

A randomized controlled trial to compare alternative strategies for preventing infant crying and sleep problems in the first 12 weeks: the COSI study

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This study was designed to test the hypothesis that a behavioural programme was used preventatively to try to reduce crying and improve night sleeping in 1- to 12-week old infants compared with educational support or existing services. The objectives were to develop strategies which can be used to inform, help and support parents of new babies. The study was a three-group prospective randomized controlled trial in West Berkshire and South Oxfordshire, making a comparison between a behavioural policy, an educational intervention and existing services. The participants were 610 mothers giving birth to term healthy infants at the Royal Berkshire Hospital, Reading between March and November 1997. The main outcome measures were interruption-free nights i.e., the number of nights each week when parents reported that their baby slept for a minimum of 5 hours; babies' fuss/crying patterns; and mothers' general well-being and approach to parenthood. There were no significant differences between the groups in the amount of fuss/crying, which gradually reduced during the 12 weeks. At 12 weeks of age, more mothers in the behavioural group reported their babies to have had seven interruption-free nights (61%), compared with the educational (53%) and the control groups (50%). This was significant at the $P < 0.05$ level. The educational and control groups did not significantly differ at any age. At 6 and 12 weeks, mothers allocated to the behavioural policy were more structured in their approach to parenting and rated it more highly for convenience. At 9 months, their babies were more likely to have a regular bedtime routine. Where mothers followed a behavioural programme, 10% more babies slept for a minimum of 5 hours at night without disturbing their parents at 12 weeks of age. This improved sleeping pattern persisted up to 9 months of age. Mothers in this group also reported a greater feeling of control and increased confidence in their ability to cope. The more widespread adoption of a behavioural approach to the management of early infant sleeping should be considered.

Key words: babies' crying; babies' sleeping; preventative strategies

Introduction

Unexplained infant crying and poor sleeping are among the most common complaints for which par-

ents seek professional advice in the first year (Forsyth *et al.*, 1985; St James-Roberts and Halil, 1991). Most babies 'sleep through the night' by 12 weeks of age (Pinilla and Birch, 1993), however, a substantial minority do not resulting in long-term adverse consequences for the infant. These include earlier discontinuation of breast feeding and the introduction of solids (Wolke *et al.*, 1995), frequent changes in for-

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mula feeds (Forsyth *et al.*, 1985), chronic sleep problems (Hellin and Waller, 1992) and an increased risk for physical abuse and neglect (Frodi, 1981). The consequences of parental stress include anxiety, exasperation and anger which can have a deleterious effect upon the maternal–infant relationship (Frodi, 1981). These problems are compounded by parental sleep deprivation.

A number of studies have compared various modifications of parental behaviour in reducing infant crying and sleeping problems with varying reported degrees of success (Barr *et al.*, 1991; Barr and Elias, 1988; Hunziker and Barr, 1986; Kerr and Jowett, 1996; McKenzie, 1991; Wolke *et al.*, 1994). These have included the use of volunteer support, the supplementary carrying of babies and the provision of educational material. A systematic review (Ramchandani *et al.*, 2000) concluded that behavioural modification was likely to prove the most effective intervention in treating babies with established settling or night waking problems. However, only one randomized controlled trial currently recorded on the Cochrane Database (Renfrew and Lang, 1999) was designed to prevent infant sleeping problems before they arise. This suggests that a structured behavioural programme together with a late evening focal feed results in more newly born, exclusively breast-fed babies sleeping for a minimum of 5 consecutive hours between midnight and 5am by the eighth week of age (described as ‘sleeping through the night’) compared with a control group (Pinilla and Birch, 1993). Although these results suggest that the intervention was outstandingly successful in these breast-fed infants, the small sample size, the withdrawal of mothers during the early weeks of the study, and the lack of evidence of compliance with the study protocol imposes limitations on the generalizability of the findings.

Based on this exploratory work, a randomized controlled trial was designed to test the hypothesis that a behavioural programme can be used, preventatively, to reduce crying and improve sleeping in 1- to 12-week old infants compared with a potentially low-cost educational intervention and existing services within the NHS.

Methods

Women were eligible for inclusion if they gave birth to their babies at the Royal Berkshire Hospital

between March and November 1997, they lived in West Berkshire or South Oxfordshire, were English speaking and literate and owned a telephone; their babies were <37 weeks gestation and had not been admitted to the Special Care Baby Unit or shown evidence of congenital abnormality. Antenatal information was distributed by community midwives. Seven to 10 days after delivery, mothers were contacted by telephone to confirm their wish to participate. Formal consent and trial entry took place during a subsequent home visit. Ethical approval was granted by the West Berkshire Research Ethics Committee.

Mother and baby pairs were randomly allocated to one of three policies at the home visit between days 8 and 12. The randomization schedule was computer-generated at the National Perinatal Epidemiology Unit in Oxford using balanced blocks of differing sizes ranging from three to 15. Within each block, the allocation to each of the three policies was represented an equal number of times. Initial data collection tools, together with the random allocation, were packaged within sealed, opaque envelopes, each bearing a sequential trial number. These were prepared by the trial administrator. Once the envelope had been opened in the home, the mother was considered to have entered the study.

Interventions

Behavioural intervention

This was a modification of that used by Pinilla and Birch (1993). Mothers were asked to:

- introduce a ‘focal feed’ between 22.00 and 24.00 hours;
- try not to rock, hold or feed babies to sleep, minimize interaction during the night and emphasize differences in day/night lighting;
- after 3 weeks of age and providing babies were gaining weight satisfactorily, to gradually lengthen the interval between night feeds by resettling baby without feeding. The aim was to progressively lengthen night time feed intervals by disassociating the act of waking at night and being fed. It should be noted that parents were instructed not to leave the infant alone crying for long periods of time.

During the home visit, time was taken to explain

the intervention. This was endorsed in a five page A5 sized leaflet which detailed each stage.

Educational intervention

This policy had two components: an 11 page, A5 sized, information booklet produced in consultation with health visitors which incorporated a range of practices currently in common use related to managing/preventing infant crying and promoting good patterns of sleeping. The content of the booklet was discussed during the home visit. Mothers were also provided with a dedicated telephone helpline organized by a voluntary support group – CRYSIS.

Control group

Mothers and babies received the standard community services offered by health visitors and GPs, as did all the trial participants.

Mothers were asked to comply with their allocated policy for a minimum of 12 weeks. At 3, 6, 9 and 12 weeks, each of the groups received telephone calls from one of the research assistants to encourage and confirm compliance, to complete a record of their babies' crying and sleeping patterns and to answer any queries.

The primary outcome measures were the number of 'interruption-free nights' per week and measures of babies' crying. An interruption-free night was defined as a night in which parents reported their baby to remain asleep for 5 hours or more between 10pm and 6am. This definition reflects video-recorded evidence that most infants wake in the night, but return to sleep without waking their parents (Minde *et al.*, 1993). The focus here was on instances where infant night waking was detected by parents, usually because of crying, since it is parents who seek NHS help for such problems. Likewise, the measures of infant crying and fussing recorded parents' perceptions of how much their babies usually cried and fussed in the morning (6am–noon), afternoon (noon–6pm), evening (6pm–midnight) and night (midnight–6am). Mothers were asked to fill in weekly logs of the number of interruption-free nights that occurred during week 1 through to week 12. The Crying Patterns Questionnaire (St James-Roberts and Halil, 1991) was completed by telephone interviews with mothers when their baby was 3, 6, 9 and 12 weeks of age.

Secondary measures included mothers' general

well-being, approach to baby care, and perception of their babies' temperaments. Maternal well-being was measured at 6 and 12 weeks, using the Edinburgh Post-natal Depression Scale (Cox *et al.*, 1987). The mothers' approach to baby care was assessed using Crockenberg's 10 item scale of maternal responsiveness (Crockenberg and Smith, 1982) at 6 and 12 weeks, while summary ratings of how satisfied mothers were with their approach to baby care, and how convenient they found it, were completed at 12 weeks. Whether the mothers perceived their babies to have a difficult temperament was measured at 6 and 12 weeks using the Infant Characteristics Questionnaire (Bates, 1984; Bates *et al.*, 1979). The babies' weight gain, health and use of medications were monitored throughout the first 12 weeks. Method of infant feeding was not targeted as one of the main outcomes because the rigorous process of randomization would ensure that mothers had an equal chance of allocation to any of the groups whatever their chosen feeding preference. In reality, the proportion of infants fed by breast, bottle and a mixture of both breast and bottle did not differ between the groups.

At 9 months, the mothers completed a checklist to report: 1) whether or not their baby had a regular bedtime routine; 2) whether they had contacted their health visitor or GP specifically because of their baby's crying or sleeping problems in the last 6 months; 3) who they had approached for help.

Economic evaluation

An economic evaluation was conducted to estimate the annual total cost to the NHS of infant crying and sleeping problems in the first 12 weeks of infancy and to assess the cost-effectiveness of interventions aimed at reducing infant crying and sleeping problems. These analyses are reported elsewhere (Morris *et al.*, 2001).

Sample size and data analysis

The sample size of 600 mothers was estimated to detect a reduction of 30 minutes per day (25%) in babies' crying with 80% power and 5% significance. Data were entered and analysed at the Thomas Coram Research Unit using SPSS (Statistical Package for Social Sciences). Primary analysis was by intention to treat. Following descriptive analyses to examine the distribution of the data, differences between the groups were examined using a one-way analysis of variance or

chi-squared analysis for the frequency data. Secondary analysis included stratification by parity and other predictor values.

Results

Of the 3403 women who gave birth, 2663 (78%) met the eligibility criteria. Most women not entered into the trial were either unable to be approached as they had been discharged home within the first few hours of childbirth before they could be visited on the post-natal wards (942 (35%)) or they exercised their right not to participate when contacted within the first 10 days following delivery (Figure 1). Random allocation of the remaining 610 mothers generated groups which were similar in terms of descriptive variables (Table 1).

Table 2 shows the number of interruption-free nights in each group as reported in the night sleep log. All three groups showed a rapid increase, particularly between weeks 3 and 9 but at 11 and 12 weeks of age infants and parents in the behavioural group had significantly more interruption-free nights than infants in the educational or control groups ($P < 0.05$). At 12 weeks of age, 61% of the behavioural group parents, compared to 53% and 50% in the educational and control groups, respectively, reported their babies to have had seven interruption-free nights. The educational and control groups did not differ at any age.

The perceived amounts of time the babies spent crying and fussing did not differ between the groups at any age. In the first weeks, the babies spent around 2 hours a day fussing and crying; this gradually reduced to around 1 hour in 24 by 3 months of age. The daily peak of crying time was between 6pm and midnight. Babies' gender, and birth order had little effect on the findings.

There was no difference between the groups in the mothers' mean EPDS scores or the number who reported high scores. Those who scored 13 or above were contacted and offered the choice of referral to the health visitor or GP. In all cases mothers had already contacted the support services or accepted the offer of referral.

Neither of the interventions had a significant effect on the infants' weight gain over the first 3 months. At 6 and 12 weeks, mothers in the behavioural group were more likely to report using a

structured approach to infant care ($P = 0.02$ and 0.001 , respectively). At 12 weeks, mothers in the behavioural group rated their approach to care more convenient and easy to implement than mothers in the other groups ($P = 0.02$). There was no effect of the interventions on the mothers' ratings of their enjoyment in looking after their babies or of their babies' temperaments. At 9 months, 10% more mothers in the behavioural than in the educational or control groups reported that their baby had a regular bedtime routine. At this time, significantly fewer of the behavioural than educational and control group mothers reported having sought help for crying or sleeping problems in the preceding 6 months (14% compared with 24% and 21% respectively; $\chi^2 = 6.01$, 2df, $P = 0.05$).

Discussion

This study has yielded the largest data set currently available concerning babies' crying and sleeping problems during the early weeks. This is a time when most parents are adjusting to the demands of their new role and striving to establish a balance between domestic routine and the possibility of returning or continuing to work.

The findings provide evidence for an effect of the behavioural intervention in increasing the number of interruption-free nights. By the 12th week, 61% of parents in the behavioural group compared to 50% of the control group reported that their babies had night-time sleep periods which lasted for 5 hours or more on seven nights of the week. The implication is that a programme, which encourages babies to recognize day/night cues, helps them to remain settled at night. There was no difference between the groups in the reported amounts of infant fussing and crying during the day or at night-time. This result is consistent with previous studies that normal variations in parental behaviour have a limited effect upon their babies' crying pattern within the first 3 months (St James-Roberts *et al.*, 1995). Overall, there was little or no evidence of benefit of the educational intervention over and above that reported by mothers who received the existing services.

At 9 months, parents in the behavioural group were more likely to report a regular bedtime routine indicating that this approach continued to be effective. At this age, fewer mothers in the behav-

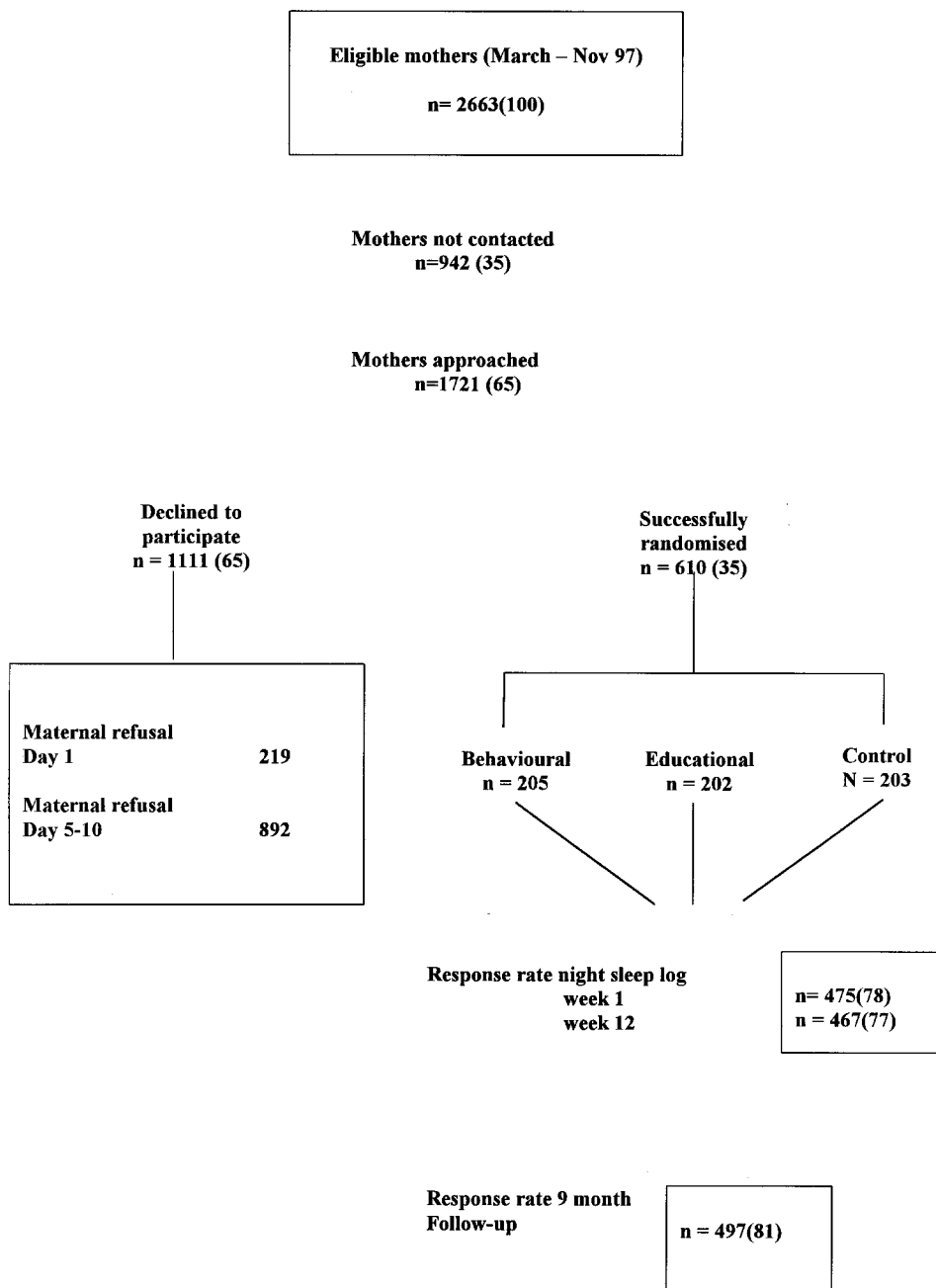


Figure 1 Participation and response rates – n(%).

Table 1 Descriptive variables at trial entry

	Behavioural group (n = 205)	Educational group (n = 202)	Control group (n = 203)
Mothers			
Mean age [SD]	30 [5.32]	31 [4.97]	31 [5.37]
Primiparae (%)	96 (47)	97 (48)	108 (53)
Babies			
Mean weeks gest age [SD]	40 [1.27]	39.5 [3.08]	40 [2.61]
Mean birthweight grams [SD]	3443 [449.80]	3473 [452.50]	3449 [528.18]
Type of delivery			
Normal (%)	133 (65)	130 (64)	116 (57)
LSCS (%)	51 (25)	41 (20)	54 (27)
Assisted (%)	21 (10)	31 (15)	33 (16)
Socio/economic variables			
Mothers married	164 (80)	175 (87)	166 (82)
Other children in household <5 years old	86 (42)	89 (44)	73 (36)

Results are numbers or means of infants or mothers with percentage or SD in brackets.

Table 2 Mean (95% CI) 'interruption-free nights' per week at each age

	Behavioural group (n = 205)	Educational group (n = 202)	Control group (n = 203)
Week 1	1.10 (0.85–1.35)	1.13 (0.87–1.38)	1.13 (0.81–1.45)
Week 2	1.29 (0.99–1.59)	1.33 (1.03–1.64)	1.29 (0.96–1.61)
Week 3	1.44 (1.12–1.76)	1.60 (1.27–1.93)	1.42 (1.07–1.78)
Week 4	1.73 (1.39–2.08)	1.87 (1.50–2.23)	1.64 (1.28–2.00)
Week 5	2.27 (1.88–2.67)	2.28 (1.89–2.67)	2.02 (1.61–2.42)
Week 6	3.02 (2.61–3.43)	2.94 (2.53–3.35)	2.63 (2.19–3.07)
Week 7	3.73 (3.30–4.15)	3.52 (3.11–3.92)	3.35 (2.89–3.81)
Week 8	4.25 (3.85–4.66)	4.23 (3.83–4.62)	4.00 (3.54–4.46)
Week 9	4.75 (4.35–5.14)	4.77 (4.36–5.17)	4.41 (3.94–4.87)
Week 10	5.19 (4.83–5.55)	4.92 (4.55–5.30)	4.80 (4.38–5.23)
Week 11	5.65 (5.33–5.98)	5.21 (4.85–5.58)	5.11 (4.69–5.54)
Week 12	5.79 (5.48–6.11)	5.24 (4.86–5.61)	5.22 (4.81–5.63)

The group differences were statistically significant at weeks 11 and 12 ($P < 0.05$).

iournal group had approached their health visitors because of concern about their babies' crying or sleeping in the last 6 months.

The findings presented here suggest that, if introduced routinely, the behavioural intervention used in this study could lead to an improvement of around 10% in the number of babies who regularly remain settled for 5 hours a night by 12 weeks of age. Furthermore, parents liked the 'common sense' approach and clear structure of the routine, which they did not find overly rigid or prescriptive but which enhanced their confidence in their ability to cope. The question of importance to clinicians is whether the results justify the widespread adoption of this approach.

In interpreting these results, a number of issues need to be taken into account. Although the number of refusals before randomization was relatively high, the number of mothers entered into the trial (35%) was similar to the percentage reported in other trials in the field of maternity care (McCandlish *et al.*, 1998).

Ethically, mothers were free to refuse to take part without giving a reason for their decision. Some of them volunteered that the demands of coping with a new baby were proving overwhelming and they could not contemplate the data collection required by involvement in the study. Perhaps this decision was not altogether surprising given the current trend to discharge mothers home as

soon as possible after delivery (35%, $n = 942$ in this study). Overall, mothers who agreed to take part remained committed to the trial as illustrated by the high response rates which were similar across all the groups and maintained throughout the study, including the 9 month follow-up. Despite these challenges, the results of the COSI study may well be generally applicable to routine practice among similar women in similar settings, many of whom might benefit from a more structured approach to settling their babies at night time. Detailed discussion of the possible implications of this study for health care policy has been published elsewhere (St James-Roberts *et al.*, 2001).

Conclusions

On the basis of the results of this study, it would be a mistake to draw definitive or prescriptive guidelines for practice. The evidence suggests that no matter which of these three strategies is employed during the first 12 weeks, each baby will eventually cry less and feed less frequently at night. The way that mothers decide to care for their babies must depend on what works for them within the family unit. Nevertheless, it should be reassuring for mothers to know that, given the plethora of advice they may receive from professionals, the media, friends and family members, (much of which may be conflicting), there is no completely right or wrong way to care for babies in the early weeks. The most important thing is that they should feel happy, relaxed and comfortable with the choices that they make. However, the results of this study suggest that some mothers may benefit from a more structured approach to settling their babies at night. In doing so, parents would need to be reassured that it would be necessary to maintain such a nightly routine over several weeks in order to consolidate a behavioural response in their babies. Mothers and babies who do not respond well to such a routine will learn to develop their own ways of establishing good sleeping patterns which are acceptable in their lifestyle.

Overall, the results provide evidence to enable individual women and health professionals to make informed decisions about which of these approaches is preferable in their particular circumstances.

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