

Effect of a consultation teaching behaviour modification on sleep performance in infants: a randomised controlled trial

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Up to 46% of parents report infant sleep problems.¹⁻⁵ These include not sleeping through the night, delay in achieving sleep, and atypical behaviour at waking. These sleep disturbances may have serious negative consequences, including postnatal depression, family breakdown and child abuse.^{3,6,7} Disturbances may be long-lasting, with one study finding that, based on parental reports, 41% of children with sleeping disturbance at 8 months still had difficulties at 3 years.⁷

Studies of sleep achievement show that all individuals, including babies, "learn" to fall asleep with certain external environmental cues.^{1,8,9} Sleep initiation is repeated several times during the night, as all individuals repeatedly awoken for brief periods. However, these awakenings and returns to sleep are usually not understood by parents. It has been suggested that parents can inadvertently contribute to unwelcome night crying when they rock, hold, pat or feed their infant to sleep. The child may learn to re-initiate sleep repeatedly by signalling (crying) for the parent to repeat similar behaviours.¹⁰

Techniques of resolving sleep problems in infants and young children that have shown the best and most persistent results involve behaviour modification.^{4,11,12} Given the widespread nature of the problem and the potential for serious consequences, preventing sleep problems may be a superior strategy. Behavioural interventions have a well reported efficacy in decreasing sleep disturbance from the time of birth.^{5,11-13} Given the frequency of these problems and their impact upon family life, a simple intervention available from primary care services would be of value.

This study evaluated the impact of a single consultation with a trained registered nurse recommending proven behaviour-modification approaches in improving sleep in newborns.

ABSTRACT

Objective: To evaluate the effect of a behaviour modification program, taught to parents in a single visit to a trained nurse, in improving sleep performance in newborn infants.

Design: Randomised controlled trial.

Setting and participants: 268 families with normal newborn infants in the community, recruited between October 1996 and March 1997 from birth notices published in a South Australian daily newspaper.

Intervention: A 45-minute consultation with a nurse 2-3 weeks after the birth, including a tutorial discussion on normal sleep patterns in newborn infants, supported by retained written material and, for infants with weight gain < 30 g daily, referral to their usual postnatal care provider.

Main outcome measures: Hours of daytime sleep (0600-1800), night sleep (1800-0600) and total sleep per 24 h; and number of daily records with total sleep \geq 15 h per 24 h, assessed by 7-day sleep diary at ages 6 and 12 weeks.

Results: 268 families returned at least one sleep diary (137/171 intervention, 131/175 control), recording 3273 days. Two intervention infants were referred for low weight gain. Total sleep time was 15 h or more per 24 h on 62% of recorded days in the intervention group, compared with 36% in the control group ($P < 0.001$). At 6 weeks of age, intervention infants slept a mean 1.3 h per day more than control infants (95% CI, 0.95-1.65), comprising a mean 0.5 h more night sleep (95% CI, 0.32-0.69) and 0.8 h more daytime sleep (95% CI, 0.56-1.07). At 12 weeks, intervention infants slept a mean 1.2 h per day more (95% CI, 0.94-2.14), comprising 0.64 h more night sleep (95% CI, 0.19-0.89) and 0.58 h more daytime sleep (95% CI, 0.39-1.03). There was no significant difference in crying time between the groups.

Conclusions: A single consultation supported by written material in the first 3 weeks of a child's life improves sleep performance at 6 weeks of age. This improvement is maintained at 3 months.

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METHODS

Study population

Families were recruited from birth notifications published in the *Adelaide Advertiser*, the only South Australian daily newspaper, between October 1996 and March 1997. Contact details were obtained from the telephone directory.

Parents were contacted by telephone within 2 weeks of their child's birth and invited to participate in a study of sleep performance in healthy newborns. Those who agreed to participate were asked about

the baby's health and medical history. Those who refused were not formally asked for their reasons.

Inclusion criteria included delivery at 36-42 weeks' gestation, English-speaking mother, telephone in the home, and the mother intending to provide full-time care to her infant for at least the first 12 weeks after birth. A criterion for exclusion was admission of the infant to a neonatal intensive care unit for illness within the first 2 weeks after birth.

Parents who agreed to participate were mailed a consent form.

A sample size of 130 per group was determined, based on the minimum number of participants required to detect a predicted effect of a 30% increase in the proportion of children achieving 15 hours of sleep per 24 hours with a power of 90%.¹⁴ The period of 15 hours was chosen empirically as a reference point based on clinical experience.

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1 Advice about infant sleeping given to parents in the intervention group

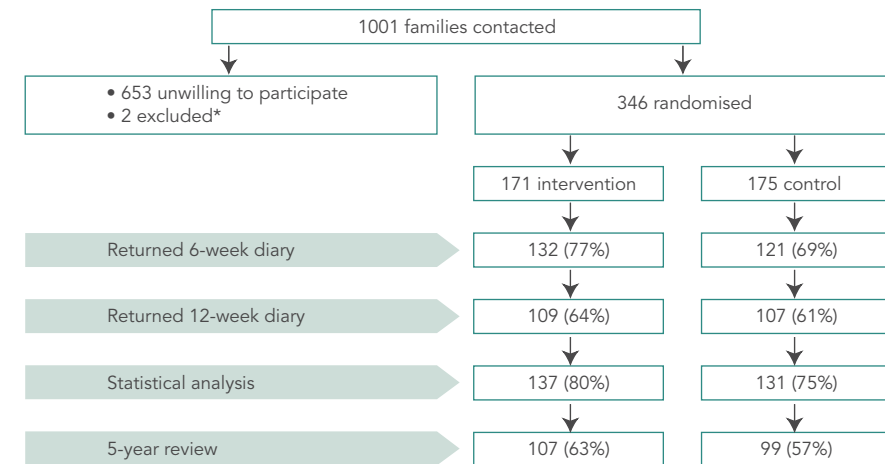
Parents were informed that:

- Infant sleep is cyclical, with repeated episodes of arousal within a block of sleep.
- Environmental factors or “cues of sleep” influence transitions to sleep and can be learned, altered and relearned.
- Thus, sleep achievement is a “learned” skill.
- Fatigue interferes with the performance of learned skills (ie, sleep achievement), and tearfulness in a well-fed neonate may reflect fatigue rather than pain.
- Parent-independent sleep cues are the most useful for developing “independent sleep skills”. Parents were encouraged to minimise handling at the time of sleep achievement.

It was recommended that parents focus on:

- Allowing an infant to be in a “parent-independent” position at initial sleep achievement.
- Regarding crying at sleep initiation as being due to tiredness and best handled by minimal parental response.
- Leaving a settling infant for a minimum of 5 minutes before responding if the infant is crying; this time interval is to be extended by 5 minutes for each additional return visit to the child.

2 Flow of participants in the study of sleep performance



* Excluded because of neonatal intensive care admission.

The study was approved by the Human Ethics Committee of the Adelaide Women's and Children's Hospital.

Randomisation

Participants were randomly assigned to the control or intervention group once they had consented, using a blind, block-randomisation schedule. Blocking ensured that, after every eight participants were recruited, numbers were equal in each group. A specific staff member was responsible for group allocation.

Intervention

Parents and infants in the control group received usual care from their health providers.

Parents in the intervention group were invited to attend a 45-minute consultation with a trained research nurse at the

Adelaide Women's and Children's Hospital when their infant was 2–3 weeks old. Both parents were encouraged to attend. The consultation included a tutorial discussion and advice on normal sleep patterns in newborn infants (summarised in Box 1). Each family was also given a 50-page book reinforcing the information.¹⁵

To avoid the use of behavioural techniques in children who were hungry, infants were assessed during the consultation for general well being and weight gain. If weight gain was less than about 30 g per day, parents were advised and encouraged to see their usual postnatal care provider for definitive guidance.

Assessment

All participants were asked to record a sleep diary for 7 consecutive days when their

child was aged 6 weeks and again at 12 weeks; recording began on the first day after the child turned 6 weeks and then 12 weeks. The sleep diary allowed every 10-minute period over 24 hours to be scored for the child being asleep, awake, feeding or crying. Parents recorded data when convenient.

5-year review

For 5-year review, we attempted to contact all families who had returned at least one sleep diary. Contact details were obtained from original research records, the telephone book or national electoral rolls. Families were contacted by telephone or mail and asked to participate in a follow-up study. Those consenting were interviewed by telephone and asked whether they were currently living together, separated or divorced.

Statistical analysis

Diary entries were aggregated to provide sleep and crying totals for daytime (0600 to 1800), night (1800 to 0600) and 24 hours. Sleep and crying totals from each diary were dual-entered into the Epi Info statistical software package.¹⁶ Statistical analysis, on a strict intention-to-treat basis, was performed for the 6-week and 12-week data separately. Each analysis contained seven repeated measurements, one for each 24-hour period in the week of interest. To compensate for multiple sampling of the same children, we used repeated-measures analysis with generalised estimating equations in SAS.^{17,18}

Family socioeconomic status was determined from postcode using the Socioeconomic Index For Australia.¹⁹

RESULTS

We contacted 1001 families; 346 provided written consent and were randomised (175 to the control group and 171 to the intervention group). Parents who did not wish to participate were not asked for their reasons, but many volunteered that they were too busy with their newborn or not interested.

Flow of participants in the study is shown in Box 2. All 171 families randomised to the intervention group attended the consultation. Two infants were identified with low weight gain and referred to their usual postnatal care provider; they continued in the study.

Of the 346 families randomised, 268 (77%) returned at least one sleep diary (137 intervention, 131 control), and 200 returned

3 Comparison between study groups and all births in South Australia in 1997

	Intervention (n = 137)	Control (n = 131)	Total (n = 268)	All births in state (n = 18 361)
No. females	72 (53%)	65 (50%)	137 (51%)	48.9%
SEIFA disadvantage				
Quartile 1	23 (17%)	31 (24%)	54 (20%)	33.1%
Quartile 2	17 (12%)	19 (15%)	36 (13%)	21.9%
Quartile 3	40 (29%)	32 (24%)	72 (27%)	18.3%
Quartile 4	57 (42%)	49 (37%)	106 (40%)	26.7%

SEIFA = Socioeconomic Index For Australia. Higher quartiles correspond to higher socioeconomic groups.

both (103 intervention, 97 control). The diaries recorded 3273 24-hour cycles (not all diaries were completed for all days). No records had to be discarded because of errors.

Box 3 compares sociodemographic characteristics between the 268 families who returned diaries and all births in the state of South Australia in 1997. While there was no socioeconomic imbalance between the intervention and control groups, the sample as a whole had a higher proportion of families from higher socioeconomic groups.

Sleep and crying behaviour

The number of daily records with at least 15 hours of total sleep per 24 hours was compared between the intervention and control groups (Box 4). A highly significant association was found, with at least 15 hours of sleep achieved on 62% of recorded days in the intervention group, compared with 36% in the control group ($P < 0.001$).

Other sleep outcomes are compared between the intervention and control groups in Box 5. The intervention group had greater mean total hours of sleep, hours of night sleep and hours of daytime sleep per 24 hours than the control group at both 6 and 12 weeks. The maximum difference occurred for female infants at 12 weeks for all three variables, with those in the intervention group achieving a mean 1.44 hours more total sleep per 24 hours (95% CI, 1.22–2.93), 0.65 hours more night sleep (95% CI, 0.18–1.12), and 0.98 hours more daytime sleep (95% CI, 0.50–1.46) than controls.

Mean hours of crying are also compared between groups in Box 5. No significant differences were found.

5-year review

Of the 268 families included in the analysis, 223 (83%) were able to be contacted after 5 years, and 206 consented to follow-up: 107 (52%) of those randomised to the intervention group and 99 (48%) of those randomised to the control group.

Thirteen families (6% of 206) reported either separation or divorce (six intervention and seven control families). Four families (2%) had divorced, and a fifth was about to complete divorce proceedings (all from the control group).

DISCUSSION

We found that a single consultation soon after a child's birth giving parents advice about infant sleeping can significantly enhance the child's sleep performance. The proportion of infants achieving a mean of 15 hours' sleep per 24 hours was significantly higher in the intervention group, as were total duration of sleep, night sleep and daytime sleep per 24 hours. Maximum improvement was 10.1 hours of additional sleep per week for female infants at 12 weeks.

The consultation also included assessment of the infant's weight gain and, for those with low weight gain, advice to parents to consult the usual primary-care provider. Attention to feeding problems is a

potential confounding factor. However, only two infants were identified as potentially underweight and referred as a result, both continuing in the study.

The improvements in sleep found in our study were greater than those in two previous randomised controlled trials of similar behavioural approaches which were shown to improve sleep.^{11,20}

The most controversial aspect of behaviour modification studies is recommending that families leave their infants to cry while "learning" to fall asleep alone. This study found no differences in mean hours of crying between the intervention and control groups.

Several factors increase the applicability of these results to the general population. The sample size was large compared with other, similar studies.^{11,12} The sample was chosen from a wide cross-section of socioeconomic strata, and randomisation was robust.

However, the study had limitations. Participants were not a random population sample. The method of recruitment and requirement to attend a metropolitan hospital meant most families were probably residents of metropolitan or outer metropolitan areas. Participants were also from higher socioeconomic groups compared with all births in the state. The consent rate was 35%, and the dropout rate was high, as found in a previous, similar study.¹¹ Parents who refused to participate overwhelmingly nominated that they were too busy with their newborn or not interested, which also reflects the results of a previous study.¹¹ Nevertheless, despite the pressures on families in the first 12 weeks after a child's birth, 77% of families who agreed to participate returned data requiring detailed record-keeping, again closely reflecting previous results.¹¹

Record-keeping was subjective. While self-reporting is liable to observer error and recall bias, the use of sleep diaries has been validated to give comparable results to objective measurements.²¹

Five-year review demonstrated a trend towards lower divorce rates in the interven-

4 Number of daily records with total sleep \geq 15 h per 24 h compared between groups at 6 and 12 weeks of age

	6 weeks			12 weeks		
	Intervention (n = 913)	Control (n = 836)	Relative risk (95% CI)*	Intervention (n = 752)	Control (n = 745)	Relative risk (95% CI)*
No. records with total sleep \geq 15 h per 24 h	599 (65.6%)	318 (38.0%)	1.72 (1.46–2.02)	432 (57.4%)	247 (33.2%)	1.82 (1.44–2.30)

* Relative risk of total sleep \geq 15 hours for intervention group compared with control group.

5 Sleep and crying behaviour compared between groups at 6 and 12 weeks of age

	6 weeks			12 weeks		
	Intervention (n = 132)	Control (n = 121)	Difference (95% CI)*	Intervention (n = 109)	Control (n = 107)	Difference (95% CI)*
Mean sleep time in 24 hours (h)						
Total	15.6	14.3	1.30 (0.95 to 1.65)	15.3	14.1	1.21 (0.94 to 2.14)
Night (1800–0600)	8.6	8.1	0.50 (0.32 to 0.69)	9.3	8.7	0.64 (0.19 to 0.89)
Daytime (0600–1800)	7.0	6.2	0.80 (0.56 to 1.07)	5.9	5.3	0.58 (0.39 to 1.03)
Mean longest uninterrupted sleep (h)						
Night (1800–0600)	4.9	4.8	0.15 (–0.11 to 0.42)	6.8	6.3	0.53 (0.23 to 1.07)
Daytime (0600–1800)	2.7	2.6	0.12 (–0.01 to 0.26)	2.4	2.3	0.10 (0.05 to 0.26)
Mean crying time in 24 hours (h)	1.0	0.9	0.06 (–0.12 to 0.25)	0.6	0.6	0.00 (–0.17 to 0.13)

* Difference = intervention group – control group.

tion group. However, as this outcome had low frequency, these data can not be used to assume a protective influence in the absence of larger studies.

Infant sleep problems are common in our community and are associated with significant morbidity. This study demonstrates the efficacy of advice describing a behavioural approach to sleep in newborn children. It offers improvements in sleep which are significant, both statistically and practically. The support is delivered by a nurse at a single visit. Such an approach is consistent with present models of general practice and might offer significant improvements in sleep for many patients.

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COMPETING INTERESTS

Dr Brian Symon is the author of the books *Your baby*, which was given to parents in the intervention group, and *Silent nights*, which discusses sleep in a manner similar to that presented in the intervention.

REFERENCES

- 1 Ferber R. Sleep, sleeplessness, and sleep disruptions in infants and young children. *Ann Clin Res* 1985; 17: 227-234.
- 2 Armstrong KL, Quinn RA, Dadds MR. The sleep patterns of normal children. *Med J Aust* 1994; 161: 202-206.
- 3 Kerr SM, Jowett SA. Sleep problems in pre-school children: a review of the literature. *Child Care Health Dev* 1994; 20: 379-391.
- 4 Ramchandani P, Wiggs L, Webb V, Stores G. A systematic review of treatments for settling problems and night waking in young children. *BMJ* 2000; 320: 209-213.
- 5 Hiscock H, Wake M. Randomised controlled trial of behavioural infant sleep intervention to improve infant sleep and maternal mood. *BMJ* 2002; 324: 1062.
- 6 Boyce P, Stubbs J. The importance of postnatal depression. *Med J Aust* 1994; 161: 471-472.
- 7 Zuckerman B, Stevenson J, Bailey V. Sleep problems in early childhood: continuities, predictive factors, and behavioural correlates. *Pediatrics* 1987; 80: 664-671.
- 8 Ferber R. *Solve your child's sleep problems*. New York: Simon & Schuster; 1985.
- 9 Richman W. A community survey of characteristics of 1–2 year olds with sleep disruptions. *Am Acad Child Psychiatry* 1981; 20: 281-291.
- 10 Johnson MC. Infant and toddler sleep. A telephone survey of parents in one community. *Dev Behav Pediatrics* 1991; 12: 108-114.
- 11 St James-Roberts I, Sleep J, Morris S, et al. Use of a behavioural programme in the first 3 months to prevent infant crying and sleeping problems. *J Paediatr Child Health* 2001; 37: 289-297.
- 12 Wolfson A, Lacks P, Fetterman A. Effects of parent training on infant sleeping patterns, parents' stress, and perceived parental competence. *J Consult Clin Psychol* 1992; 60: 41-48.
- 13 Rickert VI, Johnson CM. Reducing nocturnal awakenings and crying episodes in infants and young children. A comparison between scheduled awakenings and systematic ignoring. *Pediatrics* 1988; 81: 203-211.
- 14 Pocock S. *Clinical trials — a practical approach*. Bath: Pittman Press, 1983.
- 15 Symon B. *Your baby*. Adelaide: University of Adelaide, 1997.
- 16 Centers for Disease Control and Prevention. Epi Info, version 6.04a [computer program]. Atlanta, Ga: Centers for Disease Control and Prevention, 1996.
- 17 Liang KY, Zeger SL. Longitudinal data analysis using generalised linear models. *Biometrika* 1986; 73: 13-22.
- 18 SAS Institute. *The genmod procedure, SAS-STAT software, changes and enhancements through release 6.12*. Cary, NC: SAS Institute, 1997.
- 19 Australian Bureau of Statistics. *Information paper: 1991 census — socio-economic indexes for areas*. Canberra: ABS, 1993.
- 20 Kerr SM, Jowett SA, Smith LN. Preventing sleep problems in infants: a randomised controlled trial. *J Advanced Nursing* 1996; 24: 928-942.
- 21 Barr R, Kramer M, Boisjoly C, et al. Parental diary of infant cry and fuss behaviour. *Arch Dis Child* 1988; 63:380-387.

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