

Interventions to Support Parents Whose Babies Cry Excessively: Systematic Review

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abstract

CONTEXT: Parents report that around 10% to 20% of babies cry a lot without an apparent reason during early infancy. This “excessive” infant crying can lead to adverse outcomes, including parental depression, breastfeeding cessation, impaired parent–child relationships, and, in extreme cases, infant abuse. Cost-effective parent-support services are needed.

OBJECTIVE: To assess the effectiveness and cost-effectiveness of interventions designed to support parents of excessively crying babies.

DATA SOURCES: MEDLINE, Embase, EconLit, Web of Science, Scopus, PsycINFO, CINAHL and CENTRAL were searched from inception to 8th April 2025. The NIHR CRN database and hand-searching were used to identify further studies.

STUDY SELECTION: Comparative studies reporting parental outcomes for any intervention supporting parents of excessively crying infants aged ≤1 year were included.

DATA EXTRACTION: Two independent reviewers conducted data extraction and assessed risk of bias. Meta-analysis was performed when possible; otherwise, narrative synthesis was conducted.

RESULTS: Meta-analysis found that educational interventions significantly reduced parental stress or anxiety. Narrative analyses produced mixed findings, but components common to successful educational interventions were indicated. Meta-analyses of studies administering probiotics to infants found significant improvements in parents’ quality of life but not in parental depression. No safety data and limited economic evidence were found.

LIMITATIONS: Few studies measured similar enough parental outcomes to be pooled in meta-analysis. Risk of bias ranged from unclear to high risk.

CONCLUSIONS: Educational and probiotic interventions show promise for supporting parents of excessively crying babies. Additional controlled trials employing evidence-based interventions and outcome measures and cost-effectiveness analyses are needed to build on these findings.



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A Bilgin contributed to the design of the study and data collection instruments, collected data, drafted parts of the initial manuscript, and critically reviewed and revised the manuscript. A Betteridge, J Brown, EM Boyle, F Fusco, M Stracke, and D Wolke contributed to the design of the study and data collection instruments, collected data, and critically reviewed and revised the manuscript. (Continued)

To cite: Bilgin A, Betteridge A, Brown J, et al. Interventions to Support Parents Whose Babies Cry Excessively: Systematic Review. *Pediatrics*. 2026;158(5):e2025075063

INTRODUCTION

Parents report that around 10% to 20% of infants cry excessively during the first 4 postnatal months.^{1–3} Empirical evidence confirms that these crying episodes are often prolonged and difficult to soothe.^{4–6} Many parents find this stressful and seek professional help, making this costly for health care services.⁷ When parents cannot cope, excessive crying can lead to adverse outcomes including parental depression,⁸ early breastfeeding cessation,⁹ overfeeding,¹⁰ impaired parent–child relationships¹¹ and, in rare cases, nonaccidental injury including shaken baby syndrome (SBS)¹² and/or abusive head trauma (AHT).¹³

Historically, research initially focused on the cause of the infant crying, and particularly on gastrointestinal disorders and pain (“infant colic”), leading to interventions targeting infant or maternal diet. More recent studies of this type have examined infant gut microbiota and probiotic supplements to reduce infant crying.^{14,15} Although probiotics reduce crying in some infants,¹⁶ their effectiveness varies between countries, and they are ineffective in formula-fed infants.¹⁵ Because infants with gut disorders cannot be reliably distinguished from those without, probiotic interventions remain a promising research avenue, but are not currently recommended by medical authorities for routine clinical use.

As an alternative to gut disorder explanations for the crying, systematic reviews have identified a universal cross-cultural peak in infant crying in the early weeks after birth that declines by age 3 months.^{2,3} This pattern is considered a normal developmental stage, with most affected infants indistinguishable from others at later ages.^{17,18} In 2024, the *JAMA Pediatrics* journal parent page endorsed this developmental explanation for most cases of prolonged crying in early infancy.¹⁹

Based on evidence that prolonged infant crying can trigger SBS and/or AHT, a second group of studies has focused on parents rather than infants. These “safeguarding” interventions aim to educate parents in abuse prevention, often before the crying peak, and target entire parental communities.^{20,21} They provide universal coverage but are expensive to deliver, questioning their cost-effectiveness. Systematic and clinical reviews indicate that safeguarding interventions improve parental awareness of SBS/AHT and are valued by parents and clinicians.^{20,21} However, the evidence for reduced SBS/AHT rates remains equivocal, partly because their low incidence raises substantial methodological challenges.²¹

More recently, a third study type has evolved that provides parents with evidence-based strategies to help them manage their emotions and actions, increase their well-being, and help them to cope with excessive infant crying rather than focusing on what to avoid. These “parental support” studies often use websites, apps, and other online materials to maximize cost-effectiveness.^{22–24} They

require community health care screening systems for case identification and can be integrated into primary health care services, providing immediate support at little extra cost and potentially improving overall service cost-effectiveness.

Although parental support interventions appear promising, to our knowledge, no systematic reviews or meta-analyses of parental outcomes from such studies have been published to date. Our aim is to provide a comprehensive review of this evidence by addressing 2 key questions: (1) What interventions are effective in supporting the mental well-being and coping of parents whose infants are crying excessively? (2) How cost-effective are the interventions in supporting the mental well-being and coping of parents whose infants are crying excessively?

METHODS

This review was registered with the PROSPERO international prospective register of systematic reviews and conducted according to Cochrane²⁵ and PRISMA²⁵ guidelines.

Eligibility Criteria

We included studies of interventions targeting parents of excessively crying infants aged 1 year or younger that reported parental outcomes. Studies that reported only infant outcomes were excluded. However, interventions targeting infants could affect parental well-being indirectly. Consequently, we included studies that targeted infants that also reported parental outcomes.

Two overlapping definitions of “excessive” infant crying were used. The first definition was based on crying amounts that exceeded preset criteria such as Wessel et al’s “Rule of Threes” criteria defining a colicky infant as one who fusses or cries for more than 3 hours a day on more than 3 days a week.²⁶ These criteria have been criticized as arbitrary and impractical^{27,28} but are widely used, and many parents find infants meeting these criteria difficult to care for, with crying triggering adverse parental emotions and behaviors.^{4,6,29} More recently, excessive infant crying has been defined by parental reports that their baby’s crying is problematic or excessive.^{30,31} This approach reflects subjective parental experience and is consistent with clinical practice, where parental concern is the first point of contact. Evidence shows that many infants identified in this way do cry for prolonged periods.^{6–8}

Eligible study designs included randomized, nonrandomized or observational studies, and economic evaluations. Studies published in any language were eligible. Studies focusing only on infant outcomes, infants with diagnosed health conditions, animal/in vitro studies, case studies, case reports, or letters were excluded. Full inclusion and exclusion criteria are in Supplemental Table 1.

Searches

We searched databases from inception to April 8, 2025, including MEDLINE (Ovid), MEDLINE (PubMed), Embase (Ovid), EconLit (Ovid), Web of Science (Clarivate), Scopus (Elsevier), PsycINFO (ProQuest), CINAHL (EBSCO) and CENTRAL (Cochrane). The NIHR CRN Portfolio Database (UK) and handsearching and reference list checking were also used. Search strategies are documented in Supplemental Table 2. Results from each database were deduplicated in EndNote and during import into Covidence (<https://www.covidence.org/>).

Screening

Screening was conducted in Covidence by 2 reviewers. Two author teams independently screened the titles and abstracts and subsequently full papers of all studies.

Data Extractions

Data were extracted using Microsoft Excel. A pilot data extraction table was drafted, and feedback from the project team was incorporated into a final version. One reviewer extracted the data, and a second reviewer checked it; any disagreements were resolved by discussion.

Risk-of-Bias Assessments

The Cochrane RoB2 tool was used to assess risk of bias in randomized controlled trials (RCTs) based on the primary author-reported outcome.³² Quasi-experimental studies were assessed using the Joanna Briggs Institute (JBI) risk-of-bias tool for nonrandomized, quasi-experimental studies.³³ Case-control studies were to be assessed using the JBI risk-of-bias tool³⁴ and economic evaluations using the Drummond risk-of-bias tool³⁵; however, no studies of these types were identified. One reviewer assessed a study's risk of bias, and a second reviewer checked it. Any disagreements were resolved by discussion.

Data Synthesis

Meta-analyses were conducted for studies examining the same intervention type (eg, educational, probiotic) with similar parental outcomes (eg, stress, anxiety), and reporting sufficient data (mean, deviation, sample size) for both intervention and control groups, pre- and post-intervention. Otherwise, studies were narratively synthesized.

Meta-analyses were conducted using RevMan version 5.4³⁶ to assess overall effect sizes. Effect sizes were calculated as standardized mean difference (SMD). Analyses were based on change from baseline to follow-up using random-effects models assuming that each study had its own population parameters. Time points for outcomes were matched as closely as possible. Heterogeneity was assessed using Cochran's Q and Higgins I^2 (0% = no heterogeneity, $\geq 25\%$ = low, $\geq 50\%$ = moderate, $\geq 75\%$ = high). Methods used to assess publication bias are documented in the

Supplemental Methods section. Sensitivity analyses were performed repeating the main analyses using only studies that conducted RCTs.

RESULTS

Study Selection

From 20 203 records identified through database searches (Figure 1), 11 014 duplicates were removed, leaving 9189 records for title/abstract screening. Of these, 664 records were sought for retrieval, with 661 assessed at full paper screening stage (3 unobtainable). After excluding 617 further records and adding 8 records through gray literature searches, 29 studies were included for detailed analysis.

Study Characteristics

Table 1 summarizes the characteristics of the 29 included studies. Of these, 24 (82.8%) were RCTs and 5 (17.2%) were quasi-experimental studies. A total of 2508 participants were included, with sample sizes ranging from 13 to 241. Infant age (reported in 27 studies) ranged from 4.1 to 39.87 weeks, and parent age (reported in 17 studies) ranged from 24.28 to 35 years. Infant sex distribution varied widely (25% to 66.7% female).

The majority of studies ($N = 19$, 65.5%) assessed excessive crying using pre-established cut-off criteria for infant crying amounts (ie, Wessel's or modified Wessel's, including Rome III and Rome IV, criteria). Three studies used definitions of excessive crying that applied alternative thresholds (eg, ≥ 2 hours per day within the past week).^{39,47,63} Five studies relied on parent perceptions of problematic crying,^{40–42,61,62} 1 study included infants receiving outpatient care for infantile colic,³⁷ and 1⁴⁶ used irritability.

Interventions were mostly educational ($N = 11$, 37.9%)^{37–47} or probiotic ($N = 11$, 37.9%),^{15,48–57} with 10 probiotic studies targeting the infant and 1 targeting breastfeeding mothers.⁵¹ Other interventions included infant massage/manual therapy ($N = 3$, 10.3%),^{58,59,64} maternal dietary changes ($N = 1$, 3.5%),⁶⁰ mixed interventions (infant drug treatment and parent–infant mental health consultation; $N = 1$, 3.5%),⁶¹ infant rhythmic stimulation, ($N = 1$, 3.5%)⁶² and infant aromatherapy ($N = 1$, 3.5%).⁶³ Because some studies did not report which parent was assessed, we have referred throughout to “parents.”

Risk of Bias

Among the 24 RCTs, 18 were rated as having some concerns for risk of bias, and 6 were rated at high risk of bias because of limited details on randomization, allocation concealment and baseline characteristics,⁴⁶ deviations from intended interventions,⁴² unreported prespecified outcome data,⁴⁵ or outcome measurement (Figure 2A).^{54,58,64} Of the

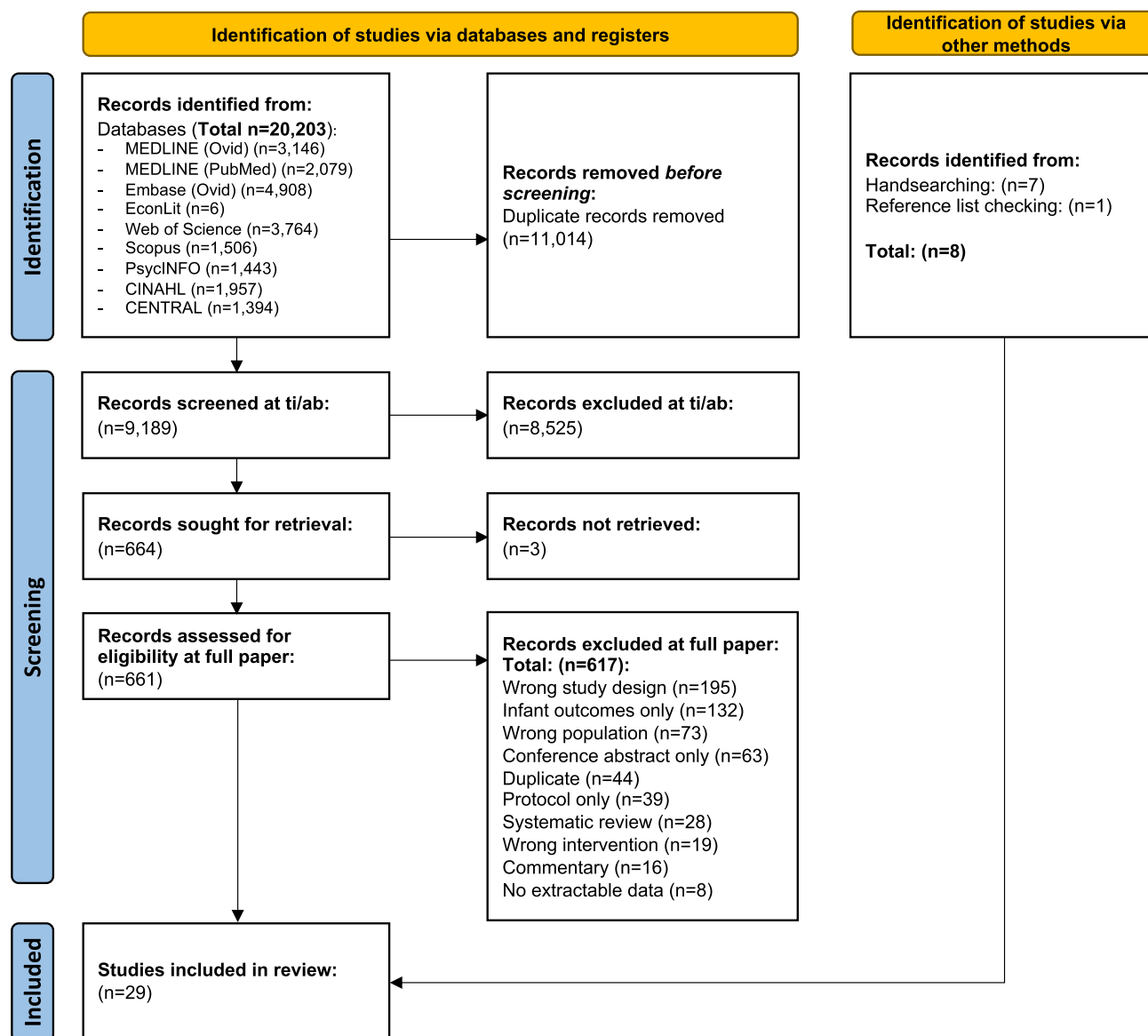


FIGURE 1.

PRISMA flow diagram.

Abbreviations: PRISMA, preferred reporting items for systematic reviews and meta-analyses; ti/ab, title/abstract.

5 quasi-experimental studies, 3 were rated at unclear risk of bias, and 2 at high risk because of issues with outcome measurements between historical controls and the intervention population³⁸ or incomplete follow-up (Figure 2B).⁶²

Outcomes

Most studies reported on parental stress, anxiety, or depression (N = 17, 58.6%), including 7 educational,^{38–41,43–45} 6 probiotics,^{15,50,52–54,57} and 4 studies of other types of interventions.^{60,62–64} Seven studies reported on parental quality of life,^{15,48,49,51,55–57} all involving probiotic interventions. Other reported outcomes included a diverse range of parental

measures, such as caregiving burden, parent–infant interaction, parenting confidence and bonding, which are summarized in Table 1 and described in the narrative synthesis.

Findings From Educational Interventions

Of the studies reporting on educational interventions, 3 assessing parental stress^{38–40} and 1 assessing parental anxiety⁴³ were included in a pooled meta-analysis because stress and anxiety are often linked⁵⁵ and measure adverse emotional response to stressors, such as excessive infant crying. In line with previous research,⁵⁵ pooling them increased the number of studies included and hence the

TABLE 1. Summary of the Included Studies										
Author (Year)	Country	Excessive Crying Definition	Intervention, Comparator, and Study Design			Baseline Characteristics			Caregiver Outcomes	Included in MA or Narrative
			Intervention Type (Name); Details; Duration; Facilitator	Study Design; Blinding; Health Care Setting	Control Type; Details	Sample Size (N)	Infant and Parents’ Ages at Assessment (M)	Infant Sex, (%) F or M	Assessed Outcomes (Questionnaire); Longest Follow-Up Duration; Caregiver Assessed	
Educational Interventions										
Alikhalili et al (2023) ³⁷	Iran	IC (no further details)	Education (blended 3-component educational, supportive, and follow-up infantile colic program); in groups of 2 or 3: face-to-face, lectures, practical exercises, and educational booklet at the end of the session; 4 sessions held within 2 weeks, each lasting 30–45 minutes; researchers	Randomized - parallel-group; no blinding; secondary care: outpatients	Routine care services	Intervention: 28 Control: 27	Infant: 5.36 weeks (intervention) 4.85 weeks (control) Parent: 29.64 years (intervention) 30.26 years (control)	Intervention: 25% F; 75% M Control: 37% F; 63% M	Caregiver burden (ZBS); 1 month; both parents	Some concerns
Gilkerson et al (2020) ³⁸	USA	Intervention: Fussy or challenging babies (as felt by the families) Control: Modified Wessel criteria (defined as crying episodes lasting on average at least 3 hours a day for 3 consecutive days by age 3 months)	Education (Fussy Baby Network); 6 months; infant/parent specialists (not further defined)	Quasi-experimental (intervention group matched with a control group drawn from an external longitudinal research project); NR; community	No treatment-Families who did not seek Fussy Baby Network services	Intervention: 29 Control: 27	Infant: 14.8 weeks (intervention) 14.7 weeks (control) Parent: 32.38 years (intervention) 31.59 years (control)	Intervention: 31% F; 69% M Control: 45% F; 55% M	Parental self-efficacy (MEQ), parental mental health (EPDS); parent stress (PSI-SF), HRU; ≥12 weeks intervention group; 6 months for control group, 3 years for HRU; mothers	High
Keefe et al (2006) ³⁹	USA	Excessive unexplained irritability (defined as >2.5 hours per day of unexplained crying)	Education (REST: reassurance, empathy, support and time-out); 4 home visits each lasting approximately 1 hour; 4 weeks; pediatric nurse	Randomized - parallel-group; single blind; home	Standard of care (not further defined)	Intervention: 64 Control: 57	Infant: 5 weeks (intervention) 5 weeks (control) Parent: 31.2 years (intervention) 31.1 years (control)	Intervention: 56% F; 44% M Control: 43% F; 47% M	Parent stress (PSI-SF); 8 weeks; families	Some concerns

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TABLE 1. Summary of the Included Studies (Continued)

Author (Year)	Country	Excessive Crying Definition	Intervention, Comparator, and Study Design			Baseline Characteristics			Caregiver Outcomes		Risk of Bias ^a	Included in MA or Narrative
			Intervention Type (Name); Details; Duration; Facilitator	Study Design; Blinding; Health Care Setting	Control Type; Details	Sample Size (N)	Infant and Parents’ Ages at Assessment (M)	Infant Sex, (%) F or M	Assessed Outcomes (Questionnaire); Longest Follow-Up Duration; Caregiver Assessed			
Lim (2014) ⁴⁰	USA	Colicky infants (not further defined)	Education (The Happiest Baby on the Block; THB); demonstration of THB and a THB information video and a phone call 2 or 3 days later for questions/concerns; 10 days; caregivers	Randomized - parallel-group; single blind; secondary care; outpatients	Standard of care (not further defined)	Intervention: 7 Control: 2	Infant: 6 weeks (intervention) 5 weeks (control) Parent: 28.4 years (intervention) 35 years (control)	NR	Parent stress (PSI-SF; sQORT, sAA), parent– child relationship (MIBS); 10 days; mothers	Some concerns	MA and Narrative	
Long (2003) ⁴¹	UK	Mothers who were distressed by their baby’s crying	Education (Crying Baby Support Programme); 2 resource manuals; 2 seminars; a workshop until the mother felt she no longer needed it; health visitors	Quasi- experimental; NR; home	Standard of care; Standard health visiting care without additional training for health visitors	Intervention: 9 Control: 10	Infant: NR Parent: 33 years	66.7% F; 33.3% M	Parent mental health (GHQ, anger, frustration, distress scale), perception of cry (cry scale), caregiving burden (ability to soothe baby, cope with the baby, enjoy the baby, tiredness), knowledge of infant crying (understanding baby), parent well-being (self-esteem), parent– child relationship (perception of baby as manipulative); 6 weeks; mothers	Unclear	Narrative	
McKenzie (1991) ⁴²	UK	Troublesome crying (defined as crying with which parents felt they could no longer cope and for which they sought help)	Education; empathetic interview plus advice to reduce stimulation; 1 time advice; pediatricians	Randomized— crossover; blinding NR; secondary care; outpatients	Empathic interview only	Intervention: 22 Control: 20	Infant: 10 weeks Parent: NR	NR	Maternal distress (10- point questionnaire); 1 month; mothers	High	Narrative	

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TABLE 1. Summary of the Included Studies (Continued)

Author (Year)	Country	Excessive Crying Definition	Intervention, Comparator, and Study Design			Baseline Characteristics			Caregiver Outcomes	Risk of Bias ^a	Included in MA or Narrative
			Intervention Type (Name); Details; Duration; Facilitator	Study Design; Blinding; Health Care Setting	Control Type; Details	Sample Size (N)	Infant and Parents’ Ages at Assessment (M)	Infant Sex, (%) F or M			
Montazeri et al (2022) ⁴³	Iran	IC based on Wessel's criteria and a pediatrician's diagnosis (not further defined)	Education; 8 counseling sessions (2–3 sessions per week) for 4 consecutive weeks; researchers plus mothers	Randomized - parallel-group; no blinding; secondary care; outpatients	Standard care: Routine postpartum training	Intervention: 18 Control: 23	Infant: NR Parent: 28.1 years (intervention) 27.4 years (control)	Intervention: 47.8% F; 52.2% M Control: 39.1% F; 60.9% M	Parent mental health (PSAS), parent–child relationship (MIAQ); 2 weeks; mothers	Some concerns	MA and narrative
Parkin et al (1993) ⁴⁴	Canada	Modified Wessel criteria (not further defined)	Education; Training with specific management techniques plus general information and reassurance; 2 weeks; mothers	Randomized - parallel-group; no blinding; secondary care; outpatients	1) SleepTight car-ride simulation device plus general information and reassurance; 2) General information/reassurance only	Intervention: 11 Control 1: 16 Control 2: 11	Infant: 5.9 weeks (intervention) 7.8 weeks (control 1) 6.3 weeks (control 2) Parent: NR	Intervention: 27% F; 73% M Control 1: 31% F; 69% M Control 2: 36% F; 64% M	Parent mental health (STAI); NR; mothers	Some concerns	Narrative
Salisbury et al (2012) ⁴⁵	USA	Wessel criteria (defined as crying for ≥3 hours a day for at least 3 days a week for at least 3 weeks)	Education (Psychosocial Family Treatment Model); 3 treatment sessions; 10 weeks; pediatrician and mental health clinician	Randomized - parallel-group; no blinding; secondary care; outpatients	Standard of care: Standard Pediatric Care	Intervention: 30 Control: 31	Infant: 7.43 weeks (intervention) 7.36 weeks (control) Parent: 29.80 years (intervention) 31.29 years (control)	Intervention: 43.33% F; 56.67% M Control: 51.61% F; 48.39% M	Parent mental health (BDI), HRIU; 10 weeks; mothers	High	Narrative
Van den Boom (1994) ⁴⁶	Netherlands	Irritability based on the NBAS/Brazelton examinations	Education: improvement of sensitive parenting, 3 sessions; 3 months; researcher Intervention 1: training + pretest; intervention 2: training+ no pretest	Randomized—other; no blinding; NR	No treatment (control 1: pretest; control 2: no pretest)	Intervention 1: 25 Intervention 2: 25 Control 1: 25 Control 2: 25	Infant: All groups: 26.07 weeks Parent (mother/father): 24.96/24.28 years (intervention1/2) 24.28/24.76 years (control1/2)	Intervention 1/2: 48%/64% F; 52%/36% M Control 1/2: 28%/48% F; 72%/52% M	Parent–child relationship (investigator-scored); 42 months; both parents, mothers, fathers	High	Narrative
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TABLE 1. Summary of the Included Studies (Continued)

Author (Year)	Country	Excessive Crying Definition	Intervention, Comparator, and Study Design			Baseline Characteristics			Caregiver Outcomes	Risk of Bias ^a	Included in MA or Narrative
			Intervention Type (Name); Details; Duration; Facilitator	Study Design; Blinding; Health Care Setting	Control Type; Details	Sample Size (N)	Infant and Parents' Ages at Assessment (M)	Infant Sex, (%) F or M	Assessed Outcomes (Questionnaire); Longest Follow-Up Duration; Caregiver Assessed		
Wolke et al (1994) ⁴⁷	UK	Excessive crying that had persisted for >4 weeks; fussing and crying for >3 hours per day, on average, over a 1-week baseline diary period	Education: Intervention 1: Empathy Intervention 2: Behavioral management; duration NR; CRY-SIS counselors	Quasi-experimental; NA; home	Standard of care	Intervention 1: 27 Intervention 2: 21 Control: 44	Infant: 17.4 weeks (intervention 1) 14.8 weeks (intervention 2) 16.1 weeks (control) Parent: 29.4 years (intervention 1) 29.0 years (intervention 2) 27.3 years (control)	Intervention 1: 44% F; 56% M Intervention 2: 43% F; 57% M Control: 57% F; 43% M	Parent caregiving burden (coping: VAS), parent-child relationship (VAS), HRU; 3 months; mothers	Unclear	Narrative
Probiotic Interventions											
Baldasarre et al (2018) ⁴⁸	Italy	Diagnosis of IC (defined as crying episodes lasting ≥3 hours per day for ≥3 days per week, within 7 days before enrollment)	Probiotic (probiotic mixture with 4 <i>Lactobacilli</i> strains, 3 <i>bifidobacteria</i> strains and 1 <i>Streptococcus thermophilus</i> strain) ^c ; 10 drops of probiotics delivered once per day, preferably in the morning before feeds; 21 days; parents	Randomized - parallel-group; double blind; secondary care: outpatients	Placebo; identical formulation without probiotics	Intervention: 27 Control: 26	Infant: 39.0 weeks (intervention) 38.5 weeks (control) Parent: NR	Intervention: 33.3% F; 66.7% M Control: 50.0% F; 50.0% M	Parental QoL (VAS); 21 days; parents (unspecified)	Some concerns	MA
Chen et al (2021) ⁴⁹	China	Rome III criteria: crying or fussing episodes lasting > 3 hours per day and occurring at least 3 days per week as assessed by data collected during the 7-day run-in period and confirmed at visit 2	Probiotic (probiotics - <i>B. animalis</i> subsp. <i>lactis</i> BB12); 10e9 CFU (6 drops per day); 21 days; parents	Randomized - parallel-group; double blind; secondary care: outpatients	Placebo; identical sunflower oil suspension but without any probiotics	Intervention: 96 Control: 96	Infant: 4.5 weeks (intervention) 4.3 weeks (control) Parent: NR	Intervention: 54.2% F; 45.8% M Control: 47.9% F; 52.1% M	Parent QoL (PedsQL); 21 days; both parents	Some concerns	MA

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TABLE 1. Summary of the Included Studies (Continued)

Author (Year)	Country	Excessive Crying Definition	Intervention, Comparator, and Study Design				Baseline Characteristics			Caregiver Outcomes	Risk of Bias ^a	Included in MA or Narrative
			Intervention Type (Name); Details; Duration; Facilitator	Study Design; Blinding; Health Care Setting	Control Type; Details	Sample Size (N)	Infant and Parents' Ages at Assessment (M)	Infant Sex, (%) F or M	Assessed Outcomes (Questionnaire); Longest Follow-Up Duration; Caregiver Assessed			
Gerasimov et al (2018) ⁵⁰	Ukraine	IC (defined as cry and/or fuss lasting >3 hours per day, occurring on >3 days per week, for the last 7 days)	Probiotic (Probiotic mixture— <i>Lactobacillus rhamnosus</i> [19070–2] and <i>Lactobacillus reuteri</i> [12246]); total dose 250e6 CFU 2 times daily (1 dose in the morning and 1 dose in the evening before feeding); 28 days; caregivers	Randomized - parallel-group; double blind; tertiary and secondary care; outpatients	Placebo; Vitamin D3 supplement	Intervention: 84 Control: 84	Infant: 6.3 weeks (intervention) 6.4 weeks (control) Parent: NR	Intervention: 52% F; 48% M Control: 48% F; 52% M	Parental mental health (EPDS); 28 days; mothers	Some concerns	MA	
Karaahmet et al (2025) ⁵¹	Turkey	IC diagnosis (characterized by crying spells lasting >3 hours a day, >3 days a week according to the Rule of Three, for 3 weeks)	Probiotic (<i>Bifidus ActiRegularis</i> supplementation in the mother's diet); 5e8 CFU once a day (80 ml) for 15 days; mothers	Randomized - parallel-group; single blind; secondary care; outpatients	Standard of care: regulation of maternal nutrition, massaging the baby at regular intervals during the day, and removing the gas after each feeding	Intervention: 15 Control: 16	Infant: 4.3 weeks (intervention) 4.2 weeks (control) Parent: 24 years and under: 46.7% (intervention) 24 years and under: 50.0% (control)	Intervention: 66.7% F; 33.3% M Control: 62.5% F; 37.5% M	Parent QoL (PQLS), parent-child relationship (MAS); 15 days; mothers	Some concerns	MA	
Maldonado-Lobon et al (2021) ⁵²	Spain	Rome III criteria (crying episodes lasting ≥3 hours per day occurring for at least 3 days per week for at least 1 week)	Probiotic intervention 1: combination of <i>L. fermentum</i> CECT5716 (1e8 CFU/day) and <i>B. Breve</i> CECT7263 (1e8 CFU/day); intervention 2: <i>B. Breve</i> CECT7263 alone (2e8 CFU/day); 28 days, caregivers	Randomized - parallel-group; no blinding; secondary care; outpatients	Simethicone: 20 mg 4 times a day in drops, half an hour before meals	Intervention 1: 57 Intervention 2: 49 Control: 44	Infant: 5.9 weeks (intervention 1) 5.7 weeks (intervention 2) 5.3 weeks (control) Parent: NR	Intervention 1: 52.6% F; 47.3% M Intervention 2: 48.9% F; 51.1% M Control: 40.9% F; 59.1% M	Parent mood (3-point scale); 4 weeks; parents	Some concerns	Narrative	

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TABLE 1. Summary of the Included Studies (Continued)

Author (Year)	Country	Excessive Crying Definition	Intervention, Comparator, and Study Design			Baseline Characteristics			Caregiver Outcomes	Risk of Bias ^a	Included in MA or Narrative
			Intervention Type (Name); Details; Duration; Facilitator	Study Design; Blinding; Health Care Setting	Control Type; Details	Sample Size (N)	Infant and Parents' Ages at Assessment (M)	Infant Sex, (%) F or M			
Mi et al (2014) ⁵³	China	IC (defined as episode of crying that lasted ≥ 3 hours a day for 3 days before initiation of treatment)	Probiotic (<i>Lactobacillus reuteri</i> 17938); 10e8 CFU (5 drops per day); caregivers	Randomized - parallel-group; single blind; NR	Placebo: Identical suspension without live organisms	Intervention: 20 Control: 19	Infant: 4.2 weeks (intervention) 4.1 weeks (control) Parent: NR	Intervention: 35% F; 65% M Control: 53% F; 47% M	Parental satisfaction (tool NR); parent mental health (EPDS); 4 weeks; mothers or both parents	Some concerns	MA
Moreno-Villares et al (2024) ⁵⁴	Multinational (Mexico, Spain)	Rome IV criteria: crying and fussing for ≥3 hours per day, for ≥3 days per week	Probiotics: <i>B. longum</i> KAP042 and <i>P. pentosaceus</i> KAP04; 10e9 CFU each in 5 drops a day, for 21 days; parents	Randomized - parallel-group; single blind; NR	<i>L. reuteri</i> DSM17938 (10e8 CFU in 5 drops a day)	Intervention: 55 Control: 57	Infant: 5.3 weeks (intervention) 5.2 weeks (control) Parent: NR	Intervention: 44.4% F; 55.6% M Control: 43.9% F; 56.1% M	Parent mental health (HADS), sleep (Likert scale); 21 days; mother; father	High	MA
Sung et al (2014) ¹⁵	Australia	Wessel's criteria (defined as crying or fussing for ≥3 hours a day for ≥3 days over 7 days)	Probiotic (<i>Lactobacillus reuteri</i> DSM 17938); 0.2e8 CFU per drop, 5 drops daily for 1 month at the same time each day; caregivers	Randomized - parallel-group; double blind; community	Placebo: maltodextrin (identical excluding probiotic bacteria)	Intervention: 85 Control: 82	Infant: 7.5 weeks (intervention) 6.9 weeks (control) Parent: NR	Intervention: 56% F; 44% M Control: NR	Parent mental health (EPDS), parent QoL (AQoL-4R, PedsQL); 6 months; mothers, families, both parents	Some concerns	MA
Szajewska et al (2013) ⁵⁵	Poland	IC (defined as crying episodes lasting ≥3 hours per day and occurring ≥3 days per week within 7 days before enrollment)	Probiotic (<i>Lactobacillus reuteri</i> DSM 17938); 1e8 CFU orally in 5 drops once daily for 21 days; parents	Randomized - parallel-group; quadruple blind; primary care	Placebo: Identical formulation excluding probiotic bacteria	Intervention: 40 Control: 40	Infant: 4.9 weeks (intervention) 5.4 weeks (control) Parent: NR	Intervention: 35% F; 65% M Control: 45% F; 55% M	Parent QoL (VAS); 28 days (1 week after treatment termination); parent/family	Some concerns	MA
Turco et al (2021) ⁵⁶	Italy	Rome III criteria (not further specified)	Probiotic (<i>Lactobacillus reuteri</i> DSM 17938); in partially hydrolyzed formula with reduced lactose content plus maltodextrin; dose NR, 28 days; caregivers	Randomized - parallel-group; double blind; NR	Standard of care: standard formula	Intervention: 124 Control: 117	Infant: 39.24 weeks (intervention) 39.31 weeks (control) Parent (mother/father): 30.54/33.07 years (intervention) 29.97/33.41 years (control)	Intervention: 46.8% F; 53.2% M Control: 51.3% F; 48.7% M	Parent QoL (PedsQL); 60 days; both parents, mothers, fathers	Some concerns	MA

(Continued on next page)

TABLE 1. Summary of the Included Studies (Continued)

Author (Year)	Country	Excessive Crying Definition	Intervention, Comparator, and Study Design			Baseline Characteristics			Caregiver Outcomes		Included in MA or Narrative
			Intervention Type (Name); Details; Duration; Facilitator	Study Design; Blinding; Health Care Setting	Control Type; Details	Sample Size (N)	Infant and Parents' Ages at Assessment (M)	Infant Sex, (%) F or M	Assessed Outcomes (Questionnaire); Longest Follow-Up Duration; Caregiver Assessed	Risk of Bias ^a	
Xinias et al (2017) ⁵⁷	Greece	IC (defined as unsoothable crying episodes for >3 hours a day for ≥ 3 days a week since at least 1 week)	Probiotic: lactose-reduced symbiotic partial whey hydrolysate formula with <i>Bifidobacterium lactis</i> BB12; dose NR, 1 month; parents	Quasi-experimental; NA; secondary care: unclear	Standard of care: standard formula	Intervention: 40 Control: 20	Infant: 4.3 weeks (intervention) 6.1 weeks (control) Parent: NR	NR	Parent QoL, sleep, parent-child relationship, parent stress, social interaction (all assessed using a study-specific questionnaire); 1–2 months; both parents	Unclear	MA
Other Interventions											
Ates Besinik et al (2024) ⁵⁸	Turkey	Rome IV criteria (no further details)	Massage/manual therapy; therapeutic touch; 3 consecutive days per week, 1 session per day and 10 minutes per session; 2 weeks; practitioner	Randomized - parallel-group; single blind; secondary care: outpatients	Routine care	Intervention: 32 Control: 32	Infant: 7.21 weeks (intervention) 6.93 weeks (control) Parent: NR	Intervention: 43.75% F; 56.25% M Control: 43.75% F; 56.25% M	Parent-infant interaction (ICS); 2 weeks; mothers	High	Narrative
Carnes et al (2024) ⁵⁹	Australia, Switzerland, UK	Rome IV criteria: crying and fussing and difficult to console for >3 hours per day, for 3 days or more, for 1 week or more	Massage/manual therapy; specific light touch osteopathic treatment plus standard of care; intervention for 10–20 minutes; up to 4 intervention sessions; 2-week period; osteopathic physicians	Randomized - parallel-group; single blind; private osteopathic clinics	Nonspecific light touch osteopathic treatment plus standard of care	Intervention: 32 Control: 34	Infant: 5.7 weeks (intervention) 6.1 weeks (control) Parent: 33.5 years (intervention) 33.4 years (control)	Intervention: 53.1% F; 43.8% M Control: 55.9% F; 44.1% M	Parenting confidence (KPCS), parent experience Likert scale; 14 days; mothers or both parents	Some concerns	Narrative
Iacovou et al (2018) ⁶⁰	Australia	Wessel criteria (defined as crying episodes lasting for >3 hours a day for ≥3 days a week and for ≥3 weeks)	Dietary (Low-FODMAP diet); meals provided to ensure adherence; 10 days; mothers	Randomized - crossover; double blind; community	Standard of care: typical Australian diet	Total population: 13	Infant: 6.3 weeks Parent: 34 y	54% F; 46% M	Parent mental health (DASS), parent stress (DASS); 8 to 10 days average; mothers	Some concerns	Narrative

(Continued on next page)

TABLE 1. Summary of the Included Studies (Continued)

Author (Year)	Country	Excessive Crying Definition	Intervention, Comparator, and Study Design				Baseline Characteristics			Caregiver Outcomes	Risk of Bias ^a	Included in MA or Narrative
			Intervention Type (Name); Details; Duration; Facilitator	Study Design; Blinding; Health Care Setting	Control Type; Details	Sample Size (N)	Infant and Parents’ Ages at Assessment (M)	Infant Sex, (%) F or M	Assessed Outcomes (Questionnaire); Longest Follow-Up Duration; Caregiver Assessed			
Jordan et al (2006) ⁶¹	Australia	Persistent crying/ irritability based on parent complaint	Mixed: drug treatment: antireflux medication ranitidine (3 mg/kg 3 times a day) and cisapride (0.2 mg/kg 4 times a day) plus standard medical and nursing care; parents facilitated antireflux medication or placebo arms, health care professionals facilitated infant mental health consultation arm	Randomized - parallel-group; double blind; secondary care: inpatients	1) Placebo; identical in appearance plus standard medical and nursing care 2) Infant mental health consultation	Intervention: 34 Control 1 (placebo): 29 Control 2 (infant mental health consultation): 40	Infant: 14.3 weeks (intervention) 14.8 weeks (control 1) 13.0 weeks (control 2) Parent: Mother 29 years; Father 31 years (intervention) Mother 29 years; Father 32 years (control 1) Mother 29 years; Father 31 years (control 2)	Intervention: 36% F; 64% M Control 1: 52% F; 48% M Control 2: 52% F; 48% M	Parent experience (EMQ), HRU; 4 weeks; mothers	Some concerns	Narrative	
Novosad et al (2003) ⁶²	USA	Mothers who complained that their infant was so fussy that it was a source of stress for her	Rhythmic stimulation (Breathing Bear); provides tactile stimulation; used every day from age 5 weeks to 6 months; mothers	Quasi- experimental; NA; home	Placebo: nonbreathing bear	Intervention: 35 Control: 37	Infant: 5 weeks (intervention) 5 weeks (control) Parent: NR	Intervention: 60% F; 40% M Control: 51.3% F; 48.7% M	Parent stress (PSI), parent mental health (BDI); 7 months; mothers	High	Narrative	
Sahebkharam et al (2022) ⁶³	Iran	Colic (defined as a ≥2-hour episode of crying during 24 hours for ≥3 days within the past week)	Aromatherapy (lavender oil): for at least 15 minutes twice a day for 6 days, 3 days inhalation and following 3 days apply to abdominal skin; 1 week; mothers with the help of researchers (details not given)	Randomized - parallel-group; double blind; secondary care: outpatients	Placebo: Sweet almond oil (same procedure as intervention)	Intervention: 34 Control: 32	Infant: 39.58 weeks (intervention) 39.87 weeks (control) Parent: 27.82 years (intervention) 27.50 years (control)	Intervention: 38.2% F; 61.8% M Control: 43.8% F; 56.3% M	Parent mental health (EPDS); 7 days; mothers	Some concerns	Narrative	

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TABLE 1. Summary of the Included Studies (Continued)												
Author (Year)	Country	Excessive Crying Definition	Intervention, Comparator, and Study Design			Baseline Characteristics			Caregiver Outcomes		Risk of Bias ^a	Included in MA or Narrative
			Intervention Type (Name); Details; Duration; Facilitator	Study Design; Blinding; Health Care Setting	Control Type; Details	Sample Size (N)	Infant and Parents' Ages at Assessment (M)	Infant Sex, (%) F or M	Assessed Outcomes (Questionnaire); Longest Follow-Up Duration; Caregiver Assessed			
Schwenla et al (2025) ⁶⁴	Germany	Rome IV criteria: Crying or fussing for ≥3 hours a day for ≥3 days within a week	Massage/manual therapy; osteopathic treatment (3 treatments lasting 20–30 minutes delivered once a week); osteopathic physicians	Randomized - parallel-group; no blinding; private osteopathic clinics	Placebo (placed on a waiting list and not given active treatment)	Intervention: 50 Control: 50	Infant: 5.3 weeks (intervention) 5.9 weeks (control) Parent: 32.3 years (intervention) 32.0 years (control)	Intervention: 56% F; 44% M Control: 42% F; 58% M	Parent stress (NRS), parenting confidence (KPCS); 3 weeks; mothers	High	Narrative	
Abbreviations: AQoL-4R, Assessment of Quality of Life; BDI, Beck Depression Inventory; CFU, colony-forming units; DASS, Depression Anxiety Stress Scales; EMO, Experience of Motherhood Questionnaire; EPDS, Edinburgh Postnatal Depression Scale; F, female; FODMAP, fermentable oligosaccharides, disaccharides, monosaccharides, and polyols; GHQ, General Health Questionnaire; HADS, Hospital Anxiety and Depression Scale; HRU, health care resource use; IC, infant colic; ICS, Infant Colic Scale; KPCS, Karitane Parenting Confidence Scale; M, male; MA, meta-analysis; MAS, Maternal Attachment Scale; MEQ, Maternal Self-Efficacy Questionnaire; MIAQ, Mother–Infant Attachment Questionnaire; MIBS, Mother-to-Infant Bond Scale; NA, not applicable; NBAS, Neonatal Behavioral Assessment Scale; NR, not reported; NRS, numeric rating scale; PedsQL, Pediatric Quality of Life Inventory; PQLS, Postpartum Quality of Life Scale; PSAS, Postpartum Specific Anxiety Scale; PSI, Parenting Stress Index; QoL, quality of life; sAA, salivary alpha-amylase; sCORT, salivary cortisol; SF, short form; STAI, State-Trait Anxiety Inventory; VAS, visual analog scale; ZBS, Zarit Burden Scale.												
^a Levels of risk of bias—RCTs: High, some concerns, low; quasi-experimental: high, unclear, low.												
^b Although relevant parental outcomes were measured, study not included in the MA because of the unsuitability of the reported data for MA.												
^c Four different strains of lactobacilli (<i>L. paracasei</i> DSM 24733, <i>L. plantarum</i> DSM 24730, <i>L. acidophilus</i> DSM 24735, and <i>L. delbrueckii</i> subsp. <i>bulgaricus</i> DSM 24734), 3 strains of bifidobacteria (<i>B. longum</i> DSM 24736, <i>B. breve</i> DSM 24732, and <i>B. infantis</i> DSM 24737), and 1 strain of <i>Streptococcus thermophilus</i> DSM 24731.												

(A)

Intention-to-treat	Unique ID	Study ID	Experimental	Comparator	Outcome	Weight	D1	D2	D3	D4	D5	Overall	
	1	Sung 2014	Probiotic	Placebo	EPDS	NA	+	+	!	!	!	!	Low risk
	2	Gerasimov 2018	Probiotic	Vitamin D3	EPDS	NA	+	+	+	!	+	!	Some concerns
	3	Baldassarre 2018	Probiotic Mixture	Placebo	QoL by VAS	NA	+	!	+	!	+	!	High risk
	4	Keefe 2006	Homebased intervention p	Standard of care	PSI SF	NA	!	!	+	+	+	!	
	5	Iacovou 2018	Low-FODMAP diet	Typical Australian diet	DASS	NA	+	+	+	!	!	!	
	6	Szajewska 2013	Lactobacillus reuteri	Placebo	QoL by VAS	NA	+	+	+	!	+	!	
	7	Salisbury 2012	Family-centered treatment	Standard Care	BDI	NA	+	!	+	!	+	!	
	8	Alikhalili 2023	Education programme	Routine care	ZBS	NA	!	!	+	!	!	!	
	9	McKenzie 1991	Advice	Empathy	Maternal distress	NA	!	+	+	!	!	!	
	10	Parkin 1993	Management techniques; c	General information and reea	Anxiety by STAI	NA	+	+	+	!	!	!	
	11	Lim 2014	THB	Standard Care	PSI-SF	NA	+	+	!	!	+	!	
	12	Maldonado-Lobon 2	Probiotic	Simethicone	Parent mood	NA	!	+	+	!	+	!	
	13	Mi 2014	Probiotic	Placebo	EPDS	NA	!	+	+	!	+	!	
	14	Turco 2021	Probiotic	Standard formula	PedsQL	NA	+	+	+	!	+	!	
	15	van den Boom 1994	Training/education	No treatment	Maternal interactive beh	NA	+	+	+	!	!	!	
	16	Carnes 2024	Specific touch	Non-specific touch	Confidence score	NA	+	+	+	!	!	!	
	17	Chen 2021	Probiotic Mixture	Placebo	PedsQL	NA	+	+	+	!	+	!	
	18	Sahebkharam 2022	lavender oil aromatherapy	Placebo (sweet almond oil ar	EPDS	NA	+	+	+	!	+	!	
	19	Montazeri 2022	Counselling	services as usual	MIAQ	NA	+	!	+	!	+	!	
	20	Jordan 2006	Ranitidine plus cispapride	Placebo; infant mental healt	EMQ	NA	!	+	+	!	+	!	

D1 Randomisation process
 D2 Deviations from the intended interventions
 D3 Missing outcome data
 D4 Measurement of the outcome
 D5 Selection of the reported result

(B)

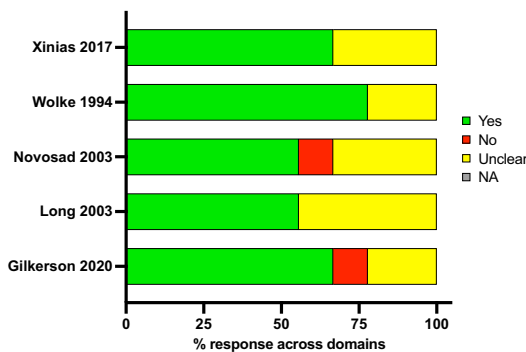


FIGURE 2.

Risk-of-bias assessments for (A) randomized clinical trials or (B) quasi-experimental studies assessed using either the Cochrane RoB2 tool or the JBI RoB tool for nonrandomized, quasi-experimental studies.

Abbreviations: JBI, Joanna Briggs Institute; RoB, risk of bias.

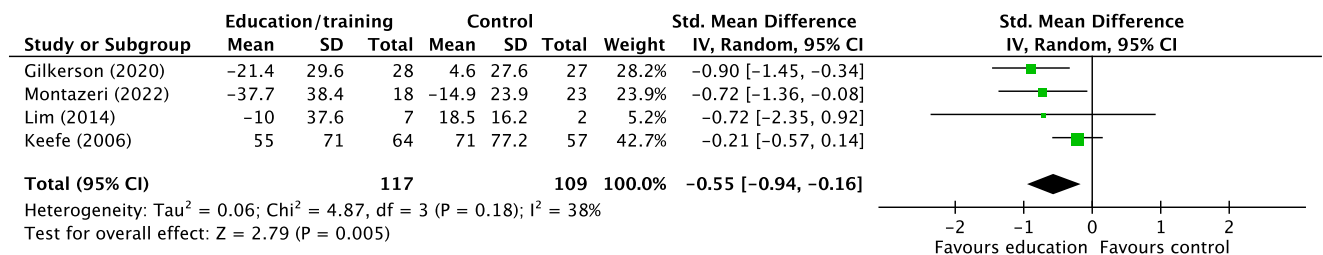


FIGURE 3.

Meta-analysis of the impact of education-based interventions on parental stress or anxiety. Three studies reported on stress levels that were all based on PSI-SF scores. One study⁴³ reported a PSAS anxiety score.

Abbreviations: PSAS, Postpartum Specific Anxiety Scale; PSI-SF, Parenting Stress Index–Short Form.

reliability of findings. The resulting meta-analysis (Figure 3) found that parents who received educational interventions had lower stress or anxiety than controls

(SMD -0.55 , 95% CI -0.94 to -0.016 , $P = 0.005$) with moderate heterogeneity ($I^2 = 38\%$). The effect size was moderate with the use of trim and fill, suggesting no publication

bias. Further, the Begg and Mazumdar rank correlation ($P = 0.50$) and Egger et al's test ($P = 0.83$) were not significant, suggesting no evidence of publication bias (Supplemental Figure 1). Following Cochrane recommendations,²⁵ excluding the quasi-experimental study³⁸ from the analysis yielded a similar effect size (SMD -0.35 , 95% CI -0.67 to -0.004 , $P = 0.03$), but reduced heterogeneity ($I^2 = 1\%$) (data not shown).

For educational interventions not included in meta-analysis, 2 studies reported reduced maternal depression, anxiety, and stress levels^{41,44} whereas 1 study reported no significant effects on maternal depression.⁴⁵ Education-based interventions were reported to reduce parental caregiving burden.^{37,41,47} Except for a nonsignificant finding for mother-to-infant bonding,⁴⁰ educational interventions positively influenced parenting behaviors and mother-infant relationships, including greater mother enjoyment of her baby,⁴¹ a better mother-infant relationship,^{43,47} more sensitive and co-operative parenting behaviors,⁴⁶ reduced maternal distress,⁴² enhanced maternal self-esteem,⁴¹ and improved knowledge⁴¹ compared with control groups. Given the heterogeneity among the educational interventions included in these analyses, an important question is whether successful interventions shared methodological components. To explore this, we conducted a secondary narrative analysis of the 11 studies reporting parental benefits (4 from the meta-analysis and 7 from the narrative review). Table 2 presents the findings. All 11 successful educational interventions combined information on infant crying with guidance to support parental coping. More than half the interventions (1) collected information through history taking and provided reassurance about the infant's crying, health, and development; (2) gave parents evidence-based guidance on the normal development of infant crying; (3) discussed parenting methods for managing crying; (4) presented evidence-based strategies to help parents to control their emotions and actions, support their well-being, and enhance coping; (5) encouraged seeking social support; and (6) provided parents with take-home materials to reinforce the content of the clinic sessions.

Findings From Probiotic Interventions

Of the 11 studies reporting on probiotic interventions, 10 were included in separate meta-analyses (4 on parental depression^{15,50,53,54} and 7 on quality of life^{15,48,49,51,55-57}). No evidence of an effect of probiotic-based interventions on parental depression was found compared with controls (SMD -0.04 , 95% CI -0.31 to 0.24 , $P = 0.79$), with moderate heterogeneity between studies ($I^2 = 51\%$) (Figure 4A). The effect size remained the same with the use of trim and fill, indicating no publication bias. Further, the Begg and Mazumdar rank correlation ($P = 0.73$) and Egger et al's test ($P = 0.14$) were not significant, confirming the lack of publication bias (Supplemental Figure 1). The single

probiotic intervention study⁵² not included in the meta-analysis reported significant improvements in parental mood with *Bifidobacterium breve* CECT7263 (Bb) probiotics alone compared with Bb plus *Lactobacillus fermentum* CECT5716 probiotics or simethicone.

A separate meta-analysis found significant improvement in parental quality of life after probiotic-based interventions compared with controls (SMD 2.15 , 95% CI 0.71 – 3.60 , $P = 0.004$), although heterogeneity between studies was high ($I^2 = 99\%$) (Figure 4B). The effect size remained large with the use of trim and fill, indicating no publication bias. Further, the Begg and Mazumdar rank correlation ($P = 0.08$) was not significant; however, Egger et al's test ($P < 0.001$) was significant, suggesting some publication bias (Supplemental Figure 1). Excluding the quasi-experimental study⁵⁷ did not change the findings, with the effect size and heterogeneity remaining similar (SMD 2.24 , 95% CI 0.72 – 3.96 , $P < 0.001$, $I^2 = 99\%$) (data not shown).

Findings From Other Interventions

No meta-analysis was possible for other intervention types. The narrative evidence for the impact of massage/manual therapy on parental outcomes was mixed: 1 study reported no impact on parenting confidence or experience,⁵⁹ another reported improved parent-infant relationships,⁵⁸ and a third reported reduced stress, insecurity/helplessness, and improved daily activities⁶⁴ compared with control groups. These studies were rated at some concerns ($n = 1$) or high risk ($n = 2$) of bias. Findings for the impact of other interventions were limited, with only 1 study available for each intervention type.

Safety and Economic Outcomes

No studies reported parent safety outcomes. Four studies (2 RCTs^{45,61} and 2 quasi-experimental studies^{38,47}) reported on economic outcomes, all focusing on health care resource use. One RCT reported fewer mother-infant unit admissions,⁶¹ whereas another found reduced emergency department visits, nonroutine pediatrician visits, and pediatrician telephone calls following an education-based intervention.⁴⁵ One quasi-experimental study reported that parents who received an education-based intervention had an average of 7 health care contacts over 3 months,³⁸ whereas another reported no difference in the number of doctor or health visitor treatment contacts.⁴⁷

DISCUSSION

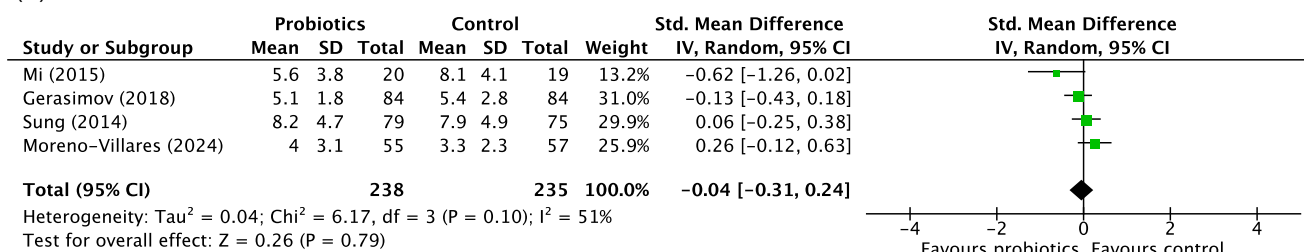
Many parents find prolonged, unexplained infant crying to be stressful.^{1,8,65} This systematic review and meta-analysis is the first, to our knowledge, to focus specifically on the effectiveness and cost-effectiveness of "parental support" interventions, which help parents of excessively crying babies to manage their emotions and actions, increase their

First Author (Year); Included in the MA or Narrative Analysis	Who Delivers Intervention/ Intervention Method and Dose	Intervention Protocol Based on a Written Manual	Information Provided About the Normal Development of Infant Crying and its Causes	History Taken to Gather Information and Provide Reassurance About This Infant's Crying, Health and Development	Discusses Parenting Methods for Managing Excessive Infant Crying (eg, Soothing Methods)	Listens and Responds to Parental Concerns, Perceptions, or Fears	Discusses Strategies for Managing Parental Emotions, Behaviors, and Health	Encourages Parent to Seek Social Support From Family/ Friends/ Other Sources	It's Safe to Walk Away if the Crying is Intolerable, Providing Baby is in a Safe Place	Enhances Parental Sensitivity, Empathy, or Attunement	Provides Take-Home Educational Materials or Homework (Leaflet, Worksheet, Video) to Back Up to Clinic Sessions
Alkhalili et al (2023) ³⁷ ; Narrative	Researcher/in-person face-to-face to groups of 2 or 3 parents, plus telephone follow-up; 4 sessions, each 30–45 minutes, within 2 weeks		Yes	Yes	Yes		Yes	Yes			Yes
Gilkerson et al (2020) ³⁸ ; MA	Trained infant-parent specialist/in-person 1-to-1 2-hour sessions plus telephone follow-up for up to 6 months				Yes	Yes	Yes	Yes		Yes	
Keefe et al (2006) ³⁹ ; MA	Pediatric nurse specialist/4 in-person 1-to-1 1-hour home visits, length unspecified, within 4 weeks		Yes	Yes			Yes	Yes			Yes
Lim (2014) ⁴⁰ ; MA	Investigator certified by Happy Baby Education Association/ single 1-to-1 in-person session, length unspecified plus telephone follow-up				Yes			Yes			Yes
Long (2003) ⁴¹ ; Narrative	Health visitor (specially trained community nurse) in-person 1-to-1 clinic session lasting 1.5 hours, then shorter sessions and telephone follow-ups until mother no longer required it	Yes		Yes		Yes		Yes			Yes
McKenzie (1991) ⁴² ; Narrative	Pediatrician/single in-person 1-to-1 clinic session, length unspecified		Yes		Yes				Yes		
Montazeri et al (2022) ⁴³ ; MA	Unclear/eight in-person sessions, length unspecified, within 4 weeks		Yes		Yes		Yes				

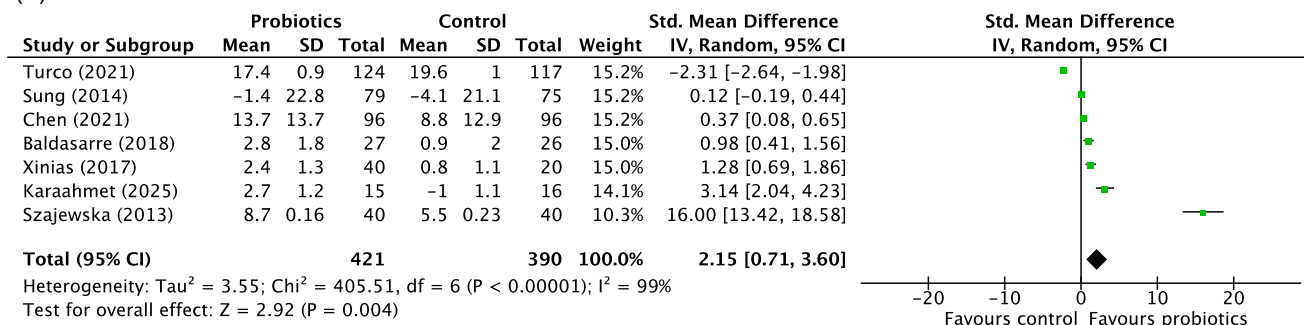
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TABLE 2. Components of Successful Educational Interventions Targeting Parents of Excessively Crying Infants (Continued)											
First Author (Year); Included in the MA or Narrative Analysis	Who Delivers Intervention/ Intervention Method and Dose	Intervention Protocol Based on a Written Manual	Information Provided About the Normal Development of Infant Crying and its Causes	History Taking Used to Gather Information and Provide Reassurance About This Infant's Crying, Health and Development	Discusses Parenting Methods for Managing Excessive Infant Crying (eg, Soothing Methods)	Listens and Responds to Parental Concerns, Perceptions, or Fears	Discusses Strategies for Managing Parental Emotions, Behaviors, and Health	Encourages Parent to Seek Social Support From Family/ Friends/ Other Sources	It's Safe to Walk Away if the Crying is Intolerable, Providing Baby is in a Safe Place	Enhances Parental Sensitivity, Empathy, or Attunement	Provides Take-Home Educational Materials or Homework (Leaflet, Worksheet, Video) to Back Up Clinic Sessions
Parkin et al (1993) ⁴⁴ ; Narrative	Pediatrician/single in-person 1-hour face-to-face session followed by home visits by public health nurse as necessary		Yes	Yes	Yes		Yes	Yes			
Salisbury et al (2012) ⁴⁵ ; Narrative	Behavioral pediatrician and mental health clinician/3 in-person 1-to-1 sessions, length unspecified, within 6 weeks			Yes	Yes	Yes	Yes	Yes			Yes
Van den Boom (1994) ⁴⁶ ; Narrative	Unclear/3 in-person 1-to-1 sessions, length unspecified, within 3 months				Yes					Yes	
Wolke et al (1994) ⁴⁷ ; Narrative	Parent Cry-sis team members with experience of excessive infant crying/telephone-delivered 1-to-1 sessions; length and number of sessions unspecified		Yes	Yes	Yes						Yes
Number of interventions included this component		1	6	6	9	3	6	7	1	2	6
Abbreviation: MA, meta-analysis.											

(A)



(B)

**FIGURE 4.**

Meta-analysis of the impact of probiotics-based interventions on (A) parental depression or (B) family or maternal quality of life. Parental depression outcomes were based on EPDS or HADS-D scores. QoL outcomes were based on PedsQoL, PQLS, or overall QoL scales.

Abbreviations: EPDS, Edinburgh Post-natal Depression Scale; HADS-D, Hospital Anxiety and Depression Scale; PedsQoL, pediatric quality of life inventory; PQLS, Postpartum Quality of Life Scale; QoL, quality of life.

well-being, and enable them to cope with their baby's crying.

Two main findings emerged. First, meta-analysis showed that educational interventions reduced parental stress or anxiety, with a moderate effect size. This finding indicates that teaching coping strategies to parents can reduce the emotional reactions involved in caring for a baby who cries excessively. This result is potentially important because frustration where parents cannot control emotional responses to infant crying can trigger infant abuse.^{18,20}

The narrative analysis of educational interventions was less consistent, with only 7 of 11 studies reporting parental benefits, likely reflecting diversity in intervention components or outcome measures. To clarify this, a secondary narrative analysis explored the detailed methodological components of the interventions found to help parents (4 from the meta-analysis and the 7 from the first narrative analysis). More than half of these interventions taught strategies to help parents to control their emotions and actions, support their well-being, and encourage them to seek social support. This finding aligns with evidence from observational studies that parents of excessively crying infants often worry that the crying is a sign the infant is ill,⁶⁶ blame themselves for causing the crying,⁶⁶ feel guilty and emotionally stressed,^{67,68} and withdraw socially because they fear disapproval.⁶⁷ These results highlight the importance of

addressing parental interpretations of crying in interventions. They provide novel and promising findings regarding the components likely to be needed in future interventions. However, because the methods used were exploratory, their main implication is to identify the need for prospective studies to build on these findings.

The second main finding, from a meta-analysis of the effect of probiotic interventions, indicated improvements in parental quality of life with a large effect size. This effect may reflect reductions in infant crying found in some of these studies, thereby decreasing its adverse impact on parents. However, probiotics did not improve parental depression, suggesting that psychological benefits for parents may require other interventions directly targeting parents. Evidence for the impact of other interventions (eg, manual/massage therapy, aromatherapy) remained limited, mixed, and inconclusive.

STRENGTHS AND LIMITATIONS

Strengths of this review include the use of an extensive, inclusive, and up-to-date search strategy: all database searches were conducted from inception to April 8, 2025, without restrictions on date, language, or study design. To minimize reviewer error and bias, 2 reviewers were involved in all steps of the systematic review process, in line

with Cochrane guidance. Multiple tests for study or publication bias had largely negative findings. Previous systematic literature reviews (SLRs) in this area have examined interventions targeting infant crying or infant safeguarding, but none specifically assessed ways to support parents of excessively crying babies. Nine SLRs were identified that included parental outcomes as secondary or other outcomes of interest, with search dates ranging from April 2012 to May 2023.^{69–77} Most assessed a single intervention type: educational (n = 4),^{70,74,76,77} manual therapy (n = 2),^{71,72} probiotics (n = 1),⁷⁵ or dietary modifications (n = 1).⁷³ The number of studies reporting on parental outcomes included in these SLRs ranged from 0 to 12, with some SLRs seeking but not finding relevant data. In sum, this SLR provides the most comprehensive and up-to-date analysis of the evidence on providing parents with support to help them manage their emotions and actions, increase their well-being, and help them to cope with excessive infant crying.

Several limitations should be noted when considering our findings. Many studies failed to measure similar enough parental outcomes to be pooled in meta-analysis. All studies raised some methodological concerns, whereas 6 were rated at an overall high risk of bias. Parental outcomes were sometimes poorly defined, and group sizes were typically small. Baseline characteristics were not widely or comprehensively reported, with ethnicity reported in only 5 studies. Only 2 studies were multinational, limiting the generalizability of findings. Several studies calculated group sizes using their primary outcome measure of infant crying, including parental outcomes only as secondary measures and thus may have been statistically underpowered. Only 7 studies randomized parents or mother–infant dyads rather than infants alone. Follow-up periods were limited, ranging from 7 days to 7 months. Several RCTs were unblinded or single blinded.

These findings highlight the need for methodological improvements in future research. This was expected, partly because many of the studies predated recent improvements in methodological rigor. Importantly, however, the consistency of the findings from meta-analyses reported here makes it improbable that the 2 main findings of this systematic review are due to these methodological deficiencies.

GAPS IN THE EVIDENCE

As well as the main findings, several gaps in the evidence and associated goals for future research were identified. No studies reported on core parent safety outcomes, revealing a substantial dearth of evidence on critical adverse events such as illness, hospitalization, and employment. Economic evidence was limited to 4 studies, and no cost-effectiveness analyses were found. Some studies grouped “parents” without distinguishing between mothers and fathers; only 3 reported outcomes specifically for

fathers. Because fathers and male partners are disproportionately responsible for infant abuse,²⁰ they need to be distinguished. No comparative real-world (observational) studies were identified. As noted, the educational interventions included were diverse in content, delivery, and intensity. Although common components of successful educational interventions were identified, our exploratory analyses do not clarify which components, alone or in combination, are most cost-effective, pointing to the need for further research to confirm their importance.

Future studies using standardized, evidence-based parental outcome measures, particularly relating to parental mental health, emotions, cognitions, behaviors, and quality of life, are needed because this would allow evidence to be combined in meta-analyses. Research uncovering the processes that link parental emotions and cognitions with behaviors and providing independent assessments of parental behavior would further strengthen the evidence base. Determining whether interventions should target infants, parents, or both remains an important question.

CLINICAL IMPLICATIONS

This review found that educational interventions are effective in reducing parental stress or anxiety, implying that that these interventions should be considered as part of routine support for families presenting with excessive infant crying. The UK National Institute for Health & Care Excellence (NICE) has published recommended guidelines for clinical interventions suitable for this purpose.^{78–80} Resources, including education for front-line health care professionals, may be needed to allow these recommendations to be delivered.

The UK NICE guidelines advocate a “stepped” approach to the provision of clinical interventions, such that low intensity, cost-effective services are provided where suitable, with more intensive services reserved for cases with additional needs. With that in mind, clinicians may consider directing parents of excessively crying infants to one of the well-established websites designed to provide information about infant crying, including the peak and soothing-resistant bouts in the first 3 months found in normally developing infants (see Supplementary Table 3). Although not designed to enhance these parents’ coping strengths, these websites offer evidence-based information about the normal development of infant crying, which is one of the components of successful educational interventions identified here. There is evidence, albeit from a single study, that around 50% of parents challenged by their baby’s crying find website-presented information of this sort sufficient to provide reassurance and meet their needs.²³

Probiotics are not endorsed for routine use by medical authorities, but this review provides evidence that they may improve parental quality of life, although not

depression. Clinical judgment will be needed to decide these findings' implications for treatments.

CONCLUSIONS

Educational interventions for parents and probiotic interventions delivered to infants or mothers offer promise for improving parental outcomes in families with excessively crying babies. Additional adequately powered controlled trials, employing standardized evidence-based interventions, and parental outcome measures in adequately sized groups, together with health-economic analyses, are needed to advance clinical decision-making and service provision.

ABBREVIATIONS

AHT: abusive head trauma
Bb: *Bifidobacterium*
IC: infant colic
JBI: Joanna Briggs Institute
MA: meta-analysis
NETSCC: NIHR Evaluation Trials and Studies Coordinating Centre
NIHR: National Institute for Health and Care Research
RCT: randomized controlled trial
SBS: shaken baby syndrome
SLR: systematic literature review
SMD: standardized mean difference

SL Swift contributed to the design of the study, supervised the design of the data collection instruments, collected data, drafted parts of the initial manuscript, and critically reviewed and revised the manuscript. T Brugha contributed to the design of the study and data collection instruments and critically reviewed and revised the manuscript. I St James-Roberts coordinated the writing, contributed to the design of the study and data collection instruments, collected data, drafted parts of the initial manuscript, and critically reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

CONFLICTS OF INTEREST DISCLOSURES: The authors have no financial or nonfinancial interests to disclose.

FUNDING: This study was funded by the National Institute of Health and Care Research (NIHR) grant # 131341. NIHR Disclaimer: The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

CLINICAL TRIAL REGISTRATION: PROSPERO #CRD42024538958.

Accepted for Publication Date: May 21, 2026

<https://doi.org/10.1542/peds.2025-075063>

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