A systematic review of prevention and treatment of infant behavioural sleep problems

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Abstract

Aim: The aim of this review was to evaluate the evidence for interventions for behavioural sleep problem in infants.

Methods: Systematic review based on a search in MEDLINE, Web of Science and PsychINFO in December 2017 for articles published in English during 2007-2017 about preventive and treatment interventions for sleep problems in infants. The review included controlled trials and meta-analyses with at least 20 infants in study groups assessed according to the Grading of Recommendations Assessment, Development and Evaluation criteria.

Results: Out of 476 original articles assessed for eligibility, 12 studies were included in the synthesis. Interventions with behavioural, educational and massage strategies were evaluated. No intervention was evaluated in more than one trial. Five interventions with behavioural methods for establishing consistent routines or controlled crying showed modest short-term effects, while the evidence for elements of education was inconsistent. Studies of massage were of poor quality. Knowledge gaps were identified regarding interventions in cross-cultural context, involving fathers, in children below six months of age, in high-risk populations and consequences of interventions that include extinction.

Conclusion: Some support for short-term effects of behavioural treatment strategies was found, but more studies are needed to establish evidence.

KEYWORDS
behavioural intervention, infant, randomised controlled trials, sleep problem

1 INTRODUCTION

The evolution of sleep-wake patterns from multiple sleep episodes to one main consolidated sleep episode at night is a complex developmental process substantially engaging and challenging the parents during the first years. Sleep behaviour problems are developmentally normative; yet, parents who are able to attain appropriate strategies for settling their babies may decrease their child’s risk for long-lasting problems. It is important to establish good sleep routines and gradually teach their baby to self-soothe. If parents do not have effective strategies for settling their baby, it can lead to ongoing adjustment problems for the baby.1 Complaints about difficulty falling
asleep and multiple and prolonged night wakings are among the most common complaints to child health professionals from parents and often cause family distress.2

Sadeh and Anders have described the complex and bidirectional relationships between parenting and infant sleep in the context of a transactional model formulated by Sameroff 3 (Figure 1). In this model, the sleep of the individual infant is influenced by maturational, intrinsic constitutional, biological, temperamental and medical factors which interact with parental influences and parental interactive behaviours. Parents’ beliefs, expectations, emotions and behaviours related to infant sleep are influenced by their socio-cultural and environmental context, their own developmental history and memories, their personality and psychopathology, the infant’s age, developmental characteristic and sleep patterns. Thus, children’s sleep and sleep problem should be considered within the context of the family.

During the first year of life, sleep undergoes substantial developmental changes.2 Most babies wake at night for feeding in the early weeks, and parents expect this awakening. Parents report that most babies begin to sleep through the night by about 12 weeks of age. The failure to achieve this milestone, so that an infant continues to settle poorly or wake the parents at night after 12 weeks, accounts for most infant sleep problems.4

There is no absolute definition of what constitutes a sleep problem. Sleep disorders refer to difficulties related to sleep, including difficulty falling or staying asleep, falling asleep at inappropriate times, excessive total sleep time and abnormal behaviours associated with sleep. The two most common sleep problems for children aged zero to five years are night waking and settling problems. Sleep problems are primarily defined by caregivers, are developmentally based and depend on cultural values.5

Different definitions have been created for use in clinical settings and in research. Within the clinical realm, the second revision of the International Classification of Sleep Disorders (ICSD) uses the clinical diagnostic category of Behavioural Insomnia of Childhood, which is further classified into sleep-onset association type, limit-setting type or combined type.6 The latest renditions of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5)7 and the ICSD-38 subsume paediatric insomnia under one umbrella diagnosis (DSM-5–Insomnia Disorder and ICSD-3–Chronic Insomnia Disorder), with both diagnoses taking developmental issues into consideration. From a clinical standpoint, these definitions also require that the symptoms must be frequent, be present for a specified time and result in some significant impairment in functioning in children, parents or in the family. Mild and transient symptoms should not be labelled a sleep disorder according to these manuals.2

It is important to make a distinction between the clinical diagnoses applicable to bedtime problems and night waking in children, and the research definitions used in studies of children with the problems. Essentially, no empirical studies of sleep problems in children have utilised the clinical definitions described above. In research, commonly used indicators of sleep are total sleep duration, number of awakenings at night and difficulties settling to sleep, often operationalised into scales recorded by parents.

**Key notes**
- The review found some support for short-term effects of behavioural treatment interventions for sleep problems in infants.
- Future studies are needed to disentangle which component/s in the interventions that are most effective.
- Knowledge gaps were found regarding the effectiveness of programmes in minorities with a Non-Western background; in high-risk populations; involving fathers; involving infants below six months of age; and consequences of behavioural interventions that include extinction.

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**FIGURE 1** A transactional model of parenting and infant sleep3
Objective measurements with technical devices, such as actigraphs, have not been used much in studies of sleep problems in children.9

Sleep problems are common in children across development. Although definitions in terms of age, frequency, severity, and duration of symptoms and sample populations have varied, the prevalence of paediatric insomnia in children and adolescents ranges from 10% to as high as 80% in children with neurodevelopmental or psychiatric comorbidities.2 The most common types of sleep problems include difficulties initiating sleep and maintaining sleep, in young children commonly referred to as bedtime problems and night waking.5

Disturbed sleep is a common problem in families with small children, and identified prevalence is remarkably similar across studies even when comparing studies across cultures. In the first six months of life, between 15% and 35% of parents report a problem with their infant’s sleep, including difficulties settling their infant to sleep at the start of the night and resettling them over night.10 In a Swedish study, 30% of parents of infants aged six to 20 months reported problems with their children’s night waking. In most cases (59%), the problems had lasted for more than three months.11 These findings were rather consistent with an earlier Swedish study from the 1960s,12 suggesting a quite stable prevalence over time.

Infant sleep problems are associated with adverse consequences for mothers including fatigue,13 postnatal depression and poorer general and mental health.14 Fathers also report poorer general health and greater psychological distress linked to infant sleep problems.15

The aim of this review was to evaluate the evidence for existing methods for the prevention and treatment of sleeping problems in infancy for use in Child Health Care, and to identify important knowledge gaps that need to be filled in future research.

2 | METHODS

We searched MEDLINE, Web of Science and PsychINFO in December 2017 for articles in English published during 2007-2017 about preventive and treatment interventions for behavioural sleep problems and crying or colic in children less than two years (see 16 for search syntax). In total, 2070 unique records were found and screened through abstracts. It was soon realised that the literature on treatment for sleep disorders and infantile colic had minimal overlaps, and thus, we decided to separate sleep and colic interventions into two separate reviews. The general quality of studies was scrutinised with the Grading of Recommendations Assessment, Development and Evaluation, GRADE,17 operationalised into a checklist in Swedish by the Swedish Agency for Health Technology Assessment and Assessment of Social Services.18 We used the following criteria in the selection of articles for sleep problems: the article should include an original intervention study; sleep problems should be the target of the intervention; there should be a control group to the intervention group; the infant and parental outcomes were accepted; the majority of the children in the study population should be under two years of age; and intervention and control groups should consist of at least 20 infants each.

The search flow is described in Figure 2. All articles were screened by two researchers and discussed until consensus was reached. There were 476 reports of original studies to be screened in full text, and 12 original articles described interventions for sleeping problems that fulfilled our criteria. We found 35 reviews to be of relevance and were taken aside and read separately. Three of these contained systematic reviews or meta-analyses that fulfilled our criteria and were included in the synthesis.

3 | RESULTS

There were two main strategies for the prevention and treatment interventions for behavioural sleep problems in children in the retrieved literature.5 Behavioural strategies were the most common and were therefore referred to as behavioural interventions. Education is also often involved, often aiming to establish a bedtime routine. The studies in the review are heterogeneous in respect to the different strategies, and the interventions combined these strategies in different ways. The same elements were used with different purposes, either to prevent or to treat a sleep problem.

There were few studies of sleep interventions in study populations in the age up to 24 months. We have therefore also included studies which included older children, but where the majority of the children were in the age range up to 24 months. We did not find any individual method that had been used in more than one full-scale study, and therefore, no overall evaluation of effects according to GRADE was made. Original preventive studies are described in detail in Table 1 and original treatment studies in Table 2.

3.1 | Education

Educational programmes involved provision of information about normal sleep and crying patterns, signs or tiredness, and focus on early establishment of positive sleep habits. They may include individual and group sessions, a booklet, DVD and website with information about infant sleep and behavioural strategies to improve infant sleep problems, shape circadian rhythms and minimise the likelihood of bedtime settling problems. Several behavioural interventions have been incorporated as bedtime routines, including sleep location, parent handling during sleep initiation and parental response to night-time awakenings. Almost all programmes have incorporated the recommendation that babies should be put to bed drowsy but awake to help them develop independent sleep initiation skills at bedtime and enable them to return to sleep following naturally occurring night-time arousals without intervention. Parent education programmes have been delivered in both the prenatal period and the postnatal period. The behavioural intervention often involved educational components.5
We found three studies with an educational strategy that showed positive effects on children’s sleep habits in a short-term perspective. In a study without randomisation in Japan, mothers participated in a group presentation and received a 20-page booklet, named Baby, Sleep Well at Night, on sleep and a list of desirable and undesirable parental behaviours to promote infant sleep. A tendency towards less night waking was demonstrated at follow-up. In an RCT, The Intervention Nurses Start Infants Growing on Healthy Trajectories, education of developmentally appropriate messages about bedtime routines, sleep location and behaviours, and responses to waking were delivered at home visits including a follow-up after 52 weeks. Compared with controls, the intervention group infants were less likely to have prolonged bedtime routines and more likely to have earlier bedtimes at 16 and 40 weeks, were less likely to be fed immediately before bed and more likely to self-soothe to sleep. In the intervention group, nocturnal sleep duration was longer by 35, 25 and 22 minutes at 8, 16 and 40 weeks, respectively, while effects of the intervention had waned at follow-up at one year. Hiscock et al performed an RCT at four weeks postpartum, sending a booklet and a DVD about infant sleep and crying and parental self-care by mail. A telephone consultation was offered six to eight weeks postpartum and a group session at twelve weeks postpartum to discuss (infant) sleep problems and strategies. Intervention caregivers were less likely at six months to spend >20 minutes attending infant waking compared to caregivers receiving care as usual, but there were no differences between the groups in infant sleep, crying or feeding problems at either follow-up at four and six months. Among frequent feeders having 11 feeds or more per 24 hours, it was found at four months of age that infants in the intervention group had lower odds of having daytime sleep problems (OR 0.13, 95% confidence interval [CI] 0.03 to 0.54) and crying problems (OR 0.27, 95% CI 0.08 to 0.86) compared to the control group.

In studies with an educational strategy, the results are mixed or show no effects. One of these is Tips for Infant and Parent Sleep. The sleep intervention included a 45-minute meeting with a nurse to discuss sleep information and strategies, an 11-page booklet, and weekly phone contact to reinforce information and problem solving. In a pilot study, infants in the sleep intervention group had fewer night-time awakenings and a longer night-time sleep duration, but when the same researchers repeated the study with a larger sample,
| Authors | Sample | Setting & Delivery | Intervention details | Outcome | Was the programme effective? |
|---------|--------|-------------------|----------------------|---------|-----------------------------|
| Adachi et al (2009) | No RCT | Intervention and control groups recruited in January and February, respectively | Intervention group Education Mothers were recruited at the health check-up session for their 4-month-old infants. They received a booklet (‘Baby, Sleep Well at Night’) and participated in a group presentation on infant sleep. It contained background information and lists of desirable and undesirable parental behaviours to promote infant’s sleep. They completed questionnaires on infant sleep patterns and sleep problems at baseline. Three months later, they received a follow-up questionnaire by mail. | Both the intervention and the control group had significantly lower prevalence of infants with difficulties settling at follow-up. No differences between baseline and follow-up were found for the other sleep-related problems. Compared to baseline the control group had significantly higher prevalence of infants who woke up more than once at night at follow-up (P = .022). | Yes |
| Galland et al (2017) | RCT | 802 families with mothers, partners and their babies born without congenital abnormalities at 36.5 wk’ gestation or later were randomly allocated into one of four groups stratified on household deprivation and parity | The aim to evaluate the effectiveness of sleep education antenatally and at 3 wk postpartum to prevent infant sleep problems. Mothers were recruited at 28-30 wk’ gestation. They were allocated to one of four groups: 1 (sleep intervention), 2) food, activity and breastfeeding (FAB) intervention, 3) combination of sleep and FAB intervention, or 4) control group, revealed after they consented to participate. All groups received standard maternity and Well Child care. The sleep group received a pre-birth group education on infant sleep, reinforced through an individual home visit 3 wk postpartum. The FAB group received education and support on breastfeeding pre-birth, 1 wk and 4 mo postpartum and on physical activity 3 mo postpartum. The combination group received all the above. Questionnaires were completed pre-birth, and 4 and 6 mo postpartum. At 6 mo, accelerometers and parents’ sleep diaries recorded the infants’ activity/sleep for 48 h. | No significant differences in infant sleep problems were found between the groups. Linear or mixed linear regression models found no significant intervention effects on sleep outcomes, with 19.1% of mothers and 16.6% of partners reporting their infant’s sleep a problem at 6 mo. Actigraphy-estimated the number of waking to be significantly reduced (8%) and the duration of daytime sleep increased (6 min) in those groups receiving the sleep intervention compared with those who did not. However, these small differences were not clinically significant and not observed in 24 h of infant sleep diary data. | No |
| Authors Year | Sample | Setting & Delivery | Intervention details | Outcome | Was the programme effective? |
|--------------|--------|-------------------|----------------------|---------|-----------------------------|
| Hiscock et al (2014) | 781 infants (from 770 families) born at 32 wk gestation or later without a serious health concern and their primary caregiver were randomised | **Setting**<br>Participants’ homes and 42 well-child centres (group session) in Melbourne, Australia | The aim to evaluate a preventive programme. Caregivers were recruited at their first home visit by their maternal and child health nurse (day 7-10 postpartum)<br> Educational material, telephone consultation and group session with focus on infants’ night-time sleep problems, daytime sleep problem, sleep patterns and parental night attendances were measured with a postal survey at baseline, and 4 and 6 mo postpartum | 2014: Relative to control caregivers, intervention caregivers at 6 mo were less likely to spend >20 min attending infant waking (41% vs 51%, adjusted OR 0.66, 95% CI 0.46 to 0.95)<br> No significant differences in infant sleep problems were found between the groups<br> Infant frequent feeders (>11 feeds/24 h) in the intervention group were less likely to have daytime sleep problems (OR 0.13, 95% CI 0.03 to 0.54) or cry problems (OR 0.27, 95% CI 0.08 to 0.86) at 4 mo<br> Frequent feeders at baseline had lower odds of daytime sleep problems in the intervention group compared with the control group at 4 mo<br> The programme may be best targeted to frequent feeders | Partly, for frequent feeders |
| Paul I et al (2016) | At 2 wk, 291 dyads of mother-newborn, full term, singletons, birth weight ≥2500 gm, were recruited to intervention or control group, stratified on birth weight, gestational age and intended feeding mode (breastfeeding or formula) | **Setting**<br>Participants home in Hershey, PA, USA, and at research centre | Primiparous mother-newborn dyads were randomised after childbirth, and research nurses delivered intervention content at home visits at infant ages 3, 16, 28 and 40 wk and at a research centre visit at 1 y<br> The RP sleep component included developmentally appropriate messages about bedtime routines, sleep location and behaviours, and responses to wakings<br> Portions of the Brief Infant Sleep Questionnaire were administered 2, 8 and 52 wk after birth with expanded sleep-related data collection at 16 and 40 wk | Compared with controls, intervention group infants were less likely to have prolonged bedtime routines >45 min and more likely to have earlier bedtimes at 16 and 40 wk, were less likely to be fed immediately before bed and more likely to self-soothe to sleep<br> In intervention group nocturnal sleep duration was longer at 8, 18 and 40 wk by 35, 25 and 22 min, respectively (P < .05 for all)<br> Sleep duration at 1 y was similar between groups | Yes |
8.3.1 Bedtime routine and other interventions based on behavioral principles

A common outcome in behavioral studies is the development of a positive bedtime routine. Mindell et al. studied in an RCT the effects of setting a bedtime routine including a bath, massage, quiet activities and lights out after 30 minutes. Results from questionnaire and sleep diaries showed that the bedtime routine resulted in moderate reductions in problems of setting a bedtime routine, including a bath, massage, quiet activities and lights out after 30 minutes. A later RCT by Mindell et al. showed a significant increase in bedtime routines including a bath, massage, quiet activities and lights out after 30 minutes. The intervention group showed a greater reduction in bedtime routines compared to the control group. A meta-analysis by Mindell et al. showed that a combination of sleep education, sleep-promoting behaviors, using video and handouts, and a rating of the child’s sleep and customised evidence-based behavioral principles significantly reduced bedtime routines compared to the control group.

Table 1 (Continued)

| Authors Year | Sample | Setting & Delivery | Intervention details | Outcome | Was the programme effective? |
|--------------|--------|--------------------|----------------------|---------|------------------------------|
| Stremler et al (2013) | RCT—246 First-time mothers and their healthy singleton infants born at 37 week gestation or later were randomised to intervention or control group. | Intervention N = 123 n = 110 follow at 6 wk and/or 12 wk (105 at 6 wk, 103 at 12 wk) Missing data n = 14 at 6 wk (11%) n = 20 at 12 wk (16%) Control N = 123 N = 105 follow at 6 wk and/or 12 wk (103 at 6 wk, 102 at 12 wk) Missing data n = 20 at 6 wk (16%) n = 21 at 12 wk (17%) | Mothers were recruited from hospital postpartum units. Baseline data were collected from medical charts and a brief questionnaire. Before discharge, a nurse delivered an educational session on sleep issues and strategies to improve sleep, and a comprehensive educational booklet. 1, 2 and 4 wk after discharge, the same nurse provided telephone consultation on sleep-related issues. The infant's longest nocturnal sleep period and night awakenings were measured as above. | No significant differences in infant's longest nocturnal sleep period or number of night awakenings were found between the groups measured by actigraphy and/or sleep diary. | No |
TABLE 2 Overview of original articles in the review—treatment interventions

| Authors          | Year     | Sample                                                                 | Setting & Delivery                                                                 | Intervention details |
|------------------|----------|-----------------------------------------------------------------------|------------------------------------------------------------------------------------|----------------------|
| Hall et al       | (2015)   | RCT with 235 single or two-parent families with a healthy 5.5-8 mo old infant with moderate behavioural sleep problems | Setting: Health units and participants’ homes in Vancouver, Canada                  | During a group teaching session, they were taught on infant sleep and sleep-promoting behaviours, watched an illustrative video and received handouts (cognitive-behavioural group intervention) |
| Study 1          | Hiscock et al | Cluster RCT 328 mothers and their child born at 32 wk’ gestation or later, with mother-reported sleep problems at age 7 mo but no significant sleep disorder | Who delivered the intervention? Nurses                                               | The successive two weeks they received reinforcing and supportive four follow-up calls |
| Study 2          | Hiscock et al | Intervention N = 174 Missing data study I n = 11 at 8-10 mo (6%) n = 11 at 10-12 mo (6%) Included in analysis 168/174 (97%) | How was the intervention programme delivered? Groups teaching session with nurse and follow-up by telephone | Infant sleep disturbances were assessed the Maternal (parental) Cognitions about Infant Sleep Questionnaire (MCISQ), as well as parental sleep diaries and actigraphy for six successive days. All measures were taken before randomisation and at the 6-week follow-up |
| Study 3          | Price et al | Study 2 at 2 years of age Intervention group n = 143 out of 174 Missing data, n = 31 (18%) Control group n = 129/154 Missing data, n = 25 (16%) | Setting: Well-child clinic in Melbourne, Victoria, Australia                           | Length:—2-h teaching session and four telephone calls during a period of 3 wk |
|                  | (2012)   | Study 3 at 6 years of age Intervention n = 122/174 Missing data, n = 51 (29%) Control n = 103/154 Missing data, n = 50 (32%) | Who delivered the intervention? Well-child nurses                                     | Follow-up period—6 wk |
|                  |          |                                                                       | How was the intervention programme delivered? Individual structured nurse consultation at well-child clinic, followed-up appointment 2 wk later | Control group—The control group provided a teaching session on infant safety risks, which was reinforced by four telephone calls where nurses asked the same questions as to the intervention group. Infant sleep disturbances were assessed as above |

Mothers were recruited at a four-month visit with their Maternal & Child Health (MCH) nurse. They received a tailored consultation, handouts, and the choice of two behavioural interventions (‘controlled crying’ or ‘camping out’) at child’s age 8 mo. In graduated extinction, parents respond to their infant’s cry at increasing time intervals (ie; 2, 4, 6, 8, to 10 min), allowing an infant to learn to fall asleep by him or herself. Adult fading is an even more graduated approach to managing infant sleep problems, in which a parent sits with their infant until they fall asleep and slowly removes their parental presence over 2 to 3 wk. They were asked to keep daily sleep diaries until the follow-up appointment two weeks later, where they based on the diaries discussed sleep improvements and future goals. Mothers completed questionnaires at infant’s age 10 and 12 mo measuring infant sleep problems using a single yes/no item and infant temperament using the 5-point Global Infant Temperament Scale. The 6-year follow-up study aimed to determine long-term harms and/or benefits of an infant behavioural sleep programme at age 6 y on (1) child, (2) child-parent and (3) maternal outcomes. The main outcomes measured were child mental health, sleep, psychosocial functioning, stress regulation; child-parent relationship; and maternal mental health and parenting styles. Length: two structured 2.5-hour training sessions conducted by a paediatrician and a child psychologist, supported by a written manual. Follow-up period: at 8-10 mo, 10-12 mo; at 2, and 6 y of age, respectively. Control group—The control group received usual well-child care. The infants sleep problems and temperememt were assessed as above.
Maternal depression symptoms (Edinburgh Postnatal Depression Scale); parenting practices (Parent Behavior Checklist); child mental health (Child Behavior Checklist); and maternal report of a sleep problem (yes or no) using written questionnaires when their child turned 10 mo, 12 mo and 2 y old. **The intervention had a lasting impact on reducing maternal depression symptoms at 2 y**

Prevalence of infant sleep problems was lower in the intervention than control group at 10 mo (56% vs 68%; adjusted OR 0.58 [95% CI: 0.36 to 0.94]) and at 12 mo (39% vs 55%; adjusted OR 0.50 [0.31 to 0.80]). The association did not vary with the mother's depression score (high/low) at baseline. Infant temperament score at age 10 and 12 mo did not differ significantly between the intervention group and control group.

At 2 y, 27.3% (39 of 143) of mothers in the intervention group reported child sleep problems compared with 32.6% (42 of 129) of control mothers (adjusted OR: 0.83 [95% CI: 0.48 to 1.43]; P < .49). A **smaller proportion of intervention rather than control mothers reported sleep problems that persisted throughout the entire study, that is, at all 3 of the 10-, 12- and 24-month assessment times (11.2% [16 of 142] vs 21.7% [28 of 129]; adjusted OR: 0.51 [95% CI: 0.25 to 1.03]; P < .06)**

No evidence of differences between intervention and control families for any outcome was found at 6 y age follow-up, including children's emotional and conduct behaviour scores, sleep problems, sleep habits score, parent- and child-reported psychosocial functioning, chronic stress; child-parent closeness and conflict, global relationship, disinhibited attachment; and parent depression, anxiety and stress scores or authoritative parenting.
| Study 1 | Sample | Setting & Delivery | Intervention details |
|---------|--------|-------------------|----------------------|
| Mindell et al (2009) | RCT | Infants: N = 134 | The aim of the study was to study bedtime activities and sleep behaviour in children. They were instructed to follow usual bedtime practices throughout three weeks, and reported sleep-wake patterns for their child using BISQ (day 8, 15 and 22) and daily sleep diaries. |
| | Toddlers: N = 133 | USA | Mother-infant pairs were recruited and screened by phone through an independent market research firm. An algorithm-based Customized Sleep Profile (CSP) was provided for mothers through the internet, including a normative comparison of their child's sleep compared to other children, a rating of the child's sleep, and customised evidence-based advice on how to promote better sleep for the child. Mothers in a second group were additionally instructed to use a 3-step bedtime routine for the child, including a bath, massage/application of lotion, and quiet activities with lights out before putting their child to bed as they normally did. |
| | Control | Infants: N = 72 | No differences between baseline, week 2 and week 3 measures using BRIQ or sleep diaries. The bedtime routine resulted in significant reductions in problematic sleep behaviours for infants and toddlers, latency to sleep onset and in number/duration of night waking. |
| | Toddlers: N = 67 | USA | Children in all groups had significantly longer continuous sleep periods and less perceived sleep problems, better morning mood, longer sleep periods, and fewer mothers considering sleep a problem at the 1-year follow-up. |
| | Setting | Infants: N = 101 (96) | Children in the CSP only group had significantly earlier bedtime, and the CSP + routine group significantly later wake time at 3 wk compared to baseline and 2 wk. |
| | | Toddlers: N = 86 (84) | For total night-time sleep latencies and shorter total naptime at the 1-year follow-up compared with baseline and/or week 2 of the study. |
| | How was the intervention delivered? | Missing data: 5 in CSP, 2 in CSP + routine | The bedtime routine was delivered through a 3-step bedtime routine independent of behavioural intervention. Mothers were recruited by phone or in-person through an independent market research firm. First a week for baseline data on sleep routines. Starting week 2 of the study, they were instructed to use a 3-step bedtime routine for two weeks including a bath, massage (infants; 7-18 mo of age) or application of lotion (toddlers; 18-36 mo of age) and quiet activities with lights out before putting their child to bed as they normally did. Measures for infants and toddlers were slightly different and results were analysed separately. The child's sleep patterns (daytime and night-time) and sleep-related behaviours were assessed with an expanded version of the Brief Infant Sleep Questionnaire (BISQ) at day 8 (baseline), 15 and 22 of the study, and with a daily sleep diary. Parents were additionally asked to rate the ease of bedtime, how well the child slept the last night and the child's mood at wake-up, every day. |
| | How was the intervention programme delivered? | Control group | The control groups were informed that the aim of the study was to study bedtime activities and sleep behaviour in children. They were instructed to follow usual bedtime practices throughout three weeks, and reported sleep-wake patterns for their child using BISQ (day 8, 15 and 22) and daily sleep diaries. |
| | Personal contact for informed consent, otherwise Internet-based Study supported by Johnson & Johnson Consumer Companies | Follow-up period—2 weeks |
| | Study 1 | Study 1:272 families with mother-reported sleep problems but no significant sleep disorder at age 6-36 mo, were recruited and randomised after initial one-week baseline period, 264 with complete data were included. | Follow-up period—1 y |
| | | Study 2: N = 171 of 264 with complete data participated in study 1 | Control group—The control group were instructed to follow usual bedtime practices throughout three weeks. They completed the expanded BISQ (as above) at day 8, 15, 22 of the study and 1 y later. |
| | | | Study 1 | Mothers completed the expanded BISQ at day 8 (baseline), 15 and 22 of the study. |
| | | | Study 2 | A year after the intervention mothers were recruited to the follow-up study through an automated phone call and a subsequent email. A selection of items from the expanded BISQ was measured again, also this time through the internet. |
| | | | Setting | Internet-based intervention session |
| | | | Who delivered the intervention? | Study supported by Johnson & Johnson Consumer Companies |
| | | | How was the intervention programme delivered? | Follow-up period—1 y |
| | | | Control group—The control group were instructed to follow usual bedtime practices throughout three weeks. They completed the expanded BISQ (as above) at day 8, 15, 22 of the study and 1 y later. |
The bedtime routine resulted in significant reductions in problematic sleep behaviours for infants and toddlers, latency to sleep onset and in number/duration of night waking, \( P < .001 \)

No differences between baseline, week 2 and week 3 measures using BRIQ or sleep diaries were found in the control group with infants or the control group with toddlers

**Infants**

Results from BRIQ and/or the sleep diaries showed that infants in the intervention group had significantly shorter sleep latencies, fewer and shorter night waking, longer continuous sleep periods, less perceived sleep problems, better morning mood, longer total night-time sleep, easier bedtime and better sleep at week 2 and/or 3 of the study compared with baseline.

**Toddlers**

Toddlers in the intervention group had significantly shorter sleep latencies, fewer and shorter night waking, longer continuous sleep periods, less perceived sleep problems, better morning mood, fewer parent calls, fewer times out of the crib/bed, easier bedtime and better sleep at week 2 and/or 3 of the study compared with the baseline

**Outcome**

| Outcomes                                                                 | Study 1                                                                 |
|--------------------------------------------------------------------------|-------------------------------------------------------------------------|
| The bedtime routine resulted in significant reductions in problematic   | Children in all groups had significantly longer continuous sleep       |
| sleep behaviours for infants and toddlers, latency to sleep onset and in  | periods and less mother-perceived sleep problems at week 3 of the study  |
| number/duration of night waking, \( P < .001 \)                          | compared with baseline and week 2 of the study                           |
| No differences between baseline, week 2 and week 3 measures using BRIQ   | Children in both intervention groups additionally had shorter sleep     |
| or sleep diaries were found in the control group with infants or the     | latencies, fewer and shorter night waking, longer total night-time      |
| control group with toddlers                                            | sleep, better mood in the morning, fewer parent calls, easier bedtime   |
| **Infants**                                                              | and better sleep and week 3 of the study compared with baseline and/or   |
| Results from BRIQ and/or the sleep diaries showed that infants in the    | week 2 of the study                                                     |
| intervention group had significantly shorter sleep latencies, fewer and  | Children in the CSP only group had significantly earlier bedtime, and   |
| shorter night waking, longer continuous sleep periods, less perceived    | the CSP + routine group significantly later wake time at 3 wk compared  |
| sleep problems, better morning mood, longer total night-time sleep,     | to baseline and 2 wk                                                    |
| easier bedtime and better sleep at week 2 and/or 3 of the study         | For total naptime, number of times out of crib/bed and times the child   |
| compared with baseline and/or week 2 of the study                       | wakes on its own, no significant differences over time were found in     |
| **Toddlers**                                                             | either group                                                             |
| Toddlers in the intervention group had significantly shorter sleep       | Sleep latencies, number and duration of night waking, continuous sleep  |
| latencies, fewer and shorter night waking, longer continuous sleep      | periods and perceived sleep mother-perceived sleep problems varied      |
| periods, less perceived sleep problems, better morning mood, fewer      | significantly between groups over time                                    |
| parent calls, fewer times out of the crib/bed, easier bedtime and       | **Study 2**                                                              |
| better sleep at week 2 and/or 3 of the study compared with the baseline  | Infants in all groups had significantly fewer and shorter night waking,  |
|                                                                        | longer continuous sleep periods and fewer mothers considering sleep a   |
|                                                                        | problem at the 1-year follow-up compared with baseline and/or 3-week   |
|                                                                        | follow-up. (\( P < .001 \))                                            |
|                                                                        | Effect sizes were generally larger in the intervention groups than in   |
|                                                                        | the control group                                                       |
|                                                                        | Infants in both intervention groups had significantly more ease of      |
|                                                                        | bedtime at the 1-year follow-up compared with baseline and 3-week      |
|                                                                        | follow-up                                                               |
|                                                                        | Infants in the group who received the CSP intervention only had         |
|                                                                        | significantly shorter sleep latencies and shorter total naptime at the  |
|                                                                        | 1-year follow-up compared with baseline and/or 3-week follow-up        |
|                                                                        | No differences between baseline or 3-week follow-up, and the 1-year     |
|                                                                        | follow-up were found for total night-time sleep                         |

(Continues)

Yes
3.3 | Behavioural interventions based on extinction in different forms

Extinction-based behavioural interventions incorporate one or more of the following practices as delayed response to infant signals or cues using unmodified or graduated extinction methods including parental presence, regulation of feeding times, algorithms for sleep durations and bedtimes, and other strategies that aim to condition the infant to fall asleep in the absence of feeding or bodily contact. The treatment has two main components consisting of modifying parental cognitions about their child’s sleep-related behaviours, and modifying parental behaviours and responses to the child to modify the child’s sleep-related behaviours. Unmodified extinction, called cry-it-out method procedures for sleep problems, involves having the parents put the child to bed at a designated bedtime and then ignoring the child until a set time the next morning. Parents monitor for illness, injury, etc. Behaviours that are ignored include crying, tantrums and calling for the parents. Unmodified extinction was not included in any of the interventions described in this review.

Graduated extinction or control crying and comforting are based on the same rationale of unmodified extinction and refers to a variety of techniques. The intervention allows parents to visit the child at certain intervals. The interval between check-ins with the child was often tailored to the child’s age and temperament, and the parents’ judgement of how long they can tolerate the child’s crying. Parents can employ a fixed schedule, or they can wait progressively longer intervals (progressively increased intervals from two to ten minutes) before checking on their child. The checking procedure involves the parents comforting their child for a brief period and leaves the room. A more interactive model is staying with the child in their room and gradually withdrawing parent presence, eventually leaving the room and then adopting the periodic checking paradigm, the camping out method. The behavioural intervention often involves educational components such as information about normal sleep and crying patterns, signs of tiredness and focus on establishment of positive sleep habits.

Hiscock et al. performed a cluster randomised clinical trial with behavioural intervention for infants with sleeping problems recruited at seven months of age, delivered over one to three individual nurse consultations to parents of infants aged eight to ten months. This intervention was compared to usual care. The intervention involved controlled comforting and camping out for managing infant sleep. Parents in the intervention group reported fewer sleeping problems in the child at ten and 12 months, and a tendency to fewer sleeping problems at two years of age, 17 months after the intervention and lower rates of depression in mothers. At a follow-up five years later, Price et al. did find neither long-term harm nor benefit of the interventions on child mental health, sleep, psychosocial functioning, stress regulation, child-parent relationship, and maternal mental health and parenting styles.

3.4 | Massage

In many regions of the world, especially in the African and Asian continents, indigenous South Pacific cultures and the former Soviet Union, infant massage is a traditional practice. Healthcare practitioners in Western cultures have become interested in infant massage primarily as an intervention for infants in neo-natal intensive care units where the environment is stressful and lacking in tactile stimulation. Massage is thought to benefit sleep, respiration,
| Outcome                                                                 | Was the programme effective? |
|------------------------------------------------------------------------|------------------------------|
| Children in the intervention group had a significant decrease in number of night wakeings week 2 and week 3 of the study compared with baseline, which was not found in the control group ($P = .006$). Subsequent analyses indicated a significant reduction in number of night wakeings for children in the intervention group, but not for those in the control group. No other significant differences in sleep patterns (sleep latency, bedtime, duration of night wakeings, longest continuous sleep period, total night-time sleep, number of naps, nap duration or total sleep across 24 h) were found over time or between the intervention group and control group. Based on mother-ratings, children in the intervention group also had less bedtime difficulties, better sleep, better morning mood and less sleep problems between baseline and week 2 and 3 of the study. Except for child mood—where no significant interaction between the groups was found—the same improvements were not seen in the control group. |

Elimination and the reduction of colic and wind as well as parent-infant interaction. Increasingly, parents/caregivers of low-risk babies in the Western world are being taught massage to promote infant development and improvements in sleep, elimination and the reduction of colic and wind.\(^{22}\)

In a first Cochrane's review, some evidence was found for the positive effect of infant massage on the mother-child interaction, sleep and crying, and the child's stress hormone profile.\(^{22}\) The effects were considered to be particularly important in families where infants are stressed and have sleep problems. A later Cochrane review by Bennet et al,\(^{23}\) however, did not support the use of infant massage with low-risk groups parents and infants. Available evidence was judged to be of poor quality, and many studies did not address the biological plausibility of the outcomes being measured or the mechanisms by which change might be achieved. It should be noted, however, that Mindell et al had a massage component in two of their trials of bedtime routines, mentioned above with positive outcomes.\(^{26,28}\)

**4 | Discussion**

In this systematic review of prevention and treatment of sleep problems in infants 0-24 months of age, we retrieved studies based on behavioural strategies, education and massage. The interventions evaluated typically included items from at least two, or even all three strategies. No single intervention was studied in more than one controlled study that fulfilled our criteria, which prevented us from drawing any firm conclusions about evidence according to the GRADE criteria used.\(^{17}\)

All five studies of behavioural interventions for treatment of sleep problems demonstrated short-term effects on sleep problems. Two studies had interventions adapted to individual families that involved controlled crying or camping out along with written material and follow-up sessions.\(^{23,30}\) Three studies showed positive effects of a consistent sleep routine, of which two included bathing, massage, quiet activities and extinguished light before the child was put to bed, and one of these methods was Internet-based.\(^{25,26,28}\)

The scientific support for preventing sleep problems in infants with education programmes before and/or after birth was inconsistent. Three RCT studies showed some positive effects of such programmes,\(^{19-21}\) while two studies did not show any significant protective effect.\(^{22,24}\) There are some indications in these studies that the timing of this information may be a decisive factor, where information given before delivery or soon thereafter does not have the same effect as information given when the first transition period is over, and follow-up contacts with parents.

Two Cochrane reviews\(^{22,33}\) evaluated massage as prevention and treatment for sleep problems in infants, concluding that the available evidence was of poor quality. In the absence of indications that such massage would be harmful, one could take this as support for the use of infant massage, especially in contexts where there is poor stimulation for infants. Future research should focus on the impact of infant massage in higher-risk groups (eg demographically and socially deprived parent-infant dyads), where there may be more potential for change.

**4.1 | Negative consequences of behaviour-based interventions with sleep deprivation**

Our review of behavioural sleep interventions includes extinction methods in which parents were asked to ignore their child’s crying for a certain time. Many parents have difficulties with this, which contributes to abrasion, lack of conformity with the method and avoiding treatment. Why these methods are difficult
to implement has rarely been addressed in the literature, nor are the potentially negative consequences on parent-child interactions when parents are taught to avoid responding to children’s signals. However, a study by Price et al did not find any negative effect of extinction on child health, child-parent relationship, maternal mental health and parenting styles five years after the intervention. As described above, there are alternatives to these treatment methods, which do not have these potentially negative consequences.

4.2 Knowledge gaps

While many studies documented links between parenting and sleep problems in infants, most of these studies were focused on the mother/main caretaker, neglecting the significant role that fathers/the other caretaker may have on infant sleep development. This is surprising since many of the father-infant interactions occur around bedtime. The growing involvement of fathers in early childcare has been long identified and documented. From a developmental systems perspective, there are good reasons to assume that paternal involvement should exert significant influence on the developing child as well as on the mother. Indeed, research on paternal involvement and infant sleep provided evidence regarding the role of the father in infant sleep development. Tikotzky found that mothers were significantly more involved than fathers in daytime and night-time caregiving. A greater involvement of fathers in overall care predicted and was associated with fewer infant night wakings and with longer total sleep duration after controlling for breastfeeding. The findings highlight the importance of including fathers in developmental sleep research. Future studies should explore mechanisms underlying the relations between paternal involvement and infant sleep.

The ways in which culture and biology interact plays a major role in the establishment of sleep patterns and developmental norms and expectations regarding normal and problematic sleep. Cross-cultural research demonstrates differences between cultural contexts concerning how parents put their children to sleep and the concerns parents have about their children’s sleep.

To a large degree, parental concern about infant night waking reflects Western cultural practices and norms. This consideration does not downplay parental complaints, because parents who work Western office hours need to sleep at night themselves, and it is true that most Western infants over three months of age remain settled during infancy are an important developmental task. The most rapid development in sleep organisation takes place during the infant’s first months of life. During this time, the pattern of sleep and wakefulness is irregular. For most children, sleep begins to consolidate by six months, when they are establishing a circadian rhythm and no longer need night meals. To intervene during this time can therefore be fraught with challenges. Unsettle behaviour in the first six months can emerges out of multiple interacting factors. Crying, feeding and sleep problems interact and co-evolve, particularly in the first neuro-developmentally sensitive four months. James-Roberts discusses possible causes for few interventions during the first months, such as the human babies limit regulatory capacities or ability to learn, so that attempts to shape behaviour are less successful. Another aspect is the experience of parental unwillingness to participate in studies during the baby’s first months. Parents are primarily concerned with their baby’s well-being and growth at this age, and less inclined to introduce constraints.

4.3 Methodological aspects

Although we have tried to base our review primarily on randomised clinical trials, there are weaknesses in many of these studies of methodologic origin as many intervention studies have used parental reports, questionnaires and diaries, and not objective measurements such as actigraphy data, as outcomes. As the study by Hall et al described above, demonstrated, such objective methods do not always support the conclusions based on parental report. Lack of blinding and selection bias are other weaknesses which make it difficult to draw firm conclusions.

5 CONCLUSIONS

The message from this review is that behavioural interventions seem to be a promising strategy for treatment of behavioural sleep
problems in infants above 6 months of age. However, the combination of several methods used in the reviewed interventions makes it impossible to disentangle exactly which component/s in the diverse interventions that are the most effective, and which interventions are more suitable for universal delivery and to families with greater needs. These are questions for further studies, which preferably should evaluate individual components in behavioural sleep interventions. Important knowledge gaps were found with regard to the effectiveness of treatment and prevention programmes in minorities with a Non-Western background, prevention in high-risk population, in treatment interventions involving fathers, treatment interventions in children below six months of age and negative consequences of behavioural interventions that include extinction.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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