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Title:

Anticipatory guidance to prevent infant sleep problems within a randomised controlled trial: infant, maternal and partner outcomes at 6 months of age.

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ABSTRACT

Objective: To evaluate the effectiveness of sleep education delivered antenatally and at 3 weeks post-partum to prevent infant sleep problems at 6 months of age.

Design: Sleep intervention within a randomised controlled trial for the Prevention of Overweight in Infancy (POI study).

Participants: 802 families were randomly allocated to one of four groups: usual care (Control); sleep intervention (Sleep); food, activity and breastfeeding intervention (FAB); combined group receiving both interventions (Combination).

Interventions: All groups received standard Well Child care. The sleep intervention groups (Sleep and Combination) received an antenatal group education session (all mothers and most partners) emphasising infant self-settling and safe sleeping, and a home visit at three weeks reinforcing the antenatal sleep education. FAB and Combination groups received four contacts providing education and support on breastfeeding, food and activity up to four months postpartum.

Outcome measures: To determine the prevalence of parent-reported infant sleep problems and night waking (primary sleep outcomes), and to determine differences in infant self-settling, safe sleep practices, sleep duration, and maternal and partner reports of their own sleep, fatigue and depression symptoms (secondary sleep outcomes).

Results: Linear or mixed linear regression models found no significant intervention effects on primary and most secondary outcomes with 19.1% of mothers and 16.6% of partners reporting their infant's sleep a problem at 6 months of age. Actigraphy estimated the number of night wakings to be significantly reduced (8%) and the duration of daytime sleep increased (6 minutes) in those groups receiving the sleep intervention compared to those who did not. However, these small differences were

not clinically significant, and were not observed in 24-hour infant sleep diary data. No other differences were observed.

Conclusion: A strategy delivering infant sleep education antenatally and at three weeks postpartum was not effective in preventing the development of parent-reported infant sleep problems.

Key Words: actigraphy, night wakings, safe sleep, settling techniques, sleep duration

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The first RCT examining the efficacy of a sleep education programme to prevent infant sleep problems commencing antenatally.
- Data were collected from both mother and partner about whether their child's sleep was a problem.
- Sleep data from infants were reported both subjectively (sleep diaries) and objectively (actigraphy).
- Partners as well as mothers rated their own sleep quality across several time points.
- Key education outcomes related to infant sleep practices, such as infant self settling, were collected via parent report and may not be accurate enough to identify any intervention effects.
- The results are limited to young infants in a well-educated community which may reduce the generalisability of the findings.

INTRODUCTION

Unsettled sleep-wake behaviour peaks in the first six months of life with between 16 and 38% of parents reporting sleep problems to clinicians within the first year.[1-3] Parents' commonest concerns relate to their baby's crying,[4] amount of sleep, appropriate strategies to settle their infant to sleep,[5,6] difficulties settling to sleep and frequent night waking.[7] Infant sleep problems are expensive to treat[8] and are associated with several adverse consequences for mothers including postnatal depression,[8] fatigue,[9] as well as poorer general and mental health among those without a history of depression.[10] Although fathers have rarely been studied, they also report poorer general health and greater psychological distress linked to infant sleep problems.[10]

Infant sleep problems likely emerge from interactions between infant and parental health and behaviour, and the environment.[11] One third of infants who are unable to achieve a consolidated sleep of six hours by five months of age still cannot achieve this by 2½ years of age[12] and a short sleep duration pattern sustained across infancy and early childhood is associated with five times greater odds of children exhibiting hyperactive behaviour at five years of age.[7] Evidence also suggests that sleep problems first presenting in infancy are likely to persist into childhood[13-15] with potential for poorer cognitive development,[16-18] behaviour,[16,19] and quality of life,[20] and a greater risk of overweight or obesity.[21-24] These adverse outcomes highlight the need for early intervention to optimise sleep development.

Overall, interventions designed to treat sleep problems once they have become established have demonstrated a small to medium effect on infant nocturnal total sleep time, no effect on the number of night wakings, and small impacts on maternal mood,[25] and infant sleep.[26] Whether prevention of sleep problems might be more effective, and potentially less costly,

than attempts to treat established issues is largely unknown. Randomised controlled trials emphasising the early establishment of positive sleep practices have produced mixed findings to date.[2,27-29] These interventions were delivered postnatally,[2,28,29] or at 3 months post-partum[27] and on a one-to-one basis. None were delivered antenatally or within group sessions where families may be less stressed and more receptive to the sleep education messages. Given that a large number of infants suffer sleep problems and that the flow-on effects of these problems carry significant long-term costs to individuals, it is pertinent to investigate the effectiveness of simple prevention strategies that could be implemented as a public health measure through antenatal education and Well Child services.

We recently undertook a four-armed randomised controlled trial, the Prevention of Overweight in Infancy (POI) study,[30] to determine whether additional support and education on food, activity, breastfeeding, and sleep from late pregnancy could reduce overweight and obesity in children at two years of age. The aim of this paper was to determine whether the infant sleep education programme delivered antenatally and 3 weeks postpartum reduced the prevalence of parent-reported sleep problems and night wakings in infants up to six months of age. Secondary aims were to determine any differences in infant self-settling and safe sleep practices, sleep duration, and maternal and paternal reports of their own sleep, fatigue and depression symptoms.

METHODS

Study Design

The Prevention of Overweight in Infancy (POI) study (Clinical Trials NCT00892983) was a four-armed randomised controlled trial commencing in late pregnancy. Data from baseline (third trimester) to 6 months of age are reported here.

Participants and recruitment

All mothers booked into the single maternity hospital (> 97% of all births) serving the city of Dunedin, between May 2009 and November 2010 were potentially eligible. Letters of invitation were sent to mothers at 28–30 weeks gestation and an "opt out" recruitment strategy was used. Exclusion criteria applied before birth were: home address outside the greater Dunedin area, planning to move away in the next two years, not booked with the maternity centre or homebirth midwife before 34 weeks gestation, or unable to communicate in English or Te Reo Māori (language of the indigenous people of New Zealand). Exclusion criteria applied after birth were: identification of a congenital abnormality likely to affect feeding or growth, or the infant being born before 36.5 weeks gestation.

Randomisation

Participants were randomised to one of four groups: i) usual care (Control); ii) food, activity and breastfeeding intervention (FAB); sleep intervention (Sleep), or iv) combined intervention group receiving both the Sleep and FAB interventions (Combination). Details of allocation concealment and stratification have been described previously,[30] but briefly, stratification was based on household deprivation (tertiles: low [NZDep deciles 1–3],[31] medium [4–7] and high [8–10]) and parity including the study child (1 vs ≥2). Group allocation was revealed to the participants after they consented to participate. The statistician remained blinded to group allocation codes until primary analyses were completed.

Usual Care

Families of all four groups received standard maternity and Well Child care from a maternity care professional, and a Well Child provider of their choice. Well Child care[32] aims to maximise the health and development of all New Zealand children up to age five years (on

average 8-9 visits in the first six months of life). The Control group received this usual care only.

Interventions

Sleep

Families receiving the Sleep intervention (Sleep and Combination groups) received antenatal education delivered via a single group session (up to 1 hour), followed by one home visit at three weeks post-partum with a researcher with infant sleep training. Antenatal sessions educated all mothers and most partners about normal developmental patterns of infant sleep and emphasised infant settling to sleep unaided (i.e. self-settling or self-regulation of sleep) which appears to be a key factor in the development of healthy sleep-wake patterns and a precursor to longer sleep duration in later infancy;[33] and safe-sleep practices as measures to prevent sudden unexpected death in infancy[34] (summarised in Appendix 1). Partners were mostly fathers. Parents left equipped with a "tip sheet" related to the key education messages. The individual sessions at the 3-week home visit reinforced the antenatal sleep education and were conducted with the aid of a more detailed 15 page booklet covering the key messages for developing healthy sleep and safe sleep practices (summarised in Appendix 2). At this visit, researchers provided advice on any concerns the families had with their infant's sleep, and parents were encouraged to keep using the booklet as a valuable resource, and contact research staff at any stage should they require further sleep advice.

FAB

Mothers in the FAB group received three contacts providing education and support on breastfeeding (antenatal, one week and four months postpartum) and one on physical activity (three months postpartum) before 6 months of age. An International Board Certified Lactation Consultant worked with each family to assist with infant feeding, focussing on prolonging

exclusive breastfeeding and delaying the introduction of complementary foods until around six months of age. At three months, each family attended an Active Movement session delivered by an established local sports body. The FAB intervention is described in more detail elsewhere.[35]

Combination

This group received five intervention visits in total before 6 months of age as the FAB and Sleep antenatal session was combined.

Questionnaires

Parents completed questionnaires during home visits at baseline (third trimester, prior to allocation), and at 4 and 6 months. Questionnaires collected data relevant to outcomes of the sleep education including ratings of the baby's problematic sleep and unsettled behaviour, and of infant settling and safe sleep practices. Mothers and partners also rated perceptions of their own sleep quantity and quality, and reported the usual time they went to bed, usual sleep time (sleep onset) and usual wake time (sleep offset). Their sleep duration was calculated as the difference between sleep onset and sleep offset. Sleep latency (time taken to fall asleep) was calculated from the difference between the time they went to bed and sleep onset. Ratings of maternal and partner fatigue and depression symptoms (Edinburgh Postnatal Depression Scale[36]) were also collected. Duration of exclusive breastfeeding (i.e. the infant receiving no liquids, other than breast milk, and no solids since birth), was calculated as age to the nearest part week from the monthly questionnaires.[30]

Sleep Diary

When the infant was 6 months of age, parents were asked to complete a 48-hour diary during the 5-7 day period when actigraphy was also recorded (as described previously[37]). Time

was displayed horizontally in five-minute grid blocks. A parent was asked to indicate using an arrow the time the infant went to sleep and awoke, including daytime naps. Grid block counts with sleep and wake coding were then entered into a spreadsheet set up to automatically calculate standard sleep-wake variables.

Actigraphy

Infants wore an Actical accelerometer (Mini-Mitter Co., Inc., Bend, OR) for 5-7 days fitted on the shin. The accelerometers were initialized using 15-second epochs. Sleep onset (evening sleep time) and morning sleep offset (wake time) events were ascertained visually from activity graphs and marked in the sleep scoring program in MATLAB (MathWorks, Natick, MA, USA), from which standard sleep-wake variables, including nap counts and nap duration were determined using the count-scaled algorithm. A sleep period was defined as at least 20 minutes of sleep preceded by 5 minutes of awake with the sleep period altered for nap detection between 9am and 5pm as previously described using a minimum nap time threshold of 20 minutes.[37]

Statistical analysis

As sleep outcomes were secondary outcomes of the POI study, which was powered on detecting differences in growth (the primary outcome) between the arms of the study,[30] no relevant sample size calculations are available. The data were analysed using Stata 14.1 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP). Statistical significance was determined by two-sided $P < 0.05$ in all cases. No adjustments were made for multiple comparisons. Continuous outcome variables were compared between the four groups using linear regression models where the outcome was at a single time point and mixed linear regression with a random participant effect where multiple time points were included. Where model residuals were skewed or demonstrated heteroscedasticity, natural log

transformations were investigated, after adding one for variables including zero values. If issues with model residuals were not thereby resolved, quantile regression was used instead to model medians. All models included the stratification variables (three levels of household deprivation and two levels of parity).[38] Binary variables were similarly analysed using logistic regression and mixed logistic regression with a random participant effect. For all outcomes, a second set of models looking at the main effects of the sleep (Sleep and Combination groups vs FAB and Control) and FAB interventions (FAB and Combination groups vs Sleep and Control) were implemented providing there was no evidence of an interaction between the two interventions. The purpose of this two-step process was to maximise the power to detect main effects but, as is well known,[39] this increases Type I error rates above their nominal level and so these results should be interpreted with caution, especially in cases of marginal statistical significance.

RESULTS

Participant characteristics at baseline

Of the 847 (58%) eligible families who agreed to participate, 802 met the post-partum inclusion criteria. Table 1 presents participant characteristics, illustrating that the majority of mothers and infants were European and 48% of mothers were having their first baby. Participating mothers had a mean age of 32 years and were well educated, with 65% having completed a university degree. The majority of EPDS scores were within the range of "normal" for mothers[40] and fathers.[41] Participant flow through the study has been described elsewhere.[35]

Parental sleep at baseline

Mothers reported obtaining approximately 8.4 hours of sleep at baseline and partners 7.6 hours (Table 2). Approximately 65% of mothers reported taking 30 minutes or longer to get

to sleep (long sleep latency) and 58% of partners. Self-ratings of sleep quantity and quality for both mothers and partners were in the mid-range of a 1-8 rating scale where higher scores reflected better satisfaction with sleep quantity and better sleep quality. Categorising the satisfaction ratings by poor versus good sleep quantity or quality (ratings ≤3 versus >3) led to 29% and 21% of mothers reporting poor sleep quantity and quality respectively. For partners poor sleep quantity and quality were reported by 14% and 8% respectively.

Outcome measures

Infant sleep

Analyses of sleep diary data available at 6 months from 507 infants (Table 3) demonstrate there were no significant intervention effects related to parent-reported number of night wakings, 24 hour or overnight sleep duration, longest sleep duration, sleep efficiency, or the number of daytime naps. Actigraphy data provided from 498 infants recorded significantly fewer episodes of night waking and longer daytime sleep for infants in the groups receiving sleep interventions (Sleep and Combination groups) compared to the groups who did not receive the sleep intervention (Control and FAB groups). However the number of night wakings was reduced by 8% and the sleep duration increase was only approximately 6 minutes. No other significant intervention effects were found for the actigraphy variables. Exclusive breastfeeding duration (median 13 to 17 weeks) did not differ across the groups ($p \geq 0.323$) and thus was not considered to be a covariate that might influence night waking.

Problematic sleep

There were no intervention effects on parental reports that their infant's sleep was problematic (Table 4). In total, 16.1% (4 months) and 19.9% (6 months) of mothers reported that their infant's sleep was a problem (rated as 5-8 on an 8-point scale). In partners (mostly fathers), the prevalence was 11.7% (4 months) and 16.6% (6 months). Interestingly, there was

a lack of agreement between mothers and partners about whether or not their baby's sleep was a moderate to large problem (kappa 0.25 and 0.29 respectively). At 4 months there was no evidence of a difference between mothers and partners, but at 6 months mothers were significantly more likely (p = 0.050) to be the one reporting problems amongst the 94 discordant pairs (57 versus 37).

Settling practices

Practices relevant to sleep education on settling babies were not influenced by the interventions (Table 4) although there was a non-statistically significant tendency for groups who had received the sleep education (Sleep and Combination groups) to more frequently put their baby to sleep awake (P = 0.052). Overall more than half of the mothers reported high scores (6-7 on a scale of 1-7) for the frequency of putting their baby to sleep awake (54.2% and 60.3% at 4 and 6 months respectively), letting their baby fall asleep without them being present (51.6% and 56.8% at 4 months and 6 months respectively), and the majority reported being frequently able to recognise when their baby was tired (77.9% at 4 months and 83.2% at 6 months). A small intervention effect was found for the time it took babies to go to sleep (sleep latency; p=0.038) with significant differences in the prevalence of those reporting their infant to usually take ≥ 30 minutes (i.e. a long sleep latency) to fall asleep at 6 months (p=0.015). This was attributed to fewer infants in the Combination group (who received sleep education) having long sleep latencies.

Safe sleep practices

Practices relevant to safe-sleep messages were not influenced by the interventions (Table 4). Regular bedsharing was only practiced by a minority; overall 6.4% at 6 months. The majority of infants slept on their back, following recommended practices and few families smoked in the car while children were present or smoked in the household, with numbers too low for

analyses. Data from the control arm of the study for these safe sleep variables at infant ages 3 to 23 weeks have been published previously.[34]

Maternal and partner outcomes

At infant age 6 months, there were no differences between intervention groups for maternal or partner sleep quantity, their sleep-rated quality, nor the prevalence of long sleep latency (≥ 30 minutes) (Table 5). Similarly, scores from the maternal EPDS attained when the infant was 4 months of age and adjusted for baseline EPDS score, were the same across groups. Maternal fatigue produced mixed results at different time points with any differences observed being too small to be of clinical importance. In addition, no differences in fatigue scores were apparent between those who received the Sleep intervention (Sleep and Combination) and those who did not (FAB and Control).

DISCUSSION

Within this randomised controlled study, a brief sleep intervention consisting of antenatal education and a 3-week home visit was not effective in preventing infant sleep problems, when compared to standard care. A key education target was to encourage infants to self-settle to sleep.[42] There was a tendency towards those groups that received the sleep intervention being more likely to put their baby down to sleep awake but the differences were not statistically significant (P=0.052). We found some evidence that the sleep intervention influenced actigraphy-derived infant sleep patterns by significantly reducing the number of night wakings, and lengthening daytime sleep, but the small size of the differences encountered means they are unlikely to be clinically significant. Parental sleep, fatigue and parental symptoms of depression were not affected by the interventions.

Twenty percent of mothers reported that their 6 month-old infant's sleep was problematic for them, which is similar to other studies reporting a prevalence of 16 to 38% within the first year of life.[1-3] Parent-rated problematic sleep is a strong predictor of frequent and prolonged night wakings and difficulty settling to sleep.[43,44] Here we also collected data on partners (mostly fathers), and almost as many partners (17%) as mothers (20%) reported their child's sleep was a problem for them at 6 months of age, although there was significant discordance in mother-partner pairs. Few studies report children's problematic sleep from the partners' or fathers' perspective, but there is evidence suggesting a link between sleep problems in four- to five-year-old children and poorer paternal general health.[10]

There was limited room for improvement for some behaviours. For example, at 6 months, more than two-thirds of the parents who were in a group that did not receive the sleep intervention frequently practiced behaviours considered to be key intervention targets such as putting their baby to sleep awake or letting their baby fall asleep without a parent being present. Approximately 80% of mothers reported that they could frequently recognise when their infant was tired suggesting this may be an ineffective target to achieve change in this study population. However, we could not objectively measure the extent to which parents recognised the signs of tiredness, nor their ability to recognise the signs early enough to intervene effectively.

Although there are few studies to compare our data with directly, some target behaviours were more commonly practiced than those reported in a similar Australian RCT[2] with follow-up also at 6 months of age. In that study, 11% of parents in the control group consistently allowed their baby to fall asleep without being present (a top ranking of 5 on a 1-5 point scale of frequency). In our study 26% of parents in the control group rated this behaviour with a top ranking of 7 on a 1-7 point scale of frequency. Similarly, in the

Australian study,[2] 23% stated they could always recognise tired signs in their infant (top ranking 5) compared to our 44% (top ranking 7). These data perhaps reflect that mothers in our study were well educated with 65% having a University degree and with free access to a strong Well Child support service offered at multiple time points across the first six months of life.[32] More closely aligned was the prevalence of settling baby to sleep while awake: 33% of control children in the Australian study[2] compared to 27% in our study gave this the top ranking.

Four large RCTs have employed similar preventive strategies with a similar number of contact points,[2,27-29] (albeit intervening immediately after birth or up to 3 months of age). The outcomes of these studies, and the current one, lead us to suggest that preventive strategies may only confer benefit when delivered beyond the antenatal or immediate newborn period i.e. once parents have had time to understand their infants' sleep behaviours and patterns. One RCT intervening immediately after birth in primiparous women found no differences in infant sleep or maternal outcomes at follow-up (6 and 12 weeks post-partum),[28] whereas three RCTs intervening at 2-3 weeks,[29] 4 weeks[2] and 3 months post-partum,[27] resulted in longer infant sleep,[2] fewer symptoms of maternal depression,[2] less infant crying,[2,29] and fewer infants with sleep problems,[2] settling difficulties and night wakings[27] at follow-up. Similar positive outcomes have been found in other study designs (non-RCTs) employing preventive strategies and when the interventions were delivered at a later time point (4 months of age).[45,46] Other small trials with several more follow-up contacts have focussed on preventive strategies in target groups e.g. primiparous women[47,48] or mothers of breast-fed infants,[48] reporting some successes with infants "sleeping through the night" earlier[48] and reduced parental wakings and enhanced stability of early but not later sleep patterns.[47] As suggested by others, increasing the "dose" of intervention may be important as may be targeting high risk infants in more

need of sleep interventions.[28]

The additional antenatal and postnatal education around safe sleep practices provided by the POI study made no difference to practice, but again the ceiling for improvement was limited. Some have suggested that safe sleep education should be started during pregnancy and should be consistently reinforced throughout the first year.[49,50] Our study data indicated that safe sleep messages are reaching our community and further reinforcement of messages beyond standard Well Child care would confer no additional benefit, but we acknowledge that this may be important in other communities or cultures where unsafe sleep practices are more common.

Secondary outcomes related to parental depression symptoms, although not significant, were important to consider given that sleep disturbance is considered a risk factor for post-natal depression[51] and a previous preventive strategy has been effective in reducing maternal depression symptoms.[2] Maternal and partner subjective sleep quantity and quality, as well as symptoms of depression, were not influenced by the intervention. For mothers who have already been exposed to sleep disturbance during pregnancy, particularly within the last trimester,[52] the naturally shorter sleep-wake patterns of infants can further contribute to their own sleep loss with estimates of up to 1.5 hours of sleep lost over 24 hours in the early postnatal period.[53] In the current study, self-reported usual overnight sleep duration was reduced approximately 1 hour on average from the third trimester to 4 months post-partum, and in partners by approximately 36 minutes over the same time period. However we did not collect data on daytime napping and therefore cannot ascertain if any nighttime sleep loss was counterbalanced by daytime gain.

The study had some important limitations. First, the results are limited to young infants in a

well-educated community thereby reducing the generalisability of the findings. Second, the sleep education was targeting some practices that were expectantly already common practice leaving relatively little room for improvement. However, the prevalence of sleep problems in our participants was just as high as elsewhere, suggesting there is still much benefit to be gained from Well Child or other services delivering sleep education. A different focus might be necessary for measureable gains, for example targeting more socially disadvantaged groups and focussing on parental sleep, where small gains have been observed.[54] Furthermore, subjective reports of parental sleep practices related to our education targets, such as infant self-settling, may not be accurate enough and more objective tools for measuring this are required. Study strengths include the randomised and controlled nature of the trial, high recruitment rates and retention, the longitudinal nature of the study, novel collection of data around parents' own sleep and inclusion of the partner/father.

In conclusion, the sleep intervention administered as a prevention strategy and conducted as part of a randomised controlled trial in the POI study was not effective in preventing sleep problems in infants. The antenatal period may be too early to intervene successfully with sleep where the priority focus for families is on the impending birth. Finally, although our study, like so many others, focused on trying to achieve behaviour change through education, we acknowledge that alternative paradigms to preventing or treating sleep problems in infants have been suggested. In these alternative paradigms, infant night-waking in the first 6 months is considered to be normal, and a range of strategies are used to help parents become more synchronized with their babies' sleep-wake needs, and make decisions about what is right for them in their own unique situation with their own unique baby.[55]

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Contributions. BJT, BG and RS led the Sleep intervention, and RWT and ALH led the FAB intervention. SLC contributed to writing the manuscript. ARG designed and completed all statistical analyses and wrote the relevant sections of the manuscript. JL coordinated and led the management of the study. AN was involved in data collection. All authors had intellectual input into the manuscript, commented on drafts, and approved the final version.

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Competing Interests: None to declare

Data sharing: No additional data available.

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Table 1 Infant, maternal and partner characteristics

		n	Control (n=209)	FAB (n=205)	Sleep (n=192)	Combination (n=196)
Infant						
	Gestation (wks)	802	40.0 (1.3)	40.0 (1.3)	40.0 (1.2)	40.0 (1.2)
	Birthweight (g)	795	3522 (484)	3561 (482)	3595 (461)	3529 (493)
	Male, n (%)	802	98 (46.9)	107 (52.2)	110 (57.3)	96 (49.0)
	Parity, median (IQR)	802	2 (1)	2 (1)	2 (1)	2 (1)
	Ethnicity, n (%)	801				
	European		162 (77.5)	160 (78.4)	147 (76.6)	156 (79.6)
	Māori		24 (11.5)	19 (9.3)	14 (7.3)	18 (9.2)
	Pacific		1 (0.5)	5 (2.5)	9 (4.7)	5 (2.6)
	Asian		10 (4.8)	12 (5.9)	15 (7.8)	11 (5.6)
	MELAA[1]		4 (1.9)	2 (1.0)	2 (1.0)	3 (1.5)
	Other		8 (3.8)	6 (2.9)	5 (2.6)	3 (1.5)
Maternal						
	Age	801	31.5 (5.0)	32.1 (5.3)	31.6 (5.2)	31.0 (5.4)
	Ethnicity, n (%)	801				
	European		177 (84.7)	176 (86.3)	161 (83.8)	168 (85.7)
	Māori		15 (7.2)	9 (4.4)	8 (4.2)	14 (7.1)
	Pacific		2 (1.0)	3 (1.5)	4 (2.1)	4 (2.0)
	Asian		9 (4.3)	9 (4.4)	14 (7.3)	7 (3.6)

MELAA[1]		2 (1.0)	2 (1.0)	2 (1.0)	2 (1.0)
Other		4 (1.9)	5 (2.5)	3 (1.6)	1 (0.5)
EPDS, median (IQR)	796	7.0 (5.5)	7.0 (7.0)	7.0 (6.0)	6.0 (6.0)
Education[2]	793				
Year 11 or below		14 (6.8)	17 (8.4)	18 (9.4)	13 (6.7)
Year 12 or 13		41 (19.9)	23 (11.3)	30 (15.6)	37 (19.2)
Post-secondary		29 (14.1)	27 (13.3)	29 (15.1)	31 (16.1)
University degree or higher		122 (59.2)	136 (67.0)	115 (59.9)	112 (58.0)
Partner					
Age	576	34.5 (6.1)	34.3 (6.2)	34.7 (6.1)	34.2 (5.8)
EPDS[3], median (IQR)	575	4.0 (4.0)	4.0 (6.0)	4.0 (5.0)	4.0 (5.0)
Household					
Deprivation, n (%)	794				
1-3 (Low)		74 (35.9)	70 (34.5)	65 (33.9)	67 (34.7)
4-7 (Medium)		93 (45.2)	86 (42.4)	84 (43.8)	87 (45.1)
8-10 (High)		39 (18.9)	47 (23.2)	43 (22.4)	39 (20.2)
Income (NZD)[4], n (%)	728				
<$30,000		20 (10.4)	9 (4.8)	11 (6.4)	18 (10.3)
$30,000+ to $70,000		80 (41.7)	59 (31.4)	61 (35.3)	64 (36.6)
>$70,000		92 (47.9)	120 (63.8)	101 (58.4)	93 (53.1)

Data presented as mean (SD) unless stated otherwise

[1]MELAA refers to Middle Eastern, Latin American or African

[2]Secondary schooling in New Zealand is from year 9 to13 inclusive, post-secondary qualifications refer to all those that are non-University based.

[3]EPDS, Edinburgh Postnatal Depression Scale (0-30), higher score is worse

[4] NZD, New Zealand dollars. $70,000 represents average annual household income in the region at the time of study

Table 2 Parental sleep at baseline (third trimester)

	n	Control (n=209)	FAB (n=205)	Sleep (n=192)	Combination (n=196)
Mother					
Sleep Duration (hr)	797	8.3 (1.1)	8.4 (1.2)	8.4 (1.0)	8.3 (1.4)
Sleep latency ≥ 30 min, n (%)	797	134 (64)	130 (64)	126 (66)	133 (68)
Sleep Quantity Score[1]	802	4.4 (1.3)	4.3 (1.4)	4.2 (1.3)	4.4 (1.4)
Poor score, n (%)		54 (26)	63 (31)	61 (31)	53 (27)
Sleep Quality Score[2]	802	4.7 (1.3)	4.5 (1.3)	4.5 (1.3)	4.6 (1.4)
Poor score, n (%)		35 (17)	45 (22)	40 (21)	42 (22)
Partner					
Sleep Duration (hr)	590	7.6 (0.9)	7.6 (0.9)	7.6 (0.9)	7.7 (1.0)
Sleep latency ≥ 30 min, n (%)	548	88 (58)	89 (61)	82 (61)	69 (52)
Sleep Quantity Score[1]	577	4.0 (1.2)	3.8 (1.3)	3.9 (1.2)	4.0 (1.3)
Poor score, n (%)		18 (13)	24 (15)	15 (11)	20 (15)
Sleep Quality Score[2]	578	4.5 (1.1)	4.5 (1.3)	4.4 (1.3)	4.4 (1.4)
Poor score, n (%)		6 (4)	12 (8)	12 (9)	13 (9)

Data presented as mean (SD) unless stated otherwise

[1]From a possible score of 1 (not nearly enough) to 8 (more than enough) thus higher score is better. Poor score <= 3

[2]From a possible score of 1 (very bad) to 8 (very good) thus higher score is better at baseline

Poor score <= 3

Table 3 Infant sleep diary and actigraphy data at 6 months of age

					P value for Intervention	
	Control	**FAB**	**Sleep**	**Combination**	**Δ 4 groups**	**Δ 2 groups***
Diary[1]						
24-h sleep duration (min)	840 (96)	828 (96)	828 (90)	822 (96)	0.631	0.383
Overnight sleep duration (min)	654 (84)	648 (78)	642 (78)	636 (78)	0.248	0.086
N° night wakings**	1.5 (1.5)	2.0 (1.5)	1.5 (1.5)	2.0 (2.0)	0.397	0.729
Overnight sleep efficiency (%)	92.1 (13.6)	91.1 (12.0)	90.0 (14.3)	90.4 (12.2)	0.514	0.317
N° daytime naps	2.6 (1.3)	2.6 (1.4)	2.7 (1.4)	2.8 (1.3)	0.379	0.096
Longest sleep period overnight (min)	444 (168)	426 (186)	426 (174)	414 (168)	0.536	0.457
Actigraphy[2]						
Sleep onset (h:min)	20:12 (78)	20:12 (72)	20:24 (78)	20.24 (78)	0.415	0.102
Sleep offset (h:min)	6:54 (60)	6:54 (60)	6:54 (60)	7:00 (60)	0.293	0.319
24-h sleep duration (min)	616.4 (94.6)	618.5 (90.7)	615.1 (94.4)	621.7 (93.0)	0.554	0.635
Overnight sleep duration (min)	538.9 (105.5)	532.3 (88.2)	528.6 (99.7)	544.1 (95.1)	0.157	—
N° night wakings**	2.6 (1.6)	2.6 (1.5)	2.4 (1.4)	2.4 (1.5)	0.100	**0.018**
Total night wake (min)	107.7 (87.4)	106.2 (68.6)	104.7 (88.2)	91.4 (68.3)	0.051	0.092
Overnight sleep efficiency (%)	83.5 (12.3)	83.5 (10.4)	83.8 (12.3)	85.7 (10.6)	0.063	0.120
N° daytime naps	1.7 (0.9)	1.7 (0.8)	1.7 (0.9)	1.8 (0.8)	0.871	0.544
Nap duration (min)	91.5 (55.4)	92.3 (53.8)	98.9 (57.4)	97.0 (55.5)	0.147	**0.025**

Data presented as mean (SD) unless stated otherwise

*"Sleep" (Control and FAB combined) vs "No Sleep" (Sleep and Combination combined)

** A primary outcome

[1]Analyses use mean of two days from 507 participants with available data

[2]Analyses use mean of 3-7 days from 498 participants with available data

— No analyses due to interaction between Sleep and FAB groups

Table 4 Parent-rated sleep problems and sleep education-related outcomes from questionnaire at 4 and 6 months

Outcome	Infant age (months)	n	Control	FAB	Sleep	Combination	P value for Intervention Δ 4 groups	P value for Intervention Δ 2 groups*
Infant sleep problem score**[1,3]								
Mother-rated	4	718	2.0 (1.9)	2.3 (1.9)	2.2 (1.9)	2.0 (2.0)		
	6	701	2.2 (2.0)	2.6 (1.9)	2.4 (2.0)	2.3 (1.9)	0.176	0.961
Partner-rated	4	469	1.9 (1.8)	2.3 (1.8)	2.3 (1.8)	2.2 (1.8)		
	6	428	2.3 (1.8)	2.5 (1.9)	2.4 (1.8)	2.3 (1.7)	0.117	0.410
Infant unsettled, n (%)	4	711	11 (5.7)	16 (9.0)	11 (6.4)	11 (6.5)		
	6	700	15 (8.0)	15 (8.3)	11 (6.6)	7 (4.2)	0.557	0.375
Sleep latency ≥ 30 min, n (%)	4	715	10 (5.2%)	10 (5.6%)	16 (9.3%)	14 (8.2%)		
	6	701	18 (9.6%)	15 (8.3%)	22 (13.2%)	5 (3.0%)	**0.038**	0.160
Recognise tired signs score[2]	4	717	6.1 (0.9)	6.0 (0.9)	6.1 (0.9)	6.1 (0.9)		
	6	700	6.2 (0.8)	6.1 (0.8)	6.1 (0.9)	6.3 (0.8)	0.166	0.805
Infant put to bed awake score[2]	4	717	5.1 (1.8)	5.1 (1.8)	5.4 (1.7)	5.4 (1.8)		
	6	700	5.5 (1.8)	5.2 (1.8)	5.5 (1.8)	5.6 (1.6)	0.129	0.052
No parental contact score[2]	4	717	5.0 (1.8)	5.0 (1.7)	5.3 (1.9)	5.0 (2.0)		
	6	700	5.3 (1.8)	5.1 (1.9)	5.3 (1.9)	5.1 (2.0)	0.444	0.389
Bedsharing, n (%)	4	720	11 (5.6%)	12 (6.6%)	12 (7.0%)	17 (9.9%)		
	6	685	11 (6.0%)	12 (6.9%)	7 (4.1%)	13 (8.2%)	—	—

Smoking allowed in home, n (%)	4	717	4 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
	6	687	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—	—
Smoking allowed in car when children present, n (%)	4	702	2 (1.1%)	3 (1.7%)	2 (1.2%)	0 (0.0%)		
	6	686	1 (0.6%)	1 (0.6%)	3 (1.8%)	3 (1.8%)	—	—
Sleeping on back, n (%)	4	718	176 (90.3%)	164 (91.1%)	152 (88.9%)	150 (87.2%)	0.631	0.254
Sheepskin use, n (%)	4	720	27 (13.9%)	17 (9.4%)	26 (15.1%)	27 (15.7%)	0.374	0.240

Data presented as mean (SD) unless stated otherwise

*"Sleep" (Control and FAB combined) vs "No Sleep" (Sleep and Combination combined)

**A primary outcome

[1]From a possible score of 1 (no problem) to 8 (large problem) thus higher score is better

[2]From a possible score of 1 (never) to 7 (always) thus higher score is better

[3]mean is geometric mean

— Model not investigated due to small number of events not allowing estimating intervention effects with stratification variables included

Table 5 Maternal and partner variables at 4 and 6 months

Outcome	Infant age (months)	n	Control	FAB	Sleep	Combination	P value for Intervention Δ 4 groups	P value for Intervention Δ 2 groups*
Maternal								
Sleep quantity score[1]	4	719	4.7 (1.5)	4.6 (1.6)	4.6 (1.4)	4.7 (1.4)		
	6	700	4.6 (1.4)	4.4 (1.5)	4.5 (1.4)	4.7 (1.5)	0.622	0.395
Sleep quality score[2]	4	719	5.6 (1.3)	5.2 (1.4)	5.3 (1.4)	5.3 (1.4)		
	6	700	5.4 (1.5)	5.1 (1.3)	5.1 (1.3)	5.4 (1.5)	0.192	0.831
Fatigue score[3]	4	719	3.4 (0.8)	3.2 (0.9)	3.3 (0.9)	3.4 (0.8)		
	6	696	3.3 (0.8)	3.1 (0.9)	3.2 (0.8)	3.3 (0.8)	0.509	0.925
Sleep Duration (hr)	4	716	7.3 (1.3)	7.4 (1.4)	7.3 (1.2)	7.3 (1.1)		
	6	697	7.2 (1.2)	7.1 (1.3)	7.2 (1.2)	7.2 (1.2)	0.909	0.832
Sleep latency ≥ 30 min, n (%)	4	717	95 (49.0)	81 (45.0)	91 (52.9)	89 (52.1)		
	6	700	101 (54.0)	93 (51.4)	90 (53.9)	93 (56.4)	0.792	0.126
EPDS score[4], median (IQR)	4	718	5.0 (5.0)	5.0 (5.0)	5.0 (6.0)	4.0 (6.0)	0.544	0.392
Partner								
Sleep quantity score[1]	4	469	5.5 (1.1)	5.3 (1.3)	5.3 (1.3)	5.4 (1.2)		
	6	426	5.4 (1.1)	5.3 (1.2)	5.3 (1.4)	5.4 (1.2)	0.787	0.524
Sleep quality score[2]	4	470	4.8 (1.3)	4.7 (1.3)	4.6 (1.4)	4.9 (1.2)		
	6	427	4.7 (1.3)	4.5 (1.3)	4.6 (1.3)	4.9 (1.1)	0.275	0.801
Fatigue score[3]	4	471	3.3 (0.8)	3.2 (0.7)	3.3 (0.7)	3.4 (0.7)		

	6	427	3.2 (0.7)	3.2 (0.7)	3.3 (0.8)	3.3 (0.8)	0.917	0.469
Sleep Duration (hr)	4	458	6.9 (1.3)	6.9 (1.0)	7.1 (0.9)	7.2 (0.9)		
	6	422	6.9 (1.3)	7.0 (1.3)	7.1 (1.2)	7.2 (0.9)	0.399	0.054
Sleep latency ≥ 30 min, n (%)	4	465	62 (51.7)	71 (57.7)	58 (54.7)	64 (55.2)		
	6	426	68 (60.7)	66 (55.9)	56 (58.3)	58 (58.0)	0.902	0.763
EPDS score[4], median (IQR)	4	468	4.0 (5.0)	4.0 (6.0)	3.0 (4.0)	3.0 (4.0)	0.524	0.148

Data presented as mean (SD) unless stated otherwise

*"Sleep" (Control and FAB combined) vs "No Sleep" (Sleep and Combination combined)

[1]From a possible score of 1 (not nearly enough) to 8 (more than enough) thus higher score is better

[2]From a possible score of 1 (very bad) to 8 (very good) thus higher score is better

[3]From a possible score of 1 (complete exhaustion) to 5 (well rested) thus higher score is better

[4]EPDS, Edinburgh Postnatal Depression Scale (0-30), higher score is worse

Appendix 1. Topics covered at the antenatal group session for the Sleep and Combination groups

Why sleep?

- Critical to a child's development, health and quality of life
- Good for parents' wellbeing and more

What's normal

- Waking frequently during the night
- Active and quiet sleep cycles
- Sleeping through the night – a milestone to look forward to
- Babies can learn their sleep routines
- Babies need to be given a chance to learn to settle themselves
- Some babies learn easily – others need more help

Healthy sleep patterns

- Try to set some limits on 'handling' of baby
- Establish some regular pattern
- Notice and act on baby's tired signs early
- Darken sleeping place day and night ('cue' for sleep time)
- Try to put baby into their bed awake
- Give baby a brief chance to settle by themselves/learn to go to sleep on their own
- Keep night time quiet time – no 'play'

Safe sleeping

- Own sleep place in your room
- On back
- Clean firm tightly fitting mattress
- Keep cot clear of "extras"
- Co-sleeping is unsafe
    - If mother smoked in pregnancy
    - Adults (either) have been drinking, taking drugs, sedatives
    - Baby is less than 3 months old (for smoking and non-smoking mothers)

Looking after yourselves

- Your rest and sleep is important too
- Try to get a rest/sleep during the day
- Meals in freezer
- Limit visitors and looking after them
- Accept offers of help
- Go to bed early…soon after baby

Appendix 2: Topics covered at the one-to-one 3 week visit and included in booklet for Sleep and Combination groups

Introduction

- Benefits of sleep
- Information applies to healthy, alert babies who are feeding and growing well
- What we know about a baby's sleep:
  - Babies learn their sleep routines
  - Parents can teach their babies to be good sleepers
  - Babies need to be given a chance to settle by themselves
  - Some babies learn to sleep easily. Other babies need more help from their parents.

Normal sleep: What happens in the first year?

- How long should my baby sleep for?
  - Feeding-sleeping-waking patterns divided into four sections: 1st month, 2nd and 3rdmonth, 4th month, 6th month
- What happens when baby is sleeping?
  - Baby's active and quiet sleep cycles and associated behaviours
  - Arousals between sleep cycles – brief or full waking

General sleep and safety

- Basic safety tips for baby's sleeping place
  - Always place your baby on their back to sleep
  - Mattresses must be clean, firm and fit tightly into the frame of the cot
  - Do not use hot water bottles, electric blankets, pillows, big duvets or lots of stuffed toys (there are risks of smothering and overheating)

- Where is baby going to sleep?
  - Own cot/bassinet in parent(s) room is safest for first 3 months or longer
  - Co-sleeping (sleeping with baby in the same bed)
    - Risks of co-sleeping for Sudden Unexplained Death in Infancy (SUDI) within the NZ context outlined
    - Parental choice: If parent(s) chose to share their bed with their baby, **make sure:**
      - Bed is in the middle of the room (not against a wall)
      - Mattress fits tight in the bed frame
      - **DO NOT co-sleep** if you or your partner:
        - Smoke
        - Drink alcohol
        - Use non-prescription drugs
        - Take any sedating drugs
        - Are excessively tired
        - Are a large person or overweight
        - or have a Duvet, other loose bedding or water bed

Babys' tired signs

- Important to learn baby's tired signs

Signs of tiredness outlined
Act of tired signs to prevent overtiredness
Diagram showing cycle of feeding and sleeping well (content baby)
Diagram showing cycle of snack feeds and car naps (baby less content)

Crying: what babies do

Normal crying patterns during a baby's development
Normal crying patterns over the day
Why some babies cry a lot

Helping baby learn to develop a healthy sleep pattern

Establish a regular routine
- Times may vary; predictable patterns within each feed/awake/sleep cycle
- Setting own 'sleep clock"
- Day/night differences
- Calm, Quiet and soothing behaviours at settling time

Notice tired signs early
Put baby into cot/bassinet awake and give baby the opportunity to learn to fall asleep in their own
Avoid:
- rocking, holding or feeding baby to sleep
- bright lights, frantic and busy rocking and loud noises
- too much "busy-ness" (lots of activity) whilst baby is falling asleep

Settling a baby for sleep

Flow diagram of steps to follow

What if baby won't settle?

Steps to follow outlined:
- Remember to try and **stay calm,** and keep everything you do as **quiet** and as **soothing** as you can in **dim lighting**
- Don't take baby out of their cot immediately.
- Try and let baby settle on their own. Allow around 2-3 minutes in the first month, and 5 minutes at 3 months
- If baby keeps grizzling then wait for a further 2 minutes (use a timer … during this time go and make a cup of tea, or tell yourself the time you are going to wait and do a 2 minute activity e.g. TradeMe, YouTube, another row of knitting, put away the dishes, anything but being by the doorway waiting…) before going back to check your baby
- If necessary, talk quietly, and stroke, rub or pat your baby gently and see if this helps them quieten and settle
- If they begin to calm and settle then leave the room
- If baby starts to cry and 'wind up', baby may need another quiet feed or a cuddle and then try settling again (as before)
- If you know your baby is well fed, talk quietly as before and stroke, rub or pat your baby gently and see if this helps them quieten and settle. If they begin to calm and settle then leave the room

The very difficult to soothe baby

All babies are born with different temperaments
Good news is these babies can also learn to have healthy sleep patterns
Learning about how your own baby soothes him/herself
Remember a baby can sense how you feel; remain as calm as possible
You may need some time out to remain calm (ask you partner, a friend of relative for help)

Checking baby

Do this as quietly as you can, and where baby can't see you
Try not to pick baby up when asleep (identifying REM sleep)

Night feeding

Keep the lighting dim
If you need to talk, then talk softly and quietly with your baby
Try not to drag out the feeding, winding and changing cycle
At every chance try to place baby into the cot awake or drowsy
Because baby is still learning it is important to be consistent in what you do.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10-11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11, Table 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	11, suppl diag
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	26-27
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	30-35
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	30-35
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	30-35
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	30-35
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	none identifie
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-19
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Anticipatory guidance to prevent infant sleep problems within a randomised controlled trial: infant, maternal and partner outcomes at 6 months of age.

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Anticipatory guidance to prevent infant sleep problems within a randomised controlled trial: infant, maternal and partner outcomes at 6 months of age.

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ABSTRACT

Objective: To evaluate the effectiveness of sleep education delivered antenatally and at 3 weeks post-partum to prevent infant sleep problems at 6 months of age.

Design: Sleep intervention within a randomised controlled trial for the Prevention of Overweight in Infancy (POI study).

Participants: 802 families were randomly allocated to one of four groups: usual care (Control); sleep intervention (Sleep); food, activity and breastfeeding intervention (FAB); combined group receiving both interventions (Combination).

Interventions: All groups received standard Well Child care. The sleep intervention groups (Sleep and Combination) received an antenatal group education session (all mothers and most partners) emphasising infant self-settling and safe sleeping, and a home visit at three weeks reinforcing the antenatal sleep education. FAB and Combination groups received four contacts providing education and support on breastfeeding, food and activity up to four months postpartum.

Outcome measures: Here we report secondary sleep outcomes from the POI study: the prevalence of parent-reported infant sleep problems and night waking, and differences in sleep duration. Additional outcomes reported include differences in infant self-settling, safe sleep practices, and maternal and partner reports of their own sleep, fatigue and depression symptoms.

Results: Linear or mixed linear regression models found no significant intervention effects on sleep outcomes with 19.1% of mothers and 16.6% of partners reporting their infant's sleep a problem at 6 months. Actigraphy estimated the number of night wakings to be significantly reduced (8%) and the duration of daytime sleep increased (6 minutes) in those groups receiving the sleep intervention compared to those who

did not. However, these small differences were not clinically significant, and not observed in 24-hour infant sleep diary data. No other differences were observed.

Conclusion: A strategy delivering infant sleep education antenatally and at three weeks postpartum was not effective in preventing the development of parent-reported infant sleep problems.

Key Words: actigraphy, night wakings, safe sleep, settling techniques, sleep duration

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The first RCT examining the efficacy of a sleep education programme to prevent infant sleep problems commencing antenatally.
- Data were collected from both mother and partner about whether their child's sleep was a problem.
- Sleep data from infants were reported both subjectively (sleep diaries) and objectively (actigraphy).
- Partners as well as mothers rated their own sleep quality across several time points.
- Key education outcomes related to infant sleep practices, such as infant self settling, were collected via parent report and may not be accurate enough to identify any intervention effects.
- The results are limited to young infants in a well-educated community which may reduce the generalisability of the findings.

INTRODUCTION

Unsettled sleep-wake behaviour peaks in the first six months of life with between 16 and 38% of parents reporting sleep problems to clinicians within the first year.[1-3] Parents' commonest concerns relate to their baby's crying,[4] amount of sleep, appropriate strategies to settle their infant to sleep,[5 ,6] difficulties settling to sleep and frequent night waking.[7] Infant sleep problems are expensive to treat[8] and are associated with several adverse consequences for mothers including postnatal depression,[8] fatigue,[9] as well as poorer general and mental health among those without a history of depression.[10] Although fathers have rarely been studied, they also report poorer general health and greater psychological distress linked to infant sleep problems.[10]

Infant sleep problems likely emerge from interactions between infant and parental health and behaviour, and the environment.[11] One third of infants who are unable to achieve a consolidated sleep of six hours by five months of age still cannot achieve this by 2½ years of age[12] and a short sleep duration pattern sustained across infancy and early childhood is associated with five times greater odds of children exhibiting hyperactive behaviour at five years of age.[7] Evidence also suggests that sleep problems first presenting in infancy are likely to persist into childhood[13-15] with potential for poorer cognitive development,[16-18] behaviour,[16 ,19] and quality of life,[20] and a greater risk of overweight or obesity.[21-24] These adverse outcomes highlight the need for early intervention to optimise sleep development.

Overall, interventions designed to treat sleep problems once they have become established have demonstrated a small to medium effect on increasing infant nocturnal total sleep time,[25] either no or small effects on reducing night wakings,[25][26] and small impacts on improving maternal mood,[25] depression, fatigue, sleep quality and maternal cognitions

about their infant's sleep.[26] Whether prevention of sleep problems might be more effective, and potentially less costly, than attempts to treat established issues is largely unknown. Randomised controlled trials emphasising the early establishment of positive sleep practices have produced mixed findings to date.[2 ,27-29] These interventions were delivered postnatally,[2 ,28 ,29] or at 3 months post-partum[27] and on a one-to-one basis. None were delivered antenatally or within group sessions where families may be less stressed and more receptive to the sleep education messages. Given that a large number of infants suffer sleep problems and that the flow-on effects of these problems carry significant long-term costs to individuals, it is pertinent to investigate the effectiveness of simple prevention strategies that could be implemented as a public health measure through antenatal education and Well Child services.

We recently undertook a four-armed randomised controlled trial (RCT), the Prevention of Overweight in Infancy (POI) study,[30] to determine whether additional support and education on food, activity, breastfeeding, and sleep from late pregnancy could reduce overweight and obesity in children at two years of age. In exploratory analyses, the trial found a protective effect for obesity among groups receiving the sleep intervention.[31] The exact mechanisms by which sleep could influence obesity in early life are unclear, although the ability of an infant to learn to self-regulate his/her own sleep is considered one of the earliest biological markers of self-regulatory behaviours.[32] This enhanced sleep self-regulation could conceivably help shape other self-regulatory behaviours linked to healthy weight. Other potential mechanisms linked to insufficient sleep in children and adults include changes in neurohormonal control of appetite regulation, impacts on dietary intake, and increased sedentary activity –all favouring weight gain.[33]

The aim of this paper was to determine whether the infant sleep education programme

delivered antenatally and 3 weeks postpartum reduced the prevalence of parent-reported sleep problems and night wakings, and influenced sleep duration in infants up to six months of age (secondary outcomes of the RCT; ClinicalTrials.gov: NCT00892983). Other aims were to determine any differences in infant self-settling and safe sleep practices, and maternal and paternal reports of their own sleep, fatigue and depression symptoms (additional outcomes).

METHODS

Study Design

The Prevention of Overweight in Infancy (POI) study (Clinical Trials NCT00892983) was a four-armed randomised controlled trial commencing in late pregnancy. Data from baseline (third trimester) to 6 months of age are reported here.

Participants and recruitment

All mothers booked into the single maternity hospital (> 97% of all births) serving the city of Dunedin, between May 2009 and November 2010 were potentially eligible. Letters of invitation were sent to mothers at 28–30 weeks gestation and an "opt out" recruitment strategy was used. Exclusion criteria applied before birth were: home address outside the greater Dunedin area, planning to move away in the next two years, not booked with the maternity centre or homebirth midwife before 34 weeks gestation, or unable to communicate in English or Te Reo Māori (language of the indigenous people of New Zealand). Exclusion criteria applied after birth were: identification of a congenital abnormality likely to affect feeding or growth, or the infant being born before 36.5 weeks gestation.

Randomisation

Participants were randomised to one of four groups: i) usual care (Control); ii) food, activity and breastfeeding intervention (FAB); iii) sleep intervention (Sleep), or iv) combined

intervention group receiving both the Sleep and FAB interventions (Combination). Details of allocation concealment and stratification have been described previously,[30] but briefly, stratification was based on household deprivation (tertiles: low [NZDep deciles 1–3],[34] medium [4–7] and high [8–10]) and parity including the study child (1 vs ≥2). Group allocation was revealed to the participants after they consented to participate. The statistician remained blinded to group allocation codes until primary analyses were completed.

Usual Care

Families of all four groups received standard maternity and Well Child care from a maternity care professional, and a Well Child provider of their choice. Well Child care[35] aims to maximise the health and development of all New Zealand children up to age five years (on average 8-9 visits in the first six months of life). The Control group received this usual care only.

Interventions

Sleep

Families receiving the Sleep intervention (Sleep and Combination groups) received antenatal education delivered via a single group session (up to 1 hour), followed by one home visit at three weeks post-partum with a researcher with infant sleep training. Antenatal sessions educated all mothers and most partners about normal developmental patterns of infant sleep and emphasised infant settling to sleep unaided (i.e. self-settling or self-regulation of sleep) which appears to be a key factor in the development of healthy sleep-wake patterns and a precursor to longer sleep duration in later infancy;[36] and safe-sleep practices as measures to prevent sudden unexpected death in infancy[37] (summarised in Appendix 1). Partners were mostly fathers. Parents left equipped with a "tip sheet" related to the key education messages. The individual sessions at the 3-week home visit reinforced the antenatal sleep education and

were conducted with the aid of a more detailed 15 page booklet covering the key messages for developing healthy sleep and safe sleep practices (summarised in Appendix 2). At this visit, researchers provided advice on any concerns the families had with their infant's sleep, and parents were encouraged to keep using the booklet as a valuable resource, and contact research staff at any stage should they require further sleep advice.

FAB

Mothers in the FAB group received three contacts providing education and support on breastfeeding (antenatal, one week and four months postpartum) and one on physical activity (three months postpartum) before 6 months of age. An International Board Certified Lactation Consultant worked with each family to assist with infant feeding, focussing on prolonging exclusive breastfeeding and delaying the introduction of complementary foods until around six months of age. At three months, each family attended an Active Movement session delivered by an established local sports body. The FAB intervention is described in more detail elsewhere.[38]

Combination

This group received five intervention visits in total before 6 months of age as the FAB and Sleep antenatal session was combined.

Questionnaires

Parents completed questionnaires during home visits at baseline (third trimester, prior to allocation), and at 4 and 6 months. Questionnaires collected data relevant to outcomes of the sleep education including ratings of the baby's problematic sleep and unsettled behaviour, and of infant settling and safe sleep practices. Mothers and partners also rated perceptions of their own sleep quantity and quality, and reported the usual time they went to bed, usual sleep time

(sleep onset) and usual wake time (sleep offset). Their sleep duration was calculated as the difference between sleep onset and sleep offset. Sleep latency (time taken to fall asleep) was calculated from the difference between the time they went to bed and sleep onset. Ratings of maternal and partner fatigue and depression symptoms (Edinburgh Postnatal Depression Scale; EPDS [39]) were also collected. Duration of exclusive breastfeeding (i.e. the infant receiving no liquids, other than breast milk, and no solids since birth), was calculated as age to the nearest part week from the monthly questionnaires.[30]

Sleep Diary

When the infant was 6 months of age, parents were asked to complete a 48-hour diary during the 5-7 day period when actigraphy was also recorded (as described previously[40]). Time was displayed horizontally in five-minute grid blocks. A parent was asked to indicate using an arrow the time the infant went to sleep and awoke, including daytime naps. Grid block counts with sleep and wake coding were then entered into a spreadsheet set up to automatically calculate standard sleep-wake variables.

Actigraphy

Infants wore an Actical accelerometer (Mini-Mitter Co., Inc., Bend, OR) for 5-7 days fitted on the shin. The accelerometers were initialized using 15-second epochs. Sleep onset (evening sleep time) and morning sleep offset (wake time) events were ascertained visually from activity graphs and marked in the sleep scoring program in MATLAB (MathWorks, Natick, MA, USA), from which standard sleep-wake variables, including nap counts and nap duration were determined using the count-scaled algorithm. A sleep period was defined as at least 20 minutes of sleep preceded by 5 minutes of awake with the sleep period altered for nap detection between 9am and 5pm as previously described using a minimum nap time threshold of 20 minutes.[40]

Statistical analysis

As sleep outcomes were secondary outcomes of the POI study, which was powered on detecting differences in growth (the primary outcome) between the arms of the study,[30] no relevant sample size calculations are available. The data were analysed using Stata 14.1 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP). Statistical significance was determined by two-sided $P < 0.05$ in all cases. No adjustments were made for multiple comparisons. Continuous outcome variables were compared between the four groups using linear regression models where the outcome was at a single time point and mixed linear regression with a random participant effect where multiple time points were included. Where model residuals were skewed or demonstrated heteroscedasticity, natural log transformations were investigated, after adding one for variables including zero values. If issues with model residuals were not thereby resolved, quantile regression was used instead to model medians. All models included the stratification variables (three levels of household deprivation and two levels of parity).[41] Binary variables were similarly analysed using logistic regression and mixed logistic regression with a random participant effect. For all outcomes, a second set of models looking at the main effects of the sleep (Sleep and Combination groups vs FAB and Control) and FAB interventions (FAB and Combination groups vs Sleep and Control) were implemented providing there was no evidence of an interaction between the two interventions. The purpose of this two-step process was to maximise the power to detect main effects but, as is well known,[42] this increases Type I error rates above their nominal level and so these results should be interpreted with caution, especially in cases of marginal statistical significance.

RESULTS

Participant characteristics at baseline

Of the 847 (58%) eligible families who agreed to participate, 802 met the post-partum inclusion criteria. Table 1 presents participant characteristics, illustrating that the majority of mothers and infants were European and 48% of mothers were having their first baby. Participating mothers had a mean age of 32 years and were well educated, with 65% having completed a university degree. The majority of EPDS scores were within the range of "normal" for mothers[43] and fathers.[44] Participant flow through the study has been described elsewhere.[38]

Parental sleep at baseline

Mothers reported obtaining approximately 8.4 hours of sleep at baseline and partners 7.6 hours (Table 2). Approximately 65% of mothers reported taking 30 minutes or longer to get to sleep (long sleep latency) and 58% of partners. Self-ratings of sleep quantity and quality for both mothers and partners were in the mid-range of a 1-8 rating scale where higher scores reflected better satisfaction with sleep quantity and better sleep quality. Categorising the satisfaction ratings by poor versus good sleep quantity or quality (ratings ≤3 versus >3) led to 29% and 21% of mothers reporting poor sleep quantity and quality respectively. For partners poor sleep quantity and quality were reported by 14% and 8% respectively.

Outcome measures

Infant sleep

Analyses of sleep diary data available at 6 months from 507 infants (Table 3) demonstrate there were no significant intervention effects related to parent-reported number of night wakings, 24 hour or overnight sleep duration, longest sleep duration, sleep efficiency, or the number of daytime naps. Actigraphy data provided from 498 infants recorded significantly

fewer episodes of night waking and longer daytime sleep for infants in the groups receiving sleep interventions (Sleep and Combination groups) compared to the groups who did not receive the sleep intervention (Control and FAB groups). However the number of night wakings was reduced by 8% and the sleep duration increase was only approximately 6 minutes. No other significant intervention effects were found for the actigraphy variables. Exclusive breastfeeding duration (median 13 to 17 weeks) did not differ across the groups ($p \geq 0.323$) and thus was not considered to be a covariate that might influence night waking.

Problematic sleep

There were no intervention effects on parental reports that their infant's sleep was problematic (Table 4). In total, 16.1% (4 months) and 19.9% (6 months) of mothers reported that their infant's sleep was a problem (rated as 5-8 on an 8-point scale). In partners (mostly fathers), the prevalence was 11.7% (4 months) and 16.6% (6 months). Interestingly, there was a lack of agreement between mothers and partners about whether or not their baby's sleep was a moderate to large problem (kappa 0.25 and 0.29 respectively). At 4 months there was no evidence of a difference between mothers and partners, but at 6 months mothers were significantly more likely ($p=0.050$) to be the one reporting problems amongst the 94 discordant pairs (57 versus 37).

Settling practices

Practices relevant to sleep education on settling babies were not influenced by the interventions (Table 4) although there was a non-statistically significant tendency for groups who had received the sleep education (Sleep and Combination groups) to more frequently put their baby to sleep awake ($p=0.052$). Overall more than half of the mothers reported high scores (6-7 on a scale of 1-7) for the frequency of putting their baby to sleep awake (54.2% and 60.3% at 4 and 6 months respectively), letting their baby fall asleep without them being

present (51.6% and 56.8% at 4 months and 6 months respectively), and the majority reported being frequently able to recognise when their baby was tired (77.9% at 4 months and 83.2% at 6 months). A small intervention effect was found for the time it took babies to go to sleep (sleep latency; p=0.038) with significant differences in the prevalence of those reporting their infant to usually take ≥ 30 minutes (i.e. a long sleep latency) to fall asleep at 6 months (p=0.015). This was attributed to fewer infants in the Combination group (who received sleep education) having long sleep latencies.

Safe sleep practices

Practices relevant to safe-sleep messages were not influenced by the interventions (Table 4). Regular bedsharing was only practiced by a minority; overall 6.4% at 6 months. The majority of infants slept on their back, following recommended practices and few families smoked in the car while children were present or smoked in the household, with numbers too low for analyses. Data from the control arm of the study for these safe sleep variables at infant ages 3 to 23 weeks have been published previously.[37]

Maternal and partner outcomes

At infant age 6 months, there were no differences between intervention groups for maternal or partner sleep quantity, their sleep-rated quality, nor the prevalence of long sleep latency (≥ 30 minutes) (Table 5). Similarly, scores from the maternal EPDS attained when the infant was 4 months of age and adjusted for baseline EPDS score, were the same across groups. Maternal fatigue produced mixed results at different time points with any differences observed being too small to be of clinical importance. In addition, no differences in fatigue scores were apparent between those who received the Sleep intervention (Sleep and Combination) and those who did not (FAB and Control).

DISCUSSION

Within this randomised controlled study, a brief sleep intervention consisting of antenatal education and a 3-week home visit was not effective in preventing infant sleep problems, when compared to standard care. A key education target was to encourage infants to self-settle to sleep.[45] There was a tendency towards those groups that received the sleep intervention being more likely to put their baby down to sleep awake but the differences were not statistically significant (p=0.052). We found some evidence that the sleep intervention influenced actigraphy-derived infant sleep patterns by significantly reducing the number of night wakings, and lengthening daytime sleep, but the small size of the differences encountered means they are unlikely to be clinically significant. Parental sleep, fatigue and parental symptoms of depression were not affected by the interventions.

Twenty percent of mothers reported that their 6 month-old infant's sleep was problematic for them, which is similar to other studies reporting a prevalence of 16 to 38% within the first year of life.[1-3] Parent-rated problematic sleep is a strong predictor of frequent and prolonged night wakings and difficulty settling to sleep.[46 ,47] Here we also collected data on partners (mostly fathers), and almost as many partners (17%) as mothers (20%) reported their child's sleep was a problem for them at 6 months of age, although there was significant discordance in mother-partner pairs. Few studies report children's problematic sleep from the partners' or fathers' perspective, but there is evidence suggesting a link between sleep problems in four- to five-year-old children and poorer paternal general health.[10]

There was limited room for improvement for some behaviours. For example, at 6 months, more than two-thirds of the parents who were in a group that did not receive the sleep intervention frequently practiced behaviours considered to be key intervention targets such as putting their baby to sleep awake or letting their baby fall asleep without a parent being

present. Approximately 80% of mothers reported that they could frequently recognise when their infant was tired suggesting this may be an ineffective target to achieve change in this study population. However, we could not objectively measure the extent to which parents recognised the signs of tiredness, nor their ability to recognise the signs early enough to intervene effectively.

Although there are few studies to compare our data with directly, some target behaviours were more commonly practiced than those reported in a similar Australian RCT[2] with follow-up also at 6 months of age. In that study, 11% of parents in the control group consistently allowed their baby to fall asleep without being present (a top ranking of 5 on a 1-5 point scale of frequency). In our study 26% of parents in the control group rated this behaviour with a top ranking of 7 on a 1-7 point scale of frequency. Similarly, in the Australian study,[2] 23% stated they could always recognise tired signs in their infant (top ranking 5) compared to our 44% (top ranking 7). These data perhaps reflect that mothers in our study were well educated with 65% having a University degree and with free access to a strong Well Child support service offered at multiple time points across the first six months of life.[35] More closely aligned was the prevalence of settling baby to sleep while awake: 33% of control children in the Australian study[2] compared to 27% in our study gave this the top ranking.

Four large RCTs have employed similar preventive strategies with a similar number of contact points,[2,27-29] (albeit intervening immediately after birth or up to 3 months of age). The outcomes of these studies, and the current one, lead us to suggest that preventive strategies may only confer benefit when delivered beyond the antenatal or immediate newborn period i.e. once parents have had time to understand their infants' sleep behaviours and patterns. One RCT intervening immediately after birth in primiparous women found no

differences in infant sleep or maternal outcomes at follow-up (6 and 12 weeks post-partum),[28] whereas three RCTs intervening at 2-3 weeks,[29] 4 weeks[2] and 3 months post-partum,[27] resulted in longer infant sleep,[2] fewer symptoms of maternal depression,[2] less infant crying,[2,29] and fewer infants with sleep problems,[2] settling difficulties and night wakings[27] at follow-up. Similar positive outcomes have been found in other study designs (non-RCTs) employing preventive strategies and when the interventions were delivered at a later time point (4 months of age).[48,49] Other small trials with several more follow-up contacts have focussed on preventive strategies in target groups e.g. primiparous women[50,51] or mothers of breast-fed infants,[51] reporting some successes with infants "sleeping through the night" earlier[51] and reduced parental wakings and enhanced stability of early but not later sleep patterns.[50] As suggested by others, increasing the "dose" of intervention may be important as may be targeting high risk infants in more need of sleep interventions.[28]

The additional antenatal and postnatal education around safe sleep practices provided by the POI study made no difference to practice, but again the ceiling for improvement was limited. Some have suggested that safe sleep education should be started during pregnancy and should be consistently reinforced throughout the first year.[52,53] Our study data indicated that safe sleep messages are reaching our community and further reinforcement of messages beyond standard Well Child care would confer no additional benefit, but we acknowledge that this may be important in other communities or cultures where unsafe sleep practices are more common.

Outcomes related to parental depression symptoms, although not significant, were important to consider given that sleep disturbance is considered a risk factor for post-natal depression[54] and a previous preventive strategy has been effective in reducing maternal

depression symptoms.[2] Maternal and partner subjective sleep quantity and quality, as well as symptoms of depression, were not influenced by the intervention. For mothers who have already been exposed to sleep disturbance during pregnancy, particularly within the last trimester,[55] the naturally shorter sleep-wake patterns of infants can further contribute to their own sleep loss with estimates of up to 1.5 hours of sleep lost over 24 hours in the early postnatal period.[56] In the current study, self-reported usual overnight sleep duration was reduced approximately 1 hour on average from the third trimester to 4 months post-partum, and in partners by approximately 36 minutes over the same time period. However we did not collect data on daytime napping and therefore cannot ascertain if any nighttime sleep loss was counterbalanced by daytime gain.

The study had some important limitations. First, the results are limited to young infants in a well-educated community thereby reducing the generalisability of the findings. Second, the sleep education was targeting some practices that were expected to be common practice leaving relatively little room for improvement. However, the prevalence of sleep problems in our participants was just as high as elsewhere, suggesting there is still much benefit to be gained from Well Child or other services delivering sleep education. A different focus might be necessary for measureable gains, for example targeting more socially disadvantaged groups and focussing on parental sleep, where small gains have been observed.[57] Furthermore, subjective reports of parental sleep practices related to our education targets, such as infant self-settling, may not be accurate enough and more objective tools for measuring this are required. Study strengths include the randomised and controlled nature of the trial, high recruitment rates and retention, the longitudinal nature of the study, novel collection of data around parents' own sleep and inclusion of the partner/father.

In conclusion, the sleep intervention administered as a prevention strategy and conducted as part of a randomised controlled trial in the POI study was not effective in preventing sleep problems in infants. The antenatal period may be too early to intervene successfully with sleep where the priority focus for families is on the impending birth. Finally, although our study, like so many others, focused on trying to achieve behaviour change through education, we acknowledge that alternative paradigms to preventing or treating sleep problems in infants have been suggested. In these alternative paradigms, infant night-waking in the first 6 months is considered to be normal, and a range of strategies are used to help parents become more synchronized with their babies' sleep-wake needs, and make decisions about what is right for them in their own unique situation with their own unique baby.[58]

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Contributions. BJT, BG and RS led the Sleep intervention, and RWT and ALH led the FAB intervention. SLC contributed to writing the manuscript. ARG designed and completed all statistical analyses and wrote the relevant sections of the manuscript. JL coordinated and led the management of the study. AN was involved in data collection. All authors had intellectual input into the manuscript, commented on drafts, and approved the final version.

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Table 1 Infant, maternal and partner characteristics

		n	Control (n=209)	FAB (n=205)	Sleep (n=192)	Combination (n=196)
Infant						
	Gestation (wks)	802	40.0 (1.3)	40.0 (1.3)	40.0 (1.2)	40.0 (1.2)
	Birthweight (g)	795	3522 (484)	3561 (482)	3595 (461)	3529 (493)
	Male, n (%)	802	98 (46.9)	107 (52.2)	110 (57.3)	96 (49.0)
	Parity, median (IQR)	802	2 (1)	2 (1)	2 (1)	2 (1)
	Ethnicity, n (%)	801				
	European		162 (77.5)	160 (78.4)	147 (76.6)	156 (79.6)
	Māori		24 (11.5)	19 (9.3)	14 (7.3)	18 (9.2)
	Pacific		1 (0.5)	5 (2.5)	9 (4.7)	5 (2.6)
	Asian		10 (4.8)	12 (5.9)	15 (7.8)	11 (5.6)
	MELAA[1]		4 (1.9)	2 (1.0)	2 (1.0)	3 (1.5)
	Other		8 (3.8)	6 (2.9)	5 (2.6)	3 (1.5)
Maternal						
	Age	801	31.5 (5.0)	32.1 (5.3)	31.6 (5.2)	31.0 (5.4)
	Ethnicity, n (%)	801				
	European		177 (84.7)	176 (86.3)	161 (83.8)	168 (85.7)
	Māori		15 (7.2)	9 (4.4)	8 (4.2)	14 (7.1)
	Pacific		2 (1.0)	3 (1.5)	4 (2.1)	4 (2.0)

Asian		9 (4.3)	9 (4.4)	14 (7.3)	7 (3.6)
MELAA[1]		2 (1.0)	2 (1.0)	2 (1.0)	2 (1.0)
Other		4 (1.9)	5 (2.5)	3 (1.6)	1 (0.5)
EPDS, median (IQR)	796	7.0 (5.5)	7.0 (7.0)	7.0 (6.0)	6.0 (6.0)
Education[2]	793				
Year 11 or below		14 (6.8)	17 (8.4)	18 (9.4)	13 (6.7)
Year 12 or 13		41 (19.9)	23 (11.3)	30 (15.6)	37 (19.2)
Post-secondary		29 (14.1)	27 (13.3)	29 (15.1)	31 (16.1)
University degree or higher		122 (59.2)	136 (67.0)	115 (59.9)	112 (58.0)
Partner					
Age	576	34.5 (6.1)	34.3 (6.2)	34.7 (6.1)	34.2 (5.8)
EPDS[3], median (IQR)	575	4.0 (4.0)	4.0 (6.0)	4.0 (5.0)	4.0 (5.0)
Household					
Deprivation, n (%)	794				
1-3 (Low)		74 (35.9)	70 (34.5)	65 (33.9)	67 (34.7)
4-7 (Medium)		93 (45.2)	86 (42.4)	84 (43.8)	87 (45.1)
8-10 (High)		39 (18.9)	47 (23.2)	43 (22.4)	39 (20.2)
Income (NZD)[4], n (%)	728				
<$30,000		20 (10.4)	9 (4.8)	11 (6.4)	18 (10.3)
$30,000+ to $70,000		80 (41.7)	59 (31.4)	61 (35.3)	64 (36.6)
>$70,000		92 (47.9)	120 (63.8)	101 (58.4)	93 (53.1)

Data presented as mean (SD) unless stated otherwise

[1]MELAA refers to Middle Eastern, Latin American or African

[2]Secondary schooling in New Zealand is from year 9 to13 inclusive, post-secondary qualifications refer to all those that are non-University based.

[3]EPDS, Edinburgh Postnatal Depression Scale (0-30), higher score is worse

[4] NZD, New Zealand dollars. $70,000 represents average annual household income in the region at the time of study

Table 2 Parental sleep at baseline (third trimester)

	n	Control (n=209)	FAB (n=205)	Sleep (n=192)	Combination (n=196)
Mother					
Sleep Duration (hr)	797	8.3 (1.1)	8.4 (1.2)	8.4 (1.0)	8.3 (1.4)
Sleep latency ≥ 30 min, n (%)	797	134 (64)	130 (64)	126 (66)	133 (68)
Sleep Quantity Score[1]	802	4.4 (1.3)	4.3 (1.4)	4.2 (1.3)	4.4 (1.4)
Poor score, n (%)		54 (26)	63 (31)	61 (31)	53 (27)
Sleep Quality Score[2]	802	4.7 (1.3)	4.5 (1.3)	4.5 (1.3)	4.6 (1.4)
Poor score, n (%)		35 (17)	45 (22)	40 (21)	42 (22)
Partner					
Sleep Duration (hr)	590	7.6 (0.9)	7.6 (0.9)	7.6 (0.9)	7.7 (1.0)
Sleep latency ≥ 30 min, n (%)	548	88 (58)	89 (61)	82 (61)	69 (52)
Sleep Quantity Score[1]	577	4.0 (1.2)	3.8 (1.3)	3.9 (1.2)	4.0 (1.3)
Poor score, n (%)		18 (13)	24 (15)	15 (11)	20 (15)
Sleep Quality Score[2]	578	4.5 (1.1)	4.5 (1.3)	4.4 (1.3)	4.4 (1.4)
Poor score, n (%)		6 (4)	12 (8)	12 (9)	13 (9)

Data presented as mean (SD) unless stated otherwise

[1]From a possible score of 1 (not nearly enough) to 8 (more than enough) thus higher score is better. Poor score <= 3

[2]From a possible score of 1 (very bad) to 8 (very good) thus higher score is better at baseline

Poor score <= 3

Table 3 Infant sleep diary and actigraphy data at 6 months of age

					P value for Intervention	
	Control	**FAB**	**Sleep**	**Combination**	**Δ 4 groups**	**Δ 2 groups***
Diary[1]						
24-h sleep duration (min)	840 (96)	828 (96)	828 (90)	822 (96)	0.631	0.383
Overnight sleep duration (min)	654 (84)	648 (78)	642 (78)	636 (78)	0.248	0.086
N° night wakings**	1.5 (1.5)	2.0 (1.5)	1.5 (1.5)	2.0 (2.0)	0.397	0.729
Overnight sleep efficiency (%)	92.1 (13.6)	91.1 (12.0)	90.0 (14.3)	90.4 (12.2)	0.514	0.317
N° daytime naps	2.6 (1.3)	2.6 (1.4)	2.7 (1.4)	2.8 (1.3)	0.379	0.096
Longest sleep period overnight (min)	444 (168)	426 (186)	426 (174)	414 (168)	0.536	0.457
Actigraphy[2]						
Sleep onset (h:min)	20:12 (78)	20:12 (72)	20:24 (78)	20.24 (78)	0.415	0.102
Sleep offset (h:min)	6:54 (60)	6:54 (60)	6:54 (60)	7:00 (60)	0.293	0.319
24-h sleep duration (min)	616.4 (94.6)	618.5 (90.7)	615.1 (94.4)	621.7 (93.0)	0.554	0.635
Overnight sleep duration (min)	538.9 (105.5)	532.3 (88.2)	528.6 (99.7)	544.1 (95.1)	0.157	—
N° night wakings**	2.6 (1.6)	2.6 (1.5)	2.4 (1.4)	2.4 (1.5)	0.100	**0.018**
Total night wake (min)	107.7 (87.4)	106.2 (68.6)	104.7 (88.2)	91.4 (68.3)	0.051	0.092
Overnight sleep efficiency (%)	83.5 (12.3)	83.5 (10.4)	83.8 (12.3)	85.7 (10.6)	0.063	0.120
N° daytime naps	1.7 (0.9)	1.7 (0.8)	1.7 (0.9)	1.8 (0.8)	0.871	0.544
Nap duration (min)	91.5 (55.4)	92.3 (53.8)	98.9 (57.4)	97.0 (55.5)	0.147	**0.025**

Data presented as mean (SD) unless stated otherwise

*"Sleep" (Control and FAB combined) vs "No Sleep" (Sleep and Combination combined)

** A primary outcome

[1]Analyses use mean of two days from 507 participants with available data

[2]Analyses use mean of 3-7 days (median 4 days) from 498 participants with available data

— No analyses due to interaction between Sleep and FAB groups

Table 4 Parent-rated sleep problems and sleep education-related outcomes from questionnaire at 4 and 6 months

Outcome	Infant age (months)	n	Control	FAB	Sleep	Combination	P value for Intervention Δ 4 groups	P value for Intervention Δ 2 groups*
Infant sleep problem score**[1,3]								
Mother-rated	4	718	2.0 (1.9)	2.3 (1.9)	2.2 (1.9)	2.0 (2.0)		
	6	701	2.2 (2.0)	2.6 (1.9)	2.4 (2.0)	2.3 (1.9)	0.176	0.961
Partner-rated	4	469	1.9 (1.8)	2.3 (1.8)	2.3 (1.8)	2.2 (1.8)		
	6	428	2.3 (1.8)	2.5 (1.9)	2.4 (1.8)	2.3 (1.7)	0.117	0.410
Infant unsettled, n (%)	4	711	11 (5.7)	16 (9.0)	11 (6.4)	11 (6.5)		
	6	700	15 (8.0)	15 (8.3)	11 (6.6)	7 (4.2)	0.557	0.375
Sleep latency ≥ 30 min, n (%)	4	715	10 (5.2%)	10 (5.6%)	16 (9.3%)	14 (8.2%)		
	6	701	18 (9.6%)	15 (8.3%)	22 (13.2%)	5 (3.0%)	**0.038**	0.160
Recognise tired signs score[2]	4	717	6.1 (0.9)	6.0 (0.9)	6.1 (0.9)	6.1 (0.9)		
	6	700	6.2 (0.8)	6.1 (0.8)	6.1 (0.9)	6.3 (0.8)	0.166	0.805
Infant put to bed awake score[2]	4	717	5.1 (1.8)	5.1 (1.8)	5.4 (1.7)	5.4 (1.8)		
	6	700	5.5 (1.8)	5.2 (1.8)	5.5 (1.8)	5.6 (1.6)	0.129	0.052
No parental contact score[2]	4	717	5.0 (1.8)	5.0 (1.7)	5.3 (1.9)	5.0 (2.0)		
	6	700	5.3 (1.8)	5.1 (1.9)	5.3 (1.9)	5.1 (2.0)	0.444	0.389
Bedsharing, n (%)	4	720	11 (5.6%)	12 (6.6%)	12 (7.0%)	17 (9.9%)		
	6	685	11 (6.0%)	12 (6.9%)	7 (4.1%)	13 (8.2%)	—	—

Smoking allowed in home, n (%)	4	717	4 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
	6	687	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—	—
Smoking allowed in car when children present, n (%)	4	702	2 (1.1%)	3 (1.7%)	2 (1.2%)	0 (0.0%)		
	6	686	1 (0.6%)	1 (0.6%)	3 (1.8%)	3 (1.8%)	—	—
Sleeping on back, n (%)	4	718	176 (90.3%)	164 (91.1%)	152 (88.9%)	150 (87.2%)	0.631	0.254
Sheepskin use, n (%)	4	720	27 (13.9%)	17 (9.4%)	26 (15.1%)	27 (15.7%)	0.374	0.240

Data presented as mean (SD) unless stated otherwise

*"Sleep" (Control and FAB combined) vs "No Sleep" (Sleep and Combination combined)

**A primary outcome

[1]From a possible score of 1 (no problem) to 8 (large problem) thus higher score is better

[2]From a possible score of 1 (never) to 7 (always) thus higher score is better

[3]mean is geometric mean

— Model not investigated due to small number of events not allowing estimating intervention effects with stratification variables included

Table 5 Maternal and partner variables at 4 and 6 months

Outcome	Infant age (months)	n	Control	FAB	Sleep	Combination	P value for Intervention Δ 4 groups	P value for Intervention Δ 2 groups*
Maternal								
Sleep quantity score[1]	4	719	4.7 (1.5)	4.6 (1.6)	4.6 (1.4)	4.7 (1.4)		
	6	700	4.6 (1.4)	4.4 (1.5)	4.5 (1.4)	4.7 (1.5)	0.622	0.395
Sleep quality score[2]	4	719	5.6 (1.3)	5.2 (1.4)	5.3 (1.4)	5.3 (1.4)		
	6	700	5.4 (1.5)	5.1 (1.3)	5.1 (1.3)	5.4 (1.5)	0.192	0.831
Fatigue score[3]	4	719	3.4 (0.8)	3.2 (0.9)	3.3 (0.9)	3.4 (0.8)		
	6	696	3.3 (0.8)	3.1 (0.9)	3.2 (0.8)	3.3 (0.8)	0.509	0.925
Sleep Duration (hr)	4	716	7.3 (1.3)	7.4 (1.4)	7.3 (1.2)	7.3 (1.1)		
	6	697	7.2 (1.2)	7.1 (1.3)	7.2 (1.2)	7.2 (1.2)	0.909	0.832
Sleep latency ≥ 30 min, n (%)	4	717	95 (49.0)	81 (45.0)	91 (52.9)	89 (52.1)		
	6	700	101 (54.0)	93 (51.4)	90 (53.9)	93 (56.4)	0.792	0.126
EPDS score[4], median (IQR)	4	718	5.0 (5.0)	5.0 (5.0)	5.0 (6.0)	4.0 (6.0)	0.544	0.392
Partner								
Sleep quantity score[1]	4	469	5.5 (1.1)	5.3 (1.3)	5.3 (1.3)	5.4 (1.2)		
	6	426	5.4 (1.1)	5.3 (1.2)	5.3 (1.4)	5.4 (1.2)	0.787	0.524
Sleep quality score[2]	4	470	4.8 (1.3)	4.7 (1.3)	4.6 (1.4)	4.9 (1.2)		
	6	427	4.7 (1.3)	4.5 (1.3)	4.6 (1.3)	4.9 (1.1)	0.275	0.801
Fatigue score[3]	4	471	3.3 (0.8)	3.2 (0.7)	3.3 (0.7)	3.4 (0.7)		

	6	427	3.2 (0.7)	3.2 (0.7)	3.3 (0.8)	3.3 (0.8)	0.917	0.469
Sleep Duration (hr)	4	458	6.9 (1.3)	6.9 (1.0)	7.1 (0.9)	7.2 (0.9)		
	6	422	6.9 (1.3)	7.0 (1.3)	7.1 (1.2)	7.2 (0.9)	0.399	0.054
Sleep latency ≥ 30 min, n (%)	4	465	62 (51.7)	71 (57.7)	58 (54.7)	64 (55.2)		
	6	426	68 (60.7)	66 (55.9)	56 (58.3)	58 (58.0)	0.902	0.763
EPDS score[4], median (IQR)	4	468	4.0 (5.0)	4.0 (6.0)	3.0 (4.0)	3.0 (4.0)	0.524	0.148

Data presented as mean (SD) unless stated otherwise

*"Sleep" (Control and FAB combined) vs "No Sleep" (Sleep and Combination combined)

[1]From a possible score of 1 (not nearly enough) to 8 (more than enough) thus higher score is better

[2]From a possible score of 1 (very bad) to 8 (very good) thus higher score is better

[3]From a possible score of 1 (complete exhaustion) to 5 (well rested) thus higher score is better

[4]EPDS, Edinburgh Postnatal Depression Scale (0-30), higher score is worse

Appendix 1. Topics covered at the antenatal group session for the Sleep and Combination groups

Why sleep?

- Critical to a child's development, health and quality of life
- Good for parents' wellbeing and more

What's normal

- Waking frequently during the night
- Active and quiet sleep cycles
- Sleeping through the night – a milestone to look forward to
- Babies can learn their sleep routines
- Babies need to be given a chance to learn to settle themselves
- Some babies learn easily – others need more help

Healthy sleep patterns

- Try to set some limits on 'handling' of baby
- Establish some regular pattern
- Notice and act on baby's tired signs early
- Darken sleeping place day and night ('cue' for sleep time)
- Try to put baby into their bed awake
- Give baby a brief chance to settle by themselves/learn to go to sleep on their own
- Keep night time quiet time – no 'play'

Safe sleeping

- Own sleep place in your room
- On back
- Clean firm tightly fitting mattress
- Keep cot clear of "extras"
- Co-sleeping is unsafe
    - If mother smoked in pregnancy
    - Adults (either) have been drinking, taking drugs, sedatives
    - Baby is less than 3 months old (for smoking and non-smoking mothers)

Looking after yourselves

- Your rest and sleep is important too
- Try to get a rest/sleep during the day
- Meals in freezer
- Limit visitors and looking after them
- Accept offers of help
- Go to bed early…soon after baby

Appendix 2: Topics covered at the one-to-one 3 week visit and included in booklet for Sleep and Combination groups

Introduction

- Benefits of sleep
- Information applies to healthy, alert babies who are feeding and growing well
- What we know about a baby's sleep:
  - Babies learn their sleep routines
  - Parents can teach their babies to be good sleepers
  - Babies need to be given a chance to settle by themselves
  - Some babies learn to sleep easily. Other babies need more help from their parents.

Normal sleep: What happens in the first year?

- How long should my baby sleep for?
  - Feeding-sleeping-waking patterns divided into four sections: 1st month, 2nd and 3rd month, 4th month, 6th month
- What happens when baby is sleeping?
  - Baby's active and quiet sleep cycles and associated behaviours
  - Arousals between sleep cycles – brief or full waking

General sleep and safety

- Basic safety tips for baby's sleeping place
  - Always place your baby on their back to sleep
  - Mattresses must be clean, firm and fit tightly into the frame of the cot
  - Do not use hot water bottles, electric blankets, pillows, big duvets or lots of stuffed toys (there are risks of smothering and overheating)

- Where is baby going to sleep?
  - Own cot/bassinet in parent(s) room is safest for first 3 months or longer
  - Co-sleeping (sleeping with baby in the same bed)
    - Risks of co-sleeping for Sudden Unexplained Death in Infancy (SUDI) within the NZ context outlined
    - Parental choice: If parent(s) chose to share their bed with their baby, **make sure:**
      - Bed is in the middle of the room (not against a wall)
      - Mattress fits tight in the bed frame
      - **DO NOT co-sleep** if you or your partner:
        - Smoke
        - Drink alcohol
        - Use non-prescription drugs
        - Take any sedating drugs
        - Are excessively tired
        - Are a large person or overweight
        - or have a Duvet, other loose bedding or water bed

Babys' tired signs

- Important to learn baby's tired signs

Signs of tiredness outlined
Act of tired signs to prevent overtiredness
Diagram showing cycle of feeding and sleeping well (content baby)
Diagram showing cycle of snack feeds and car naps (baby less content)

Crying: what babies do

Normal crying patterns during a baby's development
Normal crying patterns over the day
Why some babies cry a lot

Helping baby learn to develop a healthy sleep pattern

Establish a regular routine
- Times may vary; predictable patterns within each feed/awake/sleep cycle
- Setting own 'sleep clock"
- Day/night differences
- Calm, Quiet and soothing behaviours at settling time

Notice tired signs early
Put baby into cot/bassinet awake and give baby the opportunity to learn to fall asleep in their own
Avoid:
- rocking, holding or feeding baby to sleep
- bright lights, frantic and busy rocking and loud noises
- too much "busy-ness" (lots of activity) whilst baby is falling asleep

Settling a baby for sleep

Flow diagram of steps to follow

What if baby won't settle?

Steps to follow outlined:
- Remember to try and **stay calm,** and keep everything you do as **quiet** and as **soothing** as you can in **dim lighting**
- Don't take baby out of their cot immediately.
- Try and let baby settle on their own. Allow around 2-3 minutes in the first month, and 5 minutes at 3 months
- If baby keeps grizzling then wait for a further 2 minutes (use a timer … during this time go and make a cup of tea, or tell yourself the time you are going to wait and do a 2 minute activity e.g. TradeMe, YouTube, another row of knitting, put away the dishes, anything but being by the doorway waiting…) before going back to check your baby
- If necessary, talk quietly, and stroke, rub or pat your baby gently and see if this helps them quieten and settle
- If they begin to calm and settle then leave the room
- If baby starts to cry and 'wind up', baby may need another quiet feed or a cuddle and then try settling again (as before)
- If you know your baby is well fed, talk quietly as before and stroke, rub or pat your baby gently and see if this helps them quieten and settle. If they begin to calm and settle then leave the room

The very difficult to soothe baby

All babies are born with different temperaments
Good news is these babies can also learn to have healthy sleep patterns
Learning about how your own baby soothes him/herself
Remember a baby can sense how you feel; remain as calm as possible
You may need some time out to remain calm (ask you partner, a friend of relative for help)

Checking baby

Do this as quietly as you can, and where baby can't see you
Try not to pick baby up when asleep (identifying REM sleep)

Night feeding

Keep the lighting dim
If you need to talk, then talk softly and quietly with your baby
Try not to drag out the feeding, winding and changing cycle
At every chance try to place baby into the cot awake or drowsy
Because baby is still learning it is important to be consistent in what you do.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10-11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11, Table 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	11, suppl diag
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	26-27
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	30-35
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	30-35
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	30-35
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	30-35
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	none identifie
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-19
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Anticipatory guidance to prevent infant sleep problems within a randomised controlled trial: infant, maternal and partner outcomes at 6 months of age.

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Secondary Subject Heading:	Public health
Keywords:	actigraphy, intervention, night wakings, settling techniques, sleep duration, safe sleep

Title:

Anticipatory guidance to prevent infant sleep problems within a randomised controlled trial: infant, maternal and partner outcomes at 6 months of age.

Authors:

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ABSTRACT

Objective: To evaluate the effectiveness of sleep education delivered antenatally and at 3 weeks post-partum to prevent infant sleep problems at 6 months of age.

Design: Sleep intervention within a randomised controlled trial for the Prevention of Overweight in Infancy (POI study).

Participants: 802 families were randomly allocated to one of four groups: usual care (Control); sleep intervention (Sleep); food, activity and breastfeeding intervention (FAB); combined group receiving both interventions (Combination).

Interventions: All groups received standard Well Child care. The sleep intervention groups (Sleep and Combination) received an antenatal group education session (all mothers and most partners) emphasising infant self-settling and safe sleeping, and a home visit at three weeks reinforcing the antenatal sleep education. FAB and Combination groups received four contacts providing education and support on breastfeeding, food and activity up to four months postpartum.

Outcome measures: Here we report secondary sleep outcomes from the POI study: the prevalence of parent-reported infant sleep problems and night waking, and differences in sleep duration. Additional outcomes reported include differences in infant self-settling, safe sleep practices, and maternal and partner reports of their own sleep, fatigue and depression symptoms.

Results: Linear or mixed linear regression models found no significant intervention effects on sleep outcomes with 19.1% of mothers and 16.6% of partners reporting their infant's sleep a problem at 6 months. Actigraphy estimated the number of night wakings to be significantly reduced (8%) and the duration of daytime sleep increased (6 minutes) in those groups receiving the sleep intervention compared to those who

did not. However, these small differences were not clinically significant, and not observed in 24-hour infant sleep diary data. No other differences were observed.

Conclusion: A strategy delivering infant sleep education antenatally and at three weeks postpartum was not effective in preventing the development of parent-reported infant sleep problems.

Key Words: actigraphy, night wakings, safe sleep, settling techniques, sleep duration

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The first RCT examining the efficacy of a sleep education programme to prevent infant sleep problems commencing antenatally.
- Data were collected from both mother and partner about whether their child's sleep was a problem.
- Sleep data from infants were reported both subjectively (sleep diaries) and objectively (actigraphy).
- Partners as well as mothers rated their own sleep quality across several time points.
- Key education outcomes related to infant sleep practices, such as infant self settling, were collected via parent report and may not be accurate enough to identify any intervention effects.
- The results are limited to young infants in a well-educated community which may reduce the generalisability of the findings.

INTRODUCTION

Unsettled sleep-wake behaviour peaks in the first six months of life with between 16 and 38% of parents reporting sleep problems to clinicians within the first year.[1-3] Parents' commonest concerns relate to their baby's crying,[4] amount of sleep, appropriate strategies to settle their infant to sleep,[5 ,6] difficulties settling to sleep and frequent night waking.[7] Infant sleep problems are expensive to treat[8] and are associated with several adverse consequences for mothers including postnatal depression,[8] fatigue,[9] as well as poorer general and mental health among those without a history of depression.[10] Although fathers have rarely been studied, they also report poorer general health and greater psychological distress linked to infant sleep problems.[10]

Infant sleep problems likely emerge from interactions between infant and parental health and behaviour, and the environment.[11] One third of infants who are unable to achieve a consolidated sleep of six hours by five months of age still cannot achieve this by 2½ years of age[12] and a short sleep duration pattern sustained across infancy and early childhood is associated with five times greater odds of children exhibiting hyperactive behaviour at five years of age.[7] Evidence also suggests that sleep problems first presenting in infancy are likely to persist into childhood[13-15] with potential for poorer cognitive development,[16-18] behaviour,[16 ,19] and quality of life,[20] and a greater risk of overweight or obesity.[21-24] These adverse outcomes highlight the need for early intervention to optimise sleep development.

Overall, interventions designed to treat sleep problems once they have become established have demonstrated a small to medium effect on increasing infant nocturnal total sleep time,[25] either no or small effects on reducing night wakings,[25][26] and small impacts on improving maternal mood,[25] depression, fatigue, sleep quality and maternal cognitions

about their infant's sleep.[26] Whether prevention of sleep problems might be more effective, and potentially less costly, than attempts to treat established issues is largely unknown. Randomised controlled trials emphasising the early establishment of positive sleep practices have produced mixed findings to date.[2 ,27-29] These interventions were delivered postnatally,[2 ,28 ,29] or at 3 months post-partum[27] and on a one-to-one basis. None were delivered antenatally or within group sessions where families may be less stressed and more receptive to the sleep education messages. Given that a large number of infants suffer sleep problems and that the flow-on effects of these problems carry significant long-term costs to individuals, it is pertinent to investigate the effectiveness of simple prevention strategies that could be implemented as a public health measure through antenatal education and Well Child services.

We recently undertook a four-armed randomised controlled trial (RCT), the Prevention of Overweight in Infancy (POI) study,[30] to determine whether additional support and education on food, activity, breastfeeding, and sleep from late pregnancy could reduce overweight and obesity in children at two years of age. In exploratory analyses, the trial found a protective effect for obesity among groups receiving the sleep intervention.[31] The exact mechanisms by which sleep could influence obesity in early life are unclear, although the ability of an infant to learn to self-regulate his/her own sleep is considered one of the earliest biological markers of self-regulatory behaviours.[32] This enhanced sleep self-regulation could conceivably help shape other self-regulatory behaviours linked to healthy weight. Other potential mechanisms linked to insufficient sleep in children and adults include changes in neurohormonal control of appetite regulation, impacts on dietary intake, and increased sedentary activity –all favouring weight gain.[33]

The aim of this paper was to determine whether the infant sleep education programme

delivered antenatally and 3 weeks postpartum reduced the prevalence of parent-reported sleep problems and night wakings, and influenced sleep duration in infants up to six months of age (secondary outcomes of the RCT; ClinicalTrials.gov: NCT00892983). Other aims were to determine any differences in infant self-settling and safe sleep practices, and maternal and paternal reports of their own sleep, fatigue and depression symptoms (additional outcomes).

METHODS

Study Design

The Prevention of Overweight in Infancy (POI) study (Clinical Trials NCT00892983) was a four-armed randomised controlled trial commencing in late pregnancy. Data from baseline (third trimester) to 6 months of age are reported here.

Participants and recruitment

All mothers booked into the single maternity hospital (> 97% of all births) serving the city of Dunedin, between May 2009 and November 2010 were potentially eligible. Letters of invitation were sent to mothers at 28–30 weeks gestation and an "opt out" recruitment strategy was used. Exclusion criteria applied before birth were: home address outside the greater Dunedin area, planning to move away in the next two years, not booked with the maternity centre or homebirth midwife before 34 weeks gestation, or unable to communicate in English or Te Reo Māori (language of the indigenous people of New Zealand). Exclusion criteria applied after birth were: identification of a congenital abnormality likely to affect feeding or growth, or the infant being born before 36.5 weeks gestation.

Randomisation

Participants were randomised to one of four groups: i) usual care (Control); ii) food, activity and breastfeeding intervention (FAB); iii) sleep intervention (Sleep), or iv) combined

intervention group receiving both the Sleep and FAB interventions (Combination). Details of allocation concealment and stratification have been described previously,[30] but briefly, stratification was based on household deprivation (tertiles: low [NZDep deciles 1–3],[34] medium [4–7] and high [8–10]) and parity including the study child (1 vs ≥2). Group allocation was revealed to the participants after they consented to participate. The statistician remained blinded to group allocation codes until primary analyses were completed.

Usual Care

Families of all four groups received standard maternity and Well Child care from a maternity care professional, and a Well Child provider of their choice. Well Child care[35] aims to maximise the health and development of all New Zealand children up to age five years (on average 8-9 visits in the first six months of life). The Control group received this usual care only.

Interventions

Sleep

Families receiving the Sleep intervention (Sleep and Combination groups) received antenatal education delivered via a single group session (up to 1 hour), followed by one home visit at three weeks post-partum with a researcher with infant sleep training. Antenatal sessions educated all mothers and most partners about normal developmental patterns of infant sleep and emphasised infant settling to sleep unaided (i.e. self-settling or self-regulation of sleep) which appears to be a key factor in the development of healthy sleep-wake patterns and a precursor to longer sleep duration in later infancy;[36] and safe-sleep practices as measures to prevent sudden unexpected death in infancy[37] (summarised in Appendix 1). Partners were mostly fathers. Parents left equipped with a "tip sheet" related to the key education messages. The individual sessions at the 3-week home visit reinforced the antenatal sleep education and

were conducted with the aid of a more detailed 15 page booklet covering the key messages for developing healthy sleep and safe sleep practices (summarised in Appendix 2). At this visit, researchers provided advice on any concerns the families had with their infant's sleep, and parents were encouraged to keep using the booklet as a valuable resource, and contact research staff at any stage should they require further sleep advice.

FAB

Mothers in the FAB group received three contacts providing education and support on breastfeeding (antenatal, one week and four months postpartum) and one on physical activity (three months postpartum) before 6 months of age. An International Board Certified Lactation Consultant worked with each family to assist with infant feeding, focussing on prolonging exclusive breastfeeding and delaying the introduction of complementary foods until around six months of age. At three months, each family attended an Active Movement session delivered by an established local sports body. The FAB intervention is described in more detail elsewhere.[38]

Combination

This group received five intervention visits in total before 6 months of age as the FAB and Sleep antenatal session was combined.

Questionnaires

Parents completed questionnaires during home visits at baseline (third trimester, prior to allocation), and at 4 and 6 months. Questionnaires collected data relevant to outcomes of the sleep education including ratings of the baby's problematic sleep and unsettled behaviour, and of infant settling and safe sleep practices. Mothers and partners also rated perceptions of their own sleep quantity and quality, and reported the usual time they went to bed, usual sleep time

(sleep onset) and usual wake time (sleep offset). Their sleep duration was calculated as the difference between sleep onset and sleep offset. Sleep latency (time taken to fall asleep) was calculated from the difference between the time they went to bed and sleep onset. Ratings of maternal and partner fatigue and depression symptoms (Edinburgh Postnatal Depression Scale; EPDS [39]) were also collected. Duration of exclusive breastfeeding (i.e. the infant receiving no liquids, other than breast milk, and no solids since birth), was calculated as age to the nearest part week from the monthly questionnaires.[30]

Sleep Diary

When the infant was 6 months of age, parents were asked to complete a 48-hour diary during the 5-7 day period when actigraphy was also recorded (as described previously[40]). Time was displayed horizontally in five-minute grid blocks. A parent was asked to indicate using an arrow the time the infant went to sleep and awoke, including daytime naps. Grid block counts with sleep and wake coding were then entered into a spreadsheet set up to automatically calculate standard sleep-wake variables.

Actigraphy

Infants wore an Actical accelerometer (Mini-Mitter Co., Inc., Bend, OR) for 5-7 days fitted on the shin. The accelerometers were initialized using 15-second epochs. Sleep onset (evening sleep time) and morning sleep offset (wake time) events were ascertained visually from activity graphs and marked in the sleep scoring program in MATLAB (MathWorks, Natick, MA, USA), from which standard sleep-wake variables, including nap counts and nap duration were determined using the count-scaled algorithm. A sleep period was defined as at least 20 minutes of sleep preceded by 5 minutes of awake with the sleep period altered for nap detection between 9am and 5pm as previously described using a minimum nap time threshold of 20 minutes.[40]

Statistical analysis

The RCT was powered on detecting differences in growth (the primary outcome) between the arms of the study,[30] therefore no relevant sample size calculations are available. The prevalence of parent-reported infant sleep problems, the number of night wakings and sleep duration at six months of age are secondary outcomes of the RCT as reported here. All other outcomes reported are considered additional outcomes of the RCT. The data were analysed using Stata 14.1 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP). Statistical significance was determined by two-sided $P < 0.05$ in all cases. No adjustments were made for multiple comparisons. Continuous outcome variables were compared between the four groups using linear regression models where the outcome was at a single time point and mixed linear regression with a random participant effect where multiple time points were included. Where model residuals were skewed or demonstrated heteroscedasticity, natural log transformations were investigated, after adding one for variables including zero values. If issues with model residuals were not thereby resolved, quantile regression was used instead to model medians. All models included the stratification variables (three levels of household deprivation and two levels of parity).[41] Binary variables were similarly analysed using logistic regression and mixed logistic regression with a random participant effect. For all outcomes, a second set of models looking at the main effects of the sleep (Sleep and Combination groups vs FAB and Control) and FAB interventions (FAB and Combination groups vs Sleep and Control) were implemented providing there was no evidence of an interaction between the two interventions. The purpose of this two-step process was to maximise the power to detect main effects but, as is well known,[42] this increases Type I error rates above their nominal level and so these results should be interpreted with caution, especially in cases of marginal statistical significance.

RESULTS

Participant characteristics at baseline

Of the 847 (58%) eligible families who agreed to participate, 802 met the post-partum inclusion criteria. Table 1 presents participant characteristics, illustrating that the majority of mothers and infants were European and 48% of mothers were having their first baby. Participating mothers had a mean age of 32 years and were well educated, with 65% having completed a university degree. The majority of EPDS scores were within the range of "normal" for mothers[43] and fathers.[44] Participant flow through the study has been described elsewhere.[38]

Parental sleep at baseline

Mothers reported obtaining approximately 8.4 hours of sleep at baseline and partners 7.6 hours (Table 2). Approximately 65% of mothers reported taking 30 minutes or longer to get to sleep (long sleep latency) and 58% of partners. Self-ratings of sleep quantity and quality for both mothers and partners were in the mid-range of a 1-8 rating scale where higher scores reflected better satisfaction with sleep quantity and better sleep quality. Categorising the satisfaction ratings by poor versus good sleep quantity or quality (ratings ≤3 versus >3) led to 29% and 21% of mothers reporting poor sleep quantity and quality respectively. For partners poor sleep quantity and quality were reported by 14% and 8% respectively.

Outcome measures

Infant sleep

Analyses of sleep diary data available at 6 months from 507 infants (Table 3) demonstrate there were no significant intervention effects related to parent-reported number of night

wakings, 24 hour or overnight sleep duration, longest sleep duration, sleep efficiency, or the number of daytime naps.. Actigraphy data provided from 498 infants recorded significantly fewer episodes of night waking and longer daytime sleep for infants in the groups receiving sleep interventions (Sleep and Combination groups) compared to the groups who did not receive the sleep intervention (Control and FAB groups). However the number of night wakings was reduced by 8% and the sleep duration increase was only approximately 6 minutes. No other significant intervention effects were found for the actigraphy variables. Exclusive breastfeeding duration (median 13 to 17 weeks) did not differ across the groups ($p \geq 0.323$) and thus was not considered to be a covariate that might influence night waking.

Problematic sleep

There were no intervention effects on parental reports that their infant's sleep was problematic (Table 4). In total, 16.1% (4 months) and 19.9% (6 months) of mothers reported that their infant's sleep was a problem (rated as 5-8 on an 8-point scale). In partners (mostly fathers), the prevalence was 11.7% (4 months) and 16.6% (6 months). Interestingly, there was a lack of agreement between mothers and partners about whether or not their baby's sleep was a moderate to large problem (kappa 0.25 and 0.29 respectively). At 4 months there was no evidence of a difference between mothers and partners, but at 6 months mothers were significantly more likely ($p=0.050$) to be the one reporting problems amongst the 94 discordant pairs (57 versus 37).

Settling practices

Practices relevant to sleep education on settling babies were not influenced by the interventions (Table 4) although there was a non-statistically significant tendency for groups who had received the sleep education (Sleep and Combination groups) to more frequently put their baby to sleep awake ($p=0.052$). Overall more than half of the mothers reported high

scores (6-7 on a scale of 1-7) for the frequency of putting their baby to sleep awake (54.2% and 60.3% at 4 and 6 months respectively), letting their baby fall asleep without them being present (51.6% and 56.8% at 4 months and 6 months respectively), and the majority reported being frequently able to recognise when their baby was tired (77.9% at 4 months and 83.2% at 6 months). A small intervention effect was found for the time it took babies to go to sleep (sleep latency; p=0.038) with significant differences in the prevalence of those reporting their infant to usually take ≥ 30 minutes (i.e. a long sleep latency) to fall asleep at 6 months (p=0.015). This was attributed to fewer infants in the Combination group (who received sleep education) having long sleep latencies.

Safe sleep practices

Practices relevant to safe-sleep messages were not influenced by the interventions (Table 4). Regular bedsharing was only practiced by a minority; overall 6.4% at 6 months. The majority of infants slept on their back, following recommended practices and few families smoked in the car while children were present or smoked in the household, with numbers too low for analyses. Data from the control arm of the study for these safe sleep variables at infant ages 3 to 23 weeks have been published previously.[37]

Maternal and partner outcomes

At infant age 6 months, there were no differences between intervention groups for maternal or partner sleep quantity, their sleep-rated quality, nor the prevalence of long sleep latency (≥ 30 minutes) (Table 5). Similarly, scores from the maternal EPDS attained when the infant was 4 months of age and adjusted for baseline EPDS score, were the same across groups. Maternal fatigue produced mixed results at different time points with any differences observed being too small to be of clinical importance. In addition, no differences in fatigue scores were

apparent between those who received the Sleep intervention (Sleep and Combination) and those who did not (FAB and Control).

DISCUSSION

Within this randomised controlled study, a brief sleep intervention consisting of antenatal education and a 3-week home visit was not effective in preventing infant sleep problems, when compared to standard care. A key education target was to encourage infants to self-settle to sleep.[45] There was a tendency towards those groups that received the sleep intervention being more likely to put their baby down to sleep awake but the differences were not statistically significant (p=0.052). We found some evidence that the sleep intervention influenced actigraphy-derived infant sleep patterns by significantly reducing the number of night wakings, and lengthening daytime sleep, but the small size of the differences encountered means they are unlikely to be clinically significant. Parental sleep, fatigue and parental symptoms of depression were not affected by the interventions.

Twenty percent of mothers reported that their 6 month-old infant's sleep was problematic for them, which is similar to other studies reporting a prevalence of 16 to 38% within the first year of life.[1-3] Parent-rated problematic sleep is a strong predictor of frequent and prolonged night wakings and difficulty settling to sleep.[46 ,47] Here we also collected data on partners (mostly fathers), and almost as many partners (17%) as mothers (20%) reported their child's sleep was a problem for them at 6 months of age, although there was significant discordance in mother-partner pairs. Few studies report children's problematic sleep from the partners' or fathers' perspective, but there is evidence suggesting a link between sleep problems in four- to five-year-old children and poorer paternal general health.[10]

There was limited room for improvement for some behaviours. For example, at 6 months, more than two-thirds of the parents who were in a group that did not receive the sleep intervention frequently practiced behaviours considered to be key intervention targets such as putting their baby to sleep awake or letting their baby fall asleep without a parent being present. Approximately 80% of mothers reported that they could frequently recognise when their infant was tired suggesting this may be an ineffective target to achieve change in this study population. However, we could not objectively measure the extent to which parents recognised the signs of tiredness, nor their ability to recognise the signs early enough to intervene effectively.

Although there are few studies to compare our data with directly, some target behaviours were more commonly practiced than those reported in a similar Australian RCT[2] with follow-up also at 6 months of age. In that study, 11% of parents in the control group consistently allowed their baby to fall asleep without being present (a top ranking of 5 on a 1-5 point scale of frequency). In our study 26% of parents in the control group rated this behaviour with a top ranking of 7 on a 1-7 point scale of frequency. Similarly, in the Australian study,[2] 23% stated they could always recognise tired signs in their infant (top ranking 5) compared to our 44% (top ranking 7). These data perhaps reflect that mothers in our study were well educated with 65% having a University degree and with free access to a strong Well Child support service offered at multiple time points across the first six months of life.[35] More closely aligned was the prevalence of settling baby to sleep while awake: 33% of control children in the Australian study[2] compared to 27% in our study gave this the top ranking.

Four large RCTs have employed similar preventive strategies with a similar number of contact points,[2,27-29] (albeit intervening immediately after birth or up to 3 months of age).

The outcomes of these studies, and the current one, lead us to suggest that preventive strategies may only confer benefit when delivered beyond the antenatal or immediate newborn period i.e. once parents have had time to understand their infants' sleep behaviours and patterns. One RCT intervening immediately after birth in primiparous women found no differences in infant sleep or maternal outcomes at follow-up (6 and 12 weeks post-partum),[28] whereas three RCTs intervening at 2-3 weeks,[29] 4 weeks[2] and 3 months post-partum,[27] resulted in longer infant sleep,[2] fewer symptoms of maternal depression,[2] less infant crying,[2,29] and fewer infants with sleep problems,[2] settling difficulties and night wakings[27] at follow-up. Similar positive outcomes have been found in other study designs (non-RCTs) employing preventive strategies and when the interventions were delivered at a later time point (4 months of age).[48,49] Other small trials with several more follow-up contacts have focussed on preventive strategies in target groups e.g. primiparous women[50,51] or mothers of breast-fed infants,[51] reporting some successes with infants "sleeping through the night" earlier[51] and reduced parental wakings and enhanced stability of early but not later sleep patterns.[50] As suggested by others, increasing the "dose" of intervention may be important as may be targeting high risk infants in more need of sleep interventions.[28]

The additional antenatal and postnatal education around safe sleep practices provided by the POI study made no difference to practice, but again the ceiling for improvement was limited. Some have suggested that safe sleep education should be started during pregnancy and should be consistently reinforced throughout the first year.[52,53] Our study data indicated that safe sleep messages are reaching our community and further reinforcement of messages beyond standard Well Child care would confer no additional benefit, but we acknowledge that this may be important in other communities or cultures where unsafe sleep practices are more common.

Outcomes related to parental depression symptoms, although not significant, were important to consider given that sleep disturbance is considered a risk factor for post-natal depression[54] and a previous preventive strategy has been effective in reducing maternal depression symptoms.[2] Maternal and partner subjective sleep quantity and quality, as well as symptoms of depression, were not influenced by the intervention. For mothers who have already been exposed to sleep disturbance during pregnancy, particularly within the last trimester,[55] the naturally shorter sleep-wake patterns of infants can further contribute to their own sleep loss with estimates of up to 1.5 hours of sleep lost over 24 hours in the early postnatal period.[56] In the current study, self-reported usual overnight sleep duration was reduced approximately 1 hour on average from the third trimester to 4 months post-partum, and in partners by approximately 36 minutes over the same time period. However we did not collect data on daytime napping and therefore cannot ascertain if any nighttime sleep loss was counterbalanced by daytime gain.

The study had some important limitations. First, the results are limited to young infants in a well-educated community thereby reducing the generalisability of the findings. Second, the sleep education was targeting some practices that were expected to be common practice leaving relatively little room for improvement. However, the prevalence of sleep problems in our participants was just as high as elsewhere, suggesting there is still much benefit to be gained from Well Child or other services delivering sleep education. A different focus might be necessary for measureable gains, for example targeting more socially disadvantaged groups and focussing on parental sleep, where small gains have been observed.[57] Furthermore, subjective reports of parental sleep practices related to our education targets, such as infant self-settling, may not be accurate enough and more objective tools for measuring this are required. Study strengths include the randomised and controlled nature of

the trial, high recruitment rates and retention, the longitudinal nature of the study, novel collection of data around parents' own sleep and inclusion of the partner/father.

In conclusion, the sleep intervention administered as a prevention strategy and conducted as part of a randomised controlled trial in the POI study was not effective in preventing sleep problems in infants. The antenatal period may be too early to intervene successfully with sleep where the priority focus for families is on the impending birth. Finally, although our study, like so many others, focused on trying to achieve behaviour change through education, we acknowledge that alternative paradigms to preventing or treating sleep problems in infants have been suggested. In these alternative paradigms, infant night-waking in the first 6 months is considered to be normal, and a range of strategies are used to help parents become more synchronized with their babies' sleep-wake needs, and make decisions about what is right for them in their own unique situation with their own unique baby.[58]

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Contributions. BJT, BG and RS led the Sleep intervention, and RWT and ALH led the FAB intervention. SLC contributed to writing the manuscript. ARG designed and completed all statistical analyses and wrote the relevant sections of the manuscript. JL coordinated and led the management of the study. AN was involved in data collection. All authors had intellectual input into the manuscript, commented on drafts, and approved the final version.

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Competing Interests: None to declare

Data sharing: No additional data available.

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Table 1 Infant, maternal and partner characteristics

		n	Control (n=209)	FAB (n=205)	Sleep (n=192)	Combination (n=196)
Infant						
	Gestation (wks)	802	40.0 (1.3)	40.0 (1.3)	40.0 (1.2)	40.0 (1.2)
	Birthweight (g)	795	3522 (484)	3561 (482)	3595 (461)	3529 (493)
	Male, n (%)	802	98 (46.9)	107 (52.2)	110 (57.3)	96 (49.0)
	Parity, median (IQR)	802	2 (1)	2 (1)	2 (1)	2 (1)
	Ethnicity, n (%)	801				
	European		162 (77.5)	160 (78.4)	147 (76.6)	156 (79.6)
	Māori		24 (11.5)	19 (9.3)	14 (7.3)	18 (9.2)
	Pacific		1 (0.5)	5 (2.5)	9 (4.7)	5 (2.6)
	Asian		10 (4.8)	12 (5.9)	15 (7.8)	11 (5.6)
	MELAA[1]		4 (1.9)	2 (1.0)	2 (1.0)	3 (1.5)
	Other		8 (3.8)	6 (2.9)	5 (2.6)	3 (1.5)
Maternal						
	Age	801	31.5 (5.0)	32.1 (5.3)	31.6 (5.2)	31.0 (5.4)
	Ethnicity, n (%)	801				
	European		177 (84.7)	176 (86.3)	161 (83.8)	168 (85.7)
	Māori		15 (7.2)	9 (4.4)	8 (4.2)	14 (7.1)
	Pacific		2 (1.0)	3 (1.5)	4 (2.1)	4 (2.0)

Asian		9 (4.3)	9 (4.4)	14 (7.3)	7 (3.6)
MELAA[1]		2 (1.0)	2 (1.0)	2 (1.0)	2 (1.0)
Other		4 (1.9)	5 (2.5)	3 (1.6)	1 (0.5)
EPDS, median (IQR)	796	7.0 (5.5)	7.0 (7.0)	7.0 (6.0)	6.0 (6.0)
Education[2]	793				
Year 11 or below		14 (6.8)	17 (8.4)	18 (9.4)	13 (6.7)
Year 12 or 13		41 (19.9)	23 (11.3)	30 (15.6)	37 (19.2)
Post-secondary		29 (14.1)	27 (13.3)	29 (15.1)	31 (16.1)
University degree or higher		122 (59.2)	136 (67.0)	115 (59.9)	112 (58.0)
Partner					
Age	576	34.5 (6.1)	34.3 (6.2)	34.7 (6.1)	34.2 (5.8)
EPDS[3], median (IQR)	575	4.0 (4.0)	4.0 (6.0)	4.0 (5.0)	4.0 (5.0)
Household					
Deprivation, n (%)	794				
1-3 (Low)		74 (35.9)	70 (34.5)	65 (33.9)	67 (34.7)
4-7 (Medium)		93 (45.2)	86 (42.4)	84 (43.8)	87 (45.1)
8-10 (High)		39 (18.9)	47 (23.2)	43 (22.4)	39 (20.2)
Income (NZD)[4], n (%)	728				
<$30,000		20 (10.4)	9 (4.8)	11 (6.4)	18 (10.3)
$30,000+ to $70,000		80 (41.7)	59 (31.4)	61 (35.3)	64 (36.6)
>$70,000		92 (47.9)	120 (63.8)	101 (58.4)	93 (53.1)

Data presented as mean (SD) unless stated otherwise

[1]MELAA refers to Middle Eastern, Latin American or African

[2]Secondary schooling in New Zealand is from year 9 to13 inclusive, post-secondary qualifications refer to all those that are non-University based.

[3]EPDS, Edinburgh Postnatal Depression Scale (0-30), higher score is worse

[4] NZD, New Zealand dollars. $70,000 represents average annual household income in the region at the time of study

Table 2 Parental sleep at baseline (third trimester)

	n	Control (n=209)	FAB (n=205)	Sleep (n=192)	Combination (n=196)
Mother					
Sleep Duration (hr)	797	8.3 (1.1)	8.4 (1.2)	8.4 (1.0)	8.3 (1.4)
Sleep latency ≥ 30 min, n (%)	797	134 (64)	130 (64)	126 (66)	133 (68)
Sleep Quantity Score[1]	802	4.4 (1.3)	4.3 (1.4)	4.2 (1.3)	4.4 (1.4)
Poor score, n (%)		54 (26)	63 (31)	61 (31)	53 (27)
Sleep Quality Score[2]	802	4.7 (1.3)	4.5 (1.3)	4.5 (1.3)	4.6 (1.4)
Poor score, n (%)		35 (17)	45 (22)	40 (21)	42 (22)
Partner					
Sleep Duration (hr)	590	7.6 (0.9)	7.6 (0.9)	7.6 (0.9)	7.7 (1.0)
Sleep latency ≥ 30 min, n (%)	548	88 (58)	89 (61)	82 (61)	69 (52)
Sleep Quantity Score[1]	577	4.0 (1.2)	3.8 (1.3)	3.9 (1.2)	4.0 (1.3)
Poor score, n (%)		18 (13)	24 (15)	15 (11)	20 (15)
Sleep Quality Score[2]	578	4.5 (1.1)	4.5 (1.3)	4.4 (1.3)	4.4 (1.4)
Poor score, n (%)		6 (4)	12 (8)	12 (9)	13 (9)

Data presented as mean (SD) unless stated otherwise

[1]From a possible score of 1 (not nearly enough) to 8 (more than enough) thus higher score is better. Poor score <= 3

[2]From a possible score of 1 (very bad) to 8 (very good) thus higher score is better at baseline

Poor score <= 3

Table 3 Infant sleep diary and actigraphy data at 6 months of age

					P value for Intervention	
	Control	**FAB**	**Sleep**	**Combination**	**Δ 4 groups**	**Δ 2 groups***
Diary[1]						
24-h sleep duration (min)**	840 (96)	828 (96)	828 (90)	822 (96)	0.631	0.383
Overnight sleep duration (min)**	654 (84)	648 (78)	642 (78)	636 (78)	0.248	0.086
N° night wakings**	1.5 (1.5)	2.0 (1.5)	1.5 (1.5)	2.0 (2.0)	0.397	0.729
Overnight sleep efficiency (%)	92.1 (13.6)	91.1 (12.0)	90.0 (14.3)	90.4 (12.2)	0.514	0.317
N° daytime naps	2.6 (1.3)	2.6 (1.4)	2.7 (1.4)	2.8 (1.3)	0.379	0.096
Longest sleep period overnight (min)	444 (168)	426 (186)	426 (174)	414 (168)	0.536	0.457
Actigraphy[2]						
Sleep onset (h:min)	20:12 (78)	20:12 (72)	20:24 (78)	20.24 (78)	0.415	0.102
Sleep offset (h:min)	6:54 (60)	6:54 (60)	6:54 (60)	7:00 (60)	0.293	0.319
24-h sleep duration (min)**	616.4 (94.6)	618.5 (90.7)	615.1 (94.4)	621.7 (93.0)	0.554	0.635
Overnight sleep duration (min)**	538.9 (105.5)	532.3 (88.2)	528.6 (99.7)	544.1 (95.1)	0.157	—
N° night wakings**	2.6 (1.6)	2.6 (1.5)	2.4 (1.4)	2.4 (1.5)	0.100	**0.018**
Total night wake (min)	107.7 (87.4)	106.2 (68.6)	104.7 (88.2)	91.4 (68.3)	0.051	0.092
Overnight sleep efficiency (%)	83.5 (12.3)	83.5 (10.4)	83.8 (12.3)	85.7 (10.6)	0.063	0.120
N° daytime naps	1.7 (0.9)	1.7 (0.8)	1.7 (0.9)	1.8 (0.8)	0.871	0.544
Nap duration (min)	91.5 (55.4)	92.3 (53.8)	98.9 (57.4)	97.0 (55.5)	0.147	**0.025**

Data presented as mean (SD) unless stated otherwise

*"Sleep" (Control and FAB combined) vs "No Sleep" (Sleep and Combination combined)

**Secondary outcome to the main RCT.[30] All others variables are additional outcomes

[1]Analyses use mean of two days from 507 participants with available data

[2]Analyses use mean of 3-7 days (median 4 days) from 498 participants with available data

— No analyses due to interaction between Sleep and FAB groups

Table 4 Parent-rated sleep problems and sleep education-related outcomes from questionnaire at 4 and 6 months

Outcome	Infant age (months)	n	Control	FAB	Sleep	Combination	P value for Intervention Δ 4 groups	P value for Intervention Δ 2 groups*
Infant sleep problem score**[1,3]								
Mother-rated	4	718	2.0 (1.9)	2.3 (1.9)	2.2 (1.9)	2.0 (2.0)		
	6	701	2.2 (2.0)	2.6 (1.9)	2.4 (2.0)	2.3 (1.9)	0.176	0.961
Partner-rated	4	469	1.9 (1.8)	2.3 (1.8)	2.3 (1.8)	2.2 (1.8)		
	6	428	2.3 (1.8)	2.5 (1.9)	2.4 (1.8)	2.3 (1.7)	0.117	0.410
Infant unsettled, n (%)	4	711	11 (5.7)	16 (9.0)	11 (6.4)	11 (6.5)		
	6	700	15 (8.0)	15 (8.3)	11 (6.6)	7 (4.2)	0.557	0.375
Sleep latency ≥ 30 min, n (%)	4	715	10 (5.2%)	10 (5.6%)	16 (9.3%)	14 (8.2%)		
	6	701	18 (9.6%)	15 (8.3%)	22 (13.2%)	5 (3.0%)	**0.038**	0.160
Recognise tired signs score[2]	4	717	6.1 (0.9)	6.0 (0.9)	6.1 (0.9)	6.1 (0.9)		
	6	700	6.2 (0.8)	6.1 (0.8)	6.1 (0.9)	6.3 (0.8)	0.166	0.805
Infant put to bed awake score[2]	4	717	5.1 (1.8)	5.1 (1.8)	5.4 (1.7)	5.4 (1.8)		
	6	700	5.5 (1.8)	5.2 (1.8)	5.5 (1.8)	5.6 (1.6)	0.129	0.052
No parental contact score[2]	4	717	5.0 (1.8)	5.0 (1.7)	5.3 (1.9)	5.0 (2.0)		
	6	700	5.3 (1.8)	5.1 (1.9)	5.3 (1.9)	5.1 (2.0)	0.444	0.389
Bedsharing, n (%)	4	720	11 (5.6%)	12 (6.6%)	12 (7.0%)	17 (9.9%)		
	6	685	11 (6.0%)	12 (6.9%)	7 (4.1%)	13 (8.2%)	—	—

Smoking allowed in home, n (%)	4	717	4 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
	6	687	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—	—
Smoking allowed in car when children present, n (%)	4	702	2 (1.1%)	3 (1.7%)	2 (1.2%)	0 (0.0%)		
	6	686	1 (0.6%)	1 (0.6%)	3 (1.8%)	3 (1.8%)	—	—
Sleeping on back, n (%)	4	718	176 (90.3%)	164 (91.1%)	152 (88.9%)	150 (87.2%)	0.631	0.254
Sheepskin use, n (%)	4	720	27 (13.9%)	17 (9.4%)	26 (15.1%)	27 (15.7%)	0.374	0.240

Data presented as mean (SD) unless stated otherwise

*"Sleep" (Control and FAB combined) vs "No Sleep" (Sleep and Combination combined)

**Secondary outcome to the main RCT.[30] All others variables are additional outcomes

[1]From a possible score of 1 (no problem) to 8 (large problem) thus higher score is better

[2]From a possible score of 1 (never) to 7 (always) thus higher score is better

[3]mean is geometric mean

— Model not investigated due to small number of events not allowing estimating intervention effects with stratification variables included

Table 5 Maternal and partner variables at 4 and 6 months

Outcome	Infant age (months)	n	Control	FAB	Sleep	Combination	P value for Intervention Δ 4 groups	P value for Intervention Δ 2 groups*
Maternal								
Sleep quantity score[1]	4	719	4.7 (1.5)	4.6 (1.6)	4.6 (1.4)	4.7 (1.4)		
	6	700	4.6 (1.4)	4.4 (1.5)	4.5 (1.4)	4.7 (1.5)	0.622	0.395
Sleep quality score[2]	4	719	5.6 (1.3)	5.2 (1.4)	5.3 (1.4)	5.3 (1.4)		
	6	700	5.4 (1.5)	5.1 (1.3)	5.1 (1.3)	5.4 (1.5)	0.192	0.831
Fatigue score[3]	4	719	3.4 (0.8)	3.2 (0.9)	3.3 (0.9)	3.4 (0.8)		
	6	696	3.3 (0.8)	3.1 (0.9)	3.2 (0.8)	3.3 (0.8)	0.509	0.925
Sleep Duration (hr)	4	716	7.3 (1.3)	7.4 (1.4)	7.3 (1.2)	7.3 (1.1)		
	6	697	7.2 (1.2)	7.1 (1.3)	7.2 (1.2)	7.2 (1.2)	0.909	0.832
Sleep latency ≥ 30 min, n (%)	4	717	95 (49.0)	81 (45.0)	91 (52.9)	89 (52.1)		
	6	700	101 (54.0)	93 (51.4)	90 (53.9)	93 (56.4)	0.792	0.126
EPDS score[4], median (IQR)	4	718	5.0 (5.0)	5.0 (5.0)	5.0 (6.0)	4.0 (6.0)	0.544	0.392
Partner								
Sleep quantity score[1]	4	469	5.5 (1.1)	5.3 (1.3)	5.3 (1.3)	5.4 (1.2)		
	6	426	5.4 (1.1)	5.3 (1.2)	5.3 (1.4)	5.4 (1.2)	0.787	0.524
Sleep quality score[2]	4	470	4.8 (1.3)	4.7 (1.3)	4.6 (1.4)	4.9 (1.2)		
	6	427	4.7 (1.3)	4.5 (1.3)	4.6 (1.3)	4.9 (1.1)	0.275	0.801
Fatigue score[3]	4	471	3.3 (0.8)	3.2 (0.7)	3.3 (0.7)	3.4 (0.7)		

	6	427	3.2 (0.7)	3.2 (0.7)	3.3 (0.8)	3.3 (0.8)	0.917	0.469
Sleep Duration (hr)	4	458	6.9 (1.3)	6.9 (1.0)	7.1 (0.9)	7.2 (0.9)		
	6	422	6.9 (1.3)	7.0 (1.3)	7.1 (1.2)	7.2 (0.9)	0.399	0.054
Sleep latency ≥ 30 min, n (%)	4	465	62 (51.7)	71 (57.7)	58 (54.7)	64 (55.2)		
	6	426	68 (60.7)	66 (55.9)	56 (58.3)	58 (58.0)	0.902	0.763
EPDS score[4], median (IQR)	4	468	4.0 (5.0)	4.0 (6.0)	3.0 (4.0)	3.0 (4.0)	0.524	0.148

Data presented as mean (SD) unless stated otherwise. All are variables are additional outcomes of the main RCT[30]

*"Sleep" (Control and FAB combined) vs "No Sleep" (Sleep and Combination combined)

[1]From a possible score of 1 (not nearly enough) to 8 (more than enough) thus higher score is better

[2]From a possible score of 1 (very bad) to 8 (very good) thus higher score is better

[3]From a possible score of 1 (complete exhaustion) to 5 (well rested) thus higher score is better

[4]EPDS, Edinburgh Postnatal Depression Scale (0-30), higher score is worse

Appendix 1. Topics covered at the antenatal group session for the Sleep and Combination groups

Why sleep?

- Critical to a child's development, health and quality of life
- Good for parents' wellbeing and more

What's normal

- Waking frequently during the night
- Active and quiet sleep cycles
- Sleeping through the night – a milestone to look forward to
- Babies can learn their sleep routines
- Babies need to be given a chance to learn to settle themselves
- Some babies learn easily – others need more help

Healthy sleep patterns

- Try to set some limits on 'handling' of baby
- Establish some regular pattern
- Notice and act on baby's tired signs early
- Darken sleeping place day and night ('cue' for sleep time)
- Try to put baby into their bed awake
- Give baby a brief chance to settle by themselves/learn to go to sleep on their own
- Keep night time quiet time – no 'play'

Safe sleeping

- Own sleep place in your room
- On back
- Clean firm tightly fitting mattress
- Keep cot clear of "extras"
- Co-sleeping is unsafe
    - If mother smoked in pregnancy
    - Adults (either) have been drinking, taking drugs, sedatives
    - Baby is less than 3 months old (for smoking and non-smoking mothers)

Looking after yourselves

- Your rest and sleep is important too
- Try to get a rest/sleep during the day
- Meals in freezer
- Limit visitors and looking after them
- Accept offers of help
- Go to bed early…soon after baby

Appendix 2: Topics covered at the one-to-one 3 week visit and included in booklet for Sleep and Combination groups

Introduction

- Benefits of sleep
- Information applies to healthy, alert babies who are feeding and growing well
- What we know about a baby's sleep:
  - Babies learn their sleep routines
  - Parents can teach their babies to be good sleepers
  - Babies need to be given a chance to settle by themselves
  - Some babies learn to sleep easily. Other babies need more help from their parents.

Normal sleep: What happens in the first year?

- How long should my baby sleep for?
  - Feeding-sleeping-waking patterns divided into four sections: 1st month, 2nd and 3rdmonth, 4th month, 6th month
- What happens when baby is sleeping?
  - Baby's active and quiet sleep cycles and associated behaviours
  - Arousals between sleep cycles – brief or full waking

General sleep and safety

- Basic safety tips for baby's sleeping place
  - Always place your baby on their back to sleep
  - Mattresses must be clean, firm and fit tightly into the frame of the cot
  - Do not use hot water bottles, electric blankets, pillows, big duvets or lots of stuffed toys (there are risks of smothering and overheating)

- Where is baby going to sleep?
  - Own cot/bassinet in parent(s) room is safest for first 3 months or longer
  - Co-sleeping (sleeping with baby in the same bed)
    - Risks of co-sleeping for Sudden Unexplained Death in Infancy (SUDI) within the NZ context outlined
    - Parental choice: If parent(s) chose to share their bed with their baby, **make sure:**
      - Bed is in the middle of the room (not against a wall)
      - Mattress fits tight in the bed frame
      - **DO NOT co-sleep** if you or your partner:
        - Smoke
        - Drink alcohol
        - Use non-prescription drugs
        - Take any sedating drugs
        - Are excessively tired
        - Are a large person or overweight
        - or have a Duvet, other loose bedding or water bed

Babys' tired signs

- Important to learn baby's tired signs

Signs of tiredness outlined
Act of tired signs to prevent overtiredness
Diagram showing cycle of feeding and sleeping well (content baby)
Diagram showing cycle of snack feeds and car naps (baby less content)

Crying: what babies do

Normal crying patterns during a baby's development
Normal crying patterns over the day
Why some babies cry a lot

Helping baby learn to develop a healthy sleep pattern

Establish a regular routine
- Times may vary; predictable patterns within each feed/awake/sleep cycle
- Setting own 'sleep clock"
- Day/night differences
- Calm, Quiet and soothing behaviours at settling time

Notice tired signs early
Put baby into cot/bassinet awake and give baby the opportunity to learn to fall asleep in their own
Avoid:
- rocking, holding or feeding baby to sleep
- bright lights, frantic and busy rocking and loud noises
- too much "busy-ness" (lots of activity) whilst baby is falling asleep

Settling a baby for sleep

Flow diagram of steps to follow

What if baby won't settle?

Steps to follow outlined:
- Remember to try and **stay calm,** and keep everything you do as **quiet** and as **soothing** as you can in **dim lighting**
- Don't take baby out of their cot immediately.
- Try and let baby settle on their own. Allow around 2-3 minutes in the first month, and 5 minutes at 3 months
- If baby keeps grizzling then wait for a further 2 minutes (use a timer … during this time go and make a cup of tea, or tell yourself the time you are going to wait and do a 2 minute activity e.g. TradeMe, YouTube, another row of knitting, put away the dishes, anything but being by the doorway waiting…) before going back to check your baby
- If necessary, talk quietly, and stroke, rub or pat your baby gently and see if this helps them quieten and settle
- If they begin to calm and settle then leave the room
- If baby starts to cry and 'wind up', baby may need another quiet feed or a cuddle and then try settling again (as before)
- If you know your baby is well fed, talk quietly as before and stroke, rub or pat your baby gently and see if this helps them quieten and settle. If they begin to calm and settle then leave the room

The very difficult to soothe baby

All babies are born with different temperaments
Good news is these babies can also learn to have healthy sleep patterns
Learning about how your own baby soothes him/herself
Remember a baby can sense how you feel; remain as calm as possible
You may need some time out to remain calm (ask you partner, a friend of relative for help)

Checking baby

Do this as quietly as you can, and where baby can't see you
Try not to pick baby up when asleep (identifying REM sleep)

Night feeding

Keep the lighting dim
If you need to talk, then talk softly and quietly with your baby
Try not to drag out the feeding, winding and changing cycle
At every chance try to place baby into the cot awake or drowsy
Because baby is still learning it is important to be consistent in what you do.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10-11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11, Table 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	11, suppl diag
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	26-27
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	30-35
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	30-35
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	30-35
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	30-35
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	none identifie
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-19
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.