

## RESEARCH

# Effect of behavioural-educational intervention on sleep for primiparous women and their infants in early postpartum: multisite randomised controlled trial

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Robyn Stremler *assistant professor and adjunct scientist*<sup>1,2</sup>, Ellen Hodnett *professor*<sup>1</sup>, Laura Kenton *trial coordinator*<sup>1</sup>, Kathryn Lee *professor*<sup>3</sup>, Shelly Weiss *staff neurologist and assistant professor*<sup>2,4</sup>, Julie Weston *senior trial coordinator*<sup>1</sup>, Andrew Willan *senior scientist and professor*<sup>2,5</sup>

<sup>1</sup>Lawrence S Bloomberg Faculty of Nursing, University of Toronto, Toronto, ON, Canada; <sup>2</sup>Hospital for Sick Children (SickKids), Toronto, ON, Canada; <sup>3</sup>Department of Family Health Care Nursing, University of San Francisco, CA, USA; <sup>4</sup>Department of Pediatrics, University of Toronto, Toronto, ON, Canada; <sup>5</sup>Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

## Abstract

**Objective** To evaluate the effectiveness of a behavioural-educational sleep intervention delivered in the early postpartum in improving maternal and infant sleep.

**Design** Randomised controlled trial.

**Setting** Postpartum units of two university affiliated hospitals.

**Participants** 246 primiparous women and their infants randomised while in hospital with an internet based randomisation service to intervention (n=123) or usual care (n=123) groups.

**Interventions** The behavioural-educational sleep intervention included a 45-60 minute meeting with a nurse to discuss sleep information and strategies to promote maternal and infant sleep, a 20 page booklet with the content discussed, and phone contacts at one, two, and four weeks postpartum to reinforce information, provide support, and problem solve. The usual care group received calls at weeks one, two, and four to maintain contact without provision of advice.

**Main outcome measures** Primary outcome was maternal nocturnal (9 pm to 9 am) sleep (minutes) and secondary outcome was longest stretch of infant nocturnal sleep (minutes) measured at six and 12 weeks postpartum by actigraphy. Other outcomes measured at six and 12 weeks were number of maternal and infant night time awakenings by actigraphy, fatigue visual analogue scale, general sleep disturbance scale, and Edinburgh postnatal depression scale. Rates of exclusive breast feeding were measured at 12 weeks postpartum only.

**Results** All women who completed any outcome measures at six or 12 weeks were included in analysis. Sleep outcomes were completed at one or both of six and 12 weeks postpartum for 215 of 246 (87%) women

(110/123 intervention and 105/123 usual care). Longitudinal mixed effects model analyses indicated no significant differences between the groups on any of the outcomes. The estimated mean difference in maternal nocturnal sleep between the intervention and usual care groups was 5.97 minutes (95% confidence interval -7.55 to 19.5 minutes, P=0.39). No differences in any outcomes were noted based on the specific nurse delivering the intervention or the number of phone contacts received.

**Conclusion** A behavioural-educational intervention delivered in the early postpartum, in hospital, and in the first weeks at home, was ineffective in improving maternal and infant sleep or other health outcomes in the first months postpartum.

**Trial registration** ISRCT No 13501166.

## Introduction

In the first 12 weeks postpartum, sleep disturbance is profound. For mothers, care of and interactions with their infant at night reduce the amount and continuity of sleep achieved<sup>1-4</sup> and contribute to considerable fatigue.<sup>5,6</sup> Sleep disturbance is greater for first time mothers,<sup>7</sup> perhaps because of the novel cognitive and psychological challenges of the maternal role. Given that chronic sleep deprivation and fragmentation considerably increase the risk of mood disorders, lapses in cognitive function, and decreased wellbeing,<sup>8-13</sup> effective interventions to improve sleep could improve women's postpartum health. Despite the ubiquitous experience of sleep disturbance for primiparous women, healthcare practitioners have little to offer in terms of effective interventions to reduce sleep deprivation or fatigue. While maternal sleep is affected by the infant's sleep-wake

Correspondence to: R Stremler, Lawrence S Bloomberg Faculty of Nursing, University of Toronto, 155 College Street, Toronto, ON, Canada, M5T 1P8 [robyn.stremler@utoronto.ca](mailto:robyn.stremler@utoronto.ca)

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**Appendix:** TIPS booklet

activity, the infant's activity also is shaped by interaction with his or her mother.<sup>14</sup> Indeed, many parents report difficulty with managing infant night waking and settling to sleep,<sup>15 16</sup> and there is evidence that infant sleep problems can persist into later childhood if not treated.<sup>17</sup>

Randomised controlled trials of interventions aimed at promoting infant sleep in the first few postpartum months<sup>18-21</sup> have provided parents with basic education on infant sleep and training in strategies to limit the development of unwanted sleep associations, increase the infant's ability to self soothe, and offer environmental and social cues that shift the infant's sleep to the night time. All of these trials found longer, less fragmented sleep periods for infants who received the experimental intervention. These studies, however, used parents' reports of infant sleep patterns using sleep diaries, rather than the more valid reliable approach of an objective measure such as actigraphy.<sup>22</sup> No study included interventions to improve maternal sleep or examined the effects of the intervention on maternal sleep outcomes. There are strategies independent from infant sleep that could improve maternal sleep. For example, use of sleep hygiene, cognitive behavioural strategies, and relaxation techniques might help women with difficulty falling asleep because of anticipation of infant awakening.<sup>23</sup> Provision of support for the emotional demands of parenting while sleep deprived, guidance on reasonable expectations of maternal and infant sleep in the early postpartum, and support in problem solving could decrease negative appraisal of sleep loss and maximise opportunity for sleep.<sup>24</sup>

Given the physical, emotional, and cognitive demands on postpartum women, the known decrements to these abilities brought on by sleep deprivation, and the opportunity for postpartum women to play a role in shaping their own and their infant's sleep behaviours, we evaluated a sleep intervention aimed at both women's and infants' sleep. We designed a behavioural-educational intervention to provide information, strategies, and support related to promotion of infant and maternal sleep. In preparation for a multisite randomised controlled trial, we conducted a pilot trial to establish feasibility and acceptability of the trial methods and to evaluate the intervention with 30 primiparous women.<sup>25</sup> Our pilot work suggested benefit to the experimental group in increased maternal night time sleep, fewer infant night time awakenings, and longer stretches of infant night time sleep at six weeks postpartum. Results from the pilot study laid the foundation for a larger definitive trial with the potential to change current practice, which would determine effectiveness of the intervention at 12 weeks postpartum, when most infants are physiologically able to sleep for a longer uninterrupted period without a feeding. Our hypotheses were that women who received the sleep intervention would achieve more minutes of sleep at night and that their infants would achieve longer stretches of sleep at night.

## Methods

### Participants

Women were recruited from the postpartum units of two university affiliated hospitals (one level III with 3600 births/year; one level II with 2500 births/year) in Toronto, Canada, between March and December 2008. Eligible women (single or with partners) were those who had given birth for the first time; had a healthy singleton baby born at gestational age 37 weeks or greater; lived in the greater Toronto area, and planned to provide fulltime infant care for at least the first 12 weeks after birth. Women with previous miscarriages at less

than 20 weeks' gestation were eligible if the most recent pregnancy resulted in a first child. Women were excluded if there were maternal or infant complications requiring a prolonged hospital stay; they used drugs that affect sleep (such as benzodiazepines); they had a poorly controlled chronic illness; they were unable to read or understand English; or there was no telephone in the home. Women also were excluded if they (or their partner) had experienced stillbirth or perinatal death after 20 weeks' gestation; used drugs or alcohol beyond social use; or had been diagnosed with a sleep disorder (such as sleep apnoea, narcolepsy). Women with partners who had children from another relationship or who were working night shifts were also excluded.

### Design and procedures

We carried out a multisite randomised controlled trial with stratification by site (figure 1). Consenting women had baseline data (such as birth weight, mode of delivery) collected from their medical charts, filled out a brief questionnaire (such as plans to bed share with infant, depression score), and were randomised. Randomisation was centrally controlled, concealed, in random blocks of four and six, and stratified by centre with a secure web based randomisation service ([www.randomize.net](http://www.randomize.net)). To limit the possibility of contamination, we enrolled only one woman per hospital room at one time, and women assigned to the intervention group were asked not to share the intervention with other women. A sleep intervention nurse delivered the behavioural-educational intervention to women assigned to the experimental group as soon as possible after randomisation and before discharge from hospital. The same nurse telephoned the woman at one, two, and four weeks after discharge home. Women allocated to the usual care group had access to standard postpartum care in hospital.

Once home, women in the usual care group received a phone call from a research assistant at weeks one, two, and four after discharge to maintain contact and increase compliance with completion of outcome measures. No advice or support related to maternal or infant sleep was given to women in the usual care group. At six and 12 weeks postpartum a research assistant with no training in sleep interventions and who was blinded to group allocation visited all mothers in their homes. Participants were asked not to discuss their group assignment with the research assistants, and study staff were instructed not to inquire as to participants' group allocation. We did not formally evaluate any unblinding of study staff. Actigraphy was performed over four consecutive days and nights, as per recommendations of the standards of practice committee of the American Academy of Sleep Medicine,<sup>26</sup> to objectively measure maternal and infant sleep. After the fourth night of actigraphy the research assistant returned to the woman's home to collect the actigraphs and corresponding sleep diaries and to ask the mother to complete a short self administered questionnaire. Actigraphy data were analysed with autoscoring programs run by research assistants who had no contact with research participants and who were blinded to group allocation. Women were given a \$C25 (£16, €18, \$23) gift certificate at completion of data collection at each of six and 12 weeks, in recognition of their time and commitment.

### Intervention

While maternal and infant sleep are concerns throughout the postpartum, our intervention was designed to promote sleep rather than solve sleep problems that had developed, necessitating early timing of the intervention. Although other sleep promotion interventions have been delivered late in

pregnancy,<sup>18 21</sup> we sought to take advantage of cues from and experiences with the participant's own infant and also avoid a focus on impending labour and birth. Behavioural-educational interventions use active learner involvement and participatory learning to develop knowledge and skills for change,<sup>27</sup> and we thought this would be most successful in hospital in the early postpartum with the infant's and mother's behaviour and responses as exemplars. Our multimodal approach of in hospital (session with nurse), community (phone calls), and self learning (booklet) strategies reflects the nature of contact with health professionals a new mother has in Canada in the first few months postpartum. If our approach was found to be effective, training for all in hospital postpartum nurses, public health nurses, and other healthcare professionals who work with women in the early postpartum could ensue, similar to efforts to successfully support breast feeding.

The intervention was slightly altered from the version offered in our pilot work.<sup>25</sup> The number of phone calls was reduced from five to three because of challenges contacting participants each week and redundancy of calls when no new issues were raised. Also, based on women's concerns and questions, we included more information regarding the intersection of sleeping with crying and feeding issues.

At a time convenient for the mother, the sleep intervention nurse met with the mother on the postpartum unit for 45-60 minutes, discussed mother and baby sleep issues and strategies to improve both, and provided support and encouragement around the woman's ability to achieve good sleep for herself and her infant. The mother's partner or other support person attended the session if they wanted but were not required to be present. The mother also received a 20 page booklet (Flesch Kincaid reading grade level 7.5) elaborating on these ideas and strategies discussed (see appendix; this work is licensed under a Creative Commons Attribution-Non-Commercial 3.0 Unported License and is also available upon request from [www.stremlerresearch.com/tips](http://www.stremlerresearch.com/tips)), and she was encouraged to refer to it during the first few weeks at home. Support was also provided during phone calls at one, two, and four weeks after hospital discharge in which information and strategies covered in the first meeting were reviewed and the mother was guided in problem solving with any sleep related issues that arose. Topics covered included maternal sleep hygiene, strategies for increasing opportunities for maternal sleep, maternal relaxation techniques, acknowledgement of the challenges of parenting and sleep deprivation, information on infant sleep structure and interpreting infant cues, strategies for infant sleep promotion, and strategies for promoting infant night-day entrainment and self-soothing (box 1). The advice given aimed to be culturally sensitive and respect individual family choices related to infant care such as room sharing, bed sharing, and infant feeding. The approach was to accept these individual family choices, avoid assumptions related to infant care (such as that the infant sleeps in his or her own room in a crib), and allow for multiple approaches to maternal and infant sleep practices.

### Sleep intervention nurse training and intervention fidelity

Four part time sleep intervention nurses, all with more than five years of perinatal nursing experience, attended an eight hour training session (box 2). Role play of in hospital sessions and follow-up phone calls were a key part of training, and each sleep intervention nurse received a take home training manual. Each sleep intervention nurse practised delivery of the in hospital session with a postpartum woman in hospital who was not a study participant. Practise interventions were audiotaped and

reviewed by the principal investigator to ensure intervention fidelity before assigning sleep intervention nurses to their first participant. After the study launch, every two weeks the sleep intervention nurses asked a study participant for permission to audiotape their interaction so that continued review would ensure intervention fidelity and consistency.

### Outcome measures

The primary outcome was maternal nocturnal (9 pm-9 am) sleep (in minutes) at six and 12 weeks postpartum as measured by actigraphy. The actigraph was worn around the wrist in adults (Octagonal Basic Motionlogger, Ambulatory Monitoring) and around the ankle over a sock in infants (MicroMini Motionlogger, Ambulatory Monitoring). The actigraph detects and records continuous motion data, which are translated into digital counts across one minute intervals. Congruence between polysomnography and actigraphy indicates adequate validity and reliability when sleep is assessed in healthy young adults, including women of childbearing age,<sup>26 28</sup> with 88% agreement between the two methods. Actigraphy has also been used successfully to study sleep-wake patterns in newborn and older infants<sup>22 29 30</sup> and has an overall 95% minute by minute agreement with direct observation of infant sleep-wake states<sup>31</sup> and 89-94% agreement with polysomnography.<sup>32</sup> Data from the actigraphs were downloaded and analysed with Action 4 software (Ambulatory Monitoring) and Cole-Kripke (adult) and Sadeh (infant) algorithms. Given that late third trimester sleep is disturbed compared with sleep before pregnancy<sup>7</sup> and that labour and birth and the hospital environment interfere with women's sleep, there is no valid baseline objective measurement for postpartum women's sleep in either late pregnancy or the immediate postpartum.

Women and infants began wearing the actigraphs on the Monday closest to when the infant achieved six and 12 weeks of age and wore them continuously until we picked them up on Friday; this approach avoid data recording on weekends when young adults tend to alter their sleep times. Women were asked to press an event marker on their actigraphs to indicate when they attempted sleep and when they got up again.

Each participant used a maternal-infant sleep diary to record bed, wake, nap, and feeding times and removal of the actigraph (for example, for bathing) throughout the day. These data aided interpretation of the actigraphy data. For example, sleep diaries confirmed that periods of complete inactivity on actigraphy corresponded to notes in the diary that actigraphs were removed and also verified that artefacts in actigraphy recording aligned with reports of the infant sleeping while in motion (for example, in a baby swing or stroller).<sup>33</sup> When artefacts were present, data were re-coded appropriately with Action4 actigraphy analysis software.

Our secondary outcome was the infant's longest nocturnal (9 pm-9 am) sleep period (in minutes) at six and 12 weeks postpartum, measured by actigraphy. Other outcomes measured at six and 12 weeks included maternal and infant night time awakenings by actigraphy, morning fatigue recorded daily in the sleep diary with the fatigue visual analogue scale<sup>34</sup> (Fatigue-VAS), subjective sleep disturbance with the general sleep disturbance scale<sup>35</sup> (GSDS), and depressive symptoms with the Edinburgh postnatal depression scale<sup>36</sup> (EPDS) recorded on the six and 12 week questionnaires. Exclusive breast feeding was evaluated by maternal report in the 12 week questionnaire; mothers classified how they were breast feeding according to definitions from the World Health Organization.<sup>37</sup>

**Box 1 Topics covered by sleep intervention group***Infant sleep structure and sleep promotion strategies*

- Every baby is different and you will learn to recognise your baby's patterns
- Newborns have cycles of sleep with brief awakenings
- Not all babies need to be rocked or fed to help them go to sleep
- Strategies to let baby sleep/settle on own
- Crying might indicate fatigue; crying is communication
- Infants are active in their sleep
- Turn down the baby monitor
- Swaddle if the baby startles itself awake
- When to wake the baby to feed versus allowing to sleep
- How to prevent baby falling asleep at the breast

*Differentiating between night and day*

- Bright lights can disrupt night time sleep; expose baby to some daytime light
- Limit social interaction and play at night
- Begin a short bedtime routine

*Sleep hygiene for mothers*

- Make sleep a priority
- Your bedroom should be cool, quiet, dark and reserved for sleep/intimacy
- Try relaxing activities before bed
- Don't discuss major issues/worries before bed
- Exercise regularly, ideally outdoors
- Limit caffeine; avoid alcohol, nicotine, heavy meals

*Support around parenting and sleep*

- Be realistic about what needs to be done; accept/ask for help from others
- Learning how to care for your new baby can be overwhelming
- Relaxation strategies might help you sleep
- It is difficult to have interrupted sleep when learning to be a new parent
- Limit visitors in the first few weeks

**Box 2 Training programme for sleep intervention nurses***Content to be understood*

- Basic neurobiology of sleep and circadian rhythms
- Normal sleep patterns for infants and postpartum women
- Development of infant sleep
- Role of sleep in health and disease
- Consequences of sleep deprivation
- Randomised controlled trials of infant sleep promotion
- Each strategy recommended in the trial and its evidence base

*Skills to be achieved*

- Relaxation strategies
- Interactive discussion strategies
- Facilitation of participatory learning
- Provision of problem solving by phone

Before randomisation, women were asked to fill in the general sleep disturbance scale for the last week of their third trimester of pregnancy before contractions began. Women also filled in the Edinburgh postnatal depression questionnaire at baseline and answered questions related to perceived social support<sup>38</sup> and intention to bed share, room share, and breast feed exclusively. Effects of baseline variables were explored in the final analysis.

**Sample size**

Our required sample size was based on detecting a 30 minute difference between the intervention and usual care groups with

respect to mean maternal nocturnal sleep. A meta-analysis of adults undergoing cognitive behavioural therapy for insomnia<sup>39</sup> and a randomised controlled trial of women using a pharmacological approach to insomnia<sup>40</sup> have shown that a 30 minute increase in nocturnal sleep time resulted in improvements in subjective evaluation of sleep quality. For postpartum women, a mean increase of 30 minutes a night in nocturnal sleep time would represent a substantial contribution of 210 minutes a week toward an important sleep debt in a chronically sleep deprived population. By using a longitudinal model with two observations per participant (six and 12 weeks) and data from maternal nocturnal sleep times from our pilot work<sup>25</sup> ( $\sigma^2=4573$ ), a two sided  $\alpha$  (level) of 0.05, and a power of at least 90%, we

calculated that we needed 105 per group or 210 women in total. To account for 10% loss of data and loss of participants to follow-up, we planned to recruit 234 women. When it was determined that our rate of loss to follow-up was actually closer to 15%, we extended recruitment so that we enrolled 246 women. We used a Bonferroni adjusted nominal two sided level of 0.007 to account for multiple testing and to maintain an overall level of 0.05.

## Statistical methods

Actigraphy data were exported directly from Action4 into Microsoft Access 2007 (Microsoft Corporation, Redmond, WA); all other data were double entered by research assistants. SAS version 9.1 (SAS Institute, Cary, NC) was used for data analysis. Descriptive statistics (means, standard deviations, proportions) were used to describe demographic and baseline variables. As per the "intent to treat" approach, participants' data were analysed according to the groups to which they were randomly assigned, regardless of treatment received. Sleep variables were averaged across the four nights of actigraphy recording at each time point. For all sleep variables (morning Fatigue-VAS scores, general sleep disturbance scores and Edinburgh postnatal depression scores) we used longitudinal mixed model analyses. The models included fixed effects for treatment arm, time (six versus 12 weeks), and the stratification variable (centre). For the Edinburgh postnatal depression and general sleep disturbance scores the corresponding baseline score was included as a covariate. There was a random effect for subject. Other covariates were considered when appropriate, including mode of delivery, intention to bed share with the infant, intention to breast feed, intention to room share with the infant, and baseline perceived social support scores. We used generalised estimating equations, as facilitated by the SAS procedure GENMOD, for parameter estimation and a Fisher exact test to compare treatment arms with respect to exclusive breast feeding; relative risk and corresponding 95% confidence limit were calculated.

## Results

### Flow of participants, sample characteristics, compliance, and follow-up

In 10 months of recruiting, we assessed 1163 women as potentially eligible by chart review and asked them if a research assistant could provide them with a detailed explanation of the study and further assess their eligibility. Of the 958 (82%) women who were assessed, 276 (28%) were not eligible, usually because they were unavailable at one of the data collection times (n=49), were discharged from hospital too soon to arrange a sleep intervention nurse to visit (n=39), or because of a language barrier (n=39). Of 682 eligible women, 246 (36%) agreed to participate and were randomised; 123 women to each group (figure 1). Of the 436 (64%) women who declined enrolment, 288 (40%) stated they were not interested and 217 (30%) thought they would be too busy in the early postpartum to participate.

Table 1 shows characteristics of the participants. Caesarean birth rates were higher in the usual care group (46%) than in the intervention group (35%). Longer lengths of stay for women who experienced caesarean delivery allowed for greater opportunity for recruitment of those women to the trial, resulting in a higher rate of caesarean delivery in our study than in the general postpartum population. The intervention and usual care groups were similar on all other baseline and demographic variables. Mothers had a mean age of 32 years, most had a partner (97%), and most had post-secondary education (90%). The sample was racially diverse, with women identifying

themselves as Asian (20%), black (7%), Hispanic (3%), and multiracial (1%).

All but seven women (n=239, 97%) received the sleep intervention while still in hospital. The seven (3%) women who were unable to do so received the intervention over the phone at home (n=3), the booklet (n=3), or a combination of the two (n=1). Reaching women for postpartum phone calls required multiple attempts and coordination with their infant care giving activities. Of the women in the intervention group, 78 (63%) received three postpartum phone calls, and 23 (19%) received two phone calls before determination of outcomes at six weeks, giving a sleep intervention group mean of 2.38 (SD 0.95) calls. Of the women in the usual care group, 70 (57%) received three phone calls to maintain rapport, resulting in a usual care group mean of 2.36 (SD 0.91) calls.

## Outcomes

All women who completed any outcome measures at six or 12 weeks were included in analysis. At follow-up times when actigraphy data were lost because of file corruption (31 (7.4%) baby files and 37 (8.9%) maternal files) we substituted data from the sleep diary. Sleep outcomes were completed at one or both of six and 12 weeks postpartum for 215 of 246 (87%) women (110/123 intervention and 105/123 usual care). Longitudinal mixed model analyses indicated no significant differences between groups on any of the primary, secondary, or other outcomes (table 2). The estimated mean difference in maternal nocturnal sleep between the sleep intervention and usual care groups was 5.97 minutes (95% confidence interval -7.55 to 19.5 minutes; P=0.39). At 12 weeks postpartum, 71 (69%) women in the intervention group and 66 (66%) in the usual care group were exclusively breast feeding (relative risk of exclusive breast feeding 1.04 (0.86 to 1.26; P=0.66).

Tables 3 and 4 show median scores related to all maternal outcomes, and table 5 shows mean scores related to all infant outcomes. With a similar longitudinal model, but not including treatment group, there were no differences in any outcomes noted based on the specific nurse delivering the intervention or the number of phone calls received.

### Use of sleep advice, co-intervention, acceptability of trial

At 12 weeks, 103 (84%) women in each group responded to the final questionnaire related to other sources of sleep information, their views on participation in the trial, and, for women in the intervention group, their use of the sleep advice and strategies given.

An equal number of women in the intervention (n=63, 61%) and usual care groups (n=63, 61%) sought information related to maternal or infant sleep from other sources. Among all the participants, 85 (41%) women consulted books, 73 (35%) women accessed the internet, and 72 (35%) women asked other mothers for advice. Only 29 (14%) women asked a physician, and nine (4%) women asked another healthcare professional for information on sleep.

More women in the intervention group (n=91, 88%) than in the usual care group (n=76, 74%) said that they liked their contacts with study staff. More women in the usual care group (n=81, 79%) than in the intervention group (n=68, 66%) said that they liked the exercise of keeping a sleep diary. Most women (n=86, 83%) in the intervention group liked receiving information about sleep from the study nurse and also liked the written material they received (n=81, 79%). Only four women in each group

(3.9%) indicated they would probably not participate in the study if they had to do it over again.

It was not the intention of the intervention that each piece of advice be used by every woman; rather we expected that each woman would try many, but not all of the tips, depending on her unique needs and abilities. Each of the suggested strategies to improve infant sleep was reported as used by at least 79% of the women (range n=82-100, 79-97%) in the intervention group with the exception of advice to avoid letting the baby sleep during feedings (n=69, 67%) and to involve partners and other family members in implementing the sleep advice (n=76, 74%). Fewer than half of the women (range n=33-49, 32-48%) used advice related to use of cigarettes, alcohol, drugs for postpartum pain, changing negative thoughts about sleep, and turning down the volume on baby monitors. Many women probably reported not using these tips because these sleep inhibitors were not relevant to their lives—for example, they might not smoke or have negative thoughts about sleep. At least 60% of women (range 64-96, 62-93%) used other advice related to maternal sleep, with the exception of the strategies of progressive muscle relaxation (n=25, 24%), deep breathing (n=37, 36%), writing down worries before sleep (n=30, 29%), and avoiding computer and television use before bedtime (33, 32%).

## Discussion

This multisite randomised controlled trial found no effect on maternal and infant sleep or other important health outcomes of a behavioural-educational sleep intervention delivered by nurses in the early postpartum. While the women who participated in our trial valued receiving information about sleep, felt positive about their participation, and reported using many of the suggested strategies, there were no differences between groups on the main outcomes.

### Strengths and weaknesses of this study

Strengths of our study include pilot testing and standardisation of the intervention, formal training of our nurses, systematic checks of fidelity of the intervention throughout the study, excellent compliance rates for receipt of the in hospital and phone call portions of the intervention, and less than 15% loss to follow-up. The self reported outcomes we used have excellent psychometric properties and were administered in the presence of research assistants who were unaware of group allocation. Furthermore, research assistants who analysed objective sleep data were also blinded to group assignment.

Other strengths of this study are the inclusion of both infant and maternal sleep and other outcomes and use of actigraphy to objectively measure sleep. In previous studies of infant sleep interventions, parents' reports might have overestimated improvements in infant sleep in intervention groups. Our pilot study used only two nights of actigraphy data, which might also explain the differences in findings between our pilot and large scale trials. In our pilot study participants might have experienced nights with much more or much less sleep than usual, leading to an overestimation of differences between groups.<sup>25</sup> In our pilot work women in the intervention group slept about seven hours a night at six weeks postpartum, while women in the usual care group slept 57 minutes less; this was a significant difference. In our large scale trial, however, mean night time sleep in both groups was about six and a half hours a night at six weeks, perhaps representing regression toward the mean.

Though racial diversity of our sample was a strength of our work, the participants were predominantly socially advantaged,

thereby limiting generalisability. Baseline rates of symptoms of postpartum depression were lower and rates of social support and exclusive breast feeding higher than in the general population. Work published since the design of our trial suggests that maternal-infant sleep interventions might be more effective in socially disadvantaged groups. Lee and Gay found that an intervention aimed at modifying the sleep environment to minimise parental sleep disruption was effective in increasing nocturnal sleep time for disadvantaged women but not for couples with high levels of resources.<sup>41</sup> Participants with less social advantage also had worse baseline sleep. Future maternal-infant behavioural sleep interventions should be tested in disadvantaged families or parents who report severe sleep disturbance or infant sleep problems in the early postpartum. We did not preferentially enrol new mothers deemed at high risk of sleep difficulties as we viewed the intervention as a means to prevent sleep problems in a population in which sleep disturbance was to be expected.

### Meaning of the study and possible explanations

The lack of observed effect found from the behavioural-educational maternal-infant sleep intervention evaluated in this study suggests that such a service should not be adopted as standard care. In the past few decades, interest in sleep as a health issue and the number of scientific publications on sleep have grown exponentially.<sup>42</sup> Our trial took place three years after our pilot study; it could be that information on strategies to improve sleep was more readily available to our participants. Skill in accessing health information via books, websites, and connection with other mothers could allow for little additional gain from other sleep interventions. Given that many women in both the intervention and usual care groups (61%) sought out information about sleep on their own, women in the usual care group might have implemented maternal and infant sleep improvement strategies independently, offering a possible explanation for the lack of difference between groups. Our refusal rate (64%) was similar to another trial that recruited women in hospital in the immediate postpartum<sup>19</sup> and was not unexpected given that first time parents are occupied with infant care and maternal recovery in the immediate postpartum. The women who did agree to participate were probably highly motivated to learn about and influence their infant's sleep. As evidence of this, we had excellent compliance with the completion of sleep diaries by all participants, and many women in the usual care group (n=81, 79%) reported that they liked keeping a sleep diary. The information and insight gained through keeping a sleep diary alone might have helped the participants in the usual care group in improving their own and their infant's sleep. A better understanding of our participants' cognition around infant sleep and belief in their own ability to shape sleep through implementation of strategies might have helped to explain the lack of difference between groups.

The content of the sleep intervention might not have been robust enough to elicit changes in maternal and infant sleep, although recommendations were evidence based, such as sleep hygiene and relaxation techniques derived from effective interventions for adult insomnia. Acceptability of the content might have limited its effectiveness as fewer women reported use of some of the strategies aimed at improving maternal sleep, such as progressive muscle relaxation and deep breathing. This could also indicate the need for more guided practice than we provided in our intervention. Although women in the intervention group reported which tips and strategies they used, we do not have a measure of their proximity to the actions we intended; this would

be possible only through video surveillance of parent and infant night time behaviours and interactions. For example, while women reported they used the tip to “allow the infant to fuss for a bit before responding” we do not know the frequency of use or their efficacy in carrying out the advice. Future intervention studies could benefit from examinations of recommended behaviours through monitoring in the home. This would also provide more information related to the influence of infant sleep location and infant proximity to the sleeping mother, infant feeding method, and feeds during the night, which could better illustrate the uptake and implementation of strategies presumed to influence maternal and infant sleep.

It might be that the early newborn period is too soon to influence maternal and infant sleep or that the early postpartum is such a period of great change and role adjustment that implementing sleep strategies is not a priority for all families. Future studies should examine the effects on sleep of our intervention delivered several months into the postpartum, thereby allowing women time to recover from labour and birth and gain parenting experience and yet intervening before their own sleep strategies have been firmly established. We have made our intervention booklet publicly available (see appendix and [www.stremmlerresearch.com/tips](http://www.stremmlerresearch.com/tips)) so that our intervention can be adapted for testing at other time points in the postpartum period or in populations that might be of greater risk of sleep problems or their sequelae, such as postpartum depression. Also, although we observed no difference in sleep outcomes between groups in our trial, given that women valued the written information they received, we consider it important to make the intervention booklet publicly available to those who are interested in the suggested strategies.

Our advice and recommended strategies might have conflicted with some participants' views of their role in supporting their infant's sleep, thereby reducing implementation of components of the intervention. Evidence suggests that maternal beliefs around limit setting, distress at the infant's demands at night, and doubts around parenting ability influence night time parenting behaviour.<sup>14 43 44</sup> An in depth examination of mothers' comfort with, and motivations for, influencing their infant's sleep might show differences in ability to enact advice to promote self soothing in their infants.

Differences in infant or maternal sleep could have been observed beyond our final measurements at 12 weeks postpartum if families required more time to implement strategies or if changes to sleep behaviours required more time to be observable. Intervening in hospital and training all postpartum staff to do so, as we envisioned would occur if our intervention was effective, however, cannot be justified if evidence of effectiveness of the intervention is not observed in the first few months postpartum.

The “dose” of our intervention might not have been large enough to be effective. Had women received more face to face interactions with the sleep intervention nurse, or had we not reduced follow-up phone calls to three from the five calls placed in our pilot study, women might have had more guidance, reinforcement, and support in increasing sleep promoting behaviours. However, we wanted our intervention to align with the current amount of contact women have with nurses in the postpartum period through a short stay in hospital followed by brief telephone contact once home. Similarly, the possibility exists that the training and supervision of the nurses providing the intervention was not enough preparation for the role. We also wanted to train our sleep intervention nurses in a manner that would be replicable with the time and financial resources available in typical postpartum care settings in Canada. Our

goal was not to train nurses to provide highly specialised sleep treatment services but rather to provide training in sleep interventions similar in scope to that required to expand nurses' practice to any new but relevant issue in health promotion.

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Contributors: RS (principal investigator) conceptualised and designed the trial, obtained funding, directed implementation, completed data analysis and interpretation, wrote the draft manuscript, and is guarantor. EH and KL (co-investigators) assisted in all trial activities including design, funding, implementation, data interpretation, and manuscript preparation. LK (trial coordinator) assisted in all trial implementation procedures including participant recruitment, overseeing intervention implementation and data collection procedures, and performing database management activities. SW (co-investigator) assisted in trial funding and data interpretation and was available for clinical consultation during implementation. JW (senior trial coordinator) assisted in all trial activities including design, funding, budget management, data interpretation, and manuscript preparation and all trial implementation procedures including completing participant recruitment, overseeing intervention implementation, and data collection procedures, and performing database management activities. AW (co-investigator and biostatistician) assisted in design, funding, data analysis and interpretation, and manuscript preparation. All authors have commented on the manuscript.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: This study was approved by the University of Toronto research ethics board and the ethical review boards of the two participating hospitals (St Michael's Hospital, Toronto, Ontario, Canada, Approval ID: REB 07-303; Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada, Approval ID: 371-2007) and informed consent was given by all participants.

Data sharing: No additional data available.

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**What is already known on this topic**

- Maternal sleep disturbance is common in the postpartum, with primiparous women particularly affected
- Postpartum sleep deprivation is associated with higher rates of depression and reports of increased fatigue
- Trials of behavioural interventions to increase infant sleep observed an increase in infant sleep consolidation and fewer infant awakenings as reported by parents
- Our pilot intervention of a behavioural-educational intervention showed improvements in objectively measured maternal and infant sleep at six weeks postpartum

**What this study adds**

- A behavioural-educational intervention delivered in the early postpartum, in hospital and in the first weeks at home, was ineffective in improving maternal and infant sleep in the first months postpartum

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## Tables

**Table 1 | Baseline characteristics of primiparous women and their infants randomised to sleep intervention or usual care. Figures are numbers (percentage) unless stated otherwise**

	Sleep intervention (n=123)	Usual care (n=123)
Mean (SD) time from delivery to enrolment (days)	0.9 (0.7)	1.1 (0.9)
Mean (SD) maternal age (years)	32.6 (5.0)	31.8 (4.9)
Married or in stable relationship	119 (97)	120 (98)
Education:		
Elementary	2 (2)	2 (2)
High school	5 (4)	12 (10)
University or college	85 (69)	74 (60)
Postgraduate education	30 (24)	33 (27)
Unknown	1 (1)	2 (2)
Racial background:		
Asian	25 (20)	24 (20)
Hispanic	4 (3)	3 (2)
White	82 (67)	74 (60)
Black	10 (8)	7 (6)
Mixed	1 (1)	11 (9)
Unknown	1 (1)	4 (3)
Mean (SD) gestational age (weeks)	39.2 (1.1)	39.3 (1.1)
Type of delivery:		
Spontaneous vaginal	62 (50)	48 (39)
Assisted vaginal	18 (15)	18 (15)
Caesarean section	43 (35)	57 (46)
Male infant	59 (48)	60 (49)
Mean (SD) birth weight (g)	3351 (390)	3409 (474)
Postpartum complications	5 (4)	5 (4)
EPDS:		
Mean (SD) score	6.4 (4.4)	6.0 (3.8)
Score >12	10 (8)	3 (2)
GSDS:		
Mean (SD) score	54.3 (19.1)	54.3 (19.5)
Score >42	87 (71)	94 (76)
Total (SD) MSPSS score	6.5 (0.7)	6.3 (1.0)
Planning to room share to some extent	109 (89)	107 (87)
Planning to bed share to some extent	34 (28)	32 (26)
Planning to exclusively breast feed	114 (93)	109 (89)

EPDS=Edinburgh postnatal depression scale (score range 0-30, score >12 indicates at risk for postpartum depression); GSDS=general sleep disturbance scale (score range, 0-147, score >42 indicates poor sleeper); MSPSS =multidimensional scale of perceived social support (score range 1-7, higher scores indicate greater support).

**Table 2| Models for outcomes related to sleep, fatigue, subjective sleep disturbance, and postpartum depression in primiparous women and their infants randomised to sleep intervention or usual care and in all women over time**

	Sleep intervention –usual care		Week 12–week 6		Compared with baseline	
	Difference/rate ratio (95% CI)	Standard error, P value	Difference/rate ratio (95% CI)	Standard error, P value	Regression coefficient for baseline	Standard error, P value
Nocturnal sleep, maternal	5.97* (–7.55 to 19.5)	6.90, 0.39	39.3* (32.1 to 46.5)	3.68, <0.001	—	—
Longest stretch of nocturnal sleep, infant	–0.18* (–16.1 to 15.8)	8.13, 0.98	59.5* (48.0 to 71.0)	5.87, <0.001	—	—
Fatigue VAS	3.64* (–0.72 to 8.00)	2.23, 0.10	–8.52* (–10.87 to –6.17)	1.20, <0.001	—	—
EPDS score	0.21* (–0.62 to 1.04)	0.42, 0.62	–0.81* (–1.31 to –0.32)	0.25, 0.001	0.40 (0.29 to 0.51)	0.06, <0.001
GSDS score	1.11* (–2.64 to 4.86)	1.91, 0.56	–4.90* (–6.95 to –2.85)	1.05, <0.001	0.29 (0.18 to 0.40)	0.06, <0.001
Night awakenings, maternal	–0.012† (–0.12 to 0.10)	0.056, 0.83	0.019† (–0.039 to 0.077)	0.03, 0.53	—	—
Night awakenings, infant	0.036† (–0.043 to 0.12)	0.040, 0.37	–0.25† (–0.31 to –0.19)	0.031, <0.001	—	—

Fatigue VAS=fatigue visual analogue scale; EPDS=Edinburgh postnatal depression scale; GSDS=general sleep disturbance scale. Models for 12 weeks minus 6 weeks and comparison with baseline include both sleep intervention and usual care participants

\*Mean difference.

†Log rate ratio.

**Table 3| Maternal sleep and subjective sleep disturbance outcomes at 6 and 12 weeks in primiparous women and their infants randomised to sleep intervention or usual care. Figures are medians (interquartile range)**

	Sleep intervention*	Usual care†
Nocturnal sleep (minutes):		
6 weeks	397 (362-428)	387 (359-424)
12 weeks	440 (402-469)	431 (396-468)
Longest stretch of nocturnal sleep (minutes):		
6 weeks	144 (114-174)	136 (114-167)
12 weeks	153 (125-208)	155 (122-192)
No of night awakenings:		
6 weeks	8.8 (6.8-11.5)	9.3 (6.9-11.3)
12 weeks	9.3 (5.5-12.0)	9.0 (6.7-12.0)
Daytime sleep (minutes):		
6 weeks	34 (15-70)	45 (24-72)
12 weeks	32 (6.7-67)	35 (15-64)

\*n=109 at 6 weeks and 103 at 12 weeks.

†n=103 at 6 weeks and 102 at 12 weeks.

**Table 4| Fatigue, postpartum depression, and subjective sleep disturbance outcomes at 6 and 12 weeks in primiparous women and their infants randomised to sleep intervention or usual care. Figures are means (SD)**

	Sleep intervention	Usual care
Fatigue VAS*:		
6 weeks	40.3 (18.4)	37.0 (17.9)
12 weeks	32.8 (20.5)	28.2 (16.9)
EPDS†:		
6 weeks:		
Mean score (SD)	5.6 (4.0)	5.3 (3.9)
>12 (%)	7 (6)	5 (5)
12 weeks:		
Mean score (SD)	4.8 (4.0)	4.5 (3.8)
>12 (%)	3 (3)	4 (4)
GSDS†:		
6 weeks:		
Mean (SD)	39.4 (15.4)	37.6 (17.2)
>42 (%)	45 (42)	35 (34)
12 weeks:		
Mean (SD)	34.5 (17.9)	32.8 (16.2)
>42 (%)	34 (33)	33 (32)

Fatigue VAS=fatigue visual analogue scale (score range 0-100, higher scores indicate greater fatigue); EPDS=Edinburgh postnatal depression scale (score range 0-30, score > 12 indicates at risk for postpartum depression); GSDS=general sleep disturbance scale (score range, 0-147, score > 42 indicates poor sleeper).

\* At 6 weeks, n=109 in intervention group and n=103 in usual care group. At 12 weeks n=102 in intervention group and n=103 in usual care group.

†At 6 weeks, n=108 in intervention group and n=104 in usual care group. At 12 weeks n=103 in the intervention group and n=103 in usual care group.

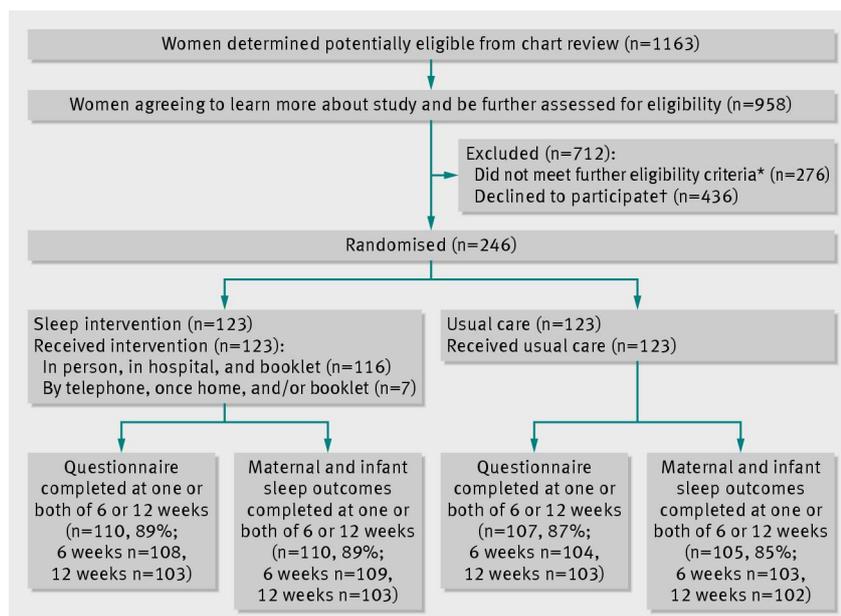
**Table 5| Infant sleep outcomes at 6 and 12 weeks in babies of primiparous women randomised to sleep intervention or usual care**

Mean (SD)	Sleep intervention*	Usual care†
Nocturnal sleep (minutes):		
6 weeks	472 (60)	458 (51)
12 weeks	531 (53)	521 (56)
Longest stretch of nocturnal sleep (minutes):		
6 weeks	180 (56)	169 (45)
12 weeks	229 (84)	240 (87)
No of night awakenings:		
6 weeks	11.8 (3.6)	11.2 (3.4)
12 weeks	9.0 (3.3)	9.0 (4.1)
Daytime sleep (minutes):		
6 weeks	186 (86)	184 (89)
12 weeks	180 (81)	191 (90)
Longest stretch of daytime sleep (minutes)		
6 weeks	67 (33)	64 (27)
12 weeks	68 (33)	73 (35)

\*n=109 at 6 weeks and 103 at 12 weeks.

†n=103 at 6 weeks and 102 at 12 weeks.

## Figure



Flow of participants through trial. \*Reasons for ineligibility: not available at 6 or 12 week data collection times (n=49), being discharged from hospital too soon (n=39), language barrier (n=39), not going to be full time caregiver at night (n=23), lived outside study area (n=22), partner works night shift (n=16), woman or partner has sleep disorder (n=11), partner has another child (n=9), hospital roommate already enrolled (n=9), uses drugs that affect sleep (n=5), uses drugs or alcohol to excess (n=2), no telephone (n=1), lives in shelter (n=1). †Reasons for refusal: not interested (n=176), too busy (n=133), too overwhelmed or worried (n=25), worried about commitment (n=19), didn't want to wait in hospital for intervention (n=11), didn't like actigraphs (n=11), didn't like home visits (n=11), felt already knew enough about sleep (n=10), too tired (n=9), partner not interested or not available to discuss (n=8), lots of support already (n=7), didn't like study routines/length (n=6)