (Australia)*	6	55	313	3	2	Community	Sleep and cry-fuss problems (Parent-Report)	CBCL (overall BP, EXT, INT)
Wolke 2002 (Germany)	5	101	64	3.8	9.7	Clinical	Modified Wessel criteria	SDQ (overall BP, EXT, INT, ADHD)
Sleeping								
Cook 2019 (Australia)*	7	446	647	12	5; 11	Community	Questionnaire-based sleep problem	SDQ (overall BP)
Cook 2020 (Australia)	9	283	360	7	4; 10	Community	Awakenings ≥3 times/night in the last week	DAWBA (ADHD, EXT, INT)
O'Callaghan 2010 (Australia)	7	754	2943	6	5; 14	Community	Sleeplessness most days/a few times a week	CBCL (ADHD)
Price 2012 (Australia)	4	225	–	7	6	Community	Parent-reported sleep problem	SDQ (overall BP, EXT, INT)
Scher 2005 (Israel)	6	13	12	12	3.5	Community	Night waking and settling difficulties	CBCL (overall BP)
Thunström 2002 (Sweden)	7	27	25	8.5	5.5	Community	≥15 min. to fall asleep; awakenings ≥3 times/night ≥5 nights/week. for ≥6 months	Standardized Parental Interview, Standardized Clinical Interview (EXT, ADHD)
Zuckerman 1987 (United Kingdom)	6	56	–	8	3	Community	≥1 h to settle after waking; awakenings ≥3 times/night; problem causing severe disruption to the mother's sleep	BSQ (EXT, INT, ADHD)
Östberg 2011 (Sweden)*	3	125	227	13	7.3	Clinical	Referred (sleep problem)	Connor's scale, RCBQ (EXT, INT)

(*continued*)

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TABLE 1 Continued

Study	Study quality (NOS)	N (baseline)		Age (mean)		Sample		Analyzed follow-up outcomes
		RPs	HC	Baseline (months)	Follow-up (years)	Clinical vs. community	RP assessment criteria	Outcomes (Categorization)
Wake 2006 (Australia)*	6	85	313	8	2	Community	Sleep and cry-fuss problems (Parent-Report)	CBCL (overall BP, EXT, INT)
Eating								
Dahl 1992/1994 (Sweden)	6	25	240	7.8	4; 9.6	Clinical	Refusal to eat and/or eating problem ≥1 month	Rutter PBQ, HSQ (overall BP, ADHD)
Motion 2001 (United Kingdom)	5	28	10669	6	3.9	Community	Eating difficulties for 4 weeks	SDQ (ADHD, EXT)
Östberg 2011 (Sweden)*	3	52	227	13	7.6	Clinical	Referred (eating problem)	Connor's scale, RCBQ (EXT, INT)
Crying/Sleeping/Eating								
Becker 2004 (Germany)	9	175	264	3	2; 4.5; 8; 11	Community	>1 SD ≥ mean for one factor=SRP, >1 SD ≥ mean for irritable and somatic functioning = MRP	MPI (overall BP, ADHD)
Bilgin 2020 (Germany)	7	469	977	5	8	Community	Cry duration ≥2 h/d, cry amount > avg., difficult to soothe; wakes up ≥2 times/ night, ≥15 min at night; eating difficulties, vomiting, disordered mouth/tongue movement	CBCL (ADHD)
Cook 2019 (Australia)*	7	59	647	12	5; 11	Community	Presence and severity of sleep problems, excessive crying; coughed/choked food; global temperament, mood swing	SDQ (overall BP)
DeGangi 1993 (United States)	6	9	13	9.5	4	Clinical	>20 min. to fall asleep, >2 waking/night	SHQ (overall BP, ADHD)
DeGangi 1996 (United States)	5	13	-	18.5	3	Clinical	>20 min. to fall asleep, >2 waking/night	CBCL, expert observation (overall BP, ADHD)
DeGangi 2000 (United States)	5	22	38	18.5	3	Clinical	>20 min. to fall asleep, >2 waking/night	SHQ, clinical diagnosis (overall BP)
Forsyth 1991 (United States)	7	115	205	4	3.5	Community	parent-reported sleep problem	CBCL (overall BP)
Hyde 2012 (Australia)	7	480	4356	6	5; 14	Community	Colic, sleeplessness, eating problems, overactivity	CBCL (overall BP, EXT, INT)
Östberg 2011 (Sweden)*	3	53	227	13	7.5	Clinical	Referred (sleep/eating problem)	Connor's sale, RCBQ (EXT, INT)
All studies								
Total	6	5091	29,491	6.5***	5.5***			

*Due to different RPs group comparisons, these studies are listed multiple times, however they were only considered once for the calculation of total means and Ns ("All studies").
**Of the RPs group.
***Not adjusted for sample size (adjusted means baseline: 5.4months; follow-up: 5.8years). ADHD = Attention-deficit-hyperactivity disorder; avg. = average; BP = behavioural problem; BSQ = Behavioral Style Questionnaire; CBCL = Child Behavior Checklist; DAWBA = Development and Well-Being Assessment; DICA-R = Diagnostic Interview for Children and Adolescents-Revised; EXT = externalizing problems; HSQ = Home and School Questionnaire; INT = internalizing problems; MPI = Mannheim Parent Interview; MRP = multiple regulatory problems; N = number of subjects; NOS = Newcastle-Ottawa-Scale; PIC = Personality Inventory for Children; Rutter PBQ = Rutter Preschool Behavior Questionnaire; RCBQ = The Rutters Children's Behaviour Questionnaire; RPs = regulatory problems; SDQ = Strengths and Difficulties Questionnaire; SHQ = Sensorimotor History Questionnaire; SRP = single regulatory problem.

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confidence intervals (CIs). In addition, *p*-values were used to describe the test-for-null outcome effects. Heterogeneity among studies was assessed with I^2 value (48), with $p < .05$ and $I^2 \geq 50\%$ indicating significant heterogeneity. Publication bias was assessed for the primary outcomes by using funnel plots and Egger's regression test for funnel plot asymmetry (42, 49) for analyses with ≥10 studies. In addition, we used the trim and fill method which yields an estimate of the effect size after the publication bias (50) and the fail-safe test (estimated number of studies needed in order to obtain a non-significant result).

The following subgroup analyses were added for all outcomes: (i) sample (community vs. clinical), (ii) RP definition (strict vs. lenient), (iii) type of RPs (crying vs. sleeping vs. eating; only for comparison of single RPs vs. multiple and single RPs vs. HC), and (iv) age at baseline (≤6 vs. >6 months). We conducted random effects meta-regression analyses to identify potential moderators including (i) age at baseline, (ii) age at follow-up, (iii) percentage male, (iv) sample size, and (v) study quality (NOS). To account for a potential change of symptoms with age, we added an additional analysis for any RPs looking at the overall behavioral problems reported for the following age groups only: 2–6, 7–10, 11–14.

Results

Search results

The initial search resulted in 3,794 hits. Altogether, 3,705 studies were excluded on the title/abstract level. Of the remaining 89 references 59 articles were excluded after full text review, yielding 30 studies (10, 12, 13, 15, 17–20, 32, 51–69) (**Figure 1**) that were included in this meta-analysis.

Study characteristics

A total of 30 studies reported on 34,582 participants (RPs: $n = 5091$, control: $n = 29{,}491$; baseline = 6.5 ± 4.5 months, follow-up = 5.5 ± 2.8 years, male = 52%). Single RPs were examined in 25 studies ($n = 3897$; crying problems: studies = 13, $n = 1577$; sleeping problems: studies = 9, $n = 2014$; eating problems: studies = 3, $n = 105$; not specified: studies = 2, n = 201), multiple RPs in 9 studies ($n = 1194$). Five studies reported co-occurrence of RPs but only analyzed the outcome of single RPs (11, 13, 56, 60, 62) (**Table 1**, Online Resource **Supplementary Table S1**).

The overall study quality was high with a mean NOS score of 6.2 ± 1.3 (median = 6, 95% CI = 6–7) and a NOS ≥7 (indicating high study quality) in 13 of 30 studies (43%) (Online Resource **Supplementary Table S2**).

The cumulative incidence of overall behavioral problems in children with previous RPs and HCs

The meta-analytically calculated cumulative incidence of overall behavioral problems in children with previous RP was

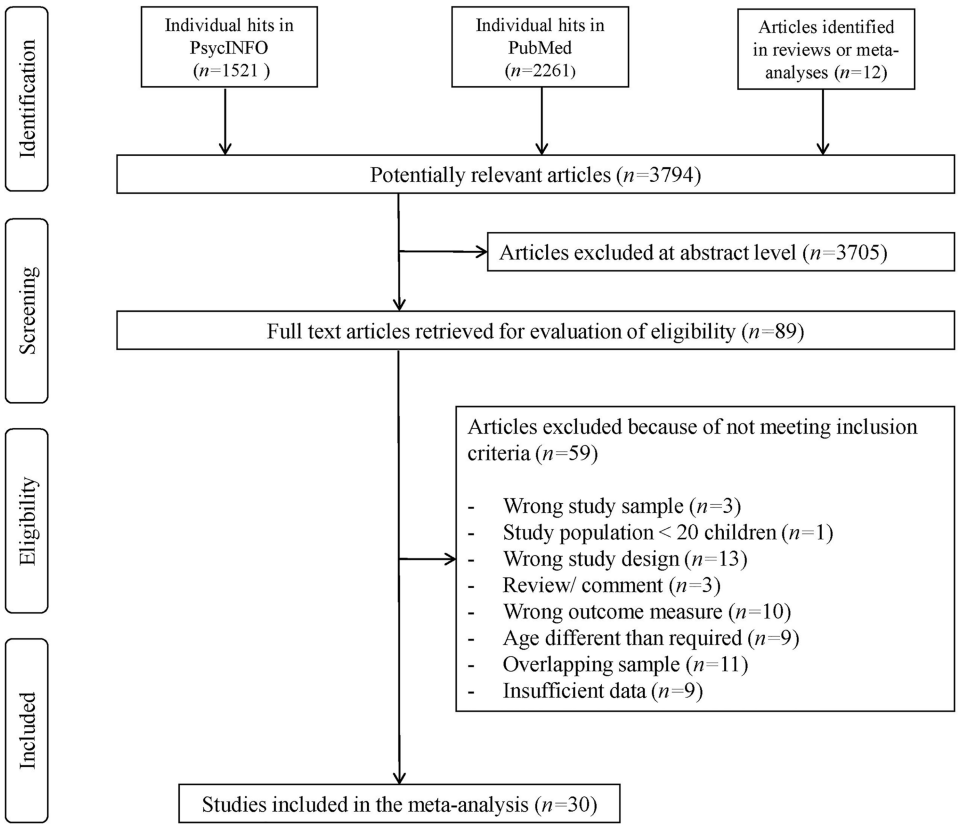

FIGURE 1
PRISMA diagram of the systematic literature search.

0.233 (95% CI = 0.179–0.298, studies = 18, $n = 2873$), indicating that 23.3% of those with RPs during infancy developed behavioral problems later (Table 2). Of note, is that this is nearly 4 times more frequent than in HCs that had a cumulative incidence of overall behavioral problems of 0.067 (95% CI = 0.043–0.104, studies = 10, $n = 3699$). No significant subgroup differences or moderating effects emerged in children with previous RPs, except for smaller sample sizes that were associated with higher overall behavioral problems ($p = 0.022$) (Online Resource Supplementary Table S3).

Overall behavioral problems of infants with RPs compared to HCs

When meta-analytically comparing the overall behavioral problems of children with previous single and multiple RPs during infancy to HCs (studies = 26, $n = 31,177$), those with RPs had significantly more behavioral problems (SMD = 0.381, 95% CI = 0.296–0.466, $p \leq 0.0001$) (Figure 2).

The Egger's test (intercept = 1.422, 95% CI = 0.6–2.25, $p = 0.003$) indicated potential publication bias. After adjustment for 6 potentially missing studies using the trim-and-fill method, the SMD decreased to 0.339 (95% CI = 0.243–0.434).

No significant effects emerged in the subgroup or meta-regression analyses. However, effects sizes were particularly high (SMD = 0.685, 95% CI = 0.295–1.074, $p \leq 0.001$) in the clinical sample compared to the community sample (SMD = 0.348, 95% CI = 0.275–0.422, $p \leq 0.001$) (Table 2). Effect sizes were alike, regardless of the follow-up age (see Table 3).

Comparison of single and multiple RPs

The overall behavioral problems of children with single RPs (studies = 23, $n = 26,789$) and with multiple RPs during infancy (studies = 8, $n = 7474$) were significantly more pronounced compared to HCs (single RPs: SMD = 0.372, 95%, CI 0.281–

TABLE 2 Primary outcomes and specific behavioral problem outcome categories.

OVERALL BEHAVIORAL PROBLEMS							
CUMULATIVE INCIDENCE			COMPARISON OF ANY RPs TO HEALTHY CONTROLS				
SUB-GROUP	N (*n*)	Incidence	N (*n*)	SMD	Result: *p*-value	Heterogeneity	
						p-value	I^2
All Studies	18 (2873)	0.233	26 (31,177)	**0.381**	**<0.001**	<0.001	56.9
Community sample	11 (2603)	0.201	19 (30,057)	**0.348**	**<0.001**	0.070	34
Clinical sample	7 (270)	0.300	7 (1120)	**0.685**	**<0.001**	<0.001	78.2
Strict[a]	16 (1682)	0.234	24 (23,806)	**0.381**	**<0.001**	<0.01	65.4
Lenient[b]	2 (1191)	0.233	2 (7371)	**0.333**	**<0.001**	0.84	0.00
Crying problems	6 (609)	0.268	11 (9116)	**0.493**	**< 0.001**	<0.001	66.6
Sleeping problems	4 (1060)	0.231	7 (5319)	**0.266**	**< 0.001**	0.206	29.1
Eating problems	0		3 (11,228)	0.231	0.072	0.256	26.6
Single RPs[c]	13 (2182)	0.228	23 (26,789)	**0.377**	**<0.001**	56.1	<0.001
Multiple RPs[c]	6 (687)	0.248	8 (7474)	**0.415**	**<0.001**	77.1	<0.001
≤6 months	8 (892)	0.274	13 (11,012)	**0.405**	**<0.001**	<0.001	63.7
>6 months	10 (1981)	0.208	13 (21,585)	**0.355**	**<0.001**	0.020	50.1
EXTERNALIZING PROBLEMS							
All Studies	11 (1544)	0.201	16 (25,702)	**0.362**	**<0.001**	0.001	62.065
INTERNALIZING PROBLEMS							
All Studies	8 (1443)	0.160	12 (13,865)	**0.343**	**<0.001**	0.602	0.000
ADHD							
All Studies	8 (1065)	0.242	11 (15,019)	**0.461**	**<0.001**	0.071	41.701

SMDs (standardized mean differences) >0 indicate that a specific continuous outcome (e.g., symptom severity) was more pronounced in those with regulatory problems (RPs). *P*-values ≤ 0.05 were considered statistically significant and are marked in bold together with the respective SMD. For more details about overall behavioral problems see Online Resource 1 Supplementary Table S3 and Online Resource Supplementary Table S5 for subgroup analyses of the outcomes externalizing problems, internalizing problems and ADHD; CI = confidence interval; Coeff = coefficient; N = number of comparisons; n = number of subjects; n/a = not applicable; SMD = standardized mean difference.

[a]Strict definition = structured interview or questionnaire based.

[b]Lenient definition = one-item parent report.

[c]Including separate single and multiple RPs within a study.

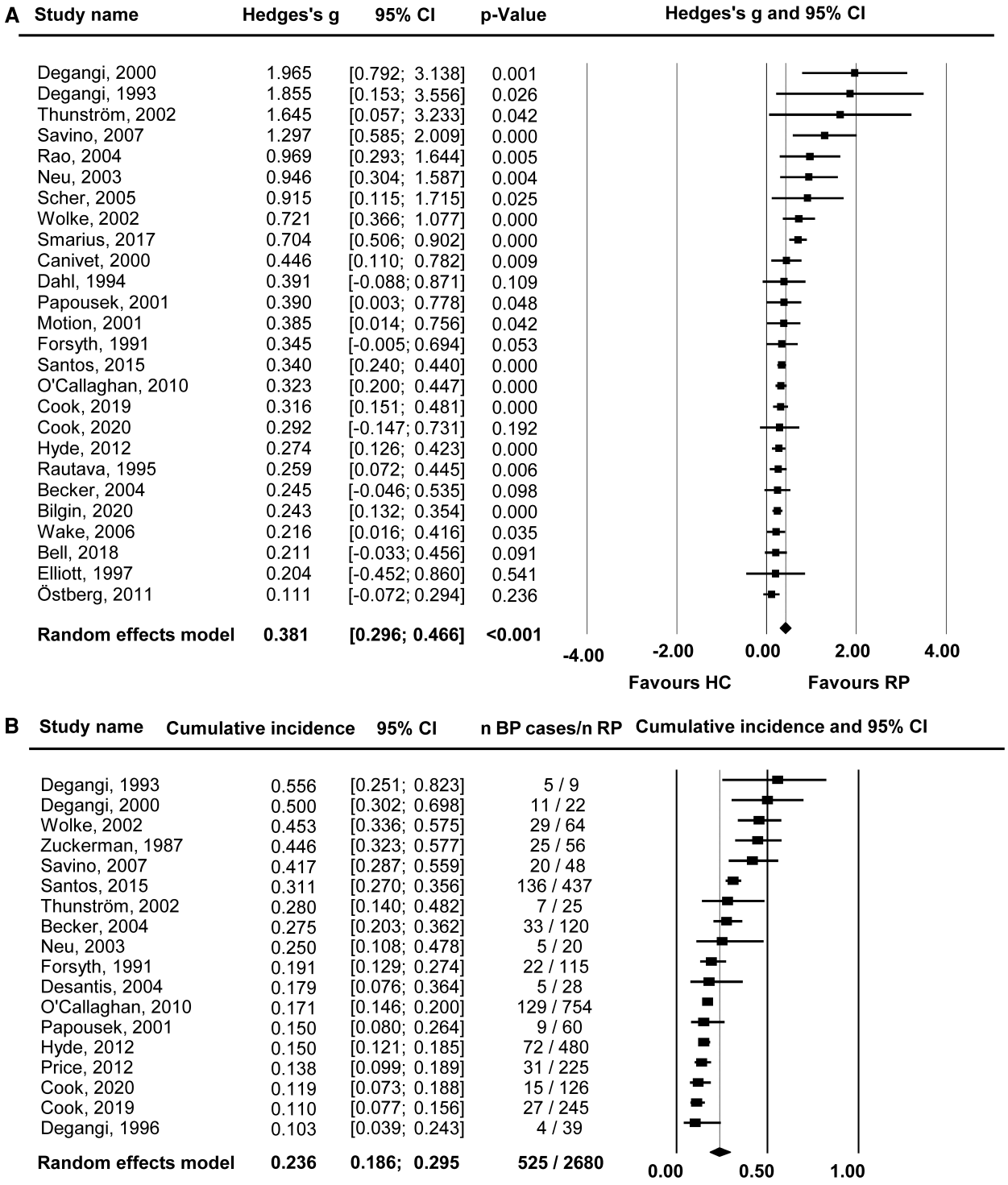

FIGURE 2
Overall behavioural outcomes (any regulatory problems vs. healthy controls). Forest plot of (A) standardized mean difference (Hedges's g) and (B) cumulative incidence for overall behavioural problems in children with any regulatory problems (RPs) in infancy vs. healthy controls (HC). SMDs > 0 indicate that a specific outcome was more pronounced in the RPs than the HC group. Black whiskers mark the 95% confidence interval (CI).

0.462, $p \leq 0.0001$; multiple RPs: SMD = 0.419, 95% CI 0.200–0.639, $p \leq 0.001$). Children with multiple RPs during infancy did not show significantly more overall behavioral problems than those with single RPs (studies = 4, $n = 961$, SMD = 0.149, 95% CI = −0.250–0.549, $p = 0.463$) (see Online Resource **Supplementary Table S4**).

Type of rp: crying vs. Sleeping vs. Eating problems

The overall behavioral problems of children with excessive crying (SMD = 0.493, 95% CI = 0.336–0.651, $p \leq 0.001$) and sleeping problems (SMD = 0.266, 95% CI = 0.138–0.395, $p \leq 0.001$) were

TABLE 3 Comparison of overall behavioral problems in single RPs vs. multiple RPs vs. healthy controls and different age groups at follow-up.

OVERALL BEHAVIORAL PROBLEMS SINGLE RPs vs. MULTIPLE RPs vs. HEALTHY CONTROLS					
COMPARISON	N (*n*)	SMD	Result: *p*-value	Heterogeneity	
				p-value	I^2
Single RPs vs. HCs	23 (26,789)	**0.372**	**<0.001**	<0.01	56.1
Multiple RPs vs. HCs	8 (7474)	**0.419**	**<0.001**	<0.001	77.1
Single RPs vs. Multiple RPs	4 (961)	0.149	0.463	<0.001	82.5
OVERALL BEHAVIORAL PROBLEMS OF ANY RPs vs. HEALTHY CONTROLS AND DIFFERENT AGE GROUPS AT FOLLOW-UP					
3–6 years	21 (31,495)	**0.363**	**<0.001**	0.008	48.1
7–10 years	7 (4138)	**0.334**	**<0.001**	0.201	35.2
11–14 years	4 (9347)	**0.395**	**<0.001**	0.002	48.9

SMDs (standardized mean differences) > 0 indicate that a specific continuous outcome (e.g., symptom severity) was more pronounced in those with regulatory problems (RPs). *P*-values ≤ 0.05 were considered statistically significant and are marked in bold together with the respective SMD; CI = confidence interval; Coeff = coefficient; HCs = healthy controls; N = number of comparisons; n = number of subjects; SMD = standardized mean difference.

significantly more pronounced compared to HCs, while no significant effect on childhood outcomes emerged in those with eating problems during infancy (SMD = 0.231, 95% CI = −0.021–0.482) (see **Table 2** and Online Resource **Supplementary Table S3**). In-between subgroup differences (crying vs. sleeping vs. eating problems) were not significant ($p = 0.128$).

Externalizing problems, internalizing problems, and ADHD

Children with previous RPs were also more frequently affected by externalizing problems (RPs: cumulative incidence = 0.201, 95% CI = 0.141–0.279; HCs: cumulative incidence = 0.067, 95% CI = 0.028–0.151, SMD = 0.362, 95% CI = 0.253–0.472, $p = 0.001$), internalizing problems (RPs: cumulative incidence = 0.160, 95% CI = 0.120–0.209; HCs: cumulative incidence = 0.083, 95% CI = 0.063–0.109, SMD = 0.343, 95% CI = 0.284–0.403, $p \leq 0.001$), and ADHD (RPs: cumulative incidence = 0.242, 95% CI = 0.157–0.354; HCs: cumulative incidence = 0.076, 95% CI = 0.026–0.201, SMD = 0.461, 95% CI 0.317–0.605, $p = 0.071$) (**Table 2**). For subgroup and meta-regression analyses see Online Resource **Supplementary Table S5**.

Discussion

This meta-analysis aimed to comprehensively quantify the association between RPs in infancy and the occurrence of behavioral problems during childhood. A total of 30 prospective longitudinal studies were included to examine the association between RPs and behavioral problems across a wide range of clinically relevant outcomes, including overall problem behavior, externalizing behavior, internalizing behavior, and ADHD symptoms.

Results indicate a cumulative risk of 23.3% for children with RPs compared to 6.7% for HCs to develop overall behavioral problems throughout their childhood (2–14 years). Considering that the incidence of behavioral problems is nearly 4 times more frequent after RP's (even though the effect sizes were small to medium only), early prevention could have a substantial effect by shifting the distribution in the total population for millions of children worldwide.

Our analysis found that behavioral problems after RPs were extensive and include externalizing behavior, internalizing behavior, and ADHD which is in line with the results of the meta-analysis by Hemmi et al. (16). We also found comparable effect sizes regardless of the follow-up age, indicating that the behavioral problems that are reported in young children who had already suffered from RPs, do not seem to improve with age.

The underlying reasons that might explain the association between RPs and behavioral problems during childhood cannot be explained by our analysis. From a relational perspective, due to the complex early interplay between parents and infants in the development of self-regulation, one can differentiate behavioral, environmental, developmental, interactional, and mental health variables on the parental and infant side which might contribute to ongoing behavioral problems later on (4, 7, 70).

Our results are in line with a cascade model of child development: Early problems with regulation may provide the starting point of a trajectory of dysregulated behaviors, such as problems to sustain attention (51, 71). Consequently, RPs that develop at an early stage in life may affect learning processes and the ability to regulate emotions and behaviors later in childhood as well, predicting a higher risk for clinical disorders in childhood and adolescence (72). Developmental milestones might not be accomplished, leading to continuing deficits reflected in later behavioral problems (13). In contrast to this model, which suggests that a high amount of problems during infancy may lead to more severe problems during childhood, our results do not indicate a significant difference with regards to behavioral symptom severity during childhood depending on the extent of RP (single or multiple RPs) during infancy.

However, these results should be interpreted carefully as this analysis was based on four studies only: Three out of these four studies (11, 53) found evidence that multiple RPs were associated with more behavioral problems than single RPs, while data of one study presented opposite results (73), leading to an overall non-significance in this meta-analytic comparison. Looking at single RPs in sub-group analyses for overall behavioral problems, SMDs were 0.493 for crying problems and 0.266 for sleeping problems. It might

be that the overall severity of single and/or multiple RPs – other than the type and amount of RPs – other than the type and amount of RPs – might be of importance: The association of RPs and behavioral problems was way more pronounced in the clinical sample (SMD = 0.685) compared to the community sample (SMD = 0.348). These results are underlined by a study that found "persistent excessive crying" to be associated with a higher risk to develop multiple RPs (74).

From a neurobiological perspective, RPs in infancy, attention problems, and internalizing behavior in childhood have been associated with dysregulation of the hypothalamic-pituitary-adrenal (HPA) axis (67, 75, 76). Furthermore, more deficient self-regulation has been demonstrated in a particular gene polymorphism of the dopaminergic system contributing to multiple RPs (77), ADHD, and externalizing behavior in childhood (78). Thus, self-regulatory problems primarily obvious as RPs in infancy may be expressed as other forms of emotional dysregulation in early childhood, such as disrupted mood and anger disorder, anxiety, impulsivity or hyperactivity in preschoolers, with an elevated risk for behavioral problems in childhood (7, 73, 79).

Evidence suggests preterm birth, infant temperament or general cognitive impairment as precursors of behavioral or attention problems which have been also associated with an elevated risk for RPs (73, 80–83). These results are affirmed by our subgroup analysis for overall behavioral problems that showed stronger effect sizes in clinical samples compared to community samples. A possible explanation could be that clinically referred children might already have been exposed to multiple risk factors, such as obstetric adversities or severe relational or psychosocial family problems (16).

However, not all infants with early vulnerability and RPs develop behavioral problems in childhood. To investigate associated trajectories or underlying factors more precisely, longitudinal studies are needed which take the mutual parent-child-model with different factors from both perspectives into account and include the prenatal period, which might shape infant´s regulatory skills before birth (4, 27, 84). Besides the challenges that cause distress in parents of an infant with primary self-regulatory deficits, there are several parental factors that may promote RPs, affect the parent-infant interaction, and need further attention in future studies. Among them, parental mental health, particularly maternal depression, hostility and anxiety, parental mentalization, and the quality of parenting behavior are central (4, 7, 23, 70). If parents are less able to co-regulate and compensate an infant´s difficultness, or cannot read the infant's signals and react in a prompt and sensitive way to it due to their own impairment, there might be an elevated risk for persistent RPs and later behavioral or attentional problems (4, 70, 84, 85).

Strengths and limitations

The findings of the conducted meta-analysis are consistent with the existing meta-analysis by Hemmi et al. (16) and extend the scope of the negative impact of RPs on childhood behavioral problems. A considerable effort was made to include as much data as possible in this meta-analysis whilst maintaining strict inclusion criteria: Additional information from eleven studies was included in this meta-analysis. Using strict inclusion criteria and methodological rigor, we aimed to rule out as many sources of potential bias as possible. In this context, we excluded three studies that Hemmi et al. (16) had included (including a control group with transient RPs and a follow-up age younger than two years). Moreover, we expanded methods by also reporting on the cumulative incidence of behavioral problems during childhood.

There was high heterogeneity in the data. Identified studies were heterogeneous with respect to sample characteristics, RP definition, measurement instruments, number of subscales, outcomes, and follow-up duration (range 2.5–11 years) which likely contribute to the heterogeneity of the results. Many different forms of defining and assessing RPs existed across countries and centers. Consequently, the use of standardized tools that focus on parent and infant behaviors for enhanced comparability in further research is needed. Since most studies assessed infant RPs and child behavior using parent reports rather than objective measures or clinician observation, a reporting bias might influence the results. For example, maternal "overrating" of the children's behavior might be rooted in maternal stress and/or the continued perception of the child as being difficult (20, 73). Therefore, in future research more objective and multi-informant measures of child behavior (e.g., clinical observation, teacher reports), parental characteristics, and the parent-infant interaction should be used (86).

Moreover, some studies showed co-occurrence of RPs but only reported behavioral problem outcomes for single RPs and did not control for any other RPs. Previous research found that crying, sleeping, and eating problems often coexist (6, 13). Hence, non-reported or non-assessed co-occurrence of RPs might lead to a biased conclusion regarding the effects of single RPs. More longitudinal prospective studies are needed to enable a profound investigation of the association of RPs, behavioral problems, and potential confounders. Although we included a set of study-specific moderators in the meta-regressions, the inclusion of other essential moderators, such as maternal depression, preterm birth, parent-infant interaction, childhood trauma or childhood attachment was limited because comparable information of potentially relevant confounders was often lacking.

Clinical implication

From a clinical perspective, our findings highlight the need for a better understanding of predictors of childhood behavioral problems and clinical disorders. The results suggest the importance of early monitoring, detection, and intervention for families with an infant affected by RPs to prevent the development of further behavioral problems. From a primary health care perspective, this is crucial information for pediatricians and parental counseling in childcare.

Overall, the knowledge about the impact of RPs on later behavioral problems should be used to develop and evaluate specific prevention programs focusing, for example, on parent-infant psychotherapy (87, 88). The mutual perspective of RPs offers several optional starting points for interventions for disrupted parent-infant interactions to reduce parental stress and foster further child development. Strengthening parents self-efficacy to adapt to their infant´s needs and difficulties is just as important as identifying and treating emotional distress, particularly

postpartal depression or anxiety which might keep parents from adequately understanding or supporting their infant (70).

Conclusion

The present findings provide a comprehensive view of the development of behavioral problems in children with RPs. Results showed a robust positive association with small to medium effect size between RPs in infancy and childhood problem behavior and indicate the importance of further prospective longitudinal studies on the association between infant RPs and child development.

Though we found no significant difference regarding single RPs compared to multiple RPs, these findings should be replicated longitudinally and promote further investigations and interventions for infants with a single RP as well. With the help of prevention programs, RPs could be identified and treated at an early stage, reducing long-term consequences. Moreover, untreated behavioral problems and clinical disorders are associated with high health care costs and represent a relevant burden for affected families (89). Therefore, family counselors and pediatricians should assess potential crying, sleeping, and eating problems and the level of parental stress in a structured way at regular intervals during infancy to identify those who might be at risk of persistent RPs and developing behavioral problems in childhood.

Data availability statement

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

Author contributions

The work was conceptualized and designed by BG and PS. Data were collected, analyzed and interpreted by PS, HB, and BG. The article was drafted by BG and PS. After critical revision of APK, AK, MGH and SM, the work was finalized by HB. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frcha.2022.1099406/full#supplementary-material.

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Preschool-based mother-child emotional preparation program improves emotional connection, behavior regulation in the home and classroom: a randomized controlled trial

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Introduction: Based on the theory that increasing emotional connection and reducing emotional stress between mother and child at home will reduce dysregulated behavior in the classroom, we tested a novel family-based school intervention aimed at facilitating mother-child emotional connection. This question has gained great importance following the COVID-19 pandemic, as child mental health has been declared a national emergency.

Methods: Subjects were randomized into two groups; one (Control: $n = 32$) receiving the standard curriculum in a large community-based preschool education program, and another (MCEP) receiving the standard curriculum plus the Mother Child Emotional Preparation Program (MCEP: $n = 30$). Two to eight MCEP mother-child pairs participated in eight elective weekly 2-h group sessions over a 16-week period. During the 2-h sessions, the pairs were engaged in face to face calming sessions. At 6 months post-enrollment, we assessed mother-child emotional connection on the Welch Emotional Connection Screen (WECS). In addition, mothers and teachers completed validated questionnaires and instruments.

Results: We found that the percentage of MCEP mother-child pairs who became emotionally connected at 6 months was five-fold higher than Control pairs (47.4%, vs. 8.3% $p = 0.004$, effect size = 0.44). Also at six months, MCEP children had fewer behavioral symptoms ($p = 0.024$)) (effect size >0.5); fewer autism symptoms ($p = 0.048$) (effect size = 0.53); fewer emotional symptoms ($p = 0.01$) (effect size >0.76); better personal, social skills ($p = 0.045$) (effect size = 0.51); better executive function ($p = 0.032$) (effect size = 0.59). Importantly, teachers reported MCEP children showed more improved behavior in the classroom, compared to controls.

Abbreviations

ASQ, ages and stages questionnaire; ATEC, autism treatment evaluation checklist; Brief-P, preschool version of the behavior rating inventory of executive function; CES-D, center for epidemiologic studies depression scale; CLC, children's learning centers of fairfield county; EC, emotional connection; MCEP, mother-child emotional preparation program; FNI, family nurture intervention; NS, nurture specialist; SDQ, strength and difficulties questionnaire; SWYC, survey of wellbeing of young children; WECS, Welch emotional connection screen; post-tx, post-treatment.

Discussion: This trial was retrospectively registered in the clinicaltrial.gov registry (NCT02970565) on April 9, 2019.

KEYWORDS

emotional dysregulation, classroom behavior, relational health, socioemotional behavior, family intervention, ASQ questionnaire, autism treatment evaluation checklist, Welch Emotional Connection Screen

Introduction

Antisocial behavior in preschool-aged children has been increasing for decades in the US (1, 2). Preschoolers now have the highest rates of school expulsion of all age groups. Such adverse behavior in childhood often leads to lifelong social exclusion and considerable personal distress into adulthood (3) (4), and imposes high public and private expenditure for treatments (5–7).

During the conduct of this study, the problem worsened as the result of the COVID-19 pandemic. The situation has left teachers increasingly burned out—A recent survey of over 4,500 preK-12 teachers at nationwide public, private and charter schools (8) asked, How has your teaching changed during the 2021–2022 year? Among other categories, respondents reported

- Overall workload increased 81%;
- Spending more time addressing students' mental health increased 80%;
- Classroom interruptions during instruction increased 45%.

Over the last 10 years, numerous Cochrane reviews and meta-analyses have examined the efficacy and effectiveness of various intervention programs designed to tackle the rising problem of emotional, behavioral, and developmental disorders in preschool-aged children. Interventions include psychosocial interventions for ADHD (9), psychological interventions targeting behavioral inhibition and anxiety (10), cognitive behavioral therapy (CBT) (11), school-based interventions to prevent anxiety and depression in young children (12), Incredible Years Teacher Classroom Management (IYTCM) for adverse socioemotional behavior (13) and Parent Management Training (PMT) for behavior problems (14).

There are numerous interventions for preschool children that treat parents and children together. Parent-Child Interaction Therapy (PCIT) is a well-established treatment for behavioral, hyperactivity and oppositional-defiant problems in children, with more than 40 years of research behind it (15). A variation of PCIT, PCIT-ED, focuses on emotion development (16). Cool Little Kids, focuses on anxiety (17) and Child-parent psychotherapy (CPP) is a well-studied psychodynamic treatment that targets the parent's and the child's experience of their relationship as the most

Some preschool-based interventions include families. However, the focus of these interventions is on improving the individual child's development. For instance, Ray et al. (18) developed the Increased Health and Wellbeing in Preschools (DAGIS) intervention to enhance preschoolers' self-regulatory abilities and energy balance-related behaviors through a program involving educators and the children's families. However, results demonstrated no improvement when accounting for parental education level. Kochanska (19) found that in a longitudinal study of parent-preschool-aged child pairs, high "mutual responsive orientation," corresponded to mothers using less power and children internalizing more maternal values and rules. A recent meta-analysis showed evidence that parenting programs integrated into early childhood education may have an effect on children's behavioral outcomes (20). While these studies involved family members, their outcome measures concentrated on the child or on the mother alone, not on the dyad.

The systematic reviews listed above point out that some interventions for preschool-aged children have shown both efficacy and effectiveness. However, nearly all reviews conclude that current interventions show limited or inconclusive effects on overall adverse classroom behavior. Another common conclusion is that due to small effect size and due to the length and cost of treatment programs, current treatment models are not suitable in their present form for wide scaling that would meet the emergent needs (21, 22). The shortage of effective behavioral interventions has left preschool educators struggling to find alternative solutions.

To address the problem, we developed a novel school-based program—Mother-child Emotional Preparation (MCEP) in partnership with the Children's Learning Centers of Fairfield County (CLC), a leading community-based pre- school education program serving ~1,000 families annually in Stamford, CT. The challenge was to develop a scalable, low-cost group treatment model that would avoid placing significant financial, administrative or teaching burden on the Center's already stretched resources. The goal was to reduce classroom behavioral disturbances such that the teachers could deliver their curriculum with fewer disruptions. MCEP is a preventative group family intervention that is designed to help parents prepare the child emotionally for the pre-school educational experience. MCEP is based on calming cycle theory (23). The theory predicts that repeated mother-child calming sessions can reduce child adverse behavior at home and in school.

MCEP is novel in its engagement of both mother and child in a full range of emotional expression during mutual sensory calming sessions. Our hypothesis is that empathy is evoked when the mother (or other person) expresses the full range of their deep feelings. When a child responds to the mother's expression of emotion and shows signs of empathy to the mother, a temporary break in connection begins to repair. Repair needs to be mutual and on-going to be effective for both members of the pair. Both the mother and child learn that repair can be achieved through emotional communication. The connected child is thereafter able to connect and co-regulate with teachers and others once the pattern is established with the mother and family members. CLC leadership has reported that the children who were in the MCEP

program changed the classroom environment with their positive affect and better regulated behavior so much so that teachers were freer to address problems such as learning difficulties of the non- symptomatic children for whom teachers did not have the band-width to address prior to MCEP.

We found that MCEP improved mother-child emotional connection as assessed by the WECS and significantly improved child behavior at home and in school. We discuss the implications of our findings for preschool education, along with strengths and limitations of the study.

Methods

Trial design

The MCEP study was a parallel-group, single blind RCT that was approved by the Columbia University IRB (AAAT0109). Subjects for this study were a non-probability convenience sample of mainly low socioeconomic status families. The method is presented as per the CONSORT guidelines (24). The trial was prospectively registered in the clinicaltrial.gov registry (NCT02970565).

Participants and setting

The study was conducted at Children's Learning Centers of Fairfield County in Stamford, CT, a community-based preschool education center. CLC has eight sites and three programs: School Readiness, Child Development and Head Start (25). Families must meet various criteria to be eligible for enrollment in one of CLC's programs (Head Start & Early Head Start, Child Development and School Readiness). According to CLC's Parent Manual (25), programs vary by funding and eligibility requirements. Head Start is a free federal program that operates under a standardized curriculum with eligibility based on poverty. In the Child Development program, parents must work 30 h per week to be eligible for specific Connecticut-funded programs (25).

Recruitment

We recruited families continuously from all CLC programs. Study staff recruited at orientations, teacher/parent meetings and distributed flyers during child drop-off/pick-up. Teachers signed a consent form to collect teacher- report data. CLC staff discussed the study with parents and encouraged teacher referrals. The primary recruitment method was recruiting mothers in-person during child drop-off/pick-up.

Eligibility

Children were eligible for the study if they were between the age of two and four- and one-half years of age at the recruitment date. In addition, the child had to be a singleton without any genetic or congenital disorder or motor disability. Mothers had to be at least 18 years old, able to speak, read and write in English or Spanish; and be living with her child full-time. Exclusion criteria for mothers included: severe mental illness or any other medical conditions preventing play activities; involvement with the Department of Children and Families; struggling with drug or alcohol abuse; pregnancy (second trimester) that could interfere with the lap-based procedures (see below); or unable to commit to the study schedule. Demographics for each group at each time point are presented in **Supplementary Figure S1**.

Consent procedures

After verbal consent, mothers completed Study Eligibility and Demographics Forms, and the CLC Release information sharing in person or by phone, with the CLC Release signed at the first in-person contact. Mothers signed a consent form at the time of the baseline assessment and then, if allocated to the intervention arm, were assigned to a MCEP group.

Randomization

Participants arrived 30 min before the first MCEP session for group assignment. Prior to first subject enrollment, a computer-generated block randomization sequence ensured balanced assignment. Based on the group's size as estimated prior to the first session, cards denoting MCEP or Control were placed in envelopes. Upon arrival, we handed the mother a sealed envelope. If control, we informed the mother she was randomized to the CLC Standard Curriculum and that she may leave. If intervention, we asked mothers and children to stay for the first MCEP group session. See Consort flow Chart (**Figure 1**) for final group assignment numbers. Note: In **Figure 1**, the number of subjects shown at enrollment (baseline), and at the first and second follow-up (approximately 2 and 6 months) reflect the number of subjects with scorable videos. The numbers of subjects with questionnaire data were, in some cases, different from the number with videos.

Control group

Control group children participated in the CLC standard curriculum with no additional procedures. Classroom activities varied by age and ability, and classroom structure varied by program. All CLC programs used the Connecticut Early Learning and Development Standards and the Connecticut Preschool and Assessment Framework combined with the Creative Curriculum (25). CLC's Head Start Program uses the Creative Curriculum, in addition to the Head Start Child Development and Early Learning Framework. Child Development and School Readiness programs used Connecticut Data Observation and Tracking

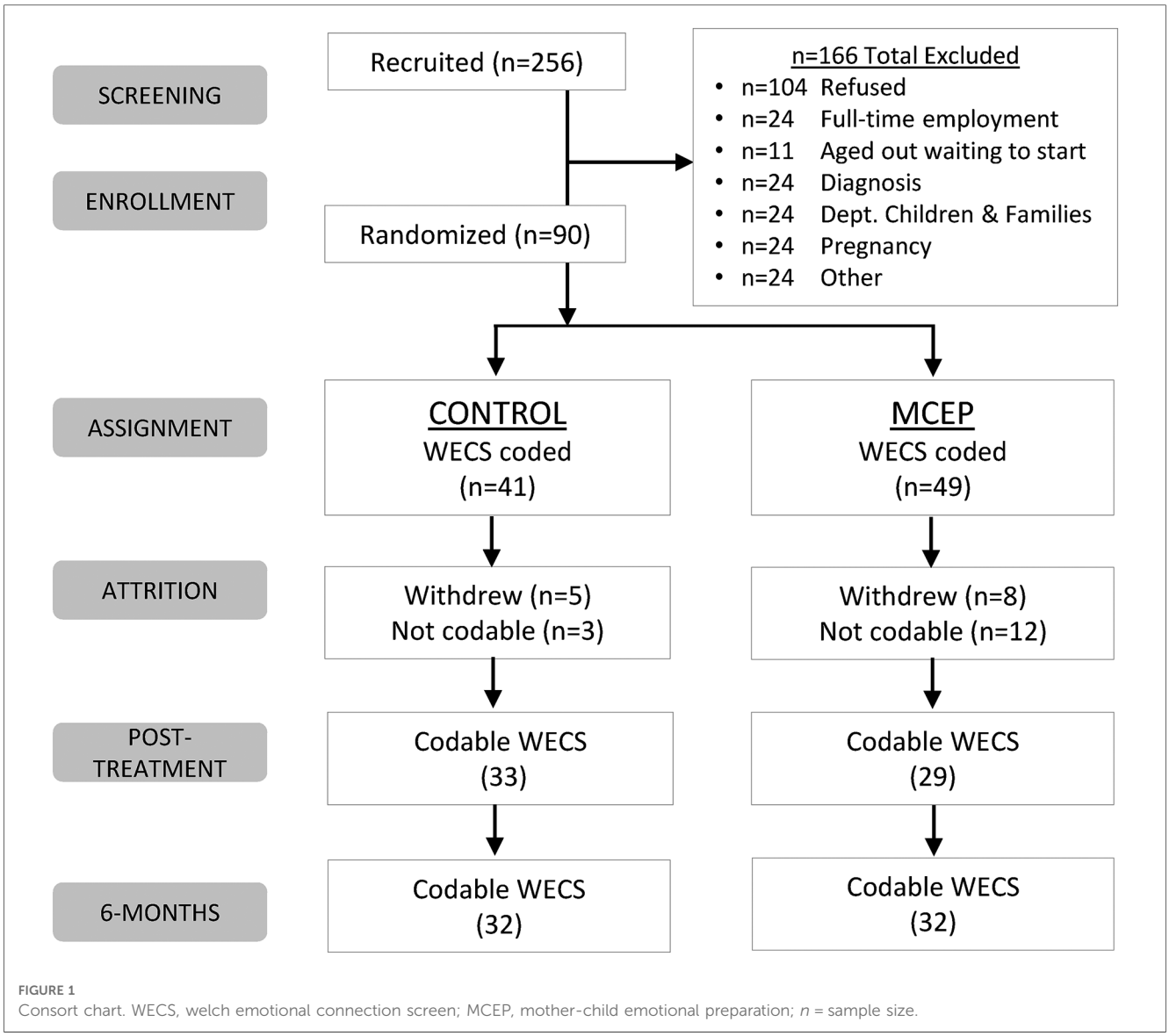

FIGURE 1
Consort chart. WECS, welch emotional connection screen; MCEP, mother-child emotional preparation; *n* = sample size.

System, and CLC's Head Start and Early Head Start sites use the Teaching Strategies Gold system to track student progress (25). CLC teaches emotional literacy through the Yale RULER curriculum at all sites.

Intervention methods

Mother-child dyads randomized to the intervention arm received facilitated MCEP group calming sessions. In this study, two specially trained Nurture Specialists, both licensed clinical social workers, facilitated the parent-child intervention and provided emotional support during sessions. Each mother-child dyad participated in two to eight 2-h group sessions over 16 weeks, which we held in a classroom or small meeting room.

As described in prior literature (26, 27), calming sessions consisted of a child sitting on the mother's lap and cycling through a range of verbal and non-verbal emotional expressions. A key goal of the session was to assure the dyad maintained close physical and sensory contact throughout the session.

This communication typically dealt with current or past upsets or other previously unprocessed feelings. A successful calming session included four phases. In the first phase, DISCOMFORT AND DISTRESS, the mother and child displayed and expressed separate distress for routine topics. Children sometimes rejected their mother's request to sit and talk by wriggling away, becoming restless and dysregulated, or by being unable to control their own emotional state.

The second phase, CONFLICTS AND UPSET, involved the mother and child expressing upset about the other's behavior. The child's *separate distress* often prompted the mother to feel her own disrupted connection. The Nurture Specialist helped the mother and child identify and express their feelings to one another. For example, Mom, tell your child: how you feel when he/she doesn't look at you; how you want to feel when you're together; how you feel when you are apart from them; How you

feel when your child screams/hits/kicks. How you feel during a tantrum.

The child was prompted to tell mom: what makes you mad, sad or worried; how you feel when mom goes to work; how you feel when you can't buy candy; when you are worried about mom. Sometimes in this phase, the mother cried (e.g., feeling sadness discussing separation or joy at the story of the birth), which also led to the child orienting to her and to feel her emotional state. The child often responded to the mother's upset with tender behaviors and empathic communication. Mothers were encouraged to use comforting touch, genuine emotional expression, soothing, and eye contact to mutually resolve the upset and bring each other into a calm state.

Once the upset was fully processed, the dyad typically began to soften toward one another and reached mutual resolution. This signaled the beginning of the third phase, CONFLICT RESOLUTION. In this phase, Nurture Specialists used verbal prompts to help the mother elicit her deep emotion by tapping into her emotional memories, by way of asking to tell the child her birth story or other stories when she was the child's age. In response to the mother's emotional expression, the child will often orient to the mother's face with direct gaze, rapt attention and, often, loving touch. Once conflicts and upset were processed and the two were oriented to one another without rejection, they reciprocated by tenderly hugging and gazing at each other warmly and began to discuss good as well as upsetting behavior (e.g., child noncompliance or maternal inattention or separation), and talked about plans to avoid upsets.

The final stage of the calming session, MUTUAL CALM, was characterized by cuddly closeness, with mother and child breathing quietly, maintaining a deep mutual gaze and warm, open verbal and non-verbal communication, with observable relaxation and reciprocal pleasure in each other's embrace. Following the first session, mothers made a brief report of their home calming sessions (e.g., handling of tantrums and child noncompliance). Following each session, the Nurture Specialists encouraged mothers to continue preventative and reparative calming sessions on a regular basis at home, especially during conflict, tantrums or signs of upset.

Assessment tools

Welch emotional connection screen (WECS)

We measured mother-child emotional connection using the Welch Emotional Connection Screen (WECS) assessment tool (28). WECS concurrent validity was demonstrated using indicators of emotional connection coded in observational software by independent teams of coders. The WECS construct validity was established by showing pairs rated emotionally connected had healthier autonomic responding in the still-face paradigm (SFP) and more approach-seeking behavior with mother during the recovery phase of the SFP (28). WECS predictive validity was shown by demonstrating pairs rated emotionally connected at age 6 months had fewer behavior problems at age 3, as reported by mothers (29).

We trained a team of six coders blinded to all other study data on a remote platform. Coders first achieved reliability with scores of the WECS creators on a training set of mother and preschool-aged child videos derived from other samples, with each coder required to achieve an intra-class correlation for each dimension of the WECS of at least 0.85. Thereafter, the team advanced to coding 13 cases from the current CLC trial sample. We established further reliability by having coders cross-code one another's cases. Coders achieved reliability with one another individually with scores no lower than 0.85. The average intra-class correlation coefficients for each dimension of the WECS pooled across coders were: Attraction = 0.93, Vocal = 0.93, Facial = 0.95, Sensitivity/Reciprocity = 0.94. Each study pair had repeated WECS observations. The baseline and post-treatment WECS scores were coded by different coders, such that no blinded coder coded the same dyad more than once.

The WECS composite emotional connection score is made up of four behavioral modes of expression, as defined by Hane et al. (28). They are:

1. Mutual Attraction (shared gaze, mutually seeking physical closeness and proximity)
2. Mutual Vocal Communication (warmth in vocal tone and amount and content of vocal behavior of mother; consistent and warm vocal responsiveness from child; connection through voice);
3. Mutual Facial Communication (expressions of positivity, laughter, joy and and sustained eye gaze);
4. Mutual Sensitivity and Reciprocity (well-timed reciprocal social sensitivity to each other's expressed emotions).

The WECS is scored on a nine-point Likert scale, starting at 1.00. The lowest rating corresponds to the least emotionally connected. Scores increase by .25 increments up to a total of 3.00, which corresponds to the most emotionally connected rating. The four separate mode scores are totaled to give a WECS total score. A score equal to or greater than 9.00 was the threshold for determining whether a study pair were emotionally connected. In a few cases, it was not possible to score one of the modes of expression. In these cases, we totaled the other three scores, divided by three and multiplied by four to obtain an estimate of the total score.

The Welch orienting lapcheck

We used the Welch Orienting Lapcheck (**Figure 2**) to test the pair's emotional reaction to one another. This test is designed to capture the behavior and physiology associated with the mother and infant/child autonomic socioemotional reflex (ASR) (30) which is triggered when the two encounter one another physically and emotionally face to face. The test begins when the mother seats her infant on her lap or asks her child to sit on her lap. The mother was instructed to interact normally with her child for 2–5 min. The test is video-recorded and mother and infant/child are wired for electrocardiograms (ECG). Behaviors were coded with the Welch Emotional Connection Screen (WECS) (28).

FIGURE 2
Schematic showing face to face orientation during Welch Orienting Lapcheck. The face to face orientation and physical contact is necessary to trigger the autonomic socioemotional reflex (ASR). The behaviors that result from the autonomic reflex are measured using the Welch emotional connection screen (WECS) and determine whether the autonomic "states" of the pair are "connected" or "disconnected".

Center for epidemiologic studies depression scale (CES-D)

We measured mothers' depression on the CES-D. The CES-D is a 20-question self-report form that asks the individual to rate whether he or she experienced a given emotion (e.g., "I felt fearful") "rarely or none of the time", "some or a little of the time", "occasionally or a moderate amount of time" or "most or all of the time" (31). Mothers completed the CES-D at the baseline, post-treatment and 6-month time points.

Survey of well-being of young children (SWYC)

The SWYC, a short, simple questionnaire completed by the parent of a child under 5 years, captures the parent's assessment of children's motor, language, social and cognitive development, as well as emotional/behavioral functioning, and any familial risk factors (32). It covers three domains of functioning: Behavior and Emotion, Family Risk Factors, and Development. Mothers completed the appropriate survey according to the child's age at each time-point.

Autism treatment evaluation checklist (ATEC)

The ATEC, developed by Rimland and Edelson (33) at the Autism Research Institute, was completed by mothers in this study. It consists of 4 subtests: I. Speech/Language Communication (14 items); II. Sociability (20 items); III. Sensory/Cognitive Awareness (18 items); and IV. Health/Physical/Behavior (25 items). We present results using the total score across these subtests.

Strength and difficulties questionnaire (SDQ)

The SDQ is a brief behavioral parental report questionnaire for children 3–16 years old (34). The version used in this study included 25 items divided between five scales: emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, prosocial behavior.

Ages and stages questionnaire (ASQ)

The ASQ was developed by Jane Squires and Diane Bricker (35, 36) and in this study was filled out by mothers. It consisted of six items covering five developmental areas: communication, gross motor, fine motor, problem solving, and personal-social.

Behavior rating inventory of executive function—preschool (Brief-P)

The Brief-P examines everyday behaviors associated with specific domains of executive functioning in children aged 2–5 years (37). It was completed by mothers in this study and includes 63 items in five non-overlapping scales forming a Global Executive Composite (GEC) and three overlapping summary indexes each with two scales based on theoretical and statistical considerations. The Inhibitory Self-Control Index (ISCI) is composed of the Inhibit and Emotional Control scales, the Flexibility Index (FI) is composed of the Shift and Emotional Control scales, and the Emergent Metacognition Index (EMI) is composed of the Working Memory and Plan/Organize scales.

Blinding

Study staff (other than the NSs) outcome assessors, and coders were blinded to the randomization sequence. Mothers were not blinded.

Statistical methods

The primary, pre-declared outcome for this RCT was the percent of dyads judged to be emotionally connected at the Post-treatment and 6-month time points. Emotional connection Yes/No codes were converted into 1/0 and analyses of covariance, controlling for baseline were used to test for intervention effects. Additional analyses compared groups' emotional connection over time. Specifically, chi-squared analyses were used to test for group differences in the percentage of dyads that changed from not connected at baseline to connected at follow-up. Effect size calculations were based on either Cohen's-d or the Phi-coefficient.

We analyzed depressive symptoms (CES-D) using repeated measures ANOVA across the three data acquisition time-points (baseline, Post-Intervention and 6 month). We analyzed the effects of the intervention at the post- treatment and 6-month time points for the SWYC using analyses of covariance, controlling for baseline SWYC scores. We computed correlations (Pearson) to determine relationships between the WECS four factors and the WECS composite score and the SWYC (see

Supplementary Table S2). These analyses were conducted for the overall group combining controls and intervention and then, for each group separately. Finally, we analyzed total scores or selected items from four additional questionnaires (ATEC, SDQ, ASQ, Brief-P) administered at the 6-month time- point using analyses of covariance, controlling for baseline scores.

Results

MCEP mother-child pairs were more emotionally connected at 6 months

The RCT primary outcome of this RCT was mother-child emotional connection, as measured on the Welch Emotional Connection Screen (WECS). The CONSORT flow diagram (Figure 1) shows the numbers of mother- child pairs from screening to enrollment between 2018 and 2020. We enrolled and group assigned at total of 90 pairs (41 control; 49 MCEP). Supplementary Table S1 provides demographic characteristics of pairs at three time-points.

We hypothesized that a greater percentage of MCEP pairs (vs. Control pairs) would be emotionally connected post-treatment (end of intervention) and at the 6-month follow-up. Table 1 summarizes the effects of the intervention on emotional connection when assessed at post-tx (2-months) and 6-months. At Baseline and post- treatment there was no significant difference between groups. However, at the 6-months, a greater percentage of MCEP pairs (47%) were emotionally connected compared to controls (16%) ($p - 0.007$, effect size = 0.83) (see Figure 3).

A second set of analyses assessed how many pairs remained emotionally connected between post-intervention and six months. We found that at 6 months MCEP pairs remained connected, while Control pairs significantly decreased (47.4%, vs. 8.3% $p = 0.004$, effect size = 0.44) (see Supplementary Figure S1).

In addition to the above analyses based on the binary coding of WECS scores (EC+ or EC−, using a cut-off of 9 or better for EC+) we also ran ANOVAs using the total WECS scores across the four domains (attraction, vocal communication, facial communication, sensitivity). As for the binary coding, there was a highly significant effect of MCEP on WECS total scores at 6 months (Effect Size = 0.81). Below are the means (±SE) for WECS total scores at the Post-Tx and 6-month time points.

TABLE 1 WECS scores at post-Tx and 6 months.

	Control	MCEP	
At Post-Tx	8.22 ± 0.22 ($n = 33$)	8.37 ± 0.23 ($n = 29$)	$F(1,60) = 0.21$, $p = 0.65$
	(Median = 8.50)	(Median = 8.67)	
At 6 months	7.43 ± 0.26 ($n = 32$)	8.61 ± 0.26 ($n = 32$)	$F(1,62) = 10.56$, $p = 0.002$, ES = 0.81
	(Median = 7.38)	(Median = 8.75)	

COVID had no effect on the treatment scores. Two-way ANOVA analyses on the interaction between intervention and COVID was not significant [$F(1,60) = 1.00$, $p = 0.32$]. MCEP, mother-child emotional preparation; p = Probability; ES, effect size; n = sample size.

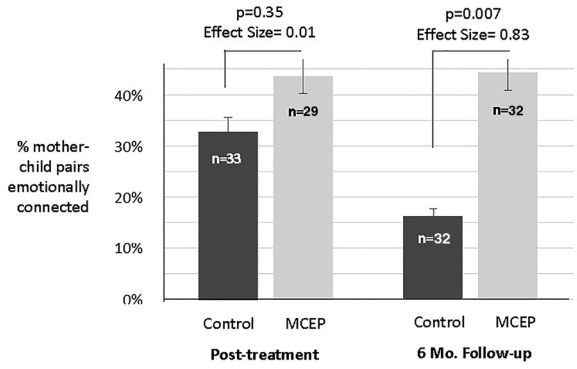

FIGURE 3
Mother-child emotional connection. Percent of pairs rated emotionally connected on the Welch emotional connection scale (WECS) at the end of the 8-weeks intervention and at 6 months follow-up. Note the % MCEP pairs emotionally connected remained approximately the same, while the % SC pairs emotionally connected actually dropped from 33% to 16%. MCEP, mother-child emotional preparation; n = sample size.

MCEP mothers reported significant behavioral improvement at 6 months

SWYC preschool pediatric symptom checklist

Figure 4 shows the values for the total number of symptoms reported by parents for four SWYC subscales (Externalizing, Internalizing, Attention Problems, and Parenting Challenges). At both the Post-Intervention and 6-month time points, MCEP significantly decreased the number of child behavioral symptoms (4.29 vs. 2.13, $p = 0.024$, with an effect size greater than 0.5.

Four domains of the WECS (mutual attraction, facial, vocal and sensitivity). Across all subjects, at the 6-month time-point, all WECS codes were negatively correlated with behavioral problems (i.e., better WECS scores were associated with fewer problems; only facial scores did not reach statistical significance). However, when broken down by group at 6 months, none of these correlations were significant in the control group whereas the total WECS, vocal and facial scores were significantly related to behavioral symptoms in the MCEP group (see Supplementary Table S2).

Four other parent-rated measures of behavior

Six aspects of the WECS codes were analyzed; emotionally connected yes/no, total WECS score and scores for each of the four modes. Significant findings from analyses of four additional assessments are presented. There were no differences at baseline for ATEC, SDQ, and Brief-P. There was no baseline measure for ASQ. At six-month follow-up, these results show that MCEP children had fewer symptoms of autism (ATEC total score), fewer emotional problems (SDQ, emotional symptoms), better social interactions (ASQ, personal-social), and improved cognitive flexibility (Brief-P, Set shifting). (For complete statistics, see Supplementary Table S3). The effect sizes are robust, ranging from .68 to .91 for the four behavioral outcome measures at 6-month follow-up. This indicates strong sustained effects of the intervention (see Figure 5).

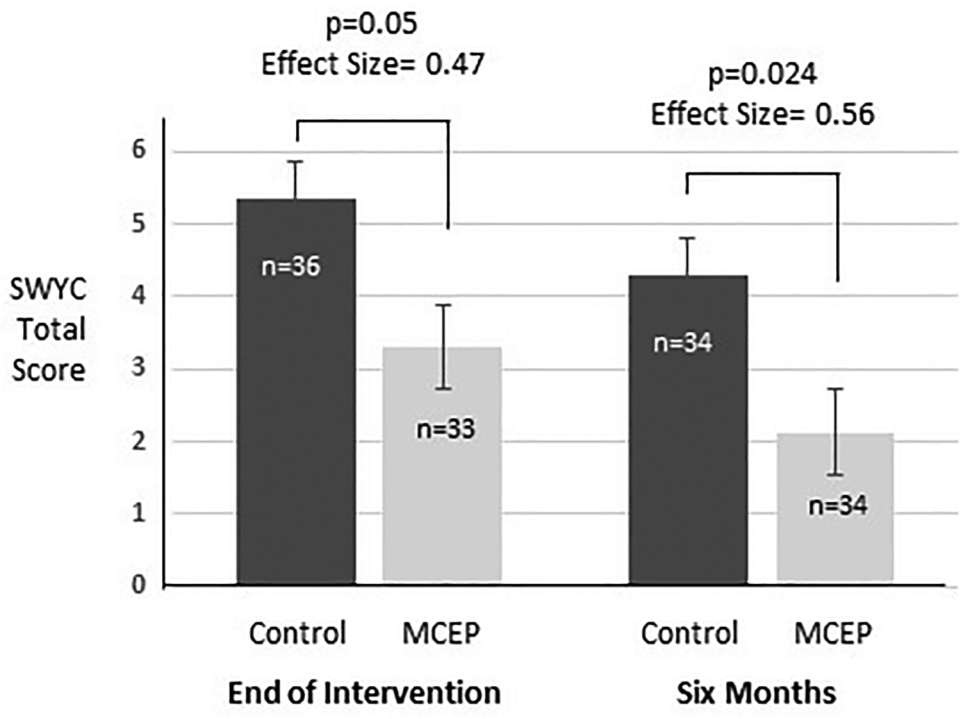

FIGURE 4
Comparison of SWYC scores. Total scores for the 18 item Survey of Well-Being of Young Children (SWYC) preschool pediatric symptom checklist at time-points 1 and 2. These analyses control for SWYC total scores at baseline (at time of enrolment). Baseline scores were included in these ANOVAs. MCEP, mother-child emotional preparation; *n* = sample size.

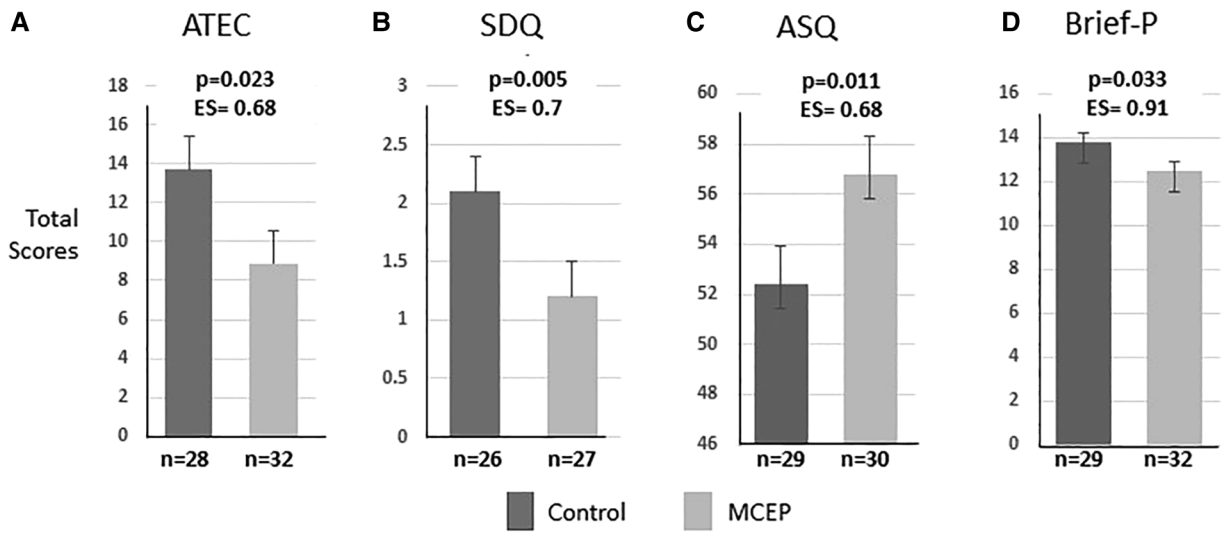

FIGURE 5
Child behavior outcomes at 6-month follow-up. Total scores on four widely used behavioral measures in preschool-aged children. The results for ATECT, SDQ, Brief-P were controlled for baseline. There was no baseline for ASQ. Note that MCEP scores were significantly better than controls on all four measures. (A) ATEC, autism treatment evaluation checklist—*fewer autism symptoms*. (B) SDQ, strength and difficulties questionnaire—*fewer emotional symptoms*. (C) ASQ, ages & stages questionnaire—*better personal, social skills*. (D) Brief-P, preschool version of the behavioral rating inventory of executive function—*better executive function*. Note that the large effect size (ES) indicates the intervention effect is large enough to be noticeable in the average size class. The analyses for each measure control for baseline (at the time of enrolment). MCEP, mother-child emotional preparation; *n* = sample size.

Teachers reported MCEP children showed significant behavioral improvement in at 6 months

Prior to the onset of COVID and the resultant cancellation of live classroom sessions, the SDQ was filled out by the CLC teaching staff. In total, there were 21 teacher reports that spanned enrollment to the 6- month time point (controls, $n = 11$; MCEP, $n = 10$).

At the time of enrollment (baseline) the total SDQ scores for emotional behavioral disorders did not differ between controls (mean = 7.6, SD = 5.0) and MCEP (mean = 8.5, SD = 4.6), $t = 0.46$, $p = 0.65$). The change (0–6 months) in SDQ Total Difficulties Score (Total Score = Emotional Scale + Conduct Scale + Hyperactivity Scale + Peer Problem Scale) approached statistical significance ($t = 1.89$, $p = 0.076$), with MCEP children showing greater declines in problems from baseline to six-months (control mean = + 0.82, SD = 5.96; MCEP mean = −3.30, SD = 3.92) with an effect size (Cohen's d) of 0.76. The percentage of control children which showed a decline in Total Difficulties was 36% in controls (4 of 11) vs. 80% in MCEP (8 of 10; $X^2 = 4.07$, $p = 0.044$, effect size (Fisher's $Z = 0.47$) (see Figure 6).

For 20 of these 21 teacher reports, we also had parent reports. Concordant with the teacher reports, mother SDQ reports indicated 40% (4 of 10) of the control and 80% (8 of 10) of the MCEP children showed reductions in total EBD scores from enrollment to the 6-month time point. For baseline (enrollment) SDQ EBD total scores, there was a good correlation between parent (mother) and teacher scores. Pre-COVID cohort, $N = 29$ (control and MCEP combined), $r = 0.53$, $p = 0.003$. This indicates a general agreement between mothers and teachers on how children were behaving. During COVID teachers reports could not reflect school behavior as children were remote.

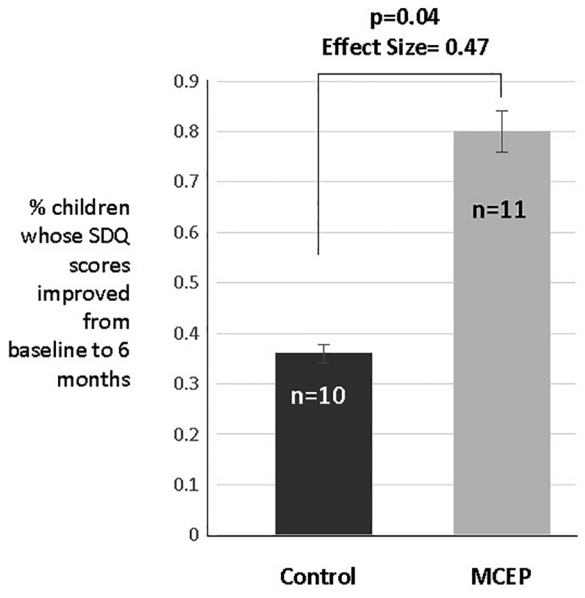

FIGURE 6
Teacher rated SDQ. According to the teacher, the percentage of control children which showed a decline in total difficulties was 36% (4 of 11) vs. 80% in MCEP (8 of 10); $X^2 = 4.07$, $p = 0.04$, effect size (Fisher's $Z = 0.47$). SDQ, strength and difficulties questionnaire; MCEP, Mother-child emotional preparation.

Maternal depressive symptoms (CES-D)

We analyzed CES-D scores without controlling for various covariates and found no significant reduction in mother-reported depressive symptoms in either group. However, we considered whether there might be factors that could impact CES-D scores that need to be taken into account. Accordingly, we re-ran ANOVAs on 6-month scores for several possible covariates; child sex, maternal age, pre/post COVID, child age at enrollment, ACES scores. Of these covariates, two were found to be significant correlates of CES-D scores at 6 months, child age and the ACES score. When these two variables were included in the model, the effects of MCEP were found to be significant [$F(1,63) = 5.34$, $p = 0.024$]. To better understand how these covariates impacted the effects of MCEP on maternal depressive systems we ran post-hoc tests in which subjects were stratified by age and in which extreme values of ACES scores (>5, $n = 6$) were excluded.

We found that mothers of children over four had higher CESD scores. The first of these analyses showed that the effects of MCEP on reducing CES-D scores were significant for mothers with children <4 years of age (control $n = 20$, mean = 12.1 ± 10.0SD; MCEP $n = 23$, mean = 6.5 ± 6.6SD, $t = 2.19$, $p = 0.035$, ES = 0.60). For mothers with children of age there was no significant effect of MCEP and CES-D scores were lower than for the younger cohort (control $n = 13$, mean = 4.9 ± 5.6SD; MCEP $n = 11$, mean = 4.4 ± 6.5SD, $t = 2.19$, $p = 0.035$, ES = 0.60). Thus, MCEP was found to reduce maternal symptoms but not in mothers of older children whose CES-D scores were much lower at baseline.

In the second analysis we excluded the 6 mothers who reported high levels of childhood trauma 3 control (mean CES-D = 20.0) and 3 MCEP (mean CES-D = 17.3). After removing these 6 subjects, the effects of MCEP were significant (control $n = 30$, mean = 8.2 ± 7.8SD; MCEP $n = 31$, mean = 4.7 ± 4.2SD, $t = 2.17$, $p = 0.035$, ES = 0.59). These analyses suggest that the depressive symptoms of women with high levels of childhood trauma were resistant to the positive effects of MCEP. However, most women showed decreases in depressive symptoms 6 months after entering the MCEP program.

School staff survey showed widespread support for continuing the MCEP program

During the second half of the MCEP study, CLC staff were asked if they thought this program should be continued. A total of 72 teachers and staff responded and 89% supported continuation of MCEP and its integration into CLC (see Figure 7).

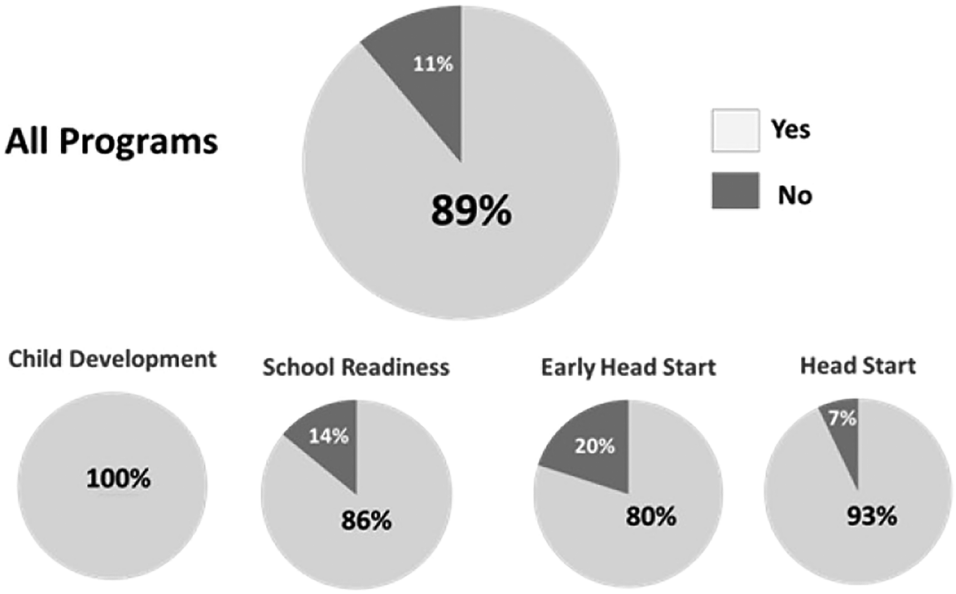

FIGURE 7
Results of a survey conducted among CLC preschool education staff following the completion of the randomized controlled trial. Question: "Should the MCEP program be integrated into the standard curriculum?" CLC, Children's Learning Centers of Fairfield County; MCEP, mother-child emotional preparation.

Discussion

The results of this RCT conducted within a community-based preschool education curriculum show that the group MCEP intervention model was successfully implemented and resulted in significant positive changes in emotional connection and in both parent and teacher-reported child behavior at home and in the classroom. We found that MCEP increased the percentage of emotionally connected dyads 6 months after enrollment in the study, as measured by the Welch Emotional Connection Screen (WECS) assessment tool. The emotional connection construct describes a shared "behavioral state", which is measurable via the WECS. As stated in the methods section, the emotional connection construct was validated in a prematurely born sample at 4 months of age. Our findings presented here validate the emotional connection construct in a preschool-aged child population.

We found that MCEP dyads not connected at the time of enrollment were five times more likely to become emotionally connected by the 6-month follow-up. In addition, dyads in the intervention group showed ~50% reduction in behavioral problems as measured on the SYWC assessment measure. There were also less symptomatic emotional behaviors (SDQ), fewer symptoms related to autism (ATEC), improved socio-emotional function (ASQ), and greater cognitive flexibility (Brief-P).

We referred to this preschool intervention as Mother-child Emotional Preparation- (MCEP) to distinguish it from Family Nurture Intervention in neonatal intensive care unit model (FNI-NICU), which Welch and team designed for mothers and prematurely born infants. Both FNI-NICU and MCEP are based on the same calming cycle theoretical framework, which is not age-specific (26).

The FNI-NICU model was designed to overcome mother and infant autonomic stress and dysregulation after premature birth. The intervention was adapted from clinical practices developed by Welch in the 1970's (38). RCTs of FNI-NICU at Morgan Stanley Children's Hospital of New York (ClinicalTrials.gov identifier NCT01439269) showed that intervention babies had significantly accelerated brain development and autonomic regulation by term age (39–41), and that results at term age correlated with significantly improved neurodevelopment, social-relatedness, and attention at the 18-month follow-up (42). In addition, mothers of intervention babies showed improved quality of maternal care (42) and improved maternal anxiety and depressive symptoms at 4-months (23). Both FNI mothers and children had better physiological regulation at 5 years (43). The results show that an intervention aimed at enhancing mother-infant emotional connection can improve biobehavioral functioning and developmental trajectories of preterm infants.

Studies have demonstrated that child behavior and physiology are mediated by family and community relationships (44, 45). These relationships influence the child's socioemotional and physiological wellbeing. The mother-child relationship serves as the primary biological and psychological stress-modulating relationships (47–48). Thus, a stressful mother-child relationship can impair the child's socioemotional and neurological development, and stress responsivity (49, 50). It is crucial to repair a suboptimal mother-child relationship as early as possible during development to avoid chronic activation of their stress response systems (51).

Many current therapies focus on behavior and stress responses of the dysregulated child apart from the mother (52) Such therapies aim to help the child self-manage emotions and emotion-related motivational and physiological states in order to change the child's behavior and temperament (53). At the core of temperamental regulation is a construct of effortful control, defined as "the efficiency of executive attention—including the ability to inhibit a dominant response and/or to activate a subdominant response—to plan, and to detect errors" (54).

As noted in the introduction, there are many tested interventions for preschool children. However, none of these has leveraged the power of engaging both mother and child together in developing emotional connection and co- regulation (vs. self-regulation) in a school-based program and none have shown the breadth of improvements demonstrated using MCEP. MCEP is novel in active engagement of both mother and child in early childhood relationship-based intervention paving the way for sustained effects on child development and relational health (23, 26, 28, 39, 41–43). Results of this MCEP trial add to evidence that calming cycle theory and mother-infant emotional connection set the foundation for optimal child emotional and behavioral development.

In many interventions in this age group in similar settings, the child is treated separately from the parent. Teachers often serve as parental stand-ins and focus on self-regulatory activities (55–58). These interventions aim to enhance teacher-student relationships and improve child classroom behaviors by helping the child to better self-regulate emotions.

Other programs, such as Nurse Family Partnership target the foundational mother-child relationship in the home to support better socioemotional behavior in the classroom (59). A limited number of Head Start studies of programs that allow parents to become more directly engaged in additional parent-child activities, such as parent-child play, reading bedtime routines, reading daily, and reading frequency, have shown an overall positive effect on classroom behavior (60).

CLC currently employs the RULER (61) school-based teaching program and strategy within its standard curriculum to improve adverse child classroom behavior. RULER is designed to modify the quality of classroom social interactions, so that the social climate becomes more supportive, empowering, and engaging. This is accomplished by teaching children emotion regulation by solidifying their emotion identification skills, and integrating skill-building lessons and tools so that teachers and students develop their emotional literacy. The teaching-focused RULER model proved somewhat effective in the classroom. However, CLC staff reported the program was not keeping up with the growing numbers and severity of dysregulated child behavior in the classroom.

In this group model, mothers and children engaged in calming sessions at school and continued in the home prior to encountering the daily pre-school socioemotional classroom experience. The intervention is based on calming cycle theory (26, 27), which posits that child socioemotional behavior is autonomic state-dependent (as opposed to psychological trait-dependent). Symptomatic anti-socioemotional behavior in the home and at school is the result of autonomic state dysregulation. MCEP changes anti-socioemotional behavior to pro- socioemotional behavior through regular parent-child calming sessions that reinstate adaptive parent-child co-regulation of the child's and mother's autonomic states. Once established, the co-regulation may extend to school teachers and staff and pro-socioemotional behaviors emerge. Note the high percentage of CLC teachers (89%) (**Figure 7**) who want MCEP to be included in the standard curriculum MCEP involves fostering close, authentic and reciprocal emotionally calming interactions between mother and child during group sessions. MCEP targets mutual mother-child emotional connection as a powerful mediator of the dyad's ability to cope with stress (26, 27).

MCEP is novel in its engagement of both mother and child in a full range of emotional expression during mutual sensory calming sessions. Our hypothesis is that empathy is evoked when the mother (or other person) expresses the full range of their deep feelings. When a child responds to the mother's expression of emotion and shows signs of empathy to the mother, a temporary break in connection begins to repair. Repair needs to be mutual and on-going to be effective for both members of the pair. Both the mother and child learn that repair can be achieved through emotional communication. The connected child is thereafter able to connect and co-regulate with teachers and others once the pattern is established with the mother and family members. CLC leadership has reported that the children who were in the MCEP program changed the classroom environment with their positive affect and better regulated behavior so much so that teachers were freer to address problems such as learning difficulties of the non- symptomatic children for whom teachers did not have the band-width to address prior to MCEP.

Limitations

Subjects for this study were a non-probability convenience sample of mainly low socioeconomic status, which could limit result generalizability. Their lack of access to behavioral, emotional and developmental care options may have limited the effect sizes of MCEP measures. We conducted several secondary and ancillary analyses. As no penalty for multiple assessments were applied to these tests, our results should be considered preliminary. However, one of the two prospectively declared outcome tests for emotional connection (time-point 2), was found to be significant at the 0.015 level. COVID interrupted and ended many of the follow-ups. Nonetheless, it is important to note that effect sizes on all the outcomes were substantial and of potentially great importance to the well-being of the child, mother and their relational health.

Conclusion

The calming sessions employed in MCEP engage mothers and children in face-to-face interaction in a mutually calming way that achieves emotional connection without the need for expensive

curriculum or toys/stimuli. The simplicity of MCEP underlies both the scalability and the efficacy of the program. The skills acquired by the pair generalize to home readily, as minimal time is required to reconnect emotionally and mutually calm with each other each day.

As well, MCEP techniques are feasible and actionable, because expenses are minimal and techniques may be applied in multiple settings or at any time point. Improvements in mother-child emotional connection and in child behavior were significant, with large effect sizes. The fact that these effects were independent of maternal ACES is highly meaningful in this challenged preschool population. MCEP is easily scalable to other community preschools as well as to kindergartens because it could be executed by the schools' own childhood professional staff trained in the MCEP program.

Future directions

While the MCEP program also showed improvement in maternal depressive symptoms, this effect was moderated by a maternal history of childhood adversity. Given the small number of participants reporting high ACES in this study, it is imperative to do future research with a larger sample size. It would be especially fruitful to recruit women who have a history of childhood adversity, who may be struggling with childhood behavioral problems at home. Future studies will include other important variables, such as the efficacy of a Father-child emotional preparation program. Remote schooling during COVID prompted the development of a virtual model of MCEP. We are currently conducting feasibility trials of the virtual MCEP model to test its efficacy and effectiveness. While challenging initially, preliminary results suggest that a remote, internet-based platform speeds dissemination and makes MCEP more accessible, not just to mother and child but to the whole family at home. Moreover, a virtual model may prove generalizable to diverse populations without compromising efficacy and effectiveness

Data availability statement

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by Columbia University Irving Medical Center IRB. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frcha.2023.1232515/full#supplementary-material

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Infant regulatory problems and the quality of dyadic emotional connection—a proof-of-concept study in a multilingual sample

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Background and aims: Close autonomic emotional connections with others help infants reach and maintain homoeostasis. In recent years, infant regulatory problems (RPs, i.e., crying, sleeping, and feeding or eating problems) have surged. This study has two aims: (1) Provide proof-of-concept that dyadic autonomic emotional connection between infants and parents can be reliably assessed with a brief screening, irrespective of language and culture. (2) Assess in a heterogeneous pilot sample whether the persistence of RPs during infancy is negatively associated with the quality of dyadic autonomic emotional connection.

Methods: 30 children aged 3–68 months (47% female) and their parents (83% mothers) were assessed during regular neonatal follow-up visits in Germany. Seven (23%) dyads were immigrants whose primary language was not German. At each assessment, paediatricians asked parents about infant's crying, sleeping, and feeding or eating problems. Dyadic interactions were rated by a multilingual team with the standardised universal Welch Emotional Connection Screen (uWECS) on four dimensions (attraction, vocalisation, facial communication, sensitivity/reciprocity).

Results: Aim 1: An international team of raters was trained remotely to rate the uWECS. Reliability of $\alpha > .90$ with standard raters was achieved irrespective of language mismatches (i.e., all raters scored several videos with languages they did not understand). Intra-class correlation coefficients (*ICCs*) among five main raters for the four uWECS dimensions ranged from .98–.99. Aim 2: Infants ($n = 15$ assessed longitudinally) had mean RP scores of 1.20 (SD = 1.26). Dyads had mean uWECS scores of 7.06 (SD = 2.09). Linear regression analysis showed that more persistent RPs in infancy were associated with lower uWECS scores [$\beta = -.53$, *95% CI* = (-1.47, -.18), $p = .017$], after controlling for child sex and gestational age.

Conclusion: This study provides proof-of-concept that the quality of mutual autonomic emotional connection among socio-culturally and linguistically heterogeneous samples can be reliably assessed with the uWECS, a brief screening that can be easily implemented in clinical practice. Pilot data suggests that persistent RPs during infancy are negatively associated with the quality of dyadic autonomic emotional connection. Replication of these findings in larger samples is warranted. Future studies need to address how to facilitate successful emotion regulation for today's children and future generations.

KEYWORDS

regulatory problems, dyadic interactions, emotional connection, behaviour observation, linguistic heterogeneity

Introduction

Societies and human life across the world are rapidly changing due to factors such as global warming and increased migration. Across cultures, our species' evolution and survival universally depend on the formation of close relationships with others (1, 2). Ludwig and Welch (3) have proposed that social interaction between mother and infant is a dynamic process that already starts *in utero* and follows a conditional autonomic socioemotional reflex (ASR) and emotional connection. The ASR is dynamically shaped by reciprocal learning and co-regulatory change via various biological cycles, such as sleep-wake, signalling, feeding, and breathing (3). These co-regulatory or calming cycles of emotional connection are intended to facilitate homoeostasis, and their quality has profound impact on infant development that can last life-long (3). Here, mother-infant autonomic emotional connection is qualitatively distinct from the widely used more colloquial or "psychological" emotional connection construct (4). However, rates of both types of emotional connection have been low in recent years, while infants and parents have been under severe mental stress (5–7). Simultaneously, infant regulatory problems (RPs, i.e., crying, sleeping, and feeding or eating problems) have surged in recent years (8, 9), with many parents seeking support from health professionals. Research suggests a continuous feedback loop, with infant RPs increasing parenting stress (10), while stressed parents may respond with poorer parenting quality (11, 12), which may then further exacerbate poor regulatory behaviour in their children (13). In light of these challenges for today's families, we lack information about the association between infant regulatory problems and the quality of emotional connection with their parents.

Autonomic emotional connection is dependent upon vocal signalling, feeding, and sleeping, which are fundamental for infant survival and healthy development (14). Persistent difficulties with self-regulating these behaviours may result in RPs such as waking up many times and not settling back to sleep at night or neophobia to food (15, 16). Most early RPs are transient, but a combination of multiple problems or persistent RPs are associated with high risk for behaviour regulation difficulties (17–22) and emotional disorders later in life (23). The definition of infant RPs includes excessive crying after 3 months of age, as well as feeding and/or sleeping problems after 6 months of age (24). Approximately 20% of infants experience some of these RPs (18, 25), while previous studies have found that 2%–9% may have persistent RPs across more than one assessment point (15, 24, 26).

In general, self-regulation is a multifaceted construct including complex bodily and behavioural-cognitive functions. Of these, emotion and behaviour regulation are particularly relevant for children's school readiness, wellbeing, and life-course success (27, 28). Consequently, researchers, practitioners, and families alike are highly interested in environmental factors such as parenting that can support children's growing self-regulatory skills. For instance, maternal sensitivity, defined as adaptive, prompt, and responsive parenting has been found to foster dyadic co-regulation of behaviour (29, 30). However, social interactions are bidirectional in nature, and characterised by constant feedback loops. Accordingly, early social behaviour and caregiving should not be seen as unidirectional but instead assessments should capitalise on the bidirectionality and mutuality in the exchange of behaviours (1, 31). Here, two key features are synchrony and autonomic emotional connection, i.e., the dynamic and reciprocal adaptation of behaviours, co-regulation, and shared affect between two interactive partners (32). High synchrony is associated with healthy development across multiple dimensions (33), while early-life risks such as maternal chronic stress or preterm birth are negatively associated with dyadic synchrony (29, 34–37).

Synchrony and mutual autonomic emotional connection are not culturally-specific constructs, they are universal and form fundamental building blocks of human behaviour. In light of growing cultural and linguistic diversity worldwide due to increased migration (38, 39), the availability and implementation of equitable assessment tools that use a universally accessible language has become paramount. Minimal and easy language approaches provide solutions for overcoming some of the complexity, ambiguity, and cultural variability of emotion words (40), so that assessment tools can be valid and reliable for use in a wide range of countries and professional settings.

The original Welch Emotional Connection Screen (*WECS*) (31, 40) was created to specifically assess the parent-child autonomic emotional connection construct. In this study, we use

a version of the WECS that was made universally accessible using a minimal language version with Clear Explicit Translatable Language (31, 40), now referred to as the universal *uWECS*.

The current study has two aims:

(1) Provide proof-of-concept that dyadic autonomic emotional connection between infants and parents can be reliably assessed with the brief uWECS screening, irrespective of raters' and participants' languages and cultures.
(2) Assess in a pilot sample whether the persistence of RPs during infancy is negatively associated with the quality of dyadic autonomic emotional connection. We hypothesized that infants with more persistent RPs would have lower quality of dyadic emotional connection with their mothers or fathers.

Materials and methods

Data were collected as part of a retrospective single centre cohort study. The study protocol was approved by the ethics committee of the University Duisburg-Essen (23-11268-BO). Children aged 3–68 months and their parents were assessed as part of regular neonatal follow-up visits at a children's hospital in a large metropolitan region in Western Germany. Assessments with infants aged 24 months and younger were corrected for prematurity, while assessments with children older than 24 months were carried out according to chronological age.

Regulatory problems

As part of neurodevelopmental examinations during regular neonatal follow-up visits at 3, 6, and 12 months of age, paediatricians asked parents about their infant's crying, sleeping, and feeding or eating behaviour. Definitions of crying, sleeping, and feeding or eating problems were derived from previous studies (24, 41). Specifically, paediatricians entered free text of the specific problems as described by parents at each visit, including intensity, frequency, and situational context into the database. Text chunks were extracted and jointly coded by a multiprofessional team (BM, JJ) according to the predefined protocol. Specific problems ranged from excessive, prolonged (>3 h daily) and intensive crying without apparent reason resulting in bluish lips and hands at 3 months, to problems with sleeping through the night, frequent waking and difficulties falling back to sleep at 12 months, or very picky eating or refusal of solid food, for example. The occurrence of clinical problems in one or more areas at an assessment was coded as 1 (vs. 0 = no problem). These were then summed into a variable that indicated the persistence (0 = never to 3 = RPs at all assessment points throughout infancy).

Dyadic interactions

Video recording was performed to assess the quality of emotional connection between child and parent either before medical and standardised testing during follow-up or at the end of the appointment, depending on the regulatory state of the child (i.e., awake and not hungry at the start of the interaction recording). Parents were instructed to hold their child on their lap so they could be in good eye contact with each other. They were asked to interact with their child as they normally would for 3–5 min in their mother tongue (L1) without using any objects, toys, or food. The video camera was positioned on a tripod so that the child's face could be seen well in profile, as could the parent's face while the dyad was sitting on a chair. Sounds and speech were recorded via an integrated microphone. The dyad was left alone in the room for the observation period, but a staff member was nearby in visual and/auditory contact.

uWECS

Video-recorded dyadic interactions between children and parents were rated by a multilingual international team with the Welch Emotional Connection Screen in Clear Explicit Translatable Language (WECS-CETL) (31, 40, 42), now referred to as the Universal WECS (uWECS) (see Hane et al., this special edition). The team of trained raters consisted of multiple professions, including neonatologists, psychologists, an occupational therapist, and a paediatric nurse. The WECS is a short interactive task and coding system, it has very good concurrent and construct validity. Higher emotional connection is correlated with healthier infant autonomic and behavioural stress responding (31). The WECS has been validated for infancy and into preschool age (31, 43, 44). The WECS includes four continuous dimensions (*attraction*, *vocalisation*, *facial communication*, and *sensitivity/reciprocity*) that were translated from the CETL words of the uWECS into the different languages represented among the coders according to a structured group process of translation within the training context as needed. Like the WECS, the uWECS includes dimensional scores and a binary rating of the dyad's emotional connection (yes/no; see Supplementary Appendix 1 for a parallel presentation of the full English and German uWECS positive and negative dimensional coding descriptions).

Each dimension was coded on a scale from 1 (lowest) to 3 (highest) according to 0.25 intervals (see Supplementary Appendix 2). *Attraction* was coded according to bidirectional gaze, physical proximity to each other, and mutual touch. Higher scores were given for gazing at, leaning into, and touching or reaching for the other with the goal of maintaining or establishing a connection. Gaze aversion or physical avoidance received low scores. *Vocalisation* was rated according to mutual warmth in vocal tone, amount of vocal stimulation from the mother, vocal or behavioural responsiveness from the child, and overall reciprocity of utterances. A high score was given to dyadic partners whose vocal behaviour was directed to the other to establish or maintain a connection. A low score was given for silence, lack of reciprocity, a negative/harsh tone of voice, or prolonged infant fussing or crying. *Facial*

communication was coded according to mutually positive emotions expressed with the face such as smiling, joy, and empathy. Low scores were given for flat or negative facial affect, or when expressed emotions were not reciprocally matching each other. *Sensitivity/Reciprocity* was determined based on the dyad's social sensitivity to each other's expressed emotions or anticipated/identified needs. Harmonious and synchronous interactions received high scores.

Reliability analyses (Aim 1) were carried out on the individually scored dimensions. Here, by design, this proof-of-concept study included language mismatches such that each rater scored several videos of dyadic interactions in languages they did not understand. For Aim 2, the scores on each dimension were averaged across all raters and then summed into one continuous uWECS score (range 4–12). For the final binary rating, in line with previous studies (31), dyads with a continuous uWECS score ≥9 were considered emotionally connected.

Biological and medical characteristics

Information on infant sex, perinatal medical risks, and age at assessment was retrieved from medical records.

Parent questionnaires

Mothers and fathers answered a set of demographic and psychosocial background questions, including information on their level of education according to the International Standard Classification of Education (ISCED) (45), mother tongue (L1), and country of birth.

Results

Table 1 shows that the 30 children in the sample had comparatively high perinatal risks and were of diverse backgrounds. Seven (23%) dyads had an immigrant background and spoke a first language other than German during the uWECS assessment. The subsample assessed longitudinally throughout infancy ($n = 15$) was characterised by equally high diversity.

Aim 1

An international, multiprofessional team of raters in Germany and Finland was trained remotely by MW and AH with weekly

TABLE 1 Descriptive sample characteristics.

	Total sample ($N = 30$)	Longitudinal subsample ($n = 15$)
Child sex [female, *n* (%)]	14 (47%)	10 (67%)
Gestational age [weeks, *M* (SD)]	30.80 (4.18)	29.60 (3.96)
Birth weight [grams, *M* (SD)]	1,660 (853)	1,500 (837)
Multiples [yes, *n* (%)]	11 (37%)	5 (33%)
Perinatal medical risks		
Intraventricular haemorrhage [IVH, grade 1–2, *n* (%)]	6 (20%)	3 (20%)
Periventricular leukomalacia [PVL, *n* (%)]	0	0
Necrotizing enterocolitis [NEC, *n* (%)]	1 (3%)	1 (7%)
Focal intestinal perforation [FIP, *n* (%)]	2 (7%)	0
Respiratory distress syndrome [RDS, *n* (%)]	19 (63%)	10 (67%)
Bronchopulmonary dysplasia [BPD, *n* (%)]	4 (13%)	2 (13%)
Regulatory problems at 3 months [*n* (%)]	13 (46%)[a]	6 (40%)
Regulatory problems at 6 months [*n* (%)]	7 (27%)[a]	6 (40%)
Regulatory problem at 12 months [*n* (%)]	7 (27%)[a]	7 (47%)
Regulatory problem persistency [*M* (SD)]	–	1.20 (1.26)
Age at uWECS assessment [months, *M* (SD)]	26.63 (24.31)	34.60 (22.25)
uWECS score [*M* (SD)]	7.06 (2.09)	7.43 (1.98)
Emotionally connected [yes, *n* (%)]	9 (30%)	5 (33%)
uWECS language [*n* (%)]		
German	23 (77%)	12 (80%)
Turkish	2 (7%)	2 (13%)
Russian	2 (7%)	–
Kurdish	2 (7%)	–
Twi	1 (3%)	1 (7%)
uWECS adult partner [*n* (%)]		
Biological mother	23 (77%)	12 (80%)
Biological father	5 (17%)	2 (13%)
Foster mother	2 (7%)	1 (7%)
Mothers' education [ISCED level, *M* (SD)]	5.17 (2.02)	5.13 (1.92)
Fathers' education [ISCED level, *M* (SD)]	5.28 (1.71)	5.20 (1.66)

[a]Please note that only a subsample was assessed.

1.5-hour sessions between October 2022 and February 2023 to administer and rate the uWECS. The training started with coding instructions for US-based dyadic interaction videos in English or Spanish language (see Hane et al., this edition). From December 2022, videos with participants from Germany were used. The training group members independently scored 10 videos for blinded reliability testing in February 2022. Reliability of $\alpha > .90$ on the continuous dimensions and of kappa = 1.0 on the binary uWECS score with the standard raters (MW, AH) was achieved irrespective of language mismatches (i.e., all raters scored two to six videos with languages they did not understand). Next, the German-Finnish rating team scored the 30 dyads in the current sample ($n = 23$ spoke German, $n = 7$ spoke Russian, Turkish, Kurdish, or Twi during the interaction) and reliabilities were reassessed on group-level. Again, by design, there were language mismatches such that the German raters each scored seven videos they did not understand, while the Finnish rater understood none of the languages used in any of the interactions. Despite this heterogeneity, intra-class correlation coefficients (*ICCs*) among the five main raters for the four uWECS dimensions ranged from .98–.99. Dyads had mean uWECS scores of 7.06 (SD = 2.09, range 4.10–9.95, 30% were emotionally connected).

TABLE 2 Associations between persistency of regulatory problems in infancy and uWECS scores ($n = 15$).

Dependent variable uWECS	*B*	SE	*β*	*p*	95% confidence interval for *B*
Regulatory problems	-.82	.29	-.53	.017	-1.47, -.18
Gestational age	.28	.09	.56	.011	.08, .48
Child sex	.95	.76	.23	.242	-.74, 2.63

Aim 2

The 15 children who had been assessed longitudinally throughout infancy and childhood had mean RP scores of 1.20 (SD = 1.26). Dyads had mean uWECS scores of 7.43 (SD = 1.98, 33% were emotionally connected) at mean age 34.60 months (SD = 22.25, range 12–68 months). A multivariable linear regression analysis showed that the persistence of RPs in infancy (predictor of interest) was negatively associated with uWECS scores [$B = -.82$, SE = .29, $\beta = -.53$, 95% CI = (−1.47, -.18), $p = .017$], after controlling for child sex and gestational age (see Table 2 and Figure 1).

Discussion

This proof-of-concept study shows that the quality of mutual dyadic emotional connection among socio-culturally and linguistically heterogeneous samples can be reliably assessed with the brief 3-minute uWECS, despite a-piori planned language mismatches between raters and participants. In addition, confirming our hypothesis, pilot data showed that the persistence

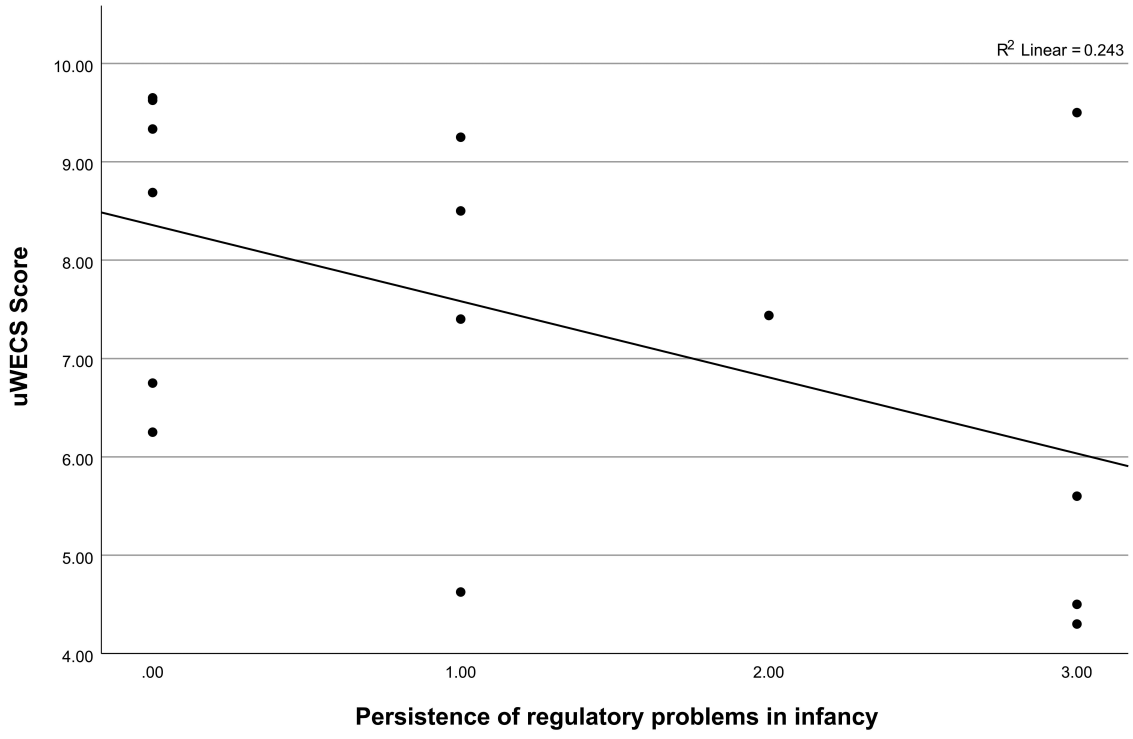

FIGURE 1
Association between the persistence of RPs during infancy and the uWECS score of mutual autonomic emotional connection ($n = 15$).

of RPs in infancy was negatively associated with the quality of emotional connection, after controlling for child sex and gestational age.

Calming cycle theory proposes that the ASR and autonomic emotional connection are fundamental building blocks of all mammalian behaviour (3). Accordingly, although acknowledging that each and every culture is shaped by unique contextual processes, it can be argued that a universal instrument such as the uWECS reliably captures the quality of mutual autonomic emotional connection across highly heterogeneous groups of dyads across diverse international contexts. Providing this proof-of-concept is critically important for evidence-based research and practice with globally growing cultural and linguistic diversity due to increased migration (38, 39). Indeed, although long neglected, the availability and implementation of equitable assessment tools that use a simple, universally accessible language has become paramount in the health sciences (40, 46). Moreover, it is well established that using their L1 in early dyadic interactions of parents with their children should be encouraged and facilitated (47–49). Therefore, following such recommendations that recognise the value and importance of families' linguistic and cultural heritage, mothers and fathers are always instructed to use their L1 during the uWECS interaction. Providing proof-of-concept that raters from very heterogeneous professional and language backgrounds can reliably code these 3-minute standardised interactions for emotional connection helps overcome the global lack of equitable, culture-fair screening tools (50) and associated language barriers, misunderstandings, and misdiagnoses.

Our results confirmed our hypothesis that more persistent RPs in infancy were prospectively associated with lower quality of mutual emotional connection between children and their mothers or fathers. Infant RPs represent both causes and consequences of broken emotional connection within a complex continuous feedback loop of co-regulatory changes that include foundational biological cycles such as signalling, sleep-wake, feeding, and breathing (3, 51, 52). Our pilot sample consisted of children born preterm with an average gestational age of 29.60 weeks, who had spent the first weeks of their lives in the neonatal intensive care unit (NICU). It is well documented that on top of the neurodevelopmental problems and medical complications triggered by preterm birth, the neonatal treatment itself causes pain and trauma that may affect the development of the stress response system (53, 54). At the same time, infants' mothers also need to recover from the medical complications and trauma associated with a preterm birth, while both mothers and fathers face the stress of caring for a severely ill newborn. This may have long-term adverse consequences for the quality of mutual emotional connection and co-regulation (55, 56), and even result in severe consequences such as shaken baby syndrome (57). However, human nature has also equipped us with the ability to repair broken emotional connections (3, 7, 58), which deserves special attention among dyads at-risk for persistent dysregulation. The uWECS offers a valuable screening tool for early identification of suboptimal ASR and autonomic emotional connection, while its integrated treatment component, the Family Nurture Intervention, provides a seamless opportunity to help dyads reconnect and repair their natural ability to co-regulate (7, 59).

This study has several strengths but also limitations. We were able to provide proof-of-concept that a heterogeneous team of health care professionals can reach reliability in rating videorecordings of the brief uWECS interactions independent of language with only few remote sessions. The data from our clinical sample were collected prospectively and coded according to predefined protocols. A detailed documentation of participants' background characteristics allows comparison of their contextual experiences to other samples. However, overall our sample was very small, we did not assess mothers' and fathers' perceived daily stress levels or mental health which represent important confounders, and infant RPs were evaluated as part of an anamnestic approach during standard follow-up care. Replication of findings as part of large, socioeconomically and culturally diverse, prospective observational studies is warranted.

Conclusion

This study provides proof-of-concept that the quality of dyadic autonomic emotional connection among linguistically diverse samples of infants and their parents can be reliably assessed with the uWECS, a brief screening that can be easily implemented in clinical practice. Pilot data suggests that persistent RPs during infancy are negatively associated with the quality of dyadic emotional connection. Replication of these findings in large and heterogeneous samples is needed. Future studies need to address how to facilitate successful emotion regulation for today's children and future generations.

Data availability statement

The datasets presented in this article are not readily available because there is no consent to the transfer of data to third parties for participants' privacy right reasons. Requests to access the datasets should be directed to britta.huening@uk-essen.de.

Ethics statement

The studies involving humans were approved by Ethical Committee of the Medical Faculty, University Duisburg-Essen, Germany. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin.

Author contributions

JJ: Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing, Conceptualization, Data curation, Formal Analysis, Supervision, Validation,

Visualization. A-KD: Conceptualization, Data curation, Investigation, Methodology, Writing – review & editing. MB: Data curation, Investigation, Methodology, Writing – review & editing, Validation. JB: Data curation, Investigation, Methodology, Validation, Writing – review & editing. EJ-O: Investigation, Methodology, Writing – review & editing. MR: Investigation, Methodology, Writing – review & editing, Resources. RL: Methodology, Writing – review & editing, Conceptualization, Validation. AH: Methodology, Supervision, Writing – review & editing, Resources. MW: Conceptualization, Methodology, Resources, Supervision, Validation, Writing – review & editing. BH: Methodology, Project administration, Resources, Supervision, Writing – review & editing, Investigation, Writing – original draft, Conceptualization, Data curation, Funding acquisition, Validation.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frcha.2023.1304235/full#supplementary-material

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Community health nurses' concerns about infant regulatory problems are predictive of mental disorders diagnosed at hospital: a prospective cohort study

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Introduction: Regulatory problems of eating, sleeping, and crying in infancy may index mental health vulnerability in older ages, and knowledge is needed to inform strategies to break the developmental trajectories of dysregulation in early childhood. In this study, we examined the prospective associations between infant regulatory problems at the age of 8–10 months identified by community health nurses (CHN) and mental disorders diagnosed in hospital settings in children aged 1–8 years.

Methods: From a cohort of all newborn children in 15 municipalities in the Capital Region of Copenhagen ($N = 43{,}922$) we included all children who were examined by CHNs at the scheduled home visit at the age of 8–10 months ($N = 36{,}338$). Outcome measures were ICD-10 mental disorders diagnosed at public hospitals and reported to the National Patient Register. Logistic regression included data on child and family covariables obtained from population registers.

Results: The CHNs reported concerns regarding sleep in 7.7% of the study population, feeding and eating in 19.1%, combined sleeping and eating problems in 3.6%, and incessant crying in 0.7%. A total of 1,439 children (4% of the study population) were diagnosed in hospital settings with an ICD-10 mental disorder between the ages of 11 months and 8 years. Analyses adjusted for a range of perinatal and family adversities showed an increased risk of any neurodevelopmental disorder among children with CHN concerns of feeding and eating (odds ratio (OR) 1.36 (95% confidence interval (CI) 1.14–1.63)) and co-occurrent problems of feeding and eating and sleep (OR 1.60 (95% CI 1.14–2.26)). For autism-spectrum disorders, an increased risk was seen among children with co-occurrent problems of both feeding and eating and sleep (OR 1.73 (95% CI 1.07–2.79)). Concern about feeding and eating was also associated with an increased risk of behavioral and emotional disorders (OR 1.27 (95% CI 1.03–1.56)). Concern about incessant crying at the age of 8–10 months was not associated with a diagnosed mental disorder, but findings may reflect low statistical power due to low frequency of concern.

Discussion: CHN concerns mirror a group of developmentally vulnerable children. Further research is needed to explore the possibilities of preventive intervention within the general child health surveillance to address the developmental psychopathology of dysregulation in early ages.

KEYWORDS

children, community health nurses, incessant crying, eating problems, infants, mental disorders, sleeping problems, regulatory problems

1 Introduction

Persistent problems of feeding, sleeping, and incessant crying in infancy are often referred to as infant regulatory problems (RP) (1–3). RPs represent the extreme on a continuum of problem severity, ranging from normal variations to problems that exceed deviations in the normal development, overall influencing the wellbeing of the child (1–3). Infants' regulation of sleep, feeding and eating, and emotional reactions matures during the early postnatal months, highly influenced by innate vulnerabilities and the external regulatory support provided by the parents. The first 4 months of life are a period of adaptation and maturation in which transitory problems of regulation is frequent (3). The current conceptualization of RPs includes problems that are pervasive and persistent over time, and exceeding the variations being considered within the normal developmental range (4). Still, the concept and definition of RPs in infancy is not fully validated (5, 6). Different criteria and questions are used across studies to define when the problems are outside the normal range (3, 5).

According to the available literature, RPs may affect one-fifth of all infants (1, 2, 4). There is an increased risk seen in children born with perinatal adversities, as well as children from families of psychosocial adversities, and in particular maternal mental health problems and parent–child relational problems (2). Longitudinal data have found that RPs in infancy are associated with a wide range of mental health problems in childhood and adolescence (1, 3–21). The frequency and possible developmental impact of RPs point to public health approaches to the early detection and interventions addressing infants with RP. This is to reduce the developmental risk of mental health problems in childhood and beyond, as well as the long-term consequences of such problems (22–24).

A meta-analysis from 2011 that included clinical/high-risk as well as community-based studies found an overall increased risk of behavioral problems, externalizing, and attention-deficit/hyperactivity disorder (ADHD) later in childhood among children with RPs in infancy (1). A meta-analysis from 2023 (6) found a cumulative risk of behavioral problems of 23.3% for children with RPs compared to 6.7% for healthy controls. The outcome measures included externalizing behavior, internalizing behavior, and ADHD, most often assessed by parents' use of rating scales. The meta-analysis did not find any important subgroup differences or moderating effects among children with infancy RPs. The effect sizes were comparable regardless of the follow-up age. In addition, studies exploring the neurodevelopmental outcome of infancy RPs in clinical as well as population-based cohorts have found associations with autism spectrum disorders (ASD) and ADHD (3, 5, 7–14, 16–19, 21, 25).

The co-occurrence of two or more RPs has consistently been found associated with an increased cumulative risk of mental disorders (3, 4, 18). Moreover, co-occurrent or combined RPs have been suggested to be infancy markers of early dysregulation vulnerability tracking into the emotional, cognitive, and behavioral dysregulation of a range of mental disorders later in development (4, 18). Among the potential perinatal and psychosocial risk factors investigated, particularly preterm birth, maternal mental health problems and parent–child relationship problems have been found associated with increased developmental risk in infants with RPs (2, 14, 25–27). Altogether, the available evidence suggests that RPs in infancy may predict psychopathology across childhood and beyond (18). These suggestions point to the identification of RPs in infancy providing a window of opportunity to target intervention toward developmental cascades of dysregulation early in childhood through strategies to improve the parenting of vulnerable infants (2–4, 23).

Within the community child healthcare, a window of opportunity to target infancy RPs may be provided by health professionals working with infants and their families. In Denmark, the municipality child healthcare includes scheduled home visits from community health nurses (CHNs) to all families with a newborn child. These services are free of charge and attended by more than 95% of families with infants (20, 28). The CHNs are registered nurses with a 1.5-year formalized education, including the theoretical and clinical aspects of child assessments and communication with parents. In accordance with the recommendations from the National Health Authority, the CHNs offer at least five home visits during the first postnatal year. The main agenda of the home visits is the CHN's evaluation of the child's physical and mental health, and a dialog with the parents about the developmental needs of the child, including action regarding further support or referrals if needed. In connection with the home visits, the CHN fills in a standardized record. The record is based on the CHN's examination and observation of the child and on a conversation with the parents and is an overall conclusion regarding the child's development and wellbeing (20, 28, 29). If the child does not develop age-appropriately, the CHN records a concern for that area, including concern relating to sleep, eating, or crying. In the international literature, the CHN's recordings are described as a concern, attention, or red flag, which indicate that something is different, wrong, odd, or troubling (30).

Although there are many studies that demonstrate an association between RP in infancy and mental health problems in childhood, there are still many unsolved issues. For instance, only few studies investigated the mental disorders according to defined diagnostic criteria, such as the criteria of the International Classification of Diseases, ICD-10 (5, 14). In addition, only few studies included a broad range of mental disorders as outcome measures (1, 4, 6). Further, the pattern of association between specific kinds of dysregulation and mental health problems varied across studies, and so did the effect sizes. Yet another unsolved issue relates to confounding due to well-established risk factors underscoring the need for comprehensive adjustment for confounders in studies of the prospective association between RPs in infancy and mental disorders in childhood.

The aim of this study was to examine the prospective association between CHN-observed concerns of RPs in infancy and child mental disorders diagnosed within hospital settings. The main hypothesis was that indicators of RPs identified in municipality settings during infancy would be predictive of mental disorders diagnosed later in childhood.

2 Methods

2.1 Study design and study population

The study is based on a prospective cohort of children followed from birth to their eighth birthday. The study included data on the standardized recordings from home visits from municipalities who are part of the Child Health Database collaboration. These recordings contain a range of information on family factors and child development, and they include recordings of the CHN's concerns about sleeping problems, eating problems, and incessant crying. Among the available data, we used information about RPs from the home visit when the child was aged 8–10 months, considering that problems within the first 6 months may be transitory and fading (2, 20). The records also included the child's unique person identification number making it possible to link data from the CHN's recordings to data from Danish national registers (the National Birth Register, the Danish National Patient Register, and the Civil Registration System). For the present study, we applied the following criteria of inclusion criteria: (1) all newborns from 15 municipalities in the Copenhagen region in Denmark, representing a mixture of metropolitan, urban, and rural areas; (2) children born between 1 January 2002 and 31 December 2010, i.e., they had their eighth birthday before 1 January 2019; (3) having data about regulatory problems and other requested data from the CHN records; (4) no diagnosed mental disorder before the age of 11 months; and (5) having data about all applied covariates (confounder variables). The total number of children born in the 15 municipalities between 2002 and 2010 was 43,922. The eligible study population included the 36,338 children who complied with the inclusion criteria. Not all children had data on all three RPs explored ($N = 9{,}712$) and only for a few children had the CHN registered a concern for all three regulation problems ($n = 11$). Because of that, we did not conduct analyses with combined data on all three RPs. The analyses of sleeping problems used a subpopulation of 31,322 children, the analyses of eating problems used a subpopulation of 26,437 children, the analyses of combined sleeping and eating problems used a subpopulation of 25,960 children, and the analyses of incessant crying used a subpopulation of 13,987 children.

2.2 Measures

The *predictor variables* were regulatory problems at the age of 8–10 months derived from the CHNs' records. The CHN registered a concern in the child's record at the home visit at the age of 8–10 months if the CHN had concerns about RPs. The records are based on the overall conclusion from the parents' information and observations of the child during the home visit. To optimize the reliability of the recordings, the CHN used a manual of definitions. The CHN registered a concern regarding the following: (1) *sleep* if the child had not developed a stable sleep pattern, or if the child's sleep did not meet the child's need for sleep, summarized as a dichotomous variable, +/− concern regarding sleep; (2) *feeding and eating* in case of deviation from this definition: "The child gets a combination of breast milk/formula and solid food; there are no eating problems; the child drinks from a cup; the food meets the nutritional recommendations from the health authorities", summarized as a dichotomous variable, +/− concern regarding feeding and eating, and (3) *incessant crying* if it is not possible to comfort the child when crying, summarized as a dichotomous variable, +/− concern regarding incessant crying. The term *concern* is a concept traditionally used by Danish CHNs to describe worrisome or risky conditions in the child or the caregiver environment (22), just like the concept's attention and red flag (30).

The main *outcome variable* was any mental disorder diagnosed in clinical settings at hospitals from a child aged 11 months to the child's eighth birthday. The mental disorders comprise all F-diagnoses (F00–F99) from the ICD-10 Classification of Mental and Behavioral Disorders: clinical descriptions and diagnostic guidelines (31). This included general developmental disorders (F70–F79), specific developmental disorders (F80–83), pervasive and other developmental disorders (F84–89), hyperkinetic disorders (F90), attention-deficit disorder without hyperactivity (F98.8), mood disorders, emotional and stress-related disorders (F30–F34, F38–F45, F48, F93), disorders of eating and sleep (F50–F51, F98.2), disorders of behavioral (F91–F92), and of social functioning (F94.1–F94.2, F94.8). Information on mental disorders in clinical settings was obtained from the Danish National Patient Register, which included all hospital contacts with a 100% coverage (32). Referrals and treatments at hospitals are free of charge in Denmark. The clinical diagnostic assessments included examinations in pediatric and psychiatric in- and outpatient and emergency settings completed by medical doctors in accordance with the diagnostic criteria of ICD-10 (33).

We summarized the outcome data into three dichotomous variables: at least one diagnosed mental disorder between the ages of 11 months and 8 years (yes, no), at least one diagnosed neurodevelopmental disorder (34), including intellectual disability, autism-spectrum disorders and disorders of hyperactivity and inattention (yes, no), and at least one diagnosed behavioral or emotional disorder (yes, no).

The analyses included a range of *covariates* from three sources. From the *National Birth Register*: gestational age (born in the 37th week or later vs. before); birth weight (<2,500, 2,500–3,999, and >3,999 g); congenital malformation (yes, no); mother's age at childbirth (<25 vs. ≥25); father's age at childbirth (<25 vs. ≥25); pregnancy complications (yes, no); cesarean section (yes, no); and Apgar score (9–10 vs. less). From the *Civil Registration System*: parents' education at childbirth (5 or more years of completed university education, other higher education, completed high school, completed vocational education, and primary school); family composition (child lives with both parents, yes vs. no); and parents' origin (2, 1, or 0 parents of Danish origin). From the *CHN records*: Concern about the mother's mental health in the first 6 months after delivery, defined as "signs of depressive mood, anxiety, sleep problems, neglect of overt problems, or referred to psychiatric care" (dichotomized into concern at 0 vs. at least one home visit); and

concerns about the parent–child relationship in the first 6 months after delivery, defined as any deviation from the following description: "The child is attended to; has appropriate clothing; the parents offer the child stimulating activities, are calm and confident in their behavior resulting in a positive interaction; the parents can detect and meet the child's needs; the parents are aware of the child's weeping and can comfort the child; the parents understand and respond properly to older siblings' reactions" (dichotomized into concern at 0 vs. at least one home visit).

2.3 Statistical procedures

The first step was contingency tables for the inspection of data and use of the chi-square test for heterogeneity. The second step was logistic regression analysis of the association between regulatory problems at the age of 8–10 months and diagnosed mental disorders from the age of 11 months until the eighth birthday, adjusted for the abovementioned covariates. The logistic regression analysis used RPs (one at a time, followed by a combination of sleeping and eating problems) as independent variables with diagnosed mental disorders as the outcome variables. The adjustment for covariates included three steps. Model 1 adjusts for all prenatal and perinatal conditions (sex, parity, gestational age, birth weight, congenital malformation, pregnancy complications, cesarean section, Apgar score, mother's age, father's age, parents' education, parents' employment, family composition, parents' origin). Model 2 adjusts for exposures within the first 6 postnatal months as measured by the CHN's concern about the mother's mental health and the CHN's concerns about the parent–child relationship. Finally, Model 3 adjusts for the entire list of covariates from Models 1 and 2.

2.4 Data protection and ethical issues

The data collection was approved by the Research & Innovation Organization at the University of Southern Denmark (registration number 11,667) and the Danish Regional Council (registration number R-22030405), and it complied with national regulations of data protection and consent. Data were passed on from the municipalities to the National Institute of Public Health, as described in the Data Protection Legislation, and comply with the Danish codex for integrity in research (35). Linkage with register data was administered by Statistics Denmark and the involved researchers did not have access to personal identification.

3 Results

3.1 Descriptive information

In Table 1, the characteristics of the eligible and the applied study populations are illustrated by all the included variables. The composition of the eligible and the applied study populations are almost identical. The proportion of infants with sleep problems, eating problems, combined sleeping, and eating problems and problems with incessant crying was 7.7%, 19.1%, 3.6%, and 0.7%, respectively. Of the eligible study population, 4% had been diagnosed with at least one mental disorder in the period between 11 months and 8 years.

3.2 Logistic regression analyses

Tables 2–5 show the odds ratio (OR) (95% confidence interval (CI)) for mental disorders between the ages of 11 months and 8 years by RPs at the age of 8–10 months. A significant association was seen between sleeping problems at the age of 8–10 months and at least one behavioral or emotional disorder (OR 1.39 (95% CI 1.07–1.81)) (Table 2). The associations between sleeping problems and mental disorders attenuated when adjusted for the covariates measured within the first 6 postnatal months (concerns about the mother's mental health and the parent–child relationship).

Significant associations were seen between eating problems at the age of 8–10 months and three of the outcome variables (Table 3): at least one diagnosed mental disorder (adjusted OR 1.32 (95% CI 1.14–1.54)); at least one behavioral or emotional disorder (adjusted OR 1.27 (95% CI 1.03–1.56)); and at least one neurodevelopmental disorder (adjusted OR 1.36 (95% CI 1.14–1.63)). Once again, the association between eating problems and mental disorders attenuated when adjusted for concerns about the mother's mental health and parent–child relationship (Table 3).

Table 4 shows the longitudinal associations of a combination of sleeping and eating problems. These combined problems were associated with a significantly increased risk of at least one mental disorder (adjusted OR 1.43 (95% CI 1.07–1.92)) and at least one neurodevelopmental disorder (adjusted OR 1.60 (95% CI 1.14–2.26)), and among them, of diagnosed autism-spectrum disorders (adjusted OR 1.73 (95% CI 1.07–2.79)), but not disorders of hyperactivity and inattention. When adjusting for exposures regarding the mother's mental health and the parent–child relationship within the first 6 postnatal months, an overall pattern of attenuations of associations was seen (Table 4).

Finally, Table 5 shows that problems of incessant crying were not associated with an increased risk of diagnosed mental disorders. In these analyses, the adjustment for covariates, both those concerning prenatal, perinatal, and postnatal conditions, resulted in a considerable reduction of the OR estimates.

4 Discussion

4.1 Main findings

More than 20% of all infants have at least one CHN-reported regulatory problem, which is a prevalence estimate corresponding to prevalence estimates reported from studies using other kind of informants (1, 17). Approximately 4% of the infants in the population received at least one diagnosis of a mental disorder

TABLE 1 The eligible and applied study populations characterized by all included variables.[a]

	Eligible total study population ($N = 36,338$) *n* (%)	Applied study populations			
		Sleeping problems subpopulation ($N = 31,322$) *n* (%)	Eating problems subpopulation ($N = 26,437$) *n* (%)	Sleeping and eating subpopulation ($N = 25,960$) *n* (%)	Incessant crying subpopulation ($N = 13,987$) *n* (%)
Regulatory problems at age 8–10 months					
Sleeping problems	—	2,403 (7.7)	—	—	—
Eating problems	—	—	5,053 (19.1)	—	—
Sleeping or eating problems	—	—	—	5,794 (22.3)	—
Sleeping and eating problems	—	—	—	942 (3.6)	—
Incessant crying problems	—	—	—		93 (0.7)
Diagnosed mental disorder					
At least one diagnosed mental disorder between 11 months and 8 years	1,439 (4.0)	1,246 (4.0)	1,064 (4.0)	1,043 (4.0)	545 (3.9)
At least one diagnosed behavioral or emotional disorder	710 (2.0)	622 (2.0)	533 (2.0)	524 (2.0)	281 (2.0)
At least one diagnosed neurodevelopmental disorder including disorders of intellectual disability, ASD, and ADHD	970 (2.7)	840 (2.7)	710 (2.7)	697 (2.7)	364 (2.6)
Autism spectrum disorders (F84)	456 (1.3)	404 (1.3)	345 (1.3)	340 (1.3)	193 (1.4)
Disorders of hyperactivity and inattention (F90, F98.8)	500 (1.4)	429 (1.4)	366 (1.4)	362 (1.4)	203 (1.5)
Intellectual disability (F70–79)	194 (0.5)	162 (0.5)	134 (0.5)	130 (0.5)	59 (0.4)
Perinatal covariates					
Male sex	18,606 (51.2)	15,933 (50.9)	13,420 (50.8)	13,127 (50.6)	7,235 (51.7)
First born child	14,646 (40.4)	12,793 (40.8)	10,797 (40.8)	10,601 (40.8)	5,753 (41.1)
Gestational age <37 weeks	2,278 (6.3)	1,9741 (6.2)	1,606 (6.1)	1,573 (6.1)	844 (6.0)
Birth weight <2,500 g	1,635 (4.5)	1,388 (4.4)	1,138 (4.3)	1,110 (4.3)	625 (4.5)
Birth weight ≥4,000 g	6,305 (17.4)	5,485 (17.5)	4,559 (17.2)	4,480 (17.3)	2,423 (17.3)
Congenital malformation	2,188 (6.0)	1,896 (6.1)	1,614 (6.1)	1,581 (6.1)	840 (6.0)
Pregnancy complications	3,050 (8.4)	2,645 (8.4)	2,279 (8.6)	2,237 (8.6)	1,098 (7.9)
Cesarean section	3,050 (21.0)	6,537 (20.9)	5,677 (21.5)	5,562 (21.4)	2,870 (20.5)
Apgar score <9	832 (2.3)	722 (2.3)	590 (2.2)	584 (2.3)	312 (2.2)
Mother's age <25 years	4,398 (12.1)	3,699 (11.8)	3,076 (11.6)	2,997 (11.5)	1,689 (12.1)
Father's age <25 years	2,293 (6.3)	1,905 (6.1)	1,571 (5.9)	1,538 (5.9)	886 (6.3)
Family covariates					
High parental level of education[b]	10,601 (29.2)	9,167 (29.3)	7,929 (30.0)	7,844 (30.2)	4,180 (29.9)
Child lives with both parents	32,191 (88.6	27,902 (89.1)	23,477 (88.8)	23,067 (88.9)	12,358 (88.4)
Two parents of Danish origin	27,417 (75.5)	23,886 (76.3)	20,166 (76.3)	19,822 (76.4)	10,468 (74.8)
Two parents in employment[c]	30,229 (83.2)	26,291 (83.9)	22,277 (84.3)	21,889 (84.3)	11,911 (85.2)
Concerns about the mother's mental health in the first 6 months after delivery	9,945 (27.4)	8,538 (27.3)	7,197 (27.2)	7,034 (27.1)	3,827 (27.4)
Concerns about parent–child relationships in the first 6 months after delivery	3,944 (10.9)	3,304 (10.6)	2,667 (10.1)	2,571 (9.9)	1,378 (9.9)

[a]ASD, autism-spectrum disorders; ADHD, attention-deficit/hyperactivity disorder.
[b]Parents' educational attainment at the child's birth, categorized into five hierarchical levels from higher education (5 or more completed years at university) to primary school only (9 years at school); each child was categorized by the parent in the household with the highest education.
[c]In employment and/or education, for mothers defined as before maternity leave; sickness benefit included in employment. Data on employment refer to the year before the year of birth.

between the ages of 11 months and their eighth birthday, a figure that also corresponds with findings from other studies with similar sources of data (33).

CHNs' concerns regarding sleeping problems at the age of 8–10 months were not predictive of hospital diagnosed mental disorders before the child's eighth birthday, when adjusted for potential confounders. For comparison, Winsper and Wolke (3) found an association between parent-reported sleeping problems in infancy and childhood dysregulated behavior measured by the parent's questionnaires. This is consistent with the findings in the meta-analyses by Hemmi et al. (1) and Galling et al. (6), in which most studies were based on parents' reports at baseline as well as at the outcome measurement. Persistent sleeping problems in infancy were also associated with behavior problems, attention,

TABLE 2 Crude and adjusted OR (95% CI) for diagnosed mental disorders from the age of 11 months to the eighth birthday by sleeping problems at age 8–10 months (n = 31,322).[a]

Outcome measure	Crude OR (95% CI)	Model 1[b]	Model 2[c]	Model 3[d]
At least one diagnosed mental disorder	1.19 (0.97–1.45)	1.18 (0.97–1.45)	1.08 (0.88–1.32)	1.11 (0.90–1.36)
At least one behavioral or emotional disorder	**1.39 (1.07–1.81)**	**1.39 (1.07–1.81)**	1.24 (0.95–1.62)	1.28 (0.98–1.67)
At least one diagnosed neurodevelopmental disorder	1.19 (0.93–1.51)	1.18 (0.93–1.51)	1.07 (0.84–1.37)	1.11 (0.87–1.41)
Autism-spectrum disorders (F84)	1.14 (0.81–1.62)	1.16 (0.82–1.65)	1.07 (0.75–1.52)	1.11 (0.78–1.58)
Disorders of hyperactivity and inattention (F90, F98.8)	1.07 (0.76–1.52)	1.06 (0.75–1.50)	0.95 (0.67–1.35)	0.98 (0.69–1.39)
Intellectual disability (F70–79)	1.14 (0.66–1.97)	1.10 (0.63–1.91)	0.93 (0.54–1.62)	0.95 (0.54–1.65)

Bold values indicate a statistically significant result.
[a]OR, odds ratio; CI, confidence interval.
[b]Adjusted for sex, parity, gestational age, birth weight, congenital malformation, pregnancy complications, cesarean section, Apgar score, mother's age, father's age, parents' education, parents' employment, family composition, parents' origin.
[c]Adjusted for concerns about the mother's mental health in the first 6 months after delivery, concerns about the parent–child relationship in the first 6 months after delivery.
[d]Adjusted for sex, parity, gestational age, birth weight, congenital malformation, pregnancy complications, cesarean section, Apgar score, mother's age, father's age, parents' education, parents' employment, family composition, parents' origin, concerns about the mother's mental health in the first 6 months after delivery, concerns about the parent–child relationship in the first 6 months after delivery.

TABLE 3 Crude and adjusted OR (95% CI) for diagnosed neurodevelopmental disorders before the eighth birthday by eating problems at the age of 8–10 months (n = 26,437).[a]

Outcome measure	Crude OR (95% CI)	Model 1[b]	Model 2[c]	Model 3[d]
At least one diagnosed mental disorder	**1.36 (1.18–1.57)**	**1.40 (1.21–1.63)**	**1.25 (1.08–1.45)**	**1.32 (1.14–1.54)**
At least one behavioral or emotional disorder	**1.32 (1.08–1.61)**	**1.38 (1.12–1.70)**	1.20 (0.97–1.47)	**1.27 (1.03–1.56)**
At least one diagnosed neurodevelopmental disorder	**1.41 (1.19–1.68)**	**1.45 (1.21–1.73)**	**1.28 (1.07–1.53)**	**1.36 (1.14–1.63)**
Autism-spectrum disorders (F84)	**1.28 (1.00–1.65)**	**1.38 (1.06–1.78)**	1.23 (0.95–1.59)	1.29 (0.99–1.67)
Disorders of hyperactivity and inattention (F90, F98.8)	1.17 (0.91–1.50)	1.21 (0.94–1.57)	1.03 (0.80–1.34)	1.11 (0.85–1.44)
Intellectual disability (F70–79)	**1.68 (1.15–2.45)**	1.41 (0.95–2.10)	1.40 (0.95–2.08)	1.25 (0.84–1.85)

Bold values indicate a statistically significant result.
[a]OR, odds ratio; CI, confidence interval.
[b]Adjusted for sex, parity, gestational age, birth weight, congenital malformation, pregnancy complications, cesarean section, Apgar score, mother's age, father's age, parents' education, parents' employment, family composition, parents' origin.
[c]Adjusted for concerns about the mother's mental health in the first 6 months after delivery, concerns about the parent-child-relationship in the first 6 months after delivery.
[d]Adjusted for sex, parity, gestational age, birth weight, congenital malformation, pregnancy complications, cesarean section, Apgar score, mother's age, father's age, parents' education, parents' employment, family composition, parents' origin, concerns about the mother's mental health in the first 6 months after delivery, concerns about the parent–child relationship in the first 6 months after delivery.

TABLE 4 Crude and adjusted OR (95% CI) for diagnosed neurodevelopmental disorders before the eighth birthday by combined sleeping and eating problems at the age of 8–10 months (n = 25,960).[a]

Outcome measure	Crude OR (95% CI)	Model 1[b]	Model 2[c]	Model 3[d]
At least one diagnosed mental disorder	**1.42 (1.06–1.89)**	**1.58 (1.18–2.12)**	1.28 (0.96–1.71)	**1.43 (1.07–1.92)**
At least one disorder of behavior and emotions	**1.52 (1.03–2.23)**	**1.65 (1.12–2.43)**	1.34 (0.91–1.98)	1.46 (0.98–2.16)
At least one diagnosed neurodevelopmental disorder	**1.55 (1.11–2.17)**	**1.76 (1.26–2.47)**	1.38 (0.99–1.93)	**1.60 (1.14–2.26)**
Autism-spectrum disorders (F84)	1.58 (0.99–2.53)	**1.89 (1.18–3.03)**	1.48 (0.93–2.37)	**1.73 (1.07–2.79)**
Disorders of hyperactivity and inattention (F90, F98.8)	1.15 (0.68–1.94)	1.31 (0.78–2.22)	1.02 (0.60–1.72)	1.14 (0.67–1.94)
Intellectual disability (F70–79)	1.75 (0.85–3.59)	1.65 (0.80–3.41)	1.33 (0.65–2.73)	1.37 (0.66–2.88)

Bold values indicate a statistically significant result.
[a]OR, odds ratio; CI, confidence interval.
[b]Adjusted for sex, parity, gestational age, birth weight, congenital malformation, pregnancy complications, cesarean section, Apgar score, mother's age, father's age, parents' education, parents' employment, family composition, parents' origin.
[c]Adjusted for concerns about the mother's mental health in the first 6 months after delivery, concerns about the parent–child relationship in the first 6 months after delivery.
[d]Adjusted for sex, parity, gestational age, birth weight, congenital malformation, pregnancy complications, cesarean section, Apgar score, mother's age, father's age, parents' education, parents' employment, family composition, parents' origin, concerns about the mother's mental health in the first 6 months after delivery, concerns about the parent-child-relationship in the first 6 months after delivery.

and hyperactivity problems in the studies by Schmid and Wolke (17) and the study by Baumann et al. (7). Both studies were methodologically different from our study since they included a population-based sample of neonatal high-risk children and used baseline parent interviews and neurological examinations.

We found CHNs' concern of eating problems at the age of 8–10 months associated with an increased risk of at least one behavioral or emotional disorder, and at least one diagnosed neurodevelopmental disorder. This finding is in line with other studies using observations recorded by community physicians and health nurses (5, 13) or

TABLE 5 Crude and adjusted OR (95% CI) for diagnosed neuro-developmental disorders before the eighth birthday by incessant crying at age 8–10 months (n = 13,987).[a]

Outcome measure	Crude OR (95% CI)	Model 1[b]	Model 2[c]	Model 3[d]
At least one diagnosed mental disorder	1.71 (0.74–3.93)	1.53 (0.66–3.59)	1.49 (0.64–3.43)	1.41 (0.60–3.32)
At least one behavioral or emotional disorder	2.21 (0.81–6.06)	1.93 (0.69–5.38)	1.85 (0.67–5.12)	1.71 (0.61–4.78)
At least one diagnosed neurodevelopmental disorder	1.69 (0.62–4.63)	1.50 (0.53–4.22)	1.49 (0.54–4.09)	1.41 (0.50–3.98)
Autism-spectrum disorders (F84)	2.40 (0.75–7.66)	2.21 (0.68–7.20)	2.20 (0.69–7.03)	2.13 (0.65–6.95)
Disorders of hyperactivity and inattention (F90, F98.8)	0.74 (0.10–5.31)	0.59 (0.08–4.37)	0.63 (0.09–4.52)	0.53 (0.07–4.01)
Intellectual disability (F70–79)	[e]	[e]	[e]	[e]

[a]OR, odds ratio; CI, confidence interval.
[b]Adjusted for sex, parity, gestational age, birth weight, congenital malformation, pregnancy complications, cesarean section, Apgar score, mother's age, father's age, parents' education, parents' employment, family composition, parents' origin.
[c]Adjusted for concerns about the mother's mental health in the first 6 months after delivery, concerns about the parent–child relationship in the first 6 months after delivery.
[d]Adjusted for sex, parity, gestational age, birth weight, congenital malformation, pregnancy complications, cesarean section, Apgar score, mother's age, father's age, parents' education, parents' employment, family composition, parents' origin, concerns about the mother's mental health in the first 6 months after delivery, concerns about the parent–child relationship in the first 6 months after delivery.
[e]Not calculated, too few observations.

parent interviews (17) as baseline information in infancy and measuring the outcome at the ages of 1.5, 8, or 10–12 years. The effect size was smaller in the current study, which conducted a comprehensive adjustment for confounders.

The combination of sleeping and eating problems was predictive of at least one diagnosed mental disorder and at least one diagnosed neurodevelopmental disorder, and in particular ASD, but not ADHD. In a high-risk sample, Schmid and Wolke (17) found persistent RPs predictive of a diagnosis of ADHD at school age, even when controlled for psychosocial and neurological confounders, such as gestational age, sex, maternal age at birth, socioeconomic status (SES), parent–infant relationship index, family adversity index, psychosocial stress index, and breastfeeding. Finally, we did not find any association between incessant crying at 8–10 months of age and diagnosed mental disorders in childhood. The significance of excessive or incessant crying in infancy has been explored in several high-risk as well as community-based samples, overall suggesting an increased risk of neurodevelopmental disorders (1, 3, 7, 8, 15–17, 36). The study by Lemcke (36) had many similarities with our study: it included a large, unselected Danish study population and used hospital-based diagnoses as the outcome measure. Still, in the study by Lemcke, RPs were measured by interviews with mothers when the child was aged 6 and 18 months and children were followed until the age of 11 years, which includes a period of increasing incidence of referrals to hospital around the first year of schooling. The findings from this study point to incessant crying at 6 months and sleeping problems at 18 months being associated with later neurodevelopmental disorders, although with modest effect sizes. For comparison with our study, the lack of significance of associations might reflect an observation period, not including the peak of referrals and diagnoses of ASD and ADHD, the extensive confounder control, and finally, limited power due to a relatively small number of cases (n = 93).

Compared to most studies exploring the association between infancy RPs and mental health outcome later in childhood as reviewed by Hemmi et al. (1) and Galling et al. (6), the associations found in the current study were weaker overall, which may be explained by the following. First, in contrast to most prior studies but one, we used mental disorders diagnosed in the hospital settings as the outcome, thus including bias of referral regarding the most common mental health problems, namely emotional and behavioral problems, which seldomly extend the threshold of referral to hospital settings in younger ages. These kinds of problems are rather treated in a community setting or settings of private practicing psychologists (33). Second, most other studies used parent-reported questionnaires that cover the more common emotional and behavioral problems. Third, in contrast to other studies of the longitudinal associations of RPs using parents as informants at both baseline and follow-up, we used CHNs as informants at baseline, and clinical disorders diagnosed in clinical settings as the outcome. This approach reduces the risk of informant bias; however, on the other hand it might introduce bias due to referrals being associated with the expressed concern of the CHNs. Finally, in comparison with prior studies, our study highlights the possibilities of extensive confounder control using the CHNs' records and comprehensive information from Danish national registries covering all citizens in the population (35). When including data from the first 6 months of the child's life to adjust for influences regarding the mother's mental health and the parent–child relationship, we found a clear attenuation of the longitudinal associations, in line with findings from other studies (2, 25, 27). Overall, we consider the character of baseline as well as outcome information, and the extensive confounder control applied in the present study to the weakening of the statistical associations between RPs and mental disorders.

Our study explored measures of concern of RPs recorded by CHNs working within municipality healthcare, and this particular methodological approach has to be considered when discussing the associations found. We used the CHN's overall concern about the child's sleeping, feeding and eating, and excessive crying as the index of RPs, acknowledging that this index needs further validation. Further, making use of existing service settings as the frame of baseline assessments, leave us with unmeasured confounding due to potential intervention done within the study period from measuring exposure and outcome, including initiating referrals to hospital settings. Importantly, the content of Danish community healthcare includes the possibilities of individualized support to parents of vulnerable infants and, furthermore,

possibilities of referral to specialized treatment within the municipality or the health services. Unfortunately, our data do not allow for the exploration of character or the magnitude of intervention offered in municipality settings in the time span explored. Still, the potentials of identification infancy markers of psychopathology based on the CHN (20, 22, 23) has been further explored within municipality settings in Denmark, resulting in the development of standardized measures to identify and intervene toward early developmental psychopathology (5, 24, 28, 37).

4.2 Strengths and limitations

The strengths of the study include the longitudinal design, the large and unselected study population, the use of health professionals' systematic assessment of RPs in infancy, including clinical diagnoses of mental disorders from national population registries, and the comprehensive adjustment for confounders using data from registers and databases with a complete coverage of the population. The major limitation of our study is the validity of the CHNs' data regarding RPs, which has not been examined. Still, the data collection by CHNs follows specific guidelines to strengthen the reliability of the recordings.

4.3 Implications

In this study, the CHNs' observations followed specific guidelines and are described as concerns, which indicate that something is different or troubling (30). Future studies may benefit from using available standardized assessment methods developed and validated for CHNs' early identification of regulatory problems in a community health setting (5, 28). Moreover, it is important to further explore mediating and moderating factors influencing the longitudinal associations between RPs and mental disorders. Further, previous studies have found that children with multiple RPs are especially at risk for mental disorders (1, 3, 4, 18), and further investigation of studies characterized by CHNs' concerns regarding multiple RPs is needed. Our study focused on referred children diagnosed in a hospital setting, leaving emotional and behavioral disorders sparsely explored as these conditions rarely lead to referral to hospital settings in younger ages. It means that we are potentially excluding many children with undiagnosed mental health problems. Wishing to include emotional and behavioral mental disorders in children calls for more global psychometric measures feasible for use in population-based research, e.g., measures such as the Strengths and Difficulties Questionnaire.

From a clinical and public health point of view, the findings from the present study highlight the relevance of identifying RPs among infants to potentially break developmental trajectories leading to mental disorders. Importantly, identifying early problems should be followed by an intervention addressing the parenting of vulnerable infants, overall helping parents to meet the needs of infants with regulatory problems, to be applied in clinical as well as in municipality settings. Danish community healthcare includes the services from CHNs, who are trained to identify children who are not developing in an age-appropriate way and to communicate with parents about the developmental needs of the child (24). Still, research is needed to further explore CHNs' potentials regarding the prevention of mental health problems in early childhood (37), and specifically, how the existing CHN surveillance program can deliver the frame for intervention to infants with regulatory problems.

Data availability statement

The data analyzed in this study is subject to the following licenses/restrictions: To get access to data underlying this article, approval from both the Danish Regional Council and the individual municipalities is necessary. Requests to access these datasets should be directed to TP, tppe@sdu.dk.

Ethics statement

This study was reviewed and approved by the Research & Innovation Organization at the University of Southern Denmark (registration number 11,667) and the Danish Regional Council (registration number R-22030405), and it complied with national regulations of data protection and consent.

Author contributions

SP: Formal Analysis, Writing – original draft, Conceptualization, Data curation, Investigation, Methodology. BH: Writing – original draft, Conceptualization, Investigation, Methodology. TP: Writing – review and editing, Conceptualization, Data curation, Investigation, Methodology, Project administration. JA: Writing – review and editing, Conceptualization, Investigation, Methodology. AS: Writing – review and editing, Conceptualization, Investigation, Methodology.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Regulatory problems and developmental psychopathology within the first 2 years of living—a nested in cohort population-based study

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Background: Infancy regulatory problems (RP) of sleep, feeding and eating, and excessive crying are thought to play a key role in the development of psychopathology in childhood, but knowledge of the early trajectories is limited.
Objective: To explore RP at ages 8–11 months and the associations with mental health problems at 1½ years, and assess the influences of maternal mental health problems and relationship problems.
Methods: RP was explored in a nested in-cohort sample (N = 416) drawn from a community-based cohort (N = 2,973). Cohort children were examined by community health nurses, using a mental health screening, which included seven items of RP. Follow-up at 1½ years included diagnostic assessment according to the International Classification of Diseases, ICD-10, and the Diagnostic Classification of Mental Health and Developmental Disorders in Infancy and Early Childhood: Revised edition, DC:0-3R. Data analyses included logistic regression models and analyses of the mediation effect of maternal mental health and relationship problems.
Results: RP of sleep were associated with a 2-fold increased risk of child mental disorder specifically sleep disorders, adjusted odds ratio (OR) 9.3 [95% confidence interval (CI): 2.0–42.9], disorders of behavior and emotions, adjusted OR 2.9 (95% CI: 1.0–8.4), and DC:0-3R regulatory disorders, adjusted OR 2.7 (95% CI: 1.0–7.5). Children with RP of feeding and eating showed an increased risk of overall mental disorder, adjusted OR 1.4 (95% CI: 0.7–2.4), and specifically, feeding and eating disorders, adjusted OR 6.0 (95% CI: 1.6–21.7), disorders of behavior and emotions, adjusted OR 2.2 (95% CI: 0.9–5.8), as well as DC:0-3R regulatory disorders, adjusted OR 1.6 (1.0–7.5). RP of emotional regulation were associated with increased risk of any mental disorder, adjusted OR 1.5 (1.0–2.4), and specifically behavioral and emotional disorders, adjusted OR 2.2 (95% CI: 0.9–5.9) and DC:0-3R relationship disorders, adjusted OR 1.8 (95% CI: 0.9–3.8). The mediation effect of maternal mental health problems and relationship problems ranged between 0% and 48%.
Conclusion: RP at ages 8–11 months is associated with increased risk of ICD-10 and DC:0-3R disorders at 1½ years. Study findings highlight a group of vulnerable infants in need of preventive intervention to break the early trajectories of psychopathology.

KEYWORDS

regulatory problems (RP), infancy, developmental psychopathology, mental disorders, community-cohort

Introduction

Mental health development in infancy and early childhood includes the dynamics of the infants' inborn capacities and the progressive integration of physiological and emotional influences, as well as the attentional and cognitive stimulation. Overall, the infants' development occurs within a frame of the increasingly differentiated reactions to internal and external sensory inputs, coregulated and nurtured by the parents (1, 2). Along with the maturation of child's self-regulation, the child becomes increasingly able to express a variety of needs and emotions that parents can respond to, and depending on the congenital resources of the infant and the resources of caregivers, this process can be facilitated or impaired (3). The regulation of sleep, appetite, feeding and eating, and sensitivity in reactions to internal as well as external stimuli are central features in the infants' development, and studies of premature infants and infants with developmental vulnerabilities have shed light on the longitudinal impact of problems in the regulation of sleep, appetite, feeding and eating, and sensitivity in reactions to annoying internal and external stimuli (2, 4). Also, infants born at term and without developmental vulnerabilities may suffer from excessive crying, sleep problems or problems in feeding and eating. Nevertheless, these problems are mostly temporary, usually fading during the first 6 months of living, along with increasing maturity of the infants' regulatory capacities and the parents increasingly effective coregulation (2, 3). A minor part of the infant population may, however, suffer from persisting problems beyond 6 months, broadly conceptualized as temperamental difficulties or regulatory problems (RP). These problems challenge the parenting, and longitudinally they are considered to influence the mental health of the child (5). Within the field of early developmental psychopathology, problems on the regulation of neurophysiological and emotional/behavioral reactions have gained increasing interest in clinical settings (6), reflected by the conceptualization of regulatory disorders as a clinical entity (7) and the development of the Diagnostic Classification Zero-to-Three (8). The concept of RP—including excessive crying, sleep problems, and problems of feeding and eating (9–11) — have been investigated in clinical samples as well as community studies (9, 10), regarding both solitary problems of sleeping, crying, or feeding and eating, as well as co-occurring combined or complex RP. Longitudinal studies of RP cover a wide range of outcomes, including cognitive development (12, 13); attachment (14); attention (15); disorders of neurodevelopment, including pervasive developmental disorders and autism disorders (16–20) as well as attention deficit and hyperactivity disorder (ADHD) (11, 18, 19, 21–23). In particular, childhood behavioral problems and dysregulation (10, 11), and internalizing and externalizing problems (24) have been found to be associated with infancy RP. Notably, a dose–response pattern has been suggested in which increasing numbers of RP may track into developmental paths of dysregulation having onset in early childhood (11); and, possibly, showing persistence across development, leaving the child with an increased risk of symptoms of depression, and psychotic and borderline personality disorder in adolescence (25).

The risk factors of RP have repeatedly been shown to include a range of pre-, peri-, and postnatal factors associated with child neurodevelopmental vulnerability, including preterm birth, as well as factors associated with compromised psychosocial resources in the family (9, 10, 26). The importance of maternal mental health problems in early child development is increasingly documented (27–29), and the early parent–child relations and the quality of parenting is suggested to play a key role in the risk mechanisms leading to child psychopathology (18, 20). Specifically regarding RP, the developmental vulnerability of the child is suggested to be influenced by parents' mental health via parents' emotional availability, and—beyond nurturing and care—their ability to interpret and respond to the signals and reactions of the child (11, 15, 30–32). However, the available literature yields no firm conclusions regarding the influence of maternal mental health problems and parent–child relationship problems on the early risk mechanisms of RP and emotional and behavioral dysregulation and developmental psychopathology (9, 32, 33).

A meta-analysis including 22 clinical and community studies of infancy RP (10) found externalizing problems and problems of attention deficit and hyperactivity, ADHD, to be the strongest outcome of any regulatory problem, with a particularly high risk in families of multiple risks. This meta-analysis was recently updated to include a total of 30 clinical as well as community-based studies published in 1987–2020 (9). A total of 34,582 participants were included, assessed at baseline at 6.5 ± 4.5 months, and at follow-up at ages 5.5 ± 2.8 years. Most of the studies reviewed concerned excessive crying (13) and sleep (9), whereas feeding and eating problems were investigated in only three studies. The cumulative incidence for behavioral problems during childhood was 23.3% in children with RP, with a higher risk found among infants with multiple RP (9). The study limitations highlighted include the heterogeneity of the data and study samples, unvalidated definitions of RP, measurement problems, and reporting bias as most studies build on parents' reports both at baseline and outcome. Moreover, the authors of the recent review underscore the need to include measures of parental health and the parent–child relation as potential mediators (9).

Longitudinal studies of combined regulatory problems in early childhood investigated in community-based studies have recently been specifically reviewed (32). This review highlights the gap in epidemiological studies of the early course of RP as advance markers of developmental psychopathology tracking into the range of mental health problems in early childhood (32).

In sum, the available research evidence converges on the longitudinal risk associated with RP in infancy, underscoring the need for research that specifically adds to the knowledge on early developmental trajectories of dysregulation as a prerogative to preventive intervention to address mental health in early childhood (9–11).

The possibilities of identification of infants in need of preventive intervention regarding mental health have previously been explored in the Copenhagen Child Cohort using the

municipality child health surveillance and settings and routines of community health nurses (CHNs) as the frame (34). Based on the finding of a window of opportunity at child ages 8–11 months, a standardized measure, PUF [Mental Health Development (in Danish: Psykisk Udvikling og Funktion)], has been developed and validated to capture the range of potential mental health vulnerabilities in early ages. The PUF includes 28 items covering child development and behavioral and emotional regulation, of which three items concern sleep; four items feeding and eating; and four items emotional regulation, including excessive crying (16, 35, 36). The overall predictive validity of the PUF as a screening measure has previously been explored using an item–response analytic approach suggests that a cutoff at three or more problems across the 28 PUF items are predictive of psychopathology measured as ICD-10 diagnoses. In addition, previous investigation of the very early pathways of RP of sleeping, feeding and eating, and excessive crying measured as the CHNs global concern recorded at home visits between birth and 6 months, and RP measured using the PUF at 8–11 months (31), suggest that RP beyond the first 2 months of living may develop seemingly independent of early exposures to maternal mental health problems and parent–child relationship problems (31).

Nevertheless, research data on the developmental pathways of RP and associated psychopathology in the first years of living is scarce, leaving a gap in knowledge on targets of intervention to effectively address RP in a period of life in which intervention has the strongest preventive potential regarding the child's future mental health.

Objectives

This study aims to extend the investigation of the longitudinal associations of RP measured in community settings at child ages 8–11 months and clinically diagnosed mental health problems and psychopathology at age 1½ years, with a specific focus on the mediating role of maternal mental health problems and mother–infant relationship problems in early infancy (0–6 months). We hypothesize that the different kinds of RP will be differentially associated with child psychopathology within the same area of mental health, but also that RP may act as a transdiagnostic marker of dysregulation and overall mental health vulnerability. Also, we hypothesize that the mediating effect of maternal mental health problems and mother–infant relationship problems on the risk associations may differ across areas of child psychopathology.

Materials and methods

Setting, study population, and design

The study was conducted within the healthcare settings of 11 Danish municipalities, in which CHNs offer home visits to all infant families. In these municipalities, the CHNs use a standardized record, at child ages 0–2, 2–6, and 8–11 months, to systematically register the information obtained regarding child health and development, parent–child relations, and the family background. The CHN's recordings include information from the parents as well as the results of the CHNs' child assessments and observations of parent–child relations at the home visit [for detailed information of the setting and records see Ref. (31)]. In the study municipalities, the CHNs use the PUF measure at the home visit at ages 8–11 months to make the overall evaluation of child mental health (35) (see Supplementary Appendix I).

The study population was consecutively enrolled from March 2011 to April 2013, and of 3,263 children enrolled, a total of 2,973 (91%) having full data on the PUF assessment at ages 8–11 months were included. A nested in-cohort sample of children with three or more problems according to the overall PUF assessments ($N = 237$), and children from a random sample of every seventh from the remaining cohort of low problems scores ($N = 179$) were diagnostically assessed at age 1½ years [see Ref. (16) for further description of the sampling]. The background characteristics of the study sample compared to the remaining cohort have been described in a previous paper (16), and are shown in Supplementary Appendix II.

Measures

RP at 8–11 months were identified by CHNs using the PUF measure (16, 36), and we defined RP as at least one problem recorded in one of the domains of sleeping (three items), feeding and eating (four items), or emotional regulation including excessive crying (four items) (see Supplementary Appendix I). Combined RPs were defined as two or more simultaneously recorded RP in at least two domains of either sleeping, feeding and eating, and emotional regulation; all dichotomized into yes/no variables.

At 1½ years, the children were examined during a 2 hour session with the parent being present throughout, using a previously validated procedure (37, 38). The assessments were done by a child research nurse and an infant-toddler psychologist. Assessments included interviewing the parents, developmental testing, as well as clinical observations and video recordings of the child's behavior during play and during a meal, both in interaction with the parents and in interaction with the examiners. The parents' interview included the Mannheim Eltern Interview; the Child Behavior Checklist (CBCL) 1½-5, parent version; the Checklist for Autism and Toddlers (CHAT) and the Infant Toddler Symptom Checklist (ITSCL) (for further description of the assessment measures see Ref. (38). An infant-toddler psychologist examined the child's development using the Bayley Scales of Infant and Toddler Development (BSID II). Parent–child relations were examined using the Parent–Infant Early Relation Assessment, providing standardized information on the communication, interaction, and emotional relations between parent and child. In line with the procedure described in Skovgaard et al. (38), two child psychiatrists experienced in infant and toddler mental health (AO, AS) reviewed the information obtained at the child assessment to complete the

diagnostic assessment in accordance with the defining criteria of the International Statistical Classification of Diseases, 10th Revision (ICD-10) (39) and the Diagnostic Classification of Mental Health and Developmental Disorders of Infancy and Early Childhood: Revised edition (DC:0–3R) (8). The diagnostic assessment included independent rating of all cases and discussion to obtain consensus in case of divergence among the two raters (38). The assessments were blinded to the group members of the high vs. the low score group. The reliability of diagnostic assessment at ages 1½ years using measures as in the present study has previously been established (37).

Danish population registries and the Community Health Nurses Record provided comprehensive information on a range of child and family variables, including child sex, gestational age, whether parents were cohabiting at the time of the child's birth, the parents' country of birth, and parents' years of schooling (35).

Assessments of maternal mental health problems and mother–child relationship in the first six postnatal months were done by CHNs at home visits at child ages 2–4 weeks, 2–3 months, and 4–6 months. During the home visits of mean 60 min, the CHN follows a standardized manual to evaluate whether the mother has mental health problems or not, based on the mother's information during the home visit, and the CHN's evaluation on the presence of depressive symptoms, anxiety, or other psychological problems (31). The CHN evaluates the parent–child relationship from the parents' description of their relation to the child and from her observation of the mother's handling of the child, the emotional expressions, quality of contact, and the overall interaction between the mother and child. The CHN made her final recordings based on the presence of a problem or not, in accordance with the manual (31).

Data analyses

Descriptive statistics included the frequencies of RP and the background characteristics of child and parents at baseline, and of ICD-10 and DC:0-3R disorders diagnosed at age 1½ years.

The items of RP were included in the analyses as dichotomized variables (Table 1). We analyzed outcome in the following main groups of ICD-10 diagnoses: neurodevelopmental disorders (F84, F88, F89, F90, F80.9, F80.2, F70.9, and R41.8); emotional and behavioral disorders (F91, F92, F93, F94.1, F94.2, and F94.8); feeding and eating disorders (F98.2); sleep disorders (F51); and the DC:0-3 R diagnoses regulatory disorders and relationship disorders. Associations between RP at age 8–11 months and the main groups of ICD-10 and DC:0–3R disorders were examined by logistic regression models and results were reported as odds ratio (OR) with 95% confidence interval (CI).

The regression models included four steps: first, we included sex, gestational age, cohabitating parent, parents' country of birth, and parent schooling. Second, we separately added maternal mental health. Third, we added mother–child relationship variables. Finally, we included all variables from steps 1–3 simultaneously. These analyses were based on complete-case data (omitted participants with any missing data for one or more of the variables adjusted for). Mediation analysis for binary outcomes was carried out following the general methodology by MacKinnon et al. (40). Specifically, proportions mediated for early maternal mental health problems and relationship problems were estimated by means of the ratio between the direct mediated effect and the total effect using estimates on the log odds scale (41). Accompanying approximate 95% confidence intervals were also estimated using the corresponding standard errors on the log odds scale. Due to the small sample size statistical tests were not applied as power was low as is the case for many mediation analyses (42). However, a tentative cutoff for claiming substantial mediation around 30%–40% may be used (41). Statistical analyses were performed with the statistical program SAS, version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

The background characteristics of study participants ($N = 416$) are shown at Table 2, and for comparison with the entire cohort in Supplementary Appendix II.

The description and frequency of RP in the study sample are shown in Table 1. Overall, the most common problem at ages 8–11 months was RP of feeding and eating affecting 39.4% of the study participants, whereas RP of emotional regulation including excessive crying affected 28.6%, and RP of sleeping 21.6%. A total of 114 children (27%) had two or more RP.

Overall, a total of 115 children were diagnosed with an ICD-10 disorder, of which neurodevelopmental disorders and disorders of behavior and emotions, and adjustment disorders were the most common (see Supplementary Appendix III). Among DC:0-3R diagnoses, regulatory disorders were diagnosed in 38 children (9.1%); whereas the DC:0-3R diagnoses of relationship disorders were the most common of all diagnoses, found in 66 of the children (15.9%) (see Supplementary Appendix III).

The univariate associations of maternal mental health problems and mother–child relationship problems recorded between birth and child age 6 months, and RP at ages 8–11 months, and main groups of ICD-10 and DC:0-3R disorders at 1½ years are shown in Supplementary Appendix IVA and B. Univariate analyses showed no significant associations between early maternal and relationship problems and RP at 8–11 months, whereas maternal mental health problems were associated with increased risk of any ICD-10 disorder OR 1.7 (95% CI: 1.1–2.8) and DC:0-3R regulatory disorders OR 2.0 (95% CI: 1.0–4.1). Mother–child relationship problems were associated with increased risk of any ICD-10 disorder OR 2.1 (95% CI: 1.1–4.1), and in particular DC:0-3R relationship disorders OR 2.5 (95% CI: 1.2–5.2). Logistic regression models of the associations between RP and main groups of ICD-10 diagnoses at 1½ years are shown in Table 3. RP of sleep was associated with a more than 2-fold increased risk of any mental disorder, adjusted OR 2.6 (OR 95% CI: 1.3–5.2), and behavioral and emotional disorders, adjusted OR 2.9 (95% CI: 1.0–8.4). Associations were overall independent

TABLE 1 Variables of regulatory problems (RP) assessed by community health nurses (CHNs) at child ages 8–11 months ($N = 416$). Stratified on children of high and low risk of mental health vulnerability.[a]

Regulatory problem	Description	Frequency, *n* (%)	
		High scores ($n = 237$)	Low scores ($n = 179$)
Sleeping			
Stable sleeping pattern Falling asleep time Interrupted sleep	The child has established a steady pattern for sleeping and being awake The child falls asleep within 1 hour The child is able to sleep at least three consecutive hours		
Any problem of sleep regulation		82 (34.5)	8 (4.5)
Regulation of eating and feeding			
Appetite regulation Eats too little Refusal to eat Vomiting without otherwise being ill	The child indicates clearly when it is hungry or full The child has to be pressured to eat enough The child refuses food even though it has not eaten for a long period of time The child vomits more than once a week		
Any problem of eating and feeding regulation		152 (63.9)	12 (6.7)
Emotional regulation, incl. excessive crying			
Generally happy and satisfied Often irritable, fussy, dissatisfied Cries often Emotionally blunted	The child is happy and satisfied more than 80% of its waking time The child has at least two episodes every day where it is irritable, fussy, dissatisfied The child cries more than 1 hour every day The child shows no happiness, has limited facial expression and seems sad more than 50% of its waking time		
Any problem of emotional regulation, incl. excessive crying		108 (45.5)	11 (6.2)
Combined problems			
Problems in ≥2 of the above areas	Any combination of problems from at least two of the above areas of sleeping, eating and feeding and emotional regulatory problems	112 (47.1)	- (-)[b]

[a]Ammitzbøll et al. (16).
[b]Less than five numbers in a cell are not reported to secure anonymity.

TABLE 2 Background characteristics of the study participants ($N = 416$).

Sample characteristics	Frequency, *n* (%)	Missing, *n* (%)
Child factors		
Gender		
Male Female	213 (51.2) 203 (48.8)	0 (0)
Gestational age		
Preterm (<37 weeks) Term (≥37 weeks)	32 (7.9) 371 (92.1)	13 (3.1)
Family factors		
Parent born outside a Nordic country		
Yes No	108 (26.0) 308 (74.0)	0 (0)
Mother's years of schooling		
Low (≤10 years) High	28 (10.5) 239 (89.5)	149 (35.8)
Parents living together at child's birth		
No Yes	24 (6.0) 374 (94.0)	18 (4.3)
Mother mental health problems		
Yes No	117 (31.1) 259 (68.9)	40 (9.6)
Mother–child relationship problems		
Yes No	40 (10,6) 338 (89.4)	38 (9.1)

For a more detailed overview of the characteristics of the participants at 1½ years ($N = 416$) and the remaining cohort see Supplementary Appendix II.

of adjustment for child perinatal and family adversities and maternal mental health problems and relationship problems in the first 6 months of the child's life. The mediation proportion of both maternal mental health problems and relationship problems were 11% (CI: 0–51) or less.

RP of feeding and eating was associated with an increased risk of any ICD-10 disorder, however, attenuated in adjusted analyses, adjusted OR 1.4 (95% CI: 0.7–2.4). Maternal mental health problems in the first 6 months of the child's life accounted for a mediation proportion of 22% (CI: 0–70) on outcome, whereas relationship problems showed no influences. No significantly increased risk was found between RP of feeding and eating and behavioral and emotional disorders or neurodevelopmental disorders.

The associations of RP of emotional regulation including excessive crying and any ICD-10 disorder faded in analyses adjusting for a range of child, family, and relational adversities, adjusted OR 1.1 (95% CI: 0.6–2.1). The mediation proportion on outcome was highly influenced by relationship problems 48% (CI: 0–88), but not by maternal mental health (mediation proportion 0%). Regarding the associations between RP of emotional regulation and behavioral and emotional disorders, adjusted OR 2.2 (95% CI: 0.9–5.8), the mediating proportion of maternal mental health problems and relationship problems were 5% (CI: 0–50) or less. Combined RP was associated with increased risk of any ICD-10 mental disorder, adjusted OR 1.9 (95% CI: 1.0–3.5), and the mediating proportion of maternal mental health problems and relationship problems were 7% (CI: 0–48) and 13% (CI: 0–52), respectively. Likewise, an increased risk of behavioral and emotional disorders was found in children with combined RP, adjusted OR 2.4 (95% CI: 0.9–6.4), and the mediating proportion due to maternal mental health

TABLE 3 Associations (OR) for main groups of ICD-10 of mental disorders at 1½ years by regulatory problems at 8–11 months and mediation proportion (MP %) of early (0–6 months) maternal mental health problems and relationship problems ($N = 416$).

	Any ICD-10 disorder[a]	Any ICD-10 disorder[b]	Any developmental disorder[a]	Any developmental disorder[b]	Any behavioral or emotional disorder[a]	Any behavioral or emotional disorder[b]
Regulatory problem	OR (CI)	OR (CI) MP[c]% (CI)	OR (CI)	OR (CI) MP[c]% (CI)	OR (CI)	OR (CI) MP[c]% (CI)
Sleeping problem ($n = 90$)	**2.9 (1.8–4.7)**	**2.6 (1.3–5.2)**	1.7 (0.8–3.6)	1.0 (0.3–3.3)	**2.2 (1.1–4.7)**	**2.9 (1.1–8.2)**
		10% (0–45)		–		11% (0–51)
Eating and feeding problem ($n = 164$)	**1.5 (1.0–2.4)**	1.3 (0.7–2.4) 22% (0–70)	1.0 (0.5–2.1)	0.5 (0.2–1.4) –	0.9 (0.4–1.8)	1.1 (0.4–3.1) –
Problems of emotional regulation incl. excessive crying ($n = 119$)	**1.5 (1.0–2.4)**	1.1 (0.6–2.1) 48% (0–88)	1.1 (0.5–2.4)	0.5 (0.2–1.7) –	2.0 (0.9–4.0)	2.2 (0.9–5.9) 5% (0–56)
Combined RP ($n = 114$)	**2.3 (1.4–3.6)**	**1.9 (1.0–3.5)**	1.2 (0.5–2.5)	0.4 (0.1–1.4)	1.6 (0.8–3.3)	2.4 (0.9–6.4)
		7% (0–48)/ 13% (0–52)		–		4% (0–52)/ 8% (0–54)

Bold: p-value <0.05.
[a]Unadjusted ($N = 416$).
[b]Adjusted for gender, gestational age, parent born outside a Nordic country, mother less than 10 years of school, parents not living together at childbirth, and maternal mental health problems and mother–child relationship problems measured at child ages 0–6 months ($N = 247$).
[c]MP: the mediation proportion % (CI) of early (0–6 months) maternal mental health and relationship problems by mean of the ratio between the mediated effect and the total effect.

problems and relationship problems was 4% (CI: 0–52) and 8% (CI: 0–54), respectively.

Overall, no increased risk of neurodevelopmental disorders was found in children having infancy RP, whether being RP of sleeping, feeding, and eating, emotional regulation or combined RP.

As shown in Table 4, a pattern of association of problems within the same domain of mental health was seen in children with RP of sleeping, showing a more than 9-fold increased risk of an ICD-10 sleep disorder at 1½ years, adjusted OR 9.3 (95% CI: 2.1–42.9), mediated by less than 10% (CI: 0–42) by maternal mental health problems and relationship problems in infancy. Likewise, children with RP of feeding and eating showed a highly increased risk of feeding and eating disorder, adjusted OR 4.6 (95% CI: 0.9–22.7). Also, children with RP of emotional regulation showed an increased risk of behavioral and emotional disorders, adjusted OR 2.2 (95% CI: 0.9–5.8), overall indicating continuity of specific problems of dysregulation within the first years of living. Associations of problems from different areas of psychopathology were seen among children having RP of sleeping in infancy, being at an increased risk of feeding and eating disorders too, adjusted OR 3.7 (95% CI: 0.8–16.2), whereas no such patterns were seen regarding RP of feeding and eating, and RP of emotional regulation. The mediating proportion on outcome was 8% (CI: 0–48) or less.

The outcome of DC:0-3R diagnoses of regulatory disorders (Table 5) was characterized by increased risk seen across the range of RP in infancy, but most pronounced in RP of sleeping, adjusted OR 2.7 (95% CI: 1.0–7.5). Overall, associations to DC:0-3R regulatory disorders faded in analyses adjusting for the range of child, family, and relational adversities (Table 5). Regarding sleeping RP, the mediating proportion of maternal mental health problems and relationship problems were 11% (CI: 0–52) and 18% (CI: 0–63), respectively, whereas no mediating effect was

TABLE 4 Associations (OR) for disorders of sleeping and eating and feeding at 1½ years by regulatory problems at 8–11 months and mediation proportion (MP %) of early (0–6 months) maternal mental health problems and relationship problems ($N = 416$).

	Eating and feeding disorder[a]	Eating and feeding disorder[b]	Sleep disorder[a]	Sleep disorder[b]
Regulatory problem	OR (CI)	OR (CI) MP[c]% (CI)	OR (CI)	OR (CI) MP[c]% (CI)
Sleeping problem ($n = 90$)	**2.8 (1.0–8.4)**	3.7 (0.8–16.2)	**7.1 (2.3–21.9)**	**9.3 (2.0–42.9)**
		–		8% (0–42)
Eating and feeding problem ($n = 164$)	**6.0 (1.6–21.7)**	4.6 (0.9–23.7) –	2.1 (0.7–6.2)	2.4 (0.6–9.9) –
Problems of emotional regulation incl. excessive crying ($n = 119$)	0.4 (0.1–1.8)	0.8 (0.2–4.3) –	1.4 (0.5–4.3)	0.5 (0.1–3.0) –
Combined RP ($n = 114$)	**2.8 (1.0–8.1)**	3.5 (0.8–14.5)	**5.1 (1.7–15.5)**	**5.6 (1.2–25.6)**
		–		7% (0–48)

Bold: p-value <0.05.
[a]Unadjusted ($N = 416$).
[b]Adjusted for gender, gestational age, parent born outside a Nordic country, mother less than 10 years of school, parents not living together at childbirth, and maternal mental health problems and mother–child relationship problems measured at child ages 0–6 months ($N = 247$).
[c]MP: the mediation proportion % (CI) of early (0–6 months) maternal mental health and relationship problems by mean of the ratio between the mediated effect and the total effect.

TABLE 5 Associations (OR) for DC:0-3R diagnosis of regulatory and relationship disorders at 1½ years by regulatory problems at 8–11 months and mediation proportion (MP %) of early (0–6 months) maternal mental health problems and relationship problems ($N = 416$).

	Regulatory disorder[a]	Regulatory disorder[b]	Relationship disorder[a]	Relationship disorder[b]
Regulatory problem	OR (CI: 95%)	OR (CI) MP[c]% (CI)	OR (CI)	OR (CI) MP[c]% (CI)
Sleeping problem ($n = 90$)	**2.0 (1.0–4.2)**	**2.7 (1.0–7.5)**	1.5 (0.8–2.6)	1.4 (0.6–3.2)
		11% (0–52)/ 18% (0–56)		17% (0–72)
Eating and feeding problem ($n = 164$)	1.6 (0.8–3.1)	1.6 (0.6–4.2) –	1.2 (0.7–2.0)	1.4 (0.7–2.9) –
Problems of emotional regulation incl. excessive crying ($n = 119$)	1.7 (0.9–3.4)	1.2 (0.4–3.3) –	**1.8 (1.0–3.1)**	1.8 (0.9–3.8) –
Combined RP ($n = 114$)	1.4 (0.7–2.9)	1.5 (0.5–4.1)	1.4 (0.8–2.5)	1.7 (0.8–3.5)
		–		11% (0–63)

Bold: p-value <0.05.
[a]Unadjusted ($N = 416$).
[b]Adjusted for gender, gestational age, parent born outside a Nordic country, parents less than 10 years of school, patent living together at childbirth, and maternal mental health problems and mother–child relationship problems measured at 0–6 months ($N = 247$).
[c]MP: the mediation proportion % (CI) of early (0–6 months) maternal mental health and relationship problems by mean of the ratio between the mediated effect and the total effect.

seen in children having RP of feeding and eating and emotional regulation including excessive crying.

Associations of infancy RP and DC:0-3R relationship disorders were seen across the range of problems, but most pronounced for RP of emotional regulation including excessive crying, adjusted OR 1.8 (95% CI: 0.9–3.8). Notably, maternal mental health problems had no mediating effect on outcome, whereas mother–child relationship problems accounted for a mediating proportion of 17% (CI: 0–72).

Combined RP was associated with an increased risk of ICD-10 diagnosis, adjusted OR 1.9 (95% CI: 1.0–3.5), and particularly sleep disorders, adjusted OR 5.6 (95% CI: 1.2–25.6), whereas no significant associations were found to DC:0-3R regulatory and relationship disorders (Tables 3–5).

Discussion

In this longitudinal study, nested in a community-based cohort, we found infancy RP of sleeping, feeding and eating, and emotional regulation including excessive crying being associated with an increased risk of ICD-10 and DC:0-3R disorders diagnosed by experienced clinicians at child ages 1½ years. This increased risk persisted in analyses adjusted for exposures to a range of perinatal child and family adversities, including maternal mental health problems and relationship problems within the first 6 months of the child's life. Specific analyses focusing on the mediating proportion of maternal health problems and relationship problems showed less than 50% mediation.

The study was embedded in the municipality child healthcare in 11 municipalities in which the community health nurses, CHNs, use the validated PUF measure to screen for developmental vulnerabilities at child ages 8–11 months (35). The PUF measure includes validated items on RP of sleeping, feeding and eating, and emotional regulation including excessive crying (see Supplementary Appendix I). Most other studies of RP have been based on a diverse range of questionnaires to parents (9, 10, 32), leaving comparisons between studies challenging. Among studies using elaborated questionnaires, a study exploring RP over the first 18 months (33) in very preterm and preterm infants used items at 6 and 18 months which are very similar to ours, except for the feeding and eating item used in our study "vomits without otherwise being ill," and three items on emotional regulation: "not happy and satisfied"; "often irritable and fussy"; "emotional blunted." For comparison with the influential ALSPAC study (11), the same differences are seen regarding items concerning indicators of feeding and eating problems, whereas the indicators of sleeping problems overall correspond to the three sleep items used in our study at ages 8–11 months: "The child has not yet established a stable sleep pattern"; "difficulties falling asleep"; and "interrupted sleep." The items on crying in the previously mentioned studies correspond to one of the items on emotional regulation in our study (16, 36), whereas our other indicators of emotional regulation are more in line with the one used in the Mannheim Study of Children at Risk, building temperamental difficulties (43).

The landmark study by DeGangi et al. (44) investigated symptoms of DC:0-3 regulatory disorders within the following domains: self-regulation, including variables on fussiness, irritability, crying, self-calming; attention; sleep; eating and feeding; tactile and auditory hypersensitivity; and emotional functioning using ITSCL, to parents (45). Based on a differentiated approach to the severity of RP in infancy and comprehensive measurements of child psychopathology at ages 30 months, this study highlighted that mild to moderate symptoms of regulatory disorders seem to fade over time, whereas severely disturbed children continued with impairing symptoms across the range of diagnoses investigated, including sleep disorders and parent–child relationship disorders (44). The measurements of regulatory problems in this study have much in common with the items used in our study, and the longitudinal findings do also concur with our findings, overall highlighting a

group of regulatorily challenged children who suffer from persistent problems across their first years of living.

Findings from newer studies focusing on RP within the first years of living have shown a strong correlation of regulatory problems measured at ages from 6 to18 months (33) and up to 36 months (11). Among studies exploring mental health outcomes of infancy RP, several population-based cohorts have found an increased risk of parent-reported internalizing and externalizing or emotional and behavioral problems and disorders in older ages (11, 25, 30, 46, 47). In line with previous findings on mental health outcomes in older children, we found a highly increased risk of behavioral and emotional disorders identified already at 1½ years. Further, by including the range of child mental health problems and disorders in a comprehensive examination at follow-up, we extend the current understanding of the early pathways of dysregulation and developmental psychopathology in young ages (33, 44). We thus found homotypic stability of problems within the same domain e.g., infancy problems of sleeping being associated with clinical symptoms and diagnoses of sleep disorders at 1½ years; and feeding and eating problems being associated with symptoms and diagnoses of feeding and eating disorders at 1½ years. Also, a tendency of heterotypic association was seen among children with RP of sleeping and ICD-10 disorders of feeding and eating, overall indicating a transdiagnostic impact of having any RP. Homotypic continuity is characterized by consistency, similarity, and predictability of behaviors or internal states across different developmental phases, whereas heterotypic continuity does not imply longitudinal consistency of specific problems or symptoms, but rather an unspecific predictability across domains of mental health (48). Our findings based on data from very early childhood thus add to the knowledge on homotypic and heterotypic stability of psychopathology, which hitherto mostly have been explored in older ages.

Analyses of the mediating proportion of maternal mental health problems and mother–child relationship problems in early infancy indicate that maternal health problems may have an impact on the outcome in infants having RP of feeding and eating, whereas parent–child relationship problems seem to influence the outcome in infants with RP of emotional regulation in particular. In contrast, problems with sleeping appeared to be influenced to a lesser extent in general, but equally by maternal mental health problems and mother–child relationship problems. Still, our findings are far from conclusive due to small sample size and low power of calculations. However, being based on a community-based population and including the adjustment for a range of potential confounders, the study findings add to the current knowledge on the complex longitudinal influences of parental and relational factors (18, 49, 50). Previous research has highlighted the mediating role of maternal depression and anxiety and the impact of parental sensitivity on infants' stress reactivity and dysregulation (24, 30, 51–54), underscoring the overall importance of further investigation of the link between infancy RP and parenting quality (15). As suggested, this approach may run in parallel with research in methods to improve parenting among regulatory vulnerable infants (55, 56).

Overall, the findings from the present study agree with findings from previous longitudinal population-based studies exploring outcomes of infancy RP (9, 10). Of these, the vast majority have been studying parent-reported internalizing and externalizing problems and disorders in school-ages and beyond [see Ref. (32) for an overview]; a few have investigated neurodevelopmental disorders in clinically referred children (19, 22). Across these studies exploring a longer developmental period, the risk of unmeasured confounding is considerable, overall hampering the possibilities of identification of overt targets of preventive intervention in early childhood (32).

In contrast, we have been able to describe risk associations and developmental psychopathology within a narrow age span and in a developmental period, in which intervention has the highest preventive potentials. Moreover, by describing frequently occurring developmental phenotypes of impairing child problems that challenge parenting in a key developmental period, our study findings may be directly transferable to clinical and public health settings, in which parents of infants with RP have contact with health professionals, and so potentially ameliorate the possibilities of early identification and timely intervention.

Early identification of developmental vulnerability has to run in parallel with strategies to promote child development and reduce the risk of mental health problems and disorders (57), optimally integrating sensitive parenting and social learning as described, for example, in the Video-based Intervention to Promote sensitive Parenting (VIPP), which has shown promising results, also among regulatory disturbed infants (56, 58, 59).

Strengths and limitations

The major strengths of the study include the large population-based study sample; the standardized assessments of RP at baseline (35); information on RP; and child, relational and family characteristics from standardized municipality records, as well as data on possible confounders obtained from national registries. Further strengths include the comprehensive face-to-face examinations at 1½ years and the diagnostic classification of psychopathology according to ICD-10 and the Diagnostic Classification of Mental Health and Developmental Disorders of Infancy and Early Childhood, DC:0-3R (8) with established reliability (37).

Notably, the combination of information from parents and community health nurses at baseline, and the follow-up assessments blinded of RP at baseline, by experienced clinicians, altogether optimizes the validity of data collected, and overall reduces the risk of information bias.

The study is embedded in existing service settings and carried out by CHNs which is a strength regarding the generalizability of the results of the study.

However, the strengths of being based on existing municipality settings and the existing routines of the CHNs must be understood in relation to the psychometric uncertainties given by the conditions of measuring RP within these settings. The items included as measures of RP in our study have been preliminary

examined concerning the construct and predictive validity (16, 36), but the reliability of the CHNs assessments and recordings of the RP items has not been established.

Notably, the most important limitations of the study concern the validity of the concept of RP, being far from well-defined, leaving considerable methodological challenges to the assessments and classification of RP, and thereby challenging comparisons between studies. Still, these limitations are universal to all studies of RP, as highlighted in recent reviews (9, 32).

Another limitation of our study concerns the potential selection bias, given a lower participation of children from families of higher socioeconomic risks, but on the other hand, a relatively higher participation of children having maternal mental health and relationship problems reported within the first 6 months of the child's life. This selective dropout has been accounted for in the adjusted analyses, and overall, it is not considered to qualitatively influence the results found (60).

Even though our sample size was not very small ($N = 416$), several of the variables recorded in the municipality health nurse record were missing. This particularly influences the power of mediation analyses, which therefore mostly should be seen as data exploration for generating hypotheses about potential mediation effects. Notably, as missing data appeared to occur completely at random, our findings based on complete-case (adjusted) analyses remain unbiased.

Conclusion, implications, and future research

Children who show RP of sleeping, feeding and eating, and of emotional regulation including excessive crying in late infancy (8–11 months) have an up to doubled risk of mental disorders at 1½ years, most pronounced regarding RP of sleeping. Exploring a population-based sample and being able to adjust for potential perinatal or psychosocial family determinants, the study findings point to RP as important markers of mental health vulnerabilities that should be addressed promptly to prevent the progression from dysregulation tracking into child psychopathology in older ages.

The phenomenology and developmental pathways of RP shown call for methods of preventive intervention that focus on parents' abilities to understand and meet their child's regulatory vulnerability in a sensitive and developmentally appropriate way. These methods should be applied in clinical as well as in public health settings, such as the municipality child healthcare service; and overall, be built on evidence-based measures to promote sensitive parenting and strategies of social learning.

However, more research is needed to validate the clinical and developmentally important aspects of regulatory problems in early childhood, as well as research into measures of the reliable identification of these problems. Likewise, more research is needed to qualify effective and feasible methods of sensitive parenting with the potential to break the developmental trajectories of dysregulation and psychopathology early in childhood.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding authors.

Ethics statement

The study was conducted as part of existing services in the participating municipalities. The Research Ethics Committee of the Capital Region of Denmark was conducted and had no demands on further clearance. The Danish Data Protecting Agency accepted the project as a subproject in the notification of the CHD, J.nr. 2010-54-1044. Parents gave their consent for participation in the PUF assessment at age 9–10 months and at age 1½ years.

Author contributions

JA: Conceptualization, Formal analysis, Investigation, Project administration, Writing – original draft, Writing – review & editing, Data curation, Methodology. AO: Methodology, Writing – review & editing, Conceptualization, Funding acquisition, Investigation. SL: Methodology, Writing – review & editing, Conceptualization, Investigation. CR: Methodology, Writing – review & editing, Supervision, Formal analysis. AS: Conceptualization, Data curation, Investigation, Methodology, Writing – original draft, Writing – review & editing, Supervision.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frcha.2024.1330999/full#supplementary-material

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Helping parents to cope with infant regulatory disorders

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The term Regulatory Disorders (RDs) refers to infants and young children who cry a lot, have poorly organised sleep-waking, or whose feeding is impaired. The characteristic they share is a failure to acquire autonomous self-control of these key behaviours, which most children develop in the first postnatal year. The concept of RDs is helpful in highlighting this question of how infant self-regulation is, or isn't, accomplished, in drawing these characteristics together and distinguishing them from others, and in focusing research and clinical attention on a common, but relatively neglected, set of concerns for families. The main focus for research into RDs has been on the nature and causes of the infant behaviours involved. Here, the aim is to highlight the part played by parents, since that is central to the provision of clinical services for RDs. Three points are made. (1) The contributions of parents include: detection and monitoring of RDs; generating the resulting healthcare service costs; maintaining their own wellbeing, since that is in their infant's best interest; delivering interventions to help infants and families, which are almost always provided by parents. Parenting may be involved in maintaining RDs in some cases. (2) Substantial differences exist between infant RD cases in the behaviours involved, the age at which they present, the complexity and severity of the RD, and in their persistence over time and age. Most cases have one, rather than all three RDs, making them the most common type seen by clinicians. Evidence is summarised that interventions tailored to fit the RD involved can be effective in these cases. Multiple and sustained RDs are much rarer, but associated with greater risk of long-term psychological and behavioural impairments. They are a priority, but less is known about the contributions of parenting and child factors to these cases. (3) The focus on parents with infants requires joined-up paediatric and adult mental health services. After summarising three main requirements for such services, an example designed to fulfil these requirements is described to illustrate what a service for supporting families with RDs might look like.

KEYWORDS

infant crying, infant sleep, infant feeding, regulatory disorders, parenting

Introduction

One of the most important tasks for young children is to develop control of their own sleep, waking and feeding behaviours. This transition to infant autonomous regulation of these crucial behaviours does not always go smoothly. The term Regulatory Disorders refers to cases involving prolonged infant crying, poorly organised sleep-waking, or impaired feeding. Surveys have found that more than a third of infants exhibit at least one of these behaviours, making them common challenges for parents and families and costly concerns for healthcare systems (1, 2). For brevity, we will refer to infant and child Regulatory Disorders and their synonyms Regulatory Disturbances and Regulatory

Problems as RDs. Together with this collection of articles, the publication of three systematic reviews, the most recent including meta-analysis of 30 studies, is evidence of the growing interest in RDs (3–5).

Historically, the main focus for research into RDs has been on the nature and causes of the infant behaviours involved. In contrast, the aims in this article are to: (1) Highlight the importance of parental contributions and the need for equal attention to them; (2) Propose that the focus for primary healthcare services should include supporting parents in gaining coping skills; (3) Summarise the evidence that methods developed by psychologists and psychiatrists to support parental mental health, including cognitive behaviour therapy, provide cost-effective techniques for this purpose.

Because our focus is on parents, it is worth saying at the outset that we do not intend to imply that parents cause infant RDs. There is ample evidence that all three RDs are associated with parental factors, such as anxiety, depression, and parenting behaviours, particularly in clinical samples (6–15). However, these are observational studies, which leave the direction of causation unclear. That is, these studies cannot establish whether the parenting factor was the initial trigger for the infant RD, whether the infant RD caused the parental problem, or whether a third factor (such as genetic confounding) contributed to both parental and infant elements. We cannot assume that all infants are inherently good at regulating their crying, sleep, or feeding. Some may be slower to mature or learn, or have a strong biological basis to their behaviour, so that they need extra parenting support compared to most infants. There is evidence, for example, that some babies cry a lot in spite of highly sensitive and responsive parenting (16, 17).

In principle, randomised controlled trials (RCTs), which intervene to change parenting behaviours in one group, compared to a control group, provide the strongest evidence about causation. We will examine the available RCTs in more detail below, but it is sufficient here to note that the findings are complex and leave causal directions uncertain. Similarly, a recent systematic review of the evidence was unable to conclude whether inadequate parenting contributes to infant RDs (5). Behaviour genetic studies, which provide a powerful tool for examining causation, indicate too that RDs are complex problems with multiple interacting causes (18–21). Lastly, there is evidence that factors within young infants are often involved (22). However, these factors are heterogeneous, that is, they vary greatly between cases. Understanding that diversity is essential for interventions designed to help infants and their families, particularly where parents are responsible for delivering the interventions, as they usually are. We will return to develop these points below.

Heterogeneity among infant and child RDs

The term and concept of RDs is helpful in identifying characteristics shared by some young children, distinguishing them from other characteristics such as intellectual impairments, and focusing research and clinical attention on a common, but relatively neglected, set of concerns for families. As noted above, the three RD types share a focus on the acquisition of autonomous self-control, that is, young children's ability to regulate their own crying, sleeping and feeding behaviours.

Although the notion of RDs is helpful, there are substantial differences between individuals in the behaviours involved, the age at which they present, the complexity and severity of the RD, and in their persistence over time and age. Infant crying and parental concern about unexplained or "excessive" crying peaks at about 5–6 weeks of age, occurs most often in the afternoon and evening, and reduces substantially by 12 weeks of age (23–26). In contrast, infant sleep problems involve waking at night in older infants (27, 28). Newborn infant sleeping periods are short and vary little between day and night. By three months of age, most infants begin to sleep for longer periods in the night than day, and by six months about 70% of them have the long night-time sleep periods typical of mature sleep-waking and highly valued by parents (27). The approximately 30% of infants who do not make this transition are said to have poorly regulated sleep, or "sleeping problems" (27).

The development of infant feeding self-regulation is particularly complex. From birth, infants need to coordinate sucking, breathing and swallowing to establish effective feeding. Sucking is initially automatic and reflexive, but becomes voluntary by four months of age. Infants must learn to recognise, respond to, and express their internal biological signals of hunger and satiety to caregivers to regulate milk intake. At about six months complementary feeding begins, during which infants acquire oral motor skills in biting, chewing and swallowing a range of textures and flavours, as well as the ability to self-feed. Disorders of feeding can occur if any of these aspects of early feeding is impaired. Feeding problems often emerge during key feeding transitions, such as moving from breast- or bottle-feeding to cup-feeding, starting solid foods, or at the initiation of self-feeding.

It is important to distinguish clinically relevant feeding problems from developmentally typical behaviours that parents nevertheless find troublesome. Refusal of new foods (neophobia) affects many toddlers towards the end of the first year, but often resolves with time. "Picky eating" is the rejection of both familiar and unfamiliar foods, leading to inadequate variety or quantity of foods consumed, which too is common among infants and toddlers (29, 30).

In contrast, severe and prolonged feeding disturbances are classified as either "avoidant/restrictive food intake disorder" (ARFID) (29) or pediatric feeding disorder (PFD) (31). ARFID is defined as persistent failure to meet appropriate nutritional and/or energy (calorie) requirements, alongside any of: failure to achieve expected weight gain or weight faltering; significant nutritional deficiency; dependence on nutritional support (e.g., tube-feeding or nutritional supplements); or marked interference with psychosocial functioning. Feeding disturbances can occur in any of, or all of, three domains: feeding/eating too little (poor appetite and low interest in feeding/food); eating a very restricted number of foods (avoidance of foods based on sensory sensitivity, such as texture or taste); or fear of feeding/eating due

to conditioned aversion (often following unpleasant consequences such as vomiting or abdominal pain). For ARFID to be diagnosed the feeding disturbance cannot be caused solely by a concurrent medical or developmental condition or must exceed that which would be expected with the condition; lack of available food and culturally sanctioned practice must also be ruled out. PFD is broader than ARFID and includes feeding disturbances directly caused by medical co-morbidities and developmental delay, as well as those occurring in healthy infants who are otherwise developing as expected. PFDs are defined as the inability to consume sufficient food and liquids to meet nutritional and hydration requirements (e.g., infant is growing slower than expected or experiencing weight faltering), and include feeding impairments linked to any of medical, nutritional, skill-based or psychosocial dysfunction. Chronic (vs. acute) PFDs persist for ≥ 3 months. Both ARFID and PDF are relatively new definitions (first appearing in 2013 and 2019, respectively).

As well as differences in the developmental course of the three RD types, most individuals have one or other, not all three. Their prevalence varies according to the definition and methods used, but parents typically report excessive crying in around 10%–20% of 1-3-month-old infants (26, 32), and sleep problems in about 30% of 6-12-month-old infants (28, 33, 34). About 25% of parents report a feeding difficulty of some kind in otherwise healthy infants (1), and up to 50% of infants and toddlers are reported to be "picky eaters" (30). In comparison, in a large cohort of five-month-old German infants, 4.2% had both sleep and feeding problems, 4.6% crying and sleeping problems, 3.9% crying and feeding problems, and just 1.9% had all three RDs (22).

In the long-term, the causes underlying these differences between RD cases are an important target for research. There is already evidence that infants and toddlers with multiple and persistent RDs are particularly likely to have serious long-term impairments such as attention, cognitive and behavioural problems (3, 4, 35). This alone indicates a need to prioritise identification and support for these cases. In addition, it suggests that some individuals have impaired physiological and/or psychological regulatory systems which are responsible both for their early RDs and for later impairments in their social, emotional and behavioural development. However, that does not seem to be true for most cases with single crying, sleeping or feeding RDs (4, 36–40). The peak in infant crying in the early weeks typically resolves without any intervention by 3–4 months of age, and most infants who cry a lot at this early stage then develop normally (36, 38, 41). Crying problems do occur at later ages, but are much rarer and are associated with long-term mental and behavioural impairments, suggesting that these cases may differ from those whose crying is confined to the early months (40, 42–45). Most infant and toddler sleep problems are transitory or intermittent, so that only around 5% have sleep problems across multiple ages (46–48). However, severe and persistent sleeping problems do predict later disorders, particularly anxiety and emotional disorders, in some cases (49, 50). Chronic picky eating (from infancy or toddlerhood to childhood), also affects a small number of children (approximately 3%–4%) (30, 51, 52): for most, this is a transient phase. Yet, single infant feeding RDs, too, are sometimes associated with emotional and behavioural disturbances later in childhood (53, 54). What distinguishes these cases remains uncertain, although here too RD severity may be a key factor. For example, one study found that 63% of infants diagnosed with ARFID between 1.5 and 3 years of age continued to have moderate or severe malnutrition at 11 years of age (53). Adults seeking treatment for ARFID commonly report longstanding highly selective feeding beginning in early infancy, such as only accepting one type of formula, or having difficulty transitioning from exclusive milk-feeding onto solid foods (55).

Unless this heterogeneity between, and even within, the three RDs is explicitly recognised, the risk is that infants found to have them will be thought of as a homogeneous group with a common underlying neuro-behavioural and psychological condition needing a common treatment. Indeed, some reports have already grouped individuals with single and multiple RDs together without acknowledging their diversity.

Because RDs have only recently been recognised by researchers and clinicians, we lack routine surveillance methods for identifying them. It follows that research studies have had to devote considerable resources to finding cases, particularly those with multiple problems which are much rarer. This alone makes it easy to understand why some recent studies have amalgamated multiple and persistent RD cases (22, 35). Yet, there is already evidence that single crying, sleeping and feeding problems often involve normal individual differences in developmental processes, while infant learning is more critical for sleeping RDs, and some forms of feeding disorders, than for excessive crying in early infancy (1, 17, 56, 57). It follows that any remedial intervention needs to take these differences, as well those between single and multiple RD cases, into account. Clinicians need to know that most RD cases they encounter will involve single problems, and to have resources available to identify them and to deliver a suitably tailored, cost-effective, intervention. In turn, being given this guidance by their trusted healthcare professional should provide many parents with immediate reassurance and practical help. We will revisit below what such a service might look like.

Parental contributions to infant and child RDs

1. Identification of RDs and Impact on Healthcare Services.

For obvious reasons, parents, not infants or young children, approach healthcare services for guidance and are responsible for the associated costs. Ideally these initial contacts should lead to objective measures to distinguish the infant behaviours and identify the physiological and psychological factors underlying them. Existing methods, such as audio and video recording, polygraphy, and actigraphy can provide some evidence of this type (58–60). However, these methods are currently cumbersome, expensive, have their own limitations (61), and are not widely used. Instead, most studies have relied on parental reports of RDs, measured as yes/no responses or ratings of RD

severity (e.g., none/mild; moderate; severe), overlooking the evidence that individual parental characteristics and vulnerabilities influence how parents perceive, respond to, and report infant RDs (62–64). It follows that, where a parental report is all that is available, it is unclear how far it measures an infant or parent. This is less critical for clinical purposes, since clinicians start with a parental report of a RD, then seek to unravel the infant, parental, and situational factors involved step by step. Further, interventions for RDs are almost always delivered by parents, so that supporting them is likely to be inherent in any intervention. Fortunately, methods for screening parental wellbeing are available for clinical use and can be included in the intervention process. For research trying to understand the infant part of RDs, however, objective measures which distinguish infant from parental components of RDs are needed. The implication is that parental reports are a key part of clinical practice, but should be thought of as "red flags" identifying families in need of support rather than as definitive measures of infants or children.

2. The clearest evidence that parental responses to RDs may sometimes contribute to good or poor outcomes at later ages comes from randomised controlled trials (RCTs). In particular, there is substantial RCT evidence that intervention programmes based on behavioural principles and delivered by parents are effective in improving night-time sleeping in infants 6 months old or older (27, 56). There are, however, caveats to this conclusion:

    - The findings apply in the short to medium term, but often wash out long-term, such as by 9 years of age (65). This leaves unclear whether parents did not sustain their allotted parenting methods, or whether the child's underlying vulnerabilities re-asserted themselves.
    - Although many parents find behavioural programmes helpful and effective (66–68) some find them unacceptable and consider their disadvantages to outweigh their benefits (69).
    - In infants under six months old, most RCTS have found behavioural interventions effective in preventing sleep problems (57, 70–75) but some found little or no benefit (76–78). This may be because of infant immaturity, because many parents experiment with a variety of parenting methods during early infancy (79, 80), or because these studies failed to achieve significant differences between intervention and control groups. Parents sometimes omit to follow all the recommendations involved in behavioural programmes (17), making RCTs involving infants particularly hard to carry out. When planning clinical interventions, parents' individual and culturally-based judgements need to be taken into account.

In sum, these RCT findings indicate that behavioural methods can be recommended by professionals to help many families to manage infant sleep problems in the short to medium term (65). As well as this evidence, clinicians need to assess parents' preferences, and discuss other ways of coping, from the outset (47).

With regard to feeding problems, the consensus among clinicians is that a parent need not worry if a child is:

- Eating something from each of the main food groups on most days (vegetables or fruit; potatoes, pasta, bread or rice; meat, fish or pulses; milk, cheese or yoghurt)
- Gaining weight as expected (i.e., following their weight centile)
- Active and healthy

However, many parents find feeding problems to be stressful and there is clinical and epidemiological evidence that parents who feel anxious about their infant's food or milk intake may adopt controlling (e.g., pressuring or force-feeding) or indulgent feeding practices (e.g., cajoling or making a different meal), which can prolong or exacerbate feeding problems (6, 9, 64). Instead, responsive feeding—responding appropriately, quickly, and sensitively to an infant's feeding cues—is considered by professional organisations worldwide to be the optimum approach for parents to follow to support infants in developing healthy feeding behaviours. With responsive feeding, parents offer age-appropriate foods, model eating, provide structure (what, when and where to feed) and set reasonable limits; infants are allowed to reject or accept foods, and to self-feed without pressure. Responsive feeding is a core recommendation for the prevention and treatment of infant feeding problems, with parents being advised to focus on *how* to feed rather than the amount of food consumed by the infant (64).

Within a responsive feeding framework, a helpful recent review has summarised the different behavioural strategies parents could implement for each type of feeding problem (64). The UK's Scientific Advisory Committee on Nutrition, too, has recommended: (1) *repeated exposure* to new foods (giving the infant many opportunities to try a new food, without pressure) is important for their acceptance; and (2) offering a *variety* of foods helps infants increase their acceptance of new flavours (81). A single RCT found that following a "baby-led weaning approach" (letting the infant self-feed from the start of complementary feeding) resulted in earlier self-feeding, less pickiness and greater enjoyment of food at 2 years of age, compared to traditional spoon-feeding (65). More RCTs are needed, but this evidence indicates that parents can be supported in preventing or resolving feeding difficulties if they arise and, at the very least, not making them worse (44).

Altogether, the evidence above makes it plausible that parenting in response to early RDs may sometimes influence later child development outcomes. It also points to parenting strategies which may form part of a clinical intervention which is helpful for many RD cases involving sleep or feeding problems in at least the short to medium term.

Twin studies are powerful designs for disentangling the relative contribution of genetic and environmental influences on variation in behaviour, and there have been several such studies of infant sleep and feeding (although not infant crying). On the whole, these studies indicate that both genetic and environmental factors are important, although their relative influence varies across the behaviours. In infancy, genetic factors explain only 17% of the variation in parent-reported sleep duration, with environmental

factors playing the most important role and, in particular, those that are shared entirely by co-twins (e.g., parental sleep hygiene practices) (82). In contrast, genetic factors play a major role in shaping variation in some feeding behaviours, explaining 53%–84% of individual differences in enjoyment of feeding, responsiveness to feeding cues, satiety sensitivity and feeding speed, during the period of exclusive milk-feeding at around 3 months of age (18). Picky eating and neophobia also show moderate to high genetic influence (46% and 58% respectively) in toddlerhood (16 months), while environmental influences shared by co-twins are more important for picky eating (46%) than for neophobia (22%) (19). In the first longitudinal study of picky eating and neophobia combined, spanning 5 age points from toddlerhood to early adolescence, shared environmental influence was only observed at 16 months of age, but had disappeared by early childhood; on the other hand, genetic influences on picky eating and neophobia increased over time (e.g., from 60% at 16 months of age to 84% by 3 years of age) (20). The most recent systematic review, too, has concluded that feeding disorder causation typically involves a complex process of interplay between genetic and parenting factors (83). There is no evidence of shared environmental influence on ARFID; rather, susceptibility to this disorder is largely heritable (79%), at least in childhood (21). Collectively, these twin studies indicate that parents may find it easier to resolve sleep problems than feeding problems, and that feeding problems may be more modifiable in infancy and toddlerhood than in childhood. These studies also underline that parents are often not to blame for the onset of feeding problems, and that they may need considerable support with managing them.

Although RCTs and behaviour genetic studies provide strong evidence about causation, they are difficult and costly to implement, particularly where long-term follow-up is involved. Instead, most studies, particularly of multiple RDs, have employed observational designs, often prospectively at successive ages, using statistical analyses to unravel the contribution of infant and parental factors. In particular, the Bavarian Longitudinal Study has followed up a large cohort of medically at-risk infants and families from birth (35, 84), incorporating normative community groups and a parallel study in Finland for comparison. Strengths include some use of objective measures and reports from professionals to substantiate parental reports. In their most recent publication, this study has followed up the participating infants to 26–30 years of age (22). Broadly, these researchers propose a "cascade" model whereby early multiple and persistent RDs predispose some individuals to emotional, behavioural, and attentional problems in childhood, which then predispose them to psychological, behavioural and social regulatory disorders as adolescents and adults, independent of the contribution of parenting factors. These conclusions are reminiscent of the New York Longitudinal Study of temperament in the 1960s-80s, which first provided scientific credence for the view among parents that some children are constitutionally difficult. However, with the advances in methodology and conceptual modelling employed by the Bavarian study, their conclusions are particularly authoritative.

While the Bavarian study may be the leading one of its kind, a 2020 systematic review of relationships between parenting behaviour and infant regulation examined 107 studies, most of which were observational (5). They found few consistent results. They were unable to draw any conclusions about the contribution of inadequate parenting to infant RD development, but found evidence of a relationship between positive parenting behaviour and positive infant self-regulation, with differences according to age, measurement method and infant behaviour. Specifically, maternal sensitivity, responsiveness, supportiveness and positive affect were associated with good infant self-regulation. Whether this relationship reflects effects of parenting on infant behaviours, indicates that well-regulated infants are easier for parents to care for, or is due to a third factor such as shared genetic influence, remains unclear. Rather, the implication of this finding is to point to the need for more methodologically robust studies of how RDs affect parental emotions and coping behaviours, as well as studies of positive and negative parenting.

Targeting healthcare interventions for RDs

Arising from the points made above, an obvious question is whether infant crying, sleeping and feeding problems are problems for infants or parents? The starting point, at least for healthcare interventions, is to anticipate "both". Despite calling them infant problems, the immediate impact of RDs is on parents. Although many parents cope, there is evidence that substantial numbers will experience distress, frustration, anxiety and/or depression (12, 13, 85), while a small minority will harm the infants in their care (86). Even if the infants involved are healthy, parental wellbeing is in their best interests. Regardless, too, of whether parents maintain infant RDs, they have to cope with them on a daily basis and, in most cases, to deliver the intervention programme clinicians recommend. The lack of evidence that parenting causes infant RDs needs to be kept in mind, since parents who perceive clinicians to be blaming them, or who lose trust in their clinician, are unlikely to maintain involvement as partners in supporting their infant's development.

Historically, recognition of the need to focus on parents as part of RDs can be traced back to the need to prevent "Shaken Baby Syndrome", now known as Abusive Head Trauma (87). This form of infant abuse was found to result in brain injury and often triggered by infant crying (88). Studies of ways to raise parental awareness of the dangers of Abusive Head Trauma, and evaluations of their effectiveness, followed (88). Other adverse outcomes of infant crying reported include abandoning breast feeding, over-feeding, and impaired parent-child relationships and child development (89). Since that time, the list of RDs has broadened to include other behaviours which challenge parents, and services to safeguard infants and children have been introduced by many healthcare providers (90).

The focus on parents with infants requires traditional professional boundaries to be crossed, to join up paediatric and adult mental health services. As these joined-up services embed

in healthcare systems, there is a need to consider what form they should take and who should provide them. Their nature is likely to depend on the healthcare systems involved and the resources available to them. Because we are most familiar with the UK National Health Service, we will focus on the experience and evidence accumulated in the UK, but the core requirements seem likely to be similar across countries and healthcare systems.

Requirement 1: The services need to be embedded in primary healthcare, that is, in provisions which provide front-line surveillance, monitoring and safeguarding for all parents with infants and young children, with links to tertiary services where specialised treatments are needed. In the UK, General Practitioner doctors, community nurse Midwives and Health Visitors, and allied professionals, provide services of this sort. In particular, Health Visitors provide statutory healthcare for all families at ages which coincide with infant RDs, traditionally involving home visits which allow them an opportunity for surveillance. Approached from an adult mental health perspective, the UK Maternal Mental Health Alliance, and Managed Clinical Network for Perinatal Mental Health in Scotland, have developed services to support parental (particularly maternal) mental health in the community (91–93). These adult services do not at present include an explicit focus on infant RDs, in spite of evidence that irritable, unsettled infants can trigger mental health impairments in vulnerable mothers (94). They do not yet provide joined-up services, but have the potential to develop them.

Requirement 2: The services must be shown to be effective, and cost-effective, in supporting families tackling RDs. In particular, where attention to RDs needs to be added to existing workloads, the service needs to deliver better value for money. As an example, studies of interventions to prevent Abusive Head Trauma in Canada and North America have published evidence that the interventions are cost-effective over the longer-term (95). In the UK, the National Institute for Health and Care Excellence recommends a stepped-care model for parental wellbeing support, including during the postnatal period (92). This model involves use of low-cost supports in most cases, with more expensive interventions, such as direct one-to-one contacts, reserved for cases with additional needs. Fortunately, suitable online healthcare provisions, such as websites and apps, have coincided with these recommendations (96–99).

Requirement 3: the service needs to include two main elements: (i) gathering information about the infant behaviours involved, including their impact on parents and the need for further steps to support infant wellbeing; (ii) exploring and supporting parents' coping, including their emotions, thoughts and actions. Many parents find RDs stressful and they are associated with parental frustration and poor mental health (12, 13, 85). While the direction of causation remains uncertain, interventions need to assess, support and safeguard both infants and parents.

Clinical groups in America and Germany have developed family interventions designed to support both parents and infants and children, including those with RDs (100, 101). Because they are delivered by clinicians directly to parents, they may be relatively expensive, particularly for primary care use in the general community. To date, most of the evidence of their effectiveness has come from case-studies without control groups, but one controlled study compared three such treatments with routine services when delivered to 193 mothers with postpartum depression. The treatments included interaction guidance based on Mc Donough's (101) principles, a psychodynamic treatment which included a focus on parental attachment, a non-directive counselling approach, and treatment as usual in the UK NHS (102). Compared to routine services, all three interventions reduced maternal depression at 4.5 months, although only psychodynamic therapy met clinical criteria for improvement. However, none of the interventions continued to show improvements at the 9-month outcome assessments and none of them improved on the spontaneous rate of remission from depression at longer-term (9, 18 or 60 month) outcomes. Similarly, a randomised controlled trial of a psychological intervention to improve maternal depression in the UK found improvements, but not clinically significant long-term benefits (103). It is plausible that cases where maternal postnatal depression is triggered by an infant RD will remit if the RD involved resolves, but the evidence available does not, as yet, confirm that explanation.

An example: the Surviving Crying (SC) service and study

Because of the fledgling nature of services to support parents of infants with RDs, this intervention is briefly described to give a blueprint for what a service for families with RDs might look like. As its title indicates, the intervention was developed to support parents with infants they judge to be crying excessively. This includes recognising that infant crying, and parental concern about it, peak in the first few postnatal months, and that interventions involving parenting can be helpful, but not reliable in stopping the "unsoothable" crying bouts which are the primary concern for many parents (85, 104). It follows that interventions for this RD type need to be delivered early, rapidly, and to target helping parents to cope in getting through this trying period.

The SC intervention includes three main elements: a website, a booklet based on the website, and a short programme of Cognitive Behaviour Therapy (CBT) sessions delivered to parents by a specially trained healthcare professional, such as a Health Visitor (89). All participating parents are provided with the website and booklet, while about half choose to have the, more expensive, CBT sessions (89). CBT-based methods were selected because of evidence of their effectiveness in supporting adult mental health and wellbeing, including parents during the postnatal period, and because they are recommended for this purpose by the National Institute for Health and Care Excellence (105).The CBT-based sessions with parents follow a manual designed to provide the professional with step-by-step guidance. Typically, sessions start with history-taking to identify the crying features worrying the parent, since these are what have brought the parent to seek help. As well as the crying amount, this commonly includes

parent's inability to soothe the baby, concern that the crying is a sign of ill health, worry that the baby is not getting enough to eat, and anxiety that the crying is the parent's fault and reflects inadequate parenting. The Crying Patterns Questionnaire (25) provides a brief standardised, freely available, interview for collecting this information. This is used to assess the crying, show parents their concerns are being taken seriously, confirm the infant's health, provide reassurance and guidance, and identify any follow-up or referral needs. When used at successive ages, it allows progress to be tracked.

This first part of the session needs to be tailored to the RD in question. The Brief Infant Sleeping Questionnaire (34) is suitable for screening for infant sleep problems, and the Infant and Child Feeding Questionnaire can identify infants or children at risk of a paediatric feeding disorder (106). "What matters to me" is a questionnaire developed by parents of children with ARFID (107) to capture their concerns, perceived impact on their child and themselves, and their hopes for treatment/goals, which can be used to assess outcomes that parents value highly.

The second part of each session turns attention to the parent (s), using CBT-based techniques to support them in developing coping strategies which help them manage their emotions and actions and ensure their own and their infant's wellbeing. Steps to take if the baby's crying becomes overwhelming are prominent both in the CBT-based sessions and website/booklet. Standardised questionnaire assessments of depression and anxiety are used to track parents' mental health and wellbeing. This part of the intervention appears likely to be broadly similar across different RD types.

The findings from this study so far are that receipt of the SC materials was associated with improvements in parental mental health and coping, that both parents and Health Visitors wanted the SC materials to be included in the NHS, and that Health Visitors could be trained, mostly online, to deliver the materials successfully under routine NHS conditions (108). Supported by the UK National Institute for Health and Care Research, a randomised controlled trial to evaluate the effectiveness and cost of the resulting SC service is underway. Further information is available on request.

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ISJR: Conceptualization, Methodology, Project administration, Visualization, Writing – original draft, Writing – review & editing. CL: Conceptualization, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Preschool mother-child emotional preparation program leads to significant improvement in autonomic regulation: a randomized controlled trial

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Introduction: Many studies have documented the profound impact that the mother-child relationship has on child sociality and behavior. However, the biological mechanisms that govern the relationship are poorly understood. We developed a mother-child emotional preparation program (MCEP), based on a novel autonomic nervous system learning mechanism. MCEP is hypothesized to condition the child's autonomic nervous system to better meet the preschool socioemotional classroom challenges.
Methods: We conducted a randomized controlled trial of MCEP, comparing a group of children receiving standard curriculum with children receiving standard curriculum plus MCEP. Previously, we reported that the MCEP mother-child dyads (vs controls) were more emotionally connected at six months post intervention and MCEP children (vs controls) displayed better socioemotional behavior at home and in the classroom. At six months post intervention, mothers and children underwent a stressful interaction-interruption paradigm, during which we acquired child ECG. We analyzed heart rate and several measures of child heart rate variability obtained during the 10-minute post-stress recovery period.
Results: We found that MCEP children showed better autonomic regulation following the stressor, as measured by lower heart rate ($p = 0.017$) and increased high frequency respiratory sinus arrhythmia (RSA) or vagal tone ($p = 0.043$). Surprisingly, despite a sample size limited by COVID ($n = 12$ and 12), the effect sizes were large (g's ranging from 0.89 to 1.09). In addition, we found significant correlations with large effect sizes between autonomic measures and scores on the Welch Emotional Connection Screen (WECS).
Discussion: These findings support the conclusion that MCEP had a significant positive impact on child autonomic regulation in response to stress, which correlates with behavioral assessments of emotional connection. We discuss theoretical considerations and the implications of our findings for preschool education programs in general. This trial was retrospectively registered (clinicaltrial.gov registry NCT02970565) three months after the start of the first recruitment on April 9, 2019.

KEYWORDS

autonomic regulation, mother-child, socioemotional behavior, preschool behavior, emotional connection, autonomic conditioning, stress responding

Introduction

Antisocial behavior in preschool-aged children has been increasing for decades. In the US preschoolers now have the highest rates of school expulsion of all age groups (1). Antisocial behavior in childhood often leads to lifelong social exclusion and considerable personal distress and dysfunction into adulthood (2) and imposes high public and private expenditure for treatments (3, 4).

Antisocial behavior among preschool-aged children has worsened because of the COVID-19 pandemic and has been declared a *national emergency* (5).

Over the last 10 years, numerous reviews and meta-analyses have examined the efficacy and effectiveness of various intervention programs designed to address the rising problem of emotional, behavioral, and developmental disorders in preschool aged children, including psychosocial interventions for ADHD (6); psychological interventions targeting behavioral inhibition and anxiety (7); cognitive behavioral therapy (CBT) (8); school-based interventions to prevent anxiety and depression in young children (9); Incredible Years Teacher Classroom Management (IYTCM) for adverse socioemotional behavior (10), and Parent management training (PMT) for behavior problems (11).

Overall, results of such interventions show limited or inconclusive effect on overall adverse classroom behavior and most are not suitable in their present form for scaling, due to small effect size and/or the limited availability, length and cost of treatment programs. The situation has left teachers increasingly burned out, and preschool educators struggling to find alternative solutions.

To address the preschool behavioral problem (12), we co-developed a novel Emotional Preparation program (MCEP) with Children's Learning Centers of Fairfield County (CLC), a leading community-based pre-school education program serving ~1,000 families annually in Stamford, CT. MCEP is a preventative group family intervention facilitated by trained specialists and designed to help parents prepare their child for the pre-school socioemotional experience. We conducted a randomized controlled trial (RCT) of MCEP at CLC (ClinicalTrials.gov Identifier: NCT03442439), comparing a group of children receiving CLC's standard curriculum with a group receiving standard curriculum plus MCEP.

Previously, we reported that the MCEP mother-child dyads (vs. controls) were more emotionally connected at six months post accrual and MCEP children (vs. controls) displayed better socioemotional behavior at home and in the classroom (13). In addition to behavioral benefits, we recorded real-time physiological data to better inform decisions on whether to integrate the preventative practices into CLC's preschool standard curriculum. Specifically, we examine here the effects of MCEP on child physiological responding to stress, as measured by heart rate and heart rate variability in-vivo, during a 20-min recovery period after a series of interrupted interactions with their mother.

It is well-established that individual differences in the quality of parent-child interaction are associated with infant and child stress response at a physiological level (14, 15). Electrocardiogram (ECG) methodology has been utilized by previous studies to measure *in vivo* cardiac activity as an assessment of stress reactivity and recovery (16). Infant parasympathetic regulation during a relational stressor is associated with maternal sensitivity (17, 18), parental responsiveness (19), and mother-child coordination of affective behaviors (20).

We have proposed that mothers and infants are biologically designed to co-regulate one another's autonomic state through an autonomic 'calming cycle' conditioning process. The process starts during gestation and results in the formation of an interpersonal autonomic socioemotional reflex (ASR) (21, 22), which can be measured by Welch Emotional Connection Screen (WECS) (23).

Measuring the mother and infant relationship in terms of the autonomic socioemotional reflex (ASR) requires rethinking the biological mechanisms mediating the mother-child relationship. Conventional constructs, such as attachment and bonding, focus on conscious and unconscious cortical learning mechanisms. In contrast, ASR theory posits that mother/infant emotions are controlled by highly conserved primitive learning mechanisms operating outside of consciousness. ASR theory proposes that specialized primary autonomic (i.e., cardiac) reflexes form between mother and fetus during gestation via autonomic learning or conditioning.

We posit that the ASR (24) is present in all vertebrate species, and is arguably mediated by the oldest and most highly conserved learning mechanism—*functional Pavlovian or autonomic conditioning* (21, 25). Our theoretical advance is that the autonomic conditioning mechanism can be exploited (e.g., via calming cycle intervention) to lower average resting HR in the face of socioemotional challenge (26).

The idea was inspired by a phenomenon originally reported by Pavlov in 1925 when he described how the emotional relationship between a dog and trusted master profoundly impacted the dog's cardiac function and behavior. Pavlov's term for the phenomenon was "cardiac" or 'social' reflex (27). We have applied Pavlov's concept to the specific mother-child relationship. Due to their critical role in infant and child development, we have termed the mechanism the *autonomic socioemotional reflex (ASR).*

The ASR is a special case of the highly conserved *orienting reflex.* Dysfunctional orienting is highly correlated with socioemotional pathologies in infants and children, including social fear, anger, anxiety, depression and autism. Orienting stems from activation of highly conserved autonomic defensive and appetitive motivational systems that evolved to sustain life, assuring the survival of species. In this respect, the ASR orienting phenomenon in humans does not differ significantly from other species, from which it was conserved.

The ASR mechanism provides a biological explanation for mother-infant behaviors that are measured on the uWECS. In previous studies, we have shown the orienting behaviors of preterm infants at 4 months as measured on the WECS correlated with cardiac physiology (Hane).

Theoretically, WECS behaviors reflect the autonomic physiology that is driving the behavior. Therefore, the WECS can

be used to monitor the health of the mother/infant autonomic relationship. We have reported mother-child behavior as measured with the WECS In a separate report in this special issue (Welch et al). This study reports the cardiac.

Over the past few decades, vagal tone research among newborns and children has yielded important insights into social behavior, social interactions, and human psychology (28, 29). Heart rate variability, defined as the variation in intervals between consecutive heartbeats, has been used as a physiological indicator of regulatory processes, reflecting changes in autonomic regulation of heart rate. The sympathetic nervous system and parasympathetic nervous system both play a role in the regulation of heart rate, and to some extent can be indexed by measures of variability (30, 31). For example, the standard deviation of R-R peak intervals reflects overall variability, which is influenced by both sympathetic and parasympathetic nervous system activity (SNS and PNS respectively). Whereas, variation in successive R-R intervals, often termed high frequency HRV or respiratory sinus arrhythmia (RSA), largely reflects PNS activity mediated by the vagus nerve.

The theory that RSA (changes in heart rate with respiration} were due to variation in parasympathetic control of heart rate was originally based on Hering's observations that specific vagal fibers that were cardioinhibitory had a respiratory rhythm (32). Confirmation from years of basic and clinical research by many investigators has led to the conclusion that measuring changes in heart rate that occur at frequencies associated with respiration provides an indirect index of vagal tone (33–35).

Vagal tone helps maintain the dynamic autonomic regulation important for cardiovascular health. In a healthy human heart, there is a dynamic relationship between the PNS and SNS. PNS control predominates at rest, resulting in an average (adult) HR of 75 bpm (36). The vagus nerve can exert its effects more rapidly (<1 s) than sympathetic nerves (>5 s) (37). Since these divisions can produce opposite actions on HR, their net effect on HR depends on their balance of activity. While the SNS often changes reciprocally to PNS activity, under some conditions the two can be activated or increased at the same time (i.e., co-activated) (38).

Our primary hypothesis in this study was that MCEP would lead to an increase in cardiac parasympathetic activity, indexed by the amplitude of RSA, or vagal tone. This was based on findings from our prior studies of the effects of Family Nurture Intervention (FNI) for preterm infants, an intervention with the same emotional connection goals as MCEP. In that trial, we found that FNI accelerated the maturation of vagal tone during the stay in the neonatal intensive care unit (Insert ref 46). In long term follow-up studies, FNI increased vagal tone out to 5 years of age (39). Accordingly, in the current trial of MCEP we hypothesized that the MCEP intervention, also designed to increase mother/child emotional connection would lead to increases in vagal tone.

Two secondary hypotheses were also specified based on prior results. As noted above we have recently published results from the preschool CLC RCT which showed that children randomized to the MCEP intervention group were more likely to be emotionally connected as indexed by WECS scores six months after the last intervention session (13). Here we tested the hypothesis that there would be significant relationships between emotional connection scores on the WECS and physiology. Also based on this prior paper we hypothesized that HR and/or vagal tone would be correlated with scores on the SWYC.

Hypothesis 1. At six months post intervention, children in the MCEP group (vs. control group) would have higher vagal tone and lower HR during the 20-min recovery period.

Hypothesis 2. Vagal tone and HR would be correlated (positively and negatively respectively) with scores on the WECS (i.e., higher WECS scores would be associated with higher vagal tone and lower HR during the 20-min recovery period.

Hypothesis 3. HR and vagal tone of children in the MCEP group (vs. control group) would be associated with better behavioral outcomes as assessed by the SWYC.

Materials and methods

Study design

This study was a parallel-group, single blind randomized controlled trial. The method is presented as per the CONSORT guidelines (40). This trial was registered in the clinicaltrial.gov registry (NCT03908268) on April 9, 2019 (Note that after registration the name of the intervention was changed from Family Nurture Intervention to Mother Child Emotional Preparation- MCEP). The central hypothesis of the RCT was that children in the treatment group would show increased short- and long- term emotional connection, as measured by the Welch Emotional Connection Screen (WECS). The study also assessed the impact of MCEP on child behavior in the home and classroom and autonomic markers of child emotion regulation. CLC's goal was to determine whether MCEP could be and should be added to CLC's standard curriculum.

Participants and setting

MCEP was developed to be integrated into the standard curriculum at the CLC school locations. Children's Learning Center of Fairfield County (CLC), a community-based preschool facility that provides high quality, early childhood education programs for children between six weeks and five years of age at eight locations throughout Stamford, Connecticut (Children's Learning Centers of Fairfield County, 2016). Programs provided by CLC include Head Start, Early Head Start, and School Readiness and Child Development. Participants of the study were recruited by study staff at CLC orientations and teacher/parent meetings. Flyers were also distributed to CLC families during child drop-off and pick-up times. Teachers signed a consent form to enable collection of teacher-report data. CLC staff also discussed the study with enrolling parents and encouraged teachers to refer their students.

The National Education Association has placed a priority on socio-emotional learning for students and educators (41). Accordingly, CLC standard curriculum includes RULER, an evidence-based approach that teaches a child to recognize and labeling emotional feelings (42). The MCEP intervention compliments RULER but differs in strategy. MCEP engages the parents in emotional connection activities to be practiced in the home that proactively promote parent-child co-regulation, which in turn sustains positive feelings and ability to co-regulate with the teachers during the school day.

Eligibility

Families were eligible for this study according to the following criteria: had a child that was 2–4.5 years of age at the recruitment date; mother was at least 18 years old; mother was able to speak, read, and write in English or Spanish; mother lived with her child full-time. In addition, the child had to be a singleton without a genetic or congenital disorder or motor disabilities. Mothers were excluded from the study if they had severe mental illness or any other medical conditions preventing play activities; were involved with the Department of Children and Families; struggled with drug or alcohol abuse; were advanced in pregnancy (2nd trimester or further) which would interfere with their ability to conduct lap-based procedures (described below); or were unable to commit to the study schedule.

Consent procedures

Mothers were verbally consented and then asked to fill out Study Eligibility and Demographics Forms, as well as a CLC Release of Information Form. If an eligible mother did not have time, forms were completed over the phone later, and the CLC Release was signed at the first in-person contact at the time of their baseline assessment.

Randomization process

Following consent, subjects were assigned to either one of two groups: An intervention group, which participated in the standard curriculum plus two to eight 2-hour calming sessions in a group setting; or, a control group, which received only the standard CLC curriculum (See Figure 1 Consort Chart).

The control group children participated in the standard CLC curriculum, with no additional procedures. Classroom activities varied by age and ability. Classroom structure also varied by

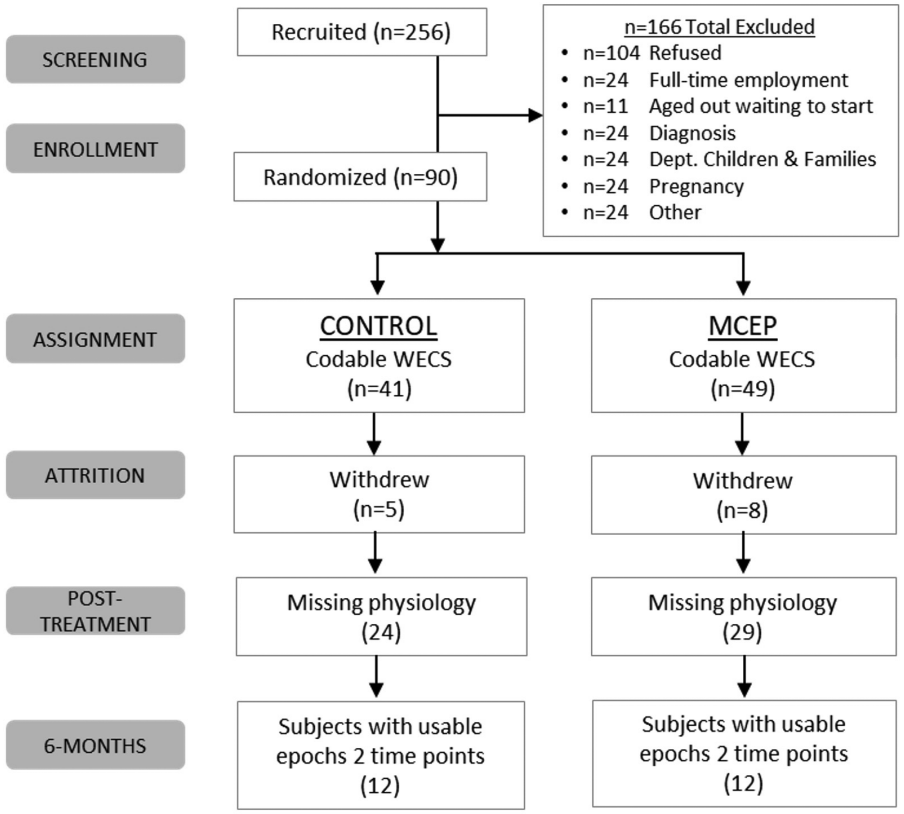

FIGURE 1
Consort chart. MCEP, Mother-Child Emotional Preparation; *n* = sample size; WECS, Welch Emotional Connection Screen.

program. For example, although most CLC students are enrolled in a full-day program, some attend a half-day program.

Intervention methods

The intervention group dyads participated in MCEP sessions led by two specially trained licensed clinical social workers (Nurture Specialists). Two to eight dyads participated in each session, which was held in CLC space. In this study, the Nurture Specialists were licensed social workers. Sessions took place on a variable schedule over the course of sixteen weeks (i.e., mothers chose any 8 of 16 weeks to attend). The Nurture Specialists engaged mother-child dyads in calming sessions.

Calming sessions began with the child sitting facing mother on her lap. Behavior typically cycled through four distinct phases (43): (1) *Separate mother and child distress*. Mothers were asked to look at the child, describe behavior she wants to see from the child, and express any feelings in response to the child's current or home behavior. This typically elicited protest, crying or avoidant orienting behavior from the child. The child often pushed the mother away or tried to escape from the lap. (2) *Mutual engagement of distress*. While expressing her feelings, mothers would also express frustration and describe negative emotions, and sometimes cry. The mother's release of emotion, typically triggered a change of orientation from avoidant to attraction to the mother. (3) *Mutual resolution of distress*. At this point in the session, the child often responded to the mothers' distress with sustained eye contact, tender behaviors and vocal communication, which moved the cycle in to the final stage. To aid in completing the cycle, Nurture Specialists encouraged the mother to use comfort touch, genuine emotional expression and eye contact. The mother's genuine expression of emotional feeling most often elicited reciprocal empathic response from the child. (4) *Mutual resolution and calm*. Mutual calm was observable as quiet embrace, eye contact and soothing talk. During this resolution phase, the dyad engaged in mutual comforting and settled into a state of mutual calm (i.e., autonomically co-regulated state), characterized by mother and child breathing calmly, maintaining a deep mutual gaze, and having open verbal and non-verbal communication with relaxation and reciprocal pleasure in each other's closeness.

Following the calming session, mothers were instructed to continue these calming cycles on a regular basis at home, especially when either child or mother was upset.

Physiology study cohort

Among the 90 participants recruited for the initial emotional connection study from this RCT (44), largely due to the onset of the Covid pandemic, only 34 subjects were able to returned for ECG data collection at both the baseline and 6-month timepoints. Of these 34, 32 were able to provide epochs for HRV analyses at the baseline timepoint while 29 were able to provide epochs for HRV analyses at the 6-month timepoint. After filtering out all epochs that had a "Percent Good" value of less than 70%, we were left with 273 epochs from the baseline timepoint (provided by 31 participants) and 153 epochs from the 6-month timepoint (provided by 25 participants).

Of the remaining participants, 24 ($n = 12$ control and $n = 12$ MCEP) had both baseline and 6- month data to be used for statistical analyses (Figure 1). Demographic data (age, sex, etc.) of the 24 participants included in the statistical analysis are presented in Table 1.

Physiological assessment

Electrocardiogram (ECG) data was collected and digitized at 1,000 Hz using a Noldus/Biopac MP160 System at approximately six months post-accrual, as part of the Parent-Child Stress Recovery Paradigm designed by authors Welch and Hane (Figure 2). For this study, we analyzed ECG data collected during the 20-minute recovery phase of the 30-min paradigm. The paradigm is designed to test the extent to which mother and child can recover (i.e., return to baseline parasympathetic/cardiac physiology) following a stressful (dysregulating) double separation. In the paradigm, during the 20-minute recovery period, the mother sat in a chair with the child facing her in her lap. There were no toys or distractions in the room. The mother

TABLE 1 Demographics of subjects.

	SC ($n = 12$)	E-Prep ($n = 12$)
	Mean (SD)	Mean (SD)
Age at enrollment (years)	3.99 (0.48)	3.68 (0.21)
Age at 6-month follow-up (years)	4.54 (0.47)	4.23 (0.22)
Household size	4.17 (0.94)	4.42 (0.90)
	N (%)	*N* (%)
Parental marital status		
Married or living together	8 (66.7)	9 (75)
Hispanic ethnicity		
Mother	9 (75)	10 (83.3)
Father	9 (75)	11 (91.7)
Mother's education		
Some schooling	1 (8.3)	2 (16.7)
High school or GED	4 (33.3)	2 (16.7)
Some college or associates	5 (41.7)	7 (58.3)
Bachelors or graduate degree	2 (16.7)	1 (8.3)
Unknown	0 (0)	0 (0)
Father's education		
Some schooling	3 (25)	5 (41.7)
High school or GED	4 (33.3)	2 (16.7)
Some college or associates	4 (33.3)	2 (16.7)
Bachelors or graduate degree	0 (0)	2 (16.7)
Unknown	1 (8.3)	1 (8.3)
Employment status		
Mother is employed	5 (41.7)	5 (41.7)
Missing	0 (0)	1 (8.3)
State/federal assistance		
Yes	7 (58.3)	7 (58.3)
Unknown	2 (16.7)	0 (0)
Male	6 (50)	4 (33.3)

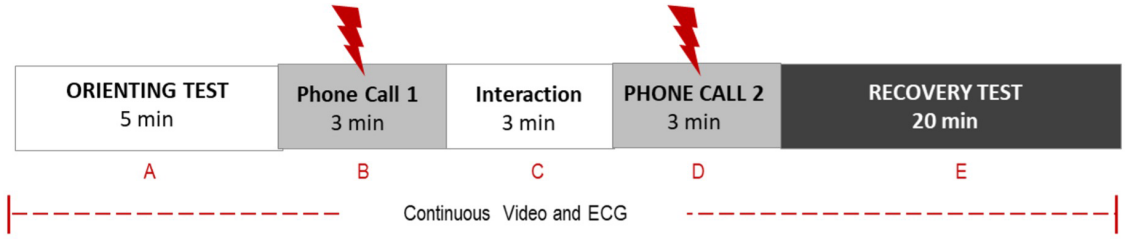

FIGURE 2
Parent-child stress recovery paradigm. This ~30-min face-to-face communication paradigm is designed to determine the extent to which a parent-child dyad can return to baseline behavior (segment A) and parasympathetic/cardiac physiology following the dysregulation caused by two separation phone calls. Dyadic behaviors are coded from video recordings with Welch Emotional Connection Screen (WECS). Autonomic physiology is measured by heart rate and heart rate variability.

was told to engage her child in conversation, and that she would receive two separate important three-minute phone calls during the interaction session. She was told that she should devote all her attention to these important calls and none to her child. Following each call, the mother was instructed to return her full attention to her child and resume their interaction.

Welch emotional connection screen

Prior to the phone call disruption and during the 6-month post-enrollment follow-up, mothers and children were observed interacting in a 5 min face-to-face interaction that was later coded for EC with the WECS (23). The WECS is a brief observational tool that assesses the degree of emotional connection between mother and infants/children ages 0–6 years. Dyads are rated on a 9-point scale with 25 increments for: *Mutual Attraction* (use of shared gaze, proximality and touch); *Mutual Vocal Affect* (mutual use of voice); *Mutual Facial Expressiveness* (mutual facial affect); and *Mutual Sensitivity and Reciprocity* (mutual sensing and responding to each other) to initiate and sustain a connection with each other. A higher score indicates a dyad who is high on EC, manifesting the capacity to remain close, share affect, and engage in face-to-face interactions in a calm, mutually comfortable state of togetherness.

The WECS has been validated in preterm (23); full-term (45) infants and preschool-aged children (13).

Heart rate variability analyses (vagal tone)

There are many analytical approaches to measuring RSA but all are based on capturing the amount of variation in heart rate that is associated with respiration. The first step in these analyses is locate the time when each non-artifact R-wave occurred. For this current study we used *R-DECO*, an open-sourced Matlab-based graphical user interface (46, 47) to automatically locate ECG R-wave peaks. Then, using the interactive graphic displays of R-DECO we inspected the ECG wave-forms and R-wave peak marks and manually inserted, deleted or moved peaks when appropriate.

Before computing various measures of RR-interval variability, using our own software (see definitions below), we detected and deleted RR interval values that were outside normal minimum and maximum RR- intervals. For these thresholds we used published data for three age ranges corresponding to the ages of children in our study (29, 47). These ranges are given in Table 2. In addition, we accepted RR-intervals only if successive R-R intervals changed by no more than 20%.

Each 20-minute RR-interval file was analyzed in 3 min epochs with a sliding window which overlapped epochs by 1.5 min. Within each epoch, we calculated the percent of good data, that is, the total number of RR-intervals accepted divided by the total number of RR-intervals prior to the deletions based on the criteria described above. To increase data quality, statistical analyses were restricted to include only epochs that had percents good data greater than 70%. The values for a given subject included in these analyses were the medians from the included epochs. Subjects were only included in the analyses if they provided median values at both the baseline timepoint and 6-month timepoint. Overall, these procedures yielded an average of 8.8 good data epochs at baseline and 6.0 good epochs at the six-month follow-up.

Our software computed many parameters which followed the definitions and terms used by Shaffer and Ginsberg (Shaffer & Ginsberg, 2017).

Heart Rate: The inverse of an average of all good intervals within each epoch was used to compute mean heart rate (HR).

SDNN (Standard deviation of normal-to-normal RR-intervals, a time-domain measure of the standard deviation of R-R Intervals within an epoch, reflecting both parasympathetic and sympathetic influences on HR.

TABLE 2 R-R intervals for three age ranges.

Child	R-R interval		
Age range	Frequency range	Min ms	Max ms
2.5–3.49 Years	LF (Low)	428	800
3.5–4.49 Years	MF (Medium)	444	867
4.5–5.49 Years	HF (High)	460	923

RMSSD (Root mean square of successive differences), a time-domain measure of differences between R-R intervals). RMSSD is obtained by calculating each successive R-R interval between heartbeats and calculating the average change in R-R-intervals from one beat to the next. Then each of these values are squared and the result is averaged before the square of the total is obtained. Compared to SDNN, the RMSSD is thought to be affected more by parasympathetic activity.

Frequency-Domain Measures of R-R Interval Variability. Autoregressive modeling was used to separate heart rate variability into its component Low (LF) and High (HF) rhythms that operate in different frequency ranges. Spectral power in the LF and HF frequency bands was obtained by calculating the area under the R-R interval time series within each band's frequency range: LF (0,040,15 Hz), HF (0.24–1.04 Hz). LF and HF values were log transformed (ln) prior to performing analyses.

Respiratory Sinus Arrythmia (RSA). RSA was taken as the primary marker of cardiac-linked parasympathetic regulation. High resting RSA can represent a flexible and adaptive physiological response system to a challenge while a low resting RSA can reflect maladaptive regulatory mechanisms (48). RSA in this study was calculated using the Porges-Bohrer Method (Porges & Bohrer, 1990).

Statistical analyses

Hypothesis 1. At six months post intervention, children in the MCEP group (vs. control group) would have higher vagal tone and lower HR during the 20-min recovery period.

This hypothesis was tested by comparing HRV value for MCEP subjects vs. controls at the six-month time point. However, the tests used (ANCOVAs) took into account the values for these parameters at baseline and, based on prior literature, also included age and sex as additional covariates. Following these analyses we computed effect sizes Hedge's g (31), which essentially describes how large the mean effect of the intervention was compared the variance in the data.

Hypothesis 2. Vagal tone and HR would be correlated (positively and negatively respectively) with scores on the WECS (i.e., higher WECS scores would be associated with higher vagal tone and lower HR during the 20-min recovery period.

This hypothesis was tested by computing Pearson Product Moment correlations between WECS scores obtained during 5 min of face-to-face interactions while the child was on the mother's lap at the 6-month time point and the HR and vagal tone values obtained during the 20-minute period of HRV analyses.

Hypothesis 3. HR and vagal tone of children in the MCEP group (vs. control group) would be associated with better behavioral outcomes as assessed by the SWYC.

This hypothesis was tested by computing Pearson Product Moment correlations between SYWC scores at the 6-month time point and the HR and vagal tone values obtained during the 20-minute period of HRV analyses.

Results

Hypothesis 1. At six months post intervention, children in the MCEP group (vs. control group) would have higher vagal tone and lower HR during the 20-min recovery period.

With regard to the primary outcome variables, HR was lower and vagal tone was higher in the MCEP group. (See Figure 3).

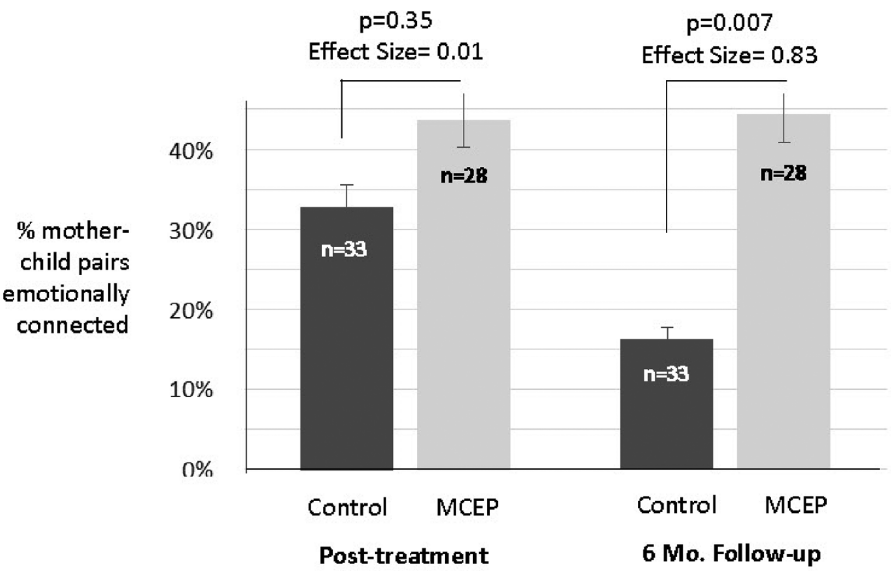

FIGURE 3
Heart rate and respiratory sinus arrythmia at 4 months. Graphs showing means (±SE) for HR (**A**) and RSA (**B**) for SC and MCEP children approximately 4 months after their last intervention session. Statistics were based on analyses of covariance with sex, age at testing and baseline (enrollment) values as covariates. The means shown were adjusted for these covariates. Note the substantial Effect sizes for both physiological measures, indicating effects of MCEP may be observable in a small classroom size sample.

Analyses of covariance testing for group differences at the 6-month time point were also run for SDNN, RMSSD, low frequency R-R interval variability (LF), high frequency R-R interval variability (HF) (see Table 4). Three of these measures of HRV: SDNN (p-value = 0.027); RMSSD (p-value = 0.047) and LF power (p-value = 0.028) were significantly higher in the MCEP group. The sixth variable, HF power, did not quite reach statistical significance (p-value = 0.073). Effect size calculations also showed that all HRV parameters assessed were much greater in children who underwent the intervention than those who did not (R-R interval Hedge's g = 1.09, SDNN Hedge's g = 1.00, RMSSD Hedge's g = 0.89, LF-power Hedge's g = 0.98, HF-power Hedge's g = 0.80, RSA Hedge's g = 0.91).

Hypothesis 2. Vagal tone and HR would be correlated (positively and negatively respectively) with scores on the WECS (i.e., higher WECS scores would be associated with higher vagal tone and lower HR during the 20-min recovery period.

The test of Hypothesis 1 showed that children in the intervention group had lower heart rates and higher vagal tone at the six-month follow-up. The following analyses tested the hypothesis that at this time point there would be significant relationships (correlations) between WECS scores and physiology. Results showed that for the Attraction domain and for the total WECS scores there were significant negative correlations with HR; the children of dyads showing greater mutual attraction and total WECS scores had lower HRs. In addition, for Attraction there was significant positive correlation with RSA. These results are given in Table 3.

TABLE 3 Correlations between WECS scores and HR and RSA at the 6-month follow-up.

WECS Domain	HR	RSA
Attraction	**(24) $r = -0.511$, $p = 0.011$***	**(24) $r = 0.492$, $p = 0.015$***
Vocal	(22) $r = -0.367$, $p = 0.092$	(22) $r = 0.270$, $p = 0.225$
Facial	(23) $r = -.357$, $p = 0.094$	(23) $r = 0.267$, $p = 0.218$
Sensitivity	(24) $r = -.380$, $p = 0.067$	(24) $r = 0.313$, $p = 0.136$
Total	**(24) $r = -.407$, $p = 0.048$***	(24) $r = 0.053$, $p = 0.091$

Data are for the 24 subjects with good physiological recordings at baseline and 6-month included in the results above. Results are for the mutual domain and total WECS scores. Some subjects had missing WECS codes for some domains (n). Bolded numbers indicate significant p-value.
*Indicates that p-values remained <0.05 after controlling for child age, sex and group.

Hypothesis 3. HR and vagal tone of children in the MCEP group (vs. control group) would be associated with better behavioral outcomes as assessed by the SWYC.

In a prior report we found that MCEP resulted in improvements in behavior as measured on the Survey of Well Being of Young Children (SWYC) (13). Here, we found children with worse SWYC scores tended to have higher heart rate (r = +0.39, $n = 24$, $p = 0.057$, effect size = 0.41).

Discussion

The primary aim of this study was to assess the impact of MCEP on autonomic markers of socioemotional physiology in a preschool population. Despite the reduced number of subjects due to COVID, our findings are consistent with the interpretation that the MCEP intervention (vs. controls) had sustained effects on parasympathetic activity, including heart rate and vagal tone.

Consistent with our hypothesis, children in the MCEP group (vs. control group) showed significantly lower heart rates (longer R-R intervals) and increases in RSA and several measures of HRV at approximately 6-months following the intervention. In addition, the Hedge's g values for all HRV parameters for MCEP vs. controls results were quite large.

Analyses of the relationships between WECS emotional connection scores and physiology showed that children in dyads with the lowest WECS scores (i.e., less emotionally connected) had higher HRs and lower vagal tone (RSA) than children in the better-connected dyads. Moreover, we have previously reported there was an effect of MCEP on behavioral problems as measured by the SWYC (13). Fewer problems on the SWYC correlated with higher WECS scores (13), suggesting behaviors measured on the SWYC should also correlate with physiology. In fact, that is what we found. HR was correlated with SWYC behaviors. Taken together, these findings support a link between WECS behaviors and autonomic state.

Theoretical and research considerations

Over the past few decades, vagal tone research among newborns and children has yielded important insights into social behavior,

TABLE 4 Group differences in various measures of heart rate variability.

HRV parameter	FNI		SC		P-value	Effect size
	Mean	SD	Mean	SD		
R-R Interval (s)	0.59	0.04	0.55	0.04	**0.017**	**1.09**
SDNN (s)	0.05	0.01	0.04	0.01	**0.027**	**1.00**
RMSSD (s)	0.03	0.01	0.03	0.01	**0.047**	**0.89**
LF-power (see Table 2)	−6.21	0.51	−6.73	0.51	**0.028**	**0.98**
HF-power (see Table 2)	−7.50	0.71	−8.09	0.71	0.073	**0.80**
RSA (ln ms^2)	4.54	0.72	3.86	0.72	**0.043**	**0.91**

FNI, family nurture intervention preschool; SC, standard curriculum; SD, pooled-weighted standard deviation.
Bolded P-value numbers = <0.05. Bolded Effect Size = highly significant.
Group Mean values were adjusted for baseline measurement, sex, and age at 6-months). Effect Size calculations are Hedge's g with a 95% CI.

social interactions, and human psychology (28, 29). Heart rate variability, defined as the variation in intervals between consecutive heartbeats, has been used as a physiological indicator of regulatory processes, reflecting changes in autonomic regulation of heart rate. The sympathetic nervous system and parasympathetic nervous system both play a role in the regulation of heart rate, and to some extent can be indexed by measures of variability (30, 31). For example, the standard deviation of R-R peak intervals reflects overall variability, which is influenced by both sympathetic and parasympathetic nervous system activity (SNS and PNS respectively). Whereas, variation in successive R-R intervals, often termed high frequency HRV or respiratory sinus arrhythmia (RSA), largely reflects PNS activity mediated by the vagus nerve.

Vagal tone helps maintain the dynamic autonomic regulation important for cardiovascular health. In a healthy human heart, there is a dynamic relationship between the PNS and SNS. PNS control predominates at rest, resulting in an average (adult) HR of 75 bpm (36). The vagus nerve can exert its effects more rapidly (<1 s) than sympathetic nerves (>5 s) (37). Since these divisions can produce opposite actions on HR, their net effect on HR depends on their balance of activity. While the SNS often changes reciprocally to PNS activity, under some conditions the two can be activated or increased at the same time (i.e., co-activated) (38). While there is widespread agreement that modulation of heart rate variability or *vagal tone* helps maintain the dynamic autonomic regulation important for cardiovascular health, there are anomalies in the data, referred to as the *vagal paradox* (49) as well as in the possible evolutionary underpinnings of the relationship between vagal tone and socio-emotional regulation. We have proposed that this relationship can be explained by what we have termed the *autonomic socioemotional reflex (ASR)*, which in this study is an external cardiac feedback loop mechanism dependent on mother-child co-regulation. This external loop is distinct from the internal self-regulating CNS feedback loop mechanisms.

We posit that the ASR (24) is present in all vertebrate species, and is arguably mediated by the oldest and most highly conserved learning mechanism—*functional Pavlovian or autonomic conditioning* (21, 25). Our theoretical advance is that the autonomic conditioning mechanism can be exploited (e.g., via calming cycle intervention) to lower average resting HR in the face of socioemotional challenge (26).

Previously, we tested aspects of the ASR and calming cycle theories (21, 22, 50) among prematurely born infants and their mothers in two RCTs of *Family Nurture Intervention* in the neonatal intensive care unit (FNI-NICU) (51). Results from both trials supported the study hypotheses. In the original trial, FNI led to greater maternal sensitivity during routine caregiving behavioral interactions (52), lowered infant heart rate in the hospital (26), enhanced autonomic regulation at term age (53), accelerated brain maturation in frontal regions at term age (54, 55), lowered symptoms of maternal depression at four months (27), and improved neurobehavioral outcomes at 18 months of age (56) and improved theory of mind at 4 and 5 years of age (57). In the two RCTs of FNI-NICU, EEG analyses showed that FNI mother-infant calming sessions in the NICU increased prefrontal power (44) and altered the development of brain-wide cortical activity networks such that by term age they closely resembled a comparison group of full-term infants (58).

The results of this preschool study suggest that a calming cycle intervention like that used in the FNI-NICU trials may be effective in regulating adverse socioemotional behavior in preschool aged children 2–5 years of age.

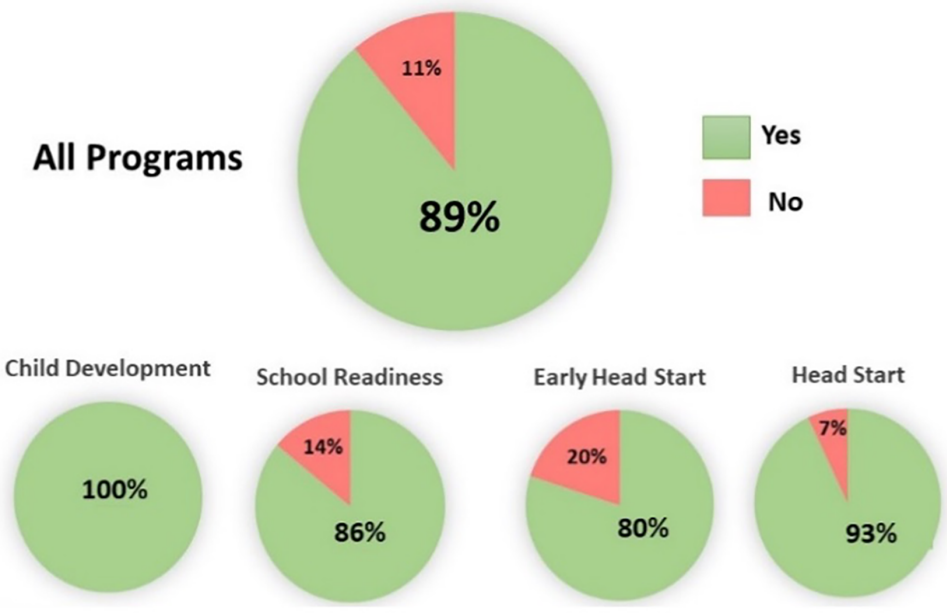

FIGURE 4
Percent staff who want to make MCEP part of standard CLC curriculum. Breakdown by CLC program.

Implications for practice

Viewing the parent-child relationship as being mediated by the ASR has two distinct clinical advantages. First, as mentioned above, the primary reflex provides a novel target that avoids the negative stigmatizations associated with mental health. The MCEP intervention involves routines that can be practiced by the family in the home. Second, the ASR provides new ways to quickly assess the health of the parent-child emotional relationship (i.e., whether the relationship is adaptive or maladaptive). Since the ASR physiology is correlated with WECS behaviors, the behavioral state of the relationship can be monitored moment to moment with the WECS. The hypotheses and study design of this effectiveness trial were formulated based on CLC's routine standard preschool curriculum conditions. Therefore, the outcomes of the trial provided essential data necessary to inform possible changes in curriculum going forward. For instance, following completion of the study, based in part by observed changes in MCEP child behavior, CLC staff indicated they supported making MCEP part of standard CLC curriculum (See Figure 4). Teaches also indicated that MCEP participation helped strengthen the important parent-teacher alliance.

MCEP targets the parent-child relationship, the foundation of socioemotional behavior regulation (59). This approach is potentially less costly than comparable behavioral intervention models. MCEP is designed to reduce the child's stress reactivity by engaging parents in the child's autonomic nervous system conditioning at home. Current models, which are typically designed to change the thought processes of the parent or child and to help the child self-regulate emotions at school or in external programs, create a financial burden to the school and community (4).

Finally, the large effect size in our classroom-size sample is noteworthy (60). Robert Coe, from the School of Education, University of Durham, England explains why (61). "Effect size' is a simple a way of quantifying the size of the difference between two groups. It is easy to calculate, readily understood and can be applied to any measured outcome in Education or Social Science. It is particularly valuable for quantifying and comparing the effectiveness of a particular intervention." A strength of our study is that the results allow CLC to move beyond, "Does it work or not?" to the far more useful, "How well does it work in the standard classroom?" Not only was the efficacy of the MCEP statistically significant, but the size of the effect was also large, meaning that MCEP can have a positive effect on child behavior within the average preschool classroom. In many ways, therefore, the size of the effect might be the most important result of our study.

Construct validity

The *emotional connection* construct describes a shared behavioral state, which is measurable via the WECS. Our previously published behavioral findings (13) validate the emotional connection construct in a preschool-aged child population. The construct *co-regulation* describes shared autonomic state physiology and points to an external feed-back loop control system, in this case between mother and child (22). This is in stark contrast with current theory, which holds that emotional behavior is subject to an internal feed-back loop control system. The fact that emotional connection correlates with the child's autonomic state, and the child's autonomic state can be changed through the calming cycle intervention strongly suggests that the parent, the mother in this case, is key in the regulation of both the child's autonomic state and the child's behavior. We have proposed a sensory signaling pathway by which this co-regulation occurs (22).

It is noteworthy that the *baseline* EC state of the dyad was associated with recovery from stress. This finding is consistent with our work with infants (23) and extends it to young children, with further evidence that higher EC is associated with the child's ability to rejoin mother following relational stress and recover in a healthy autonomic state. Relational stress, such as waiting for teacher attention in the preschool classroom, is commonplace. Children who can manage such daily stressors with a physiological state of calmness may be less likely to show anger, impatience, and other forms of dysregulation that place them at-risk for removal from the preschool classroom.

There are additional aspects to this study and its findings that should also be noted. As stated in the introduction, there have been other intervention programs that address emotional, behavioral, and developmental deficits in children. MCEP differs from these programs in its simplicity and brevity, and ability to produce the physiological results seen in this study with eight or fewer 2-hour group sessions. In addition, the effects we see among children who received the intervention as compared to those who did not were measured at the 6-month timepoint, approximately 4 months after the intervention program was finished, indicating the intervention's sustained effect over time.

Limitations

Several limitations to this study should be considered. Firstly, this study was done by recruiting a non-probability convenience sample of mainly low socioeconomic status and Hispanic-identifying individuals. The most significant limitation of the study was the small sample sizes for subjects with both baseline and 6-month data. Due to the impact of the COVID-19 pandemic, acquisition of physiological data was halted because a sizeable portion of the study's original sample were not able to come in for their 6-month timepoint physiology assessment. Comparing the demographic data of those enrolled vs. those who returned, the only significant difference observed between the two samples was that the original sample had a greater proportion of males in the intervention group compared the intervention group of this study. Yet, such a small sample size, it could be possible that these results are due to chance. However, the large effect sizes found in the study support the efficacy of the intervention.

Future studies

Additional analyses are needed to explore several more questions. For example, it would be interesting to see if the change we report here in 6-month heart rate variability occurs gradually or suddenly. It would also be interesting to include other variables into the model that account for variation between subjects. Lastly, with a larger sample it would be interesting to see if covariates such as race, ethnicity and socioeconomic status influence these findings.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Columbia University IRB New York. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin.

Author contributions

MW: Conceptualization, Funding acquisition, Project administration, Resources, Writing – original draft, Writing – review & editing. RL: Conceptualization, Investigation, Project administration, Resources, Supervision, Writing – original draft, Writing – review & editing. JK: Formal Analysis, Methodology, Software, Validation, Visualization, Investigation, Writing – original draft, Writing – review & editing. VR: Investigation, Writing – review & editing. AH: Conceptualization, Formal Analysis, Validation, Visualization, Writing – review & editing. MJ: Project administration, Writing – review & editing. AW: Project administration, Writing – review & editing. MM: Conceptualization, Formal Analysis, Methodology, Project administration, Software, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Mind-mindedness in mothers of infants with excessive crying/sleeping/eating disorders

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Introduction: Excessive crying, sleeping, and eating disorders are among the most prevalent mental health diagnoses in the first 3 years of life and involve significant health service use. Parents of infants with excessive crying/sleeping/eating disorders report high levels of stress, since they feel incapable of soothing and/or nurturing their baby. Infants' distress can lead to a breakdown in parents' mentalizing abilities and, more specifically, parental mind-mindedness in the parent-child interaction. Moreover, the signals of infants with excessive crying/sleeping/eating disorders tend to be equivocal and difficult to read. This also might contribute to lower parent-child interaction quality. Until now, parental mind-mindedness, which is regarded as a prerequisite for sensitivity, has not been investigated in mothers of infants with excessive crying/sleeping/eating disorders. We investigated whether mind-mindedness in mothers of infants with excessive crying, sleeping and/or eating disorders differed from a healthy control group. We supposed that mothers of infants with excessive crying/sleeping/eating disorders would use (1) less appropriate mind-related comments (AMRCs), and (2) more non-attuned mind-related comments (NAMRCs) than mothers in the control group.
Methods: Our sample consisted of 44 mothers and their infants who were patients in a socio-paediatric clinic in Germany. The children were diagnosed with excessive crying, sleeping and/or eating disorders according to DC:0-5 (= clinical group). The control group was composed of 64 healthy children and their mothers. Maternal mind-mindedness was coded during a free-play interaction.
Results: Results showed that mothers of infants with excessive crying, sleeping and/or eating disorders used both more AMRCs ($p = .029$) as well as more NAMRCs ($p = .006$) than mothers in the control group.
Discussion: The findings are discussed in terms of implications for interventions (e.g., enhancing mind-mindedness trough video-feedback).

KEYWORDS

maternal mind-mindedness, infancy, excessive crying, sleeping disorders, eating disorders, regulatory problems/disorders

Introduction

Excessive crying, sleeping, and eating problems/disorders are highly prevalent in infancy and toddlerhood, and are one of the most frequent reasons for clinical referral (1). This symptom group is often referred to as "regulatory problems" (RPs) (2, 3). The prevalence rates vary depending on the definition of the problem (vs. disorder), the population as well as the applied measurements. With regard to excessive crying,

prevalence rates vary from 5%–26% (4–6), whereas sleeping problems range from 10%–33% (7–9), and eating problems from 15%–43% (4, 9–11). About 20% of the infants show one or more (and in parts persistent) problems in those areas (2, 3, 12, 13). Infants with multiple and/or persistent RPs have a heightened risk of developing mental health problems in childhood (12, 13, 14–18), in adolescence (14), and adulthood (12, 19–22). A meta-analysis (23) showed that about 23.3% of the infants with RPs develop behavior problems during childhood, and that behavior problems are particularly pronounced in infants with multiple RPs.

Theoretical models argue that persistent RPs or clinically relevant disorders such as sleep onset or night waking disorder or excessive crying disorder (24) are best described and understood in a relational context: They are frequently embedded in a family system with high psychosocial stress and problems in the parent-child relationship/interaction (2). Indeed, studies showed that having an infant suffering from RPs puts parents under enormous stress (9, 25). Moreover, parents of infants with RPs report lower levels of self-efficacy, more social isolation (2, 26, 27) and more symptoms of depression and anxiety (28, 29). Furthermore, the parent-child interaction quality in parents of infants with RPs can be constrained (30, 31–33). Additionally, bonding difficulties (34, 35) as well as lower parental mentalizing abilities (36) in parents of infants with RPs are reported.

Maternal mind-mindedness (MM) is regarded as a "bridge" between mentalization and sensitivity "at the interface between representational and behavioral operationalization of caregiver-child interaction" [(37), p. 408] and is defined as the caregiver's proclivity to view the infant as an intentional agent with autonomous mental states. In infancy, MM is assessed using a free-play interaction between the caregiver and the infant, coding the caregiver's comments on the infant's mental states as appropriate vs. non-attuned. Appropriate mind-related comments (AMRCs) refer to the caregiver's correct interpretation of the infant's mental state, whereas non-attuned mind-related comments (NAMRCs) refer to incorrect interpretations. A large number of AMRCs (controlling for overall verbosity) is interpreted as high MM. A large number of NAMRCs is regarded as being less optimal with regard to MM, as it is indicative that caregivers misinterpret the child and are more focused on their own agenda than on the child [e.g., (38)]. AMRCs and NAMRCs are not related to each other (39–42), and are thus regarded as independent scales of the same construct [see also (43)] Beyond infancy, MM is assessed by coding the number of mental attributes the parent uses when asked to describe the child (= interview-measure).

Many studies have demonstrated that the number of the caregiver's AMRCs in the parent-child interaction is predictive of several positive outcomes on the child's side. Examples here are higher attachment security (44–48), better emotion regulation (49, 50), better executive functions (51), higher empathy (52), better theory of mind skills (53–57), and lower rates of behavior problems (58, 59). In contrast, NAMRCs have been identified as a risk factor for the development of behavior problems (60). With regard to attachment security, Meins and colleagues (41) found that both AMCRs and NAMCRs uniquely predicted child attachment security (disorganized vs. organized attachment status). Interestingly, mothers of children with an insecure-resistant attachment style produced more NAMRCs (but not more AMRCs) than mothers of insecure-avoidant children.

Studies with populations in which psychosocial risk factors are present showed heterogenous findings. In an investigation in which mothers had a severe mental illness, Schacht et al. assessed MM and found that mothers with a borderline personality disorder showed lower MM as assessed via the interview measure (i.e., they used proportionally less mental attributes to describe their child) than healthy mothers (61). In a later study, assessing AMRCs and NAMCRs in the mother-child interaction, mentally ill mothers scored lower than healthy mothers for both AMRCs and NAMRCs (62), whereas in another sample, mothers with mental illness only produced more NAMRCs than a healthy control group (62). Investigating MM (using the interview-measure) in a group of parents of children who had been referred to Child Mental Health Service, lower MM (i.e., a lower proportion of mental attributes to describe their child) was found (63), whereas in samples of parents of children with developmental disorders, no differences in MM (also using the interview-measure) were found (64, 65).

Being mind-minded towards an infant diagnosed with a mental health disorder referring to the symptom group of RPs (i.e., crying, sleeping and/or eating disorders) can be very challenging for parents, since signals of those children tend to be equivocal and difficult to read. Also, infants with RPs tend to show more difficult temperamental features, such as fussiness (66) and negative emotionality (28). Moreover, it is well known that high stress, which is common in parents of infants with RPs (2, 25), is likely to lead to a break-down of mentalizing abilities (67). Caregivers of infants with RPs might also be inconsistently attuned to infants, comparable to caregivers of children with a resistant attachment style (41). Since parenting stress (65, 68) as well as infant negative affect (69, 70) have been identified as risk factor of low MM, we supposed that maternal MM would be constrained in mothers of infants with excessive crying, eating and/or sleeping disorders. Specifically, we supposed that mothers of infants with excessive crying/sleeping/eating disorders would use (1) fewer AMRCs, and (2) more NAMRCs compared to a non-clinical control group. Moreover, as further exploratory analyses, we tested the association between maternal MM and the number of infant disorders in the clinical group.

Materials and methods

Study design and sample

The sample of the present study consisted of $N = 108$ children and their mothers. The clinical sample was a sub-sample ($n = 44$) that was drawn from an ongoing study that investigated psychosocial and genetic factors influencing early child mental disorders. Children were inpatients at a socio-paediatric clinic in Germany that is specialized in the treatment of early regulatory

and developmental disorders. Child mental disorders were classified according to axis I of the DC:0-5 (24). The DC: 0-5 is a multiaxial classification system for children aged 0–5 years, and was developed as an attempt to do justice to the complexity of mental disorders in infancy and early childhood The clinical disorders on axis I are complemented by four other axes: relationship context (axis II), physical health and illnesses (axis III), psychosocial stressors (axis IV) and developmental skills (axis V). In the present study, only axis I diagnosis was assessed.

Inclusion criteria for the present study were as follows: (1) Children were 0–18 months old, (2) mothers had good German language competencies and spoke German with their child, (3) children were diagnosed with one or more of the following diagnoses according to DC:0-5: excessive crying disorder, sleeping disorder, eating disorder. A night waking disorder was diagnosed in 30% of the children in the clinical group. On the other hand, 26.67% suffered from a sleep onset disorder. Undereating disorders were diagnosed in 15% of the children, 6.67% fulfilled the criteria of an excessive crying disorder, and 21.87% of the children were diagnosed with "other eating/sleeping/crying disorder". Of the children in the clinical group, 65.9% had one diagnosis, while 34.1% had multiple (more than one) diagnoses. None of the children had a global developmental delay. The mean week of gestation was $M = 37.23$ ($SD = 5.30$). 9 children were born before 37 weeks of gestation. There were no significant differences between children born before and after 37 weeks of gestation in MM within the clinical group [AMRC ($t(41) = 0.23$, $p = .823$, NAMRC ($t(41) = -1.44$, $p = .158$].

The control group ($n = 64$) were participants of a longitudinal study (2007–2017) that investigated social-cognitive development from infancy to childhood [e.g., see (71–73)]. The third measurement point of the longitudinal study (2008) was conducted when children were 12 months old. The results recorded during this measurement point were used in the present study. The families were recruited from public birth records and were mainly from the middle class of an urban area in Germany. A screening for mental health disorders was not conducted with the control group; however, parents were asked to report whether their child had any diagnosed physical or mental disorder, and whether the child received any medical care or therapy. Infants were only included if they were healthy, full-term and did not have any pre- or perinatal complications. Addresses were obtained through local birth records.

The ethics committee of the Technical University of Munich approved of the study (registration number: 2019-34_9-S-SR).

Measures

Maternal MM

Maternal MM (74) was assessed using a videotaped free play interaction in a laboratory setting (control group), respectively in the clinic at the beginning of the hospital stay (clinical group). The duration of the play interaction was 9 min in the control group and $M = 12.37$ min ($SD = 3.27$) in the clinical group. The mothers and their child were seated on a carpet on the floor where age-appropriate toys were provided (e.g., cars, dolls, plush toys, books, toy blocks). Mothers were asked to play with their child as they usually would do at home.

First, all comments that were mind-related were identified. Mind-related comments were defined as any comment that (a) uses an internal state term to comment on the infant's mental states (e.g., talking about desires, emotions, cognitions); or (b) any utterance that is meant to be a dialogue said/thought by the infant (for a more detailed description of the coding, see (39, 75). Mind-related comments were coded as appropriate if the coder agreed with the mother's reading of the infant's current internal state (e.g., the mother says "You want the ball?" while the infant is reaching towards the ball). Furthermore, if the mother clarified how to proceed after a pause in the interaction, her comment was rated as appropriate. Comments linking a current activity with similar events in the past or future were also coded as appropriate (e.g., the mother says "Do you remember our car?" while the infant is playing with a toy car).

Mind-related comments were coded as non-attuned if the mother commented upon the infant's mental state in a non-attuned manner. Five cases in which a mental state comment was coded as non-attuned were described as follows: (a) if the researcher disagreed with the mother's reading of the infant's internal state (e.g., the mother says "You are bored with the ball" while the infant is actively playing with it); (b) if the mother commented on events which were unrelated to the infant's current activity (e.g., without having talked about the grandmother before, the mother says "Do you want to visit granny tomorrow?"); (c) if the mother tried to engage the child in a new activity while the child was actively engaged in something else; (d) if the mother attributed internal states to the infant which were not implied by the infant's behavior, but appeared to be projections of her own internal states (e.g., the mother says "You think about your dad whom you love so much, don't you?"); (e) if maternal comments were made in which the referent was not quite clear, such as "You like that!" when the infant was not attending to any particular object or event.

To control for verbosity, scores for AMRCs as well as NAMRCs were expressed as a proportion of the total number of comments, i.e., all comments (= sentences) regardless whether they contained AMRCS/NAMRCs or not). All the videos were coded by one observer, and 25 percent ($n = 27$) of the videos were coded by another observer using the verbal transcripts of the first coder, but watching the videos again. Cohen's Kappa resulted an average κ value of.70.

MM has been shown to have sufficient construct and predictive validity. For example, the number of AMRCs was found to be positively related to both maternal sensitivity (40, 46, 76) and child attachment security (41, 44). Also, MM has been related to children's developmental outcomes: As an example, the number of AMRCs resulted as a better predictor for later child theory of mind skills than maternal sensitivity (40). Furthermore, there is evidence for temporal stability of NAMRCs (55).

TABLE 1 Comparison of demographic characteristics between groups.

Characteristics	Clinical group ($n = 44$)	Control group ($n = 64$)	p
Maternal age (years), mean (*SD*)	33.04 (4.17)	33.24 (4.37)	.490
Education/qualified for university entrance, %	63.6%	75.0%	.217
Child age (months), mean (*SD*)	9.61 (4.02)	11.63 (.41)	.002**
Child gender, %	45.5%	43.8%	.739
Single child, %	68.3%	65.6%	.570

**$p < .01$, two-tailed significance level.

Statistical analyses

The analyses were conducted using SPSS 29. First, significant group differences between the clinical group and the control group were investigated using *t*-Tests. Intercorrelations between all study variables were conducted in the entire sample. In order to figure out whether there were differences in AMRCs and NAMRCs between the clinical group and the control group, two ANCOVAs with group as factor and child age as covariate were conducted. Since two confirmatory analyses were carried out, *p*-values of the ANCOVAs were adjusted for multiple testing using the Bonferroni-method. Effect sizes were interpretated according to Cohen (77) ($\eta^2_{part.} = 0.01$ = small, $\eta^2_{part.} = 0.06$ = medium, $\eta^2_{part.} = 0.14$ = large effect). In the clinical group, further exploratory analyses (correlations) between MM and number of child diagnoses were conducted.

Results

Descriptive analyses

Firstly, the two groups were compared with regard to their demographic characteristics. Significant group differences only emerged with regard to child age (see Table 1); thus, child age was included as a covariate in further inferential analyses.

The descriptives of maternal MM are depicted in Table 2. The number of both AMRCs and NAMRCs were calculated as weighted scores, dividing the number of AMRCs and NAMRCs through the total number of comments.

Intercorrelations of the study variables (demographic characteristics, AMRCs and NAMRCs) were carried out using the entire sample ($N = 108$) (Table 3).

TABLE 2 Frequencies of total comments and mind-mindedness comments, as well as frequencies of mind-mindedness comments weighted by total comments.

	Clinical group ($n = 44$)		Control group ($n = 64$)	
	Mean (SD)	Range	Mean (SD)	Range
Total Comments	81.45 (42.45)	15–203	103.36 (34.97)	18–181
AMRCs	5.18 (4.67)	1–23	4.19 (4.08)	0–17
NAMRCs	1.18 (1.60)	0–6	0.59 (1.08)	0–5
Weighted AMRCs	0.07 (0.04)	0.01–0.21	0.04 (0.03)	0.00–0.11
Weighted NAMRCs	0.02 (0.02)	0.00–0.10	0.00 (0.01)	0.00–0.03

TABLE 3 Intercorrelations among the study variables ($N = 108$).

Variables	1	2	3	4	5	6	7
1. AMRCs	–						
2. NAMRCs	.09	–					
3. Maternal education	.02	.09	–				
4. Child gender	−.02	−.06	−.07	–			
5. Child age	−.45***	−.16	−.03	.09	–		
6. Maternal age	.03	−.04	−.02	.02	.06	–	
7. Single child	.01	−.06	−.05	.04	.01	−.29*	–

*$p < .05$, ***$p < .001$, two-tailed significance level; AMRCs and NAMRCs are weighted scores.

Inferential analyses

Two ANCOVAs with group (clinical/nonclinical) as factor and (1) AMRCs as well as (2) NAMRCs as dependent variables and child age as a covariate were calculated. Results showed that mothers in the clinical group produced significantly more AMRCs, $F(1, 105) = 6.16$, $p_{Bonferroni} = .029$, $\eta^2_{part.} = .06$, as well as more NAMRCs, $F(1, 105) = 9.20$ $p_{Bonferroni} = .006$, $\eta^2_{part.} = .08$, than the control group (see Figure 1). Given our sample size of $N = 108$, these effect sizes can achieve a power of 0.73 and 0.82 respectively.

Further exploratory analyses between maternal MM and the number of child disorders (single vs. multiple disorders) within the clinical group showed a significant positive correlation between NAMRCs and the number of child disorders, $r = .338$ ($p = .025$), whereas the number of AMRCs were not significantly related to the number of disorders ($r = -.233$, $p = .128$).

Discussion

The present study is the first study to investigate maternal MM in a group of infants with mental health disorders and to apply the DC:0-5 in order to diagnose excessive crying, sleeping, and eating disorders (Table 4). In the study, maternal MM in mothers of infants with excessive crying, sleeping and/or eating disorders were compared to maternal MM in a nonclinical control group. We supposed that mothers in the clinical group would use less AMCRs and more NAMCRs than mothers of the control group.

Regarding the descriptive results, correlational analyses revealed that infant age was negatively associated with AMCRs.

TABLE 4 Frequency and percentages of diagnoses.

Diagnosis	Frequency	%
Sleep onset disorder	16	25.81
Night waking disorder	18	29.03
Undereating disorder	9	14.52
Exzessive crying	4	6.45
Other crying/sleeping/eating disorders		
Other sleeping disorders	6	9.68
Other eating disorders	8	12.90
Other crying disorders	1	1.61

Multiple selection of different diagnoses possible.

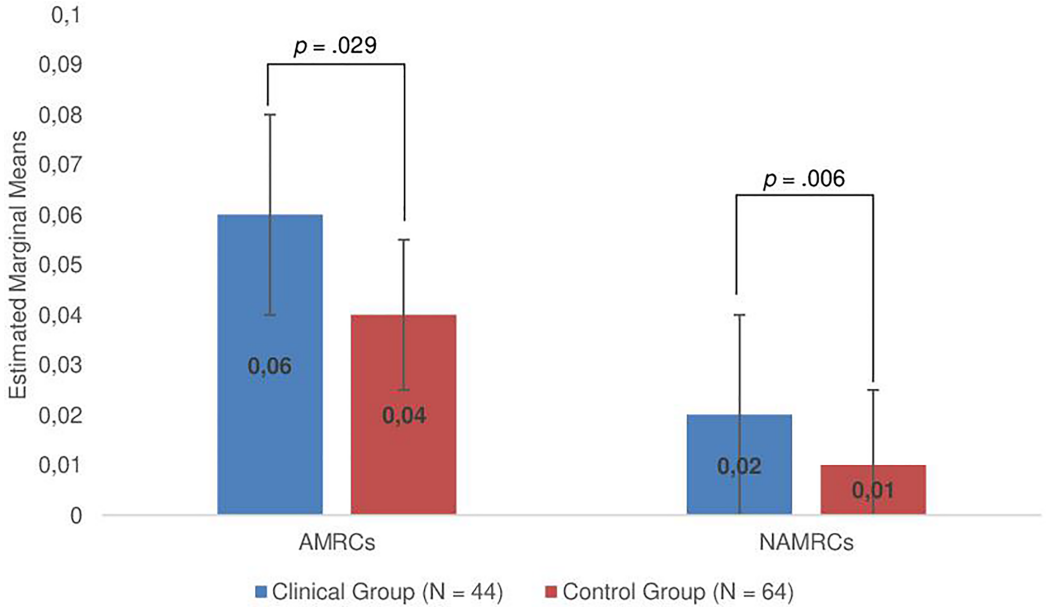

FIGURE 1
Group differences regarding maternal MM (controlling for child age; error bars show standard errors); *$p < .05$, **$p < .01$, two-tailed significance level. AMRCs (appropriate mind-related comments) and NAMRCs (non-attuned mind-related comments) are weighted scores. *P*-values were adjusted using the Bonferroni-method.

This might indicate that with growing age, children's mental states become harder to read, likely because their theory of mind further develops (78), and when they begin to walk, their social world becomes increasingly larger (79). However, these results should not be overstated due to the exploratory character of the analyses.

Inferential analyses showed that mothers in the clinical group used both more AMRCs as well as more NAMRCs than the control group, with a moderate effect size. This result was surprising as we expected mothers to make less AMRCs instead of more AMRCs. It indicates that parents of infants with excessive crying, sleeping and/or eating disorders do not lose their interest, but rather have a high propensity to comment on their infant's mental states—which is likely to happen as a result of repeated experiences of unsuccessful attunement. In fact, they tend to use lots of mind-related comments, probably as desperate attempts to make sense of their child's equivocal signals. This is comparable to hyper-mentalizing (i.e., the tendency to excessively try to make sense of behaviors, often leading to misinterpretations of others' mental states), which is also regarded as low reflective functioning (80). The results of this study are thus to a certain extent in line with studies reporting lower MM as well as lower reflective functioning in parents of children with mental health problems (63, 81, 82). Specifically, our findings are to a certain extent in line with Georg et al. who found more pre-mentalizing in mothers of infants with regulatory problems (36). Pre-mentalizing isn't directly comparable to the MM coding, as MM doesn't assess if mother's comments are hostile. Pre-mentalizing means that parents don't see infants' behavior as an expression of their mental states, and thus view it as hostile vs. that they mentalize but misinterpret their child's mental states. However, what often follows from pre-mentalizing is that parents attribute the wrong intentions to the child which is comparable to some types of NAMCRs. Our results also fit to Meins et al.'s (56) finding that mothers of infants with an insecure-resistant attachment style produce more NAMRCs than mothers of infants with an insecure-avoidant attachment style: Mothers of so-called "difficult" children (i.e., children with an insecure-ambivalent attachment style and/or children with a regulatory disorder) seem to have the tendency to refer a lot to the child's mental states, but often misinterpret their child's signals. Thus, consistently taking the child's perspective seems to be much more difficult for parents having a "difficult to read"-child with a mental health disorder/regulatory disorder.

Further exploratory analyses showed that the number of child disorders was related to more NAMRCs, indicating that severity of the child's mental illness is associated with a greater probability to misinterpret the child's mental states. It might be that parents of an infant with excessive crying or/and sleeping/eating disorders, in some instances, tend to interpret the infant's signals as being intentional and hostile against the parent since they are not successful in soothing or nurturing their baby. This experience can, in turn, lead to high stress levels, feelings of guilt, but also aggression (83, 84). In the case of high stress, reflective functioning in the context of relationships tends to break down, leading to more pre-mentalizing modes (85).

In sum, the present study supports theories on parental reflective functioning [e.g., (85)]. It shows that maternal MM can be rather inconsistent (both appropriate and non-attuned) in the context of infant mental health disorders/regulatory disorders. This could be the starting point of a vicious circle in the

parent-child interaction (2, 86) and enhance the risk of negative sequel with regard to child development (13, 16). However, both directions of effects seem reasonable. Parents may be more inconsistent in MM as a result of the child's difficulties/disorder, or inconsistent MM may influence child difficulties/disorder. This unanswered question should be investigated in depth by applying a longitudinal design beginning ideally directly after childbirth.

Following up on Bilgin and Wolke's (87) findings that there were no reciprocal relations between infant regulatory problems and maternal sensitivity, it might be that the production of many AMRCs compensates for many NAMRCs. This would implicate that using many NAMRCs does not necessarily lead to lower sensitivity, given that mothers use more AMRCs at the same time. This hypothesis should be tested in subsequent studies.

Strengths and limitations

This is one of the first studies to use the DC:0-5 for diagnosing mental health disorders in infancy. Furthermore, this is the first study using the observational measure of MM in the context of infant mental health disorders. Thus, a strength of the study is the exclusive use of objective measures, which are known to be more valid than self-report measures [e.g., (88)].

The study also has some limitations. First, mental health status was not assessed via a diagnostic tool in the control group. Thus, it cannot be ruled out completely that mental health disorders were also present in the control group. Another limitation is that both participants of the clinical as well as the control group were rather highly educated, which limits generalizability of the results. Furthermore, whereas the control group was assessed in 2008, the clinical group was recruited from 2020 to 2023. Thus, it cannot be ruled out that the assessment of the two groups in different decades might have affected our results. Even if research doesn't report any significant changes in means of MM across mothers born in different decades, the study should be replicated with mothers raising their kids in the same decade. Also, causal conclusions may not be drawn from our findings due to the cross-sectional design of the study. As mentioned above, future studies should use a longitudinal design with several measurement points in order to rule out the direction of effects.

Implications for clinical practice

Our findings have important implications for intervention. As prior research has shown that maternal MM can be regarded as prerequisite for sensitivity (44), and is a predictor of child secure attachment (40), it is worth focusing on the improvement of MM in the treatment of excessive crying, sleeping, and eating disorders. Our results indicate that especially parents who have a child with multiple disorders need help urgently. Early intervention in the context of severe RPs targeting toward strengthening the parent-child relationship is crucial in order to prevent negative developmental pathways (89). One intervention that focuses explicitly on parental reflective functioning is "Minding the Baby" [MTB, (82)]. MTB is an attachment-based, interdisciplinary home visiting intervention, aiming at the promotion of parental reflective functioning from pregnancy onward. It includes integrating elements of infant–parent psychotherapy, adult psychotherapy, family/couple counseling as well as concrete support of the parent. Slade et al. demonstrated the effectiveness of the intervention (82). The authors showed that reflective functioning was more likely to increase over the course of the intervention in mothers of the intervention group compared to mothers of the control group, and that infants of the intervention group were more likely to show secure attachment. Furthermore, video intervention therapy [VIT, (90)] is a well-established and widely used intervention in the treatment of infant regulatory disorders [see also (3)]. Thus, a combination of a mentalization based approach together with interventions targeting at enhancing maternal sensitivity also on a behavioral level (e.g., through video feedback) might be a very helpful approach in the context of early regulatory disorders. Further research is needed to evaluate the effectiveness of concrete intervention strategies in the context of early regulatory disorders.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The study was approved by the ethical commission of the Technical University Munich. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin.

Author contributions

ML-D: Conceptualization, Formal Analysis, Investigation, Methodology, Supervision, Writing – original draft. SK-A: Writing – review & editing. SM: Writing – review & editing, Data curation, Formal Analysis, Writing – original draft. VM: Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Translation, cross-cultural adaptation and validation of the universal Welch Emotional Connection Screen using primary and bilingual Spanish-speaking coders of videotaped mother-child interactions

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Introduction: Using clear explicit translatable language, we translated the Welch Emotional Connection Screen into a new universal language instrument, the *English uWECS*. In this study, we had two aims: Aim 1 was to establish *concurrent validity* of the uWECS by comparing scores coded by primary Spanish-speaking coders using the Spanish translation of the uWECS to scores coded by bilingual, secondary Spanish-speaking coders using the oWECS. Aim 2 was to establish the *criterion-related validity* in terms of oWECS and uWECS performance in tracking change in autonomic emotional connection (AEC) during the course of an intervention among preschool aged children.

Methods: We created a library of 52 five-minute Spanish-speaking mother-child videos that were collected during a randomized controlled trial of Mother-Child Emotional Preparation intervention (MCEP). The videos were collected at two time points, at enrollment and at a 6-month follow-up. The subsample of Primary Spanish-Speaking dyads from the MCEP study were coded by two independent teams of coders. We trained primary English-speaking (bilingual Spanish) coders on the oWECS, using the original training program. A different team of primary Spanish-speaking coders coded the same cases using the novel uWECS guide and trained briefly for reliability with the Spanish uWECS translation materials.

Results: We found that the Spanish oWECS and Spanish uWECS ratings from the baseline and 6-month follow-up observations were robustly correlated, with intraclass correlations ranging from .81 to .84 and all p-values<.001, thus demonstrating sound concurrent validity for the uWECS. The oWECS and uWECS scores also achieved parallel results when evaluating the efficacy of the MCEP for primary Spanish-speaking dyads. Both the AEC scores of the oWECS [$F(1, 27) = 4.31$, $p < .05$] and the scores of the uWECS [$F(1,27) = 4.06$, $p < .05$] similarly demonstrated significant change post intervention, thus demonstrating sound criterion-related validity of the uWECS.

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Discussion: These findings demonstrate that the uWECS can be used to measure parent/child AEC in linguistically diverse populations and cultures.

KEYWORDS

emotional behavior, screening tool, translatability, emotional connection, mother-child interaction, videotape assessment

Introduction

Research focusing exclusively on translation of observational methodologies for use by linguistically diverse populations is scarce. However, cross-cultural validation of observational methods is necessary to validate the construct being coded. Only if the instrument itself is readily translatable, is it possible to determine whether the measure is capturing the same central construct in a way that is applicable, meaningful, and relevant across cultures and languages (1). Some self-reported health status measures have been adapted for use in languages other than the source language (2). However, the cross-cultural adaptation process is also important when an instrument is used in a different language/setting/time to reduce the risk of introducing bias into a study (3). Research questionnaires are not always translated appropriately before they are used in new temporal, cultural or linguistic settings (4). The results based on such instruments may therefore not accurately reflect the central constructs they are designed to measure.

In recent years, efforts have been made to translate and adapt Western assessment tools that measure emotional constructs for use in diverse languages and cultures, e.g., tools that assess a child's psychological self-regulation of emotions, or the child's ability to identify and manage their emotions and feelings (5, 6). The same attention has not been paid to the translation of observational methodologies used to rate mutual emotional constructs between parents and young children. However, one recent study demonstrates the importance and challenges involved in doing so. Schneider and colleagues coded the quality of mother-child interaction to validate the Responsive Interaction for Learning (RILF) measure for use with Brazilian families (7). This study applied back-translation (English to Portuguese, and back again to English) before training primary or exclusively Portuguese-speaking coders to ensure the cultural and linguistic validity of the coding. This back-translation approach revealed that some terms did not clearly translate (e.g., "mind reading") and scaling and descriptive anchors were not relevant as written (e.g., 3 items were reworded and scaling changed/extended). These issues were resolved by modifying the RILF, in order to make it relevant for Portuguese coders—resulting in a validated Portuguese version of the measure, the RILF-P (7). Importantly, the same labor-intensive procedure would need to be followed for adapting the RILF to other languages.

The uWECS overcomes this issue with o*ne core translation of the instrument*—i.e., translating the WECS into Clear, Explicit, Translatable Language (CETL); (8) to assess the behavioral indicators of autonomic emotional connection between mother and child. Autonomic emotional connection (AEC) is a construct that describes the emotional behaviors of mother and baby that are triggered by the autonomic nervous system. Based upon clinical observations of parents and children from diverse cultures speaking multiple languages, we created a novel assessment tool, the original English Welch Emotional Connection Screen (oWECS) to assess the AEC construct. The idea behind the oWECS was that the AEC construct itself was intuitive and common to all cultures and therefore language should not be a barrier. The primary language of the oWECS authors was English and the instrument was validated in English using conventional psychometric measures in English (9). The English oWECS assessment form consists of four behavioral subscales: Attraction, Vocal Communication, Facial Communication and Sensitivity-Reciprocity, along with a maximum of four very simple and user-friendly English descriptors to help the coder determine a score for each subscale domain (See Figure 1). Training on the oWECS included viewing a webinar in English and rating a set of training videos of English-speaking mother-child dyads. Trainees typically took a few weeks to achieve reliability and then advanced to using the oWECS in their research or clinical practice.

In the course of oWECS trainings and usage, it turned out that the simple English descriptors on the oWECS form led to interpretive and semantic confusion for both native and non-native English speakers, as well as for coders with different levels of education. A collaboration between author Welch and authors Vanhatalo and Goddard, who are experts in the field of natural semantic metalanguage (10, 11) led to creation of a version of the oWECS that was linguistically accessible to users across cultures, the Universal WECS (uWECS) (See Figure 2) (8). In so doing, the team utilized ~65 so-called semantic primes, words that can be translated into any known language and retain their semantic representation, and that are unable to be defined using simpler terms. For example, while the term "mutual gaze" is not directly translatable into every language. Hence mutual gaze in the oWECS is written as "mother often looks at child's face; at the same time child looks at the mother's face" in uWECS.

Recently, in partnership with the Children's Learning Centers of Fairfield County (CLC), we completed a randomized controlled trial (RCT) of Mother-Child Emotional Preparation intervention (MCEP) (ClinicalTrials.gov Identifier: NCT03442439). CLC is a leading community-based pre-school education program serving ~1,000 diverse families annually in Stamford, CT. The trial compared a group of children receiving CLC's standard curriculum with a group receiving standard curriculum plus MCEP. The school teaches emotional literacy (i.e., seeks to increase children's "emotional intelligence") through the Yale RULER curriculum, with an emphasis on English and Spanish. However, reaching all students is a challenge, since CLC students

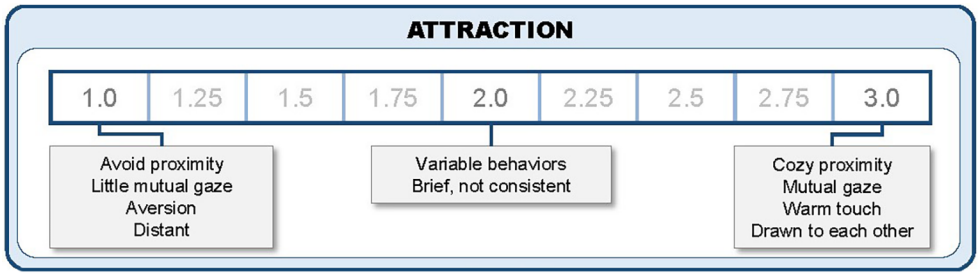

FIGURE 1
The original English version of the welch emotional connection screen (oWECS).

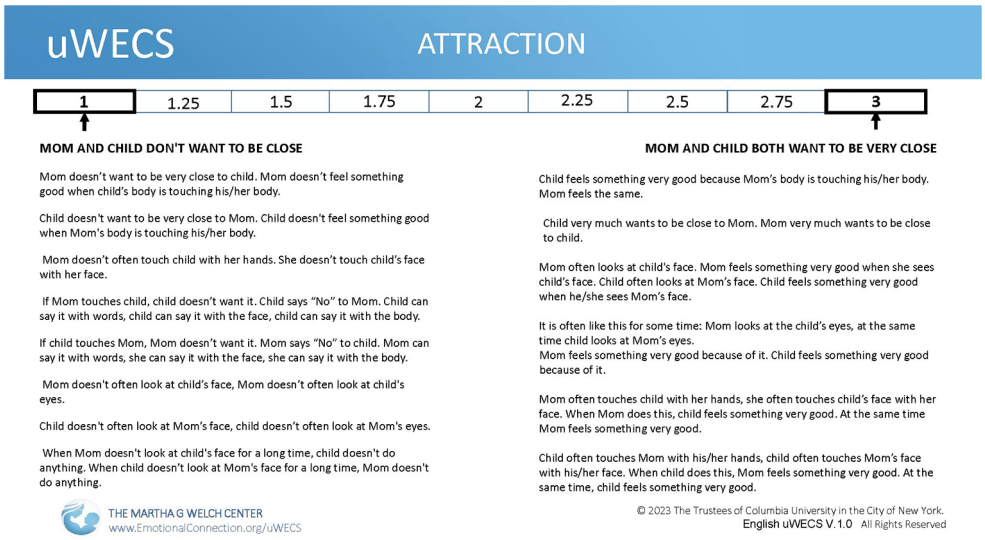

FIGURE 2
The English version of the universal welch emotional connection screen (uWECS) score sheet. Shown is the Attraction subscale with descriptors in clear, explicit translatable language. The idea behind the universal assessment tool is that the descriptors can easily be translated into any language and that by themselves the descriptors provide sufficient information to the observer that no additional training is necessary.

come from as many as 30 different countries. MCEP is different from the RULER program in that it aims to increase the child's regulatory capacity by fostering AEC *with the parent*, as opposed to emotional intelligence of the child. The primary outcome of the RCT was AEC, as measured by the oWECS. In a separate publication (see Welch et al. in this special collection (12), we report that MCEP significantly improved AEC, as well as behavior regulation in the classroom and in the home.

In this paper, we use data from the MCEP RCT to validate the uWECS. We used videotaped interactions between mother-child subjects who were primary Spanish speaking to code the uWECS and who were blinded to the coding of the oWECS, which was coded by bilingual, primary English/secondary Spanish speaking coders. In doing so, we sought to demonstrate that the Spanish translation of the uWECS, when coded by Primary Spanish-Speaking coders, would yield results similar to the oWECS, when coded by coders who had access to much more elaborate behavioral descriptors written in English.

We had two aims: (1) to demonstrate *concurrent validity* of the Spanish uWECS, by having primary Spanish speaking coders (Spanish^{P}) code the Spanish uWECS, compared with original oWECS coding by bilingual English^{P}/^{S}Spanish coders as presented in the MCEP efficacy study (12) and; (2) to demonstrate *criterion-related validity* by examining whether the uWECS ratings performed similarity to the oWECS ratings in evaluating the efficacy of the MCEP for only those dyads who spoke Spanish throughout the study (i.e., in the intervention sessions and in the observations filmed for research purposes). We hypothesized that the Spanish uWECS would: (1) achieve concurrent validity with the oWECS and (2) demonstrate criterion-related validity with oWECS vis-à-vis similar demonstration of the efficacy of the MCEP program.

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Methods

Mother-child emotion preparation (MCEP) trial

Mother-Child Emotion Preparation (MCEP) is a preschool mother-child intervention aimed at improving mutual emotion expression and autonomic emotional connection (AEC) between mother and child in a culturally and linguistically diverse sample. MCEP is a *culturally competent* program, in the sense that it encourages mothers to communicate when possible in the mother's primary language (e.g., the language spoken to the mother when she was a child). We conducted a randomized-controlled trial of MCEP together with Children's Learning Centers of Fairfield County in Stamford, CT, (CLC) a community-based preschool education center. Mothers signed a consent form at the time of the baseline assessment and randomized to either a standard CLC curriculum group (SC) or a SC plus MCEP intervention group (MCEP). See Welch et al. (12), for a full description of the MCEP study.

Mother-child dyads randomized to the MCEP group received facilitated MCEP calming sessions in a group setting (4 to 8 mother-child pairs per group). Two specially trained *Nurture Specialists (NSs)*, both licensed clinical social workers, facilitated the parent-child intervention and provided emotional support during sessions. Each mother-child dyad participated in two to eight two-hour group sessions over sixteen weeks, which took place in a classroom or small meeting room at CLC. Calming sessions consisted of a child sitting on the mother's lap and cycling through a range of verbal and non-verbal emotional expression. This communication typically dealt with current or past upsets or other previously unprocessed feelings. A successful calming session included mother and child expressing a full range of emotions, including discomfort and distress, conflict and upset, conflict resolution and mutual calm. See (12) for a full description of the MCEP sample and procedure.

The efficacy of the MCEP across the full RCT sample has been demonstrated and includes increased mother-child emotional connection, reduced behavior problems as per teacher and parent report (12) and healthier autonomic responding to stress in children (13).

Subjects

Children were eligible for the study if they were between 2 and 4.5 years of age at the recruitment date. In addition, the child had to be a singleton without genetic or congenital disorder or motor disability. Mothers had to be at least 18 years old, able to speak, read and write in English or Spanish; and be living with her child full-time. Mothers were excluded for severe mental illness or any other medical conditions preventing play activities; involvement with the Department of Children and Families; struggling with drug or alcohol abuse; pregnancy (second or third trimester) that could interfere with the lap-based procedures (see below); and if they were unable to commit to the study schedule.

More than half of families enrolled in the MCEP trial identified as Latinx, first-generation immigrants who spoke Spanish at home. This subgroup was bilingual, with Spanish being the primary language spoken and English being a second language.

From the subjects in the trial, we selected the sub-cohort of 52 primary Spanish-speaking dyads (See Table 1). There were two language groups at the time of enrollment, one whose primary language was Spanish and one whose primary speaking language was English. The two groups do not differ significantly from one another on these demographics (all p-values > .10). While 50% of

TABLE 1 Demographics of participants at time of enrollment.

	Primary Spanish speaking	Primary English speaking
	n = 52	*n* = 38
Age at enrollment	Mean ± SD	Mean ± SD
Mothers' age (years)	33.65 (4.79)	35.11 (5.24)
Child	3.9 (.39)	3.65 (.51)
Sex of child		
Male	26 (50.0)	23 (60.5)
Female	26 (50.0)	15 (39.5)
	n (%)	*n* (%)
Ethnicity of mother		
Hispanic	52 (100)	19 (50)
Non-Hispanic	0	19 (50)
Race of mother		
White	9 (17.3)	11 (28.9)
Black	0	7 (18.4)
Asian	0	4 (10.5)
Hawaiian/Pacific Islander	0	1 (2.6)
Indigenous	0	1 (2.6)
Other/not Reported	43 (82.7)	14 (36.8)
Mother relationship status		
Single	8 (15.4)	11 (28.9)
Married	23 (44.2)	22 (57.9)
Partner/Cohabitating	12 (23.1)	1 (2.6)
Partner/living Apart	3 (5.8)	0
Separated	5 (9.6)	2 (5.3)
Divorced	0	2 (5.3)
Not Reported	1 (1.9)	0
Mothers' education		
Some schooling	14 (26.9)	7 (18.4)
High school or GED	18 (34.6)	13 (34.2)
Some college or associate's	11 (21.2)	6 (15.8)
Bachelor's and/or graduate degree	8 (15.4)	10 (26.4)
Unknown	1 (1.9)	2 (5.3)
Mothers' employment		
Employed	30 (57.7)	20 (52.6)
Unemployed	21 (40.4)	17 (44.7)
Unknown	1 (1.9)	2 (5.3)
State/federal assistance		
Receive assistance	28 (53.8)	20 (52.6)
Do not receive assistance	18 (34.6)	14 (39.5)
Unknown	6 (11.5)	3 (7.9)

the English-speaking subsample identified as Hispanic, those mothers reported English as their primary language spoken at home and hence were not in the sub-cohort used for the present study. Spanish-speaking mothers identified as Hispanic, and the large majority did not report their race, perhaps due to the lack of breadth in the demographic categories provided. Due to Covid-related school closures, there was a higher than anticipated attrition at the 6-month follow-up visit (See (12). Of the 52 Spanish-speaking families at the time of enrollment, 31 returned, representing 40.4% attrition from school closure. Those who did not return did not significantly differ from those who did, with all *p*-values on key demographics >.10.

Assessment tools

Original welch emotional connection screen [oWECS; (9)]

The primary outcome for the MCEP trial was *autonomic emotional connection* (AEC), as assessed on the original *Welch Emotional Connection Screen (oWECS)* (9). The Lap-Check test is designed to capture the behavioral indicators of the AEC construct (see Figure 3), including the concomitant physiology (13), both of which are associated with the mother and infant/child *autonomic socioemotional reflex* (*ASR*) (14).

The oWECS rates mother-child AEC on four modality subscales: mutual *Attraction*, *Vocal Communication*, *Facial Communication, Mutual Sensitivity and Reciprocity* (see Figure 2). Each WECS dimension is rated on a 9-point scale, with scale anchors tied to behavioral descriptions at 1 (low), 2 (variable/mixed), and 3 (high). Scale ranges include.25 increments between each anchor (i.e., **1**, 1.25, 1.5, 1.75, **2**, 2.25, 2.5, 2.75, **3**). A high score on each dimension indicates that the dyad is emotionally connected via this modality. For this study, these four-dimensional WECS scores were averaged to create a composite AEC score that aligns with this scaling for interpretation—e.g., an oWECS score of 1–1.5 is low; 1.75–2.25 mid-range; and 2.5–3 high on AEC.

Mother-child AEC was assessed at baseline (i.e., enrollment) and 6-months following enrollment during a brief (5 min) emotional exchange known as the *Welch Orienting Lap Check* (12). During the Lap Check, mothers sat with their child on their lap in a face-to-face position and engaged with their child as they usually would for 5 min. There were no toys, food items, drinks, electronic devices, books or other objects of distraction in the room. Electrocardiogram (ECG) recordings were acquired from mother and child during this observation (for ECG results, see Myers et al., under review).

Universal welch emotional connection screen (uWECS)

The oWECS coding instrument was translated using Clear, Explicit, Translatable Language (CETL) (See Figure 3) to provide global access to the WECS and for any language speaker and for varying literacy levels of coders (8). In addition to increasing accessibility of measurement of AEC globally, the uWECS also opens the door for valid assessment of parent-infant/child interactions that are key to evaluating the efficacy of early relational health interventions in diverse samples such as was done with MCEP. CETL language is a derivative of Natural Semantic Metalanguage (NSM) (10, 15), or a lexicon of words identified by linguists to be translatable into any language globally (16).

For this study, the uWECS was translated into Spanish by a NAATI (National Accreditation Authority for Translators and Interpreters: https://www.naati.com.au/) certified translator linguist, who we used to ensure the highest professional translation standard. Of note, the professional translation did not differ from the translation completed by a Primary Spanish-speaking social worker and a Spanish-speaking undergraduate

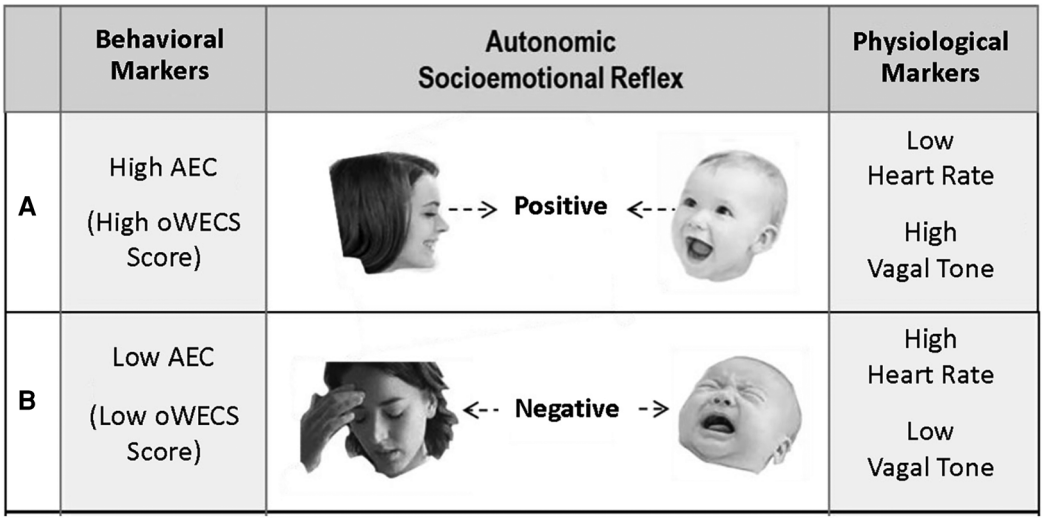

FIGURE 3
Schematic showing the opposite behavioral and physiological markers associated with the autonomic socioemotional reflex. Note that the hypothesized correlation between autonomic emotional connection (AEC) markers as assessed by the oWECS behavioral scores and physiological markers as assessed by heart rate and vagal tone.

research assistant. In all three cases the translation of uWECS was additionally verified by back-translation with no words lost/altered. Professionally translated uWECS in Arabic, Chinese (Mandarin), English, Finnish, German, Italian, Polish, Russian, Spanish, Turkish are available for download at www.emotionalconnection.org.

Statistical approach

This study had two aims. The first aim was to examine the concurrent validity of the Spanish uWECS. We hypothesized that the scores would be highly correlated. To test this hypothesis, we computed intraclass correlations (ICC); vs. Simple Pearson correlations. The ICC is calculated by determining both the linear trend and the similarity in mean values of the ratings of coders. The ICC is hence more conservative and appropriate for determining the reliability of observational coding with continuous/scaled measurement. Our second aim was to examine the criterion-related validity of the uWECS. We computed two ANOVA's to assess the significance of the MCEP and control groups on the oWECS and the uWECS. We hypothesized that the overall AEC scores on Spanish uWECS in the current study would demonstrate efficacy of the MCEP RCT (12) similar to the oWECS scores.

Coding

All videos were selected from the MCEP RCT on the basis of language spoken in the observations (see Welch et al., 2023 this edition) (See Table 2).

In Part 1 of the concurrent validity study, coders using the English oWECS were trained to reliability by the first author, a primary English-speaking trainer, using a slide presentation and a practice set of videos of mother-child dyads with a wide range of AEC scores. A team of six coders achieved reliability on the training set of the English oWECS in 2–3 weeks. Those coders trained on the oWECS training set then went on to achieve interrater reliability on 20% of the full MCEP sample. This training and coding were completed remotely (i.e., over Zoom) in the Spring of 2020 and supervised by the first author.

In Part 2 of the concurrent validity study, two coders using the Spanish uWECS were given a simple introduction to the concept of autonomic emotional connection (AEC) by the first author. Coders then achieved reliability on the uWECS working independently with the uWECS-Spanish prompts. Training, reliability and coding on the uWECS was completed in 2024 at Williams College under the supervision of the first author.

In Part 1 of the concurrent validity study, the lap-check videos of primary English- speaking dyads were recorded in English and the Spanish speaking dyads were recorded in Spanish. All videos in Part 1 were coded by a team of six primary English-speaking coders, half of whom were bilingual and fluent in Spanish as a second language. oWECS Coders achieved reliability on 16 cases from the MCEP sample. The average intra-class correlation coefficients for each dimension of the WECS pooled across coders were as follows: Attraction = 0.93, Vocal = 0.93, Facial = 0.95, Sensitivity/Reciprocity = 0.94. Coding was then completed by the reliable coders, with no coding of the same case twice (i.e., if a coder A coded baseline, then coder B coded the 6-month follow-up for that dyad). All coders were blind to all other study data.

In Part 2 of the study, two primary Spanish speaking coders trained exclusively together on the Spanish uWECS and achieved interrater reliability across 16 cases coded independently and in duplicate. ICC ratings were as follows: Attraction: .879; Vocal .978, Facial: .950; Sensitivity/Reciprocity: .953. Coding was then completed by the reliable coders, with no coding of the same case twice (i.e., if a coder A coded baseline, then coder B coded the 6-month follow-up for that dyad). All coders were blind to all other study data.

Results

Aim 1: concurrent validity of the uWECS

We examined concurrent validity of the uWECS by comparing the subscales and overall AEC scores on the the English oWECS (See Table 3).

Results showed that MCEP significantly improved AEC for primary Spanish speaking dyads when rated with the English oWECS *and* the Spanish uWECS. Results support the concurrent validity of the uWECS.

TABLE 2 Concurrent validity study coding details.

	Part 1 English oWECS (12)				Part 2 Spanish uWECS (www.emotionalconnection.org)	
	Lapcheck VIDEOS primary Spanish	Lapcheck VIDEOS primary English	CODERS primary English		Lapcheck VIDEOS primary Spanish	CODERS primary Spanish
Baseline	$n = 52$ (56%)	$n = 39$ (44%)	$n = 91$ (100%)	Baseline	$n = 52$ (56%)	$n = 52$ (100%)
6 months	$n = 31$ (46%)	$n = 36$ (54%)	$n = 67$ (100%)	6 months	$n = 31$ (46%)	$n = 31$ (100%)

MCEP was facilitated in Spanish and in English. At baseline, 56% of the dyads were primary Spanish speaking and were faciliated by primary Spanish speaking therapist. 42% of the dyads were primary English speaking facilitated in English. For the first part of our coding study, Spanish and English videos were coded by primary English speakers and English videos were coded by primary English speakers. For the second coding study, Spanish videos were coded by primary Spanish coders. (See Table 3 for pooled intraclass correlations).

TABLE 3 Pooled intraclass correlations between the English oWECS and the Spanish uWECS scores at baseline and six months post-enrollment.

Subscales	Intraclass correlation coefficient (ICC)
Attraction	.81*
Vocal communication	.82*
Facial communication	.84*
Sensitivity/reciprocity	.81*
Average emotional connection score	.86*

oWECS, original welch emotional connection screen (9); uWECS, universal welch emotional connection screen (8); MCEP, mother-child emotional preparation program.
*$p < .001$.

Note that Table 3 shows the intraclass correlations between English oWECS and Spanish uWECS pooled across the baseline and 6-month post-enrollment observations. The associations are robust, ranging from .81 to .84, with the composite average scores on both instruments achieving an ICC of.86. All values are significant at $p < .001$. Agreement between the ratings from blinded, independent teams of coders on the English oWECS and the Spanish uWECS demonstrate sound concurrent validity of the uWECS.

The validity of the uWECS opens the door for researchers across the globe to use the instrument for research or clinical practice without linguistic barriers for the coder.

Aim 2: criterion-related validity of the uWECS

We examined criterion-related validity of the uWECS by comparing overall AEC scores on the English oWECS and Spanish uWECS. First, two ANOVAs were computed to examine the MCEP sub group and control group differences at baseline and six months post-enrollment on English oWECS and Spanish uWECS scores. As expected, given random assignment, there were no significant differences at baseline between scores. However, at 6-month follow-up, controlling for baseline scores, analyses of covariance (ANCOVA's) performed on the English oWECS and Spanish uWECS data revealed that the MCEP group showed the same significant improvement in AEC on both instruments: English oWECS, $F(1, 27) = 4.31$, $p < .05$, $\eta_p^2 = .14$; and Spanish uWECS, $F(1, 27) = 4.06$, $p < .05$, $\eta_p^2 = .13$ (Figure 4). These similar results in evaluation of the AEC construct on the two instruments support criterion-related validity of the uWECS.

Discussion

In this study, we demonstrated both concurrent and criterion-related validity of the uWECS (8), a universally translatable version of the original Welch Emotional Connection Screen (oWECS) (9). Findings mark an important advance in the field of early intervention by demonstrating the value in applying assessment tools that work effectively and equally across cultures and languages to interventions that may (or may not) be competent across cultures and languages.

Results of this validation study indicate that nothing is "*lost in translation*" by minimizing grammatical complexity, word choice, and literacy level in the creation of the uWECS instrument. The

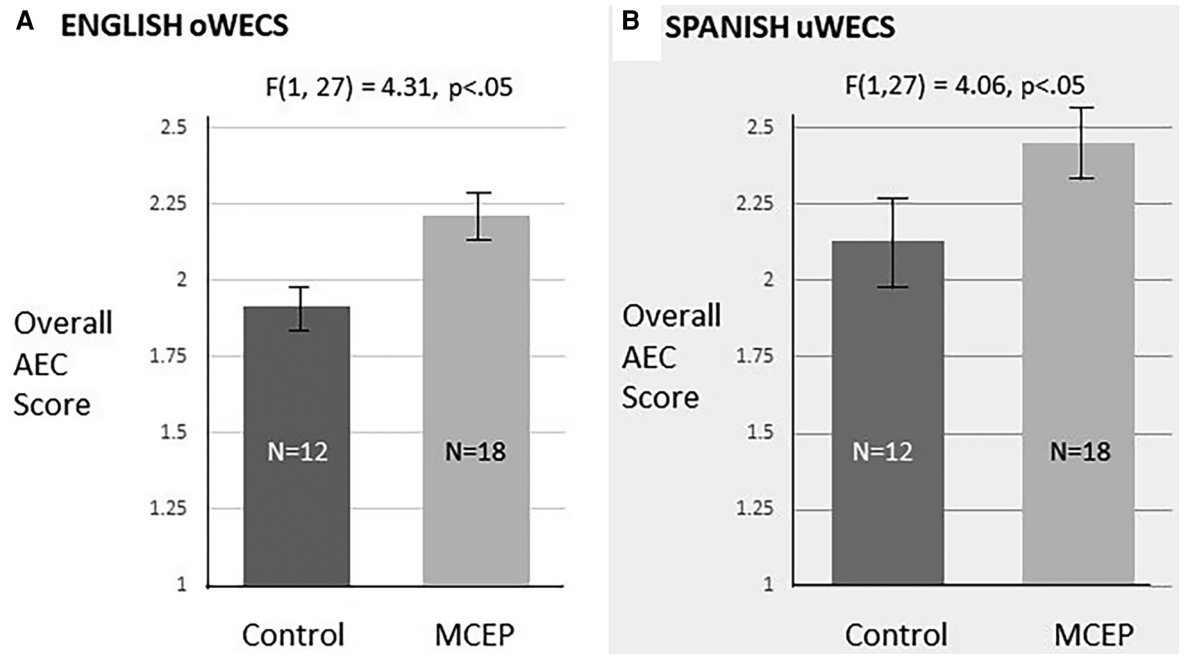

FIGURE 4
Graphs showing average overall autonomic emotional connection (AEC) scores on the English oWECS and spanish uWECS at 6 months post enrollment. (A) The English oWECS was coded by primary English speaking coders trained to reliability via a traditional method. (B) The Spanish uWECS was coded by primary Spanish speaking coders using only the uWECS form with little training. Note that both codings showed significant increase in overall emotional connection scores. The Spanish uWECS results were very similar to the English oWECS results. These results confirm Aim 2 of the study by establishing criterion-related validity of the uWECS. Both analyses controlled for baseline scores.

findings of Jakael et al., (This issue under Review) further support that coders were able to achieve reliability in a multilingual online training session, as the uWECS was readily translatable live and in the training platform to both German and Finnish for a group of coders that included both bilingual (i.e., English/German or English/Finnish) and monolingual German or Finnish coders. The uWECS paves the way for clinicians and researchers around the globe to reliably rate AEC with a validated uWECS instrument.

In addition to validating the uWECS in another language, the demonstrated efficacy of MCEP for exclusively Spanish-speaking dyads underscores the cultural competence of the MCEP. We note that MCEP demonstrated sustained efficacy despite losing approximately 40% of the sample size due to Covid-related school closure. In addition, the efficacy of MCEP for Spanish as the primary language mothers and young children suggests that MCEP is a culturally-competent intervention for Latinx mothers and children and that it was possible to make accessible in the community. Given the vulnerability of Spanish children to be removed from preschool programming (16, 17) and the evidence that emotion understanding is a challenge for young children who are learning English as a second language, the sustained increase in emotional connection for mothers and children may promote emotional awareness and understanding that carries over to the classroom environment (12).

First- and second-generation immigrant mothers are underserved in seeking support (18) and prefer informal programs to support their children in their community (19). MCEP sought to reach immigrant mothers by creating an accessible program, provided in the trusted early childhood learning center, and with other primary Spanish speaking mothers, children as well as social worker. Building from a sense of community and linguistic affiliation may have provided the safe space for mothers' expression of emotion with children, which in turn increased the likelihood that mothers would continue to tap into the MCEP curriculum tools after the program ended, thus explaining the sustained effects of MCEP on EC months after completing the intervention.

A separate report in this special topic journal provides first proof-of-concept that the quality of dyadic autonomic emotional connection among culturally and linguistically diverse infants and parents can be reliably assessed with the uWECS (see Jaekel et al. this issue under review). The study tested the use of the uWECS translated into German and Finnish in an online multilingual group training program. Results showed coders speaking diverse primary languages, including Russian, Turkish, Kurdish and Twi, achieved sound interrater reliability when coding videos.

Our sample of videos was collected in the school setting, with bilingual mothers and children working with a social worker who also spoke Spanish as their primary language. Emotion expression, which is the focal point of MCEP, was guided by the interventionist with all mothers encouraged to speak with their child in the language spoken at home. Minoritized, low income and preschoolers for whom English is a second language show more dysregulated behavior (20), placing them at-risk for loss of a key resource needed to succeed in future education. The findings here point to the value of a culturally competent assessment tool that can be used effectively in multiple languages to measure autonomic emotional connection between mother and child and in the school context. Our findings support the concurrent and criterion-related validity of the uWECS, one that can be reliably coded by coders who speak *any* language.

The uWECS offers an important tool for educators. American preschools currently lack a key resource for the children most in need of preschool programming, such as children for whom English is a second language (21). The uWECS is an assessment tool that is culturally sensitive and accurate. Emotional assessment tools and interventions are also lacking for first- and second-generation immigrant parents of young children (18, 22). Fear of deportation, discrimination, cultural incompetence, linguistic barriers and stigma deter help-seeking for Latinx immigrants (23). However recent evidence suggests that Latinx adults seeking selfcare and Latinx parents seeking help for their children report a preference to seek informal help from resources from those who speak the same language and share the same cultural experiences.

Young children are in need of tools to assess the relational health with parents to improve academic success in preschool, kindergarten and early elementary school (24). A recent study of bilingual 5–6-year-old children found that bilingual children identify emotions as well as monolingual children, but are not as adept at understanding the mental sources of emotion (i.e., desires, beliefs, memories or culture as influences of emotions) as monolingual children (25). Hence, cultural and linguistic barriers for young children may predispose them to manifesting dysregulated behavior because of a lack of understanding of the emotional states of those who do not share their language or cultural display rules.

The 'autonomic' emotional connection (AEC) is a novel construct that we created to describe the mutual behaviors of mother and baby or child that are triggered by the autonomic nervous system. AEC differs from "psychological" emotional connection construct that has been used in academic studies to describe the parent-child relationship since at least the 1990s (26). Behaviors triggered by autonomic state require special assessment in order to differentiate them from conscious and unconscious psychologically triggered behaviors. Conventionally validated assessment tools that are based on "attachment" and "bonding" theory and Psychological emotional connection constructs (27) often measure separate psychological behaviors of infant and mother but not the dyad's mutually Engaged behaviors.

Limitations and future directions

This study was limited by the loss of participating dyads due to Covid-related school closure. Hence these findings are limited by a small sample size and the context of the Pandemic. As well, while the MCEP delivered the curriculum in the school setting by a primary Spanish speaking interventionist and with other primary Spanish speaking families, it is important to note that sharing a common language does not necessarily mean shared culture, immigration status, or life history. It is esssential to replicate

this work on the Spanish u-WECS with other Spanish-speaking communities in and outside of the US. It is noteworthy that affiliation grouping by language for the MCEP, and use of the uWECS-Spanish demonstrated sustained effects for primary Spanish speaking families. This points to the clear benefit of the MCEP's approach to intervention, the sustainability of higher EC in Latinx dyads and the ability to validly measure emotional connection via a translated version of the uWECS coded by primary Spanish speaking coders. This study is limited by the singular transaltion of the uWECS into Spanish. It is important to assess the validity of the uWECS translated into other languages. Adapting and validating a universal WECS instrument paves the way for continued research in AEC globally, opening the door for continued understanding of this novel biobehavioral construct.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Columbia University Medical Center IRB. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin.

Author contributions

AH: Data curation, Formal Analysis, Investigation, Methodology, Project administration, Validation, Writing – review & editing, Writing – original draft, Conceptualization. RL: Project administration, Writing – original draft, Writing – review & editing, Visualization. AM: Data curation, Investigation, Validation, Writing – review & editing. CM: Data curation, Investigation, Validation, Writing – review & editing. UV: Conceptualization, Methodology, Visualization, Writing – review & editing. CG: Methodology, Visualization, Writing – review & editing. MJ: Investigation, Resources, Writing – review & editing. MM: Writing – review & editing. MW: Conceptualization, Funding acquisition, Resources, Writing – review & editing, Investigation, Project administration.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Early childhood psychopathology and parental mental health during the COVID-19 pandemic: the effects of pandemic restrictions on 0- to 3-year-olds

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Introduction: The COVID-19 pandemic placed many restrictions on families and affected the mental health of parents and children. The present study examines how the restrictions imposed during the pandemic and parental mental health affect early childhood psychopathology.
Method: From September 2019 to December 2021, the Outpatient Department of Family Therapy at the Institute for Psychosocial Prevention, Heidelberg surveyed a clinical sample of 249 families who sought consultation for early childhood psychopathology. Early childhood psychopathology in children aged 0–3 years was assessed using the German Questionnaire for Crying, Feeding and Sleeping and the German version of the Child Behavior Checklist 1½–5. The Patient Health Questionnaire provided information on parental depressiveness and generalized anxiety. At the same time, the Stringency Index as part of the Oxford Coronavirus Government Response Tracker indicated the severity of COVID restrictions in Germany.
Results: Dependent comparisons did not reveal significant differences in the infants' regulatory problems ($n = 165$, mean age = 8 months) during the lockdown compared to reopening phases. However, older children ($n = 84$, mean age = 25 months) exhibited more behavioral problems during lockdowns compared to reopening phases (Cohen's $d = 0.32$, $p = .04$). Subsequent regression analyses confirmed a slight increase in behavioral problems only among children aged 1.5–3 years ($p = .047$, $R^2 = .08$), but did not indicate any increase in parental mental health problems when more restrictions were in place. However, parental depressiveness had a strong independent effect on early childhood psychopathology. A hierarchical regression analysis indicated that psychopathology in children aged 1.5–3 years is best explained by female child gender, high parental depressiveness, and more severe restrictions during the COVID-19 pandemic ($p < .001$, $R^2 = .17$) whereas early childhood psychopathology in infants aged 0-1.5 years is more prevalent in younger and male children with parents experiencing higher levels of depressiveness ($p < .001$, $R^2 = .26$).

Discussion: The study found no increase in infant regulatory disorders or parental depressiveness and generalized anxiety during the pandemic. However, older children exhibited more behavioral problems during more severe pandemic restrictions. The study supports the provision of parent-child support during crises and beyond, as early childhood psychopathology was strongly associated with parental depressiveness.

KEYWORDS

COVID-19 pandemic, parental mental health, regulatory disorders, child behavioral problems, early childhood psychopathology

1 Introduction

The COVID-19 pandemic, beginning in 2020 and lasting until 2023, affected many families. To prevent the spread of the coronavirus, everyone's daily life was repeatedly restricted. Protective factors, such as leisure activities, personal social contacts, and many childcare options for young families disappeared during the resulting lockdown phases (1, 2). These constraints caused previously unprecedented stressors in many areas. Economic factors such as unemployment, along with isolation and strain, led to a spike in psychological distress among the general population (3), as well as among families and children.

Young children depend on their caregivers for help with tasks such as soothing, feeding, sleeping, and exploring, as well as during times of heightened irritation or stress (4). The authors von Hofacker et al. (5) and Charlier (6) described early childhood psychopathology in infants, namely regulatory disorders, as difficulties for young children to appropriately regulate their behavior. Early childhood psychopathology in children aged 0–3 years includes a range of symptoms such as excessive crying, sleep disturbances, feeding difficulties, defiant aggressive behavior, emotional reactivity, attention problems, depressiveness, anxiety, and social withdrawal (5, 7). The prevalence rates of specific problems vary depending on the child's age (8). For example, the prevalence of excessive crying in the first 3 months of life is approximately 16%, decreases to 6% between months 4 and 6, and is only 2.5% in 6-month-old children (8). Furthermore, gender differences have been found in aggressiveness and attention problems, with girls exhibiting fewer problems (7, 9). In infants, more boys showed regulatory problems overall (10–12), while girls appeared to cry and wake up less (13, 14).

Bronfenbrenner (15) developed a theoretical framework to explain the protective and risk factors of child development, considering environmental, situational, and interpersonal factors. The microsystem, which includes family and daycare, is the most immediate and influential system in this framework. This microsystem may have been the one most affected by the pandemic, as care options changed, and restrictions placed a considerable burden on parents. According to Tettenborn et al. (16), families self-reported childcare during the pandemic as burdensome. Bronfenbrenner's model (15) suggested that this increased burden on the parents during the pandemic may have negative effects on their children. Tettenborn et al. (16) concluded that the pandemic-related stress caused parents to lose confidence in their parenting abilities, resulting in less effective soothing attempts. The parents' ability to co-regulate their child may have declined, increasing the risk of developing or maintaining child regulatory difficulties and behavioral problems. Difficulties in caring for children during the pandemic, such as excessive parental demands, financial difficulties, disruptions to daily routines, or conflicts within the family, could have further intensified early childhood psychopathology (4, 8, 17, 18).

Research indicates a significant increase in infant crying, longer times to fall asleep, increased sleep and crying problems, and later bedtimes during periods when COVID-related restrictions were in place (16, 19). In March 2020, during the first lockdown, infants experienced more frequent awakenings, which required parents to visit their rooms more often for comfort (20). While there is no conclusive evidence that sleep quality declined during the pandemic, the number of children not meeting a standard for adequate sleep increased (21). According to surveys conducted on feeding problems, researchers found no difference between the lockdown and reopening phases (16, 19). Feeding disorders are caused by complex somatic and psychosocial factors (22). Therefore, they may be less affected by increased family stressors in the context of the pandemic. In summary, empirical evidence suggests a correlation between the pandemic and crying and sleeping problems, whereas the evidence regarding a correlation with feeding problems is inconclusive. Furthermore, studies have shown an increase in behavioral problems in young children, such as depression, anxiety, and attention problems, with the onset of the lockdown (9, 23).

Pre-pandemic literature suggests a correlation between parental mental health and early childhood psychopathology. For instance, parental depression and related difficulties in parent-child interactions are associated with early childhood psychopathology (5, 6, 24). Empirical evidence suggests that factors such as psychosocial and prenatal stress, anxiety, postnatal depression, mental illness, substance abuse, conflict, social isolation, and family distress, such as poverty, are related to early childhood psychology (4, 8, 17, 25). Postert et al. (26) and Sidor et al. (27) confirmed the

Abbreviations

CBCL, child behavior checklist 1½–5; PHQ, patient health questionnaire; QCFS, questionnaire for crying, feeding and sleeping.

relationship between parental psychological stress and their children's regulatory disorders in two German studies. Additionally, a longitudinal study by Evers et al. (28) demonstrated reciprocal effects between early childhood psychopathology and parental stress throughout early childhood. This literature suggests that parental mental health issues and high parental stress during the pandemic may worsen early childhood psychopathology. In turn, the children's psychopathology may cause negative parental mental health responses.

Xiong et al. (3) reported a significant increase in global depression (15%–48%) and anxiety symptoms (6%–52%) during the first phase of the 2020 lockdown among adults in the general population affected by the COVID-19 pandemic. Brailovskaia and Margraf (29) identified stress as the main predictor of psychological distress during the pandemic, with anxiety and depression symptoms before the first lockdown being less predictive. A study conducted in 204 countries and territories reported a correlation between infection rates and restricted mobility with a higher incidence of anxiety and major depressive disorders (30). Women and younger adults were found to be more susceptible to anxiety and major depressive disorders than men and older individuals (30). Generalized anxiety and depressive symptoms also increased among parents (31, 32). Zhang et al. (33) discovered that postpartum mothers experienced higher levels of anxiety and depression during the pandemic. In Canada and the United States, the mental health of mothers declined even more than that of childless adults (34–36).

A study conducted between April and June 2021 found that social distancing, concerns about the child, birth anxiety, separation from the child, and exposure to COVID-19-related parenting behaviors and support, were related to increased infant psychopathology (37). This relationship was mediated by reduced maternal well-being and maternal socioemotional investment. Furthermore, empirical evidence suggests that the incidence of crying and sleep disturbances increased during the pandemic when mothers reported more depressive symptoms (19). Additionally, high levels of maternal depression and anxiety were associated with lower levels of maternal-infant bonding and infants' regulatory ability (38, 39). Provenzi et al. (38) reported that parental stress mediated the effect of maternal postnatal anxiety on infant regulatory capacity. Similarly, quarantine in Italy was found to exacerbate behavioral and emotional problems in children aged 2–14 years, mediated by parental stress (40). Furthermore, maternal perceived stress was correlated with the time taken to calm infants, and the amount of infant crying and fussing (41).

Taken together, the pandemic has led to an increase in depression and anxiety (1, 3, 29). Previous research has also demonstrated a correlation between parental mental health and early childhood psychopathology (8, 24). It has not been conclusively examined whether lockdowns influenced early childhood psychopathology and whether this effect was mediated by parental depressiveness and generalized anxiety. Additionally, it has not been determined if these effects persist throughout early childhood. Prevalence rates depend on the age and gender of the children (7–9) which is why both were included as covariates in the following analyses. Furthermore, most studies conducted during the pandemic relied on convenient online samples. Examining a clinical sample of children with early childhood psychopathology may provide insights of direct relevance to parenting interventions in this population.

This study aims to investigate the relationship between early childhood psychopathology and COVID-19-related restrictions, considering parental mental health. The following relationships were expected.

Hypothesis 1. Symptoms of early childhood psychopathology differ between lockdown and reopening phases.

1 a. Parent-reported regulatory problems regarding crying, fussing, and sleeping are more severe during lockdown than during reopening phases.

1 b. There are significant differences in parent-reported feeding difficulties between lockdown and reopening phases.

1 c. Parent-reported parent-infant co-regulation difficulties regarding crying, fussing, sleeping, and feeding are more severe during lockdown than during reopening phases.

1 d. Parent-reported behavioral problems are more severe during lockdown than during reopening phases.

Hypothesis 2. When controlling for child age and gender, pandemic restrictions predict the symptomatology of parent-reported early childhood psychopathology.

Hypothesis 3. The effect of pandemic restrictions on the symptomatology of parent-reported early childhood psychopathology is mediated in part by parents' depressiveness and generalized anxiety symptoms.

Finally, this study aims to exploratively identify the most relevant variables associated with early childhood psychopathology based on the data in the current study. To identify the most relevant variables, the severity of COVID-19 restrictions, parental depressiveness and generalized anxiety as well as child gender and age are included as predictors.

2 Methods

This cross-sectional study was conducted at the Outpatient Department of Family Therapy at the Institute for Psychosocial Prevention of the University Hospital of Heidelberg. The data collection period began on September 19, 2019, after receiving approval from the Ethics Committee of the Medical Faculty of the Heidelberg University Hospital, and before the start of the pandemic. The collection period ended on December 21, 2021.

2.1 Procedure

All parents of children aged 0–3 years who consulted the Outpatient Department of Family Therapy during the respective time frame were asked to fill out questionnaires on child psychopathology and parental mental health as part of the routine diagnostic and outcome monitoring assessments. A parent or caregiver, usually the mother, received print copies of these questionnaires before the first appointment.

Additionally, the parent questionnaire by Georg et al. (42) was used to record numerous demographic and therapy-relevant variables. It contains open and closed questions on areas such as birth complications, family situation, and reason for referral.

Parents self-reported the following reasons for referral: trouble sleeping through the night (86%), issues with child development or other (37%), defiant behavior, crying episodes or aggressive behavior (35%), frequent and persistent crying (34%), eating and feeding problems (28%), and anxiety, separation anxiety or clinging behavior (10%). A total of 22% of children had already received treatment elsewhere.

TABLE 1 Classification of the study period into lockdown and reopening phases.

Phase	End of phase	Number of surveyed families with children aged 0–1.5	Number of surveyed families with children aged 1.5–3
Pre-pandemic	Mar. 20, 2020	1	20
Lockdown	May 05, 2020	3	1
Reopening	Nov. 29, 2020	48	25
Lockdown	Aug. 02, 2021	71	25
Reopening	Nov. 14, 2021	28	13
Lockdown	Dec. 31, 2021	14	0

Note that the classification of phases is determined by a median split of the Stringency Index (48).

2.2 Questionnaire for Crying, Feeding and Sleeping (QCFS)

The Questionnaire for Crying, Feeding and Sleeping [QCFS, (43)] was used to assess early childhood psychopathology in infants aged 0–1.5 years. Parents rated 49 items on a 4-point Likert scale, ranging from "never or hardly ever" to "always or daily", to determine the child's regulatory problems and three subscales (43). This study utilized the scales to measure various aspects of infant behavior and parental distress. The first scale, consisting of 24 items, measures crying, fussing, sleeping behavior, and parental perceptions (43, 44). An additional 13 items assess infant feeding problems, parental stress during feeding, and concerns about infant weight (43, 44). The third scale consists of 12 items that measure child-parent co-regulation and soothing attempts (43). The questionnaire has been validated for children aged 0–3 years (43). In this study, Cronbach's alpha ranges from .71 to .87 for the subscales and the overall scale. Pre-pandemic data was not available for 0- to 1.5-year-olds, as this questionnaire was only added to the routine data collection later.

2.3 Child Behavior Checklist 1½–5 (CBCL)

Clinical symptoms relevant for children aged 1.5 years and older include emotional reactivity, attention problems, aggressive behavior, anxiety, depressiveness, and social withdrawal (7). Furthermore, sleep problems can persist as part of psychopathological symptoms even in older children (7). Therefore, the Child Behavior Checklist 1½–5 (CBCL) was used to assess child psychopathology and behavioral problems in children aged 1.5–3 years (7, 45). Its 99 items have response options of "not applicable", "somewhat or sometimes applicable", and "accurate or frequently applicable" and assess children's emotional reactivity, anxiety and depressiveness, somatic complaints, social withdrawal, aggressive behavior, attention problems, and sleep problems (7). The CBCL total sum score in this study has a Cronbach's alpha of .94.

2.4 Patient Health Questionnaire

The German version of the Patient Health Questionnaire measures parents' depressiveness with 9 items and their generalized anxiety with 7 items according to the DSM-IV classification system (46, 47). The response options, including "not at all", "on some days", "on more than half of the days", and "almost every day" indicate symptom frequency (47). Cronbach's Alpha for the depressiveness and generalized anxiety scale are .80 and .87, respectively.

2.5 Stringency Index

As part of the Oxford COVID-19 Government Response Tracker, the Stringency Index described the severity of the restrictions imposed by governments worldwide in response to the COVID-19 pandemic (48). School closures, home office orders, workplace closures, event cancellations, contact restrictions, public transportation restrictions, curfews, domestic and international travel restrictions, and public information campaigns were included in the calculation of the index (48). Hale et al. (48) quantified the severity of these measures and reported daily values by country. The values for each day were extracted for Germany and assigned to the corresponding survey days.

In this study, the values of the Stringency Index ranged from 0 to 85.19. To test Hypotheses 2 and 3, the stringency index was used as a continuous measure of the severity of pandemic-related restrictions on the day of the survey. To test Hypothesis 1, the study period was divided into phases of lockdowns and reopening. Families who assessed their children's symptoms and their own well-being during the lockdown phase were compared with those who visited the Outpatient Department of Family Therapy during periods of less severe restrictions. The Stringency Index was subjected to a median split to differentiate between lockdown and reopening phases with the relaxation of measures. Table 1 offers an overview of the identified phases. If the value on the survey day exceeded the median of 63.43, it indicated more restrictive measures, categorizing those days as part of a lockdown phase. If the value was below 63.43, the measures were considered less restrictive. Each family was assigned to either the lockdown or the reopening phase based on the date of their data assessment in relation to their first contact with the Outpatient Department of Family Therapy. The median was reached between June 18, 2020, and

July 6, 2020. This period is assigned to the reopening phase as the index values are lower both before and after this time frame. During these 19 days, six families were surveyed. Values were set to 0 before the first reported COVID-19 case in Germany on January 27, 2020, and before the recording of the index (48).

The identified phases can be linked to specific policy measures. The survey period began on September 19, 2019. The first lockdown was initiated with the recall of 65,000 international travelers (49) and the nationwide closure of non-systemically relevant facilities on March 21, 2020 (50). It ended on May 16, 2020, with initial re-openings (51) and the official end of the first wave of infections (52). New contact restrictions led to the second lockdown phase on November 28, 2020 (53), which ended on August 2, 2021, with re-openings for vaccinated and recovering individuals (54). The third lockdown phase started on November 14, 2021, and continued until the end of the survey period on December 31, 2021. During this period, regulations regarding the wearing of masks were in effect, and in some instances, access was restricted to vaccinated, recovered, or tested individuals (55).

2.6 Sample

The clinical sample consisted of families who were given age-appropriate questionnaires on their children's early childhood psychopathology. Parents who did not provide complete information on their child's age and gender or who completed less than 75% of the questionnaires were excluded, following the recommendations of Collins et al. and Schafer (56, 57). Informed consent for study participation was obtained from $N = 249$ families. Table 2 provides a detailed list of the demographic variables. On average, the children were 14 months old (SD = 10 months), with 51.41% being female. The majority of parents (74.95%) were of German origin, and 88.25% were married. Furthermore, 21.40% of mothers and 5.83% of fathers reported a history of mental disorders in their lifetime.

2.7 Statistical analyses

All analyses were conducted using IBM SPSS Statistics version 27.0.1.0, G*Power version 3.1.9.7 (58) and R statistical software version 4.2.1 and its respective packages (59–66).

To address the issue of missing values in the questionnaires, a multiple imputation was performed based on a visual analysis indicating that the missing values were random (57, 67). The QCFS exhibited 3.92% of missing values, the CBCL 2.63%, and the Patient Health Questionnaire 0.87%.

To test Hypothesis 1, children of families who sought help during the lockdown and reopening phases were matched by age and gender using the propensity score (59, 68) to avoid bias. The group surveyed during the lockdown and the group surveyed during the reopening phases were compared using paired *t*-tests. Two phases were determined for group classification using the Stringency Index (48). The matching process resulted in 77 pairs of infants aged 0–1.5 years who were assessed by the QCFS, and 31 pairs of children aged 1.5–3 years assessed with the CBCL.

Given the likely gradual transitions between lockdown and reopening phases and the varying degrees of restrictions, the Stringency Index was utilized as a continuous measure in the subsequent analyses to capture the nuanced effects of pandemic restrictions. A regression analysis was used to investigate the impact of pandemic restrictions on early childhood psychopathology. Child age and gender were included as covariates to test Hypothesis 2, and parental mental health was added as a mediator to test Hypothesis 3. The proposed mediation model was first reported correlatively. To test the mediation model, a nonparametric bootstrap approach was performed with 10,000 Monte Carlo draws.

Finally, a hierarchical regression analysis was performed to identify the model with the optimal fit to explain early childhood psychopathology. The Stringency Index (48), the children's age and gender, and the parents' generalized anxiety and depressiveness were included as possible predictors. The Akaike Information Criterion (69) was used as a metric for evaluating the inclusion of new predictors with a lower Akaike Information Criterion indicating a better model fit.

3 Results

Table 3 displays descriptive statistics for all questionnaires. The observed overall QCFS score was below the values from a clinical comparison sample [$M = 2.23$, $SD = 0.35$, (43)], as were the observed parental depressiveness [$M = 11.7$, $SD = 5.00$, (70)], and the parental generalized anxiety [$M = 14.18$, (71)]. In accordance with the established cutoff value of 64 proposed by (45), the mean sum score on the CBCL was below the threshold for clinical significance.

TABLE 2 Demographics of the final study sample.

	Children aged 0–1.5	Children aged 1.5–3
Sample size *N*	165	84
Child mean age in months (*SD*)	8.09 (4.41)	26.58 (6.66)
Number of girls (%)	83 (50.30)	45 (53.57)
Mother mean age in years (*SD*)	32.88 (4.37)	34.10 (4.65)
Father mean age in years (*SD*)	34.66 (5.54)	35.72 (6.35)
Number of mothers of German origin (%)	145 (88.96)	72 (86.75)
Number of fathers of German origin (%)	141 (88.13)	70 (88.61)
Number of families with more than one child (%)	54 (33.33)	41 (51.90)
Number of mothers with a university degree (%)	82 (50.93)	42 (52.50)
Number of fathers with a university degree (%)	77 (49.36)	35 (46.05)
Number of married mothers (%)	118 (71.95)	64 (78.05)
Number of married fathers (%)	116 (73.41)	64 (81.01)
Number of mothers with a history of mental disorder, lifetime (%)	35 (21.74)	17 (20.73)
Number of fathers with a history of mental disorder, lifetime (%)	8 (5.03)	6 (7.41)

3.1 Early childhood psychopathology during lockdowns

Table 4 shows the results of Hypothesis 1. The score on Crying, Fussing and Sleeping Behavior on the QCFS (43) for infants aged 0–1.5 years was 0.08 points higher during lockdown than during reopening phases. The Co-regulation scale showed a mean difference of 0.09. In contrast, the mean score on the Feeding scale during lockdown was 0.06 points lower than the mean score during the reopening phase. A dependent samples *t*-test showed no significant differences for any of the subscales. Consequently, Hypotheses 1 a. ($1\text{-}\beta = .47$), Hypothesis 1 b. ($1\text{-}\beta = .24$), and 1 c. ($1\text{-}\beta = .48$) were rejected.

During lockdown, the CBCL sum score (7) for children aged 1.5–3 years was 10.83 points higher. A statistically significant increase in behavioral problems among toddlers was observed during the lockdown period compared to the reopening phases, as indicated by a paired *t*-test [$t\ (30) = 1.78$, $p = .04$, $d = 0.32$, 95% *CI* (0.53, Inf.), $1\text{-}\beta = .67$]. Therefore, Hypothesis 1 d cannot be rejected.

TABLE 3 Descriptive statistics of $n = 165$ children aged 0–1.5 and $n = 84$ children aged 1.5–3.

	M (SD)	Range
Sample with children aged 0–1.5 ($n = 165$)		
Overall QCFS score	1.38 (0.31)	0.45, 2.08
QCFS crying, fussing, sleeping	1.52 (0.42)	0.33, 2.54
QCFS feeding	.55 (0.51)	0.00, 2.46
QCFS co-regulation	2.02 (0.49)	0.58, 3.00
PHQ parental depressiveness	10.65 (5.11)	1, 25
PHQ parental generalized anxiety	8.53 (4.86)	0, 21
Sample with children aged 1.5–3 ($n = 84$)		
Total CBCL sum score	47.76 (23.90)	12, 132
PHQ parental depressiveness	7.91 (4.98)	0, 24
PHQ parental generalized anxiety	6.81 (5.00)	0, 18

QCFS, Questionnaire for Crying, Feeding and Sleeping (43); CBCL, Child Behavior Checklist 1½–5 (7); PHQ, Patient Health Questionnaire (47).

3.2 The impact of pandemic restrictions on early childhood psychopathology

Figure 1 shows the relationship postulated in Hypothesis 2. In the infant sample between ages 0–1.5, the continuous Stringency Index measuring COVID-19 restrictions (48) was not a significant predictor of infant regulatory problems ($p = .91$). The covariates infant age ($p < .001$) and infant male gender ($p = .01$) significantly predicted infant regulatory problems, assessed with the QCFS. Therefore, Hypothesis 2 was rejected for infants between 0 and 1.5 years.

The same analysis for 1.5- to 3-year-olds showed a significant effect of the Stringency Index on child behavioral problems ($p = .047$), in accordance with Hypothesis 2 for this age group. Toddler age ($p = .25$) and gender ($p = .09$) did not influence the CBCL sum score.

TABLE 4 Differences in early childhood psychopathology during phases of lockdown and phases of reopening.

	M (SD) during lockdowns	*M (SD)* during reopening	*t*	*p*	*d*	*CI*
QCFS crying, fussing, sleeping	1.57 (0.40)	1.49 (0.44)	1.12	.13	0.13	−0.04, Inf
QCFS feeding	0.52 (0.48)	0.58 (0.54)	−0.67	.51	0.08	−0.22, 0.11
QCFS co-regulation	2.08 (0.46)	1.99 (0.52)	1.12	.13	0.13	−0.04, Inf
CBCL sum score[a]	53.0 (28.3)	42.2 (19.5)	1.78	.04*	0.32	0.53, Inf

$df = 76$. QCFS, Questionnaire for Crying, Feeding and Sleeping (43); CBCL, Child Behavior Checklist 1½–5 (7).
[a] $df = 30$.
*$p < .05$.

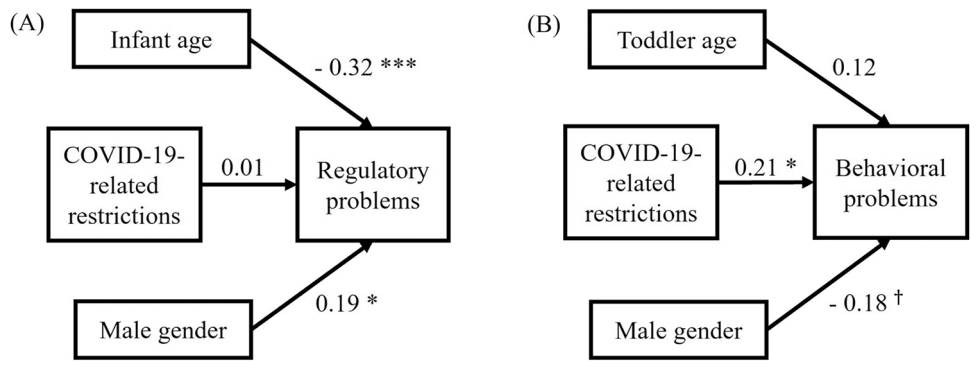

FIGURE 1
β-weights for children aged 0–1.5 years **(A)** and children aged 1.5–3 years **(B)** as postulated in hypothesis 2. Note that COVID-19-related restrictions were measured by the Stringency Index (48), infant regulatory problems by the Questionnaire for Crying, Feeding and Sleeping (43), and toddler behavioral problems by the Child Behavior Checklist 1½–5 (7). Model **(A)**: $R = .13$, $F(3, 161) = 9.05$, $p < .001$, Cohen's $f^2 = 0.17$, $1\text{-}\beta = .997$. Model **(B)**: $R^2 = .08$, $F(3, 80) = 3.41$, $p = .02$, Cohen's $f^2 = 0.13$, $1\text{-}\beta = .78$. †$p < .10$. *$p < .05$. **$p < .01$. ***$p < .001$.

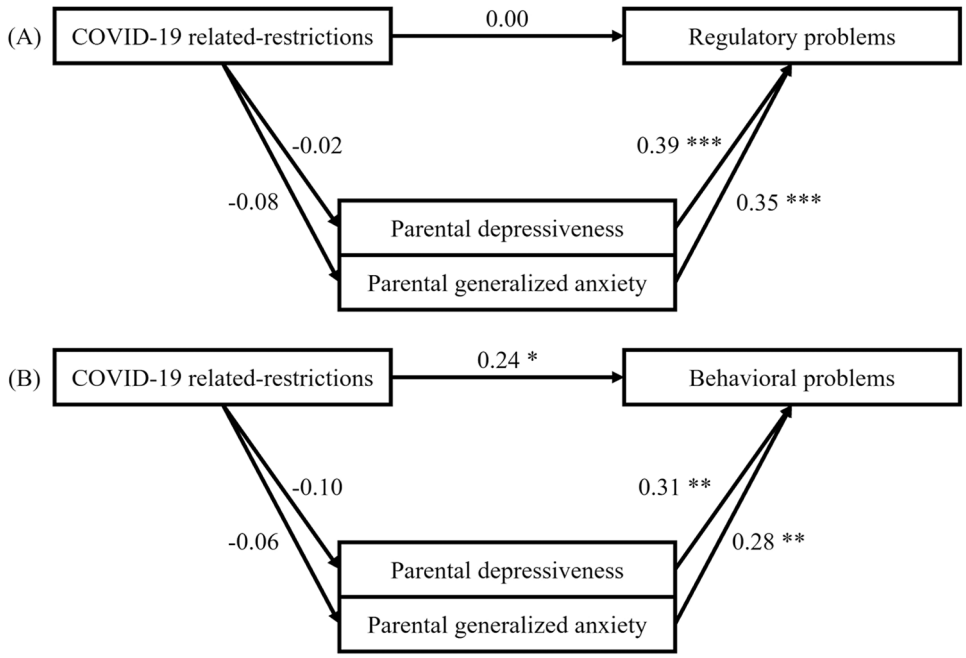

FIGURE 2
Correlations for $N = 165$ children aged 0–1.5 years (A) and $N = 84$ children aged 1.5–3 years (B) as postulated in hypothesis 3. Note that COVID-19-related restrictions were measured by the Stringency Index (48), infant regulatory problems by the Questionnaire for Crying, Feeding and Sleeping (43), toddler behavioral problems by the Child Behavior Checklist 1½–5 (7), and parental mental health by the Patient Health Questionnaire (47).

3.3 The impact of parental mental health on early childhood psychopathology

Figure 2 depicts the postulated relationships in Hypothesis 3 and the results of the mediation analyses with parental mental health as a mediator. The mean parental depressiveness as measured by the Parent Health Questionnaire (47) was 10.13 ($SD = 5.47$) during phases of lockdown and 9.36 ($SD = 4.98$) during phases of reopening. Similarly, the mean parental generalized anxiety was higher during lockdown ($M = 8.04$, $SD = 4.97$) compared to phases of reopening ($M = 7.87$, $SD = 4.99$). Pandemic restrictions did not correlate significantly with parental depressiveness (r (247) = .03, $p = .67$) nor with parental generalized anxiety ($r(247) = -.004$, $p = .95$).

For 0–1.5-year-old infants, the mediation analysis did neither reveal a main effect of the severity of pandemic restrictions on regulatory problems nor an indirect effect mediated by parental mental health [average direct effect of restrictions with depressiveness as a mediator: $\beta = .01$, $p = .89$, CI (−.12, .14); average causal mediation effect of depressiveness: $\beta = -.01$, $p = .84$, CI (−.06, .05); average direct effect of restrictions with generalized anxiety as a mediator: $\beta = .03$, p =68, CI (−.10, .16); average causal mediation effect of generalized anxiety: $\beta = -.03$, $p = .37$, CI (−.08, .03)]. Similarly, no mediation effect was observed for children aged 1.5–3 years. However, a main effect was identified for this age group, indicating that the severity of pandemic restrictions significantly predicted child behavioral problems [average direct effect of restrictions with depressiveness as a mediator: $\beta = .27$, $p = .01$, CI (.08, .46); average causal mediation effect of depressiveness: $\beta = -.03$, $p = .37$, CI (−.11, .46); average direct effect of restrictions with generalized anxiety as a mediator: $\beta = .26$, $p = .01$, CI (.07, 0.44); average causal mediation effect of generalized anxiety: $\beta = -.02$, $p = .63$, CI (−.09, .05)]. Nevertheless, Hypothesis 3 was rejected for both age groups.

3.4 Best-fit model for explaining early childhood psychopathology

Table 5 shows the best-fitting model for predicting early childhood psychopathology. The first hierarchical regression analysis indicated that infant age and gender, as well as parental depressiveness, predicted regulatory problems in 0- to 1.5-year-old infants. On average, for each additional month of age, the score on the QCFS was lower by 0.06 standard deviations, indicating fewer regulatory symptoms in older infants. Parents of male infants reported higher scores by 0.35 standard deviations. An increase in parental depression of one standard deviation was associated with a 0.37 standard deviation increase in the QCFS score. Overall, the model ($p < .001$) explained 26.35% of the variance, as measured by the adjusted R^2.

The severity of restrictions imposed during the pandemic, parental depressiveness, and children's age and gender significantly predicted the prevalence of behavioral problems in 1.5- to 3-year-olds. The severity of behavioral symptoms increased by 0.02 standard deviations for each additional month of age and decreased by 0.34 standard deviations for male toddlers. Furthermore, when pandemic-related limitations or parental depressiveness were higher by one

TABLE 5 Results of a hierarchical regression analysis to explain early childhood psychopathology.

	β	p
Sample with children aged 0–1.5		
PHQ parental depressiveness	0.37	<.001***
Age in months	−0.29	<.001***
Gender (male)	0.18	.008**
Total model[a]	–	<.001***
Sample with children aged 1.5–3		
PHQ parental depressiveness	0.32	.002**
Stringency index	0.26	.013*
Gender (male)	−0.17	.09†
Total model[b]	–	<.001***

Note that COVID-19-related restrictions were measured by the stringency index (48), infant regulatory problems by the questionnaire for crying, feeding and sleeping (43), toddler behavioral problems by the child behavior checklist 1½–5 (7), and parental depressiveness by the patient health questionnaire [PHQ, (47)]. All measures were *z* standardized.

[a]$R^2 = .26$, $F(3, 161) = 20.55$, $1\text{-}\beta = .99$.

[b]$R^2 = .17$, $F(3, 80) = 6.55$, $1\text{-}\beta = .98$.

†$p < .10$.

*$p < .05$.

**$p < .01$.

***$p < .001$.

standard deviation, symptoms were more severe by 0.26 and 0.32 standard deviations, respectively. The adjusted R^2 indicated that the model explained 16.70% of the variance.

4 Discussion

The negative effects of the COVID-19 pandemic on the mental health of families and young children have been demonstrated empirically several times. Less is known about the effects in clinical groups. The present study aimed to investigate the impact of the COVID-19 pandemic and parental mental health on early childhood psychopathology in a clinical sample seeking parent-infant/toddler psychotherapy due to child behavior problems. Consistent with Bronfenbrenner's (15) theoretical framework of protective and risk factors for child development, this study postulated that the changes in care and for families due to the pandemic negatively affected early childhood psychopathology. This effect was expected to be partially mediated by parental mental health. Our results showed that pandemic restrictions and lockdowns negatively affected young children aged 1.5–3 years, whereas an effect on children aged 0–1.5 years was not found. The symptoms of early childhood psychopathology became more pronounced in the older age group under more severe restrictions on daily life. Contrary to expectations, this effect was not mediated by parental generalized anxiety and depressiveness. Nevertheless, parental depressiveness negatively correlated with early childhood psychopathology in all age groups. More severe restrictions due to the pandemic, child female gender, and higher levels of parental depressiveness were predictive of increased behavioral problems in children aged 1.5–3 years, including emotional reactivity, anxiety, depressiveness, somatic complaints, social withdrawal, aggressive behavior, attention problems, and sleep problems. Younger age, child male gender, and high parental depressiveness, but not pandemic restrictions, predicted regulatory problems in children aged 0–1.5 years.

The findings regarding the relation of child age and gender and regulatory problems in infants between the ages of 0 and 1.5 years align with those of previous literature. Older and female infants showed fewer symptoms of regulatory problems. Similarly, previous studies independent of the pandemic reported lower prevalence rates for older and female infants (8, 10–14). Conversely, in the literature, behavioral problems in 1.5- to 3-year-old toddlers, particularly aggressiveness and attention problems, are more frequently observed in male infants (7, 9). However, the findings of this study indicated that female gender was a marginally significant predictor of behavioral problems in 1.5- to 3-year-old toddlers. This discrepancy may be because the present study utilized the CBCL sum score without examining specific behavioral problems. In future studies on the impact of pandemics, early childhood psychopathology in toddlers should be considered in a more differentiated way, for example in externalizing and internalizing problems, to investigate possible gender-specific correlations.

Despite overwhelming evidence from other studies (31, 32), parental mental health did not significantly correlate with the severity of the pandemic's restrictions. One reason for this may be that parents who stayed home to care for their children did not have to commute to work, or who worked from home may have experienced less daily stress despite the pandemic. However, as expected, parental depressiveness significantly predicted early childhood psychopathology at all ages. Consequently, this study contributes to the existing research that showed a robust correlation between parental mental health and early childhood psychopathology (8, 24, 28). This finding also aligns with Bronfenbrenner's framework, which suggests that the family microsystem significantly influences child mental health and development (15). According to our results, this effect is not linked to pandemic restrictions. For children aged 1.5–3 years, parental depressiveness and the severity of COVID-19 restrictions were independent predictors of early childhood psychopathology.

In children between the ages of 1.5 and 3, this study found that the impact of the COVID-19 restrictions on the extent of early childhood psychopathology was as expected. During periods of increased restrictions on routines and changes in daily life children in this age range exhibited more severe behavioral problems. The relation could likely result from fewer opportunities for physical activity, reduced peer contact, and more frequent changes in childcare arrangements. First, literature suggests the important role of physical activity for the mental health of children during the pandemic. Two meta-analyses confirm that physical activity can be a protective factor for behavioral problems and child mental health during the pandemic in school-age children (72, 73). Despite the effect of the pandemic on physical activity, it is plausible that the level of physical activity declined, particularly during the winter months when restrictions were typically more stringent. Therefore, the impact of reduced physical activity may extend beyond the

restrictions imposed by the pandemic. Second, reduced contact with peers during early childhood may coincide with increased social withdrawal and depressiveness (74), hindering the development of skills such as managing one's aggressive behavior, emotional reactivity, and attention regulation (75–77). Third, families may have experienced many changes in childcare responsibilities during the pandemic. As a result, children had to adapt more frequently which could have contributed to more child behavioral problems. As childcare external to the family is more prevalent among older children in Germany (78), changes in childcare, in addition to reduced physical activity and peer contact, could have particularly affected 1.5- to 3-year-olds.

This study found no evidence to support the prediction that regulatory problems in 0– to 1.5-year-olds would increase along with pandemic restrictions and lockdowns in a clinical sample. Gadermann et al. (36) found that 22% of parents reported more family conflicts, while nearly 50% experienced increased feelings of closeness within the family. It is possible that many families experienced positive consequences of the pandemic restrictions, which may have been more pronounced for children under 1.5 years of age when families care for their children at home more often. In the United States, 65% of parents working from home reported having childcare responsibilities while working (79). Due to isolation, families may have experienced a closer bond that may have strengthened parental interactional and co-regulatory skills, which may explain why regulatory problems in infants aged 0–1.5 years did not worsen during high pandemic restrictions. Furthermore, pre-pandemic data was not available for 0- to 1.5-year-olds. The pandemic may have had an overall detrimental effect on infants' regulatory behaviors that could not be detected with the available data. However, for children aged 1.5–3 years, 21% of data was collected before the first case of COVID-19 was reported in Germany and before the onset of the first lockdown. The reported effects of pandemic restrictions on behavioral problems may have been dominated by large differences between pre-pandemic data and data collected during the pandemic.

Overall, parents reported more infant regulatory problems for newborns with symptoms decreasing with each month of age. Thus, newborns appear particularly vulnerable to regulatory difficulties, just as older toddlers are more vulnerable to behavioral problems. This finding allows institutions to provide targeted interventions to young families.

Most importantly, this study highlights the significance of family support services, particularly during times of crisis. The negative effects of lockdowns on child behavioral problems could add to the burden on young families. Mental health services are inadequate in many regions, even during times of non-crisis (80). Parent-infant/toddler interventions can help parents cope with the new challenges posed by children with regulatory disorders (8). Similarly, early prevention efforts in times of crisis should not only target parents of infants under 1 year of age but also parents with older children. It is possible, that toddlers experience the negative effects of lockdowns more directly through changes in their familiar routines, physical activity and peer interactions. Finally, parental mental health support should be expanded since parental depressiveness has been shown to be an important predictor of early childhood psychopathology.

4.1 Limitations and future research

Although this study was able to include parental mental health as a mediator, future research should consider other factors that contribute to the development and maintenance of early childhood psychopathology during crisis, given that the explained variance of the included factors was less than 27%. For example, future research should include measures of physical activity, peer contact, and changes in child and family routines. Furthermore, 40% of the families in this study reported having more than one child. Thus, it is difficult to attribute poor parental mental health solely to the child presented to the Outpatient Department of Family Therapy. Research suggests that children with more older siblings have fewer regulatory problems (19). Moreover, factors such as loneliness and parental stress have been associated with poor parental mental health (3, 31), which in turn may negatively affect early childhood psychopathology. Changes in routines, child peer contact, number of children, parental loneliness, and stress were not included in this analysis. Considering these factors may contribute to a better understanding of the adverse effects of the pandemic on early childhood psychopathology and should be included in future research. The inclusion of such variables may also help explain the different findings for 0- to 1.5- and 1.5- to 3-year-olds. Nevertheless, this study addresses an important gap in the literature by investigating early childhood psychopathology in the context of the pandemic while considering parental mental health as an essential predictor of child mental health.

This study's design did not allow for a causal interpretation. For instance, it is not possible to conclude that worse parental mental health has a negative influence on early childhood psychopathology. Negative effects from early childhood psychopathology on parental mental health (81) and even reciprocal effects are possible (82). The hypotheses of this study, however, were formulated based on Bronfenbrenner's framework, which assumes that parental mental health, as part of the child's microsystem, influences child wellbeing (15).

Furthermore, a more diverse sample should be included in future research. Parents with low levels of education and migrant backgrounds were particularly affected by the pandemic (1, 39). These characteristics were not included as predictors in this study due to their limited variability in this sample. Most families reside in the Heidelberg region, have an above-average socio-economic status, and are of German origin. This may lead to confounding results in the study, as the impact of the pandemic disproportionately affected racial and ethnic minorities (39). However, since the sample is from the same region, restrictions were the same for all families. Some COVID-19 policies were partly incidence- and state-dependent [e.g., (83)]. Nevertheless, future research should aim to obtain a more diverse sample and investigate the reported relationships with differing socioeconomic variables.

Additionally, it is important to note that the participants in this study were drawn from a clinical sample. Consequently, the prevalence of parental and child psychopathology is likely higher than that in the general population, and the effects and relationships observed in this study may differ accordingly. It is important to note, however, that compared to other samples children in our study had lower levels of psychopathology. The sample mean scores on all scales of the QCFS for children aged 0–1.5 years were lower than those of the healthy and clinical comparison samples (43). Furthermore, three-quarters of children aged 1.5–3 years were reported to have behavioral problems below clinically relevant levels (45). Nevertheless, this study addresses a gap in the literature by examining a clinical sample that differs from the samples used in most other studies conducted during the COVID-19 pandemic (3).

Although this study surveyed parents with young children over several months, the cross-sectional study design has several limitations. This study was unable to specifically examine intraindividual differences. Furthermore, pre-pandemic data for this study was available for 1.5- to 3-year-old toddlers, but not for younger infants. Considering pre-pandemic data is essential for assessing the overall impact of the pandemic. To minimize the potential effects of confounding variables on the results, this study matched children regarding age and gender. Nonetheless, future research should conduct longitudinal studies and explore trajectories throughout early childhood.

Another limitation of this study design is that it only allowed us to identify an increase in early childhood psychopathology and parental mental health issues across the pandemic. The pandemic may have imposed a greater burden on the general population, resulting in an increased frequency of cases. Furthermore, families that would not otherwise be affected by early childhood psychopathology or parental mental health issues may have experienced a burden due to the pandemic and thus sought psychological help. Future studies should investigate whether more families seek help in times of crisis, such as the COVID-19 pandemic. However, this will depend on the availability of and barriers to mental health services. Additionally, it would be of interest to determine whether there is a higher prevalence of early childhood and parental psychopathology in the general population during periods of pandemic.

Furthermore, the Stringency Index may not be the most appropriate measure to assess the pandemic's impact on psychopathology. The division of the time periods during the pandemic into phases of lockdowns and reopening was based on the implementation of policy measures and a median split. First, the personal burden imposed by the pandemic may have accumulated over time, rather than being directly proportional to the severity of restrictions. Mental disorders often have incubation periods (84), and the negative effects of quarantine can persist longer than the quarantine itself (85). Consequently, the Stringency Index, which is used to measure the severity of restrictions, may not always be an appropriate metric for identifying the consequences of the COVID-19 pandemic. This is because the effects of the pandemic are often not immediately apparent, especially given the complex causes underlying the development of mental health issues and early childhood psychopathology. Second, restrictions imposed at the onset of a lockdown may have appeared to cause more significant disruptions to personal life than the same measures imposed at the end of a lockdown. Habituation effects could have reduced the perceived threat of the prolonged second COVID-19 wave. Therefore, personal restrictions and perceptions may provide more informative insights than policy measures. For example, a case of COVID-19 in the family or pre-existing medical conditions could have influenced the perceived threat of the pandemic, while the subjective feeling of isolation could have altered the perceived severity of the measures. Future research should include subjective measures of the perceived severity of the COVID-19 measures. Nevertheless, the Stringency Index remains the most objective measure of the severity of COVID-19 restrictions for each day.

Both parental mental health and the extent of early childhood psychopathology were assessed through parent reports which are not always accurate and objective (86). Some parents may have responded in a socially desirable manner, reporting fewer family problems than exist. This is supported by the fact that the sample mean scores on all scales of the QCFS were lower than those of the healthy and clinical comparison samples (43). This finding is particularly surprising given that the families were experiencing such high levels of distress that they were open and motivated to seek treatment at the Outpatient Department of Family Therapy. Further research is necessary to confirm the findings of this study, particularly with clinically diagnosed disorders in both children and parents using standardized clinical assessments, like the DC: 0–5 (87).

In general, the power was above .95 for most of the analyses. However, the power for the dependent sample *t*-test comparing the lockdown and reopening phases was between .24 and .67. These low power levels (88) may account for the absence of any observed effects of lockdowns on regulatory disorders in children aged 0–1.5 years. In addition, the multiple regression analysis explaining behavioral problems in children aged 1.5–3 years with toddler age and gender as covariates had a power of 0.78. Notwithstanding the lower power, parental depressiveness, the level of restrictions during the pandemic, and the children's gender all significantly predicted behavioral problems.

5 Conclusion

The study found no increase in infant psychopathology (0–1.5 years of age) or in parental depressiveness and generalized anxiety in a clinical sample during the pandemic overall. However, older children (1.5–3 years of age) showed more behavioral problems during more severe pandemic phases and with increasing severity of pandemic restrictions. Furthermore, early childhood psychopathology was strongly associated with parental depressiveness and anxiety, independent of the pandemic. Further longitudinal research is needed to fully understand the impact of the pandemic on infants and toddlers and its interaction with parental mental health. The significant effects of covariates like

child age and gender on early childhood psychopathology, suggest that more developmental, environmental and contextual variables, such as care arrangements, children's peer contacts, and parents' occupational solutions, should be included in analyses to improve the prediction of early childhood psychopathology during the pandemic. The present study highlights the importance of implementing parent-child interventions in early childhood, beyond infancy, to support young families in times of crisis. Because of the robust association between parental mental health and early childhood psychopathology, parent-child support services focused on parents should be available for all ages during times of crisis and beyond.

Data availability statement

The datasets presented in this article are not readily available because the personal data of surveyed families is not published with the article. Requests to access the datasets should be directed to Anna Georg, anna.georg@med.uni-heidelberg.de.

Ethics statement

The studies involving humans were approved by Ethics Committee of the Medical Faculty of the Heidelberg University Hospital. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin.

Author contributions

KK: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Writing – original draft. ST: Conceptualization, Resources, Writing – review & editing. AG: Conceptualization, Investigation, Methodology, Project administration, Resources, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Publisher's note

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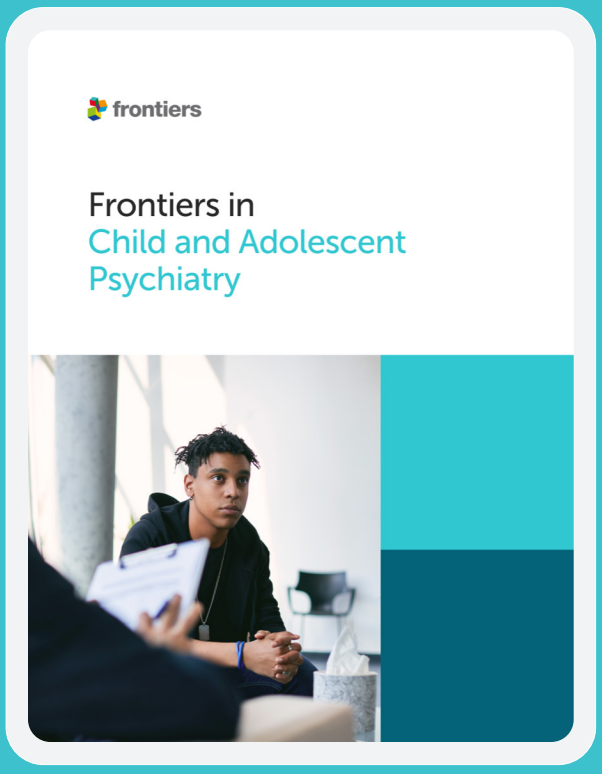

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