ORIGINAL ARTICLE

Preventing sleeping problems in infants who are at risk of developing them

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Aims: (1) To identify factors at 1 week of age which put infants at risk of failing to sleep through the night at 12 weeks of age. (2) To assess whether a behavioural programme increases the likelihood that these infants will sleep through the night at 12 weeks of age.

Methods: A community sample of 316 newborn infants was employed to identify the risk factors at 1 week of age which increased the likelihood of failing to sleep through the night at 12 weeks of age. Infants who met these risk criteria and were randomly assigned to a behavioural programme were compared with at risk infants in the control group on measures of sleeping, crying, and feeding at 12 weeks of age.

Results: Infants who had a high number (>11) of feeds in 24 hours at 1 week were 2.7 times (95% CI 1.5 to 4.8) more likely than other control group infants to fail to sleep through the night at 12 weeks of age. At 12 weeks, 82% of these at risk infants assigned to the behavioural programme, compared to 61% in the control group, slept through the night. The findings were similar in breast and bottle feeders.

Conclusions: Preventing infant sleeping problems should be more cost effective than treating them after they have arisen. This study provides evidence that it is possible to identify infants who are at risk of failing to sleep through the night at an early age, and that a simple, three step, preventive behavioural programme increases the number who sleep through the night by 21%.

In industrialised societies, around two thirds of babies develop the ability to "sleep through the night" by 12 weeks of age.[1–3] Infants who fail to do so are particularly likely to wake at night at older ages,[4] a phenomenon often called infant (or child) "sleeping problems".[5] Particularly where parents are constrained by office hours and other Western cultural practices, an infant who wakes, cries, and disturbs their own sleeping night after night can be a source of considerable distress. As a result, these problems concern many Western parents and are costly for health services.[6]

Development of the ability to sleep through the night probably requires infants to be sufficiently physically mature and to learn how to use environmental cues to regulate their behaviour. Evidence that it is possible to help parents to support this learning comes from studies which have used behavioural methods to treat problems after they have arisen. Structured behavioural programmes, which distinguish day from night time environments, withdraw rewards for night time waking and crying, and reward desired behaviours such as resettling, are effective.[5 7] However, a substantial number of parents fail to implement this approach, because it involves leaving babies to cry, which they consider cruel.[8]

In principle, prevention of infant crying or sleeping problems is preferable to treating them later. However, the suitability of behavioural programmes for this purpose depends on parents' willingness to implement them, and on babies' ability to learn from their environment at an early age. To address these issues, a randomised control trial of the cost effectiveness of a behavioural programme in the first 12 weeks of age in preventing infant sleeping problems (called COSI) was recently completed.[9] The infants were found to grow healthily, while 10% more of those given the behavioural programme slept through the night by 12 weeks of age, compared to infants in two comparison groups. Parents approved of the behavioural programme,[10] which did not require babies to be left to cry. Fewer parents in the behavioural than other groups sought help for crying or sleeping problems over the next six months.[9] These improvements were achieved with little increase in service costs.[6]

These results were encouraging. However, most (71%) infants in the general community, control group slept through the night by 12 weeks without a specific behavioural programme. These results were achieved by parents and infants with the support solely of the routine National Health Service. Given limited resources, a resulting question is whether health services should try to deliver a behavioural programme to all families. A more cost effective strategy may be to target cases "at risk" of developing later sleep problems, and to deliver the programme to them. This strategy depends on two assumptions: that it is possible to identify early on those infants who are most likely to develop later sleeping problems; and that the behavioural programme helps them.

The present study involves a reanalysis of the COSI dataset in order to address these assumptions. It asks two questions:

(1) Is it possible to identify at 1 week of age those infants who are especially likely to be unable to sleep through the night at 12 weeks of age?

(2) When such infants are given the behavioural programme, does this increase the probability that they will sleep through the night at 12 weeks of age?

METHODS

The present study is based on a randomised control trial involving mothers and babies recruited in postnatal wards of a large maternity hospital.[9] Women who delivered a live singleton baby at >37 weeks gestation at the Royal Berkshire Hospital and were registered with a general practitioner in the West Berkshire area were eligible for inclusion. Except where mothers did not speak English fluently, did not have a telephone, or where their babies had congenital anomalies or were admitted to the intensive care unit, the mothers were approached consecutively. Of 1721 mothers invited to participate, 1111 (65%) declined before randomisation. The chief

reason given was inability to cope with a newborn baby and the study requirements, which involved completing behaviour diaries and accepting random assignment to an independently selected method of baby care. Where informed consent was given (n = 610), each mother was asked to complete a single, prospectively kept, 24 hour behaviour diary of her infant's and her own caregiving behaviour at 1 week of age (baseline).

The mothers were then visited at home when their babies were 8–14 days of age, where an opaque envelope containing group allocation was opened. Group allocation was randomly predetermined using a computer program by the study administrator. A total of 205 were assigned to a behavioural programme group, 202 to an "educational booklet and telephone helpline group", and 203 to a "routine services" group. Measures of obstetric history, and of infant and demographic characteristics, were obtained by maternal questionnaire. The resulting groups, which did not differ in background, demographic or infant characteristics at baseline, are described in table 1, available on the *ADC* website (www.archdischild.com).

Behaviour diaries were used to measure the babies' and mothers' behaviour for three successive days and nights (72 hours) at 3, 6, 9, and 12 weeks of age. At 3 weeks, 184 (90%), 187 (93%), and 191 (94%) of the recruited mothers in the behavioural, educational booklet, and routine services group, respectively, returned completed diaries; reducing to 162 (79%), 164 (81%), and 152 (78%), respectively, by 12 weeks of age. Rates of attrition did not differ between groups. The validity of behaviour diaries in measuring infant crying and sleeping has been repeatedly shown,[11–13] and they have been widely used to investigate infant sleeping problems.[14–16]

Data processing and analysis

Because earlier analyses showed that the educational booklet and helpline did not change maternal or infant behaviour, compared to the routine services group,[9] the two groups were combined into a single "control group" to increase the sample size for the present study.

The data were examined in three stages. First, evidence from previous studies was used to identify infant or parent potential "risk factors" which could reduce the likelihood that infants would sleep through the night at 12 weeks of age. Each case in the control group was then scored on each of the following potential risk factors at 1 week of age: parental social class (defined by paternal occupation[1]); maternal age,[17] maternal ethnic origin,[18] and maternal highest educational level[1]; childbirth delivery type[19]; infant feeding method[4 18 20]; infant sex[1 21]; infant birth order[1 21]; and amount of infant crying, feeding, and sleeping behaviour.[4 22 23] So far as possible, each case was categorised dichotomously into "at risk" and "not at risk" categories on each factor, using the original authors' criteria, but taking into account the need for an adequate sample size. For continuous variables, such as infant sleeping and crying, the 25th or 75th centiles were chosen as cut off points, according to whether a low, or high, amount predicted failure to sleep through the night in previous research. For a few variables, previous research has employed three, rather than dichotomous, categories and these were retained. The resulting categories and sample sizes are shown in table 2, available on the *ADC* website (www.archdischild.com).

In step 2, the data were analysed to examine whether any of the infant or parental potential risk factors did, in fact, reduce the likelihood of sleeping through the night at 12 weeks of age in the present control group. For this purpose, the relation between the week 1 potential risk factors and sleeping through the night at 12 weeks was examined using χ^2 cross tabulations, employing Cramer's V coefficient as a measure of association. Logistic regression and *t* tests were used to explore these relations further.

In step 3, regression analyses assessed whether infants with these risk factors who had been randomly assigned to receive the behavioural programme were more likely than the equivalent, at risk, infants in the control group to sleep through the night at 12 weeks of age. Following previous studies, the night was defined as 7 pm to 7 am,[9] and "sleeping through the night" as continuous sleeping lasting at least five hours in at least two of three nights, according to parental report.[9 15]

RESULTS

Predicting sleeping through the night at 12 weeks of age

Cross tabulation analyses revealed that, in the present control group, only two of the potential risk factors did, in fact, significantly increase the probability that infants would fail to sleep through the night at 12 weeks of age. Babies who had >11 feeds in 24 hours at week 1 were more likely to fail to sleep through the night at 12 weeks than infants who had fewer feeds at week 1 (39% *v* 20%, Cramer's V = 0.19, $p < 0.001$, n = 295). Similarly, infants whose mothers were of non-caucasian ethnic origin were more likely to fail to sleep through the night at week 12, than infants whose mothers were of caucasian origin (54% *v* 23%, Cramer's V = 0.15, $p < 0.05$, n = 304).

Stepwise logistic regression estimated the contribution of each of these two risk factors to failure to sleep through the night at 12 weeks. The criterion for variables to enter the logistic model was set at $p < 0.05$, for removal $p > 0.10$. The total 24 hour number of feeds at week 1 emerged as the best predictor of sleeping through the night at 12 weeks ($p < 0.001$; odds ratio 2.7; 95% CI 1.5 to 4.8). Mother's ethnic origin was an additional predictor ($p < 0.05$; odds ratio 0.2; 95% CI 0.1 to 0.7; model χ^2 17.4, df = 2, $p < 0.001$). A χ^2 cross tabulation between the total 24 hour number of feeds at week 1 and the mother's ethnic origin identified no association between them. Further logistic regression analysis identified no significant interaction between the two variables in relation to the week 12 outcome. The total 24 hour number of feeds at week 1 contributed more to the logistic model (model χ^2 10.3, $p < 0.01$) than the mother's ethnic origin (model χ^2 5.5, $p < 0.05$). As documented below, ethnicity was subsequently excluded from the statistical analysis because of an inadequate sample size.

At week 1, compared to other control group infants, control group babies who had >11 feeds in 24 hours spent more time feeding, both in the day (mean (SD) minutes: 139.7 (57.1) *v* 120.3 (51.4); *t* (382) = 3.1, $p < 0.01$) and night (mean (SD) minutes: 142.8 (61.1) *v* 112.2 (52.2); *t* (382) = 4.7, $p < 0.001$). They had more feeds in the day (mean (SD) no: 7.3 (2.0) *v* 4.2 (1.2); *t* (112.9) = 13.6, $p < 0.001$) and night (mean (SD) no: 7.1 (1.8) *v* 4.1 (1.2); *t* (119.3) = 15.4, $p < 0.001$). They also spent less total time asleep during the night (mean (SD) minutes: 463.5 (76.9) *v* 493.5 (89); *t* (382) = 2.9, $p < 0.001$) and had more night fuss/cry bouts (mean (SD) no: 3.9 (2.6) *v* 2.6 (1.9); *t* (123.5) = 4.5, $p < 0.001$).

As well as failing to sleep through the night at 12 weeks, control group babies who had >11 feeds in 24 hours at week 1 slept less in total during the night at week 12 than comparison week 1 babies (mean (SD) minutes: 550.6 (59.4) *v* 568.7 (60.9); *t* (294) = 2.3, $p < 0.05$). At week 12, they also had more night fuss/cry bouts (mean (SD) no: 2.5 (1.8) *v* 1.8 (1.5); *t* (294) = 3.5, $p < 0.001$) and more feeds in the day (mean (SD) no: 5.6 (1.8) *v* 4.5 (1.5); *t* (122.2) = 5.0, $p < 0.001$) and night (mean (SD) no: 3.7 (1.5) *v* 2.5 (1.1); *t* (113.9) = 6.6, $p < 0.001$). The two groups did not differ in their total 24 hour feeding duration at week 12, but babies with >11 feeds in 24 hours at week 1 spent longer feeding at night at week 12 than babies with fewer week 1 feeds (mean (SD) minutes: 65.1 (51.2) *v* 51.2 (26.9); *t* (110) = 3.1, $p < 0.01$).

Effects of the behavioural programme

At week 1, 42 of 193 (22%) infants in the behavioural group met the criterion of >11 feeds in 24 hours, compared with 92 of 384 (24%) infants in the control group. For ethnicity, 12 of 203 (6%) infants in the behavioural group, compared to 25 of 401 (6%) infants in the control group were of non-caucasian background. By 12 weeks, the number of non-caucasian infants in the behavioural group dwindled to 10. The small number of non-caucasian infants in the behavioural group ruled out a statistically robust assessment of the effects of the behavioural programme on these infants. Analyses below focus on the groups of infants who had >11 feeds in 24 hours at 1 week of age, and we revisit ethnicity in the Discussion.

The chief question was whether at risk infants who received the behavioural programme would be more likely to sleep through the night at week 12 than at risk infants in the control group. A χ^2 cross tabulation confirmed that the behavioural programme increased the number of at risk infants who slept through the night at 12 weeks significantly, and by 21%. While only 49 of 80 (61%) of the control group infants slept through the night at week 12, 32 of 39 (82%) of the behavioural group infants did so (Cramer's V coefficient: 0.21, $p < 0.05$, $n = 119$).

There was no difference between the two at risk infant groups in their total 24 hour sleep duration, or in most other behaviours, at week 12. Table 3 (available on the *ADC* website, www.archdischild.com) provides detailed figures. However, at risk infants given the behavioural programme spent significantly more time sleeping during the night at 12 weeks than at risk infants in the control group (mean (SD) minutes: 593.0 (55.6) *v* 550.6 (59.4); t (115) = 3.8, $p < 0.001$) and woke up less often at night (mean (SD) no. of sleep bouts = 3.6 (1.0) *v* 4.3 (1.5), t (99.3) = 3.0, $p < 0.01$). At risk babies who received the behavioural programme also had significantly fewer night feeds at 12 weeks than at risk babies in the control group (mean (SD) no: 2.8 (1.3) *v* 3.7 (1.5); t (115) = 3.1, $p < 0.01$) and spent less time feeding at night (mean (SD) minutes: 50.1 (29.4) *v* 65.1 (37.8); t (115) = 2.1, $p < 0.05$). The behavioural programme had similar benefits irrespective of whether the babies were fed by breast, bottle, or a mixture (see table 3, available on the *ADC* website, www.archdischild.com).

To assess whether the behavioural programme helped the at risk infants to sleep as well as their not at risk peers, the week 12 behaviour of the at risk and not at risk infants in the behavioural group was compared. At week 12, 18% of the at risk, compared to 16% of the not at risk infants, failed to sleep through the night (a non-significant difference). At risk and not at risk behavioural programme babies had similar day and night sleeping and crying behaviour. The at risk infants still had a higher total 24 hour number of feeds at 12 weeks than the not at risk behaviour programme babies (mean (SD) no: 8.3 (2.7) *v* 6.7 (2.2); t (148) = 3.6, $p < 0.001$), but this difference was a result of more feeds in the day (mean (SD) no: 5.4 (1.9) *v* 4.3 (1.4); t (148) = 4.1, $p < 0.001$) and not in the night time.

DISCUSSION

To be included in routine health services, any programme designed to prevent infant sleeping problems should be cost effective and acceptable to parents and healthcare staff. Recent, randomised controlled trials have found that a simple, three step, behavioural programme goes a long way towards meeting these criteria.[6 9 10 15] However, given limited resources and the evidence that most babies learn to sleep through the night without a specific behavioural programme, the optimum strategy for health services may be to target cases at risk of sleeping problems and to deliver the programme to them.

The present study sought, first, to identify in a community sample the infant and parental factors which predicted infants' failure to sleep through the night at 12 weeks of age. The principal risk factor found was frequent feeding (>11 feeds per 24 hours) at 1 week of age. Approximately 25% of infants received more than 11 feeds per 24 hours at 1 week and these babies were 2.7 times more likely than other infants to fail to sleep through the night at 12 weeks of age.

To assess the benefits of the behavioural programme for these at risk cases, infants who met the criterion of >11 feeds in 24 hours at 1 week and who were assigned at random to the behavioural programme were compared with infants with >11 feeds randomised to the control group. At 12 weeks, 82% of the infants given the behavioural programme, compared to 61% of infants in the control group, slept through the night. This 21% difference was statistically significant and twice that found previously among infants in the general community, suggesting that the behavioural progamme was of particular benefit for such at risk infants. As well as longer night time sleeping, these infants fed less often at night and were comparable to babies who were not at risk on most measures of behaviour, suggesting that the behavioural programme "normalised" the night sleeping behaviour of the at risk infants at 12 weeks of age. The exception was that they still had more feeds than not at risk infants in the day, but not at night. It is not clear whether this reflects infant characteristics, parental characteristics, or both. However, assuming that in such cases parents will prefer to feed often in the day, rather than night, this can be considered a helpful outcome. An important finding was that the behavioural programme was equally effective with breast and bottle fed babies.

Non-caucasian ethnicity was also found to increase the likelihood that infants would not sleep through the night at 12 weeks. Unfortunately, the small number of such cases in the behavioural programme group ruled out statistical analysis of whether the programme was equally effective in such cases. Visual inspection of the data suggested that it had similar effects, but this remains to be tested satisfactorily.

The behavioural programme, described in more detail elsewhere,[9] consists of three main steps. First, parents are asked to maximise the difference between day and night time environments, by minimising light and social interaction at night. Second, they are asked to settle a baby judged to be sleepy in a cot or similar place, and to avoid feeding or cuddling to sleep, at night time. Third, once the baby is 3 weeks old, healthy, and putting on weight normally, they can begin to delay feeding when baby wakes at night, in order to dissociate waking from feeding. This is done gradually, using nappy changing or handling to introduce a delay, and does not involve leaving babies to cry. In keeping with these recommendations, mothers of at risk infants in the behavioural programme spent less time feeding at night at 12 weeks than mothers of at risk infants in the control group, and their babies received fewer night time feeds at this age than control cases. These findings confirm that mothers of at risk infants in the behavioural group successfully implemented the programme, with beneficial consequences.

The findings identify several questions for further analysis. First, we need to understand how the behavioural programme works. Most babies continue to wake at night as they get older, the main difference between these and infants who disturb their parents being that the latter cry and demand attention, whereas infants who "sleep through the night" according to parents, in fact resettle back to sleep without crying.[13 16] The behavioural programme may aid this normal developmental progression, by providing an environmental "scaffold" which helps babies to learn to resettle when they wake in a familiar darkened environment at night. Studies which use infrared video recording of infant sleeping, waking, crying, and resettling behaviour at night should address this issue.

Second, advice to settle infants in a cot, rather than by carrying, and to increase intervals between night feeds rather than feed often, is contrary to child care practices used widely in non-industrialised societies, which are believed to prevent

babies from crying.[24 25] Studies of the behaviour programme to date have not found increased crying among babies who receive it, but these puzzling inconsistencies warrant research.

A third issue is the need to assess how individual parents feel about, and manage, the behavioural programme. In an earlier study, implementation was patchy in some respects, and this may have been a result of parents' expectations, or the difficulties they encountered in practice in implementing the programme with their particular babies.[9] Parents' preferences may also be part of the reason why most mothers invited to take part in this study declined allocation to a randomly selected form of baby care. Since this occurred before randomisation, it does not threaten the internal validity of the findings, but does indicate the need for care in generalising the findings to parents who hold strong views about baby care. Studies which examine parental viewpoints should increase our understanding of these issues and may improve programme delivery and effectiveness.

The decision on whether or not the behavioural programme should be routinely adopted by health services involves balancing costs against benefits. On the one hand, it is important to acknowledge that an infant who fails to sleep through the night is not ill, or at greatly increased risk of later problems other than waking and crying at night. "Infant and child sleeping problems" are usually greater sources of concern for parents than for children. Further, whether or not parents wish to have their baby sleep through the night by 12 weeks of age is likely to be influenced by parents' culture and values.[26] On the other hand, many Western parents find infant and child night waking to be a source of substantial stress, both for themselves and their relationships with their children.[5 7 8 16] This problem takes up a good deal of professional time and is costly for health services,[6] while the behavioural programme adds little to health service costs.[6] Where babies feed often at 1 week of age, and having their baby sleep through the night at 12 weeks of age is a parental priority, health services may wish to consider whether the behavioural programme can be recommended to help parents to bring this about.

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The tables can be viewed on the *ADC* website (www.archdischild.com)

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