

Preventing Early Infant Sleep and Crying Problems and Postnatal Depression: A Randomized Trial



WHAT'S KNOWN ON THIS SUBJECT: Infant sleep and crying problems are common and associated with postnatal depression. No programs aiming to prevent all 3 issues have been rigorously evaluated.



WHAT THIS STUDY ADDS: A prevention program targeting these issues improves caregiver mental health, behaviors, and cognitions around infant sleep. Implementation at a population level may be best restricted to infants who are frequent feeders because they experience fewer crying and daytime sleep problems.

abstract

OBJECTIVE: To evaluate a prevention program for infant sleep and cry problems and postnatal depression.

METHODS: Randomized controlled trial with 781 infants born at 32 weeks or later in 42 well-child centers, Melbourne, Australia. Follow-up occurred at infant age 4 and 6 months. The intervention including supplying information about normal infant sleep and cry patterns, settling techniques, medical causes of crying and parent self-care, delivered via booklet and DVD (at infant age 4 weeks), telephone consultation (8 weeks), and parent group (13 weeks) versus well-child care. Outcomes included caregiver-reported infant night sleep problem (primary outcome), infant daytime sleep, cry and feeding problems, crying and sleep duration, caregiver depression symptoms, attendance at night wakings, and formula changes.

RESULTS: Infant outcomes were similar between groups. Relative to control caregivers, intervention caregivers at 6 months were less likely to score >9 on the Edinburgh Postnatal Depression Scale (7.9%, vs 12.9%, adjusted odds ratio [OR] 0.57, 95% confidence interval [CI] 0.34 to 0.94), spend >20 minutes attending infant wakings (41% vs 51%, adjusted OR 0.66, 95% CI 0.46 to 0.95), or change formula (13% vs 23%, $P < .05$). Infant frequent feeders (>11 feeds/24 hours) in the intervention group were less likely to have daytime sleep (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 months.

CONCLUSIONS: An education program reduces postnatal depression symptoms, as well as sleep and cry problems in infants who are frequent feeders. The program may be best targeted to frequent feeders. *Pediatrics* 2014;133:e346–e354

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KEY WORDS

infant, sleep, colic, postpartum depression, randomized controlled trial

ABBREVIATIONS

CI—confidence interval
EPDS—Edinburgh Postnatal Depression Scale
MCH—maternal and child health
MCISQ—Maternal Cognitions About Infant Sleep Questionnaire
OR—odds ratio
SEIFA—Socio-Economic Indexes for Areas

Dr Hiscock conceptualized and designed the study and drafted the initial manuscript; Dr Cook contributed to the conceptualization and design of the study and the initial draft of the manuscript, oversaw study data collection, carried out the initial analyses in conjunction with Dr Mensah, and reviewed and revised the manuscript; Drs Bayer, Simon, St James-Roberts, and Mr Cann contributed to the conceptualization and design of the study and reviewed and revised the manuscript; Ms Le conducted the economic analysis and reviewed and revised the manuscript; Dr Mensah carried out the initial analyses in conjunction with Dr Cook, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

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Infant sleep and crying problems such as frequent night waking and inconsolable bouts of crying are common during the first few months of life.^{1–3} They are associated with maternal depression, premature weaning, and frequent formula changes.^{4,5} Formula changes often occur when infant crying is misdiagnosed as gastroesophageal reflux or food allergy.⁶ Infant crying is the most common proximal risk factor for abusive head trauma.⁷ Together, infant sleep and cry problems make up the most common reasons parents seek help from health care professionals in the first few months.⁸ Yet despite their prevalence, few evaluated programs have tried to prevent early infant crying or sleep problems, and only 1 randomized controlled trial has explicitly aimed to prevent both.⁹

Programs aiming to prevent infant sleep problems have focused on parent education about infant self-settling strategies, normal sleep/wake patterns, low stimulation during the night, and increasing the interval between waking and night feeds. These programs have demonstrated modest improvements in parent report of infant sleep duration at 12 weeks of age.^{9–11}

Programs aiming to prevent infant crying have been less successful. This may be in part because at least some crying is unsoothable in infants,¹² regardless of parenting practices.¹³ Unsoothable crying is the most worrisome for parents.¹⁴ Thus although reducing the amount of unsoothable crying may be impossible, reducing parent perception of crying as “a problem” could be possible if parents accept that some crying is normal. A program to address this and provide parents with information about normal sleep and cry patterns and ways to encourage infants to self-settle, might reduce parental perception of infant sleep and crying as problems^{15,16} and

in doing so reduce their adverse sequelae. We therefore aimed to see if an education program, “Baby Business,” could prevent infant nighttime sleep problems (primary outcome), daytime sleep, cry and feeding problems, and number of formula changes and improve caregiver depression symptoms, cognitions, and behaviors around infant sleep, sleep quality and quantity, and health service use for the infant’s behavior and caregiver well-being. We hypothesized that compared with control caregivers, intervention caregivers would report improved infant and caregiver outcomes at infant age 4 and 6 months.

METHODS

Study Design and Participants

We invited caregivers of infants seen by their maternal and child health (MCH) nurse at their first home visit (day 7–10 postpartum) in 4 Local Government Areas in Melbourne, Australia, to take part between March 1, 2010, and June 1, 2011. The MCH nursing service is a free service offered to all Victorian families with scheduled visits covering 93% of all births. We excluded parents with insufficient English and infants born before 32 weeks’ gestation or with a serious health concern.

The research team mailed a participant information statement, consent form, and baseline questionnaire to families interested in participating. Upon receipt of written informed consent and completed questionnaire, families were randomized to either the intervention or control group, using a computer-generated random number sequence created by an independent statistician. Randomization was stratified by the referring nurse’s MCH center. The research team and families remained blind to group allocation at the time of consent and recruitment, after which blinding was not possible due to the nature of the intervention.

This trial was approved by the Human Research Ethics Committee at the Royal Children’s Hospital, Melbourne (HREC 28130). Research approval was obtained from the Victorian state Department of Education and Early Childhood Development.

Intervention

Intervention families were mailed a 27-page booklet and 23-minute DVD. The booklet contained information about normal infant sleep cycles, crying patterns, strategies to promote independent settling, and self-care for parents. The DVD contained similar information and included parents discussing settling techniques and infant tired signs, as well as settling technique demonstrations. Intervention families were also offered an individual telephone consultation at infant age 6 to 8 weeks (ie, peak infant crying time¹⁵) and a 1.5-hour parent group session at approximately infant age 12 weeks. Both encouraged parents to discuss cry or sleeping problems and to develop a tailored management plan (eg, establish a bedtime routine) to address any problems. Telephone consultations and group sessions were facilitated by trained health professionals (nurses, psychologists) with a background in infant care and followed standardized scripts. The group session was supported by a training manual (details published elsewhere).¹⁷ Staff conducting the telephone and group interventions met on a regular basis with HH (pediatrician) and JB (clinical psychologist) to monitor fidelity to content and troubleshoot clinical issues. Families allocated to the control condition received usual care provided through the MCH service.

Outcome Measures

Baseline Questionnaire

Primary caregivers reported on infant details (eg, birth weight, feeding

frequency) and whether their infant's sleep, crying, and feeding were a problem (yes/no). Primary caregivers also completed the "Doubt" subscale of the Maternal Cognitions About Infant Sleep Questionnaire (MCISQ)¹⁸ and rated themselves as a relaxed or tense person.¹⁷ Each family was assigned a local neighborhood Index of Relative Disadvantage score by home postal code (higher scores indicate better socioeconomic status) using the Socio-Economic Indexes for Areas (SEIFA).¹⁹

Infant Measures

Infant outcomes were measured by postal survey at approximately 4 and 6 months of age. The primary outcome was caregiver report of infant night sleep as a problem (yes/no; the period of "night sleep" was determined by the caregiver). Caregivers were also asked if they had experienced a problem (yes/no) with infant day sleep, crying, or feeding, and if they responded in the affirmative, to rate the severity of each problem on a 7-point Likert scale, from 1 = "hardly any problem" to 7 = "a severe problem."^{20,21} The primary caregiver completed a 72-hour infant behavior diary,²² measuring sleeping, feeding, and crying in 10-minute epochs and reported on the number and duration of night attendances to their infant over the previous week.

Caregiver Measures

Caregiver outcomes were measured at the same time points and included the Edinburgh Postnatal Depression Scale (EPDS),^{23,24} with scores >9 indicative of postnatal depression in community samples,²⁴ and sleep quality and quantity measured by 2 items adapted from the Pittsburgh Sleep Quality Index.^{25–27} Caregiver cognitions about infant sleep were measured by 4 subscales of the MCISQ¹⁸: limit setting (eg, "I should respond straightaway when my child wakes crying at night"), anger, doubt, and safety. Caregivers rated their

efficacy as a parent on a single item ranging from 1 ("not very good") to 5 ("a very good parent").²⁸ Caregivers reported on breastfeeding duration and whether they had changed their infant's formula to "manage" their infant's sleep or crying. Finally, caregivers reported on the number of visits they made to a health professional for either their infant's sleep/crying or their own well-being. Intervention caregivers also reported on the usefulness of intervention materials and components and the helpfulness of strategies given. Additional details have been published previously.¹⁷

Sample Size

To detect a relative reduction in the prevalence of caregiver reported infant sleep problems (yes/no) by 30% at infant age 4 months (ie, from 30% to 20%), 780 infants were required, with 80% power, assuming 20% loss to follow-up and a 5% significance level. This is based on 2 community surveys in which ~30% of Australian parents reported infant sleep problems at 4 months of age.^{4,29}

Statistical Analysis

Intention-to-treat comparisons of the trial arms were conducted for each follow-up. Linear regression models were fitted to estimate mean differences between trial arms for continuous outcomes and logistic regression to estimate odds ratios (ORs) comparing binary outcomes between trial arms. We conducted analyses both with and without adjustment for potential confounders chosen a priori through review of the literature (ie, infant age, gender, socioeconomic status, parenting doubt surrounding infant sleep at baseline (excluded when doubt was examined as an outcome), parenting self-efficacy and parental rating of self as a tense person). We conducted empirical bootstrap estimates to confirm the validity of the inferences made. We

then examined trends in treatment response from 4 to 6 months of infant age, using random effects regression models. We performed 2 additional post hoc tests not described in our protocol.¹⁷ These were a test of interaction between frequent feeding at baseline (ie, feeding >11 times/24 hours) and the outcomes of infant night sleep, day sleep, and crying problems as a previous sleep problem prevention trial found greater benefits for these infants³⁰; and a comparison of whether the benefits of the intervention differed for first and later born children for these outcomes. The frequency and patterns of missing data were examined, and sensitivity analyses were performed comparing the results of analyses restricted to families with complete data and analyses for which missing data were imputed by using a conservative approach.³¹ All analyses were implemented by using Stata 12.0.³²

RESULTS

Sample Characteristics and Retention

Nurses invited 1957 families to take part, of whom 770 were eligible and recruited (total of 781 infants including twins; response rate 55% of families, see Fig 1). Families were randomized to either the intervention ($n = 385$ families with 388 infants) or the control group ($n = 385$ families with 393 infants; baseline characteristics of the groups are shown in Table 1). Participating families were more likely than nonparticipating families to be of higher socioeconomic status (12.7% vs 9.1% from the highest SEIFA quintile*).³³

Almost all primary caregivers (99.6%) were mothers, with a mean age of 33 years. Infant mean age was 4.0 weeks

*SEIFA quintiles were calculated from 2011 Victorian SEIFA data (Australian Bureau of Statistics). The first quintile represents the least disadvantaged one-fifth of the Victorian population, and the fifth represents the most disadvantaged one-fifth of the Victorian population.

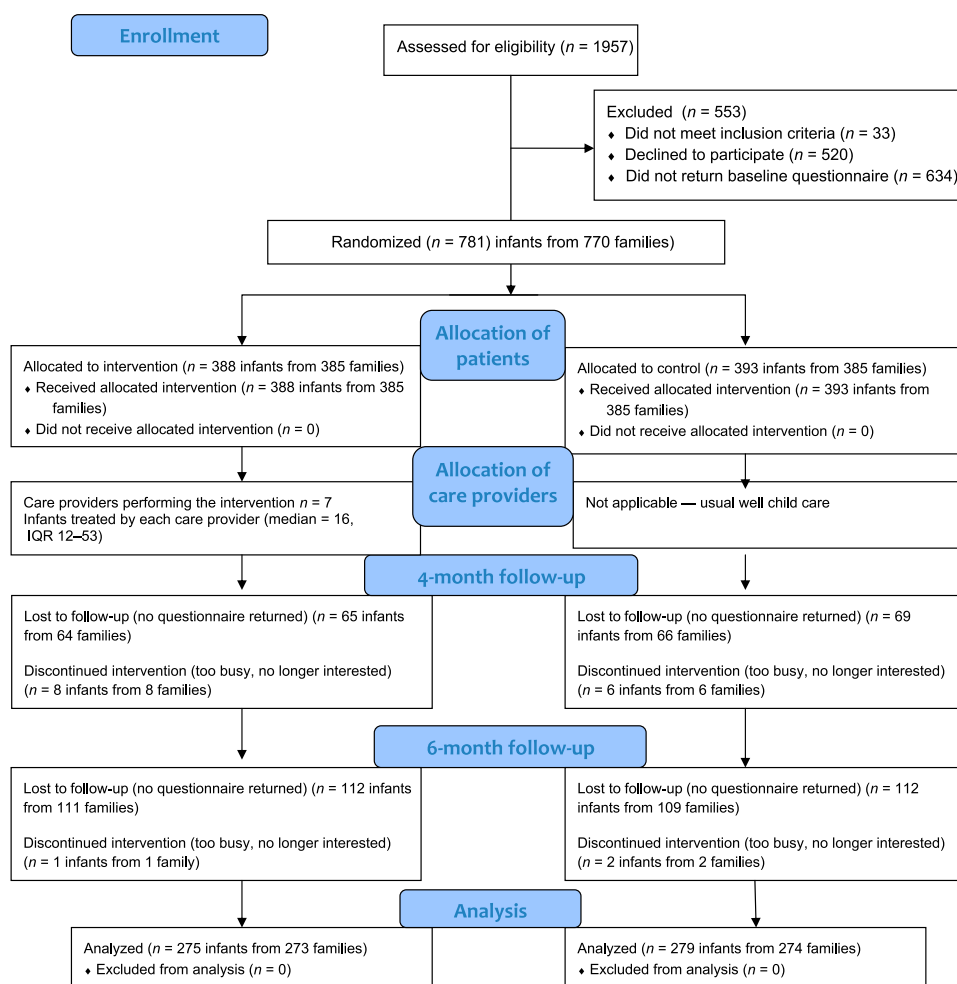


FIGURE 1
CONSORT flow diagram. IQR, interquartile range.

(± 1.4), and more than half were boys and firstborn. Aside from the primary caregiver being more likely to speak English as a first language, intervention families did not differ demographically from control families.

At 4 months' infant age, follow-up questionnaires were completed for 315 of 388 (81.2%) intervention and 318 of 393 (80.9%) control group infants, with behavior diaries completed for 264 of 388 (68.0%) intervention and 259 of 393 (65.9%) control group infants. At 6 months, follow-up questionnaires were completed for 275 of 388 (70.9%) intervention and 279 of 393 (70.9%) control group infants and behavior diaries for 224 of 388 (57.7%) intervention and 215 of 393 (54.7%) control group infants.

Diaries were discarded if they had $>20\%$ of data missing from any 24-hour period or <2 days of data recorded.

Caregivers who did not complete follow-up questionnaires were more likely than those who did to report a sleep problem at baseline (control group only, $P < .04$), to have a lower socioeconomic status (intervention $P = .01$, control $P = .02$), to have completed high school or less (intervention $P = .03$, control $P = .001$), and to speak a language other than English at home (intervention group only, $P = .02$). Similarly, caregivers who did not complete 4- or 6-month diaries sufficiently compared with those who did were more likely to be of a lower socioeconomic status, speak a language other than English at

home, and to have completed high school or less (all $P < .01$). All intervention families received the booklet/ DVD; 92.5% received the telephone consultation (mean infant age 8.8 ± 2.3 weeks), and 50.9% attended the group session (mean infant age 13.4 ± 2.3 weeks).

Infant Outcomes at 4 and 6 Months

There were no differences between groups in caregiver report of infant sleep, crying, or feeding problems at either follow-up (Table 2).

There was a differential effect of condition arm on those classified as frequent feeders (ie, >11 feeds/24 hours) at 4 but not 6 months. Infants in the intervention versus control group who

TABLE 1 Baseline Characteristics of Randomized Groups

Characteristics	Intervention	Control
Primary caregiver		
Age, y, mean (SD)	33.0 (4.4)	33.3 (4.6)
Relationship status (%)		
Married/defacto	96.4	96.9
Country of birth (%)		
Australia	71.0	66.7
Language (%)		
English	92.2	87.8
Education status (%)		
Tertiary degree or higher	71.9	70.6
SEIFA of postcode (%)		
1st quintile (highest)	12.7	9.1
2nd quintile	8.0	11.0
3rd quintile	61.4	61.6
4th quintile	6.0	6.0
5th quintile (lowest)	11.9	12.3
Infant		
Age, wk, mean (SD)	3.9 (1.3)	4.1 (1.5)
Male (%)	56	51
Birth wt, g, mean (SD)	3446.1 (528.6)	3419.2 (536.2)
Birth order (%)		
1st	56.6	55.2
2nd	30.0	31.7
≥3rd	13.4	13.0
Gestation, wk, %		
42+	7.5	5.9
37–41	86.8	86.5
33–36	5.7	7.6
Feeding (%)		
Breast only	69.3	66.7
Breast and formula	22.4	24.9
Formula only	8.2	8.4
Infant behavior		
Feeding problem (%)	24.9	25.5
Sleeping problem (%)	38.4	38.7
Crying problem (%)	27.1	27.6
Feeds per 24 h, mean (SD)	8.7 (2.4)	8.6 (2.3)
Place of sleep (%)		
Parent's bed	11.6	11.7
Own crib/bed in parent' room	62.9	59.2
Own crib/bed in other room	23.7	26.5
Primary caregiver well-being		
Self-efficacy, mean (SD)	4.0 (0.7)	3.9 (0.7)
Rating self as tense person (scoring >7, %)	27.5	26.0
Primary caregiver cognitions		
Doubt surrounding infant sleep, mean (SD)	5.6 (3.5)	5.9 (3.6)

Sample size for the intervention group infants and caregivers ranged from 373 to 388 and 380 to 386, respectively. Sample size for the control group infants and caregivers ranged from 380 to 393 and 379 to 390, respectively.

fed frequently at baseline had 87% lower odds of having daytime sleep problems (OR 0.13, 95% confidence interval [CI] 0.03 to 0.54) and 73% lower odds of having crying problems (OR 0.27, 95% CI 0.08 to 0.86, respectively). Nighttime sleep problems were similar between the 2 groups of frequent feeders. No differential effects of condition arm for infants

who were firstborn compared with later born were evident for crying problems or daytime or nighttime sleep problems.

Caregiver Outcomes at 4 and 6 Months

There were no group differences in caregiver reports of depression symptoms at 4 months. However, at 6

months, intervention group caregivers were significantly less likely to score >9 on the EPDS than control group caregivers (7.9% vs 12.9%, adjusted OR 0.57, 95% CI 0.34 to 0.94, $P = .03$). Between 4 and 6 months, there was a greater reduction in intervention caregivers scoring >9 on the EPDS compared with control caregivers ($P < .01$) and similarly a greater fall in total depression symptom scores ($P = .04$). Intervention caregivers also had fewer doubts regarding their ability to manage their infant's sleep at both time points (both $P < .02$). At 6 months, intervention compared with control caregivers were less likely to spend ≥ 20 minutes attending to their infant overnight (41% vs 51%, adjusted OR 0.66, 95% CI 0.46 to 0.95, $P = .03$) or have changed infant formula (13% vs 23%, adjusted OR 0.41, 95% CI 0.21 to 0.82, $P = .01$) and reported less difficulty setting limits (adjusted mean difference -1.22 , 95% CI -2.03 to -0.41 , $P = .003$) and less excessive concern about sudden infant death (adjusted mean difference -0.38 , 95% CI -0.67 to -0.08 , $P = .01$, see Table 3). At 4 months, intervention caregivers had sought help more often from health professionals for their infant than control group caregivers, but there was no difference at 6 months.

Program Costs

The total cost of providing the Baby Business program was A\$23 056 or approximately A\$60 per family. This comprised the cost of training health professionals (A\$1140), delivering consultation phone calls (A\$7520), running the parent group sessions (A\$6743), distribution of intervention materials (A\$3042), and overhead costs (A\$4612). Training cost was estimated as the time of trainers and trainees plus training materials. Consultation phone call cost included time spent making appointments, rescheduling families, and preparing for and delivering calls (~20 minutes). Parent group costs included

TABLE 2 Adjusted Regression Analyses at Infant Age 4 and 6 Months and Trends Between 4 and 6 Months for Categorical Variables

	4 Mo					6 Mo					Trend 4–6 Mo
	Intervention <i>n</i> (%)	Control <i>n</i> (%)	AOR	95% CI	<i>P</i>	Intervention <i>n</i> (%)	Control <i>n</i> (%)	AOR	95% CI	<i>P</i>	<i>P</i>
Infant											
Night sleep problem	147 (47)	149 (47.2)	1.01	0.73 to 1.39	.97	138 (51.1)	148 (53.4)	0.89	0.63 to 1.26	.51	.35
Day sleep problem	185 (59.3)	187 (58.8)	1.01	0.73 to 1.41	.94	104 (38.7)	120 (43.3)	0.81	0.57 to 1.16	.25	.82
Cry problem	108 (34.6)	105 (33)	1.07	0.76 to 1.51	.71	62 (23.0)	63 (22.7)	1.09	0.72 to 1.65	.69	.62
Feed problem	89 (28.3)	91 (28.6)	1.00	0.70 to 1.44	.98	43 (16.2)	57 (20.7)	0.79	0.50 to 1.24	.30	.99
≥20 min spent with baby during each night attendance	176 (61.1)	182 (62.5)	0.94	0.66 to 1.34	.74	100 (41.3)	130 (51.0)	0.66	0.46 to 0.95	.03 ^a	.15
Formula change	24 (21.2)	38 (27.7)	0.64	0.34 to 1.19	.16	18 (13.0)	31 (22.6)	0.41	0.21 to 0.82	.01 ^a	.92
Caregiver											
EPDS community cutoff (>9)	67 (22.9)	54 (18.5)	1.48	0.97 to 2.27	.07	31 (7.9)	51 (12.9)	0.57	0.34 to 0.94	.03 ^a	.003 ^a
Sleep quality not good enough	146 (47.1)	143 (45.7)	0.91	0.65 to 1.26	.57	124 (45.9)	137 (50.4)	1.16	0.82 to 1.65	.39	.28
Sleep quantity not enough	184 (59.2)	171 (54.6)	0.79	0.57 to 1.10	.16	153 (56.7)	153 (56.3)	0.99	0.69 to 1.41	.95	.81
Diet change while breastfeeding	89 (30.6)	88 (30.4)	0.99	0.69 to 1.41	.94	74 (29.5)	70 (28.3)	1.05	0.71 to 1.57	.79	.91

Analyses adjusted for infant age, gender, SEIFA rating, parent education, parenting doubt surrounding infant sleep as measured at baseline, parenting self-efficacy, and parental rating of self as a tense person. AOR, adjusted odds ratio.

^a Significant *P* value.

TABLE 3 Adjusted Regression Analyses at Infant Age 4 and 6 Months for Continuous Variables

	4 Mo					6 Mo					Trend 4–6 Mo
	Intervention Mean (SD)	Control Mean (SD)	AMD	95% CI	<i>P</i>	Intervention Mean (SD)	Control Mean (SD)	AMD	95% CI	<i>P</i>	<i>P</i>
Night sleep problem severity	3.2 (1.6)	3.1 (1.6)	0.13	−0.14 to 0.40	.34	3.3 (1.7)	3.5 (1.6)	−0.20	−0.58 to 0.17	.28	.36
Day sleep problem severity	3.3 (1.4)	3.2 (1.5)	0.17	−0.14 to 0.48	.27	3.2 (1.6)	3.1 (1.4)	0.16	−0.19 to 0.52	.37	.86
Cry problem severity	3.0 (1.5)	2.7 (1.6)	0.39	0.05 to 0.72	.02 ^a	3.1 (1.8)	2.9 (1.3)	0.30	−0.25 to 0.85	.29	.25
Feed problem severity	3.0 (1.6)	2.8 (1.6)	0.29	−0.14 to 0.72	.18	2.9 (1.8)	2.9 (1.5)	0.06	−0.63 to 0.74	.87	.50
Sleep duration (h)	14.1 (1.5)	14.0 (1.5)	0.07	−0.15 to 0.30	.52	9.8 (1.2)	9.6 (1.2)	0.16	−0.07 to 0.40	.18	.12
Cry duration (h)	1.6 (0.9)	1.5 (0.9)	0.04	−0.09 to 0.18	.52	1.3 (1.0)	1.3 (0.9)	0.01	−0.15 to 0.17	.93	.58
Age breastfeeding ceased (wk)	7.9 (4.0)	8.1 (4.8)	0.07	−1.84 to 1.98	.95	12.7 (7.3)	11.9 (7.5)	0.78	−1.89 to 3.45	.56	.39
No. night attendances	1.8 (1.6)	1.7 (1.4)	0.04	−0.21 to 0.30	.73	1.7 (1.7)	2.0 (1.6)	−0.19	−0.47 to 0.10	.20	.27
EPDS total score	6.3 (4.4)	6.0 (4.2)	0.42	−0.13 to 0.96	.13	5.1 (4.0)	5.8 (4.3)	−0.60	−1.30 to 0.11	.09	.04 ^a
Health professional visits outside of intervention, infant	5.0 (4.5)	4.0 (4.3)	0.99	0.28 to 1.70	.01 ^a	1.3 (2.2)	1.1 (1.6)	0.34	−0.02 to 0.71	.06	.86
Health professional visits outside of intervention, parent	1.8 (4.1)	2.0 (6.7)	−0.13	−1.06 to 0.80	.79	0.5 (1.8)	0.4 (1.4)	0.10	−0.16 to 0.36	.46	.28
Maternal cognitions											
Doubt	4.8 (3.7)	5.4 (4.1)	−0.76	−1.35 to −0.18	.01 ^a	3.8 (3.2)	4.5 (4.0)	−0.84	−1.43 to −0.26	.005 ^a	.37
Anger	4.2 (3.1)	3.9 (3.1)	0.33	−0.13 to 0.78	.16	3.8 (3.1)	4.0 (3.3)	−0.15	−0.67 to 0.36	.56	.19
Safety	2.4 (2.1)	2.4 (2.1)	0.08	−0.21 to 0.38	.58	1.8 (1.9)	2.1 (2.1)	−0.38	−0.67 to −0.08	.01 ^a	.07
Limit Setting	13.4 (5.0)	14.1 (5.3)	−0.68	−1.46 to 0.09	.08	11.6 (5.0)	12.8 (5.5)	−1.22	−2.03 to −0.41	.003 ^a	.55

Analyses adjusted for infant age, gender, SEIFA rating, parent education, parenting doubt surrounding infant sleep as measured at baseline, parenting self-efficacy, and parental rating of self as a tense person. Night sleep, day sleep, and cry and feeding problem severity was measured on a scale from 1 = hardly any problem, to 7 = a severe problem. *P* values and 95% CI were estimated using the bootstrap method. Sample size for infants and caregivers at the 4-mo assessment ranged from 103 to 631 and 584 to 596, respectively. Sample size for infants and caregivers at the 6-mo assessment ranged from 122 to 553 and 447 to 494, respectively. One hundred two caregivers had stopped breastfeeding at 4 mo and 133 by 6 mo. AMD, adjusted mean difference.

time spent booking appointments, rescheduling families, preparing (15 minutes), facilitating the group session

(~1 hour), and travel expenses. Program costs were assigned to families who received any component of the

program. Costs were valued in 2011 Australian dollars. No discount factor was applied.

TABLE 4 Helpfulness of Intervention Strategies (*n* = 294–298)

Strategy	Helpful (%)	Unhelpful (%)	Does not apply (%)
Information on normal baby sleep patterns	98.6	1.0	0.4
Information about normal baby crying patterns	97.3	1.7	1.0
Learning about tired signs	97.3	2.0	0.7
Information about sleep cycles	95.9	3.0	1.1
Learning about sleep cues	93.6	4.4	2.0
Learning about putting baby to bed awake	90.2	7.1	2.7
Learning how to settle my baby	89.6	8.7	1.7
Learning about baby care myths	85.8	10.5	3.7
Having someone to talk to about my baby	85.4	5.1	9.5
Learning about common medical causes of crying	84.7	8.5	6.8
Learning how to resettle my baby after a catnap	81.8	15.2	3.0
Learning about roll over feeds	74.8	15.2	10.0
Telephone numbers for other sources of help	72.6	13.0	14.4
Having someone to talk to about my own feelings	68.5	8.1	23.4
Learning about cosleeping	54.9	15.3	29.8

Use and Helpfulness of Intervention Strategies

All families reported reading the booklet, and 98% reporting watching the DVD. The majority of intervention families found the booklet to be either “quite a bit” or “a great deal” useful (40% and 38%, respectively) with similar findings for the DVD (41% and 35%, respectively). Caregivers indicated that the telephone consultation was “a little” useful (41%), followed by “quite a bit” (24%) and “a great deal” (21%) useful, whereas usefulness of the parent group was lower (“a little” 28%, “quite a bit” 32%, “a great deal” 34%). Information about normal infant sleep patterns, normal crying patterns, and learning about tired signs was most helpful (see Table 4). Despite program advice, some parents struggled to consistently put their infant down awake (only 33% did so), recognize tired signs before the infant became overtired (only 23% did so), or settle their infant without picking her or him up (only 11%; see Table 5). Ninety-five percent of families said they would

recommend the program to their friends.

DISCUSSION

In this community-based, randomized controlled trial of a program designed to prevent early infant sleep and cry problems and associated caregiver depression symptoms, we found modest benefits largely favoring caregivers. Intervention caregivers reported a slightly greater reduction in depression symptoms between 4 and 6 months and fewer symptoms at 6 months. Intervention caregivers were less likely to attend infant night wakings, change formulas to manage their infant's problems, and had less doubt, difficulty setting limits, and concerns about safety with respect to infant sleep. Such parental behaviors reduce the likelihood of the infant developing later sleep problems.³⁴ In the subgroup of infants who were frequent feeders, intervention caregivers reported fewer daytime sleep and crying problems at 4 months of age. This subgroup may represent an at-risk group whose

parents feed to try to settle, and as such, the advice in the program may have had a greater impact on parent perception of feeding and crying as problems. The effects faded by 6 months, which may reflect the natural improvement in infant crying and daytime sleep.^{2,5}

Unlike previous prevention trials aimed at improving infant nighttime sleep duration,^{9,11,30,35} we found no such improvement. This is despite our program including similar information. Our findings may differ for a number of reasons. First, the dosage of our program may be insufficient. In St James-Robert's trial,⁹ parents were telephoned at 3, 6, 9, and 12 weeks to discuss program implementation. However, Symon and colleagues¹¹ found improvements in infant sleep duration at age 12 weeks with a single 45-minute nurse consultation and booklet. Second, caregivers may not have implemented the program strategies known to foster self-settling in infants. This includes putting an infant into the crib while he or she is awake, which only one-third of our caregivers said they were able to do consistently. Third, the way in which the information was delivered may not have been effective; that is, the only face-to-face contact with parents occurred late in the intervention (mean infant age 13 weeks) and was only attended by half the parents.

Few randomized controlled trials have sought to prevent infant crying. One trial of increased carrying reduced the duration of infant crying,³⁶ but results have not been replicated.^{37,38} No randomized controlled trials have sought to reduce parent report of infant crying

TABLE 5 Frequency of Use of Intervention Strategies at 6 Month of Infant Age (*n* = 246–247)

	Never	A little	About half the time	Most of the time	All of the time	Not applicable
Put baby down awake but drowsy (%)	2.0	9.3	12.2	43.5	32.9	0.0
Recognize tired signs before overtired (%)	0.0	0.4	8.9	67.5	22.8	0.4
Settle baby without picking up (%)	8.1	17.4	19.4	43.3	10.9	0.8
Feed before midnight without waking baby (%)	26.8	20.7	5.3	13.8	18.3	15.0

as a problem. Our trial did but was unsuccessful, suggesting that for parents to accept crying as a normal infant behavior, more than education is required. The benefits for caregiver mental health happened in the absence of an improvement in infant sleep, contrary to previous studies.^{4,39} It may be that having more knowledge and appropriate expectations about infant sleep and crying behavior resulted in the observed reduction in caregiver doubt, facilitating a reduction in postnatal depression symptoms, given that the 2 have previously been linked.⁴⁰

The finding that intervention caregivers accessed more health services for their infants compared with control families at 4 months was surprising. The program booklet provided a list of other sources of help, and this may have prompted intervention families to access services.

Our study had a number of strengths. We recruited a large community sample with a diversity of sociodemographic characteristics, including infants born to experienced caregivers. We used validated measures of infant behavior (diary) and caregiver mental health. We used multiple imputation to account for missing data at follow-up with little change in our outcomes, suggesting that sample attrition has not biased our findings. Limitations include attrition rate at 6 months, use of caregiver report, and a lack of blinding of the intervention, which may lead to responder bias. However, an absence of group differences in infant outcomes suggests that the latter is unlikely. Compared with adults residing in the state of Victoria,⁴¹ our caregivers were better educated (70% with a tertiary degree or higher vs 64%, respectively) and more likely to speak English as the main language at home (87.8%–92.2%

vs 72%), so our results may not generalize to less well educated or non-English-speaking parents.

CONCLUSIONS

A relatively brief program designed to prevent infant sleep and cry problems did so, but only in infants who fed frequently. Overall, the program improved caregiver report of depression symptoms, cognitions, and behaviors around infant sleep and reduced formula changes. A population-based randomized trial is needed to determine whether the program could be more effective if it targeted frequent feeders in the first month of life or other at-risk groups such as depressed mothers. Whether the program impacts could be improved by face-to-face delivery or increased contacts and whether a more prescriptive approach would improve outcomes remains to be tested.

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