

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-014908
Article Type:	Research
Date Submitted by the Author:	27-Oct-2016
Complete List of Authors:	Galland, Barbara; University of Otago, Women's and Children's Health Sayers, Rachel; University of Otago, Women's and Children's Health Cameron, Sonya; University of Otago, Human Nutrition Gray, Andrew; University of Otago, Preventive and Social Medicine Heath, Anne-Louise; University of Otago, Human Nutrition Lawrence, Julie; University of Otago, Women's and Children's Health Newlands, Alana; University of Otago, Human Nutrition Taylor, Barry; University of Otago, Women's and Children's Health Taylor, Rachael; University of Otago, Department of Medicine
Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Public health
Keywords:	actigraphy, intervention, night wakings, settling techniques, sleep duration, safe sleep

SCHOLARONE™
Manuscripts

Title:

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

Authors:

Galland BC¹, Sayers RM¹, Cameron SL¹, Gray AR², Heath A-LM³, Lawrence JA¹, Newlands A³, Taylor BJ¹, Taylor RW⁴.

Affiliations:

¹Department of Women's & Children's Health, University of Otago, Dunedin, New Zealand

²Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand

³Department of Human Nutrition, University of Otago, Dunedin, New Zealand

⁴Department of Medicine, University of Otago, Dunedin, New Zealand

Address for correspondence:

Associate Professor Barbara Galland, Department of Women's and Children's Health, University of Otago, PO Box 56, Dunedin 9018, New Zealand.

Email: barbara.galland@otago.ac.nz Ph: +64 21 2468 700

Word Count: 4053

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

1
2
3 not clinically significant, and were not observed in 24-hour infant sleep diary data. No
4
5 other differences were observed.
6

7 **Conclusion:** A strategy delivering infant sleep education antenatally and at three
8
9 weeks postpartum was not effective in preventing the development of parent-reported
10
11 infant sleep problems.
12
13

14
15
16 **Key Words:** actigraphy, night wakings, safe sleep, settling techniques, sleep duration
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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,

1
2
3 than attempts to treat established issues is largely unknown. Randomised controlled trials
4
5 emphasising the early establishment of positive sleep practices have produced mixed findings
6
7 to date.[2,27-29] These interventions were delivered postnatally,[2,28,29] or at 3 months
8
9 post-partum[27] and on a one-to-one basis. None were delivered antenatally or within group
10
11 sessions where families may be less stressed and more receptive to the sleep education
12
13 messages. Given that a large number of infants suffer sleep problems and that the flow-on
14
15 effects of these problems carry significant long-term costs to individuals, it is pertinent to
16
17 investigate the effectiveness of simple prevention strategies that could be implemented as a
18
19 public health measure through antenatal education and Well Child services.
20
21

22
23
24 We recently undertook a four-armed randomised controlled trial, the Prevention of
25
26 Overweight in Infancy (POI) study,[30] to determine whether additional support and
27
28 education on food, activity, breastfeeding, and sleep from late pregnancy could reduce
29
30 overweight and obesity in children at two years of age. The aim of this paper was to
31
32 determine whether the infant sleep education programme delivered antenatally and 3 weeks
33
34 postpartum reduced the prevalence of parent-reported sleep problems and night wakings in
35
36 infants up to six months of age. Secondary aims were to determine any differences in infant
37
38 self-settling and safe sleep practices, sleep duration, and maternal and paternal reports of their
39
40 own sleep, fatigue and depression symptoms.
41
42
43
44
45

46 **METHODS**

47 **Study Design**

48
49 The Prevention of Overweight in Infancy (POI) study (Clinical Trials NCT00892983) was a
50
51 four-armed randomised controlled trial commencing in late pregnancy. Data from baseline
52
53 (third trimester) to 6 months of age are reported here.
54
55
56
57
58
59
60

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

1
2
3 average 8-9 visits in the first six months of life). The Control group received this usual care
4
5 only.
6
7

8 9 **Interventions**

10 11 **Sleep**

12
13 Families receiving the Sleep intervention (Sleep and Combination groups) received antenatal
14 education delivered via a single group session (up to 1 hour), followed by one home visit at
15 three weeks post-partum with a researcher with infant sleep training. Antenatal sessions
16 educated all mothers and most partners about normal developmental patterns of infant sleep
17 and emphasised infant settling to sleep unaided (i.e. self-settling or self-regulation of sleep)
18 which appears to be a key factor in the development of healthy sleep-wake patterns and a
19 precursor to longer sleep duration in later infancy;^[33] and safe-sleep practices as measures to
20 prevent sudden unexpected death in infancy^[34] (summarised in Appendix 1). Partners were
21 mostly fathers. Parents left equipped with a “tip sheet” related to the key education messages.
22 The individual sessions at the 3-week home visit reinforced the antenatal sleep education and
23 were conducted with the aid of a more detailed 15 page booklet covering the key messages for
24 developing healthy sleep and safe sleep practices (summarised in Appendix 2). At this visit,
25 researchers provided advice on any concerns the families had with their infant’s sleep, and
26 parents were encouraged to keep using the booklet as a valuable resource, and contact
27 research staff at any stage should they require further sleep advice.
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

48 49 **FAB**

50 Mothers in the FAB group received three contacts providing education and support on
51 breastfeeding (antenatal, one week and four months postpartum) and one on physical activity
52 (three months postpartum) before 6 months of age. An International Board Certified Lactation
53 Consultant worked with each family to assist with infant feeding, focussing on prolonging
54
55
56
57
58
59
60

1
2
3 exclusive breastfeeding and delaying the introduction of complementary foods until around
4
5 six months of age. At three months, each family attended an Active Movement session
6
7 delivered by an established local sports body. The FAB intervention is described in more
8
9 detail elsewhere.[35]
10

11 12 13 **Combination**

14
15 This group received five intervention visits in total before 6 months of age as the FAB and
16
17 Sleep antenatal session was combined.
18
19

20 21 22 **Questionnaires**

23
24 Parents completed questionnaires during home visits at baseline (third trimester, prior to
25
26 allocation), and at 4 and 6 months. Questionnaires collected data relevant to outcomes of the
27
28 sleep education including ratings of the baby's problematic sleep and unsettled behaviour, and
29
30 of infant settling and safe sleep practices. Mothers and partners also rated perceptions of their
31
32 own sleep quantity and quality, and reported the usual time they went to bed, usual sleep time
33
34 (sleep onset) and usual wake time (sleep offset). Their sleep duration was calculated as the
35
36 difference between sleep onset and sleep offset. Sleep latency (time taken to fall asleep) was
37
38 calculated from the difference between the time they went to bed and sleep onset. Ratings of
39
40 maternal and partner fatigue and depression symptoms (Edinburgh Postnatal Depression
41
42 Scale[36]) were also collected. Duration of exclusive breastfeeding (i.e. the infant receiving
43
44 no liquids, other than breast milk, and no solids since birth), was calculated as age to the
45
46 nearest part week from the monthly questionnaires.[30]
47
48
49
50

51 52 53 **Sleep Diary**

54
55 When the infant was 6 months of age, parents were asked to complete a 48-hour diary during
56
57 the 5-7 day period when actigraphy was also recorded (as described previously[37]). Time
58
59

1
2
3 was displayed horizontally in five-minute grid blocks. A parent was asked to indicate using an
4
5 arrow the time the infant went to sleep and awoke, including daytime naps. Grid block counts
6
7 with sleep and wake coding were then entered into a spreadsheet set up to automatically
8
9 calculate standard sleep-wake variables.
10

11 12 13 **Actigraphy**

14
15 Infants wore an Actical accelerometer (Mini-Mitter Co., Inc., Bend, OR) for 5-7 days fitted
16
17 on the shin. The accelerometers were initialized using 15-second epochs. Sleep onset (evening
18
19 sleep time) and morning sleep offset (wake time) events were ascertained visually from
20
21 activity graphs and marked in the sleep scoring program in MATLAB (MathWorks, Natick,
22
23 MA, USA), from which standard sleep-wake variables, including nap counts and nap duration
24
25 were determined using the count-scaled algorithm. A sleep period was defined as at least 20
26
27 minutes of sleep preceded by 5 minutes of awake with the sleep period altered for nap
28
29 detection between 9am and 5pm as previously described using a minimum nap time threshold
30
31 of 20 minutes.[37]
32
33
34
35
36

37 **Statistical analysis**

38
39 As sleep outcomes were secondary outcomes of the POI study, which was powered on
40
41 detecting differences in growth (the primary outcome) between the arms of the study,[30] no
42
43 relevant sample size calculations are available. The data were analysed using Stata 14.1
44
45 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP).
46
47 Statistical significance was determined by two-sided $P < 0.05$ in all cases. No adjustments
48
49 were made for multiple comparisons. Continuous outcome variables were compared between
50
51 the four groups using linear regression models where the outcome was at a single time point
52
53 and mixed linear regression with a random participant effect where multiple time points were
54
55 included. Where model residuals were skewed or demonstrated heteroscedasticity, natural log
56
57
58
59
60

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

1
2
3 to sleep (long sleep latency) and 58% of partners. Self-ratings of sleep quantity and quality for
4
5 both mothers and partners were in the mid-range of a 1-8 rating scale where higher scores
6
7 reflected better satisfaction with sleep quantity and better sleep quality. Categorising the
8
9 satisfaction ratings by poor versus good sleep quantity or quality (ratings ≤ 3 versus >3) led to
10
11 29% and 21% of mothers reporting poor sleep quantity and quality respectively. For partners
12
13 poor sleep quantity and quality were reported by 14% and 8% respectively.
14
15

16 17 18 **Outcome measures**

19 20 *Infant sleep*

21
22 Analyses of sleep diary data available at 6 months from 507 infants (Table 3) demonstrate
23
24 there were no significant intervention effects related to parent-reported number of night
25
26 wakings, 24 hour or overnight sleep duration, longest sleep duration, sleep efficiency, or the
27
28 number of daytime naps. Actigraphy data provided from 498 infants recorded significantly
29
30 fewer episodes of night waking and longer daytime sleep for infants in the groups receiving
31
32 sleep interventions (Sleep and Combination groups) compared to the groups who did not
33
34 receive the sleep intervention (Control and FAB groups). However the number of night
35
36 wakings was reduced by 8% and the sleep duration increase was only approximately 6
37
38 minutes. No other significant intervention effects were found for the actigraphy variables.
39
40 Exclusive breastfeeding duration (median 13 to 17 weeks) did not differ across the groups
41
42 ($p \geq 0.323$) and thus was not considered to be a covariate that might influence night waking.
43
44
45
46
47

48 *Problematic sleep*

49
50 There were no intervention effects on parental reports that their infant's sleep was
51
52 problematic (Table 4). In total, 16.1% (4 months) and 19.9% (6 months) of mothers reported
53
54 that their infant's sleep was a problem (rated as 5-8 on an 8-point scale). In partners (mostly
55
56 fathers), the prevalence was 11.7% (4 months) and 16.6% (6 months). Interestingly, there was
57
58
59

1
2
3 a lack of agreement between mothers and partners about whether or not their baby's sleep was
4
5 a moderate to large problem (kappa 0.25 and 0.29 respectively). At 4 months there was no
6
7 evidence of a difference between mothers and partners, but at 6 months mothers were
8
9 significantly more likely ($p = 0.050$) to be the one reporting problems amongst the 94
10
11 discordant pairs (57 versus 37).
12

13 14 15 *Settling practices*

16
17 Practices relevant to sleep education on settling babies were not influenced by the
18
19 interventions (Table 4) although there was a non-statistically significant tendency for groups
20
21 who had received the sleep education (Sleep and Combination groups) to more frequently put
22
23 their baby to sleep awake ($P = 0.052$). Overall more than half of the mothers reported high
24
25 scores (6-7 on a scale of 1-7) for the frequency of putting their baby to sleep awake (54.2%
26
27 and 60.3% at 4 and 6 months respectively), letting their baby fall asleep without them being
28
29 present (51.6% and 56.8% at 4 months and 6 months respectively), and the majority reported
30
31 being frequently able to recognise when their baby was tired (77.9% at 4 months and 83.2%
32
33 at 6 months). A small intervention effect was found for the time it took babies to go to sleep
34
35 (sleep latency; $p=0.038$) with significant differences in the prevalence of those reporting their
36
37 infant to usually take ≥ 30 minutes (i.e. a long sleep latency) to fall asleep at 6 months
38
39 ($p=0.015$). This was attributed to fewer infants in the Combination group (who received sleep
40
41 education) having long sleep latencies.
42
43
44
45
46
47

48 *Safe sleep practices*

49
50 Practices relevant to safe-sleep messages were not influenced by the interventions (Table 4).
51
52 Regular bedsharing was only practiced by a minority; overall 6.4% at 6 months. The majority
53
54 of infants slept on their back, following recommended practices and few families smoked in
55
56 the car while children were present or smoked in the household, with numbers too low for
57
58
59

1
2 analyses. Data from the control arm of the study for these safe sleep variables at infant ages 3
3 to 23 weeks have been published previously.[34]
4
5
6
7

8 9 *Maternal and partner outcomes*

10 At infant age 6 months, there were no differences between intervention groups for maternal or
11 partner sleep quantity, their sleep-rated quality, nor the prevalence of long sleep latency (≥ 30
12 minutes) (Table 5). Similarly, scores from the maternal EPDS attained when the infant was 4
13 months of age and adjusted for baseline EPDS score, were the same across groups. Maternal
14 fatigue produced mixed results at different time points with any differences observed being
15 too small to be of clinical importance. In addition, no differences in fatigue scores were
16 apparent between those who received the Sleep intervention (Sleep and Combination) and
17 those who did not (FAB and Control).
18
19
20
21
22
23
24
25
26
27
28
29

30 31 **DISCUSSION**

32 Within this randomised controlled study, a brief sleep intervention consisting of antenatal
33 education and a 3-week home visit was not effective in preventing infant sleep problems,
34 when compared to standard care. A key education target was to encourage infants to self-
35 settle to sleep.[42] There was a tendency towards those groups that received the sleep
36 intervention being more likely to put their baby down to sleep awake but the differences were
37 not statistically significant ($P=0.052$). We found some evidence that the sleep intervention
38 influenced actigraphy-derived infant sleep patterns by significantly reducing the number of
39 night wakings, and lengthening daytime sleep, but the small size of the differences
40 encountered means they are unlikely to be clinically significant. Parental sleep, fatigue and
41 parental symptoms of depression were not affected by the interventions.
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 Twenty percent of mothers reported that their 6 month-old infant's sleep was problematic for
4 them, which is similar to other studies reporting a prevalence of 16 to 38% within the first
5 year of life.[1-3] Parent-rated problematic sleep is a strong predictor of frequent and
6 prolonged night wakings and difficulty settling to sleep.[43,44] Here we also collected data
7 on partners (mostly fathers), and almost as many partners (17%) as mothers (20%) reported
8 their child's sleep was a problem for them at 6 months of age, although there was significant
9 discordance in mother-partner pairs. Few studies report children's problematic sleep from the
10 partners' or fathers' perspective, but there is evidence suggesting a link between sleep
11 problems in four- to five-year-old children and poorer paternal general health.[10]
12
13
14
15
16
17
18
19
20
21
22
23

24 There was limited room for improvement for some behaviours. For example, at 6 months,
25 more than two-thirds of the parents who were in a group that did not receive the sleep
26 intervention frequently practiced behaviours considered to be key intervention targets such as
27 putting their baby to sleep awake or letting their baby fall asleep without a parent being
28 present. Approximately 80% of mothers reported that they could frequently recognise when
29 their infant was tired suggesting this may be an ineffective target to achieve change in this
30 study population. However, we could not objectively measure the extent to which parents
31 recognised the signs of tiredness, nor their ability to recognise the signs early enough to
32 intervene effectively.
33
34
35
36
37
38
39
40
41
42
43
44
45

46 Although there are few studies to compare our data with directly, some target behaviours
47 were more commonly practiced than those reported in a similar Australian RCT[2] with
48 follow-up also at 6 months of age. In that study, 11% of parents in the control group
49 consistently allowed their baby to fall asleep without being present (a top ranking of 5 on a 1-
50 5 point scale of frequency). In our study 26% of parents in the control group rated this
51 behaviour with a top ranking of 7 on a 1-7 point scale of frequency. Similarly, in the
52
53
54
55
56
57
58
59
60

1
2
3 Australian study,[2] 23% stated they could always recognise tired signs in their infant (top
4 ranking 5) compared to our 44% (top ranking 7). These data perhaps reflect that mothers in
5 our study were well educated with 65% having a University degree and with free access to a
6 strong Well Child support service offered at multiple time points across the first six months of
7 life.[32] More closely aligned was the prevalence of settling baby to sleep while awake: 33%
8 of control children in the Australian study[2] compared to 27% in our study gave this the top
9 ranking.
10
11
12
13
14
15
16
17
18
19

20 Four large RCTs have employed similar preventive strategies with a similar number of
21 contact points,[2,27-29] (albeit intervening immediately after birth or up to 3 months of age).
22 The outcomes of these studies, and the current one, lead us to suggest that preventive
23 strategies may only confer benefit when delivered beyond the antenatal or immediate
24 newborn period i.e. once parents have had time to understand their infants' sleep behaviours
25 and patterns. One RCT intervening immediately after birth in primiparous women found no
26 differences in infant sleep or maternal outcomes at follow-up (6 and 12 weeks post-
27 partum),[28] whereas three RCTs intervening at 2-3 weeks,[29] 4 weeks[2] and 3 months
28 post-partum,[27] resulted in longer infant sleep,[2] fewer symptoms of maternal
29 depression,[2] less infant crying,[2,29] and fewer infants with sleep problems,[2] settling
30 difficulties and night wakings[27] at follow-up. Similar positive outcomes have been found in
31 other study designs (non-RCTs) employing preventive strategies and when the interventions
32 were delivered at a later time point (4 months of age).[45,46] Other small trials with several
33 more follow-up contacts have focussed on preventive strategies in target groups e.g.
34 primiparous women[47,48] or mothers of breast-fed infants,[48] reporting some successes
35 with infants "sleeping through the night" earlier[48] and reduced parental wakings and
36 enhanced stability of early but not later sleep patterns.[47] As suggested by others, increasing
37 the "dose" of intervention may be important as may be targeting high risk infants in more
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 need of sleep interventions.[28]
4
5
6

7 The additional antenatal and postnatal education around safe sleep practices provided by the
8
9 POI study made no difference to practice, but again the ceiling for improvement was limited.
10
11 Some have suggested that safe sleep education should be started during pregnancy and should
12
13 be consistently reinforced throughout the first year.[49,50] Our study data indicated that safe
14
15 sleep messages are reaching our community and further reinforcement of messages beyond
16
17 standard Well Child care would confer no additional benefit, but we acknowledge that this
18
19 may be important in other communities or cultures where unsafe sleep practices are more
20
21 common.
22
23
24
25

26 Secondary outcomes related to parental depression symptoms, although not significant, were
27
28 important to consider given that sleep disturbance is considered a risk factor for post-natal
29
30 depression[51] and a previous preventive strategy has been effective in reducing maternal
31
32 depression symptoms.[2] Maternal and partner subjective sleep quantity and quality, as well
33
34 as symptoms of depression, were not influenced by the intervention. For mothers who have
35
36 already been exposed to sleep disturbance during pregnancy, particularly within the last
37
38 trimester,[52] the naturally shorter sleep-wake patterns of infants can further contribute to
39
40 their own sleep loss with estimates of up to 1.5 hours of sleep lost over 24 hours in the early
41
42 postnatal period.[53] In the current study, self-reported usual overnight sleep duration was
43
44 reduced approximately 1 hour on average from the third trimester to 4 months post-partum,
45
46 and in partners by approximately 36 minutes over the same time period. However we did not
47
48 collect data on daytime napping and therefore cannot ascertain if any nighttime sleep loss was
49
50 counterbalanced by daytime gain.
51
52
53
54
55

56 The study had some important limitations. First, the results are limited to young infants in a
57
58
59
60

1
2
3 well-educated community thereby reducing the generalisability of the findings. Second, the
4 sleep education was targeting some practices that were expectantly already common practice
5 leaving relatively little room for improvement. However, the prevalence of sleep problems in
6 our participants was just as high as elsewhere, suggesting there is still much benefit to be
7 gained from Well Child or other services delivering sleep education. A different focus might
8 be necessary for measureable gains, for example targeting more socially disadvantaged
9 groups and focussing on parental sleep, where small gains have been observed.[54]
10
11 Furthermore, subjective reports of parental sleep practices related to our education targets,
12 such as infant self-settling, may not be accurate enough and more objective tools for
13 measuring this are required. Study strengths include the randomised and controlled nature of
14 the trial, high recruitment rates and retention, the longitudinal nature of the study, novel
15 collection of data around parents' own sleep and inclusion of the partner/father.
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30

31 In conclusion, the sleep intervention administered as a prevention strategy and conducted as
32 part of a randomised controlled trial in the POI study was not effective in preventing sleep
33 problems in infants. The antenatal period may be too early to intervene successfully with
34 sleep where the priority focus for families is on the impending birth. Finally, although our
35 study, like so many others, focused on trying to achieve behaviour change through education,
36 we acknowledge that alternative paradigms to preventing or treating sleep problems in infants
37 have been suggested. In these alternative paradigms, infant night-waking in the first 6 months
38 is considered to be normal, and a range of strategies are used to help parents become more
39 synchronized with their babies' sleep-wake needs, and make decisions about what is right for
40 them in their own unique situation with their own unique baby.[55]
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 **Acknowledgements.** We thank the families and their infants who participated in this study.
4
5 We also gratefully acknowledge the research assistance of Catherine Barker, Barbara
6
7 Churcher, Rhondda Davies, Maha Hanna, Carmen Lobb, Michelle McGrath, Amelia Needs,
8
9 Susan Peters, Nick Prosser, Megan Somerville, Bronwyn Thomas.
10

11
12
13 **Contributions.** BJT, BG and RS led the Sleep intervention, and RWT and ALH led the FAB
14
15 intervention. SLC contributed to writing the manuscript. ARG designed and completed all
16
17 statistical analyses and wrote the relevant sections of the manuscript. JL coordinated and led
18
19 the management of the study. AN was involved in data collection. All authors had intellectual
20
21 input into the manuscript, commented on drafts, and approved the final version.
22
23
24
25

26 **Funding:** This study was funded by the Health Research Council of New Zealand (grant
27
28 08/374) and the Southern District Health Board. RT is supported by the KPS Fellowship in
29
30 Early Childhood Obesity. SLC was supported by a University of Otago Health Sciences
31
32 postdoctoral fellowship. The funders had no role in study design; or in the collection,
33
34 analysis, and interpretation of data; or in the writing of the report or the decision to submit the
35
36 article for publication.
37
38
39
40

41 **Ethical Approval:** The study was approved by the New Zealand Lower South Regional
42
43 Ethics Committee (LRS/08/12/ 063) and all adult participants gave written informed consent
44
45 on behalf of themselves and their babies.
46
47
48
49

50 **Competing Interests:** None to declare
51
52
53

54 **Data sharing:** No additional data available.
55
56
57
58
59
60

REFERENCES

1. Wake M, Morton-Allen E, Poulakis Z, *et al*. Prevalence, stability, and outcomes of cry-fuss and sleep problems in the first 2 years of life: prospective community-based study. *Pediatrics* 2006;**117**:836-42.
2. Hiscock H, Cook F, Bayer J, *et al*. Preventing early infant sleep and crying problems and postnatal depression: a randomized trial. *Pediatrics* 2014;**133**:e346-54.
3. Armstrong KL, Quinn RA, Dadds MR. The sleep patterns of normal children. *Med J Aust* 1994;**161**:202-6.
4. Evanoo G. Infant crying: a clinical conundrum. *J Pediatr Health Care* 2007;**21**:333-8.
5. St James-Roberts I, Halil T. Infant crying patterns in the first year: normal community and clinical findings. *J Child Psychol Psychiatry* 1991;**32**:951-68.
6. Forsyth BW, Leventhal JM, McCarthy PL. Mothers' perceptions of problems of feeding and crying behaviors. A prospective study. *Am J Dis Child* 1985;**139**:269-72.
7. Touchette E, Cote SM, Petit D, *et al*. Short nighttime sleep-duration and hyperactivity trajectories in early childhood. *Pediatrics* 2009;**124**:e985-93.
8. Hiscock H, Bayer J, Gold L, *et al*. Improving infant sleep and maternal mental health: a cluster randomised trial. *Arch Dis Child* 2007;**92**:952-8.
9. Giallo R, Rose N, Vittorino R. Fatigue, wellbeing and parenting in mothers of infants and toddlers with sleep problems. *J Reprod Infant Psychol* 2011;**29**:236-49.

- 1
2
3 10. Martin J, Hiscock H, Hardy P, *et al.* Adverse associations of infant and child sleep
4
5 problems and parent health: an Australian population study. *Pediatrics*
6
7 2007;**119**:947-55.
8
- 9
10 11. Sadeh A, Tikotzky L, Scher A. Parenting and infant sleep. *Sleep Med Rev*
11
12 2010;**14**:89-96.
- 13
14 12. Touchette E, Petit D, Paquet J, *et al.* Factors associated with fragmented sleep at
15
16 night across early childhood. *Arch Pediatr Adolesc Med* 2005;**159**:242-9.
17
- 18 13. Zuckerman B, Stevenson J, Bailey V. Sleep problems in early childhood:
19
20 continuities, predictive factors, and behavioral correlates. *Pediatrics*
21
22 1987;**80**:664-71.
23
- 24 14. Kataria S, Swanson MS, Trevathan GE. Persistence of sleep disturbances in
25
26 preschool children. *J Pediatr* 1987;**110**:642-6.
27
- 28 15. Pollock JI. Night-waking at five years of age: predictors and prognosis. *J Child*
29
30 *Psychol Psychiatry* 1994;**35**:699-708.
31
32
- 33 16. Turnbull K, Reid GJ, Morton JB. Behavioral sleep problems and their potential
34
35 impact on developing executive function in children. *Sleep* 2013;**36**:1077-84.
36
- 37 17. Touchette E, Petit D, Seguin JR, *et al.* Associations between sleep duration
38
39 patterns and behavioral/cognitive functioning at school entry. *Sleep*
40
41 2007;**30**:1213-9.
42
43
- 44 18. Gruber R, Laviolette R, Deluca P, *et al.* Short sleep duration is associated with
45
46 poor performance on IQ measures in healthy school-age children. *Sleep Med*
47
48 2010;**11**:289-94.
49
- 50 19. Smedje H, Broman JE, Hetta J. Associations between disturbed sleep and
51
52 behavioural difficulties in 635 children aged six to eight years: a study based
53
54 on parents' perceptions. *Eur Child Adolesc Psychiatry* 2001;**10**:1-9.
55
56
57
58

- 1
2
3 20. Hiscock H, Canterford L, Ukoumunne OC, *et al.* Adverse associations of sleep
4 problems in Australian preschoolers: national population study. *Pediatrics*
5 2007;**119**:86-93.
6
7
8
9 21. Carter PJ, Taylor BJ, Williams SM, *et al.* Longitudinal analysis of sleep in
10 relation to BMI and body fat in children: the FLAME study. *BMJ*
11 2011;**342**:d2712
12
13
14
15 22. Diethelm K, Bolzenius K, Cheng G, *et al.* Longitudinal associations between
16 reported sleep duration in early childhood and the development of body mass
17 index, fat mass index and fat free mass index until age 7. *Int J Pediatr Obes*
18 2011;**6**:e114-23.
19
20
21
22
23 23. Cappuccio FP, Taggart FM, Kandala NB, *et al.* Meta-analysis of short sleep
24 duration and obesity in children and adults. *Sleep* 2008;**31**:619-26.
25
26
27
28 24. Hart CN, Jelalian E. Shortened sleep duration is associated with pediatric
29 overweight. *Behav Sleep Med* 2008;**6**:251-67.
30
31
32
33 25. Kempler L, Sharpe L, Miller CB, *et al.* Do psychosocial sleep interventions
34 improve infant sleep or maternal mood in the postnatal period? A systematic
35 review and meta-analysis of randomised controlled trials. *Sleep Med Rev*
36 2015;**29**:15-22.
37
38
39
40
41 26. Hall WA, Hutton E, Brant RF, *et al.* A randomized controlled trial of an
42 intervention for infants' behavioral sleep problems. *BMC Pediatr* 2015;**15**:181.
43
44
45
46 27. Kerr SM, Jowett SA, Smith LN. Preventing sleep problems in infants: a
47 randomized controlled trial. *J Adv Nurs* 1996;**24**:938-42.
48
49
50
51 28. Stremler R, Hodnett E, Kenton L, *et al.* Effect of behavioural-educational
52 intervention on sleep for primiparous women and their infants in early
53 postpartum: multisite randomised controlled trial. *BMJ* 2013;**346**:f1164.
54
55
56
57
58
59
60

- 1
2
3 29. Symon BG, Marley JE, Martin AJ, *et al.* Effect of a consultation teaching
4 behaviour modification on sleep performance in infants: a randomised
5 controlled trial. *Med J Aust* 2005;**182**:215-8.
6
7
8
9 30. Taylor BJ, Heath AL, Galland BC, *et al.* Prevention of Overweight in Infancy
10 (POI.nz) study: a randomised controlled trial of sleep, food and activity
11 interventions for preventing overweight from birth. *BMC Public Health*
12 2011;**11**:942.
13
14
15
16 31. Salmond C, Crampton P, Atkinson J. NZDep2006 Index of Deprivation.
17 Wellington: University of Otago. 2007.
18
19
20
21 32. Ministry of Health. Indicators for the Well Child/Tamariki Ora quality
22 improvement framework—March 2014. Ministry of Health, Wellington, New
23 Zealand; 2014.
24
25
26
27
28 33. Mindell JA, Telofski LS, Wiegand B, *et al.* A nightly bedtime routine: impact on
29 sleep in young children and maternal mood. *Sleep* 2009;**32**:599-606.
30
31
32
33 34. Galland BC, Gray A, Sayers RM, *et al.* Safe sleep practices in a New Zealand
34 community and development of a Sudden Unexpected Death in Infancy
35 (SUDI) risk assessment instrument. *BMC Pediatr* 2014;**14**:263.
36
37
38
39 35. Cameron SL, Heath AL, Gray AR, *et al.* Lactation Consultant Support from Late
40 Pregnancy with an Educational Intervention at 4 Months of Age Delays the
41 Introduction of Complementary Foods in a Randomized Controlled Trial. *J*
42 *Nutr* 2015;**145**:1481-90.
43
44
45
46
47
48 36. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development
49 of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry*
50 1987;**150**:782-6.
51
52
53
54
55
56
57
58
59
60

- 1
2
3 37. Galland B, Meredith-Jones K, Gray A, *et al*. Criteria for nap identification in
4
5 infants and young children using 24-h actigraphy and agreement with parental
6
7 diary. *Sleep Med* 2016;**19**:85-92.
8
9 38. Kahan BC, Morris TP. Improper analysis of trials randomised using stratified
10
11 blocks or minimisation. *Stat Med* 2012;**31**:328-40.
12
13 39. Kahan BC. Bias in randomised factorial trials. *Stat Med* 2013;**32**:4540-9.
14
15 40. Murray D, Cox JL. Screening for depression during pregnancy with the Edinburgh
16
17 Depression Scale (EDDS). *J Reprod Infant Psychol* 1990;**8**:99-107.
18
19 41. Matthey S, Barnett B, Kavanagh DJ, *et al*. Validation of the Edinburgh Postnatal
20
21 Depression Scale for men, and comparison of item endorsement with their
22
23 partners. *J Affect Disord* 2001;**64**:175-84.
24
25 42. St James-Roberts I, Roberts M, Hovish K, *et al*. Video Evidence That London
26
27 Infants Can Resettle Themselves Back to Sleep After Waking in the Night, as
28
29 well as Sleep for Long Periods, by 3 Months of Age. *J Dev Behav Pediatr*
30
31 2015;**36**:324-9.
32
33 43. Hiscock H, Wake M. Infant sleep problems and postnatal depression: a
34
35 community-based study. *Pediatrics* 2001;**107**:1317-22.
36
37 44. Sadeh A. A brief screening questionnaire for infant sleep problems: validation and
38
39 findings for an Internet sample. *Pediatrics* 2004;**113**:e570-e77.
40
41 45. Adair R, Zuckerman B, Bauchner H, *et al*. Reducing night waking in infancy: a
42
43 primary care intervention. *Pediatrics* 1992;**89**:585-8.
44
45 46. Adachi Y, Sato C, Nishino N, *et al*. A brief parental education for shaping sleep
46
47 habits in 4-month-old infants. *Clin* 2009;**7**:85-92.
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 47. Wolfson A, Lacks P, Futterman A. Effects of parent training on infant sleeping
4 patterns, parents' stress, and perceived parental competence. *J Consult Clin*
5 *Psychol* 1992;**60**:41-8.
6
7
8
9 48. Pinilla T, Birch LL. Help me make it through the night: behavioral entrainment of
10 breast-fed infants' sleep patterns. *Pediatrics* 1993;**91**:436-44.
11
12
13 49. Ottolini MC, Davis BE, Patel K, *et al*. Prone infant sleeping despite the "Back to
14 Sleep" campaign. *Arch Pediatr Adolesc Med* 1999;**153**:512-7.
15
16
17 50. Saririan S, Hauck FR. New recommendations to reduce the risk of SIDS: what
18 should we advise parents? *Am Fam Physician* 2006;**74**:1839-40.
19
20
21 51. Armstrong KL, Van Haeringen AR, Dadds MR, *et al*. Sleep deprivation or
22 postnatal depression in later infancy: separating the chicken from the egg. *J*
23 *Paediatr Child Health* 1998;**34**:260-2.
24
25
26
27 52. Lee KA, Zaffke ME, McEnany G. Parity and sleep patterns during and after
28 pregnancy. *Obstet Gynecol* 2000;**95**:14-8.
29
30
31
32 53. Signal TL, Gander PH, Sangalli MR, *et al*. Sleep duration and quality in healthy
33 nulliparous and multiparous women across pregnancy and post-partum. *Aust N*
34 *Z J Obstet Gynaecol* 2007;**47**:16-22.
35
36
37
38 54. Lee KA, Gay CL. Can modifications to the bedroom environment improve the
39 sleep of new parents? Two randomized controlled trials. *Res Nurs Health*
40 2011;**34**:7-19.
41
42
43
44 55. Whittingham K, Douglas P. Optimizing parent-infant sleep from birth to 6
45 months: a new paradigm. *Infant Ment Health J* 2014;**35**:614-23.
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

¹MELAA refers to Middle Eastern, Latin American or African

1
2
3
4 ²Secondary schooling in New Zealand is from year 9 to13 inclusive, post-secondary qualifications refer to all those that are non-University based.

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

6
7 ⁴NZD, New Zealand dollars. \$70,000 represents average annual household income in the region at the time of study

8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

For peer review only

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 \geq 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 \geq 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

¹From a possible score of 1 (not nearly enough) to 8 (more than enough) thus higher score is better. Poor score \leq 3

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

Poor score \leq 3

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

	Control	FAB	Sleep	Combination	P value for Intervention	
					Δ 4 groups	Δ 2 groups*
Diary¹						
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
Actigraphy²						
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)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

** A primary outcome

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

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

— No analyses due to interaction between Sleep and FAB groups

For peer review only

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

Outcome	Infant age		Control	FAB	Sleep	Combination	P value for Intervention	
	(months)	n					Δ 4 groups	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%)	—	—

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

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

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

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

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

	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)

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

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

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

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

1
2
3 **Appendix 1.** Topics covered at the antenatal group session for the Sleep and
4 Combination groups
5

6 **Why sleep?**

- 7
 - Critical to a child's development, health and quality of life
 - Good for parents' wellbeing and more

8
9

10 **What's normal**

- 11
 - 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

12
13
14
15
16
17
18

19 **Healthy sleep patterns**

- 20
 - 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'

21
22
23
24
25
26
27
28
29
30

31 **Safe sleeping**

- 32
 - 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)

33
34
35
36
37
38
39
40
41
42

43 **Looking after yourselves**

- 44
 - 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

45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 Signs of tiredness outlined
4 Act of tired signs to prevent overtiredness
5 Diagram showing cycle of feeding and sleeping well (content baby)
6 Diagram showing cycle of snack feeds and car naps (baby less content)
7

8 **Crying: what babies do**

9 Normal crying patterns during a baby's development
10 Normal crying patterns over the day
11 Why some babies cry a lot
12

13 **Helping baby learn to develop a healthy sleep pattern**

14 Establish a regular routine
15 Times may vary; predictable patterns within each feed/awake/sleep
16 cycle
17 Setting own 'sleep clock'
18 Day/night differences
19 Calm, Quiet and soothing behaviours at settling time
20 Notice tired signs early
21 Put baby into cot/bassinet awake and give baby the opportunity to learn to fall
22 asleep in their own
23 Avoid:
24 rocking, holding or feeding baby to sleep
25 bright lights, frantic and busy rocking and loud noises
26 too much "busy-ness" (lots of activity) whilst baby is falling asleep
27
28
29
30

31 **Settling a baby for sleep**

32 Flow diagram of steps to follow
33

34 **What if baby won't settle?**

35 Steps to follow outlined:
36 Remember to try and **stay calm**, and keep everything you do as **quiet**
37 and as **soothing** as you can in **dim lighting**
38 Don't take baby out of their cot immediately.
39 Try and let baby settle on their own. Allow around 2-3 minutes in the
40 first month, and 5 minutes at 3 months
41 If baby keeps grizzling then wait for a further 2 minutes (use a timer ...
42 during this time go and make a cup of tea, or tell yourself the time you
43 are going to wait and do a 2 minute activity e.g. TradeMe, YouTube,
44 another row of knitting, put away the dishes, anything but being by the
45 doorway waiting...) before going back to check your baby
46 If necessary, talk quietly, and stroke, rub or pat your baby gently and
47 see if this helps them quieten and settle
48 If they begin to calm and settle then leave the room
49 If baby starts to cry and 'wind up', baby may need another quiet feed
50 or a cuddle and then try settling again (as before)
51 If you know your baby is well fed, talk quietly as before and stroke,
52 rub or pat your baby gently and see if this helps them quieten and
53 settle. If they begin to calm and settle then leave the room
54
55
56
57
58
59
60

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 or 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

1			
2		assessing outcomes) and how	
3			
4		11b If relevant, description of the similarity of interventions	9
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	10-11
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
7			
8	Results		
9	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	11, Table 1
10	diagram is strongly	were analysed for the primary outcome	
11	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	11, suppl diag
12	Recruitment	14a Dates defining the periods of recruitment and follow-up	7
13		14b Why the trial ended or was stopped	n/a
14	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	26-27
15	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	30-35
16		by original assigned groups	
17			
18	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	30-35
19	estimation	precision (such as 95% confidence interval)	
20		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	30-35
21	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	30-35
22		pre-specified from exploratory	
23			
24	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	none identifie
25			
26	Discussion		
27	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-18
28	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	14-19
29	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-19
30			
31	Other information		
32	Registration	23 Registration number and name of trial registry	6
33	Protocol	24 Where the full trial protocol can be accessed, if available	6
34	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	19
35			

36

37 *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

38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

40

41

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-014908.R1
Article Type:	Research
Date Submitted by the Author:	14-Mar-2017
Complete List of Authors:	Galland, Barbara; University of Otago, Women's and Children's Health Sayers, Rachel; University of Otago, Women's and Children's Health Cameron, Sonya; University of Otago, Human Nutrition Gray, Andrew; University of Otago, Preventive and Social Medicine Heath, Anne-Louise; University of Otago, Human Nutrition Lawrence, Julie; University of Otago, Women's and Children's Health Newlands, Alana; University of Otago, Human Nutrition Taylor, Barry; University of Otago, Women's and Children's Health Taylor, Rachael; University of Otago, Department of Medicine
Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Public health
Keywords:	actigraphy, intervention, night wakings, settling techniques, sleep duration, safe sleep

SCHOLARONE™
Manuscripts

Title:

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

Authors:

Galland BC¹, Sayers RM¹, Cameron SL¹, Gray AR², Heath A-LM³, Lawrence JA¹, Newlands A³, Taylor BJ¹, Taylor RW⁴.

Affiliations:

¹Department of Women's & Children's Health, University of Otago, Dunedin, New Zealand

²Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand

³Department of Human Nutrition, University of Otago, Dunedin, New Zealand

⁴Department of Medicine, University of Otago, Dunedin, New Zealand

Address for correspondence:

Associate Professor Barbara Galland, Department of Women's and Children's Health, University of Otago, PO Box 56, Dunedin 9018, New Zealand.

Email: barbara.galland@otago.ac.nz Ph: +64 21 2468 700

Word Count: 4053

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

1
2
3 did not. However, these small differences were not clinically significant, and not
4
5 observed in 24-hour infant sleep diary data. No other differences were observed.
6

7 **Conclusion:** A strategy delivering infant sleep education antenatally and at three
8
9 weeks postpartum was not effective in preventing the development of parent-reported
10
11 infant sleep problems.
12
13

14
15
16 **Key Words:** actigraphy, night wakings, safe sleep, settling techniques, sleep duration
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 about their infant's sleep.[26] Whether prevention of sleep problems might be more effective,
4 and potentially less costly, than attempts to treat established issues is largely unknown.
5
6 Randomised controlled trials emphasising the early establishment of positive sleep practices
7
8 have produced mixed findings to date.[2 ,27-29] These interventions were delivered
9
10 postnatally,[2 ,28 ,29] or at 3 months post-partum[27] and on a one-to-one basis. None were
11
12 delivered antenatally or within group sessions where families may be less stressed and more
13
14 receptive to the sleep education messages. Given that a large number of infants suffer sleep
15
16 problems and that the flow-on effects of these problems carry significant long-term costs to
17
18 individuals, it is pertinent to investigate the effectiveness of simple prevention strategies that
19
20 could be implemented as a public health measure through antenatal education and Well Child
21
22 services.
23
24
25

26
27
28 We recently undertook a four-armed randomised controlled trial (RCT), the Prevention of
29
30 Overweight in Infancy (POI) study,[30] to determine whether additional support and
31
32 education on food, activity, breastfeeding, and sleep from late pregnancy could reduce
33
34 overweight and obesity in children at two years of age. In exploratory analyses, the trial found
35
36 a protective effect for obesity among groups receiving the sleep intervention.[31] The exact
37
38 mechanisms by which sleep could influence obesity in early life are unclear, although the
39
40 ability of an infant to learn to self-regulate his/her own sleep is considered one of the earliest
41
42 biological markers of self-regulatory behaviours.[32] This enhanced sleep self-regulation
43
44 could conceivably help shape other self-regulatory behaviours linked to healthy weight. Other
45
46 potential mechanisms linked to insufficient sleep in children and adults include changes in
47
48 neurohormonal control of appetite regulation, impacts on dietary intake, and increased
49
50 sedentary activity –all favouring weight gain.[33]
51
52
53

54
55
56
57 The aim of this paper was to determine whether the infant sleep education programme
58
59

1
2
3 delivered antenatally and 3 weeks postpartum reduced the prevalence of parent-reported sleep
4 problems and night wakings, and influenced sleep duration in infants up to six months of age
5 (secondary outcomes of the RCT; ClinicalTrials.gov: NCT00892983). Other aims were to
6 determine any differences in infant self-settling and safe sleep practices, and maternal and
7 paternal reports of their own sleep, fatigue and depression symptoms (additional outcomes).
8
9
10
11
12

13 14 15 **METHODS**

16 17 **Study Design**

18
19 The Prevention of Overweight in Infancy (POI) study (Clinical Trials NCT00892983) was a
20 four-armed randomised controlled trial commencing in late pregnancy. Data from baseline
21 (third trimester) to 6 months of age are reported here.
22
23
24
25
26
27

28 29 **Participants and recruitment**

30
31 All mothers booked into the single maternity hospital (> 97% of all births) serving the city of
32 Dunedin, between May 2009 and November 2010 were potentially eligible. Letters of
33 invitation were sent to mothers at 28–30 weeks gestation and an “opt out” recruitment
34 strategy was used. Exclusion criteria applied before birth were: home address outside the
35 greater Dunedin area, planning to move away in the next two years, not booked with the
36 maternity centre or homebirth midwife before 34 weeks gestation, or unable to communicate
37 in English or Te Reo Māori (language of the indigenous people of New Zealand). Exclusion
38 criteria applied after birth were: identification of a congenital abnormality likely to affect
39 feeding or growth, or the infant being born before 36.5 weeks gestation.
40
41
42
43
44
45
46
47
48
49
50
51

52 53 **Randomisation**

54
55 Participants were randomised to one of four groups: i) usual care (Control); ii) food, activity
56 and breastfeeding intervention (FAB); iii) sleep intervention (Sleep), or iv) combined
57
58
59

1
2
3 intervention group receiving both the Sleep and FAB interventions (Combination). Details of
4 allocation concealment and stratification have been described previously,[30] but briefly,
5 stratification was based on household deprivation (tertiles: low [NZDep deciles 1–3],[34]
6 medium [4–7] and high [8–10]) and parity including the study child (1 vs ≥ 2). Group
7 allocation was revealed to the participants after they consented to participate. The statistician
8 remained blinded to group allocation codes until primary analyses were completed.
9
10
11
12
13
14
15

16 17 18 **Usual Care**

19 Families of all four groups received standard maternity and Well Child care from a maternity
20 care professional, and a Well Child provider of their choice. Well Child care[35] aims to
21 maximise the health and development of all New Zealand children up to age five years (on
22 average 8-9 visits in the first six months of life). The Control group received this usual care
23 only.
24
25
26
27
28
29
30

31 32 33 **Interventions**

34 35 **Sleep**

36 Families receiving the Sleep intervention (Sleep and Combination groups) received antenatal
37 education delivered via a single group session (up to 1 hour), followed by one home visit at
38 three weeks post-partum with a researcher with infant sleep training. Antenatal sessions
39 educated all mothers and most partners about normal developmental patterns of infant sleep
40 and emphasised infant settling to sleep unaided (i.e. self-settling or self-regulation of sleep)
41 which appears to be a key factor in the development of healthy sleep-wake patterns and a
42 precursor to longer sleep duration in later infancy;[36] and safe-sleep practices as measures to
43 prevent sudden unexpected death in infancy[37] (summarised in Appendix 1). Partners were
44 mostly fathers. Parents left equipped with a “tip sheet” related to the key education messages.
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60 The individual sessions at the 3-week home visit reinforced the antenatal sleep education and

1
2
3 were conducted with the aid of a more detailed 15 page booklet covering the key messages for
4
5 developing healthy sleep and safe sleep practices (summarised in Appendix 2). At this visit,
6
7 researchers provided advice on any concerns the families had with their infant's sleep, and
8
9 parents were encouraged to keep using the booklet as a valuable resource, and contact
10
11 research staff at any stage should they require further sleep advice.
12
13

14 15 **FAB**

16
17 Mothers in the FAB group received three contacts providing education and support on
18
19 breastfeeding (antenatal, one week and four months postpartum) and one on physical activity
20
21 (three months postpartum) before 6 months of age. An International Board Certified Lactation
22
23 Consultant worked with each family to assist with infant feeding, focussing on prolonging
24
25 exclusive breastfeeding and delaying the introduction of complementary foods until around
26
27 six months of age. At three months, each family attended an Active Movement session
28
29 delivered by an established local sports body. The FAB intervention is described in more
30
31 detail elsewhere.[38]
32
33
34
35
36
37

38 **Combination**

39
40 This group received five intervention visits in total before 6 months of age as the FAB and
41
42 Sleep antenatal session was combined.
43
44
45

46 **Questionnaires**

47
48 Parents completed questionnaires during home visits at baseline (third trimester, prior to
49
50 allocation), and at 4 and 6 months. Questionnaires collected data relevant to outcomes of the
51
52 sleep education including ratings of the baby's problematic sleep and unsettled behaviour, and
53
54 of infant settling and safe sleep practices. Mothers and partners also rated perceptions of their
55
56 own sleep quantity and quality, and reported the usual time they went to bed, usual sleep time
57
58
59

1
2
3 (sleep onset) and usual wake time (sleep offset). Their sleep duration was calculated as the
4
5 difference between sleep onset and sleep offset. Sleep latency (time taken to fall asleep) was
6
7 calculated from the difference between the time they went to bed and sleep onset. Ratings of
8
9 maternal and partner fatigue and depression symptoms (Edinburgh Postnatal Depression
10
11 Scale; EPDS [39]) were also collected. Duration of exclusive breastfeeding (i.e. the infant
12
13 receiving no liquids, other than breast milk, and no solids since birth), was calculated as age
14
15 to the nearest part week from the monthly questionnaires.[30]
16
17
18
19

20 **Sleep Diary**

21
22 When the infant was 6 months of age, parents were asked to complete a 48-hour diary during
23
24 the 5-7 day period when actigraphy was also recorded (as described previously[40]). Time
25
26 was displayed horizontally in five-minute grid blocks. A parent was asked to indicate using an
27
28 arrow the time the infant went to sleep and awoke, including daytime naps. Grid block counts
29
30 with sleep and wake coding were then entered into a spreadsheet set up to automatically
31
32 calculate standard sleep-wake variables.
33
34
35
36

37 **Actigraphy**

38
39 Infants wore an Actical accelerometer (Mini-Mitter Co., Inc., Bend, OR) for 5-7 days fitted
40
41 on the shin. The accelerometers were initialized using 15-second epochs. Sleep onset (evening
42
43 sleep time) and morning sleep offset (wake time) events were ascertained visually from
44
45 activity graphs and marked in the sleep scoring program in MATLAB (MathWorks, Natick,
46
47 MA, USA), from which standard sleep-wake variables, including nap counts and nap duration
48
49 were determined using the count-scaled algorithm. A sleep period was defined as at least 20
50
51 minutes of sleep preceded by 5 minutes of awake with the sleep period altered for nap
52
53 detection between 9am and 5pm as previously described using a minimum nap time threshold
54
55 of 20 minutes.[40]
56
57
58
59
60

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

1
2
3 fewer episodes of night waking and longer daytime sleep for infants in the groups receiving
4 sleep interventions (Sleep and Combination groups) compared to the groups who did not
5 receive the sleep intervention (Control and FAB groups). However the number of night
6 wakings was reduced by 8% and the sleep duration increase was only approximately 6
7 minutes. No other significant intervention effects were found for the actigraphy variables.
8
9 Exclusive breastfeeding duration (median 13 to 17 weeks) did not differ across the groups
10
11 ($p \geq 0.323$) and thus was not considered to be a covariate that might influence night waking.
12
13
14
15
16
17
18
19

20 *Problematic sleep*

21
22 There were no intervention effects on parental reports that their infant's sleep was
23 problematic (Table 4). In total, 16.1% (4 months) and 19.9% (6 months) of mothers reported
24 that their infant's sleep was a problem (rated as 5-8 on an 8-point scale). In partners (mostly
25 fathers), the prevalence was 11.7% (4 months) and 16.6% (6 months). Interestingly, there was
26 a lack of agreement between mothers and partners about whether or not their baby's sleep was
27 a moderate to large problem (kappa 0.25 and 0.29 respectively). At 4 months there was no
28 evidence of a difference between mothers and partners, but at 6 months mothers were
29 significantly more likely ($p=0.050$) to be the one reporting problems amongst the 94
30 discordant pairs (57 versus 37).
31
32
33
34
35
36
37
38
39
40
41
42
43

44 *Settling practices*

45
46 Practices relevant to sleep education on settling babies were not influenced by the
47 interventions (Table 4) although there was a non-statistically significant tendency for groups
48 who had received the sleep education (Sleep and Combination groups) to more frequently put
49 their baby to sleep awake ($p=0.052$). Overall more than half of the mothers reported high
50 scores (6-7 on a scale of 1-7) for the frequency of putting their baby to sleep awake (54.2%
51 and 60.3% at 4 and 6 months respectively), letting their baby fall asleep without them being
52
53
54
55
56
57
58
59

1
2 present (51.6% and 56.8% at 4 months and 6 months respectively), and the majority reported
3 being frequently able to recognise when their baby was tired (77.9% at 4 months and 83.2%
4 at 6 months). A small intervention effect was found for the time it took babies to go to sleep
5 (sleep latency; $p=0.038$) with significant differences in the prevalence of those reporting their
6 infant to usually take ≥ 30 minutes (i.e. a long sleep latency) to fall asleep at 6 months
7 ($p=0.015$). This was attributed to fewer infants in the Combination group (who received sleep
8 education) having long sleep latencies.
9
10
11
12
13
14
15
16
17
18
19

20 *Safe sleep practices*

21 Practices relevant to safe-sleep messages were not influenced by the interventions (Table 4).
22 Regular bedsharing was only practiced by a minority; overall 6.4% at 6 months. The majority
23 of infants slept on their back, following recommended practices and few families smoked in
24 the car while children were present or smoked in the household, with numbers too low for
25 analyses. Data from the control arm of the study for these safe sleep variables at infant ages 3
26 to 23 weeks have been published previously.[37]
27
28
29
30
31
32
33
34
35
36

37 *Maternal and partner outcomes*

38 At infant age 6 months, there were no differences between intervention groups for maternal or
39 partner sleep quantity, their sleep-rated quality, nor the prevalence of long sleep latency (≥ 30
40 minutes) (Table 5). Similarly, scores from the maternal EPDS attained when the infant was 4
41 months of age and adjusted for baseline EPDS score, were the same across groups. Maternal
42 fatigue produced mixed results at different time points with any differences observed being
43 too small to be of clinical importance. In addition, no differences in fatigue scores were
44 apparent between those who received the Sleep intervention (Sleep and Combination) and
45 those who did not (FAB and Control).
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 present. Approximately 80% of mothers reported that they could frequently recognise when
4
5 their infant was tired suggesting this may be an ineffective target to achieve change in this
6
7 study population. However, we could not objectively measure the extent to which parents
8
9 recognised the signs of tiredness, nor their ability to recognise the signs early enough to
10
11 intervene effectively.
12

13
14
15 Although there are few studies to compare our data with directly, some target behaviours
16
17 were more commonly practiced than those reported in a similar Australian RCT[2] with
18
19 follow-up also at 6 months of age. In that study, 11% of parents in the control group
20
21 consistently allowed their baby to fall asleep without being present (a top ranking of 5 on a 1-
22
23 5 point scale of frequency). In our study 26% of parents in the control group rated this
24
25 behaviour with a top ranking of 7 on a 1-7 point scale of frequency. Similarly, in the
26
27 Australian study,[2] 23% stated they could always recognise tired signs in their infant (top
28
29 ranking 5) compared to our 44% (top ranking 7). These data perhaps reflect that mothers in
30
31 our study were well educated with 65% having a University degree and with free access to a
32
33 strong Well Child support service offered at multiple time points across the first six months of
34
35 life.[35] More closely aligned was the prevalence of settling baby to sleep while awake: 33%
36
37 of control children in the Australian study[2] compared to 27% in our study gave this the top
38
39 ranking.
40
41
42
43
44
45

46 Four large RCTs have employed similar preventive strategies with a similar number of
47
48 contact points,[2,27-29] (albeit intervening immediately after birth or up to 3 months of age).
49
50 The outcomes of these studies, and the current one, lead us to suggest that preventive
51
52 strategies may only confer benefit when delivered beyond the antenatal or immediate
53
54 newborn period i.e. once parents have had time to understand their infants' sleep behaviours
55
56 and patterns. One RCT intervening immediately after birth in primiparous women found no
57
58
59

1
2
3 differences in infant sleep or maternal outcomes at follow-up (6 and 12 weeks post-
4 partum),[28] whereas three RCTs intervening at 2-3 weeks,[29] 4 weeks[2] and 3 months
5 post-partum,[27] resulted in longer infant sleep,[2] fewer symptoms of maternal
6 depression,[2] less infant crying,[2,29] and fewer infants with sleep problems,[2] settling
7 difficulties and night wakings[27] at follow-up. Similar positive outcomes have been found in
8 other study designs (non-RCTs) employing preventive strategies and when the interventions
9 were delivered at a later time point (4 months of age).[48,49] Other small trials with several
10 more follow-up contacts have focussed on preventive strategies in target groups e.g.
11 primiparous women[50,51] or mothers of breast-fed infants,[51] reporting some successes
12 with infants “sleeping through the night” earlier[51] and reduced parental wakings and
13 enhanced stability of early but not later sleep patterns.[50] As suggested by others, increasing
14 the “dose” of intervention may be important as may be targeting high risk infants in more
15 need of sleep interventions.[28]

16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33 The additional antenatal and postnatal education around safe sleep practices provided by the
34 POI study made no difference to practice, but again the ceiling for improvement was limited.
35 Some have suggested that safe sleep education should be started during pregnancy and should
36 be consistently reinforced throughout the first year.[52,53] Our study data indicated that safe
37 sleep messages are reaching our community and further reinforcement of messages beyond
38 standard Well Child care would confer no additional benefit, but we acknowledge that this
39 may be important in other communities or cultures where unsafe sleep practices are more
40 common.
41
42
43
44
45
46
47
48
49
50
51

52 Outcomes related to parental depression symptoms, although not significant, were important
53 to consider given that sleep disturbance is considered a risk factor for post-natal
54 depression[54] and a previous preventive strategy has been effective in reducing maternal
55
56
57
58
59
60

1
2
3 depression symptoms.[2] Maternal and partner subjective sleep quantity and quality, as well
4
5 as symptoms of depression, were not influenced by the intervention. For mothers who have
6
7 already been exposed to sleep disturbance during pregnancy, particularly within the last
8
9 trimester,[55] the naturally shorter sleep-wake patterns of infants can further contribute to
10
11 their own sleep loss with estimates of up to 1.5 hours of sleep lost over 24 hours in the early
12
13 postnatal period.[56] In the current study, self-reported usual overnight sleep duration was
14
15 reduced approximately 1 hour on average from the third trimester to 4 months post-partum,
16
17 and in partners by approximately 36 minutes over the same time period. However we did not
18
19 collect data on daytime napping and therefore cannot ascertain if any nighttime sleep loss was
20
21 counterbalanced by daytime gain.
22
23

24
25
26 The study had some important limitations. First, the results are limited to young infants in a
27
28 well-educated community thereby reducing the generalisability of the findings. Second, the
29
30 sleep education was targeting some practices that were expected to be common practice
31
32 leaving relatively little room for improvement. However, the prevalence of sleep problems in
33
34 our participants was just as high as elsewhere, suggesting there is still much benefit to be
35
36 gained from Well Child or other services delivering sleep education. A different focus might
37
38 be necessary for measureable gains, for example targeting more socially disadvantaged
39
40 groups and focussing on parental sleep, where small gains have been observed.[57]
41
42 Furthermore, subjective reports of parental sleep practices related to our education targets,
43
44 such as infant self-settling, may not be accurate enough and more objective tools for
45
46 measuring this are required. Study strengths include the randomised and controlled nature of
47
48 the trial, high recruitment rates and retention, the longitudinal nature of the study, novel
49
50 collection of data around parents' own sleep and inclusion of the partner/father.
51
52
53
54
55
56
57
58
59
60

1
2
3 In conclusion, the sleep intervention administered as a prevention strategy and conducted as
4 part of a randomised controlled trial in the POI study was not effective in preventing sleep
5 problems in infants. The antenatal period may be too early to intervene successfully with
6 sleep where the priority focus for families is on the impending birth. Finally, although our
7 study, like so many others, focused on trying to achieve behaviour change through education,
8 we acknowledge that alternative paradigms to preventing or treating sleep problems in infants
9 have been suggested. In these alternative paradigms, infant night-waking in the first 6 months
10 is considered to be normal, and a range of strategies are used to help parents become more
11 synchronized with their babies' sleep-wake needs, and make decisions about what is right for
12 them in their own unique situation with their own unique baby.[58]
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27

28 **Acknowledgements.** We thank the families and their infants who participated in this study.
29 We also gratefully acknowledge the research assistance of Catherine Barker, Barbara
30 Churcher, Rhondda Davies, Maha Hanna, Carmen Lobb, Michelle McGrath, Amelia Needs,
31 Susan Peters, Nick Prosser, Megan Somerville, Bronwyn Thomas.
32
33
34
35
36
37
38

39 **Contributions.** BJT, BG and RS led the Sleep intervention, and RWT and ALH led the FAB
40 intervention. SLC contributed to writing the manuscript. ARG designed and completed all
41 statistical analyses and wrote the relevant sections of the manuscript. JL coordinated and led
42 the management of the study. AN was involved in data collection. All authors had intellectual
43 input into the manuscript, commented on drafts, and approved the final version.
44
45
46
47
48
49
50
51

52 **Funding:** This study was funded by the Health Research Council of New Zealand (grant
53 08/374) and the Southern District Health Board. RT is supported by the KPS Fellowship in
54 Early Childhood Obesity. SLC was supported by a University of Otago Health Sciences
55
56
57
58
59

1
2
3 postdoctoral fellowship. The funders had no role in study design; or in the collection,
4
5 analysis, and interpretation of data; or in the writing of the report or the decision to submit the
6
7 article for publication.
8
9

10
11 **Ethical Approval:** The study was approved by the New Zealand Lower South Regional
12
13 Ethics Committee (LRS/08/12/ 063) and all adult participants gave written informed consent
14
15 on behalf of themselves and their babies.
16
17

18
19
20 **Competing Interests:** None to declare
21
22

23
24 **Data sharing:** No additional data available.
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

REFERENCES

1. Wake M, Morton-Allen E, Poulakis Z, et al. Prevalence, stability, and outcomes of cry-fuss and sleep problems in the first 2 years of life: prospective community-based study. *Pediatrics* 2006;**117**:836-42.
2. Hiscock H, Cook F, Bayer J, et al. Preventing early infant sleep and crying problems and postnatal depression: a randomized trial. *Pediatrics* 2014;**133**:e346-54.
3. Armstrong KL, Quinn RA, Dadds MR. The sleep patterns of normal children. *Med J Aust* 1994;**161**:202-6.
4. Evanoo G. Infant crying: a clinical conundrum. *J Pediatr Health Care* 2007;**21**:333-8.
5. St James-Roberts I, Halil T. Infant crying patterns in the first year: normal community and clinical findings. *J Child Psychol Psychiatry* 1991;**32**:951-68.
6. Forsyth BW, Leventhal JM, McCarthy PL. Mothers' perceptions of problems of feeding and crying behaviors. A prospective study. *Am J Dis Child* 1985;**139**:269-72.
7. Touchette E, Cote SM, Petit D, et al. Short nighttime sleep-duration and hyperactivity trajectories in early childhood. *Pediatrics* 2009;**124**:e985-93.
8. Hiscock H, Bayer J, Gold L, et al. Improving infant sleep and maternal mental health: a cluster randomised trial. *Arch Dis Child* 2007;**92**:952-8.
9. Giallo R, Rose N, Vittorino R. Fatigue, wellbeing and parenting in mothers of infants and toddlers with sleep problems. *J Reprod Infant Psychol* 2011;**29**:236-49.
10. Martin J, Hiscock H, Hardy P, et al. Adverse associations of infant and child sleep problems and parent health: an Australian population study. *Pediatrics* 2007;**119**:947-55.
11. Sadeh A, Tikotzky L, Scher A. Parenting and infant sleep. *Sleep Med Rev* 2010;**14**:89-96.

12. Touchette E, Petit D, Paquet J, et al. Factors associated with fragmented sleep at night across early childhood. *Arch Pediatr Adolesc Med* 2005;**159**:242-9.
13. Zuckerman B, Stevenson J, Bailey V. Sleep problems in early childhood: continuities, predictive factors, and behavioral correlates. *Pediatrics* 1987;**80**:664-71.
14. Kataria S, Swanson MS, Trevathan GE. Persistence of sleep disturbances in preschool children. *J Pediatr* 1987;**110**:642-6.
15. Pollock JI. Night-waking at five years of age: predictors and prognosis. *J Child Psychol Psychiatry* 1994;**35**:699-708.
16. Turnbull K, Reid GJ, Morton JB. Behavioral sleep problems and their potential impact on developing executive function in children. *Sleep* 2013;**36**:1077-84.
17. Touchette E, Petit D, Seguin JR, et al. Associations between sleep duration patterns and behavioral/cognitive functioning at school entry. *Sleep* 2007;**30**:1213-9.
18. Gruber R, Laviolette R, Deluca P, et al. Short sleep duration is associated with poor performance on IQ measures in healthy school-age children. *Sleep Med* 2010;**11**:289-94.
19. Smedje H, Broman JE, Hetta J. Associations between disturbed sleep and behavioural difficulties in 635 children aged six to eight years: a study based on parents' perceptions. *Eur Child Adolesc Psychiatry* 2001;**10**:1-9.
20. Hiscock H, Canterford L, Ukoumunne OC, et al. Adverse associations of sleep problems in Australian preschoolers: national population study. *Pediatrics* 2007;**119**:86-93.
21. Carter PJ, Taylor BJ, Williams SM, et al. Longitudinal analysis of sleep in relation to BMI and body fat in children: the FLAME study. *BMJ* 2011;**342**:d2712.

- 1
2
3 22. Diethelm K, Bolzenius K, Cheng G, et al. Longitudinal associations between reported
4
5 sleep duration in early childhood and the development of body mass index, fat mass
6
7 index and fat free mass index until age 7. *Int J Pediatr Obes* 2011;**6**:e114-23.
8
9 23. Cappuccio FP, Taggart FM, Kandala NB, et al. Meta-analysis of short sleep duration
10
11 and obesity in children and adults. *Sleep* 2008;**31**:619-26.
12
13 24. Hart CN, Jelalian E. Shortened sleep duration is associated with pediatric overweight.
14
15 *Behav Sleep Med* 2008;**6**:251-67.
16
17 25. Kempler L, Sharpe L, Miller CB, et al. Do psychosocial sleep interventions improve
18
19 infant sleep or maternal mood in the postnatal period? A systematic review and
20
21 meta-analysis of randomised controlled trials. *Sleep Med Rev* 2015;**29**:15-22.
22
23 26. Hall WA, Hutton E, Brant RF, et al. A randomized controlled trial of an intervention for
24
25 infants' behavioral sleep problems. *BMC Pediatr* 2015;**15**:181.
26
27 27. Kerr SM, Jowett SA, Smith LN. Preventing sleep problems in infants: a randomized
28
29 controlled trial. *J Adv Nurs* 1996;**24**:938-42.
30
31 32
33 28. Stremler R, Hodnett E, Kenton L, et al. Effect of behavioural-educational intervention
34
35 on sleep for primiparous women and their infants in early postpartum: multisite
36
37 randomised controlled trial. *BMJ* 2013;**346**:f1164.
38
39 29. Symon BG, Marley JE, Martin AJ, et al. Effect of a consultation teaching behaviour
40
41 modification on sleep performance in infants: a randomised controlled trial. *Med J*
42
43 *Aust* 2005;**182**:215-8.
44
45 30. Taylor BJ, Heath AL, Galland BC, et al. Prevention of Overweight in Infancy (POI.nz)
46
47 study: a randomised controlled trial of sleep, food and activity interventions for
48
49 preventing overweight from birth. *BMC Public Health* 2011;**11**:942.
50
51 31. Taylor BJ, Gray AR, Galland BC, et al. Targeting sleep, food, and activity in infants for
52
53 obesity prevention: An RCT. *Pediatrics* 2017;**139**:e20162037.
54
55
56
57
58
59
60

- 1
2
3 32. Sadeh A, Anders TF. Infant sleep problems: Origins, assessment, interventions. *Infant*
4
5 *Mental Health Journal* 1993;**14**:17-34.
6
7 33. Van Cauter E, Holmback U, Knutson K, et al. Impact of sleep and sleep loss on
8
9 neuroendocrine and metabolic function. *Horm Res* 2007;**67**:2-9.
10
11 34. Salmond C, Crampton P, Atkinson J. NZDep2006 Index of Deprivation. Wellington:
12
13 University of Otago. 2007.
14
15 35. Health. Mo. Indicators for the Well Child/Tamariki Ora quality improvement
16
17 framework—March 2014. Wellington, New Zealand: Ministry of Health; 2014.
18
19 36. Mindell JA, Telofski LS, Wiegand B, et al. A nightly bedtime routine: impact on sleep
20
21 in young children and maternal mood. *Sleep* 2009;**32**:599-606.
22
23 37. Galland BC, Gray A, Sayers RM, et al. Safe sleep practices in a New Zealand
24
25 community and development of a Sudden Unexpected Death in Infancy (SUDI) risk
26
27 assessment instrument. *BMC Pediatr* 2014;**14**:263.
28
29 38. Cameron SL, Heath AL, Gray AR, et al. Lactation Consultant Support from Late
30
31 Pregnancy with an Educational Intervention at 4 Months of Age Delays the
32
33 Introduction of Complementary Foods in a Randomized Controlled Trial. *J Nutr*
34
35 2015;**145**:1481-90.
36
37 39. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of
38
39 the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry* 1987;**150**:782-6.
40
41 40. Galland B, Meredith-Jones K, Gray A, et al. Criteria for nap identification in infants
42
43 and young children using 24-h actigraphy and agreement with parental diary. *Sleep*
44
45 *Med* 2016;**19**:85-92.
46
47 41. Kahan BC, Morris TP. Improper analysis of trials randomised using stratified blocks or
48
49 minimisation. *Stat Med* 2012;**31**:328-40.
50
51 42. Kahan BC. Bias in randomised factorial trials. *Stat Med* 2013;**32**:4540-9.
52
53
54
55
56
57
58
59
60

- 1
2
3 43. Murray D, Cox JL. Screening for depression during pregnancy with the Edinburgh
4
5 Depression Scale (EDDS). *J Reprod Infant Psychol* 1990;**8**:99-107.
6
7 44. Matthey S, Barnett B, Kavanagh DJ, et al. Validation of the Edinburgh Postnatal
8
9 Depression Scale for men, and comparison of item endorsement with their partners.
10
11 *J Affect Disord* 2001;**64**:175-84.
12
13 45. St James-Roberts I, Roberts M, Hovish K, et al. Video Evidence That London Infants
14
15 Can Resettle Themselves Back to Sleep After Waking in the Night, as well as Sleep
16
17 for Long Periods, by 3 Months of Age. *J Dev Behav Pediatr* 2015;**36**:324-9.
18
19 46. Hiscock H, Wake M. Infant sleep problems and postnatal depression: a community-
20
21 based study. *Pediatrics* 2001;**107**:1317-22.
22
23 47. Sadeh A. A brief screening questionnaire for infant sleep problems: validation and
24
25 findings for an Internet sample. *Pediatrics* 2004;**113**:e570-e77.
26
27 48. Adair R, Zuckerman B, Bauchner H, et al. Reducing night waking in infancy: a primary
28
29 care intervention. *Pediatrics* 1992;**89**:585-8.
30
31 49. Adachi Y, Sato C, Nishino N, et al. A brief parental education for shaping sleep habits
32
33 in 4-month-old infants. *Clin* 2009;**7**:85-92.
34
35 50. Wolfson A, Lacks P, Futterman A. Effects of parent training on infant sleeping patterns,
36
37 parents' stress, and perceived parental competence. *J Consult Clin Psychol*
38
39 1992;**60**:41-8.
40
41 51. Pinilla T, Birch LL. Help me make it through the night: behavioral entrainment of
42
43 breast-fed infants' sleep patterns. *Pediatrics* 1993;**91**:436-44.
44
45 52. Ottolini MC, Davis BE, Patel K, et al. Prone infant sleeping despite the "Back to Sleep"
46
47 campaign. *Arch Pediatr Adolesc Med* 1999;**153**:512-7.
48
49 53. Saririan S, Hauck FR. New recommendations to reduce the risk of SIDS: what should
50
51 we advise parents? *Am Fam Physician* 2006;**74**:1839-40.
52
53
54
55
56
57
58
59
60

- 1
2
3 54. Armstrong KL, Van Haeringen AR, Dadds MR, et al. Sleep deprivation or postnatal
4 depression in later infancy: separating the chicken from the egg. *J Paediatr Child*
5 *Health* 1998;**34**:260-2.
6
7
8
9 55. Lee KA, Zaffke ME, McEnany G. Parity and sleep patterns during and after pregnancy.
10 *Obstet Gynecol* 2000;**95**:14-8.
11
12
13 56. Signal TL, Gander PH, Sangalli MR, et al. Sleep duration and quality in healthy
14 nulliparous and multiparous women across pregnancy and post-partum. *Aust N Z J*
15 *Obstet Gynaecol* 2007;**47**:16-22.
16
17
18
19 57. Lee KA, Gay CL. Can modifications to the bedroom environment improve the sleep of
20 new parents? Two randomized controlled trials. *Res Nurs Health* 2011;**34**:7-19.
21
22
23
24 58. Whittingham K, Douglas P. Optimizing parent-infant sleep from birth to 6 months: a
25 new paradigm. *Infant Ment Health J* 2014;**35**:614-23.
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

¹MELAA refers to Middle Eastern, Latin American or African

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

³EPDS, 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

For peer review only

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 \geq 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 \geq 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

¹From a possible score of 1 (not nearly enough) to 8 (more than enough) thus higher score is better. Poor score \leq 3

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

Poor score \leq 3

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

	Control	FAB	Sleep	Combination	P value for Intervention	
					Δ 4 groups	Δ 2 groups*
Diary¹						
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 ^o 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 ^o 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
Actigraphy²						
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 ^o 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 ^o 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)

1
2
3
4 ** A primary outcome

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

6
7 ²Analyses use mean of 3-7 days (median 4 days) from 498 participants with available data

8
9 — No analyses due to interaction between Sleep and FAB groups
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

For peer review only

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

Outcome	Infant age		Control	FAB	Sleep	Combination	P value for Intervention	
	(months)	n					Δ 4 groups	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

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

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

³mean 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		Control	FAB	Sleep	Combination	P value for Intervention	
	(months)	n					Δ 4 groups	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)	0.622	0.395
	6	700	4.6 (1.4)	4.4 (1.5)	4.5 (1.4)	4.7 (1.5)		
Sleep quality score ²	4	719	5.6 (1.3)	5.2 (1.4)	5.3 (1.4)	5.3 (1.4)	0.192	0.831
	6	700	5.4 (1.5)	5.1 (1.3)	5.1 (1.3)	5.4 (1.5)		
Fatigue score ³	4	719	3.4 (0.8)	3.2 (0.9)	3.3 (0.9)	3.4 (0.8)	0.509	0.925
	6	696	3.3 (0.8)	3.1 (0.9)	3.2 (0.8)	3.3 (0.8)		
Sleep Duration (hr)	4	716	7.3 (1.3)	7.4 (1.4)	7.3 (1.2)	7.3 (1.1)	0.909	0.832
	6	697	7.2 (1.2)	7.1 (1.3)	7.2 (1.2)	7.2 (1.2)		
Sleep latency ≥ 30 min, n (%)	4	717	95 (49.0)	81 (45.0)	91 (52.9)	89 (52.1)	0.792	0.126
	6	700	101 (54.0)	93 (51.4)	90 (53.9)	93 (56.4)		
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)	0.787	0.524
	6	426	5.4 (1.1)	5.3 (1.2)	5.3 (1.4)	5.4 (1.2)		
Sleep quality score ²	4	470	4.8 (1.3)	4.7 (1.3)	4.6 (1.4)	4.9 (1.2)	0.275	0.801
	6	427	4.7 (1.3)	4.5 (1.3)	4.6 (1.3)	4.9 (1.1)		
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 \geq 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)

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

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

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

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

1
2
3 **Appendix 1.** Topics covered at the antenatal group session for the Sleep and
4 Combination groups
5

6
7 **Why sleep?**

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

10
11
12 **What's normal**

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

19
20
21 **Healthy sleep patterns**

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

30
31
32
33 **Safe sleeping**

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

43
44
45
46 **Looking after yourselves**

- 47 • Your rest and sleep is important too
 - 48 • Try to get a rest/sleep during the day
 - 49 • Meals in freezer
 - 50 • Limit visitors and looking after them
 - 51 • Accept offers of help
 - 52 • Go to bed early...soon after baby
- 53
54
55
56
57
58
59
60

1
2
3 **Appendix 2:** Topics covered at the one-to-one 3 week visit and included in booklet
4 for Sleep and Combination groups
5
6

7 **Introduction**

8 Benefits of sleep

9 Information applies to healthy, alert babies who are feeding and growing well

10 What we know about a baby's sleep:

11 Babies learn their sleep routines

12 Parents can teach their babies to be good sleepers

13 Babies need to be given a chance to settle by themselves

14 Some babies learn to sleep easily. Other babies need more help from
15 their parents.
16
17

18 **Normal sleep: What happens in the first year?**

19 How long should my baby sleep for?

20 Feeding-sleeping-waking patterns divided into four sections: 1st month,
21 2nd and 3rd month, 4th month, 6th month
22

23 What happens when baby is sleeping?

24 Baby's active and quiet sleep cycles and associated behaviours

25 Arousals between sleep cycles – brief or full waking
26
27

28 **General sleep and safety**

29 Basic safety tips for baby's sleeping place

30 Always place your baby on their back to sleep

31 Mattresses must be clean, firm and fit tightly into the frame of the cot

32 Do not use hot water bottles, electric blankets, pillows, big duvets or
33 lots of stuffed toys (there are risks of smothering and overheating)
34
35

36 Where is baby going to sleep?

37 Own cot/bassinet in parent(s) room is safest for first 3 months or
38 longer
39

40 Co-sleeping (sleeping with baby in the same bed)

41 Risks of co-sleeping for Sudden Unexplained Death in Infancy
42 (SUDI) within the NZ context outlined

43 Parental choice: If parent(s) chose to share their bed with their
44 baby, **make sure:**

45 Bed is in the middle of the room (not against a wall)

46 Mattress fits tight in the bed frame

47 **DO NOT co-sleep** if you or your partner:

48 Smoke

49 Drink alcohol

50 Use non-prescription drugs

51 Take any sedating drugs

52 Are excessively tired

53 Are a large person or overweight

54 or have a Duvet, other loose bedding or water bed
55
56
57

58 **Babys' tired signs**

59 Important to learn baby's tired signs
60

1
2
3 Signs of tiredness outlined
4 Act of tired signs to prevent overtiredness
5 Diagram showing cycle of feeding and sleeping well (content baby)
6 Diagram showing cycle of snack feeds and car naps (baby less content)
7
8

9 **Crying: what babies do**

10 Normal crying patterns during a baby's development
11 Normal crying patterns over the day
12 Why some babies cry a lot
13

14 **Helping baby learn to develop a healthy sleep pattern**

15 Establish a regular routine
16 Times may vary; predictable patterns within each feed/awake/sleep
17 cycle
18 Setting own 'sleep clock'
19 Day/night differences
20 Calm, Quiet and soothing behaviours at settling time
21 Notice tired signs early
22 Put baby into cot/bassinet awake and give baby the opportunity to learn to fall
23 asleep in their own
24 Avoid:
25 rocking, holding or feeding baby to sleep
26 bright lights, frantic and busy rocking and loud noises
27 too much "busy-ness" (lots of activity) whilst baby is falling asleep
28
29
30
31
32

33 **Settling a baby for sleep**

34 Flow diagram of steps to follow
35

36 **What if baby won't settle?**

37 Steps to follow outlined:
38 Remember to try and **stay calm**, and keep everything you do as **quiet**
39 and as **soothing** as you can in **dim lighting**
40 Don't take baby out of their cot immediately.
41 Try and let baby settle on their own. Allow around 2-3 minutes in the
42 first month, and 5 minutes at 3 months
43 If baby keeps grizzling then wait for a further 2 minutes (use a timer ...
44 during this time go and make a cup of tea, or tell yourself the time you
45 are going to wait and do a 2 minute activity e.g. TradeMe, YouTube,
46 another row of knitting, put away the dishes, anything but being by the
47 doorway waiting...) before going back to check your baby
48 If necessary, talk quietly, and stroke, rub or pat your baby gently and
49 see if this helps them quieten and settle
50 If they begin to calm and settle then leave the room
51 If baby starts to cry and 'wind up', baby may need another quiet feed
52 or a cuddle and then try settling again (as before)
53 If you know your baby is well fed, talk quietly as before and stroke,
54 rub or pat your baby gently and see if this helps them quieten and
55 settle. If they begin to calm and settle then leave the room
56
57
58
59
60

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 or 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.

1
2
3 **Appendix 1.** Topics covered at the antenatal group session for the Sleep and
4 Combination groups
5

6
7 **Why sleep?**

- 8 • Critical to a child's development, health and quality of life
9 • Good for parents' wellbeing and more
10

11
12 **What's normal**

- 13 • Waking frequently during the night
14 • Active and quiet sleep cycles
15 • Sleeping through the night – a milestone to look forward to
16 • Babies can learn their sleep routines
17 • Babies need to be given a chance to learn to settle themselves
18 • Some babies learn easily – others need more help
19

20
21 **Healthy sleep patterns**

- 22 • Try to set some limits on 'handling' of baby
23 • Establish some regular pattern
24 • Notice and act on baby's tired signs early
25 • Darken sleeping place day and night ('cue' for sleep time)
26 • Try to put baby into their bed awake
27 • Give baby a brief chance to settle by themselves/learn to go to sleep on their
28 own
29 • Keep night time quiet time – no 'play'
30
31

32
33 **Safe sleeping**

- 34 • Own sleep place in your room
35 • On back
36 • Clean firm tightly fitting mattress
37 • Keep cot clear of "extras"
38 • Co-sleeping is unsafe
39 ○ If mother smoked in pregnancy
40 ○ Adults (either) have been drinking, taking drugs, sedatives
41 ○ Baby is less than 3 months old (for smoking and non-smoking
42 mothers)
43
44
45

46 **Looking after yourselves**

- 47 • Your rest and sleep is important too
48 • Try to get a rest/sleep during the day
49 • Meals in freezer
50 • Limit visitors and looking after them
51 • Accept offers of help
52 • Go to bed early...soon after baby
53
54
55
56
57
58
59
60

1
2
3 **Appendix 2:** Topics covered at the one-to-one 3 week visit and included in booklet
4 for Sleep and Combination groups
5
6

7 **Introduction**

8 Benefits of sleep

9 Information applies to healthy, alert babies who are feeding and growing well

10 What we know about a baby's sleep:

11 Babies learn their sleep routines

12 Parents can teach their babies to be good sleepers

13 Babies need to be given a chance to settle by themselves

14 Some babies learn to sleep easily. Other babies need more help from
15 their parents.
16
17

18 **Normal sleep: What happens in the first year?**

19 How long should my baby sleep for?

20 Feeding-sleeping-waking patterns divided into four sections: 1st month,
21 2nd and 3rd month, 4th month, 6th month
22

23 What happens when baby is sleeping?

24 Baby's active and quiet sleep cycles and associated behaviours

25 Arousals between sleep cycles – brief or full waking
26
27

28 **General sleep and safety**

29 Basic safety tips for baby's sleeping place

30 Always place your baby on their back to sleep

31 Mattresses must be clean, firm and fit tightly into the frame of the cot

32 Do not use hot water bottles, electric blankets, pillows, big duvets or
33 lots of stuffed toys (there are risks of smothering and overheating)
34
35

36 Where is baby going to sleep?

37 Own cot/bassinet in parent(s) room is safest for first 3 months or
38 longer
39

40 Co-sleeping (sleeping with baby in the same bed)

41 Risks of co-sleeping for Sudden Unexplained Death in Infancy
42 (SUDI) within the NZ context outlined

43 Parental choice: If parent(s) chose to share their bed with their
44 baby, **make sure:**

45 Bed is in the middle of the room (not against a wall)

46 Mattress fits tight in the bed frame

47 **DO NOT co-sleep** if you or your partner:

48 Smoke

49 Drink alcohol

50 Use non-prescription drugs

51 Take any sedating drugs

52 Are excessively tired

53 Are a large person or overweight

54 or have a Duvet, other loose bedding or water bed
55
56
57

58 **Babys' tired signs**

59 Important to learn baby's tired signs
60

1
2
3 Signs of tiredness outlined
4 Act of tired signs to prevent overtiredness
5 Diagram showing cycle of feeding and sleeping well (content baby)
6 Diagram showing cycle of snack feeds and car naps (baby less content)
7
8

9 **Crying: what babies do**

10 Normal crying patterns during a baby's development
11 Normal crying patterns over the day
12 Why some babies cry a lot
13

14 **Helping baby learn to develop a healthy sleep pattern**

15 Establish a regular routine
16 Times may vary; predictable patterns within each feed/awake/sleep
17 cycle
18 Setting own 'sleep clock'
19 Day/night differences
20 Calm, Quiet and soothing behaviours at settling time
21 Notice tired signs early
22 Put baby into cot/bassinet awake and give baby the opportunity to learn to fall
23 asleep in their own
24 Avoid:
25 rocking, holding or feeding baby to sleep
26 bright lights, frantic and busy rocking and loud noises
27 too much "busy-ness" (lots of activity) whilst baby is falling asleep
28
29
30
31
32

33 **Settling a baby for sleep**

34 Flow diagram of steps to follow
35

36 **What if baby won't settle?**

37 Steps to follow outlined:
38 Remember to try and **stay calm**, and keep everything you do as **quiet**
39 and as **soothing** as you can in **dim lighting**
40 Don't take baby out of their cot immediately.
41 Try and let baby settle on their own. Allow around 2-3 minutes in the
42 first month, and 5 minutes at 3 months
43 If baby keeps grizzling then wait for a further 2 minutes (use a timer ...
44 during this time go and make a cup of tea, or tell yourself the time you
45 are going to wait and do a 2 minute activity e.g. TradeMe, YouTube,
46 another row of knitting, put away the dishes, anything but being by the
47 doorway waiting...) before going back to check your baby
48 If necessary, talk quietly, and stroke, rub or pat your baby gently and
49 see if this helps them quieten and settle
50 If they begin to calm and settle then leave the room
51 If baby starts to cry and 'wind up', baby may need another quiet feed
52 or a cuddle and then try settling again (as before)
53 If you know your baby is well fed, talk quietly as before and stroke,
54 rub or pat your baby gently and see if this helps them quieten and
55 settle. If they begin to calm and settle then leave the room
56
57
58
59
60

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 or 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.

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-014908.R2
Article Type:	Research
Date Submitted by the Author:	31-Mar-2017
Complete List of Authors:	Galland, Barbara; University of Otago, Women's and Children's Health Sayers, Rachel; University of Otago, Women's and Children's Health Cameron, Sonya; University of Otago, Human Nutrition Gray, Andrew; University of Otago, Preventive and Social Medicine Heath, Anne-Louise; University of Otago, Human Nutrition Lawrence, Julie; University of Otago, Women's and Children's Health Newlands, Alana; University of Otago, Human Nutrition Taylor, Barry; University of Otago, Women's and Children's Health Taylor, Rachael; University of Otago, Department of Medicine
Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Public health
Keywords:	actigraphy, intervention, night wakings, settling techniques, sleep duration, safe sleep

SCHOLARONE™
Manuscripts

only

Title:

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

Authors:

Galland BC¹, Sayers RM¹, Cameron SL¹, Gray AR², Heath A-LM³, Lawrence JA¹, Newlands A³, Taylor BJ¹, Taylor RW⁴.

Affiliations:

¹Department of Women's & Children's Health, University of Otago, Dunedin, New Zealand

²Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand

³Department of Human Nutrition, University of Otago, Dunedin, New Zealand

⁴Department of Medicine, University of Otago, Dunedin, New Zealand

Address for correspondence:

Associate Professor Barbara Galland, Department of Women's and Children's Health, University of Otago, PO Box 56, Dunedin 9018, New Zealand.

Email: barbara.galland@otago.ac.nz Ph: +64 21 2468 700

Word Count: 4053

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

1
2
3 did not. However, these small differences were not clinically significant, and not
4
5 observed in 24-hour infant sleep diary data. No other differences were observed.
6

7 **Conclusion:** A strategy delivering infant sleep education antenatally and at three
8
9 weeks postpartum was not effective in preventing the development of parent-reported
10
11 infant sleep problems.
12

13
14
15
16 **Key Words:** actigraphy, night wakings, safe sleep, settling techniques, sleep duration
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 about their infant's sleep.[26] Whether prevention of sleep problems might be more effective,
4
5 and potentially less costly, than attempts to treat established issues is largely unknown.
6
7 Randomised controlled trials emphasising the early establishment of positive sleep practices
8
9 have produced mixed findings to date.[2 ,27-29] These interventions were delivered
10
11 postnatally,[2 ,28 ,29] or at 3 months post-partum[27] and on a one-to-one basis. None were
12
13 delivered antenatally or within group sessions where families may be less stressed and more
14
15 receptive to the sleep education messages. Given that a large number of infants suffer sleep
16
17 problems and that the flow-on effects of these problems carry significant long-term costs to
18
19 individuals, it is pertinent to investigate the effectiveness of simple prevention strategies that
20
21 could be implemented as a public health measure through antenatal education and Well Child
22
23 services.
24
25
26
27

28
29 We recently undertook a four-armed randomised controlled trial (RCT), the Prevention of
30
31 Overweight in Infancy (POI) study,[30] to determine whether additional support and
32
33 education on food, activity, breastfeeding, and sleep from late pregnancy could reduce
34
35 overweight and obesity in children at two years of age. In exploratory analyses, the trial found
36
37 a protective effect for obesity among groups receiving the sleep intervention.[31] The exact
38
39 mechanisms by which sleep could influence obesity in early life are unclear, although the
40
41 ability of an infant to learn to self-regulate his/her own sleep is considered one of the earliest
42
43 biological markers of self-regulatory behaviours.[32] This enhanced sleep self-regulation
44
45 could conceivably help shape other self-regulatory behaviours linked to healthy weight. Other
46
47 potential mechanisms linked to insufficient sleep in children and adults include changes in
48
49 neurohormonal control of appetite regulation, impacts on dietary intake, and increased
50
51 sedentary activity –all favouring weight gain.[33]
52
53
54
55
56
57

58 The aim of this paper was to determine whether the infant sleep education programme
59
60

1
2
3 delivered antenatally and 3 weeks postpartum reduced the prevalence of parent-reported sleep
4
5 problems and night wakings, and influenced sleep duration in infants up to six months of age
6
7 (secondary outcomes of the RCT; ClinicalTrials.gov: NCT00892983). Other aims were to
8
9 determine any differences in infant self-settling and safe sleep practices, and maternal and
10
11 paternal reports of their own sleep, fatigue and depression symptoms (additional outcomes).
12
13

14 15 16 **METHODS**

17 18 **Study Design**

19
20 The Prevention of Overweight in Infancy (POI) study (Clinical Trials NCT00892983) was a
21
22 four-armed randomised controlled trial commencing in late pregnancy. Data from baseline
23
24 (third trimester) to 6 months of age are reported here.
25
26
27
28

29 30 **Participants and recruitment**

31
32 All mothers booked into the single maternity hospital (> 97% of all births) serving the city of
33
34 Dunedin, between May 2009 and November 2010 were potentially eligible. Letters of
35
36 invitation were sent to mothers at 28–30 weeks gestation and an “opt out” recruitment
37
38 strategy was used. Exclusion criteria applied before birth were: home address outside the
39
40 greater Dunedin area, planning to move away in the next two years, not booked with the
41
42 maternity centre or homebirth midwife before 34 weeks gestation, or unable to communicate
43
44 in English or Te Reo Māori (language of the indigenous people of New Zealand). Exclusion
45
46 criteria applied after birth were: identification of a congenital abnormality likely to affect
47
48 feeding or growth, or the infant being born before 36.5 weeks gestation.
49
50
51
52

53 54 **Randomisation**

55
56 Participants were randomised to one of four groups: i) usual care (Control); ii) food, activity
57
58 and breastfeeding intervention (FAB); iii) sleep intervention (Sleep), or iv) combined
59
60

1
2
3 intervention group receiving both the Sleep and FAB interventions (Combination). Details of
4
5 allocation concealment and stratification have been described previously,[30] but briefly,
6
7 stratification was based on household deprivation (tertiles: low [NZDep deciles 1–3],[34]
8
9 medium [4–7] and high [8–10]) and parity including the study child (1 vs ≥ 2). Group
10
11 allocation was revealed to the participants after they consented to participate. The statistician
12
13 remained blinded to group allocation codes until primary analyses were completed.
14
15

16 17 18 **Usual Care**

19
20 Families of all four groups received standard maternity and Well Child care from a maternity
21
22 care professional, and a Well Child provider of their choice. Well Child care[35] aims to
23
24 maximise the health and development of all New Zealand children up to age five years (on
25
26 average 8-9 visits in the first six months of life). The Control group received this usual care
27
28 only.
29
30
31

32 33 **Interventions**

34 35 **Sleep**

36
37 Families receiving the Sleep intervention (Sleep and Combination groups) received antenatal
38
39 education delivered via a single group session (up to 1 hour), followed by one home visit at
40
41 three weeks post-partum with a researcher with infant sleep training. Antenatal sessions
42
43 educated all mothers and most partners about normal developmental patterns of infant sleep
44
45 and emphasised infant settling to sleep unaided (i.e. self-settling or self-regulation of sleep)
46
47 which appears to be a key factor in the development of healthy sleep-wake patterns and a
48
49 precursor to longer sleep duration in later infancy;[36] and safe-sleep practices as measures to
50
51 prevent sudden unexpected death in infancy[37] (summarised in Appendix 1). Partners were
52
53 mostly fathers. Parents left equipped with a “tip sheet” related to the key education messages.
54
55 The individual sessions at the 3-week home visit reinforced the antenatal sleep education and
56
57
58
59
60

1
2
3 were conducted with the aid of a more detailed 15 page booklet covering the key messages for
4
5 developing healthy sleep and safe sleep practices (summarised in Appendix 2). At this visit,
6
7 researchers provided advice on any concerns the families had with their infant's sleep, and
8
9 parents were encouraged to keep using the booklet as a valuable resource, and contact
10
11 research staff at any stage should they require further sleep advice.
12
13

14 15 16 **FAB**

17
18 Mothers in the FAB group received three contacts providing education and support on
19
20 breastfeeding (antenatal, one week and four months postpartum) and one on physical activity
21
22 (three months postpartum) before 6 months of age. An International Board Certified Lactation
23
24 Consultant worked with each family to assist with infant feeding, focussing on prolonging
25
26 exclusive breastfeeding and delaying the introduction of complementary foods until around
27
28 six months of age. At three months, each family attended an Active Movement session
29
30 delivered by an established local sports body. The FAB intervention is described in more
31
32 detail elsewhere.[38]
33
34
35
36
37

38 39 **Combination**

40
41 This group received five intervention visits in total before 6 months of age as the FAB and
42
43 Sleep antenatal session was combined.
44
45
46

47 48 **Questionnaires**

49
50 Parents completed questionnaires during home visits at baseline (third trimester, prior to
51
52 allocation), and at 4 and 6 months. Questionnaires collected data relevant to outcomes of the
53
54 sleep education including ratings of the baby's problematic sleep and unsettled behaviour, and
55
56 of infant settling and safe sleep practices. Mothers and partners also rated perceptions of their
57
58 own sleep quantity and quality, and reported the usual time they went to bed, usual sleep time
59
60

1
2
3 (sleep onset) and usual wake time (sleep offset). Their sleep duration was calculated as the
4
5 difference between sleep onset and sleep offset. Sleep latency (time taken to fall asleep) was
6
7 calculated from the difference between the time they went to bed and sleep onset. Ratings of
8
9 maternal and partner fatigue and depression symptoms (Edinburgh Postnatal Depression
10
11 Scale; EPDS [39]) were also collected. Duration of exclusive breastfeeding (i.e. the infant
12
13 receiving no liquids, other than breast milk, and no solids since birth), was calculated as age
14
15 to the nearest part week from the monthly questionnaires.[30]
16
17
18
19

20 21 **Sleep Diary**

22
23 When the infant was 6 months of age, parents were asked to complete a 48-hour diary during
24
25 the 5-7 day period when actigraphy was also recorded (as described previously[40]). Time
26
27 was displayed horizontally in five-minute grid blocks. A parent was asked to indicate using an
28
29 arrow the time the infant went to sleep and awoke, including daytime naps. Grid block counts
30
31 with sleep and wake coding were then entered into a spreadsheet set up to automatically
32
33 calculate standard sleep-wake variables.
34
35
36
37

38 39 **Actigraphy**

40
41 Infants wore an Actical accelerometer (Mini-Mitter Co., Inc., Bend, OR) for 5-7 days fitted
42
43 on the shin. The accelerometers were initialized using 15-second epochs. Sleep onset (evening
44
45 sleep time) and morning sleep offset (wake time) events were ascertained visually from
46
47 activity graphs and marked in the sleep scoring program in MATLAB (MathWorks, Natick,
48
49 MA, USA), from which standard sleep-wake variables, including nap counts and nap duration
50
51 were determined using the count-scaled algorithm. A sleep period was defined as at least 20
52
53 minutes of sleep preceded by 5 minutes of awake with the sleep period altered for nap
54
55 detection between 9am and 5pm as previously described using a minimum nap time threshold
56
57 of 20 minutes.[40]
58
59
60

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

1
2
3 wakings, 24 hour or overnight sleep duration, longest sleep duration, sleep efficiency, or the
4
5 number of daytime naps.. Actigraphy data provided from 498 infants recorded significantly
6
7 fewer episodes of night waking and longer daytime sleep for infants in the groups receiving
8
9 sleep interventions (Sleep and Combination groups) compared to the groups who did not
10
11 receive the sleep intervention (Control and FAB groups). However the number of night
12
13 wakings was reduced by 8% and the sleep duration increase was only approximately 6
14
15 minutes. No other significant intervention effects were found for the actigraphy variables.
16
17 Exclusive breastfeeding duration (median 13 to 17 weeks) did not differ across the groups
18
19 ($p \geq 0.323$) and thus was not considered to be a covariate that might influence night waking.
20
21
22
23
24

25 *Problematic sleep*

26
27 There were no intervention effects on parental reports that their infant's sleep was
28
29 problematic (Table 4). In total, 16.1% (4 months) and 19.9% (6 months) of mothers reported
30
31 that their infant's sleep was a problem (rated as 5-8 on an 8-point scale). In partners (mostly
32
33 fathers), the prevalence was 11.7% (4 months) and 16.6% (6 months). Interestingly, there was
34
35 a lack of agreement between mothers and partners about whether or not their baby's sleep was
36
37 a moderate to large problem (kappa 0.25 and 0.29 respectively). At 4 months there was no
38
39 evidence of a difference between mothers and partners, but at 6 months mothers were
40
41 significantly more likely ($p=0.050$) to be the one reporting problems amongst the 94
42
43 discordant pairs (57 versus 37).
44
45
46
47
48

49 *Settling practices*

50
51 Practices relevant to sleep education on settling babies were not influenced by the
52
53 interventions (Table 4) although there was a non-statistically significant tendency for groups
54
55 who had received the sleep education (Sleep and Combination groups) to more frequently put
56
57 their baby to sleep awake ($p=0.052$). Overall more than half of the mothers reported high
58
59
60

1
2
3 scores (6-7 on a scale of 1-7) for the frequency of putting their baby to sleep awake (54.2%
4 and 60.3% at 4 and 6 months respectively), letting their baby fall asleep without them being
5 present (51.6% and 56.8% at 4 months and 6 months respectively), and the majority reported
6 being frequently able to recognise when their baby was tired (77.9% at 4 months and 83.2%
7 at 6 months). A small intervention effect was found for the time it took babies to go to sleep
8 (sleep latency; $p=0.038$) with significant differences in the prevalence of those reporting their
9 infant to usually take ≥ 30 minutes (i.e. a long sleep latency) to fall asleep at 6 months
10 ($p=0.015$). This was attributed to fewer infants in the Combination group (who received sleep
11 education) having long sleep latencies.
12
13
14
15
16
17
18
19
20
21
22
23

24 25 *Safe sleep practices*

26 Practices relevant to safe-sleep messages were not influenced by the interventions (Table 4).
27 Regular bedsharing was only practiced by a minority; overall 6.4% at 6 months. The majority
28 of infants slept on their back, following recommended practices and few families smoked in
29 the car while children were present or smoked in the household, with numbers too low for
30 analyses. Data from the control arm of the study for these safe sleep variables at infant ages 3
31 to 23 weeks have been published previously.[37]
32
33
34
35
36
37
38
39
40
41
42

43 *Maternal and partner outcomes*

44 At infant age 6 months, there were no differences between intervention groups for maternal or
45 partner sleep quantity, their sleep-rated quality, nor the prevalence of long sleep latency (≥ 30
46 minutes) (Table 5). Similarly, scores from the maternal EPDS attained when the infant was 4
47 months of age and adjusted for baseline EPDS score, were the same across groups. Maternal
48 fatigue produced mixed results at different time points with any differences observed being
49 too small to be of clinical importance. In addition, no differences in fatigue scores were
50
51
52
53
54
55
56
57
58
59
60

1
2
3 apparent between those who received the Sleep intervention (Sleep and Combination) and
4
5 those who did not (FAB and Control).
6
7

8 9 **DISCUSSION**

10
11 Within this randomised controlled study, a brief sleep intervention consisting of antenatal
12
13 education and a 3-week home visit was not effective in preventing infant sleep problems,
14
15 when compared to standard care. A key education target was to encourage infants to self-
16
17 settle to sleep.[45] There was a tendency towards those groups that received the sleep
18
19 intervention being more likely to put their baby down to sleep awake but the differences were
20
21 not statistically significant ($p=0.052$). We found some evidence that the sleep intervention
22
23 influenced actigraphy-derived infant sleep patterns by significantly reducing the number of
24
25 night wakings, and lengthening daytime sleep, but the small size of the differences
26
27 encountered means they are unlikely to be clinically significant. Parental sleep, fatigue and
28
29 parental symptoms of depression were not affected by the interventions.
30
31
32
33
34
35

36
37 Twenty percent of mothers reported that their 6 month-old infant's sleep was problematic for
38
39 them, which is similar to other studies reporting a prevalence of 16 to 38% within the first
40
41 year of life.[1-3] Parent-rated problematic sleep is a strong predictor of frequent and
42
43 prolonged night wakings and difficulty settling to sleep.[46 ,47] Here we also collected data
44
45 on partners (mostly fathers), and almost as many partners (17%) as mothers (20%) reported
46
47 their child's sleep was a problem for them at 6 months of age, although there was significant
48
49 discordance in mother-partner pairs. Few studies report children's problematic sleep from the
50
51 partners' or fathers' perspective, but there is evidence suggesting a link between sleep
52
53 problems in four- to five-year-old children and poorer paternal general health.[10]
54
55
56
57
58
59
60

1
2
3 There was limited room for improvement for some behaviours. For example, at 6 months,
4 more than two-thirds of the parents who were in a group that did not receive the sleep
5 intervention frequently practiced behaviours considered to be key intervention targets such as
6 putting their baby to sleep awake or letting their baby fall asleep without a parent being
7 present. Approximately 80% of mothers reported that they could frequently recognise when
8 their infant was tired suggesting this may be an ineffective target to achieve change in this
9 study population. However, we could not objectively measure the extent to which parents
10 recognised the signs of tiredness, nor their ability to recognise the signs early enough to
11 intervene effectively.
12
13
14
15
16
17
18
19
20
21
22
23
24

25 Although there are few studies to compare our data with directly, some target behaviours
26 were more commonly practiced than those reported in a similar Australian RCT[2] with
27 follow-up also at 6 months of age. In that study, 11% of parents in the control group
28 consistently allowed their baby to fall asleep without being present (a top ranking of 5 on a 1-
29 5 point scale of frequency). In our study 26% of parents in the control group rated this
30 behaviour with a top ranking of 7 on a 1-7 point scale of frequency. Similarly, in the
31 Australian study,[2] 23% stated they could always recognise tired signs in their infant (top
32 ranking 5) compared to our 44% (top ranking 7). These data perhaps reflect that mothers in
33 our study were well educated with 65% having a University degree and with free access to a
34 strong Well Child support service offered at multiple time points across the first six months of
35 life.[35] More closely aligned was the prevalence of settling baby to sleep while awake: 33%
36 of control children in the Australian study[2] compared to 27% in our study gave this the top
37 ranking.
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55

56 Four large RCTs have employed similar preventive strategies with a similar number of
57 contact points,[2,27-29] (albeit intervening immediately after birth or up to 3 months of age).
58
59
60

1
2
3 The outcomes of these studies, and the current one, lead us to suggest that preventive
4 strategies may only confer benefit when delivered beyond the antenatal or immediate
5 newborn period i.e. once parents have had time to understand their infants' sleep behaviours
6 and patterns. One RCT intervening immediately after birth in primiparous women found no
7 differences in infant sleep or maternal outcomes at follow-up (6 and 12 weeks post-
8 partum),[28] whereas three RCTs intervening at 2-3 weeks,[29] 4 weeks[2] and 3 months
9 post-partum,[27] resulted in longer infant sleep,[2] fewer symptoms of maternal
10 depression,[2] less infant crying,[2,29] and fewer infants with sleep problems,[2] settling
11 difficulties and night wakings[27] at follow-up. Similar positive outcomes have been found in
12 other study designs (non-RCTs) employing preventive strategies and when the interventions
13 were delivered at a later time point (4 months of age).[48,49] Other small trials with several
14 more follow-up contacts have focussed on preventive strategies in target groups e.g.
15 primiparous women[50,51] or mothers of breast-fed infants,[51] reporting some successes
16 with infants "sleeping through the night" earlier[51] and reduced parental wakings and
17 enhanced stability of early but not later sleep patterns.[50] As suggested by others, increasing
18 the "dose" of intervention may be important as may be targeting high risk infants in more
19 need of sleep interventions.[28]

20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43 The additional antenatal and postnatal education around safe sleep practices provided by the
44 POI study made no difference to practice, but again the ceiling for improvement was limited.
45 Some have suggested that safe sleep education should be started during pregnancy and should
46 be consistently reinforced throughout the first year.[52,53] Our study data indicated that safe
47 sleep messages are reaching our community and further reinforcement of messages beyond
48 standard Well Child care would confer no additional benefit, but we acknowledge that this
49 may be important in other communities or cultures where unsafe sleep practices are more
50 common.
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5 Outcomes related to parental depression symptoms, although not significant, were important
6
7 to consider given that sleep disturbance is considered a risk factor for post-natal
8
9 depression[54] and a previous preventive strategy has been effective in reducing maternal
10
11 depression symptoms.[2] Maternal and partner subjective sleep quantity and quality, as well
12
13 as symptoms of depression, were not influenced by the intervention. For mothers who have
14
15 already been exposed to sleep disturbance during pregnancy, particularly within the last
16
17 trimester,[55] the naturally shorter sleep-wake patterns of infants can further contribute to
18
19 their own sleep loss with estimates of up to 1.5 hours of sleep lost over 24 hours in the early
20
21 postnatal period.[56] In the current study, self-reported usual overnight sleep duration was
22
23 reduced approximately 1 hour on average from the third trimester to 4 months post-partum,
24
25 and in partners by approximately 36 minutes over the same time period. However we did not
26
27 collect data on daytime napping and therefore cannot ascertain if any nighttime sleep loss was
28
29 counterbalanced by daytime gain.
30
31
32
33
34
35

36 The study had some important limitations. First, the results are limited to young infants in a
37
38 well-educated community thereby reducing the generalisability of the findings. Second, the
39
40 sleep education was targeting some practices that were expected to be common practice
41
42 leaving relatively little room for improvement. However, the prevalence of sleep problems in
43
44 our participants was just as high as elsewhere, suggesting there is still much benefit to be
45
46 gained from Well Child or other services delivering sleep education. A different focus might
47
48 be necessary for measureable gains, for example targeting more socially disadvantaged
49
50 groups and focussing on parental sleep, where small gains have been observed.[57]
51
52 Furthermore, subjective reports of parental sleep practices related to our education targets,
53
54 such as infant self-settling, may not be accurate enough and more objective tools for
55
56 measuring this are required. Study strengths include the randomised and controlled nature of
57
58
59
60

1
2
3 the trial, high recruitment rates and retention, the longitudinal nature of the study, novel
4
5 collection of data around parents' own sleep and inclusion of the partner/father.
6
7

8
9
10 In conclusion, the sleep intervention administered as a prevention strategy and conducted as
11
12 part of a randomised controlled trial in the POI study was not effective in preventing sleep
13
14 problems in infants. The antenatal period may be too early to intervene successfully with
15
16 sleep where the priority focus for families is on the impending birth. Finally, although our
17
18 study, like so many others, focused on trying to achieve behaviour change through education,
19
20 we acknowledge that alternative paradigms to preventing or treating sleep problems in infants
21
22 have been suggested. In these alternative paradigms, infant night-waking in the first 6 months
23
24 is considered to be normal, and a range of strategies are used to help parents become more
25
26 synchronized with their babies' sleep-wake needs, and make decisions about what is right for
27
28 them in their own unique situation with their own unique baby.[58]
29
30
31
32
33
34
35

36 **Acknowledgements.** We thank the families and their infants who participated in this study.
37
38 We also gratefully acknowledge the research assistance of Catherine Barker, Barbara
39
40 Churcher, Rhondda Davies, Maha Hanna, Carmen Lobb, Michelle McGrath, Amelia Needs,
41
42 Susan Peters, Nick Prosser, Megan Somerville, Bronwyn Thomas.
43
44
45
46

47 **Contributions.** BJT, BG and RS led the Sleep intervention, and RWT and ALH led the FAB
48
49 intervention. SLC contributed to writing the manuscript. ARG designed and completed all
50
51 statistical analyses and wrote the relevant sections of the manuscript. JL coordinated and led
52
53 the management of the study. AN was involved in data collection. All authors had intellectual
54
55 input into the manuscript, commented on drafts, and approved the final version.
56
57
58
59
60

1
2
3 **Funding:** This study was funded by the Health Research Council of New Zealand (grant
4 08/374) and the Southern District Health Board. RT is supported by the KPS Fellowship in
5 Early Childhood Obesity. SLC was supported by a University of Otago Health Sciences
6 postdoctoral fellowship. The funders had no role in study design; or in the collection,
7 analysis, and interpretation of data; or in the writing of the report or the decision to submit the
8 article for publication.
9
10
11
12
13
14
15
16
17

18 **Ethical Approval:** The study was approved by the New Zealand Lower South Regional
19 Ethics Committee (LRS/08/12/ 063) and all adult participants gave written informed consent
20 on behalf of themselves and their babies.
21
22
23
24
25
26

27 **Competing Interests:** None to declare
28
29
30
31

32 **Data sharing:** No additional data available.
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

REFERENCES

1. Wake M, Morton-Allen E, Poulakis Z, et al. Prevalence, stability, and outcomes of cry-fuss and sleep problems in the first 2 years of life: prospective community-based study. *Pediatrics* 2006;**117**:836-42.
2. Hiscock H, Cook F, Bayer J, et al. Preventing early infant sleep and crying problems and postnatal depression: a randomized trial. *Pediatrics* 2014;**133**:e346-54.
3. Armstrong KL, Quinn RA, Dadds MR. The sleep patterns of normal children. *Med J Aust* 1994;**161**:202-6.
4. Evanoo G. Infant crying: a clinical conundrum. *J Pediatr Health Care* 2007;**21**:333-8.
5. St James-Roberts I, Halil T. Infant crying patterns in the first year: normal community and clinical findings. *J Child Psychol Psychiatry* 1991;**32**:951-68.
6. Forsyth BW, Leventhal JM, McCarthy PL. Mothers' perceptions of problems of feeding and crying behaviors. A prospective study. *Am J Dis Child* 1985;**139**:269-72.
7. Touchette E, Cote SM, Petit D, et al. Short nighttime sleep-duration and hyperactivity trajectories in early childhood. *Pediatrics* 2009;**124**:e985-93.
8. Hiscock H, Bayer J, Gold L, et al. Improving infant sleep and maternal mental health: a cluster randomised trial. *Arch Dis Child* 2007;**92**:952-8.
9. Giallo R, Rose N, Vittorino R. Fatigue, wellbeing and parenting in mothers of infants and toddlers with sleep problems. *J Reprod Infant Psychol* 2011;**29**:236-49.
10. Martin J, Hiscock H, Hardy P, et al. Adverse associations of infant and child sleep problems and parent health: an Australian population study. *Pediatrics* 2007;**119**:947-55.
11. Sadeh A, Tikotzky L, Scher A. Parenting and infant sleep. *Sleep Med Rev* 2010;**14**:89-96.

- 1
2
3 12. Touchette E, Petit D, Paquet J, et al. Factors associated with fragmented sleep at night
4 across early childhood. *Arch Pediatr Adolesc Med* 2005;**159**:242-9.
5
6
7 13. Zuckerman B, Stevenson J, Bailey V. Sleep problems in early childhood: continuities,
8 predictive factors, and behavioral correlates. *Pediatrics* 1987;**80**:664-71.
9
10 14. Kataria S, Swanson MS, Trevathan GE. Persistence of sleep disturbances in preschool
11 children. *J Pediatr* 1987;**110**:642-6.
12
13 15. Pollock JI. Night-waking at five years of age: predictors and prognosis. *J Child Psychol*
14 *Psychiatry* 1994;**35**:699-708.
15
16 16. Turnbull K, Reid GJ, Morton JB. Behavioral sleep problems and their potential impact
17 on developing executive function in children. *Sleep* 2013;**36**:1077-84.
18
19 17. Touchette E, Petit D, Seguin JR, et al. Associations between sleep duration patterns and
20 behavioral/cognitive functioning at school entry. *Sleep* 2007;**30**:1213-9.
21
22 18. Gruber R, Laviolette R, Deluca P, et al. Short sleep duration is associated with poor
23 performance on IQ measures in healthy school-age children. *Sleep Med*
24 2010;**11**:289-94.
25
26 19. Smedje H, Broman JE, Hetta J. Associations between disturbed sleep and behavioural
27 difficulties in 635 children aged six to eight years: a study based on parents'
28 perceptions. *Eur Child Adolesc Psychiatry* 2001;**10**:1-9.
29
30 20. Hiscock H, Canterford L, Ukoumunne OC, et al. Adverse associations of sleep
31 problems in Australian preschoolers: national population study. *Pediatrics*
32 2007;**119**:86-93.
33
34 21. Carter PJ, Taylor BJ, Williams SM, et al. Longitudinal analysis of sleep in relation to
35 BMI and body fat in children: the FLAME study. *BMJ* 2011;**342**:d2712.
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 22. Diethelm K, Bolzenius K, Cheng G, et al. Longitudinal associations between reported
4
5 sleep duration in early childhood and the development of body mass index, fat mass
6
7 index and fat free mass index until age 7. *Int J Pediatr Obes* 2011;**6**:e114-23.
8
9
10 23. Cappuccio FP, Taggart FM, Kandala NB, et al. Meta-analysis of short sleep duration
11
12 and obesity in children and adults. *Sleep* 2008;**31**:619-26.
13
14 24. Hart CN, Jelalian E. Shortened sleep duration is associated with pediatric overweight.
15
16 *Behav Sleep Med* 2008;**6**:251-67.
17
18 25. Kempler L, Sharpe L, Miller CB, et al. Do psychosocial sleep interventions improve
19
20 infant sleep or maternal mood in the postnatal period? A systematic review and
21
22 meta-analysis of randomised controlled trials. *Sleep Med Rev* 2015;**29**:15-22.
23
24 26. Hall WA, Hutton E, Brant RF, et al. A randomized controlled trial of an intervention for
25
26 infants' behavioral sleep problems. *BMC Pediatr* 2015;**15**:181.
27
28 27. Kerr SM, Jowett SA, Smith LN. Preventing sleep problems in infants: a randomized
29
30 controlled trial. *J Adv Nurs* 1996;**24**:938-42.
31
32 28. Stremler R, Hodnett E, Kenton L, et al. Effect of behavioural-educational intervention
33
34 on sleep for primiparous women and their infants in early postpartum: multisite
35
36 randomised controlled trial. *BMJ* 2013;**346**:f1164.
37
38 29. Symon BG, Marley JE, Martin AJ, et al. Effect of a consultation teaching behaviour
39
40 modification on sleep performance in infants: a randomised controlled trial. *Med J*
41
42 *Aust* 2005;**182**:215-8.
43
44 30. Taylor BJ, Heath AL, Galland BC, et al. Prevention of Overweight in Infancy (POI.nz)
45
46 study: a randomised controlled trial of sleep, food and activity interventions for
47
48 preventing overweight from birth. *BMC Public Health* 2011;**11**:942.
49
50 31. Taylor BJ, Gray AR, Galland BC, et al. Targeting sleep, food, and activity in infants for
51
52 obesity prevention: An RCT. *Pediatrics* 2017;**139**:e20162037.
53
54
55
56
57
58
59
60

- 1
2
3 32. Sadeh A, Anders TF. Infant sleep problems: Origins, assessment, interventions. *Infant*
4
5 *Mental Health Journal* 1993;**14**:17-34.
6
7 33. Van Cauter E, Holmback U, Knutson K, et al. Impact of sleep and sleep loss on
8
9 neuroendocrine and metabolic function. *Horm Res* 2007;**67**:2-9.
10
11 34. Salmond C, Crampton P, Atkinson J. NZDep2006 Index of Deprivation. Wellington:
12
13 University of Otago. 2007.
14
15 35. Health. Mo. Indicators for the Well Child/Tamariki Ora quality improvement
16
17 framework—March 2014. Wellington, New Zealand: Ministry of Health; 2014.
18
19 36. Mindell JA, Telofski LS, Wiegand B, et al. A nightly bedtime routine: impact on sleep
20
21 in young children and maternal mood. *Sleep* 2009;**32**:599-606.
22
23 37. Galland BC, Gray A, Sayers RM, et al. Safe sleep practices in a New Zealand
24
25 community and development of a Sudden Unexpected Death in Infancy (SUDI) risk
26
27 assessment instrument. *BMC Pediatr* 2014;**14**:263.
28
29 38. Cameron SL, Heath AL, Gray AR, et al. Lactation Consultant Support from Late
30
31 Pregnancy with an Educational Intervention at 4 Months of Age Delays the
32
33 Introduction of Complementary Foods in a Randomized Controlled Trial. *J Nutr*
34
35 2015;**145**:1481-90.
36
37 39. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of
38
39 the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry* 1987;**150**:782-6.
40
41 40. Galland B, Meredith-Jones K, Gray A, et al. Criteria for nap identification in infants
42
43 and young children using 24-h actigraphy and agreement with parental diary. *Sleep*
44
45 *Med* 2016;**19**:85-92.
46
47 41. Kahan BC, Morris TP. Improper analysis of trials randomised using stratified blocks or
48
49 minimisation. *Stat Med* 2012;**31**:328-40.
50
51 42. Kahan BC. Bias in randomised factorial trials. *Stat Med* 2013;**32**:4540-9.
52
53
54
55
56
57
58
59
60

- 1
2
3 43. Murray D, Cox JL. Screening for depression during pregnancy with the Edinburgh
4
5 Depression Scale (EDDS). *J Reprod Infant Psychol* 1990;**8**:99-107.
6
7
8 44. Matthey S, Barnett B, Kavanagh DJ, et al. Validation of the Edinburgh Postnatal
9
10 Depression Scale for men, and comparison of item endorsement with their partners.
11
12 *J Affect Disord* 2001;**64**:175-84.
13
14 45. St James-Roberts I, Roberts M, Hovish K, et al. Video Evidence That London Infants
15
16 Can Resettle Themselves Back to Sleep After Waking in the Night, as well as Sleep
17
18 for Long Periods, by 3 Months of Age. *J Dev Behav Pediatr* 2015;**36**:324-9.
19
20
21 46. Hiscock H, Wake M. Infant sleep problems and postnatal depression: a community-
22
23 based study. *Pediatrics* 2001;**107**:1317-22.
24
25
26 47. Sadeh A. A brief screening questionnaire for infant sleep problems: validation and
27
28 findings for an Internet sample. *Pediatrics* 2004;**113**:e570-e77.
29
30 48. Adair R, Zuckerman B, Bauchner H, et al. Reducing night waking in infancy: a primary
31
32 care intervention. *Pediatrics* 1992;**89**:585-8.
33
34 49. Adachi Y, Sato C, Nishino N, et al. A brief parental education for shaping sleep habits
35
36 in 4-month-old infants. *Clin* 2009;**7**:85-92.
37
38
39 50. Wolfson A, Lacks P, Futterman A. Effects of parent training on infant sleeping patterns,
40
41 parents' stress, and perceived parental competence. *J Consult Clin Psychol*
42
43 1992;**60**:41-8.
44
45 51. Pinilla T, Birch LL. Help me make it through the night: behavioral entrainment of
46
47 breast-fed infants' sleep patterns. *Pediatrics* 1993;**91**:436-44.
48
49 52. Ottolini MC, Davis BE, Patel K, et al. Prone infant sleeping despite the "Back to Sleep"
50
51 campaign. *Arch Pediatr Adolesc Med* 1999;**153**:512-7.
52
53
54 53. Saririan S, Hauck FR. New recommendations to reduce the risk of SIDS: what should
55
56 we advise parents? *Am Fam Physician* 2006;**74**:1839-40.
57
58
59
60

- 1
2
3 54. Armstrong KL, Van Haeringen AR, Dadds MR, et al. Sleep deprivation or postnatal
4
5 depression in later infancy: separating the chicken from the egg. *J Paediatr Child*
6
7 *Health* 1998;**34**:260-2.
8
9
10 55. Lee KA, Zaffke ME, McEnany G. Parity and sleep patterns during and after pregnancy.
11
12 *Obstet Gynecol* 2000;**95**:14-8.
13
14 56. Signal TL, Gander PH, Sangalli MR, et al. Sleep duration and quality in healthy
15
16 nulliparous and multiparous women across pregnancy and post-partum. *Aust N Z J*
17
18 *Obstet Gynaecol* 2007;**47**:16-22.
19
20 57. Lee KA, Gay CL. Can modifications to the bedroom environment improve the sleep of
21
22 new parents? Two randomized controlled trials. *Res Nurs Health* 2011;**34**:7-19.
23
24
25 58. Whittingham K, Douglas P. Optimizing parent-infant sleep from birth to 6 months: a
26
27 new paradigm. *Infant Ment Health J* 2014;**35**:614-23.
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

¹MELAA refers to Middle Eastern, Latin American or African

²Secondary schooling in New Zealand is from year 9 to 13 inclusive, post-secondary qualifications refer to all those that are non-University based.

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

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

For peer review only

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 \geq 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 \geq 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

¹From a possible score of 1 (not nearly enough) to 8 (more than enough) thus higher score is better. Poor score \leq 3

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

Poor score \leq 3

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

	Control	FAB	Sleep	Combination	P value for Intervention	
					Δ 4 groups	Δ 2 groups*
Diary¹						
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 ^o 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 ^o 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
Actigraphy²						
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 ^o 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 ^o 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)

1
2
3
4 **Secondary outcome to the main RCT.[30] All others variables are additional outcomes

5
6 ¹Analyses use mean of two days from 507 participants with available data

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

9
10 — No analyses due to interaction between Sleep and FAB groups
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45

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	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

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

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

³mean 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		Control	FAB	Sleep	Combination	P value for Intervention	
	(months)	n					Δ 4 groups	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)	0.622	0.395
	6	700	4.6 (1.4)	4.4 (1.5)	4.5 (1.4)	4.7 (1.5)		
Sleep quality score ²	4	719	5.6 (1.3)	5.2 (1.4)	5.3 (1.4)	5.3 (1.4)	0.192	0.831
	6	700	5.4 (1.5)	5.1 (1.3)	5.1 (1.3)	5.4 (1.5)		
Fatigue score ³	4	719	3.4 (0.8)	3.2 (0.9)	3.3 (0.9)	3.4 (0.8)	0.509	0.925
	6	696	3.3 (0.8)	3.1 (0.9)	3.2 (0.8)	3.3 (0.8)		
Sleep Duration (hr)	4	716	7.3 (1.3)	7.4 (1.4)	7.3 (1.2)	7.3 (1.1)	0.909	0.832
	6	697	7.2 (1.2)	7.1 (1.3)	7.2 (1.2)	7.2 (1.2)		
Sleep latency ≥ 30 min, n (%)	4	717	95 (49.0)	81 (45.0)	91 (52.9)	89 (52.1)	0.792	0.126
	6	700	101 (54.0)	93 (51.4)	90 (53.9)	93 (56.4)		
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)	0.787	0.524
	6	426	5.4 (1.1)	5.3 (1.2)	5.3 (1.4)	5.4 (1.2)		
Sleep quality score ²	4	470	4.8 (1.3)	4.7 (1.3)	4.6 (1.4)	4.9 (1.2)	0.275	0.801
	6	427	4.7 (1.3)	4.5 (1.3)	4.6 (1.3)	4.9 (1.1)		
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 \geq 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 variables are additional outcomes of the main RCT[30]

*“Sleep” (Control and FAB combined) vs “No Sleep” (Sleep and Combination combined)

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

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

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

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

1
2
3 **Appendix 1.** Topics covered at the antenatal group session for the Sleep and
4 Combination groups
5

6
7 **Why sleep?**

- 8
 - Critical to a child's development, health and quality of life
 - Good for parents' wellbeing and more

9
10

11
12 **What's normal**

- 13
 - 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

14
15
16
17
18
19
20
21

22 **Healthy sleep patterns**

- 23
 - 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'

24
25
26
27
28
29
30
31
32
33

34 **Safe sleeping**

- 35
 - 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)

36
37
38
39
40
41
42
43
44
45
46
47

48 **Looking after yourselves**

- 49
 - 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

50
51
52
53
54
55
56
57
58
59
60

1
2
3 **Appendix 2:** Topics covered at the one-to-one 3 week visit and included in booklet
4 for Sleep and Combination groups
5
6

7 **Introduction**

8 Benefits of sleep

9 Information applies to healthy, alert babies who are feeding and growing well

10 What we know about a baby's sleep:

11 Babies learn their sleep routines

12 Parents can teach their babies to be good sleepers

13 Babies need to be given a chance to settle by themselves

14 Some babies learn to sleep easily. Other babies need more help from
15 their parents.
16
17

18 **Normal sleep: What happens in the first year?**

19 How long should my baby sleep for?

20 Feeding-sleeping-waking patterns divided into four sections: 1st month,
21 2nd and 3rd month, 4th month, 6th month
22

23 What happens when baby is sleeping?

24 Baby's active and quiet sleep cycles and associated behaviours

25 Arousals between sleep cycles – brief or full waking
26
27
28

29 **General sleep and safety**

30 Basic safety tips for baby's sleeping place

31 Always place your baby on their back to sleep

32 Mattresses must be clean, firm and fit tightly into the frame of the cot

33 Do not use hot water bottles, electric blankets, pillows, big duvets or
34 lots of stuffed toys (there are risks of smothering and overheating)
35
36
37

38 Where is baby going to sleep?

39 Own cot/bassinet in parent(s) room is safest for first 3 months or
40 longer

41 Co-sleeping (sleeping with baby in the same bed)

42 Risks of co-sleeping for Sudden Unexplained Death in Infancy
43 (SUDI) within the NZ context outlined

44 Parental choice: If parent(s) chose to share their bed with their
45 baby, **make sure:**

46 Bed is in the middle of the room (not against a wall)

47 Mattress fits tight in the bed frame

48 **DO NOT co-sleep** if you or your partner:

49 Smoke

50 Drink alcohol

51 Use non-prescription drugs

52 Take any sedating drugs

53 Are excessively tired

54 Are a large person or overweight

55 or have a Duvet, other loose bedding or water bed
56
57
58
59
60

Babys' tired signs

Important to learn baby's tired signs

1
2
3 Signs of tiredness outlined
4 Act of tired signs to prevent overtiredness
5 Diagram showing cycle of feeding and sleeping well (content baby)
6 Diagram showing cycle of snack feeds and car naps (baby less content)
7
8

9 **Crying: what babies do**

10 Normal crying patterns during a baby's development
11 Normal crying patterns over the day
12 Why some babies cry a lot
13
14

15 **Helping baby learn to develop a healthy sleep pattern**

16 Establish a regular routine
17 Times may vary; predictable patterns within each feed/awake/sleep
18 cycle
19 Setting own 'sleep clock'
20 Day/night differences
21 Calm, Quiet and soothing behaviours at settling time
22 Notice tired signs early
23 Put baby into cot/bassinet awake and give baby the opportunity to learn to fall
24 asleep in their own
25 Avoid:
26 rocking, holding or feeding baby to sleep
27 bright lights, frantic and busy rocking and loud noises
28 too much "busy-ness" (lots of activity) whilst baby is falling asleep
29
30
31
32
33

34 **Settling a baby for sleep**

35 Flow diagram of steps to follow
36
37

38 **What if baby won't settle?**

39 Steps to follow outlined:
40 Remember to try and **stay calm**, and keep everything you do as **quiet**
41 and as **soothing** as you can in **dim lighting**
42 Don't take baby out of their cot immediately.
43 Try and let baby settle on their own. Allow around 2-3 minutes in the
44 first month, and 5 minutes at 3 months
45 If baby keeps grizzling then wait for a further 2 minutes (use a timer ...
46 during this time go and make a cup of tea, or tell yourself the time you
47 are going to wait and do a 2 minute activity e.g. TradeMe, YouTube,
48 another row of knitting, put away the dishes, anything but being by the
49 doorway waiting...) before going back to check your baby
50 If necessary, talk quietly, and stroke, rub or pat your baby gently and
51 see if this helps them quieten and settle
52 If they begin to calm and settle then leave the room
53 If baby starts to cry and 'wind up', baby may need another quiet feed
54 or a cuddle and then try settling again (as before)
55 If you know your baby is well fed, talk quietly as before and stroke,
56 rub or pat your baby gently and see if this helps them quieten and
57 settle. If they begin to calm and settle then leave the room
58
59
60

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 or 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.