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Randomised controlled trial of behavioural infant sleep intervention to improve infant sleep and maternal mood

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Abstract

Objective To compare the effect of a behavioural sleep intervention with written information about normal sleep on infant sleep problems and maternal depression.
Design Randomised controlled trial.
Setting Well child clinics, Melbourne, Australia
Participants 156 mothers of infants aged 6-12 months with severe sleep problems according to the parents.
Main outcome measures Maternal report of infant sleep problem; scores on Edinburgh postnatal depression scale at two and four months.
Intervention Discussion on behavioural infant sleep intervention (controlled crying) delivered over three consultations.
Results At two months more sleep problems had resolved in the intervention group than in the control group (53/76 *v* 36/76, P=0.005). Overall depression scores fell further in the intervention group than in the control group (mean change −3.7, 95% confidence interval −4.7 to −2.7, *v* −2.5, −1.7 to −3.4, P=0.06). For the subgroup of mothers with depression scores of 10 and over more sleep problems had resolved in the intervention group than in the control group (26/33 *v* 13/33, P=0.001). In this subgroup depression scores also fell further for intervention mothers than control mothers at two months (−6.0, −7.5 to −4.0, *v* −3.7, −4.9 to −2.6, P=0.01) and at four months (−6.5, −7.9 to 5.1 *v* −4.2, −5.9 to −2.5, P=0.04). By four months, changes in sleep problems and depression scores were similar.
Conclusions Behavioural intervention significantly reduces infant sleep problems at two but not four months. Maternal report of symptoms of depression decreased significantly at two months, and this was sustained at four months for mothers with high depression scores.

Introduction

In Australia 36-46% of parents report a problem with their infant's sleep in the second six months of life,[1 2] and 10-15% of mothers experience postnatal depression in their first year postpartum.[3] Infant sleep problems and postnatal depression are both associated with increased marital stress, family breakdown, child abuse, child behaviour problems, and maternal anxiety.[3 4] Postnatal depression can adversely affect a child's cognitive development.[5]

We carried out a randomised controlled trial to determine whether a simple behavioural intervention—controlled crying—would be effective in reducing both sleep problems in infants and symptoms of depression in mothers. We used a reliable validated tool to assess symptoms.

Methods

Participants

This randomised controlled trial was nested within a larger survey. Between May 1998 and April 1999 all mothers attending routine screening sessions for infant hearing at maternal and child health centres in three local government areas in suburban Melbourne, Australia, were invited to complete a survey about their infant's sleep and their own wellbeing (94% response rate).[2] About 80% of children attend these free screening sessions, which are offered to all infants aged 7-9 months.

Survey mothers were eligible for the trial if they reported a problem with their infant's sleep and at least one of the following over the preceding two weeks: waking on more than five nights a week,[6] waking more than three times a night,[6] taking more than 30 minutes to fall asleep,[7] or requiring parental presence to fall asleep.[7] We excluded mothers with insufficient English to complete questionnaires, who were receiving treatment for postnatal depression, or who reported thoughts of self harm and infants with a major medical or developmental problem and those already receiving help for their sleep problem.

Intervention

Mothers in the intervention group attended three private consultations, held fortnightly at their local maternal and child health centre. Sleep management plans were tailored towards individual families. As well as discussing normal sleep cycles, parents were taught that settling after night waking is a learned behaviour that can be modified, infants need to be taught to fall asleep independently, factors reinforcing the sleep problem can be eliminated with appropriate behavioural interventions (see below), an infant's cry may be for more than one reason, and a bedtime routine and consistent daytime naps are desirable.

The main intervention was controlled crying, whereby parents responded to their infant's cry at increasing time intervals, allowing the infant to fall asleep by itself.[8] A few parents chose "camping out," whereby they sat with their infant until the infant fell asleep and gradually removed their presence over a period of three weeks. Overnight feeding that contributed to night waking was managed by reducing over seven to 10 days the volume of milk given or time taken to feed. When a dummy was causing problems (needing a parent to find and replace it), parents removed it or attached it to the infant's clothing overnight.

Mothers in the intervention group also received a sleep management plan, information about the development and management of sleep problems, and the same information about normal sleep patterns as the control group. They were asked to maintain daily sleep diaries until the first follow up questionnaire.

Control group
Mothers in the control group were mailed a single sheet describing normal sleep patterns in infants aged 6 to 12 months based on Australian normative data.[1] This sheet did not include advice on how to manage infant sleep problems.

Process
Mothers were randomised to the intervention or control group within two strata ("depressed" and "not depressed"). Masking occurred at three points (randomisation, data collection, and analysis). Allocation sequences were concealed from researchers and participants until allocation was complete.

We measured outcomes at two months and four months after randomisation by mailed questionnaires. The primary outcomes were maternal report of an infant sleep problem (yes or no) and symptoms of depression measured by the Edinburgh postnatal depression scale with cut off scores of >12 and $\geqslant 10$.[9 10]

Analysis
We calculated that we would need a sample of 140 women to have an 80% chance of detecting, at a two sided 5% significance level, a three point difference between the two groups in the mean change in the depression score score, with an assumed SD of 4.8[11] and a loss to follow up of 30%.

We carried out all analyses on an intention to treat basis. Fewer women than anticipated had scores that indicated clinical depression (13 in each group) so we dichotomised depression status at recruitment using community cut off points (depression score <10 and $\geqslant 10$) for analyses.

We used multiple regression models controlling for baseline Edinburgh depression score and allocated group to assess the impact of controlled crying on change in depression scores and factors associated with increased depression scores at two and four months.

Results

Participant flow and follow up
Of the 738 mothers who completed the survey, 232 were eligible to participate and left contact details and 155 of these agreed to participate. Table 1 shows the baseline variables for the intervention and control groups.

Sleep
At two months more infant sleep problems had resolved in the intervention group than in the control group (53/76 *v* 36/76, P=0.005, table 2) and remaining sleep problems were less severe in the intervention group (P=0.01). In the subgroup of depressed mothers, significantly fewer infants of mothers in the intervention group had a sleep problem at two months (26/33 *v* 13/33, P=0.001, table 2).

At two months more control mothers than intervention mothers had sought extra help (23/76 (30%) *v* 9/75 (12%), χ^2=7.54, P=0.006) (see also bmj.com). Within the control group more mothers who sought extra help reported that their infant's sleep problem had resolved (13/23 (56%) *v* 23/53 (43%), χ^2=1.11, P=0.30).

Maternal depression
At two months depression scores fell in both groups, with a slightly greater improvement in the intervention group (table 3). After we controlled for additional professional services, Edinburgh depression score, and allocated group with multiple regression the margin-

Table 1 Demographic characteristics of infants and mothers at baseline. Figures are numbers of infants and mothers unless stated otherwise

Variable	Treatment (n=78)	Control (n=78)
Infant		
Mean (SD) age (months)	8.9 (0.14)	8.6 (0.10)
Boys	42	47
Girls	41	38
Global temperament score:		
Much easier/easier than average	25	31
Average	37	28
More/much more difficult	14	16
Cannot say	2	3
Sleep		
Waking nights per week:		
0-3	2	9
4-6	24	21
7	52	48
Wakings per night:		
0-1	17	21
2	27	24
3	21	17
⩾4	13	15
Child settled by adult	45	38
Sleep problem severity score:		
1-2 (mild)	9	13
3-4 (moderate)	32	31
5-7 (severe)	37	33
Mother		
Edinburgh depression scale score:		
Mean (SD)	9.0 (0.44)	8.8 (0.49)
⩾10	44	45
Mean (SD) maternal age (years)	34.1 (3.6)	33.3 (5.6)
Maternal sleep quantity:		
More than enough/enough	4	6
Not quite enough/not nearly enough	22	21
Maternal sleep quality:		
Very good/fairly good	8	8
Fairly bad/very bad	19	22
Stress rating:		
No stress	2	5
Little/some	71	70
Much stress	5	3
Limits due to physical health problems:		
None	26	24
Few/some	48	47
Many	4	7
Limits due to emotional health problems:		
None	40	47
Few/some	35	29
Many	3	2
Demographic		
Born in Australia:		
Mothers	63	62
Fathers	59	59
English spoken at home	75	77
Marital status:		
Single	1	0
Divorced/separated	1	1
Married/cohabiting	76	77
University education:		
Mothers	55	49
Fathers	50	55
Maternal employment:		
Employed	24	22
Home duties/unemployed	54	56

Table 2 Number of mothers whose infants' sleep problems had resolved at two and four months for whole sample and subgroups according to mother's Edinburgh depression score

	Resolved at two months			Resolved at four months		
	Intervention	Control	Pvalue*	Intervention	Control	Pvalue*
Whole sample	53/76	36/76	0.005	48/75	39/71	0.26
By Edinburgh score:						
⩾10	26/33	13/33	0.001	21/32	14/30	0.13
<10	27/43	22/43	0.34	27/43	25/41	0.86

*χ^2 test.

ally significant fall in depression scores at two months for the intervention versus control group became significant (point estimate 1.4, 95% confidence interval 0.2 to 2.5, P=0.02). By four months the greater fall in depression score for intervention mothers was no longer significant, even when we controlled for extra help. For the subgroup of mothers with initial depression scores ⩾10, scores fell in both groups with a significantly greater improvement in the intervention group at two and four months (table 3).

Details of information and strategies that mothers in the intervention group found helpful are given on bmj.com.

Discussion

A simple behavioural intervention reduced infant sleep problems and maternal symptoms of depression and improved quality and quantity of mothers' sleep in the short term (two months). The same intervention also reduced symptoms of depression at four months for depressed mothers and reduced the amount of help sought from other sources. Use of the intervention did not seem to increase overall stress in a mother's life.

Strengths and weaknesses of the study

This is the first randomised controlled trial to examine the effect of an infant sleep intervention on both infant sleep and maternal report of depression. Using a validated measure of postnatal depression in a community based sample, we achieved more than 90% follow up. Although only 67% of eligible mothers entered the study, those who did not participate were more likely to report only mild sleep problems, suggesting that the intervention did reach nearly all of those really in need. However, our results may not be generalisable to mothers in other socioeconomic groups or those with severe postnatal depression.

What is already known on this topic

Infant sleep problems and postnatal depression are both common potentially serious problems

Women whose infants have sleep problems are more likely to report symptoms of depression

Uncontrolled studies in clinical populations suggest that reducing infant sleep problems improves postnatal depression, but there is no good quality evidence in the community for such effectiveness

What this study adds

A brief community based sleep intervention based on teaching the controlled crying method effectively decreased infant sleep problems and symptoms of maternal depression, particularly for "depressed" mothers

The intervention was acceptable to mothers and reduced the need for other help

Unavoidably, neither the investigator nor the mothers in the study were blind to group membership, which could have led to a bias favouring the intervention. To minimise this, all responses were gathered by written questionnaires and all contacts regarding data collection were with an independent blinded research assistant.

Sleep

The short term effect of the intervention on infant sleep is similar to that reported in two randomised controlled trials[12 13] and three uncontrolled trials in hospital (84%[14] to 87%[15] sleep problems resolved) and community (83%[7]) settings. By four months the greater resolution in the intervention group was no longer significant. This is similar to six month findings in a controlled non-randomised study of children aged 4-54 months.[16] It could have been due to the natural tendency for sleep problems to improve with time[17] or to mothers in the intervention group stopping effective behavioural strategies, or both.[15]

Maternal depression

At two months, depression scores fell by a mean of 6 points (45%) for the "depressed" mothers in the intervention group. This is identical with findings of a

Table 3 Change in Edinburgh depression scale scores between baseline and two and four months for whole sample and by depression subgroup

	Baseline to two months			Baseline to four months		
	No of women	Change (95% CI)	P* value	No of women	Change (95% CI)	P* value
Whole sample						
Intervention	76	−3.7 (−4.7 to −2.7)	0.06	75	−3.6 (−4.6 to −2.5)	0.45
Control	76	−2.5 (−3.4 to −1.7)		71	−3.0 (−4.0 to −2.1)	
By depression group:						
⩾10:						
Intervention	33	−6.0 (−7.5 to −4.0)	0.01	32	−6.5 (−7.9 to −5.1)	0.04
Control	33	−3.7 (−4.9 to −2.6)		30	−4.2 (−5.9 to −2.5)	
<10:						
Intervention	43	−2.0 (−3.1 to −0.8)	0.70	43	−1.4 (−2.6 to −0.2)	0.36
Control	43	−1.6 (−2.7 to −0.5)		41	−2.1 (−3.2 to −1.1)	

*Student's *t* test.

randomised controlled trial of intensive non-directive counselling sessions delivered by health visitors to 55 women with postnatal depression, which reduced median depression scores by 6 points three months after the intervention.[18]

Conclusions

This brief community based sleep intervention decreased infant sleep problems and symptoms of maternal depression, particularly for "depressed" mothers. The intervention reduced the need for other professional sleep services, was acceptable to mothers, was of low cost, and was minimally disruptive to families in contrast with many current strategies for postnatal depression. These findings should now be replicated in a larger study in which the intervention is offered and implemented by primary healthcare professionals.

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Perceptions of stroke in the general public and patients with stroke: a qualitative study

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Abstract

Objectives To gain insight into people's thoughts on stroke and to inform the development of educational strategies in the community.

Design Focus group discussions: two groups of people who had a stroke and their carers, and two groups of members of the general public.

Setting New South Wales, Australia.

Participants 35 people participated: 11 from the general public, 14 people who had had a stroke, and 10 carers or partners.

Main outcome measures Views on risk factors, symptoms, treatment, information resources, and prevention.

Results All groups reported similar knowledge of risk factors. People generally mentioned stress, diet, high blood pressure, age, and smoking as causes of stroke. Participants in the community group gave little attention to symptoms. Some participants who had had a stroke did not initially identify their experience as stroke because the symptoms were not the same as those they had read about. There were mixed feelings about the extent of involvement in management decisions during hospital admission. Some felt sufficiently involved, some wanted to be more involved, and others felt incapable of being actively involved.

Conclusions Symptoms of stroke are not easy to recognise because they vary so much. Presentation of information about stroke by hospital and community health services should be improved. Simple and understandable educational materials should be developed and their effectiveness monitored.

Introduction

Studies of acute intervention for stroke have shown that outcome is more favourable if the symptoms are recognised early. However, most people do not seek timely medical attention.[1–4] Many factors contribute to delays in seeking medical treatment for acute stroke, but one that should be remediable is public lack of knowledge about symptoms, which often results in delay in seeking medical care.[5]

Our previous study on public perception of warning signs, symptoms, and treatment of stroke in an urban area of Australia showed that only 73% of respondents identified the brain as the organ affected by stroke.[6] When asked how they would respond to the